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To:	Working Party on Pharmaceuticals and Medical Devices
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Subject:	Proposal for a Regulation of the European Parliament and of the Council on **in vitro diagnostic medical devices**

The Annex to this document contains a consolidated footnoted text of the articles in the proposal for a Regulation on *In vitro* diagnostic medical devices prepared by the Italian Presidency.

Chapter I[360]

Scope and definitions

Article 1

Scope

1.[361] This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices that are placed~~ ***when concerning the placing on the market, making available*** on the market or put***ting*** into service of ***in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices for human use*** [362] in the Union ~~***in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices***~~ ~~for human use~~. ***This regulation also establishes rules to be complied with by sponsors who take the responsibility for clinical performance studies.***

For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.

2. This Regulation shall not apply to:

(a) products for general laboratory use, unless such products, in view of their characteristics, are specifically [363] intended by their manufacturer to be used for *in vitro* diagnostic examination;

(b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;

(c) ~~higher metrological order~~ ***internationally certified*** reference materials.

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[360] The text in this chapter is based on DS 1516/14, it has been updated by **IT Pcy** following the meeting of the Working Party on 11 and 12 November 2014.

[361] Following MD Proposal

[362] **AT** add “and performance evaluation devices” . **IE** support

[363] **NL** replace “specifically” with “exclusively”

(d) materials used for external quality assessment schemes

(e) research-use only products.[364]

3.[365] Any device which, when placed on the market or used in accordance with the manufacturer's instructions, incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices without being an *in vitro* diagnostic medical device, shall be governed by ~~this~~ ***that*** Regulation, ~~provided that the principal intended purpose of the combination is that of an *in vitro* diagnostic medical device referred to in Article 2(2) of this Regulation~~. The ~~relevant general safety and performance~~ requirements ~~set out in Annex I~~ of ***this*** Regulation ~~(EU) [Ref. of future Regulation on medical devices]~~ shall apply ~~as far as the safety and performance of~~ ***to*** the ~~medical device~~ part that is ~~not~~ an *in vitro* diagnostic medical device ~~are concerned~~.[366] [367]

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[364] **UK** delete e) **AT** support e) **IE** insert definition of "research use only"

[365] Following MD Proposal - **BE** suggestion circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57)

[366] **UK** Add "*Where the conformity assessment of any part of such a combination product would require the involvement of a notified body, that notified body shall be competent to assess both the part that is an in vitro diagnostic medical device and the part that is a medical device that is not an in vitro diagnostic medical device.*" **AT** support

[367] **DS 1866/12 BE** With regard to the medical devices which incorporate as an integral part an in vitro diagnostic medical device it is advisable that, in order to reinforce the safety of these devices, both legislations should fully apply to the combination products which are described under Article 1 point 3 of both the Proposals for a Regulation on medical devices and for a Regulation on in vitro diagnostic medical devices.
In order also to avoid lengthy discussions on the principal intended purpose of the combination product which is either that of an in vitro diagnostic medical device or of a medical device, and taking into account that in vitro diagnostic medical devices are, in first instance medical devices, the pragmatic approach should be taken to qualify these integrally combined devices as 'medical devices'.
With regard to the applicable legislation, a modular approach would provide highest guarantee for safety and performance, where each component or part of the combination product is qualified in accordance with its intended purpose and characteristics, and accordingly subject to the relevant Regulation, including the conformity assessment. The different modules of the combination product would be subject to either the Regulation on medical devices or the Regulation on in vitro diagnostic medical devices, depending on their qualification. **IE, ES, AT** support

4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.

5. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom, nor of Council Directive 97/43~~ ***2013/59/***Euratom.[368]

6. This Regulation shall not affect national ~~laws which require~~ ***legislation with requirements concerning the organisation, delivery or financing of health services and medical care, such as*** ~~that~~ ***inter alia, the requirement that only certain health professionals or health care institutions may dispense or apply*** certain devices [369] **may only be supplied on a medical prescription** ***or that their application must be accompanied by specific professional counselling***.[370]

6a. This Regulation shall be without prejudice to national laws regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.[371]

7. ~~References to a Member State in this Regulation shall be understood as *also* including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation~~ [372]

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368 Correction, following a suggestion in **DS 1416/14 AT**

369 **DS 1367/13 BE** suggests to replace this paragraph with: "*This Regulation shall not affect national laws ~~which require~~ concerning the organisation and delivery of health services and medical care, such as the requirement that certain medical devices may only be supplied on medical prescription or the requirement that only certain health professionals may dispense certain medical devices.*" **FR, AT** support.

370 Suggestion from **DS 1416/14 AT**.

371 **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57).

372 **Pcy** proposal based on oral advice from the Council Legal Service in the Working Party.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, ~~reagent,~~[373] material or other article, [374] intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological ***or pathological***[375] process or state,
- control or support of conception,
- ~~***cleaning***,~~[376] **~~disinfection or sterilisation of any of the above-mentioned products,~~**

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[373] **ES** Change to: "…software, implant, reagent, *and other products for in vitro use,* material or other article, intended by the manufacturer…". **AT, PT** support; **BE** opposed: "the addition of "*other products for in vitro use*" would enlarge the scope of the Medical Device Regulation. As an example, as there is no exclusion of products for general laboratory use, instruments or apparatus used in the analysis of biopsies may be brought into the scope of a medical device. Examples may include instruments intended to be used for paraffin processing of tissue, microtomes, automatic staining instruments, microscopes…".

[374] **DS 1867/12 AT** add "*including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products*"

[375] **DS 1867/12 AT** add "*or pathological*"

[376] **ES** Add: "*cleaning,* disinfection or sterilisation …".

– ~~*providing information concerning a physiological or pathological process or state, a congenital abnormality, the predisposition to a medical condition or a disease, or to determine the safety and compatibility with potential recipients, to predict treatment response or reactions or to define or monitor therapeutic measures by means of in vitro examination of specimens derived from the human body, including blood and tissue donations;*~~[377] [378] [379]

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Products specifically intended for the cleaning, disinfection or sterilisation of medical devices shall be considered medical devices.

[380]

~~***Equipment intended to be used by health professionals and specifically designed to prepare a medical device for the care of the patients, with the exception of those used in a pharmacy to prepare a medicinal product, shall be considered medical devices.***~~[381] ~~*382*~~

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[377] Following MD proposal

[378] **DS 1867/12 AT** add "*provision of information concerning a physiological or pathological process or state, a congenital abnormality, the predisposition to a medical condition or a disease, or to determine the safety and compatibility with potential recipients, to predict treatment response or reactions or to define or monitor therapeutic measures by means of in vitro examination of specimens derived from the human body, including blood and tissue donations*"

[379] **ES** Replace this indent by
"– *providing information by means of in vitro examination of specimens derived from the human body, including blood and tissue donations;*". **AT** support

[380] **DS 1861/12 PL** add "*Agents for transport, nutrition and storage of organs, tissues and cells intended for transplantation shall be considered medical devices, regardless of principal mode of action of the product.*"

[381] **DS 1401/14 FR** add "*Equipment intended to be used by health professionals and specifically designed to prepare a medical device or a therapeutic product for the care of the patients, with the exception of those used in a pharmacy to prepare a medicinal product, shall be considered medical devices.*"

[382] **UK**, **PL**, **NL**, **ES**, **LT**, **IE**, **SK**, **CION** deleting the subparagraph; **FR** suggest to change the text; **PT** support.

~~The implantable or other invasive products, ***or products for delivering significant amounts and/or intensities of energy onto or into the human body***, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.~~[383]

(2) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

– concerning a physiological or pathological ***process or*** state;
– concerning a congenital abnormality;
– concerning the predisposition to a medical condition or a disease;
– to determine the safety and compatibility with potential recipients;
– to predict treatment response or reactions;
– to define or[384] monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. For the purposes of this Regulation, 'specimen receptacle' means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

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383 Deletion following the addition of the new paragraph 1a in Article 1.
384 **BE** delete "*define or*".

(3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended ~~specifically~~ [385] [386] by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically [387] [388] enable ~~or assist~~ [389]the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);

(3a) '~~invasive device' means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;~~[390]

(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons;

(5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;

(6) 'companion diagnostic' means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy; [391]

(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

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[385] Following the meeting on 11-12 September, **Pcy** proposes to delete the word "*specifically*", which was added in document 12538/14.

[386] **ES** add "*specifically*".

[387] Following the meeting on 11-12 September, **Pcy** proposes to reinstate the word "*specifically*" from the Cion proposal, which was deleted in document 12538/14.

[388] **ES** delete "*specifically*".

[389] **FR** delete "assist" in order to avoid inclusion of laboratory generic use devices. **AT, SE, BE** support

[390] **AT, FR, NL, UK, BE** delete (3a)

[391] **FR, AT, Cion** adopt FDA definition **UK** adopt Parliament amendment

(8)[392] 'single-use device' means a device that is intended to be used ~~on an individual patient~~ during a single procedure;

~~The single procedure may involve several uses or prolonged use on the same patient.~~ [393]

(8a) 'kit' means a set of components that are packaged [394]***together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof***

(8b) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose within a unique procedure;[395]

(8c) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;[396]

(9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;

(10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices[397];

(11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;

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[392] **NL** delete (8)

[393] **CZ, DE, LT, PT** delete "*The single procedure may involve several uses or prolonged use on the same patient*".

[394] **NL** replace "packaged" with "intended to be used"

[395] This is definition (13f) from document 12538/14. No changes have been done.

[396] This is definition (13g) from document 12538/14. No changes have been done.

[397] **ES** replace the end of the definition by: "… or on the *sales* packaging;".

(12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

(12a) 'performance' means ~~any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use~~ the ability of a medical device to achieve its intended purpose as claimed by the manufacturer;[398]

(12b) 'safety' means ~~reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk~~ the absence of unacceptable ~~clinical~~[399] ***risks, when using the device according to the manufacturer's instructions for use;***[400]

(12c) 'benefit' means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using a medical device for the intended purpose and in accordance with the instructions of use;[401]

(12d) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;[402]

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[398] This definition replaces definition (13a) in document 12538/14. Changes to that definition are indicated. As now proposed, the definition is taken from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[399] ES, PT, CION deleting "clinical"

[400] This definition replaces definition (13b) in document 12538/14. Changes to that definition are indicated. As now proposed, the definition is taken from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

[401] This is definition (13c) from document 12538/14. No changes have been done.

[402] This is definition (13d) from document 12538/14. No changes have been done. This definition is from GHTF/SC/N4:2012, Edition 2. **Cion** suggested alignment with GHTF definition.

(12e) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the medical device for the intended purpose, when used in accordance with the instructions of use";[403] [404] [405]

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[403] This is definition (13e) from document 12538/14. No changes have been done.

[404] **DS 1367/13 BE** add the following definitions:

"*(13a) 'performance' means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use.*

(13b) 'safety' means the avoidance of risk (or harm) caused by the device or associated with its use.

(13c) 'benefit' means the device's positive impact on health based on clinical data; referred to as clinical efficacy when based on clinical investigations and as clinical effectiveness when based on clinical experience after placing on the market. Benefit can also mean a positive impact on patient management or public health, for example for diagnostics.

(13d) 'risk' (or harm) means the device's negative impact on the overall health based on clinical investigations, other clinical data and vigilance reports. For diagnostics, the risk from false-positive or false-negative results should also be considered.

(13e) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose.

(13f) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

(13g) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.".

[405] **DS 1519/13 IT** add the following definitions:

"*(13a) 'benefit' means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using a medical device for the intended purpose and in accordance with the instructions of use*

(13b) 'safety' means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk. Safety also means avoidance of risk caused by a medical device or its use in users or other subjects

(13c) 'risk' means the combination of the probability of occurrence of harm and severity of that harm

(13d) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the medical device for the intended purpose, when used in accordance with the instructions of use.".

Definitions related to the making available of devices:

(13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(13a) 'performance' means any technical characteristics, any effects and any benefits of the device when used for the intended purpose and in accordance with the instructions of use;

(13b) 'safety' means reasonable assurance, evaluated upon valid scientific clinical evidence, that a medical device, when used for the intended purpose and in accordance with the instructions of use, provides positive effect on health outweighed the probable risks and is freedom from inacceptable risk;

(13c) 'benefit' means the positive effect on health, evaluated upon valid scientific clinical evidence, obtained using an in vitro diagnostic medical device for the intended purpose and in accordance with the instructions of use;

(13d) 'risk' means the combination of the probability of occurrence of harm and severity of that harm;

(13e) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the in vitro diagnostic device for the intended purpose, when used in accordance with the instructions of use;

(13f) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose within a unique procedure;

(13g) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;

(14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;

(15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

Definitions related to economic operators, users and specific processes:

(16)[406] ~~manufacturer' means the natural or legal person~~ ***~~with responsibility for the design~~*** ~~who manufacture s~~***~~, packaging and labelling of or fully refurbishes~~***[407] ~~a device~~ ***~~before it is placed on the market~~*** ~~or has a device designed,~~ ***~~or~~*** ~~manufactured~~ ***~~or fully refurbished~~***[408]~~, and markets that device under his~~ ***~~own~~*** ~~name or trademark~~***[409]~~***~~, regardless of whether these operations are carried out by that person himself or on his behalf by a third party~~***[410]~~.~~

~~The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.~~[411]

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406 **Pcy** replace with the 98/79/EC definition.
407 **ES** Delete: "*or fully refurbishes*".
408 **ES** Delete: "*or fully refurbished*".
409 **ES** Delete: "*or trademark*".
410 **DS1189/13 IT** add "r*egardless of whether these operations are carried out by that person himself or on his behalf by a third party*". This sentence would clarify that a manufacturer can produce medical devices or in alternative can make their medical devices be produced by a third party on his behalf.
411 Following MD proposal

~~***For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of Any person who fully refurbishes*** a device already[412] placed on the market or put into service, or ***the making of makes*** a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device***, shall be considered a manufacturer;***~~

'manufacturer' means the natural or legal person who manufactures or fully refurbishes[413] a device or has a device designed, manufactured or fully refurbished[414], and markets that device under his name or trademark[415], regardless of whether these operations are carried out by that person himself or on his behalf by a third party.[416]

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already[417] placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;[418]

(17) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer***, located outside the European Union[419],*** to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

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412 **ES** Replace the introductory part of this sentence with: "*It will also be considered manufacturer whoever fully refurbishes* a device already …".

413 **ES** Delete: "*or fully refurbishes*".

414 **ES** Delete: "*or fully refurbished*".

415 **ES** Delete: "*or trademark*".

416 **DS1189/13 IT** add "*regardless of whether these operations are carried out by that person himself or on his behalf by a third party*". This sentence would clarify that a manufacturer can produce medical devices or in alternative can make their medical devices be produced by a third party on his behalf.

417 **ES** Replace the introductory part of this sentence with: "*It will also be considered manufacturer whoever fully refurbishes* a device already …".

418 UK, NL, CION reinstate CION proposal

419 **DS 1189/13 IT** add "*located outside the European Union*".

(18) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;

(19) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

(20) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(21) 'health institution' means an organisation whose **primary**[420] purpose is the care or treatment of patients or the promotion of public health[421];

(22) 'user' means any healthcare professional or lay person who uses a device;

(23) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

Definitions related to conformity assessment:

(24) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

[420] Following MD proposal **- HU** Delete "*primary*". NL, CION reinstate primary. UK suggests to include also research; IE, NL support;

[421] **ES** Delete: "*or the promotion of public health*".

(24a) [422] ~~*"state of the art" means the highest level of all accessible and usable knowledge and development achieved at a particular time. in order to design and manufacture a device according to security and performance requirements, without having to prove any inventive activity. It is could be established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases;*~~ [423] [424] [425]

(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evidence:

(28) 'clinical evidence' means the information that supports[426] the scientific validity and performance for the use of a device as intended by the manufacturer;

(29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;

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422 Following MD Proposal

423 **DS 1937/13 FR** add definition of "*state of the art*".

424 **DK, DE, AT** do not agree with the definition proposed in document 12538/14.
DS 1439/14 BE "*'state of the art' 'the level of knowledge and development achieved in a technique or method. It is established using accessible and usable data such as standards, relevant medical, scientific and technical literature of public or private origin, patents and technical databases*.".

425 CION, DK, DE, UK, SE, ES, LT, BE deleting the definition

426 **BE** Replace "*that supports*" with "*supported by*".

(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable[427], the clinical performance supporting the intended purpose of the device;

(31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;

(32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;

(33) 'clinical performance study' means a study undertaken to establish or confirm the clinical performance of a device;

(34) 'clinical performance study protocol' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;

(35) 'performance evaluation' means the assessment and analysis of data to establish or verify the analytical and, where applicable, the clinical performance of a device;

(36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;

[427] **BE** Delete "*, where applicable,*".

(37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;

(38) 'diagnostic specificity' means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition;

(39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

(40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

(41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

(42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

(43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;

(44) 'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended purpose of that device;

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;

(45a) 'equivalence' means the ability of two or more devices, with the same intended purpose, to have ~~similar~~ ~~identical~~ similar[428] technical characteristics, and the same clinical and analytical characteristics when used as intended by their respective manufacturer, to such an extent that there would ~~be~~ not be a clinically significant difference in the performance of the devices.[429]

(46) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical performance study, whether or not related to the device for performance evaluation;

(47) 'serious adverse event' means any adverse event that led to any of the following:

– death,

– serious deterioration in the health of the subject, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or extending the duration of hospitalisation,

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

– foetal distress, foetal death or a congenital abnormality or birth defect.

(48) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

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428 NL, ES, CION not agree with "identical"; PT suggests to consider similar technical characteristics and the same biological and clinical characteristics, following MEDDEV

429 **BE** delete (45a)

Definitions related to vigilance and market surveillance:

(48a) 'Post Market Surveillance' means all activities carried out by the manufacturers and other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available[430] or put into service for the purpose of identifying any need to immediately apply any necessary ~~corrections~~, corrective or preventive actions.[431]

(49) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

(50) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;

(51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market ***including use-error,*** , any inadequacy in the information supplied by the manufacturer and any **unexpected** undesirable effect;

(52) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

– death of a patient, user or other person,

– temporary or permanent serious deterioration of the patient's, user's or other person's state of health,[432]

– serious public health threat;
[433]

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[430] Following MD proposal **- DK** add "*made available*".

[431] **DS 1870/12 SE, AT, NL** add definition of "*post market surveillance*".

[432] **UK** Add
"… person's state of health, *that resulted in any of the following:*
(i) life-threatening illness or injury,
(ii) permanent impairment of a body structure or a body function,
(iii) hospitalisation or extending the duration of hospitalisation,
(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,".
SE support

[433] **UK** Add "- *foetal distress, foetal death or a congenital abnormality or birth defect;*".
SE support

(52a)[434] ***'serious public health threat' means any event type which results in imminent risk of death, serious ~~injury~~ deterioration in state of health, or serious illness that may requires prompt remedial action;***[435] [436]

(53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation ***~~including product design modifications as well as modifications concerning the production process or technique~~***[437];

(54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

(56) 'market surveillance' means the activities carried out and measures taken by public authorities to ***check and*** ensure that ~~products~~ ***devices***[438] comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

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[434] Definition from GHTF/SC/N4/2012 Edition 2

[435] **DS 2046/13 DE** add "*'serious public health threat' means any event which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action.*"

[436] **PT** adding the second paragraph of the definition of ***'serious public health threat'*** given in the MEDDEV 2.12-1, rev. 8

[437] **DS 2046/13 DE** add "*reduce or prevent the recurrence of safety related risk; this includes product design modifications as well as modifications concerning the production process or technique*"

[438] **6804/14 DE** add "*check and to* ensure that ~~*products*~~ *devices*".

(56a) 'vigilance' means activities carried out by public authorities to systematically collect information on risks of devices available on the EU market, to assess this information and the underlying risks and measures taken to ensure that devices do not endanger health, safety or any other aspect of public health;[439]

Definitions related to standards and other technical specifications:

(57) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];

(58) 'common ~~technical~~ specifications' means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.

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[439] **6804/14 DE** add "*'vigilance' means activities carried out by public authorities to systematically collect information on risks of devices available on the EU market, to assess this information and the underlying risks and measures taken to ensure that devices do not endanger health, safety or any other aspect of public health*"
Presidency comment: Following the results of questionnaire (DS 1350/14) Presidency proposes to delete the definition of "vigilance". 24/28 Member States replied to the questionnaire. The majority of Member States (14/28) does not agree with the proposed definition of "vigilance", only 4 Member States support the proposed definition and 2 Member States are neutral. Among the 12 Member States that do not agree with the definition, six (EE, IE, ES, FR, PT, UK) do not consider necessary to define vigilance's activities. 7 Member States believe that the definition should include also responsibilities and tasks of manufacturers and other economic operators.

Article 3

Regulatory status of products[440]

1. ~~*The*~~ ***Without prejudice to Article 2(2) of Directive 2001/83,*** [441]***, at a duly substantiated request of a Member State,***[442] ***the*** Commission ~~*may*~~ ***shall***[443], ~~at the request of a Member State *or on its own initiative* *and following consultation*~~ ***with the MDCG*** ~~*and interested parties*~~***,***[444]by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an *in vitro* diagnostic medical devices or of an accessory to an *in vitro* diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.

2. The Commission shall ensure the sharing of expertise between Member States***, through MDCG,***[445] ***referred to in Article 77(d),*** in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.

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[440] Following MD Proposal Definition from GHTF/SC/N4/2012 Edition 2.

[441] Following MD Proposal - Presidency proposal in response to issue raised by **BE** and **DK**.

[442] **DE** not agree on the wording "at a duly substantiated request"; AT support

[443] **FR** Replace: "*may*" with "*shall*". **UK** Against. **DE, AT** add a deadline for acting.

[444] **UK** Replace: "*on its own initiative*" by "*and following consultation with the MDCG and interested parties*".

[445] **ES**, **DK**, **SE**, **CION** deleting "***through MDCG referred to in Article 80(d)***"

Chapter II[446]

Making available of devices, obligations of economic operators, CE marking, free movement

Article 4

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.
3. Demonstration of conformity with the general safety and performance requirements shall ~~be based on~~ ***include a*** [447] ~~clinical evidence~~ ***performance evaluation*** [448] in accordance with Article 47 [449].[450]
4. Devices that are manufactured and used within a single health institution shall be considered as being put into service.

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[446] The text in this chapter is from DS 1536/14.

[447] **DS 1041/14 UK IE** Replace "be based on" by "include"

[448] **DS 1041/14 UK IE** Replace "clinical evidence" by "performance evaluation"

[449] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
10) Does your Delegation consider that a performance evaluation report in accordance with Annex XII should be established and kept up to date for class C and D IVDs (DS 1077/14)?

[450] **DS 1077/14 BE** Add "and Annex XII".

5. With the exception of Article 59(4) ***and the relevant general safety and performance requirements set out in Annex I,***[451] the requirements of this Regulation shall not apply to devices ~~classified as class A, B and C, in accordance with the rules set out in Annex VII, and~~ [452] manufactured and used only within a single health institution, provided that ***the following conditions are met*:**[453] [454]

(a) manufacture and use ***of the device*** [455] occur [456] ~~solely~~ **only within the premises of that health institution** ~~under the health institution's~~ ***a***[457] ~~single quality management system~~,[458]

(b) [459] the **laboratory of the** [460]health institution is compliant with [461] [462]~~***accredited to***~~ [463] standard EN ISO 15189 or any other equivalent recognised ~~standard~~ **provision**.[464] [465]

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[451] **DS 01041/14 BE UK IE DS 1484/13 DE** Add "and the relevant general safety and performance requirements set out in Annex I,"

[452] **DS 1041/14 BE/UK/IE** Delete "classified as class A, B and C, in accordance with the rules set out in Annex VII, and"

[453] **DS 1041/14 BE/UK/IE** Add " the following conditions are met:" DS 1041/14 BE/UK

[454] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
6) Does your delegation consider necessary to define more detailed conditions/provisions for "in house" IVDs in the IVD Regulation (DS 1077/14, DS 1059/14)?

[455] **DS 1041/14 BE/UK/IE** Add "of the device"

[456] **DS 1484/13 DE** Replace "solely under the health institution's single quality management system, and the health institution is compliant with standard EN ISO 15189 or any other equivalent recognised standard." by "only within the facilities of the health institution."

[457] **DS 1041/14 BE/UK/IE** Replace "the health institution's" by "a"

[458] **DS 1059/14 DE-UK** Replace **"***under the health institution's single quality management system, and " by "only within the premises of that health institution"*

[459] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
7) Does your Delegation consider that the laboratory of the health institution should be compliant with EN ISO 15189 (DS 1077/14, DS 1059/14)?

[460] **DS 1059/14 DE-UK "**(b) the laboratory of the health institution is compliant with standard EN ISO 15189 or any other equivalent recognised national provision, ~~standard"~~

[461] **DS 1041/14 BE** Replace "compliant with " by "accredited to"

[462] **DS 1041/14 UK** Replace "the health institution is compliant with" by " manufacture and use of the device occur in a laboratory compliant with" DS 1041/14 UK

[463] **DS 1041/14 UK** Replace "accredited to" by "compliant with"

[464] **DS 1041/14 BE** Add ", and devices classified as class C and D are within the scope of this accreditation"

[465] **DS 1041/14 BE** /UK/IE Delete "Member States may require that the health institutions submit to the competent authority"

(c) **the health institution ascertains at the time the first device is manufactured that *the recipient patient or patient group's specific needs cannot be met by a device available on the market,*** [466] [467] [468] [469]

~~(d) the health institution provides information on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification or use.~~ [470] [471]

(d) [472] **the health institution draws up a declaration, that it shall make publicly available on request, including:**

– the name and address of the manufacturing health institution;

– the details necessary to identify the devices;

– a declaration that the devices meet the general safety and performance;

- requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification,

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[466] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
8) Does your Delegation agree that the manufacture and use of in house IVDs should be allowed only if a device that meets patient needs is not available on the market (DS 1077/14)?

[467] **DS 1041/14 IE** Add "(c) the recipient patient or patient group's specific needs cannot be met by a device available on the market,"

[468] **DS 1077/14 BE** Add :"(c) the health institution ascertains at the time the first device is manufactured that the recipient patient or patient group's specific needs cannot be met by a device available on the market;"

[469] **DS 1059/14 DE-UK** Add : "(c) the health institution give due consideration to the use of equivalent devices available on the market**"**

[470] **DS 01041/14 BE/UK/IE** Add "(d) the health institution provides information on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification or use. "

[471] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
9) Does your delegation believe that health institution should draw up a statement including details necessary to identify the manufacturing health institution, details to identify the device and a declaration concerning the compliance of the device with safety and performance requirements (DS 1059/14)?

[472] **DS 1059/14 DE-UK** Add: " d) the health institution draws up a declaration …."

(e) **the health institution compiles a documentation allowing an understanding of the production facility, the production process, the design and performance data of the devices, including the intended performance, for enabling the competent authority to assess that the general safety and performance requirements set out in Annex I of this Regulation are met**

(f) **the health institution takes all necessary measures to ensure that all devices are produced in accordance with this documentation, and**

(g)[473] **the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.**

[473] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
11) Does your Delegation consider that the health institution should review experience gained from clinical use of the device and take all necessary corrective actions (DS 1059/14)?

Member States may require that the health institutions submit to the competent authority [474] ~~***Member States shall make publically available***~~ [475]a list of ***all*** **any relevant information about** [476] such devices which have been manufactured and used on their territory [477]. ***Member States shall retain the right to restrict the manufacture and use of any specific type of such devices in relation to aspects that are not covered by this Regulation*** [478] and may make the manufacture and use of the devices concerned subject to further safety requirements **and shall be permitted access to inspect the activities of the health institutions**. [479] [480]

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474 Following MD proposal.

475 **DS 1041/14 IE** Add "Member States shall make publically available"

476 **DS 1041/14 IE** Add "all"

477 **DS 1041/14 UK** Delete "Member States shall make publically available a list of all such devices which have been manufactured and used on their territory"

478 **DS 1041/14 UK IE** Add "Member States shall retain the right to restrict the manufacture and use of any specific type of such devices in relation to aspects that are not covered by this Regulation"

479 See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
12) Does your Delegation consider that Member States should regularly inspect the health institutions established on their territory manufacturing and using in house IVDs (DS 1077/14)?

480 See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
13) Does your Delegation agree with a provision only empowering the Competent Authority to access the health institution facilities to inspect the manufacturing and using of "in house" IVDs (DS 1059/14)?

~~Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.~~ [481]

These provisions do not apply [482] ***to devices which are manufactured on an industrial scale and*** [483] ***which are used within the framework of a commercial diagnostic service.*** [484] [485] [486]

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer. ~~.~~ [487] [488] [489]

[481]" **DS 1041/14 IE** Delete "Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.

[482] **DS 1682/13 BE** Replace "These provisions do not apply" by "This exemption does not apply".

[483] **DS 1041/14 IE** Add "as part of a for profit commercial activity or"

[484] **DS 1041/14 UK IE** Add "These provisions do not apply to devices which are manufactured on an industrial scale and which are used within the framework of a commercial diagnostic service."

[485] **DS 1041/14 IE** Add "Member States shall be permitted access to inspect the activities of health institutions manufacturing medical devices to ensure their compliance with this Article. In addition, health institutions manufacturing medical devices referred to in this Article shall submit an annual report relating to the manufacture, performance and safety of the device to the Competent Authority in the Member State in which they are based."

[486] **DS 1484/13 DE** Add "These provisions do not apply to *in vitro* diagnostic medical devices which are manufactured on an industrial scale and which are used within the frame of a broad-based commercial diagnostic service."

[487] **DS 1041/14 IE** Delete "The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer."

[488] **DS 1484/13 DE**

[489] Following MD proposal

~~*Article 4a*~~ [490] [491]

~~*Genetic information, counselling and informed consent*~~ [492]

~~*1. A device may only be used for the purpose of a genetic test in the premises of an accredited according to ISO 15189 and 17025 or equivalent standard(s) laboratory if the referral is granted by persons admitted to the medical profession under the applicable national legislation after a personal consultation.*~~

~~*2. A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.*~~

~~*3. Information: Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.*~~

~~*4. Genetic counselling: Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians, geneticists and bio-scientists qualified in genetic counselling.*~~

~~*The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices.*~~

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[490] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
14) Does your delegation agree that a specific article on "Genetic information, counselling and informed consent" should be included in the IVDR?

[491] AT proposal DS 1540/13

[492] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
15) Does your Delegation agree that basic general principles connected to ethics and patients' information should be fixed in the IVDR?

~~*5. Consent: A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.*~~

~~*6. Testing of minors: In case of minors the informed consent of the parents or legal representative shall be obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated adults not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will and may be revoked at any time, without detriment to the person.*~~

~~*7. A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation from Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.*~~

~~*8. The direct-to-patient*~~ [493] ***making available on the market of genetic self-test devices is prohibited.***

~~*9. The above provisions on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or reasons of public health and order more stringent national legislation in this field.*~~

[493] See **WD MDEV-61** Summary of the replies to the Presidency questionnaire (DS 1352/14) on Chapter II
16) Does your Delegation agree with a provision to prohibit direct-to-patient making available on the market of genetic self-test device?

Article5 [494]

Distance sales

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation ~~at the latest~~[495] when the device is placed on the market[496].

2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, **whether in return for payment or free of charge**[497], for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication**, directly or through intermediaries,** to a natural or legal person established in the Union shall comply with this Regulation.

[498]**3. ~~Information society services as defined in Article 1(2) of Directive 98/34/EC offering a device to a natural or legal person established in the Union shall make easily available a copy of the EU declaration of conformity.~~ Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.**

[499]**4. A Member State on grounds of protection of public health, may require ~~from~~ the natural or legal person providing information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.**

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[494] **DS 1710/1/13**: 5 MS consider that the provisions on distance sales of medical devices should be more detailed; 10 not agree**;** HR DE ES CY MT NL PL FI SE UK consider sufficient the provisions on distance sales proposed by Cion; IE FR IT SI not agree

[495] **DS 1710/1/13** FR suggest deleting "at the latest"

[496] **HU** adding "made available"

[497] **DS 1682/13 BE** adding "whether in return for payment or free of charge**"**

[498] **DE**, **DK**, **UK**, **NL** Cion not support the wording of paragraph 3; **Pcy** reinstate paragraph 5 clearer than 3

[499] **DE**, **UK**, **NL** not agree on paragraph 4

~~**5. Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.**~~

Article 6

Harmonised standards

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

2. The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, ~~clinical~~ performance studies, clinical evidence or post-market **performance** follow-up.

3. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, **the references of which have been published in the Official Journal of the European Union.** [500]

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Article 7

Common ~~technical~~ specifications

1. Where no harmonized standards exist or where relevant harmonised standards are not sufficient, the Commission**, after having consulted the MDCG ~~and the MDAC~~**[501]**,** shall be empowered to adopt common ~~technical~~[502] specifications (~~CTS~~**CS**) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II ~~or~~, the ~~clinical evidence~~ **performance evaluation** and post-market **performance** clinical follow-up set out in Annex XII **or the requirements regarding ~~clinical investigations~~ performance studies set out in Annex XIII** [503]**.** The ~~CTS~~**CS** shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

2. Devices which are in conformity with the ~~CTS~~**CS** referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those ~~CTS~~**CS** or parts thereof.

3. Manufacturers shall comply with the ~~CTS~~**CS** unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

Article 8

General obligations of the manufacturer

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

[501] 14090/1/13 ft 10 NL/DE: the role of the MDCG in their elaboration should be highlighted.
[502] 14090/1/13 ft 9 IT/NL: scrutiny reservations. Cion: this requires careful consideration since the term is used across sectors.
[503] Following the reviewed version of Annex XII e XIII

2. Manufacturers shall draw up **and keep up to date** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.[504]

3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall draw up an EU declaration of conformity in accordance with Article 15, and affix the CE marking of conformity in accordance with Article 16.

3a. **Manufacturers shall ensure compliance with the provisions of this Regulation throughout the entire lifetime of the devices he has made available on the market or put into service.**

~~**4. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 22 and with the registration obligations referred to in Article 23.**~~

5. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 43, available to the competent authorities for a period of at least ~~five~~ ~~**ten**~~ **five** years[505] after the last device covered by the declaration of conformity has been placed on the market.

[504] **BG** implementing acts instead delegated acts

[505] 14090/1/13 ft 13 Instead of 5 years, NL suggested: 'the minimal life expectancy of the device after the last device covered by the declaration of conformity has been placed on the market'. Cion and other delegations considered that this wording would be source of **legal uncertainty**. However, if considered too short, the period of 5 years could be reviewed. 5 years after the last device seems to be reasonable.

~~Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide,~~ **Upon** request by a competent authority, **the manufacturer shall provide the full technical documentation ~~and/~~**[506] **or** a summary technical documentation (STED) [507] [508] [509] ~~and grant access to the full technical documentation upon request.~~**).**

Manufacturer with registered place of business outside the Union, to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 shall ensure that the authorised representative has ~~permanently available and~~[510] **rapid access to the necessary documentation.**

6. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or ~~CTS~~**CS** by reference to which conformity of a product is declared shall be adequately taken into account. ~~-~~**Proportionate to the risk class and the type of device, manufacturers** ~~**Manufacturers**~~ of devices, other than devices for performance evaluation , shall ~~**institute**~~ **establish, document, implement**, **maintain** and ~~**keep up to date**~~ **continually improve** a quality management system **~~and a quality management system~~** that ~~shall address at least~~ **minimizes the possibility of non-conformance to the provisions of this regulation in** the ~~following aspects :~~ **most effective manner.**[511]

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[506] **Cion** deleting "and/"

[507] DS 1710/1/13 Should the content of a summary of technical documentation be specified in the legislation? DS 1710/1/13 DK DE IE ES FR MT PL PT SI FI SE UK (12) consider that it is not necessary specify the content of a STED; HR CY IT NL (4) consider the content of a STED has to be specified in the legislation

[508] 14090/1/13 ft 14 PT/AT/IT **-** DS 1075/14 LT: adding "including the elements set out in Annex II".

[509] 14090/1/13 ft 15 UK/NL/FR: scrutiny reservations.

[510] **DE** not agree with the wording "permanently available and rapid access"; just one is necessary

[511] DS 1710/1/13 Do you agree that requirements on the quality management system as set out in Article 8(5) are sufficient? HR CY IT SI FI UK agree that requirements on the QMS are sufficient; BE DK DE IE ES FR PL PT SE not agree. DS 1009/14 text added based on German delegation proposal

[512] **The QMS consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.**

The QMS shall address at least the following aspects[513] [514] [515] [516]**:**

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;

(b) identification of applicable general safety and performance requirements and exploration of options to address these;

(c) the responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractorssubcontractors;

(e) risk management according to section I.2 of Annex I;

(f) performance evaluation, according to Art. 47 and Annex XII, including post-market performance follow-up;

(g) product realisation[517]**, including planning, design, development, production and service provision;**

(h) control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to article 23;

(i) setting-up, implement and maintain a systematic post-market surveillance plan according to Art.xx;

[512] 14090/1/13 ft 17 PT\BE\ES\UK good prefer not to mention the list of aspects to be taken into account, anyway referred in EN ISO 13485. BE suggested: "(...), shall establish, document, implement, maintain and continually improve the effectiveness of a quality management system (…)". Cion: could be considered. Pcy considered that details shall be included in the standard (EN ISO 13485) and not in the Regulation

[513] 14090/1/13 ft 18 IE/AT/NL/RO: adding: "(d) clinical evaluation; (e) complaint handling, vigilance investigation and reporting, (f) post-market surveillance and updates to risk management and clinical evaluation documentation; (g) management of corrective and preventative actions and verification of effectiveness." Cion: changes could be considered.

[514] 14090/1/13 ft 19 PL adding: "(e) documents and records control."

[515] 14090/1/13 ft 20 DK/AT: "(e) processes for the continuous updating of the technical documentation."

[516] DS 1009/14 DE

[517] 14090/1/13 ft 21 DK: adding "including the clinical evaluation and the risk analysis

~~(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;~~

~~(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;~~

~~(l) management of corrective and preventive actions and verification of their effectiveness;~~

~~(m) processes for monitoring[518] and measurement of output, data analysis and product improvement.~~[519]

7. [520]~~Proportionate to the risk class and the type of device, manufacturers~~[521]522 **Manufacturers** of devices shall ~~institute~~ **implement** and keep up to date ~~a~~ **the** ~~systematic procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'~~ **post-market surveillance plan referred to in Chapter VII, section 0, article 60b**. ~~The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market performance follow-up in accordance with Part B of Annex XII. Where post-market performance follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.~~

[518] 14090/1/13 ft 22 DK: adding: "including clinical vigilance and the risk analysis".
[519] AT adding translation procedure
[520] DE it could be better a reference to chapter VII
[521] UK reinstate the first sentence of the paragraph
[522] 14090/1/13 ft 23 This paragraph should be examined at a later stage and harmonized with provision of the chapter VII .

~~**If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures inform the notified body concerned including immediate notification to Eudamed as established by Article 23**~~.

~~**The manufacturer shall draw-up an annual report setting out the results of post-market surveillance. That report shall be part of the technical documentation**~~

8. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user ~~or patient~~. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user. **The particulars on the label shall be easily legible, clearly comprehensible and indelible**[523]**.**
   For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.

9. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform[524] **accordingly** the distributors and, where applicable, the authorised representative[525] ~~accordingly~~ **and the importers**[526]. **They shall also assume the costs of removal, repair or replacement of products deriving from these situations.**

[523] DS 1710/1/13 Special provisions on marking
Is it necessary to include a sentence like "This is a medical device" on the label and instructions for use of medical devices? 10 Agree - 4 Not agree
[524] 14090/1/13 ft 25 BE: adding "the competent authorities".
[525] 14090/1/13 ft 26 HU: adding "and the importers".
[526] 14090/1/13 ft 27 FR/PT/AT/SE/IE/CY/IT: adding "Where the device presents a risk, they shall immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question and the importer, giving details, in particular, of the non-compliance and of any corrective action taken.". DE/ES/Cion: it could be a repetition of the provisions already existing in other chapters (e.g. 61 and 62)

10. Manufacturers shall, **~~in response to a~~** ~~reasoned~~ **upon** request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority[527]. ~~They~~ **The competent authority may make a request that the manufacturer provide ~~free~~ samples of the device free of charge[528] or, where impracticable, grant access to the device. Manufacturers** shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service[529] [530].
If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the ~~incriminated~~ involved device until its demonstration of conformity to the essential requirements[531].

11. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23. [532]

[527] 14090/1/13 ft 28 IT/DE/PL: scrutiny reservations; "in an (any) official Union language which can be easily understood by that authority" seems excessive.
[528] DE, FR manufacturers shall keep available samples of the device free of charge
[529] 14090/1/13 ft 29 BE/PL/UK/AT: adding **"**If the manufacturer fails to cooperate or if the information and documentation provided is incomplete or incorrect, the competent authority may suspend the incriminated device until its demonstration of conformity to the essential requirements."
[530] 14090/1/13 ft 30 PT: adding: "In case of bankruptcy, the manufacturer shall provide all the technical documentation of the devices for which he is responsible and all the marketing and PMS registries to the competent authority of the Member State in which he is established."
[531] DS 1075/14 LT replace "essential requirements" with "general safety and performance requirements"
[532] 14090/1/13 ft 31 ES/PT/FR/SI: adding: "11. Manufacturers of medical devices shall have an insurance or equivalent financial guarantee to cover any damage to health due to safety problems of medical devices". DK/PL/HU/NL: national legislation applicable. DE/UK/CY/IT: general rules on civil liability are enough.

~~12.~~ [533] **~~-~~** [534] **~~In case of bankruptcy of the manufacturer, the manufacturer or his authorised representative shall provide all the technical documentation and the post-market surveillance plan of devices which he has placed on the market or for which he has been designated by the competent authority of the Member State in which he is established.~~**

~~13. Manufacturers of in vitro diagnostic medical devices shall have an insurance or equivalent financial guarantee~~ [535] **~~to cover any damage to health due to safety problems of medical devices.~~** [536] **~~They shall also assume the costs of removal, repair or replacement of products deriving from these situations~~** [537] **~~.~~**

Article 9

Authorised representative

1. A manufacturer of a device that is placed on the Union market~~, or bears the CE marking without being placed on the Union market,~~ who does not have a registered place of business in a Member State ~~or does not carry out relevant activities at a registered place of business in a Member State~~, shall designate a single authorised representative.

2. The designation shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

[533] DS 1710/1/13 Should a liability insurance of the manufacturers be mandatory? 6 Agree - 7 Not Agree
[534] Paragraph 12 has been deleted due the results of the questionnaire reported in DS 1710/1/13. Do you consider that the defined obligations of economic operators are appropriate? HR DK DE ES FR IT HU NL PL PT SE UK consider the defined obligations of economic operators not appropriate; IE CY MT SI FI consider the defined obligations of economic operators appropriate.
[535] DS 1710/1/13 Should it (a liability insurance of the manufacturers) be regulated by the MD and IVD Regulations? 6 Agree - 6 Not Agree
[536] UK, DK, NL, BG, DE, IE deleting paragraph 13
[537] Sentence moved to paragraph 9, Article 8

3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. **The authorised representative shall provide a copy of the mandate to the importer, pursuant to Article 11(2)(a), and, upon request, to the competent authority**[538]**.**

The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

aa. ensure that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer; [539]

a. ~~keep~~ **keep ~~at his registered place of business~~**[540] **a copy of** the technical documentation,[541] the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any ~~supplement~~ **amendments and supplements** issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

b. **comply with the registration obligations laid down in Article 23(2), (4) and (5);**

c. in response to a ~~reasoned~~[542] request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device **in an official Union language which can be easily understood by that authority**;[543] [544]

[538] 14090/1/13 ft 32 DE: deleting "The mandate shall be provided to the competent authority, upon request, and to the importer" problems of confidentiality

[539] 14090/1/13 ft 33 UK: adding "(aa) ensure that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer."

[540] PT, UK deleting "a his registered place of business" to assure that technical documentation is the most updated

[541] DS 1075/14 LT adding "STED"

[542] 14090/1/13 ft 34 PL: opposed.

[543] DE deleting last sentence; CZ, CY support

[544] ES 9.3 (c) adding "in the language determined by the law of the Member State of that authority"; this should apply for all the regulation; UK, CY, PT support

d. **forward to the manufacturer any request by a competent authority[545] for samples, or access to a device and verify that the competent authority[546] receives the samples or gets access to the device;**

e. cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;

f. immediately inform the manufacturer about complaints and reports from healthcare professionals[547], patients and users about suspected incidents related to a device for which they have been designated;

g. terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

~~To allow~~ **for** ~~the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate~~ **permanently available and rapid** ~~access to the necessary documentation in one of the official Union languages~~ **which can be easily understood by the authorised representative**~~.~~[548]

4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (5), (6), (7) and (8).

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

[545] DE which is the Authority? That of the Authorised representative? Cion, ES: not; every authority of the European Union

[546] 14090/1/13 ft 35 IT/DE/PL: scrutiny reservations; "in an official Union language which can be easily understood by that authority" seems excessive.

[547] DS 1075/14 LT deleting “healthcare professionals”

[548] Sentence moved to article 8,paragraph 5

6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

Article 10

Change of authorised representative

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

(a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material**(s) or statement(s);**

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from [549]healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

[549] DS 1075/14 LT deleting "healthcare professionals"

Article 11[550]

General obligations of importers[551]

1. Importers shall place on the Union market[552] only devices that are in conformity with this Regulation.

2. **In order to place** a device on the market[553] importers shall ~~ensure~~ **verify** the following:

   a) ~~that the appropriate conformity assessment procedure has been carried out by the manufacturer~~[554] **that the device has been CE marked and that the declaration of conformity of the device has been drawn up and is still valid;**

   b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer **and that the authorised representative is notified of the devices that the importer is placing on the market**[555] [556]

   c) [557]~~**that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;**~~

   d) ~~that the device bears the required CE marking of conformity~~[558];

   e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity~~[559];

   f) [560]that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22;

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[550] In the wording of this article we referred to the definitions reported in Article 2 (definitions (16), (17) e (18))
[551] 14090/1/13 ft 37 DE/IE/UK/CZ/BE/SE/PT/AT/NL/IT/ES: importers have not the same responsibilities as manufacturers.
[552] DS 1075/14 LT adding "and/or put into service"
[553] DS 1075/14 LT adding "and/or put into service"
[554] 14090/1/13 ft 38 PL: opposed to the deletion. DE/IE/UK/CZ/BE/SE/PT/AT/NL/IT/ES: importers have not the same responsibilities as manufacturers. Cion: 11(2)(a) the same of that is in article R4 of the decision 768/2008
[555] DS 1682/13 UK suggested the addiction
[556] DE there is no need to inform the authorized representative
[557] 14090/1/13 ft 39 CZ/LV/IT/ES/DE/UK suggested deleting the whole point c), in order to clearly delineate responsibilities between importer and authorised representative. FR/PT/PL/Cion opposed; deleted following the inclusion of point 11(2)(aa)
[558] 14090/1/13 ft 40 FR: adding "and is accompanied by the required EU declaration of conformity". Cion: the EU declaration of conformity must exist (see point c)) but needs not accompany each device.
[559] DE not agree on declaration of conformity accompanying the device; SE, Cion support
[560] 14090/1/13 ft 41 DE/LV/IT: deleting point 2.e).

[561]Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market[562] until it has been brought into conformity and shall inform the manufacturer **and, where applicable,** his authorised representative. ~~to that effect, as well as~~**, of any suspected non-conformities and, Where the importer consider or has reason to believe that the device presents a risk, he shall also inform** the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or ~~where that is not possible for practical reasons,~~ on its packaging or~~, where impracticable,~~ in a document accompanying the device.[563] They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall ~~ensure~~ **verify**[564] that the device is registered in the electronic system in accordance with Article 25(2~~).~~ **)**[565]**, ~~comply with their obligations laid down in paragraphs 3 to 5 of that Article~~ and shall add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and, if appropriate, inform the ~~relevant~~ authorised representative or the manufacturer ~~if it is not the case~~.**[566]

[561] 14090/1/13 ft 42 FR: would delete the whole sub-paragraph, as it is inconsistent with Article 11(1) and would create confusion between the obligations of manufacturers and importers
[562] DS 1075/14 LT adding "and/or put into service"
[563] DE, FR, ES concerns on this provision; AT not agree but clearness is necessary; Cion: the same in R4 paragraph 3 of decision 768/2008
[564] 14090/1/13 ft 43 PL: opposed. Cion expressed reservations on the change
[565] 14090/1/13 ft 44 FR/AT/PL/PT: the obligation to register the device in the electronic system should appear in the general obligations of the manufacturers and authorised representatives.
[566] 14090/1/13 ft 45 PL: opposed. CZ/IT: scrutiny reservations.

5. Importers shall ensure that, while a device is under their responsibility[567], storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available**.

~~6 When deemed appropriate~~

6.[568] **Where a risk has been identified** ~~with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products~~[569]~~,~~ **and** ~~investigate complaints and~~**. They Importers shall** keep a register[570] of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep~~ **provide** the manufacturer, authorised representative and distributors ~~informed of such monitoring~~[571]~~.~~ **with any information requested by them**[572]**, in order to allow them to carry out sample testing of marketed products**[573] **and investigate complaints.**

[567] 14090/1/13 ft 46 AT/IT/NL/FR: how can a medical device be under the responsibility of one operator rather than another?
[568] NL consider DS 101714
[569] 14090/1/13 ft 47 DE/CZ/SE/IT/AT/PT: deleting "carry out sample testing of marketed products"; these are manufacturers' responsibilities. FR: opposed
[570] 14090/1/13 ft 48 BE/FR/IE/PT: adding "for all devices".
[571] 14090/1/13 ft 49 DE/CZ/IT/AT: deleting "and shall keep the manufacturer, authorised representative and distributors informed of such monitoring" already provided for in 11(8).
[572] DS 1017/14 NL
[573] 14090/1/13 ft 47 DE/CZ/SE/IT/AT/PT: deleting "carry out sample testing of marketed products"; these are manufacturers' responsibilities. FR: opposed

7. Importers who consider or have reason to believe that a device which they have ~~placed~~[574] ~~**made available**~~[575] **placed** on the market is not in conformity with this Regulation shall immediately inform the manufacturer and**, where applicable**[576]**,** his authorised representative ~~and, if~~**. Where** appropriate, ~~take~~ **importers shall co-operate with the manufacturer** ~~**and, where applicable**~~**, his authorised representative** ~~**or**~~ **and the competent authorities to ensure that** the necessary corrective action to bring that device into conformity, withdraw or recall it **is taken**. **Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 4 , giving details, in particular, of the non-compliance and of any corrective action taken**[577]**.**

8[578]. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have ~~placed~~ ~~**made available**~~[579] **placed** on the market shall immediately forward this information to the manufacturer and his authorised representative[580]**,** ~~**as well as the competent authorities**~~[581] ~~**of the Member States where he is aware that the device has been made available**~~.

[574] 14090/1/13 ft 50 DE: replacing with "made available and Article 2(21) amended accordingly: 'importer' means any natural or legal person established within the Union who makes a devices from a third country available on the Union market". CZ: opposed
[575] DS 1075/14 LT replace “made available” with “placed on the market and/or put into service”
[576] 14090/1/13 ft 51 Alignment with 12(4).
[577] 14090/1/13 ft 52 FR/PT/ES: opposed to the deletion. Cion expressed reservations regarding deletion since this provision is from decision 768/2008
[578] To be reviewed following the results of questionnaire on vigilance matter.
[579] DS 1075/14 LT replace “made available” with “placed on the market and/or put into service”
[580] 14090/1/13 ft 53 DE: deleting "his authorised representative".
[581] 14090/1/13 ft 54 ES/IE/PT: only serious incidents should be reported to the competent authority, in order to avoid excessive administrative burden.

9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity ~~at the disposal of the market surveillance authorities and ensure that the technical documentation~~ **and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45**[582] ~~, can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative~~[583]**.and a copy of mandate between the manufacturer and authorised representative at the disposal of the market surveillance authorities.**

10. [584]~~Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when~~ **The national authority may make a request that** ~~the authorised representative for~~ **importer provide free samples of** ~~the device in question provides~~ **or, where impracticable, grant access to** ~~the required information~~[585]**device**~~.~~ Importers shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have placed on the market. **Importers, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.**

[582] FR reinstate "and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45"; ES, AT support; DE not support
[583] 14090/1/13 ft 55 FR/PT: opposed to the deletion. Cion expressed reservations regarding deletion
[584] 14090/1/13 ft 56 FR/ES/LV: opposed to the deletion. BE: scrutiny reservation. Instead, these delegations would add: "The national authority may also request that the importer provide, for the purposes of analysis and for justified reasons, free samples of the devices.".
[585] 14090/1/13 ft 57 FR/ES/PT/LV/BE: adding "and samples".

Article 12[586]

General obligations of distributors

1. **In the context of their activities,** ~~W~~ **w**hen making a device available on the market, distributors shall act with due care in relation to the requirements applicable **and make available on the market only those devices that are in conformity with this Regulation.**[587]

2. Before making a device available on the market distributors shall verify that the following requirements are met:

   a. the ~~**product**~~ **device** ~~bears the required CE marking of conformity~~ **has been CE marked and that the declaration of conformity of the device has been drawn up and is still valid**[588][589]; ~~**and is accompanied by the required EU declaration of conformity**[590]**;**~~

   b. the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(~~**7**~~**x 8**) ~~**and by the EU declaration of conformity**~~[591];

   c. [592]the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 24 and Article 11(3) respectively.

[586] In the wording of this article we referred to the definitions reported in Article 2 (definitions (16), (17) e (18))
[587] DE deleting paragraph 1
[588] AT This means that distributor shall open the parcel? It is not desirable; ask for a more general task;
[589] FR suggest "verify that the declaration of conformity is still valid"; PT support
[590] 14090/1/13 ft 58 FR/PT/SE/ES: adding "and that the required declaration of conformity is available".
[591] DE deleting "and by the EU declaration of conformity"; SE; PT, CZ, Cion support
[592] 14090/1/13 ft 59 DE: deleting point c) as the distributor is not able to verify it. FR/PT: opposed

[593]Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity~~. Where the device presents a risk, the~~ **The distributor shall** and inform the manufacturer and, where applicable, his authorised representative**, and** the importer as~~ of any suspected non-conformities and, if the device presents a risk, he shall also inform~~ **Where the distributor consider or has reason to believe that the device presents a risk, he shall also inform** the competent authority of the Member State in which he is established.

3. Distributors shall ensure that, while a device is under their responsibility[594], storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I[595] **and shall comply with the conditions set by the manufacturer, where available.**

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer ~~and make sure~~**. Where appropriate, distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with** ~~any~~ **competent authorities to ensure** that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. **Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43**[596]**, giving details, in particular, of the non-compliance and of any corrective action taken**[597]**.**

[593] 14090/1/13 ft 60 FR: would delete the whole sub-paragraph, as it is inconsistent with the obligation to put on the market only devices that are in conformity with the requirements of this Regulation.
[594] 14090/1/13 ft 61 AT/IT/NL/FR: how can a medical device be considered to be under the responsibility of one operator rather than another?
[595] 14090/1/13 ft 62 FR/NL: opposed to the new wording. Cion: would prefer to keep initial wording and add "and shall comply with the conditions set by the manufacturer, where available."
[596] 14090/1/13 ft 63 ES/IE/PT: only serious risks should be reported to the competent authority and the notified bodies, in order to avoid excessive administrative burden.
[597] 14090/1/13 ft 64 IE: opposed to the deletion

5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward[598] this information to the manufacturer and, where applicable, his authorised representative[599] **, as well as the competent authorities of the Member States in which they are aware that device has been made available.**[600] **They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request**.[601]

6. **Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information**[602] [603]**.** Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. **The competent authority may also request that the distributor provide, free samples of the device or, where impracticable, grant access to the device. Distributors, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.**

[598] 14090/1/13 ft 65 AT: upon request.
[599] 14090/1/13 ft 66 PT/ES: serious incidents should be notified to the competent authority of the Member State where they occurred. CZ: opposed.
[600] DE reinstate the obligation to report serious incident directly to competent authorities; SE, ES, PT support
[601] SE not agree on this register
[602] 14090/1/13 ft 67 HR/SE/AT/PT/IE: adding "Distributors shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and verify that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 45, can be made available to those authorities by the authorised representative, upon request."
[603] Cion reinstate the first sentence since it is from decision 768/2008

Article 13[604]

Person responsible for regulatory compliance

1. Manufacturers shall have ~~available within~~ **permanently and continuously at** their ~~organisation~~[605] **disposal,** at least one ~~qualified~~ person[606] ~~**responsible**~~ **in charge for regulatory compliance activities**[607] who possesses expert knowledge in the field of in vitro diagnostic medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:

   (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ **a course of study recognized**[608] **as** equivalent ~~course of study, in natural sciences,~~ **by the Member States concerned, in** medicine, pharmacy, engineering or another relevant ~~discipline~~[609] sciences, and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~medical~~ devices;

   (b) five years of professional experience in regulatory affairs ~~or~~[610] **related to devices including experience** in quality management systems ~~relating to medical devices~~.

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[604] Article 13. Person responsible for regulatory compliance
Do you consider that any of the qualification requirements for "qualified persons" are not appropriate or clear? Please specify and provide an alternative wording.
5 Agree - 7 Not Agree

[605] 14090/1/13 ft 68 DE/FR/ES/AT/BE/PT: "1. The Manufacturers shall, immediately upon commencement of his/her activities, appoint within their organization at least one qualified person who is sufficiently reliable and possesses the expert knowledge necessary for the fulfilment of the persons functions as the person responsible for regulatory compliance in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:" The main argument in favour of such a strict requirement would be that the qualified person should know the manufacturer's organization. DE added that it is essential to define the qualified person's task.
DK/SE/EE/UK/NL/LV: there is no need for the qualified person, with knowledge in the field of medical devices, to be an employee of the manufacturer organisation, as long as he/she would be permanently and continuously at the manufacturer's disposal.
Cion: recognises that requiring that the qualified person would be an employee could be a too heavy burden. Suggested taking into **account the wording of Directive 2001/83/EC ("at his disposal"**) on the same issue.

[606] 14090/1/13 ft 69 UK/BE: the name of the qualified person should be included in the EUDAMED

[607] NL manufacturer is responsible for regulatory compliance

[608] DE the equivalence is not clear; BG support

[609] 14090/1/13 ft 70 Delegations recognised that this description of the diplomas must be aligned with

[610] 14090/1/13 ft 71 FR/BE/PT: the qualified person must be competent in risk assessment and in demonstrating conformity with the essential requirements, as well as in quality management. Therefore, 5 years of cumulative experience in both fields seems crucial.

2. [611]The ~~qualified~~ person **~~responsible~~ in charge for regulatory compliance activities** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately ~~assessed~~ **checked in accordance with the quality management system under which these devices are manufactured** before a **product**[612] **~~batch~~** is released[613];

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) **that the post-market surveillance obligations ~~according~~ in accordance with Article 8(7) are complied;**

(d) **~~that the existing information concerning risks connected to devices is collected and evaluated and the necessary measures are co-ordinated as well as~~** that the reporting obligations in accordance with Articles 61 to 66 **~~concerning risks related to devices~~** are fulfilled[614615];

(e) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects,, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued;

(f) **~~collection and evaluation of existing information concerning risks connected to medical devices and co-ordination of the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to devices~~**[616 617].

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611 NL details are not necessary; DE not agree; tasks have to be clear
612 DE suggest "product release"; BG, ES, Cion support
613 14090/1/13 ft 75 IE/FR/ES: "(a) that the conformity of the devices is appropriately assessed checked in accordance with the quality system under which these devices are manufactured, before a batch is released;" DS 1682/13 IE text added based on Irish delegation proposal.
614 UK, Cion letter d is not clear;
615 14090/1/13 ft 76 DK/BG: opposed to the obligations added, as too large. DS 1682/13 DE text updated based on German delegation proposal
616 DS 1682/13 DE text added based on German delegation proposal. UK, Cion: it is not clear
617 14090/1/13 ft 77 DK: opposed

3. The ~~qualified~~ person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

[618]4. Authorised representatives shall have **permanently and continuously at** their ~~**organisation**~~ **disposal** at least one ~~qualified~~ person ~~**responsible**~~ **in charge for regulatory compliance activities** who possesses expert knowledge regarding the regulatory requirements for **medical**[619] ~~devices~~ in the Union. The expert knowledge shall be demonstrated by either of the following qualifications:

a. a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ **a course of study recognized as**[620] equivalent ~~course of study, in natural sciences,~~ **by the Member States concerned, in** medicine, pharmacy, engineering or another relevant ~~discipline~~[621] sciences , and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~in vitro diagnostic~~ ~~medical~~ devices;

b. five years of professional experience in regulatory affairs or in quality management systems relating to ~~in vitro diagnostic~~ **medical** ~~devices~~.

[618] AT deletion of paragraph 4; PT not agree
[619] Pcy reinstate to avoid confusion with IVD
[620] DE the equivalence is not clear; BG support
[621] 14090/1/13 ft 70 Delegations recognized that this description of the diplomas must be aligned with

Article 14

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers[622] if he does any of the following:

   a. makes available on the market a device under his name, registered trade name or registered trade mark[623][624], **except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation**;

   b. changes the intended purpose of a device already placed on the market or put into service;

   c. modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

   The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

2. [625]For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

   a. provision, including translation[626], of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;

[622] 14090/1/13 ft 79 DK/IT/BG: it should be clearly explained that there should be a new evaluation, a new procedure. Cion: confirmed that this is the intended meaning
[623] 14090/1/13 ft 80 ES: distributor may add his trade mark to the one of the manufacturer?
[624] AT: it is not clear the scope of this paragraph; ES presented written suggestion (DS 1329/14) concerning private label since a distributor or an importer that has a private label agreement (registered trade mark) shall not assume the responsible of the manufacturer; PT, UK support Spanish proposal
[625] 14090/1/13 ft 81 BE/SE considers that there is a safety risk; would prefer deleting this paragraph.
[626] 14090/1/13 ft 82 NL: there is a danger of misuse when the translations contain mistakes

b. changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where ~~that is not possible~~ **impracticable**, on its packaging or in a document accompanying the device[627].

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

[627] 14090/1/13 ft 83 Following a linguistic remark from DE, the text could read:
A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is not possible, on its packaging or, in exceptional cases, in a document accompanying the device:
– the activity carried out,
– his name, registered trade name or registered trade mark,
– the address at which he can be contacted and his the location can be where he is established.

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate[628], issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

Article 15

EU declaration of conformity

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall **~~accompany the device and~~** be translated[629] into ~~the~~ **an** official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.

[628] 14090/1/13 ft 84 ES/DK/UK: which kind of certificate?
[629] 14090/1/13 ft 97 PT/PL: who should be responsible for the translation?

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress[630].

Article 16

CE marking of conformity

1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity[631], ~~as presented in Annex IV.~~ **~~accompanied by the indication " in vitro diagnostic medical device", in accordance with Annex xx~~**[632]**~~.~~**

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided[633].

[630] 14090/1/13 ft 98 DE/IT: opposed, as no technical progress could be foreseen in this area. Cion: the content would be amended only if needed

[631] 14090/1/13 ft 99 FR/DK/IT/SE/BE: "accompanied by the indication 'medical device'" or SE by a symbol with that meaning. PT: would transfer such a requirement to the labelling (annexes).

[632] UK, NL not agree with the adding “accompanied by the indication "medical device", in accordance with Annex xx”; HU, CZ agree with given the information but not necessarily in association with the CE mark; Pcy consider that is better transfer the request to Annex I, point 19.

[633] 14090/1/13 ft 100 DK: it is not the best option to let the manufacturer choosing where to affix the CE marking.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 4. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.

6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

Article 17

Devices for special purposes

1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.

2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 54.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided that ~~such devices are not used on specimens taken from participants~~ **~~and the expression "demonstration devices" is visibly affixed on those devices~~**[634] a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

634 Cion, NL, UK, BE deleting the adding words

Article 18

Systems and procedure packs

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:
   (a) other devices bearing the CE marking;
   (b) medical devices bearing the CE marking in conformity with Regulation (EU)[635]
   (c) other products which are in conformity with the legislation applicable to those products[636] **only when they are used within the medical procedure or their presence in the system or procedure pack is justified**.

2. In the statement, the person referred to in paragraph 1 shall declare the following:
   (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;
   (b) that he packaged the system or procedure pack and supplied relevant[637] information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
   (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

[635] 14090/1/13 ft 102 BE/AT/ES: adding "with the exception of devices for self-testing;". DE: opposed.
[636] 14090/1/13 ft 103 PL/ES: adding "only when they are used within the medical procedure or their presence in the system or procedure pack is justified".
[637] 14090/1/13 ft 104 SE: how to define "relevant?

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market **in his own name** shall, at his choice, follow one of the procedures referred to in Annex VIII or in Part A of Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, **or where the sterilisation has not been carried out in accordance with the manufacturer's instructions** the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 40.

5. The systems or procedure packs referred to in paragraph 1shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 17 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

Article 19

Parts and components

Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device ~~without significantly changing its performance or safety characteristics~~, shall ensure that the article does not adversely affect the safety and performance of the device. ~~Substantiating~~ **Supporting** evidence[638] shall be kept available to the competent authorities of the Member States.

~~An article that is intended specifically to replace a part or component of a device and that significantly changes~~[639] ~~the performance or safety characteristics of the device shall be considered a device.~~

Article 20[640]

Free movement

Member States shall not refuse, prohibit or restrict the[641] making available or putting into service within their territory of devices which comply with the requirements of this Regulation.

[638] 14090/1/13 ft 105 DE: which kind of evidence?
[639] 14090/1/13 ft 106 PL/PT: who will establish that the changes are significant?
[640] 14090/1/13 ft 107 NL: adding provisions on promotion, in line with Article 94 of Directive 2001/83/EC. FR: promotion should be dealt at national level
[641] DS 1075/14 LT adding "placing on the market"

~~***Article 20a***~~ [642] [643]

~~***Promotion***~~

~~**1. Where medical devices are being promoted, no gifts, pecuniary advantages or benefits in kind may be supplied, offered, promised or accepted, unless they are inexpensive and relevant to the practice of medicine.**~~

~~**2. Hospitality at events for purely professional and scientific purposes or at sales promotion events shall always be strictly limited to the main objective of the event and to what is strictly necessary to attend said event.**~~

~~**3. Services rendered by healthcare professionals as part of the marketing or promotion of medical devices, shall be based on a written agreement detailing at least the exact nature of the services and remuneration. Remuneration shall be proportionate to the services rendered.**~~

~~**4. Existing measures and trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.**~~

[642] Advertising of medical devices
Do you see a need for specific provisions at EU level for the advertisement of medical devices? If the answer is positive, please specify which kind of provisions and justify.
6 Agree - 9 Not Agree

[643] DS1710/1/13 HR DK IE IT MT PL agree with a specific provision at EU level for the advertisement of medical devices. DE FR CY HU NL PT SI FI UK not agree If the answer is positive (to regulate advertisement at EU level), should they be subject to the present Regulations?
3 Agree - 2 Not Agree

Chapter III[644]

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

Article 21

Identification within the supply chain

For ~~***all***~~[645] [646] devices, other than devices for performance evaluation, economic operators shall be able to identify the following, for the period referred to in Article 8(4):

(a) any economic operator to whom they have supplied a device;

(b) any economic operator who has supplied them with a device;

(c) any health institution or healthcare professional[647] to whom they have supplied a device.

Upon request, ~~they~~ ***economic operators***[648] shall inform the competent authorities thereof.

For systems and[649] ***procedure packs, this Article shall also apply to the natural or legal person referred to in Article 18(1).***

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644 The text in this chapter is from DS 1537/14.

645 **Pcy** delete "*all*" to align with MD.

646 **DS 2003/13 BE** "*For all devices~~, other than custom-made or investigational devices,~~ economic operators shall be able to identify the following, for the period referred to in Article 8(4).*" **PT/ES** opposed to the inclusion of "*all devices*". **Cion** including all devices might be disproportionate

647 **DS 1982/13 SE** delete "*or healthcare professional*".

648 **DS 1951/13 CZ** replace "*they*" with "*economic operators*"

649 **LT** adding "systems"

Article 22

Unique device identification system[650]

1. For devices, other than devices for performance evaluation, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:
   (a) production of a UDI that comprises the following:
      (i) a device identifier specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V;
      (ii) a production identifier that identifies data related to the unit of device production.
   (b) placement of the UDI on the label of the device ~~***its packaging and, where applicable, on the device itself***~~[651] [652] [653];
   (c) storage of the UDI by the economic operators and the health institutions[654] through electronic means;
   (d) establishment of an electronic system on UDI.

2. The Commission shall designate **and monitor**[655] ~~one or several~~ ~~***a maximum of five***~~ ***the***[656] entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:
   (a) the entity is an organisation with legal personality;
   (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation;
   (c) its system for the assignment of UDIs conforms to the relevant international standards;
   (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;

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650 In this article, reinstated paragraph numbering of the Commission proposal is indicated in highlighted underline.
651 **DS 2003/13 BE** replace (b) with "*placement of the UDI on the label of the outer packaging of the device and when not applicable, on the label of the device itself*".
652 **Cion** see definition of "*label*" in point (11) of Article 2(1).
653 **Pcy** alignment with Article 24(1) of the MD proposal.
654 **DS 1982/13 SE** delete "*and the health institutions*"
655 **AT** adding "and monitor"; **SI** support
656 **Pcy** alignment with Article 24(2) of the MD proposal.

(e) the entity undertakes the following:

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be ~~three~~ ***five*** years after its designation;

(ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;

(iii) to remain in compliance with the criteria for designation and the terms of designation during the period for which it is designated.

3. Before placing a device on the market, the manufacturer shall assign to the device a UDI provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.

4. The UDI shall be placed on the label of the device~~*, its packaging, and, where applicable, on the device itself*~~[657], in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7. It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59. The device identifier shall appear on the EU declaration of conformity referred to in Article ~~17~~***15*** and in the technical documentation referred to in Annex II.

5. Economic operators ~~and health institutions~~[658] shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have supplied or they have been supplied with, ***as determined by a measure referred to in point (a~~b~~) of paragraph 7.***

[657] **Pcy** alignment with Article 24(4) of the MD proposal.
[658] **Pcy** alignment with Article 24(5) of the MD proposal.

Health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have been supplied with if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a~~*b*~~) of paragraph 7~~*9*~~.

6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public

7. ~~The~~ ***In order to ensure the uniform application of the rules laid down in this Chapter, the*** Commission ~~shall be empowered to~~ ***may*** [659]adopt ~~delegated~~ ***implementing*** acts in accordance with ***the examination procedure referred to in*** ~~***with***~~ Article ***84(3)*** ~~85~~[660]:

(a) determining the devices, categories or groups of devices, whose identification shall be based on the UDI system, as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;

(b) specifying the data to be included in the production identifier which, following a risk-based approach, may vary depending on the risk class of the device;

(c) defining the obligations of economic operators, ~~of health institutions and of professional users,~~[661] in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label[662], ~~***higher levels of packaging and on the device itself,***~~ storage of information ~~***by the economic operator and***~~ in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;

(ca) defining the devices, categories or groups of devices for which storage of the device identifier and production identifier by electronic means shall be required by healthcare institutions;[663]

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659 **FR, SI** replace "may" by "shall

660 The initial sentence of this paragraph is aligned with Article 24(7) of the MD proposal.

661 **DS 1982/13 SE** delete "*of health institutions and of professional users*"

662 **DS 1962/13 UK** add "*and on the device*"

663 **UK**, **PT, PL** reinstate paragraph (ca)

~~*(2) defining the devices, categories or groups of devices for which storage of the device identifier and production identifier by electronic means shall be required by healthcare institutions;*~~

~~(*a*d)~~*7a. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 85~~* amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.

8. When adopting the measures referred to in paragraph 7 ~~*9*~~, the Commission shall take into account the following:

(a) the protection of personal data;

(b) the legitimate interest in protecting commercially sensitive information;

(c) the risk-based approach;

(d) the cost-effectiveness of the measures;

(e) the convergence of UDI systems developed at international level***;***

(f) the need to avoid duplications in the UDI system. [664]

[664] **DS 1951/13 CZ** add "*the possible duplicities in UDI system*".

Article 23

Electronic system on registration of devices and economic operators

1.[665] The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device ***~~and procedure packs other than for professional use only, and to identify economic operators involved in the supply chain of the device~~*** and to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the ***manufacturer and, where applicable, the authorised representative and the importer*** ~~economic operators~~ are laid down in Part A of Annex V. Distributors shall identify themselves in the system by introducing their name, address and contact details.[666] [667]

2. Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.

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[665] **Pcy** deletions in this paragraph are analogous to those in Article 25(1) of the MD proposal.

[666] **DS 2003/13 BE** Eudamed is designed to enable traceability of devices within the internal market, therefore a minimal information on distributors operating in the internal market should be available through this system. This obligation should be imposed on the distributors themselves and the same rule of confirmation of the information as foreseen under point 5 of the same article should apply.

[667] **UK, SE, NL, PT, HR, ES, DK, Cion** agree on deleting distributors. **CZ**, **HU** not agree.

3.[668] ~~Within one *two* weeks after placing a device, other than a device for performance evaluation, on the market, importers shall submit to *verify that the device has been registered in* the electronic system the information referred to in *accordance with* paragraph 1 *2 and shall add their details to that registration*~~.

Within two weeks after placing a device, other than a device for performance evaluation, on the market, importers shall ~~submit~~ verify that the manufacturer or authorised representative has uploaded to the electronic system the information referred to in paragraph 1 and shall add their details to the relevant entry/entries.

Where applicable, ***importers shall also verify that the registration includes the details of the authorised representative and, if these details are not included, shall inform the relevant authorised representative ~~if this is not the case~~.***

4.[669] Within ~~one~~ *two* week*s* of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.

5. No~~t~~ later than two years after submission of the information in accordance with paragraphs 2 and 3, and then every second year, the relevant economic operator shall confirm the accuracy of the data. In the event of failure to confirm within six months of the due date, any Member State may take measures[670] to suspend or otherwise restrict the making available of the device in question within its territory until the obligation referred to in this paragraph is complied with.

6. The data contained in the electronic system shall be accessible to the public.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.

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668 The text of this paragraph is aligned to that of Article 25(3) of the MD proposal.
669 The text of this paragraph is aligned to that of Article 25(4) of the MD proposal.
670 The underlined text from the **Cion** proposal is reinstated.

Article 24[671]

Summary of safety and performance

1. In the case of devices classified as class C and D, other than devices for performance evaluation ***~~and devices emitting ionizing radiation~~***, the manufacturer shall draw up a summary of safety and performance. It shall be written in a way that is clear to the intended user ***and, if relevant, to the patient***[672]***. ~~and~~ It shall be available to the public via Eudamed***. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body. ***The manufacturer shall provide the summary with the device or otherwise mention on the label where it is available.*** [673]

[671] **CZ/DK/DE/IT/NL** these provisions do not belong to this chapter.
[672] **DS 1982/13 SE** add "*and if relevant to the patient*".
[673] Following MD proposal

1.a The summary of safety and performance shall include at least the following aspects[674]:

(a) the identification of the device and the manufacturer ;

(~~a~~b) the intended purpose of the device, including indications, contra-indications and target populations;

(~~b~~c) a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other ~~IVD~~ **in vitro** *diagnostic medical devices and other products that are not ~~IVD~~* **in vitro** *diagnostic medical devices, which are intended to be used in combination with the ~~IVD~~* **in vitro** *diagnostic medical device;*

~~(c) the limitations of the device;~~

(d) ~~the scientific validity~~ reference to harmonized standards and common (technical) specifications;

(e) the ~~analytical~~ summary of the performance evaluation report as referred to in annex XII, and relevant information on the PMPF;

(f) the metrological traceability of assigned values;

~~(g) the clinical performance;~~

~~(h) the clinical evidence;~~

~~(i) the intended clinical benefit(s);~~

(jg) ~~the required~~ suggested profile and training ~~to~~ for users;

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674 Following MD proposal

(~~k~~h) information on any residual risks and any (indirect) undesirable effects, warnings and precautions.[675]***~~;~~***

~~(l) storage conditions.~~

2. The Commission may, by means of implementing acts, set out the[676] form and the presentation of the data elements to be included in the summary of safety and performance[677]. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

Article 25

European databank

The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices].

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675 **DS 1124/1/14 REV 1 BE/DE/FR/AT** add:
"*The summary of safety and performance shall include at least the following aspects:*
(a) the identification of the device and the manufacturer ;
(b) the intended purpose of the device, including indications, contra-indications and target populations;
(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device;
(d) reference to harmonized standards and common (technical) specifications;
(e) the summary of the performance evaluation report as referred to in annex XII, and relevant information on the PMPF;
(f) the metrological traceability of assigned values;
(g) suggested profile and training for users;
(h) information on any residual risks and any (indirect) undesirable effects, warnings and precautions."
IE, PT, ES support
UK, DK, SE, NL delete

676 **DS 1468/13 AT** add "*kind*".

677 **DS 1468/13 AT** add "*of devices or specific types of devices*".

Eudamed shall include the following as integral parts:

(a) the electronic system on UDI referred to in Article 22;

(b) the electronic system on registration of devices and economic operators referred to in Article 23;

(ba) the electronic system on notified bodies referred to in Article 31(9);[678]

(c) the electronic system on information **on applications for conformity assessment and** on certificates referred to in **Article 41(1) and** Article 43(4);

(d) the electronic system on interventional clinical performance studies and clinical performance studies involving risks for the subjects set up in Article 51;

(e) the electronic system on vigilance ***and post-market surveillance*** referred to in Article 60;

(f) the electronic system on market surveillance referred to in Article 66.

[678] **DS 1961/13 FR** In order to align the writing with proposals made in the chapter IV.

Chapter IV[679]

Notified bodies

Article 26

National authorities responsible for notified bodies ***for in vitro diagnostic medical devices***[680] [681]

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out ~~third party~~[682] conformity assessment tasks under this Regulation shall designate an authority[683] that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors or subsidiaries of those bodies, hereinafter referred to as the 'national authority responsible for notified bodies'.

2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

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679 The text in this chapter is from DS 1538/1/14 REV 1.

680 IT: Take EC/920 previous work into account. First designation, then notification.

681 ES: Change article title to "notified bodies for medical devices.

682 DE: Delete "*third party*".

683 In response to a suggestion to add a plural it was noted that competent authorities are organised by the individual Member State and that the phrase "an authority" in EU law thus means "an appropriate structure that fulfils the Member State's obligations under the Treaties".

3. ***The national authority responsible for notified bodies*** ~~It~~ shall be organised so that each decision relating to ***designation or***[684] notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.

4. ***The national authority responsible for notified bodies*** ~~It~~ shall not perform any activities that ~~conformity assessment~~[685] ***notified*** bodies perform ~~nor provide consultancy services~~ on a commercial or competitive basis.

5.[686] The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States***, ~~and~~*** the Commission ***and with other relevant regulatory partners***.

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

~~Without prejudice to Article 31(3)~~[687]~~,~~ ***Where*** ~~a~~ ***the*** national authority ~~is~~ responsible for ~~the designation of~~ notified bodies ~~in the field of products other than~~ *~~in vitro~~* ~~diagnostic medical devices,~~ ***is a ~~separate~~ different authority than ~~from~~*** ~~shall ensure that~~ the ***national*** competent authority for *in vitro* diagnostic medical devices***, it shall ensure that the authority responsible for medical devices is consulted*** ~~shall be consulted~~ on ~~all~~ ***relevant*** aspects specifically related to such devices ***normally covered by the competent authority for medical devices.*** ~~also where relevant in the designation of notified bodies for other fields of products than *in vitro* diagnostic medical devices~~.[688]

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[684] DE: Suggests to add "*designation or*".
[685] DE: Replace "*conformity assessment*" with "*notified*". Cion: Text of proposal is appropriate.
[686] DE: Delete this paragraph.
[687] CZ, DK, ES, AT, PT, SE: Reservation. The effects of this reference is very unclear.
[688] FR, UK: Prefer Cion wording.

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any ~~relevant~~[689] changes ***which have a significant impact on these tasks*** ~~thereto~~. ***The Commission shall make this information publicly available.*** [690]

8. ~~***The national authority responsible for notified bodies shall actively participate in coordination and peer review assessments as described in Article 36.***~~[691] The national authority responsible for notified bodies shall be peer-reviewed every ~~second~~ ***third*** year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States***, with the support of the Commission,*** shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be ***documented and*** communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.

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689 HU: Prefers "*significant*".
690 Pcy proposal based on UK suggestion.
691 Pcy proposal based on suggestions from *inter alia* AT.

Article 27

Requirements relating to notified bodies

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, ~~***competence,***~~[692] resource and process requirements that are necessary ~~***to***~~ ***so they are competent to*** fulfil the~~ir~~ tasks for which they are designated in accordance with this Regulation. ~~Minimum~~ ***The r ~~R~~equirements***[693] to be met by notified bodies are set out in Annex VI.

1a. Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, monitoring and surveillance activities and to facilitate the assessment and oversight procedures outlined within this Chapter.

2. ***In order to ensure the uniform application of the requirements set out in Annex VI,*** The Commission ~~shall be empowered to~~ ***may*** adopt ~~delegated~~ ***implementing*** acts in accordance with Article 8~~***49(3)*** amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices~~.[694]

Article 28

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

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[692] Pcy proposal based on suggestion from AT and PT.

[693] DE, RO, SK, BE: Delete "*Minimum*". DK, ES, IT, PT, HU, FI, LIT: Keep "*Minimum*". (Harmonisation, but MS can go further if they so wish.)

[694] Pcy text based on IE suggestion. DE, ES, UK: Suggested deletion of this paragraph. PT: Suggested to keep this paragraph.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary ***provided that the*** legal or natural person that applied for conformity assessment ***has been notified of this.***[695]

4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

5. ~~***The annual assessment of notified bodies as provided for in Article 33(3) shall include verification of the compliance of subcontractors and subsidiaries of notified bodies with the relevant***[696] ***requirements set out in this Regulation.***~~
~~***The report on the assessment set out in Article 33(3) shall include the results of the audits conducted of subcontractors and subsidiaries and the other documents referred to in Article 28(4) for all subcontractors and subsidiaries of notified bodies.***~~

6.[697] ~~***When a notified body has a subsidiary or utilises a subcontractor in another Member State than the Member State where it is established and the competent authority***[698] ***for medical devices***[699] ***or the national authority responsible for notified bodies in any of the Member States concerned has reason to doubt that hat subcontractor or subsidiary complies with the requirements set out in Annex VI, those authorities shall consult with the national authority responsible for the notified body and may , if they do not agree on a satisfactory solution, request that the MDCG initiates the assessment process described in Article 30(3) and (4).***~~

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695 Pcy proposes to delete this paragraph since it is not appropriate that an applicant can decide on internal work of the notified bodies assessing his device.
696 Addition suggested by DK.
697 ES, PT. Support for paragraphs 5 and 6.
698 CZ, AT. The national authority responsible for notified bodies should have this task.
699 Suggestion by AT to specify which competent authority.

Article 29

Application by a conformity assessment body for notification

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established. ***The application shall be written in an official language or official languages specified for the purposes of this Regulation by the Member State concerned.***[700]

2. The application shall specify the conformity assessment activities ~~the conformity assessment~~[701] ***~~procedures~~*** and the ***types of***[702] devices for which the body ***applies to be notified*** ~~claims to be competent~~, supported by documentation proving compliance with all the requirements set out in Annex VI.

   In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, ~~the relevant documentation may be submitted in form of~~ a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008~~. The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body~~ ***may be submitted in support of these requirements and shall be taken into consideration by the national authority responsible for the notified body during the assessment described in Article 30. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements ~~available~~ upon request***.

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[700] Pcy proposal to clarify language requirements already here. Based on suggestions from BE, IE, ES, CY.

[701] DE suggestion.

[702] DE suggestion.

~~3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.~~[703] [704]

Article 30

Assessment of the application[705]

1. The national authority responsible for notified bodies shall ***within 30 days***[706] check that the application referred to in Article 29 is complete and ***may request the applicant to provide any missing information. ~~At the latest 60 days after receiving a complete application, i~~It shall*** draw up a preliminary assessment report.[707]

2. It shall submit the preliminary assessment report to the Commission[708] which shall immediately transmit it to the Medical Device Coordination Group established by Article 76 ('MDCG'). ~~Upon request by the Commission, the~~ ***The*** report shall be submitted by the authority in ***an official language or official languages specified for the purposes of this Regulation by the Member State***[709] ***concerned, and upon request by the Commission ~~or the MDCG~~, in an additional***[710] ~~up to three~~ official Union languages. ***Documents to support the application described in Article 27 shall be made available upon request.***

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703 DE: Delete this paragraph.
704 Pcy proposes to move this paragraph to become 33(0) since it is related to monitoring.
705 Pcy deems it necessary to stipulate deadlines.
706 Suggestion from BE.
707 SE: Implementing act necessary to specify content and format of the preliminary assessment report.
708 DE: objects to prior notification to Cion.
709 Pcy language requirement aligned with Article 29.
710 ES: No need for additional translation.

~~*2a. Within 7 days of the submission the national authority responsible for notified bodies shall schedule an on-site assessment with the applicant body at least 84 days but not more than 104 days following submission to the MDCG. The national authority shall communicate this schedule to the MDCG.*~~

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of ~~at least two~~ ***three*** experts chosen from ~~a~~ ***the*** list ~~of experts~~ who are qualified in the assessment of conformity assessment bodies ~~*referred to in Article 30a and who comply with Article 82 of Regulation (EU) [Ref. of future Regulation on medical devices] as regards the applicant conformity assessment body.*~~ The list shall be drawn up by the Commission in cooperation with the MDCG ***and shall be made publicly available***. ~~*The first expert shall come from the Member State of the applying conformity assessment body and be appointed by the Commission. The second expert shall come from another Member State and be appointed by the Member State of the applying conformity assessment body.*~~[711] ~~At least o~~One of these ~~*The third*~~ experts shall be ~~*appointed by*~~ a representative of the Commission ***and*** ~~who~~ shall lead the joint assessment team. ***The expert leading the team shall participate in the assessment of the applicant body and shall verify that the national authority responsible for notified bodies fulfils its obligations and effectively performs its designation and monitoring activities.***

3a. The joint assessment team shall be comprised of appropriate experts which reflect the conformity assessment activities and the types of devices which are subject to the application from the conformity assessment body or, in particular when this procedure is initiated in accordance with Article 35 to ensure that the specific concern can be appropriately assessed.[712]

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[711] Redraft by Pcy in response to interventions of DE. PL who held that Cion had too much power in this team.

[712] Comment regarding 3a and 3b from Pcy: The experts chosen should come from a pool that is sufficiently large to prevent that persons with vested interests evaluate an application.

~~*3b. The national authority responsible for notified bodies shall provide the joint assessment team with all relevant documents necessary to support its preliminary assessment report to allow the joint assessment team to conduct a preliminary assessment of the compliance of the applicant with the requirements and obligations in Annex VI. The documents shall be available in the languages referred to in paragraph 2.*~~

3c. The national authority for notified bodies shall provide the joint assessment team with the proposed schedule for on-site assessment at least two months in advance and its initial plan for on-site assessment of the notified body <u>at least one month in advance</u>. Following its assessment of the application the joint assessment team shall provide feedback and input into the on-site assessment plan to the national authority.

~~*If the joint assessment team, following an initial assessment, does not consider that the application is sufficient to allow an on-site assessment to proceed as provisionally scheduled it shall inform the national authority accordingly and provide its reasons within 30 days of the assignment of the team.*~~

~~*The authority shall decide whether to reject the application, to proceed with the on-site assessment in accordance with paragraph 4 or request the applicant to take action pursuant to paragraph 3d.*~~

~~*3d. The national authority responsible for notified bodies shall, based on the reasons provided by the joint assessment team or its own findings inform the applicant about measures arising from the assessment that shall be taken before the assessment can be continued. After taking those measures, the applicant shall submit an updated application, setting out in particular the measures taken. The assessment shall continue pursuant to paragraph 3b.*~~

4. Within 90 days after ~~designation~~ ***assignment*** of the joint assessment team ~~***or, where applicable, of the updating of the application pursuant to paragraph 3d***~~, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and ~~***together***~~ ***plan and*** conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. ***The national authority may decide following review of the documentation mentioned above that the application is not complete or is not sufficient to proceed to an on-site assessment and may postpone the on-site assessment for a period of 90 days to allow the applicant opportunity to correct the application.*** Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless ~~***the national authority and joint assessment team following due consideration so decide***~~ the Commission representative mentioned in Article 30(3) requests the on-site assessment.

The on-site assessment of the applicant body shall be led by the national authority responsible for notified bodies.

4a. Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement with respect to the assessment of the application.

The joint assessment team shall record non-compliances with Annex VI, ~~observations on the performance of the national authority responsible for notified bodies~~ and any observations or opportunities for improvement in a report to be provided to the MDCG, the Commission and to the relevant national authority responsible for notified bodies.

Divergent opinions shall be identified in the assessment report of the ~~***joint assessment team***~~ national authority responsible. ~~***and shall be provided to the MDCG, the Commission and the national authority responsible for notified bodies***~~.

4b. The national authority shall follow up with the applicant body to assess whether non-compliances identified during the assessment have been appropriately addressed. The joint assessment team may request and further assess follow up on findings identified during the review.

5. The national authority responsible for notified bodies shall***, following implementation of any measures arising from the assessment referred to in paragraphs 4a and 4b,*** submit its assessment report and***, if applicable, the*** ~~its~~ draft notification to the Commission***,*** ~~which shall immediately transmit~~[713] ~~those documents to~~ the MDCG and ~~to~~ the members of the joint assessment team. Upon request ~~by the Commission~~, those documents shall be submitted by the authority in *an* ~~up to three~~ official Union language~~s,~~ ***specified by the Commission***~~.~~ [714]

6. The joint assessment team shall provide its opinion regarding the assessment report ***prepared by the national authority responsible for notified bodies*** and***, if applicable,*** the draft notification within 21 days of receipt of those documents ~~and~~ ***to*** the Commission***, which*** shall immediately submit this opinion to the MDCG. Within 42 days after receipt of the opinion of the joint assessment team, the MDCG shall issue[715] a recommendation with regard to the draft notification which the relevant national authority shall duly take into consideration for its decision on the designation of the notified body.

7. The Commission may, by means of implementing acts, adopt measures setting out the modalities ***and associated documents***[716] for the application for notification referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

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713 ES, SE, UK: Cion should keep the role as intermediate.
714 Pcy: Not needed - see *e.g.* Article 30(2).
715 It is noted that the procedure should be reviewed in its entirety.
716 Based on IE suggestion.

~~*Article 30a*~~[717]

~~*Nomination of experts for joint assessment of applications for notification*~~

~~*1. Member States shall nominate experts qualified in the assessment of conformity assessment bodies in the field of in vitro diagnostic medical devices to participate in the joint assessment activities outlined in Article 30.*~~

~~*2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise. This list shall be made publicly available.*~~

Article 31

Notification procedure

1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool[718] developed and managed by the Commission ***referred to in Article 25.2(ba)***.

2. Member States may notify only conformity assessment bodies which satisfy the ***minimum*** requirements set out in Annex VI ***and for which the assessment pursuant to Article 30 was completed***.[719]

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[717] Pcy proposal based on IE suggestion. The aim is to clarify the procedure in Article 30 and to provide for the creation of a list of experts that can be selected for specific tasks. Compare deletion in 30(3).

[718] SE: Refer to Article 25. Pcy: 31(9) contains reference. Also bearing on 31(10).

[719] Pcy Change aims to clarify procedure for notification. Based on suggestion from DE, ES, AT, PL. Reference to "*Minimum requirements*" should be aligned with Article 27.

3.[720] Where a ~~***The***~~ national authority responsible for notified bodies ~~***shall not designate a notified body for any tasks related to medical devices unless***~~ ***is a separate authority from*** the competent authority for medical devices***, that authority*** shall ~~***has***~~ provide~~***d***~~, prior to the notification, a positive opinion on the notification ***with particular regard to the elements for which it is responsible at national level.*** ~~***as regards conformity assessments related to medical devices***~~ ~~and its scope~~.

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the and the type of devices which the notified body is authorised to assess.

4a. The Commission ***shall within [three] years of the entry into force of this Regulation*** ~~may~~, by means of implementing acts, ~~set~~ ***draw*** up a list of codes and ~~the~~ corresponding types of devices to ~~define~~ ***describe*** the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 84(~~2~~ ***3***).). ***The Commission may update this list utilising the provisions above arising from the coordination activities described in Article 38.***

5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

[720] DE, IT; AT, PL: Delete this paragraph. CZ, ES, FR: Prefer original wording.

6.[721] The notifying Member State shall***, without prejudice to Article 33,*** provide the Commission and the other Member States with documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. ~~It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 26(6).~~[722]

7. Within ~~***The Commission and the other Member States may, within***~~ 28 days of a ~~***the***~~ notification ~~***object to the notification on grounds relating to the designated***~~[723] ~~***body***~~, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

8. When a Member State or the Commission raises objections in accordance with paragraph 7, ~~the effect of the notification shall be suspended. In this case,~~[724] the Commission shall bring the matter before the MDCG within 1~~5~~***0***[725] days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within ***40***~~28~~ days after the matter has been brought before it. ~~If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.~~ [726]

8a.[727] ***Where the MDCG, after having been consulted in accordance with paragraph 8, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG's ~~s~~ opinion within 28 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons why the notifying Member States intends to designate or not designate the conformity assessment body.***

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721 DE Delete this paragraph - this is according to other provisions MS competence.

722 Pcy deems that this sentence is not needed, due to changes to article. CZ, IE, UK: Keep this sentence.

723 Reworded Pcy proposal. CZ, EE, IE, PT: Prefer original wording.

724 UK against deletion.

725 Suggestion by FR, UK.

726 Pcy sentence deleted since it is covered by the new paragraph 8a.

727 Pcy proposal based on IE suggestion. Takes into account DE suggestion - in para 8a and 9.

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG ~~or the Commission~~, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted ~~fully or partially~~, ***or where the notifying Member State having responded in accordance with paragraph 8a, decides to designate the conformity assessment body*** the Commission shall publish the notification accordingly within 14 days of receipt..

When publishing the notification, the Commission shall add the information relating to the notification of the notified body to the electronic system referred to in point (e) of Article 25(2) along with the documents mentioned in paragraph 5. ~~That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG mentioned in paragraph 5 of this Article~~. ~~In addition, the~~ The Commission shall include details of the opinion and response referred to in paragraphs 8 and 8a of this Article on the electronic system where it shall be accessible to Member States and the Commission.

10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.

11. The conformity assessment body-concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.[728]

Article 32

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification ~~is accepted~~ ***becomes valid***[729] in accordance with Article 31***(10)***. It shall assign a single identification number even when the body is notified under several Union acts.

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[728] Pcy addition aiming to clarify procedure.

[729] Based on suggestion by DE (for consistence).

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the ***conformity assessment*** activities ***and the types of devices*** for which they have been notified, accessible to the public ***on the electronic system referred to in Article 25***. The Commission shall ensure that the list is kept up to date.

Article 33

Surveillance, ~~M~~monitoring and re-assessment *of notified bodies*

0.[730] ***After being designated, the notified body shall update the documentation referred to in Article 29(2) whenever relevant***[731] ***changes occur, in particular regarding personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in [Annex VI/this Regulation]***[732]***, in order to enable the national authority responsible for notified bodies to monitor and verify continued ~~ous~~ compliance with all the requirements set out in Annex VI.***
Notified bodies shall, without delay, inform the national authority responsible for notified bodies of ~~any~~ relevant[733] ***changes to the documentation mentioned above.***

1. The national authority responsible for notified bodies shall ~~continuously~~ ***conduct surveillance and*** monitor***ing of***[734] the notified bodies ***based on its territory***[735]***<u>and of its subsidiaries and subcontractors</u>*** to ensure ongoing compliance with the requirements ***and the fulfilment of its obligations*** set out in ***this Regulation*** ~~Annex VI~~**.** The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority***, the Commission and other Member States***[736] to verify compliance with those criteria.

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730 This paragraph is the former paragraph 3 of Article 29.
731 <u>HU</u>. prefers "*significant*".
732 To be aligned with the wording chosen elsewhere.
733 <u>HU</u>. prefers "*significant*".
734 <u>ES, PT</u>: prefers original wording.
735 Based on <u>DE; IE</u>. suggestions.
736 <u>Pcy</u> proposal to enable broader verification.

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of ~~any~~ ***relevant***[737] changes ***referred to in paragraph 0***~~, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated~~.

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their ~~or another Member State~~'s authority ~~or by the Commission~~[738] ***and grant access to their premises upon request in accordance with paragraph 3e***[739]. ~~***For this purpose t***~~ ***The national authority responsible for notified bodies shall receive a copy of all such requests submitted by another Member State authority or by the Commission to notified bodies ~~by another Member State authority~~ based on their territory.*** The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG. ~~***For this purpose the national authority responsible for notified bodies shall receive a copy of all such requests submitted to notified bodies based on their territory.***~~ ~~The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.~~[740]

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737 HU. prefers "*significant*".
738 Deletions based on DE, PT suggestions.
739 Proposal by Pcy based on suggestion in WP meeting.
740 Deleted following DE suggestion.

3. At least once a year[741], the national authority responsible for notified bodies shall assess whether each notified body ***and the subsidiaries and subcontractors***[742] [743] under its responsibility still satisfies**y** the requirements ***and fulfil their obligations*** set out in Annex VI. This assessment shall include an on-site visit to each notified body ***and, when if necessary, to its subsidiaries and subcontractors.***

The national authority shall conduct its monitoring, and re-assessment activities in line with according to an annual assessment plan to ensure that it can effectively conduct monitoring and surveillance of a monitor the notified body's continued compliance of the notified body with the requirements of this Regulation. This plan shall provide a reasoned schedule for the frequency of assessment of the notified body and associated subsidiaries and subcontractors. The authority shall submit its annual plan for surveillance, monitoring or re-assessment for each notified body for which it is responsible of notified bodies to the MDCG and to the Commission by the end of October each year.

3a. The national authority's monitoring of notified bodies shall include, at least once a year[744], witnessed audits of the notified body personnel, including subsidiaries and subcontractors[745] when necessary[746], when conducting quality system assessments at a manufacturer's facility.

3b. The monitoring and surveillance of notified bodies conducted by the national authority responsible for notified bodies should be performed by appropriately competent and qualified personnel. The personnel may comprise both internal and external experts and should be representative of the range of devices for which the notified body is designated.

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741 IE, AT "*according to best practise*".
742 Based on PT suggestion to include subsidiaries.
743 SE: reservation about excessive burden on authorities. BE: Add "*wherever necessary*".
744 DE: not necessary once a year. NL: Too burdensome. Less binding rewording. AT: After 1st year and then every two years. IE: According to best practice ES: Witnessed audit only once.
745 PT: support.
746 Based on BE suggestion.

3c. The monitoring of notified bodies conducted by national authorities shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.

~~*The authority shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.*~~

~~*In addition, effective mechanisms shall be in place to ensure the flow of information between the national authority responsible for notified bodies and the competent authority for medical devices. Particular emphasis shall be placed on the review of clinical data relevant to the device.*~~

~~*3e. The national authority responsible for notified bodies may in addition to surveillance or re-assessment on-site assessments conduct short-notice, unannounced or 'for-cause' assessments if needed to address a particular issue or to verify compliance.*~~

3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall monitor the timely implementation of relevant corrective and preventative actions. ~~*require necessary corrective and preventative actions by the notified body. The timely implementation and subsequent effectiveness of these actions shall be monitored by the national authority responsible for notified bodies.*~~

~~*3g. The national authority responsible for notified bodies may impose specific sanctions against a notified body based on its territory based on findings as referred to in paragraph 3f. The national authority shall be able to justify, upon request of the MDCG or the Commission, the reasons for imposing sanctions on the notified body rather than making any change to the notification as provided for in Article 34.*~~

4. Three years after notification of a notified body, and again every third year thereafter, ~~the~~ ***a re-***assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). ~~At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI~~[747]

[748]

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities ***regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring and surveillance activities, including details of the verification of technical and clinical reviews conducted by the authority.*** This report ***shall be treated as confidential by the MDCG and the Commission however it*** shall contain a summary which shall be made publicly available.

~~***Each year, the notified bodies shall send an annual activity report, containing the information mentioned in Annex VI point [to be decided], to the appropriate national competent authority responsible for notified bodies and the Commission. The Commission shall forward it to the MDCG.***~~[749]

[747] Pcy: Deleted part already covered.
[748] DE: Add paragraph on authorities' need to document findings.
[749] NL: Delete - too burdensome. IE, FR, AT, UK: Support for this subparagraph.

Article 33a[750]

Technical and clinical assessments of certain notified bodies

1. In addition, as part of the surveillance activities set out in ~~paragraphs 3 and 4 of~~ Article 33 of this Regulation, national authorities responsible for notified bodies ~~submit details of their activities described in Article 33~~.3b. a plan to the MDCG for off-site assessment of a sample of reviews of clinical evaluations, submitted by manufacturers in support of class III and/or implantable medical devices~~

~~[3b. The national authority, as part of its ongoing monitoring and surveillance of notified bodies~~ shall assess an appropriate number of notified body reviews of manufacturers' clinical evaluations and technical document to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These reviews shall be conducted both off site and on-site.~~]~~[751]

2. The sample of files assessed shall be planned and representative of the types and risk of devices certified by the notified body~~. The sample chosen shall be representative~~, appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.

3. The national authority responsible for notified bodies shall assess that the review by the notified body was conducted appropriately and verify the conclusions drawn by the notified body. ~~The assessment conducted by the national authority shall utilise appropriate internal and, when necessary, external clinical expertise.~~ These assessments shall be conducted utilising common technical specifications provided for in Article 7.

~~3. The national authority responsible for notified bodies shall, when conducting its assessment, consider data relevant from the surveillance systems described in chapter VII of this Regulation, the common technical specifications available and the state of the art.~~

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[750] Based on UK suggestion. Pcy: Inclusion of this article depends on the outcome of the discussion on Article 44 and Chapter VIII (role of MDCG).

[751] Pcy question: Is this according to best practice?

4. The national authority responsible for notified bodies shall on an annual basis provide a report ~~detailing the device, the clinical evidence, the review and conclusions of the notified body and its own conclusion on this assessment~~ detailing the outcome of the assessments conducted at national level. This report shall be uploaded ~~along with the notified body assessment~~ to the European databank referred to in Article25 .

5. The assessments referred to in paragraph 1, 2 and 3 of this article shall form part of the re-assessment of notified bodies every third year in accordance with the procedure described in Article 30(2) and (3) and the assessment activities referred to in Article 35(2a). These assessment shall be conducted utilising appropriate expertise. ~~The MDCG will coordinate the joint clinical assessment of a sample of class III and/or implantable devices across the range of notified bodies informed by the sampling plan referred to in Article 33a(1).~~

~~6. The national authority responsible for notified bodies shall lead the assessment in conjunction with at least two clinical experts who have appropriate experience in assessing clinical evidence and of the type of devices in question.~~

~~7. The MDCG shall draw up a list of clinical experts identified as either national authority experts or external clinical experts identified on the basis of their clinical speciality. The Commission may also contribute experts to the joint clinical assessment teams. The MDCG will implement a system to ensure impartiality and to manage potential conflicts of interest.~~

~~8. The joint clinical assessment team will complete its assessment, in line with principles of paragraph 2 and 3 of this Article, within 30 days of all required documentation being provided to it. During this time it may seek clarification or ask questions to the notified body involved.~~

~~9. The joint clinical assessment team shall prepare a report within 15 days of completing its assessment which shall be immediately provided to the MDCG.~~

~~*10. Where a joint clinical assessment report identifies deficiencies in a notified body's assessment of the clinical evaluation, the report shall include a recommendation to the MDCG on the remedial action that it judges appropriate with respect to the device in question.*~~

~~*11. If the MDCG judges that these deficiencies are appropriately justified and evidenced, and depending on the type of nature of deficiencies concerned a remedial action will be implemented. This may include but will not be limited to, further enhanced assessment by a joint clinical assessment team on the reports submitted by the authority in accordance with Article 33a(3) and a joint clinical assessment on-site at the notified body in accordance with Article 35(3).*~~

~~*6. The Commission in cooperation with the MDCG shall produce guidance to support the operation of clinical assessments.*~~

6. The MDCG may, based on ~~performance in previous clinical assessments,~~ the reports of ~~monitoring~~ these assessments by the national authority ~~and~~ or joint assessment teams, and inputs from the market surveillance and post-market surveillance activities described in Chapter 7, recommend that the sampling, either by national authority or as part of a joint assessment activity, shall cover a greater or lesser proportion of the clinical evaluations and technical documentation assessed by a notified body.

7. ***The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 8~~4~~(3).***

Article 34

Changes to notifications

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification ***by the national authority responsible for notified bodies***. ~~***Where the change extends the scope of the notification, the***~~ The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail an ~~***the***~~ extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 31(10).

1a.[752] ***Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned one year before ceasing its activities. The certificates may remain valid for a temporary period of six months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products*** ~~***and have***~~ ***pending confirmation of the completed assessment of the devices by the end of that time period by the new notified body.***

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

   The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

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[752] Based on FR suggestion.

2a. ~~A restriction of a notification may constitute include a reduction in the conformity assessment procedures, activities or the types of devices which a notified body can assess and certify.~~

3. In the event of restriction, suspension[753] or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are ~~either processed by another notified body or~~ kept available for the national authorities[754] [755] responsible for notified bodies and ***national authorities responsible*** for market surveillance at their request.

[753] HU: delete "*suspension*" here and add new sentence: "*In the event of suspension, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are kept available for the national authorities responsible for notified bodies and for market surveillance at their request.*"

[754] HU: Only authority should provide documentation.

[755] DE: Manufacturer should be able to transfer the data elsewhere. Why need this? AT: support.

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the change to the notification have an impact on the certificates issued by the notified body and, within three months after having notified the ~~***suspension, restriction, extension, change or withdrawal of***~~ changes to the notification, shall submit a report on its findings to the Commission and the other Member States. [756] Where necessary to ensure the safety of devices on the market, that ~~***The national competent***~~ authority ~~***responsible for notified bodies***~~ shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued[757]. ~~If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.~~ ***The authority shall enter into the electronic system mentioned in Article 43 paragraph 4 all certificates which it has suspended or withdrawn and inform the competent authority for medical devices of the Member State where the manufacturer concerned or his authorised representative has his registered place of business through this electronic system. Where necessary to avoid a potential risk to the health or safety of patients, users or others the authority responsible for the manufacturer of the device or his authorised representative shall take the appropriate measures.*** [758]

5. [759] The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

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[756] ES: NCAs should also be able to recall certificates issued unduly. Also concerned with what happens with products that are in the market. It shares concerns.

[757] HU: Why not immediate effect.

[758] Based on DE suggestion supported by IE, AT.

[759] IE, AT, UK: Delete whole paragraph. But who takes over? FR concerns. ES supports paragraph but role of NCA should be limited to mediate.

(a) in the case of suspension ***or restriction*** of a notification: on condition that, ***within one month of the suspension or restriction, that the national authority has confirmed that there is no safety issue for certificates affected by the suspension or restriction and shall outline a timeline and actions anticipated to remedy the suspension or restriction. The authority, that no certificates relevant to the suspension will be issued, amended or re-issued and shall indicate whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. If the notified body does not have the capability that national authority shall confirm that,*** within three months of the suspension ***or restriction***, either the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body confirm in writing that it is ***temporarily*** assuming the functions of the notified body ***to monitor and remain responsible for the certificates*** during the period of suspension ***or restriction***;

(b) in the case of ~~restriction or~~ withdrawal of a notification: for a period of three months[760] after ~~the restriction or~~ withdrawal. The competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the ***provisional*** validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided ***that it has confirmed that there is no safety***[761] [762] ***issue associated with the devices in question and that another notified body has confirmed in writing that it will assume immediate responsibilities for these products and will have completed assessment of the devices by the end of that time*** ~~it is assuming the functions of the notified body during this~~ period.

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[760] BE: 3 months is too long time for IVDs of Class D, therefore NCA responsibility should start on Day 1.

[761] DE: NCA should judge if there is a risk.

[762] IT: Also an electronic mechanism for safety warnings is needed.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Article 35[763]

Challenge to the competence of notified bodies

1. The Commission***, in conjunction with the MDCG,*** shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VI or the obligations to which it is subject[764]. ***It shall ensure that the concerned national competent authority responsible for notified bodies is ~~and the MDCG are~~ informed and ~~are~~ is given opportunity to investigate these concerns.***[765] It may also commence such investigations on its own initiative.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.

[763] DE: Already covered in 33(4) so delete whole article. Open to use of implementing acts.
[764] AT: Compare other Regulations.
[765] DK, IE, AT, UK: MDCG should be involved.

2a. The Commission in conjunction with the MDCG may initiate the assessment process described in Article 30(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI and the investigation of the national authority is not deemed to have fully addressed the concerns . The reporting and outcome of this assessment process will follow the principles of Article 30(5) and 30(6) without necessarily the inclusion of a notification. Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list described in Article 30(3) in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 33 and as outlined in the annual plan described in paragraph 3 therein.

3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

3a. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.[766]

[766] Based on SE suggestion. (Compare article R26(3) of Decision 768/2008/EC). Could also be included in Chapter X.

Article 36

~~Peer review team assessment of national authorities responsible for notified bodies and~~ *Exchange of experience between national authorities responsible for notified bodies*

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. ***This shall address elements including:***

   (a) Development of best practice documents relating to the activities of the national authority responsible for notified bodies;

   (b) Development of guidance documents for notified bodies in relation to the implementation of this Regulation;

   (c) Training and qualification of the experts referred to in Article 30.3;

   (d) Monitoring of trends relating to changes to notified body notifications and trends in certificate withdrawals and transfers between notified bodies;

   (e) Monitoring of the application and applicability of scope codes referred to in Article 31.4a

   (f) Development of a mechanism for peer review between authorities;

   (g) Methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies for medical devices.

2. The national authorities responsible for notified bodies shall participate in a peer review in accordance with the mechanism agreed in Article 36(1).

3. The Commission shall participate in the organisation and implementation of the peer review mechanism, including the peer review activities.

4. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review ,and training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

~~***1. The national authority responsible for notified bodies shall be subject to peer review team assessment of their surveillance and monitoring activities, every three years.***~~[767] ~~[768]~~

~~***2. The peer review team assessments shall be conducted by a representative of the Commission***~~[769] ~~***together with up to two representatives from other Member States' national authorities responsible for notified bodies or national competent authorities for medical devices.***~~

~~***3. The peer review team assessment shall be organised by the MDCG***~~[770] ~~***in conjunction with the national authority responsible for notified bodies.***~~

~~***4. The peer review team shall participate in the assessment of a notified body for which the national authority is responsible during one of its planned on-site assessments as part of its surveillance activities.***~~

~~***5. The peer review team upon conclusion of its assessment shall transmit to the national authority any observations with respect to compliance of the national authority with this Regulation and any suggestions for improvement. The national authority shall be given the opportunity to respond to these observations and to comment on the peer review team assessment report prior to its finalisation.***~~

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[767] DE, PL: Useful but resource constraints. Alternative proposal on auditing procedure with Commission participation (such is the case in food safety monitoring) IT also concerned but there should be a list of profiles of the notified bodies and their activities per MS.

[768] AT, ES: Why every three years. Leave it open-ended. BE: Keep timeframe.

[769] AT: Use experience from Joint Assessment Teams when drafting this. DE: Since there are already JATs what is the benefit of additional peer-review? IE, PT: JAT is for notified bodies whereas peer review involves NCAs.

[770] BE: Annual plan should be MDCG's responsibility.

~~*6. Within 45 days of the on-site assessment the Commission representative, together with the Member State representatives on the peer review team, shall produce an on-site assessment report which shall set out any observations with respect to compliance with this Regulation and opportunities for improvement.*~~

~~*7. The national authority shall respond to the observations in the peer review team assessment report within 60 days of it being made available, and if appropriate it shall put in place a plan to address these observations.*~~

~~*8. The peer review team assessment report and the national authority's comments and response to this report shall be made available to the Member States through the MDCG. A summary of this report shall be made publicly available.*~~

~~*9. Member States shall cooperate with the peer review team assessment process, providing all required documentation and technical support to the peer review team and allow access to premises and systems so that the peer review team assessment can be conducted effectively.*~~

~~*10.*~~

~~*12. In the case referred to in the second subparagraph of paragraph 28(6), the competent authority for medical devices shall participate in the peer-review.*~~

~~*13. Detailed rules concerning peer review in Member States may be drawn up or amended in accordance with the examination procedure referred to in Article 84(3).*~~[771]

[771] Taken from DE alternative suggestion.

Article 37

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices.
The bodies notified under this Regulation shall participate in the work of that group.

Article 38

Fees[772]

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall~~, wholly or partly,~~ cover the costs relating to the activities exercised by the national authorities responsible for notified bodies ***and by the joint assessment teams***[773] in accordance with this Regulation.

~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that received a certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.~~

[772] IE, ES, UK: Delete this Article in view of Article 82 provisions. Cion: defends its proposal.
[773] Addition based on DE suggestion.

Chapter V[774]

Classification and conformity assessment

Section 1 – Classification

Article 39

Classification of in vitro *diagnostic medical devices*

1. Devices shall be divided into classes A, B, C and D, taking into account the~~ir intended~~ purpose ***intended by the manufacturer***[775] and inherent risks. Classification shall be carried out ~~***by the manufacturer***~~[776] ~~***under its responsibility***~~[777] in accordance with the classification criteria set out in Annex VII.

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority[778] of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business.

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774 The text in this chapter is from 15279/14 and has been updated by the **IT Pcy** following the Working Party on 11 and 12 November 2014. Article 42 is however from doc. 13482/14.

775 **DS 1483/13 DE** replace '*intended purpose*' by '*purpose intended by the manufacturer*'.

776 **DK, ES, AT** delete "*by the manufacturer*".

777 Following MD Proposal - **DK, ES, AT** delete "*by the manufacturer under its responsibility*". **DE, IE, IT, LT, PL, PT** it should be clarified that classification is an act of the responsibility of the manufacturer. **Pcy** compromise proposal, delete "*under its responsibility*".

778 **SK** who is the authority that decides? The current Directive states that it is the competent authority which appoints the notified body; this provision should be retained. **DK** support.

The ~~At least 14 days prior to any decision, the~~ competent authority shall notify the MDCG and the Commission of its ~~envisaged~~ decision.[779]

3. ***At*** ~~The Commission may, at~~[780] [781] [782] ~~the~~ ***a duly substantiated*** request of a Member State ***the Commission shall***[783] ~~or on its own initiative and~~ ***after consulting the MDCG, the Commission may***[784] ***decide***, by means of implementing acts, ~~decide~~ on the ***following:***

(a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification***;***

(b) ***that a device, or category or group of devices, should shall for compelling reasons of public health based on new scientific evidence, by way of derogation from the classification criteria set out in Annex VII, be classified in a higher another class***.

3a. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).

3b. ~~Those~~ ***The*** implementing acts ***referred to in paragraphs 3 and 3a and 3b*** shall be adopted in accordance with the examination procedure referred to in Article 84(3).

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779 **UK** would prefer that the communication is done after the decision has been taken. **Cion** the communication should be done before the decision has been taken to allow any necessary intervention. **DE** a decision from a national authority cannot be reviewed by **Cion**, only by a national court. **Cion** the Commission can launch an infringement procedure.
DE, ES, IT, LV what is the purpose of the communication? What is the next step following the communication?
PT, UK the decision should be communicated in order to achieve harmonisation of the classification.

780 **DS 1483/13 DE** replace '*Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide*' by '*MDCG shall, at the request of a Member State or of the Commission, give an opinion*'.

781 **DE** when there is a need to upgrade the classification, the MDCG can take the initiative? The Commission can take the initiative? Would it be done by means of delegated acts?

782 **DS 1483/13 DE** add the following sentence: '*The Commission shall take a final decision following the MDCG' s opinion by means of an implementing act, adopted in accordance with the examination procedure referred to in Article 88 (3).*'

783 **DE, AT** there should be a deadline for Cion to act.

784 **Pcy** compromise proposal.

4. In ***order to ensure the uniform application of the classification criteria set out in Annex VII*** ~~the light of technical ***and scientific***~~[785] ~~progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73~~, the Commission ~~shall be empowered to~~ ***may*** adopt ~~delegated~~ ***implementing*** acts[786] in accordance with Article ~~85~~ ***84*** ~~as regards the following:~~

~~(a) deciding, that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;~~

~~(b) amending or supplementing ***updating*** the classification criteria set out in Annex VII.~~[787]

The Commission shall take into account any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73.[788]

Section 2 – Conformity assessment

Article 40

Conformity assessment procedures

1. Prior to placing a device on the market[789] ~~***or its putting into service***~~[790] [791], manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.

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785 **DS 1257/13 AT** suggested to add "*and scientific*". **Cion** agreed.

786 **DK, ES, CY, AT, PT** in relation to point (a), would prefer implementing acts (instead of delegated acts) to be adopted on the initiative of the national authorities.
UK opposed to the delegated acts, suggested deleting the paragraph.
DK delegated acts provision should be moved to paragraph 3.
IT doubts whether delegated acts are the more appropriate.

787 **DS 1483/13 DE** replace '*shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following: (a) deciding*' by '*after having received an opinion by the MDCG, shall by means of an implementing act, adopted in accordance with the examination procedure referred to in Article 88 (3) decide*'. Delete point (b).

788 Following MD Proposal.

789 **Pcy** to add "*or its putting into service*" would imply that in-house products should be subject to a conformity assessment; According to the preliminary results of the questionnaire, delegations prefer to define specific requirements for in-house products.

790 **BE, ES, AT, PT, SE, Cion** reinstate the deleted words.

791 WP 11-12 November 2014: **BE, ES, AT, SK, Cion** add "*or its putting into service*".

~~*1a. Prior to putting into service devices that are not placed on the market, with the exception of in-house devices*~~[792]~~*, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.*~~[793]

2. Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance~~,~~ ***and*** design dossier examination and batch verification~~,~~ as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX~~,~~ coupled with a conformity assessment based on production quality assurance including batch verification~~,~~ as specified in Annex X.

In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify ***by laboratory testing***[794] [795] ***the claimed performance and the***[796] compliance of the device with the applicable C~~T~~S, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent,[797] [798] [799] as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. ***Laboratory tests performed by a reference laboratory shall focus on in particular analytical sensitivity using reference materials***[800] ~~*and diagnostic sensitivity using specimens from early and established infection*~~. [801] [802]

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792 Following MD Proposal - Following the answers to question 1.2 of the questionnaire on Chapter II, article 4 (4).

793 Following MD Proposal - **Pcy** compromise proposal.

794 **DS 1484/13 DE** add '*by laboratory testing*'.

795 **FR** delete "*by laboratory testing*".

796 **DS 1365/13 BE** add '*the claimed performance and the*'.

797 **DS 1484/13 DE** delete '*when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent,*'.

798 **DK, AT, Cion** reinstate Cion text.

799 The highlighted text has been reinstated.

800 **Cion** delete "*Laboratory tests…*".

801 **DS 1484/13 DE** add '*Laboratory tests performed by a reference laboratory shall focus on in particular analytical sensitivity using reference materials and diagnostic sensitivity using specimens from early and established infection.*'. **DK, FR** delete.

802 **Cion** delete '*and diagnostic using specimens from early and established infection*'.

For companion diagnostics intended to be used to assess the patient eligibility for treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[803] or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

3. Manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance~~,~~ as specified in Annex VIII, ***except for its Chapter II,*** with assessment of the ~~design documentation within the~~[804] technical documentation on a representative[805] basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination~~,~~ as specified in Annex IX coupled with ***a*** conformity assessment based on ***product conformity verification*** ~~production quality assurance,~~ as specified in Annex X.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall ***follow the procedure for ~~design dossier~~ technical documentation***[806] ***examination*** ~~fulfil the supplementary requirements~~ set out in Section 6.1 of Annex VIII or in ~~Section 2 of~~ Annex IX.[807]

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803 OJ L 311, 28.11.2001, p. 67.

804 **AT** delete. **DE** support.

805 **AT** representative basis should be clarified and more detailed. **DE** support.

806 **AT** replace "*design dossier*" by "*technical documentation*". **DE** support.

807 **DS 1365/13 BE** replace '*fulfil the supplementary requirements set out in Section 6.1 of Annex VIII or in Section 2 of Annex IX*' by '*follow the procedure for design dossier examination set out in Section 6.1 of Annex VIII or in Annex IX*'.

~~For~~ ***In addition, for ~~all~~*** companion diagnostic intended to be used ~~to assess the patient eligibility ***for*** to a treatment~~[808] with a specific medicinal product, the notified body ***shall follow the procedure for design dossier examination and***[809] shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

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808 **Cion** "*use*" is broader than "*eligibility*".

809 **DS 1365/13 BE** replace '*For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, the notified body*' by '*In addition, for all companion diagnostic intended to be used to assess the patient eligibility for treatment with a specific medicinal product, the notified body shall follow the procedure for design dossier examination and*'.

810 ~~**DS 1365/13 BE** add:~~
~~'*3a. In the case of devices classified as class C and D, other than devices for performance evaluation, the draft summary of safety and performance, drawn up in accordance with Art. 24, shall be validated by the notified body involved in the conformity assessment.*~~
~~*In the case of following devices, other than devices for performance evaluation, the clinical evidence report, referred to in Section 3 of Part A of Annex XII shall be validated by the notified body involved in the conformity assessment:*~~
~~*(i) companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product; or*~~
~~*(ii) devices intended to be used in screening for or in the diagnosis of cancer; or*~~
~~*(iii) devices intended for human genetic testing.*~~'.

4. Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall ***follow the procedure for design dossier examination*** ~~fulfil the supplementary requirements~~ set out in Section 6.1 of Annex VIII ~~***or in Annex IX***~~[811].

5. Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II.

However, if the devices ~~are intended for near-patient testing,~~[812] ~~or if they~~ are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be limited:

~~(a) in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII,~~[813]

(b) in the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with securing and maintaining sterile conditions,

(c) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.[814] [815] [816]

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811 **DS 1365/13 BE** replace '*fulfil the supplementary requirements set out in Section 6.1 of Annex VIII or in Section 2 of Annex IX*' by '*follow the procedure for design dossier examination set out in Section 6.1 of Annex VIII or in Annex IX*'.

812 **DS 1365/13 BE** delete '*are intended for near-patient testing*'.

813 **DS 1365/13 BE** delete point (a).

814 **DE** delete references to '*aspects of manufacture*'.

815 **SE** should only concern Class A products.

816 **FR, AT** delete point (c).

6.[817] Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.[818]

7. Devices ***intended to be used in clinical performance studies, including devices***[819] for performance evaluation shall be subject to the requirements set out in ~~Articles 48 to 58~~ ***Annex XII***.[820]

8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language. Otherwise they shall be available in an official Union language acceptable to the notified body.[821] [822]

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817 This paragraph is reinstated.
818 **AT, Cion** reinstate paragraph 6.
819 **DS 1365/13 BE** add '*intended to be used in clinical performance studies, including devices*'.
820 **DE, AT** replace references to art. 48 – 58.
821 **DE** correspondence between notified body and manufacturer should be recorded.
822 **ES** should be drafted in the language of the competent authority of the manufacturer.

9. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:
   – the frequency and the sampling basis of the assessment of ~~the design documentation within~~ the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C;
   – the minimum frequency of unannounced factory inspections[823] and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;
   – the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or
   – the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, design dossier examination and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

~~10.~~[824] ~~In the light of technical ***and scientific*** progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing ***updating*** the conformity assessment procedures set out in Annexes VIII to X.~~

[823] **FR** replace '*inspections*' by '*audits*'.
[824] Following MD Proposal –**DE, AT** support

Article 41

Involvement of notified bodies

1 Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities[825], the conformity assessment procedures and the devices concerned. ~~An~~ ***Without prejudice to Article 44***[826] ***an*** application may not be lodged in parallel with ~~more than one~~ ***another*** notified body for the same conformity assessment activity.

2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment***, by means of the electronic system referred to in article 23***.[827] [828]

2a. Manufacturers shall ~~also~~ declare whether they have withdrawn an application with another notified body prior to the decision of that notified body.[829]

3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.

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[825] **DE** delete "*conformity assessment activities*".

[826] Article on change of Notified Body.

[827] **DS 1365/13 BE** add '*This information shall be available to the Competent Authorities through the European databank on medical devices*'.

[828] **DE** add "*by means of the electronic system referred to in article* "; **CZ**, **AT** support.

[829] **UK** manufacturers should also have to declare whether they have withdrawn an application with another notified body prior to the decision. **ES, HU, PT** Support.

4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical[830] ***and scientific*** competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.[831]

[832]

Article 42[833] [834]

Mechanism for scrutiny of certain conformity assessments

1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24 **and, as soon as available, a summary of the notified body's preliminary conformity assessment report**. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.

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[830] **DS 1257/13 AT** add '*and scientific*'.

[831] **DE** delete this provision, already in Annex. **Cion** preferable to keep this in the body of text and not in the Annex.

[832] **DS 1520/13 FR** add new paragraph: '*5. The notified body shall perform unannounced factory inspections of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, including sampling, as described in paragraph 4.4 of Annex VIII.*'
HU Support. **Cion** Cannot put this in the text.

[833] This Article comes from document 13482/14. It should be aligned to the solution for the scrutiny mechanism of the Regulation on Medical devices in a way that reflects the differences between MDs and IVDs. (The corresponding Article 44 of that Regulation is set out in doc. 17152/14, together with changes to Article 42, Article 45 and Annexes VIII and IX of that Regulation as well as a new Article 81a. See also doc. 15546/14.)

[834] **Pcy** following MD Proposal

2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may ~~request the notified body to~~ submit ~~a~~ **comments on the** summary of the **notified body's** preliminary conformity assessment **report or ask for additional information that for scientifically valid grounds is necessary for the analysis of the summary of the notified body's preliminary conformity assessment report** ~~prior to issuing a certificate~~. ~~Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4) of Regulation [Ref. of future Regulation on medical devices].. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.~~

~~Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.~~

3. **Within 28 days of receipt of the additional information referred to in paragraph 2, t**~~T~~he MDCG may submit comments ~~on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended~~. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with **paragraph 2 and** paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.

5. Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific categories or groups of devices, other than devices of class D, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

   Measures pursuant to this paragraph may be justified only by one or more of the following criteria:

   (a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;
   (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;
   (c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;
   (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;
   (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

6. The Commission shall make a summary of the comments submitted in accordance with paragraph **2 or paragraph** 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.

8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Article 43

Certificates

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XI.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment[835] in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

[835] **DE** The meaning of re-assessment should be clarified.

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into this electronic system information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.

5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.

Article 44[836]

Voluntary change of notified body

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body[837] and the incoming notified body. This agreement shall address at least the following aspects:
   (a) the date of invalidity of certificates issued by the outgoing notified body;
   (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
   (c) the transfer of documents, including confidentiality aspects and property rights;
   (d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.
   (e)[838] ***the date ~~of transfer~~ after which the full responsibility for the manufacturer's products including products assessed by the outgoing Notified Body is ~~are~~ assigned to the ~~new~~ incoming notified body;***
   (f) the last serial number or batch number for which the outgoing Notified Body is responsible.[839]

2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

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[836] **PT** include deadline for voluntary change. **Cion** Could include '*date of transfer*' so products after that date would be assigned to the new notified body.
[837] **DE** delete "*the outgoing notified body*".
[838] Former point (ca) reworded.
[839] **ES, PT** asked for including serial number, batch number and lot number.

Article 45

Derogation from the conformity assessment procedures

1. By way of derogation[840] from Article 40, any competent authority may authorise, on duly justified request, the placing on the market or putting into service[841], within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety[842] [843] ~~***health if the effectiveness and safety and performance of that device can be presumed according to the current state of scientific knowledge***~~.[844]

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service[845] of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.[846]

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840 **AT** derogation should be issued for a specific device. **SK** which competent authority can authorise a derogation?

841 **DE** delete '*or putting into service*'.

842 Reinstated words.

843 **DS 1520/13 FR** replace '*patient safety*' by '*health of patients if the effectiveness and safety of that device are presumed according to the current state of scientific knowledge.*' **ES** support.

844 **DK, DE, ES, NL, AT, PT, UK** delete the last sentence of paragraph 45(1) and the corresponding provision in paragraph 45(3).

845 **DE** delete '*or putting into service*'.

846 **SE** suggested setting out some criteria for when there is an obligation to inform the Commission.

3. ~~Upon request by a Member State and where this is in the interest of~~ ***Following an information as referred to in paragraph 2, the Commission, in exceptional cases relating to a*** public health ***threat*** or patients ~~safety~~ ***health in several Member States, if the effectiveness and safety and performance of that device can be presumed according to the current state of scientific knowledge*** ~~in more than one Member State, the Commission~~[847] [848] may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).[849] [850]

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[847] **DS 1229/14 FR** replace "*Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission*" with "*Following an information as referred to in point 2, the Commission, in exceptional cases relating to public health threat or patients safety in several Member States, if the effectiveness and safety of that device can be presumed according to the current state of scientific knowledge* "

[848] **NL** replace '*Upon request by a Member State and where this is in the interest of public health or patient safety*' with '*Upon request by a Member State or where this is in the interest of public health and patient safety*'. **LV, PL** support.

[849] **NL** more detail required – not clear how **Cion** will deal with this procedure. **PL** support.

[850] **DE** delete Art 45(3). **ES, PL, SK** support.

Article 46[851]

Certificate of free sale[852]

1. For the purpose of export and upon request by a manufacturer ***or an authorised representative***, the Member State[853] in which the manufacturer ***or the authorised representative*** has its registered place of business shall issue a certificate of free sale declaring that the manufacturer ***or the authorised representative, as applicable,*** is ~~properly~~ established[854] ~~***registered in the Member State in question***~~ and that the device in question bearing the CE-marking in accordance with this Regulation may be ~~legally~~[855] marketed in the Union. The certificate of free sale shall ~~be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the~~ ***set out the identification of the device in the electronic system set up under Article 23. Where a notified body has issued a*** certificate referred to in Article 43***, the certificate of free sale shall set out the number of the certificate*** ~~issued for the device in question~~.[856] [857]

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

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851 **Pcy** following MD Proposal - Text based on the document MDEV-51 (10 April 2014).

852 This Article should be associated with a new recital:
"*(X) It is appropriate that certificates of free sale contain information that makes it possible to use the European databank on medical devices (Eudamed) in order to obtain information on the device and in particular whether it is on the market, no longer manufactured, withdrawn from the market or recalled and on any certificate on its conformity.*"

853 **DE** It should be specified that the Competent Authority must issue the certificate.

854 Highlighted words are reinstated.

855 **DS 1520/13 FR** delete '*legally*'

856 **DS 1365/13 BE** replace '*shall be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the certificate referred to in Article 43 issued for the device in question.*' by '*represents the status at the date of issue. It shall not indicate a period of validity.*' **DE, ES, IT, PL, PT** support.

857 **DS 1520/13 FR** replace '*which shall not exceed five years and shall not exceed the validity of the certificate referred to in Article 43 issued for the device in question*' by '*That period shall not exceed the validity of the certificate.*'.

Chapter VI

~~Clinical evidence~~ *Performance evaluation and performance studies*[858]

Article 47[859]

General requirements regarding clinical evidence

1.[860] ~~The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence~~.

Confirmation of conformity with the requirements, in particular those concerning the performance characteristics referred to in Section I and Section II.6 of Annex I and where applicable other requirements of Annexes IIa under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s)[861] ***and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on scientific validity, analytical and clinical performance data***[862] ***providing sufficient clinical evidence.***

The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance ~~which shall correspond to~~ The level of evidence should be appropriate to the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with ~~the principles set out in~~ this Article and with Part A of Annex XII.

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858 **DS 1340/14 BE, DE, IE, AT**.

859 **DS 1340/14 BE, DE, IE, AT**.

860 Following MD proposal and DS 1340/14.

861 **DS 1340/14 BE, DE, IE, AT** interference(s) and cross-reaction(s) more appropriate for IVDs than undesirable side-effects (MD).

862 **DS 1340/14 BE, DE, IE, AT** scientific validity, analytical and clinical performance data (IVD) are analogous to the clinical data(MD).

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer ***and be based on a continuous process of ~~clinical~~ performance evaluation, following a ~~clinical~~ performance evaluation plan***.[863]

3.[864] ***A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with the principles set out in this Article and with Annex XII:***

(a) scientific validity;

(b) analytical performance;

(c) clinical performance[865]***.***

The data and conclusions drawn from the assessment of these elements shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit(s) and safety will be achieved according to the state of the art in medicine. The clinical evidence ***derived from performance evaluation*** shall ~~include~~ ***provide scientifically valid assurance, ~~including~~*** ~~all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device, as described in Section 1 of Part A of Annex XII~~ ***that the relevant general safety and performance requirements set out in Annex I, under normal conditions of use, are fulfilled***.

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[863] **17945/13 Part A 1** Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer. To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan. The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.

[864] **DS 1340/14 BE, DE, IE, AT**.

[865] **DS 1340/14 BE, DE, IE, AT** Performance data was required in all cases, but that it may not always be necessary to conduct a clinical performance study and suggested that this should be clearly stated in the text.
Working doc. MDEV-26 (Brussels, 4 July 2013) Working Party on 16 July 2013 (2.D §4) This clarification is provided in Annex XII

~~4.~~[866] ~~Where demonstration of conformity with the general safety and performance requirements based on performance data or parts thereof is not deemed appropriate~~ ***~~applicable~~***~~, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the characteristics of the device and, in particular, its intended purpose(s), the intended performance and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of analytical performance evaluation alone shall be duly substantiated in the technical documentation referred to in Annex II.~~

5.[867] The scientific validity data, the analytical performance data and~~, where applicable,~~[868] the clinical performance data ***and their assessment*** shall be ~~summarised~~ ***documented in reports*** as part of a ~~clinical evidence~~ ***performance evaluation*** report referred to in Section ~~3~~ ***1.4*** of Part A of Annex XII***, that shall include the clinical evidence derived from it***. The ~~clinical evidence~~ ***performance evaluation*** report shall be ~~included or fully referenced in~~ ***part of*** the technical documentation referred to in Annex II relating to the device concerned.

6.[869] The ~~clinical evidence~~ ***performance evaluation*** and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's ***post-market performance follow-up plan, as part of the*** post-market surveillance plan referred to in Article 8(6). ***The performance evaluation report shall be updated at least annually with these data. For devices classified as class C and D, the summary of safety and performance referred to in Article 24(1) shall be updated where necessary.***

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[866] **DS 1340/14 BE, DE, IE, AT** Repetition of the information provided in Annex XII.

[867] **DS 1340/14 BE, DE, IE, AT**.

[868] **DS 1340/14 BE, DE, IE, AT** The '*where applicable*' should be deleted, as it clarified in the annex that when clinical performance data or parts thereof is not applicable, then this shall be duly substantiated in the performance evaluation report.

[869] **DS 1340/14 BE, DE, IE, AT**.

~~7.~~[870] ~~The manufacturer shall ensure that the device for performance evaluation complies with the general requirements of this Regulation apart from the aspects covered by the performance evaluation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.~~

~~The manufacturer shall undertake to keep available to the competent authorities and the EU reference laboratories the documentation allowing an understanding of the design, manufacture and performances of the device, including its expected performance, so as to allow assessment of conformity with the requirements of this Regulation. This documentation shall be kept for at least five years after the performance evaluation of the device in question has ended.~~

Article 48[871]

General requirements regarding ~~clinical~~[872] *performance studies*

1. ~~Clinical~~ Performance studies shall be subject to ***the provisions of Articles 48 to 58 of*** this Regulation if they are conducted ***under*** ~~for~~ one or more of the following ***conditions*** ~~purposes~~:

   (a) ***where invasive sample taking is done only for the purpose of the performance study*** ~~to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers~~;

   (b) ***where it concerns an interventional clinical performance study as defined in Article 2(37)*** ~~to verify that devices achieve the intended benefits to the patient as specified by the manufacturer~~;

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[870] **DS 1340/14 BE, DE, IE, AT** Moved to Article 48(1b).

[871] **DS 1340/14 BE, DE, IE, AT**.

[872] **DS 1340/14 BE, DE, IE, AT** There is also a possibility to have the need for invasive sampling in the phase of the analytical performance studies. Definition (33) 'clinical performance study' means a study undertaken to establish or confirm the clinical performance of a device. Performance studies where invasive samples are taken to establish or confirm the analytical performance of a device (which might incur some risk to subjects) would be excluded from the scope of Art 48-58, if one reverted to clinical performance studies only.

(c) ***where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies***[873] ~~to determine any limits to the performance of the devices, under normal conditions of use~~***;***

(d) in case of performance studies involving companion diagnostics[874]***;***

(e) in case of clinical performance studies with high public health impact[875].

1a. Performance studies using only left-over specimens shall be conducted in line with relevant ethical and data protection requirements but are not subject to Articles 48 to 58 of this Regulation.

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873 **DS 1340/14 BE, DE, IE, AT** The text "*where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies*" comes from former Article 49(6)

874 **DS 1340/14 BE, DE, IE, AT** Compare Article 49(6) and doc. 11423/14.

875 **DS 1340/14 BE, DE, IE, AT** This indent is based on a suggestion from a minority of experts and therefore placed in square brackets, *e.g.* performance studies on vCJD.

1b.[876] ***The manufacturer shall ensure that the a device used for performance evaluation***[877] ***complies with the general requirements of this Regulation apart from the aspects covered by the performance evaluation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.***

The manufacturer shall undertake to keep available to the competent authorities and the EU reference laboratories the documentation allowing an understanding of the design, manufacture and performances of the device, including its expected performance, so as to allow assessment of conformity with the requirements of this Regulation. This documentation shall be kept for at least five years after the performance evaluation last placing on the market of the device in question has ended.

2. ***Performance*** ~~Clinical performance~~ studies shall be performed in circumstances similar to the normal conditions of use of the device.

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[876] **DS 1340/14 BE, DE, IE, AT** This paragraph is identical to Article 47(7) of document 11423/14 except for some words.

[877] **DS 1340/14 BE, DE, IE, AT** Definition (36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;
'device for performance evaluation' concern these devices that are not yet fully in conformity with the requirements of the IVD legislation, but which are provided *outside* the manufacturer's own premises for further performance evaluation.
It is restricted to a labelling requirement: it provides the possibility to ensure that 'device for performance evaluation' will not be marketed or used for medical purposes.
The requirement set on devices that are used for performance evaluation (Articles 48 to 58) with regard to the protection of the health and safety of the patient, user and other persons, shall also be applicable to those devices used in environments *inside* the manufacturer's own premises.

3.[878] Where the sponsor is not established in the Union, ~~he~~ ***that sponsor*** shall ensure that a ***natural or legal person*** ~~contact person~~ is established in the Union ***as its legal representative***. ~~That contact person~~ ***Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and*** shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that ~~contact person~~ ***legal representative*** shall be considered as communication to the sponsor.

Member States may choose not to apply paragraph 1 as regards performance studies to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a legal representative on their territory in respect of that performance study who shall be the addressee for all communications with the sponsor provided for in this Regulation.

4. All ~~clinical~~ performance studies ***shall*** ~~***must***~~ ***be carried out in accordance with the Helsinki Declaration, and*** shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such ~~clinical~~ performance studies are protected and that the ~~clinical~~ data generated in the ~~clinical~~ performance study are going to be reliable and robust.

5. All ~~clinical~~ performance studies shall be designed, conducted, recorded and reported in accordance with Section 2 of Annex XII.

~~6.~~[879] ~~For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.~~ ~~***The same requirements shall apply by analogy to analytical performance studies of companion diagnostics.***~~

[878] Following MD proposal and DS 1340/14.
[879] **DS 1340/14 BE, DE, IE, AT**.

6a.[880] *A performance study according to paragraph 1 may be conducted only where all of the following conditions are met:*

(a) the performance study was subject to an authorisation by a competent authority of the Member State(s) concerned, in accordance with this Regulation, unless otherwise stated;

(b) an independent Ethics Committee, set up according to national law, has issued a favourable opinion on the planned performance study;

(c) the sponsor or its legal representative is established in the Union;

(d) the foreseeable risks and inconveniences to the subject are medically justifiable when weighed against the device's potential relevance for medicine;[881]

(e)[882] *the subject or, where the subject is not able to give informed consent, his or her legal representative has given informed consent, according to Article 29 of Regulation (EU) no 536/2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC*[883]*;*

(f) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;

(g)[884] *the sponsor has provided an insurance policy according to national provisions, a guarantee or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk in the event that a person is killed or a person's body or health is harmed or impaired in the course of the performance study;*

(h) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;

(i) the analytical performance has been demonstrated, in case of clinical performance studies;

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880 **DS 1340/14 BE, DE, IE, AT**.

881 **AT** this shall not be prerogative to individual or group benefit.

882 Following MD Proposal.

883 ***OJ L 158 27.5.2014 p. 1.***

884 Following MD Proposal.

(j) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention.

Article 49

Application for interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

~~1.~~[885] ~~Before making the first application, the sponsor shall procure from the electronic system referred to in Article 51 a single identification number for a clinical performance study conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical performance study in accordance with Article 50.~~

2. The sponsor of a ~~clinical~~ performance study ***according to Article 48(1)*** shall submit[886] ***by means of the electronic system referred to in Article 51*** an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in ***Section 2 of Annex XII and in*** Annex XIII. ***The electronic system referred to in Article 51 shall generate a union wide unique single identification number for this performance study which shall be used for all relevant communication in relation to the performance study concerned.***[887] Within ~~six~~ ***fifteen***[888] days after receipt of the application, the Member State concerned shall notify the sponsor whether the ~~clinical~~ performance study falls within the scope of this Regulation and whether the application is complete.

~~Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.~~[889]

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885 Following MD Proposal.
886 Following MD Proposal.
887 Following MD Proposal.
888 Following MD Proposal.
889 Following MD Proposal.

3. Where the Member State finds that the ~~clinical~~ performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ~~six~~ ***thirty*** days for the sponsor to comment or to complete the application.

Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be ~~considered as withdrawn~~ ***deemed to have lapsed***. ***Where the sponsor considers the application is complete but the competent authority does not , the application shall be considered as rejected.***[890]

The ~~Where the~~ Member State ~~has *to*~~ ***shall notify*** ~~not notified~~ the sponsor ~~according to paragraph 2~~ within ***ten*** ~~three~~ days[891] following receipt of the comments or of the completed application~~, *whether*~~ the ~~clinical~~ performance study ***is*** ~~shall be~~ considered as falling within the scope of this Regulation and the application ~~shall be considered~~ ***is*** complete***d***[892].

4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph***s*** 2 ***or 3*** shall be the validation date of the application. ~~Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.~~[893]

4a. In the period during which the application is being assessed the Member State may request, additional information from the sponsor. The expiry of the deadline pursuant to the second indent of paragraph 5(b) shall be suspended from the date of the first request until such time as the additional information has been received.

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[890] Following MD Proposal.
[891] Following MD Proposal.
[892] Following MD Proposal.
[893] Following MD Proposal.

5.[894] The sponsor may start the ~~clinical~~ performance study in the following circumstances:

(a) in the case of ~~devices for~~ performance ~~evaluation classified as class C or D, as soon as~~ ***studies according to Article 48(1)(a) and where the specimen collection does not represent a major clinical risk to the subject of the study, immediately after the validation date of application described in paragraph 4, provided that the competent ethics committee in*** the Member State concerned has ***issued a favourable opinion*** ~~notified the sponsor of its approval~~;

(b) in ~~the~~ case of ~~devices for~~ ~~performance evaluation classified as class A or B immediately after the~~ date of application ~~***date of validation***~~, ~~provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical performance study are~~ protected ***performance studies according to Article 48(1)(b), (c), (d) and (e) or performance studies other than those referred to in subparagraph (a):***

- ***as soon as the Member State concerned has notified the sponsor of its approval and the competent Ethics committee in the Member State concerned has issued a favourable opinion, or***
- ***after the expiry of 60 days after the validation date referred to in paragraph 3, unless the Member State concerned has notified the sponsor within that period of its refusal and provided that the Ethics committee in the Member State concerned has issued a favourable opinion***;[895]

~~(c) after the expiry of 35 ***60*** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.~~

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[894] Following MD proposal and DS 1340/14.

[895] **DS 1002/14 DE – DS 1446/13 AT**.

6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the study site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.

7. The Commission shall be empowered to adopt ~~delegated~~ ***implementing*** acts in accordance with Article ~~85~~ ***86*** amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the clinical performance study that is laid down in Chapter I of Annex XIII.

Article 50

Registration of interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

1. Before commencing the ~~clinical~~ performance study, the sponsor shall enter ***the following information regarding the performance study which shall be accessible to the public through*** ~~in~~ the electronic system referred to in Article 51 ~~the following information regarding the clinical performance study~~:
   (a) the single identification number of the ~~clinical~~ performance study;
   (b) the name and contact details of the sponsor and, if applicable, his ***legal representative*** ~~contact person~~ established in the Union;
   (c) the name and contact details of the natural or legal person responsible for the manufacture of the device ~~for performance evaluation~~, if different from the sponsor;
   (d) the description of the device ~~for performance evaluation~~;
   (e) the description of the comparator(s), if applicable;
   (f) the purpose of the ~~clinical~~ performance study;

(g) the status of the ~~clinical~~ performance study.

(h) for interventional clinical performance studies additional data necessary to register a clinical performance study in a public registry which is a primary or partnered registry of, or a data provider to, the WHO ICTRP. [896] [897]

2. Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 51.

~~3.~~ The information ***referred to in article 51(4)*** shall be accessible to the public, through the electronic system referred to in Article 51**.** ~~, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:~~

~~(a) protection of personal data in accordance with Regulation (EC) No 45/2001,~~

~~(b) protection of commercially sensitive information,~~

~~(c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.~~

4. No personal data of subjects participating in the clinical performance study shall be accessible to the public.

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[896] This point is based on Article 25(6) of the Clinical Trials Regulation.

[897] **DS 1340/14 BE, DE, IE, AT** Consider bringing the list of public accessible information into alignment with WHO format *cfr* MD regulation, specifically for interventional clinical performance studies.

Article 51

Electronic system on interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

1. The Commission shall, in collaboration with the Member States, set up***,*** ~~and~~ manage ***and maintain***[898] an electronic system ***(portal and database)*** on interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

(aa) to create the single identification numbers for such clinical performance studies***; and***

(ab) ***to be used as an entry point for the submission of applications for performance studies***[899] referred to in Article 49(~~1~~***2***)***,*** ~~and to collate and process the following information:~~ ***for registration according to Article 50 and for all other submission of data, or processing of data in this context;***

~~(a) the registration of clinical performance studies in accordance with Article 50;~~

(b) ***for*** the exchange of information ***relating to performance studies in accordance with this Regulation*** between the Member States and between them and the Commission ~~in accordance with Article 54~~; ***and***

~~(c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;~~

(ca) for information by the sponsor according to Article 57;

(d) ***for reporting*** ~~the reports~~ on serious adverse events and device deficiencies referred to in Article 57~~(2) in case of single application in accordance with Article 56~~.[900]

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[898] Following MD Proposal.
[899] Following MD Proposal.
[900] Following MD Proposal.

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No ~~[Ref. of future Regulation on clinical trials]~~ ***536/2014 as concerns performance evaluation studies of companion diagnostics***[901]. With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.

2a. Within one week of any change occurring in relation to the information referred to in paragraph 1 or in Article 50(1), the sponsor shall update the relevant data in the electronic system referred to in this Article.[902]

3. The Commission shall be empowered to adopt implementing acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No ***536/2014*** ~~[Ref. of future Regulation on clinical trials]~~. Article 50 ***paragraphs*** (3) and (4) shall apply.

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901 Comment: Experts don't see a need for interoperability of both systems. In principle only an exchange of data e.g. in case of performance studies of companion diagnostics would be relevant.

902 Moved from Article 50(2) to this Article.

4.[903] ***The information shall be accessible to the public, through the electronic system referred to in Article 51, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:***

(a) protection of personal data in accordance with Regulation (EC) No 45/2001,

(b) protection of commercially confidential[904] ***information, in particular through taking into account the status of the marketing authorisation for the device, unless there is an overriding public interest in disclosure,***

~~***(c)***~~ ***effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.***

Registration information according to Article 50 shall not be considered confidential.

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903 It was discussed to move Article 50(3) to become 51(4).

904 **WP July 8/9 DK** p3 c) clarify "*commercial sensitive*" **ES** support, **Pcy** specify the term "sensitive", harmonize with CTR.

Article 52

Interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies with devices authorised to bear the CE marking

1. Where a ~~clinical~~ performance study is to be conducted to further assess devices which are authorised in accordance with Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as 'post-market ***performance*** follow-up ~~performance~~ study', the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally[905] invasive or burdensome procedures. ***The notification shall be made by means of the electronic system referred to in Article 51. It shall be accompanied by the documentation referred to in Section 2 of Annex XII and in Annex XIII.***[906] ***Article 48 paragraph 5 points (b) to (i),*** Articles ~~48(1) to (5),~~ 50, 53, 54(1) and 55(1), the first subparagraph of Article 55(2) and the relevant provisions of Annexes XII and XIII shall apply.[907]

2. If the aim of the ~~clinical~~ performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48 to 58 shall apply.

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[905] **DS 1340/14 BE, DE, IE, AT** "additional" in "*additionally invasive or burdensome procedures*" means only for the purpose of the study in addition to the standard procedures.

[906] Following MD proposal.

[907] Following MD proposal.

Article 52a[908]

Modifications to performance studies

The sponsor shall notify immediately the Member State(s) concerned any changes made to the documents submitted pursuant to Article 49 paragraph 1 after having received an approval or favourable opinion pursuant Article 49 paragraph 5. The notification shall be made by means of the electronic system referred to in Article 51. The changed documents shall be attached to the notification and the changes shall be marked.

Article 53

Substantial modifications to interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

1. If the sponsor ***intends to*** introduce~~s~~[909] modifications to a ~~clinical~~ performance study that are likely to have a substantial impact on the safety or rights of the subjects or on the robustness or reliability of the ~~clinical~~ data generated by the study, he shall notify[910] ***by means of the electronic system referred to in Article 51*** the Member State(s) concerned[911] of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII[912] ***changes shall be marked***.

2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on considerations ***according to Article 51a paragraph 4 or the ethics committee concerned has refused a favourable opinion based on grounds according to Article 51c paragraph 4*** ~~of public health, patient safety or public policy~~.[913]

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908 Following MD proposal.
909 Following MD proposal.
910 Following MD proposal.
911 Following MD proposal.
912 Following MD proposal.
913 Following MD proposal.

Article 54

Information exchange between Member States on interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

1. Where a Member State has refused, suspended or terminated a ~~clinical~~ performance study, or has called for a substantial modification or temporary halt of a ~~clinical~~ performance study, or has been notified by the sponsor of the early termination of a ~~clinical~~ performance study on safety grounds, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 51.

2. Where an application is withdrawn by the sponsor prior to a decision by a Member State that Member State shall inform all the other Member States and the Commission of that fact, by means of the electronic system referred to in Article 51.

Article 55

Information by the sponsor in the event of temporary halt or termination of interventional clinical performance studies or of other ~~clinical~~ performance studies involving risks for the subjects of the studies

1. If the sponsor has temporarily halted a ~~clinical~~ performance study on safety grounds ***or has early terminated a performance study***[914], he shall inform the Member States concerned within 15 days of the temporary halt ***or early termination, providing a justification***[915].

[914] Following MD proposal.
[915] Following MD proposal.

2. The sponsor shall notify each Member State concerned of the end of a ~~clinical~~ performance study in relation to that Member State~~, providing a justification in the event of early termination~~[916]. That notification shall be made within 15 days from the end of the ~~clinical~~ performance study in relation to that Member State.

If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the ~~clinical~~ performance study. That notification shall be made within 15 days from the overall end of the clinical performance study.

3. Within one year from the end ***or early termination***[917] of the ~~clinical~~ performance study, the sponsor shall submit to the Member States concerned ***through the electronic system referred to in Article 51*** ~~a summary of the results of the clinical performance study in form of~~[918] a ~~clinical~~ performance study report referred to in Section 2.3.3 of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the ~~clinical~~ performance study report within one year, it shall be submitted as soon as it is available. In this case, the ~~clinical~~ performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the ~~clinical~~ performance study are going to be submitted, together with an explanation.

Article 56[919]

Interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies conducted in more than one Member State[920]

1. By means of the electronic system referred to in Article 51, the sponsor of the ~~clinical~~ performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned ***who have voluntarily agreed to that procedure concerning that performance study***.

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916 Following MD proposal.
917 Following MD proposal.
918 Following MD proposal.
919 Following MD proposal.
920 Following MD proposal.

2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. ~~If that Member State does not wish to be the coordinating Member State, it~~ ***Concerned Member States*** shall ~~agree~~, within six days ~~of submission~~ of the ~~single~~ application, ***agree on one of them taking the role of*** ~~with another Member State concerned that the latter shall be~~ the coordinating Member State. If ~~no other Member State accepts to be the~~ ***they do not agree on a*** coordinating Member State, the ~~Member State~~ ***one*** proposed by the sponsor shall ~~be the coordinating Member State~~ ***take that role***. ~~If another Member State than the one proposed by the sponsor becomes coordinating Member State, the~~ ***The*** deadlines referred to in Article 49~~(2)~~ shall start on the day following the ***notification of the coordinating Member State to the sponsor (notification date)*** ~~acceptance~~.

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned. [921]

The coordinating Member State shall:

(aa) within six days[922] ***of receipt of the single application notify the sponsor that it is the coordinating Member State;***

[921] Following MD proposal.

[922] **DS 1479/14 AT** Replace "*6 days*" by "*ten days*".

(a) within ~~6~~ ***10***[923] days of receipt of the single application notify the sponsor whether the ~~clinical~~ performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the coordinating Member State in relation to the verification that the ~~clinical~~ performance study falls within the scope of this Regulation and that the application is complete,[924] ***having taken into account considerations expressed by the other Member States concerned,***[925] except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII.[926] ***Concerned Member States may communicate to the reporting Member State any considerations relevant to the validation of the application within seven days from the notification date.*** Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII is complete;

~~(b) establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5).~~[927]

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923 Following MD proposal.
924 Following MD proposal.
925 **DS 1479/14 AT** Add "*having taken into account considerations expressed by the other Member States concerned*,".
926 Following MD proposal.
927 Following MD proposal.

(c) establish the results of its assessment in a draft assessment report to be transmitted within x days after the validation date to the concerned Member States. Until day y after the validation date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within z days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49 (5), except for Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII, which shall be assessed separately by each Member State concerned.[928]

As concerns the assessment of the documentation related to Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII, done separately by each Member State, the Member State may request, on a single occasion, additional information from the sponsor. The expiry of the deadline pursuant paragraph 2 shall be suspended from the date of the request until such time as the additional information has been received.

3a. Each Member State concerned shall notify the sponsor through the EU portal as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the reporting date. An authorisation of a performance study subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

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[928] **DS 1479/14 AT** suggestion for MD Regulation: Replace "*establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5).*" by "*The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating competent authority that shall be taken into account by concerned Member States when deciding on the sponsor's application. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 59(4). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*"

3b. Where the conclusion of the coordinating Member State is that the conduct of the clinical performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State concerned.

Notwithstanding the previous subparagraph, a Member State concerned may disagree with the conclusion of the reporting Member State concerning the area of joint assessment only on the following grounds:

(a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;

(b) infringement of national law;

(c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 3 point (c).

Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States concerned , and to the sponsor.

3c. A Member State concerned shall refuse to authorise a clinical performance study if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 4a, or if it finds, on duly justified grounds, that the aspects addressed in Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII are not complied with, or where an ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

3d. Where the conclusion of the coordinating Member State report is that the clinical performance study is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

4. The substantial modifications referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in Article 53 shall be carried out under the direction of the coordinating Member State.[929]

5. For the purpose of Article 55(3), the sponsor shall submit the ~~clinical~~ performance study report to the Member States concerned by means of the electronic system referred to in Article 51.

6. The Commission shall provide ~~secretarial~~[930] ***administrative*** support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

Article 56a[931]

Review of performance studies rules

Five years after the date referred to in the first paragraph of Article 97, the Commission shall make a report on the application of Article 58 of the present Regulation and propose a review of the provision of Article 58 in order to ensure a coordinated assessment procedure of performance study conducted in more than one Member State.

Article 57

Recording and reporting of events occurring during interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies

1. The sponsor shall fully record any of the following:
   (a) an adverse event identified in the ~~clinical~~ performance study protocol as critical to the evaluation of the results of the ~~clinical~~ performance study ***according to the performance study plan*** ~~in view of the purposes referred to in Article 48(1)~~;
   (b) a serious adverse event;

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929 Following MD proposal.
930 Following MD proposal.
931 Following MD proposal.

(c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) new findings in relation to any event referred to in points (a) to (c).

2. The sponsor ***by means of the electronic system referred to in Article 51*** shall report to all Member States where a ~~clinical~~ performance study is conducted without delay any of the following[932]:

(a) a serious adverse event that has a causal relationship with the device ~~for performance evaluation~~, the comparator or the study procedure or where such causal relationship is reasonably possible;

(b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a ~~clinical~~ performance study is performed under the same ~~clinical~~ performance study protocol as the one applying to a ~~clinical~~ performance study covered by this Regulation.

[932] Following MD proposal.

4. In the case of a ~~clinical~~ performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a ~~clinical~~ performance study needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market performance follow-up studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.[933]

Article 58

Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following:

(a) harmonised forms for the application for ~~clinical~~ performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 51;

[933] Following MD proposal.

(c) harmonised forms for the notification of post-market ***performance*** follow-up ~~performance~~ studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53;

(d) the exchange of information between Member States as referred to in Article 54;

(e) harmonised forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Chapter VII[934]

Post-market surveillance, v~~V~~igilance and market surveillance

SECTION 0 – POST-MARKET SURVEILLANCE

Article 58a[935] [936]

Post-market surveillance system of the manufacturer

~~***1. The manufacturer shall ensure compliance with the provisions of this Regulation throughout the entire lifetime of the devices he has made available on the market or put into service.***~~[937]

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[934] The text of this chapter has been developed by **IT Pcy** based on the text of Chapter VII of the MD Regulation set out in document 14488/14.

[935] This article is based on Article 60a in document 10146/14. Since it is a new article, and in order to facilitate reading, the changes to 10146/14 are not indicated.

[936] **NL** proposal on post-market surveillance: **DS 1360/2/13, DS 1017/14** (Article 12(5) e Annex II - technical documentation: *7. The post-market data. 7. information, including feedback and complaints, provided by users, distributors, importers*), **DS 1104/14** (Annex II), **DS 1351/14 (**Last proposal on PMS issue) DK: **DS 1204/14** (Art. 60a,2 - Register of incidents) IT Questionnaire:

1) Does your delegation agree on the Dutch proposal (DS 1360/2/13) which establishes specific provision for the manufacturer's obligations in the post marketing surveillance activity and a modification in Annex II accordingly?

YES	NO	Neutral	No answer	Comments
22	0	2	1	Respondent Member States: 25/28

If the answer is yes:

1.1) Does your delegation agree that post marketing surveillance provisions are to be referred only to the manufacturer and to its legal representative as provisions referred to in chapter II are sufficient for all other economic operators?

YES	NO	Neutral	No answer	Comments
19	2	1	3	Respondent Member States: 25/28

1.2) Does your delegation agree that post marketing surveillance activities are to be carried out by the manufacturer for the whole lifetime of the medical device?

YES	NO	Neutral	No answer	Comments
19	1	3	2	Respondent Member States: 25/28

[937] **Pcy** proposes to move this paragraph to Article 8.

2. For any device, proportionate to the risk class and appropriate for the type of device, manufacturers ~~of devices~~[938] shall plan,[939] establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system according to Art. 8(6).

3. The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.

4. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the ~~risk/benefit risk determination analysis~~ and risk management, the design and manufacturing information, the instructions for use and the labelling;

(b) to update the performance evaluation;

(c) to update the summary of safety and performance as referred to in Article 24;

(d) for the identification of needs for preventive, corrective or field safety corrective action;

(e) for the identification of possibilities to improve the usability, performance and safety of the device;

(f) when relevant, to contribute to the post-market surveillance of other devices.[940] [941]

The technical documentation shall be updated accordingly.[942]

~~5. Updates according to paragraph 4 shall be reflected in the technical documentation.~~

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938 **UK** suggestion contained in the response to **IT Pcy** Questionnaire.

939 **DE, IE, AT, PT** add "*plan*". **BE** opposed.

940 **IE** suggestion.

941 **DE** wording unclear

942 Replaces paragraph 5 following an **AT** comment.

6. If in the course of the post-market surveillance a need for preventive [943] and corrective action is identified, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body and the competent authorities concerned. ~~The identification of~~ When a serious ~~an~~ incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with ~~shall induce actions according to~~ Article 59.

Article 58b[944]

Post-market surveillance plan

The post-market surveillance system as referred to in Article 58a shall be based [945] on a post-market surveillance plan, the requirements of which are set out in Section 1.1 of Annex IIa. The post-market surveillance plan ~~which~~ shall be part of the technical documentation ~~as specified in Annex II.~~[946]

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943 **DE** preventive action has not been defined

944 This article is based on provisions in Article 60a in document 10146/14.

945 **SE** suggests "shall be described in"

946 Add cross-reference in Annex II.

Article 58c

Periodic safety update report[947]

1. Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken.

Throughout the lifetime of the device concerned this report shall set out:

(a) the conclusion of ~~conclude on~~ the benefit risk determination;

(~~a1~~b) ~~include~~ the main findings of the Post Market Performance Follow-up Report[948] *and*

(~~a2~~c)[949] *the volume of sales of devices and an estimate of the population that use the device involved and, where appropriate, ~~for reusable in vitro diagnostic medical devices~~ the usage frequency of the device*[950]

The report shall ~~(b)~~ be updated at least annually; and ~~(c)~~ be part of the technical documentation as specified in Annex II.

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947 **Pcy** The periodic safety update report is the single summary document on post-market surveillance

948 **Pcy** proposal based on IT Questionnaire

949 IT Questionnaire:

2.1) Does your delegation agree that the Periodic Safety Updated Report should include the volume of sales data and an estimate of the population exposed to the device?

YES	NO	Neutral	No answer	Comments
18	3	3	1	Respondent Member States: 25/28

950 **DE**, **IE** suggestion contained in the responses to **IT Pcy** Questionnaire

2. Manufacturers of devices in class D shall submit reports by means of the electronic system referred to in Article 64a to the notified body involved in the conformity assessment in accordance with Article 40. The notified body shall ~~will~~ review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.

3. Manufacturers of devices other than those referred to in paragraph 2, ~~I, IIa and IIb~~ shall make reports available to the notified body involved in the assessment and to competent authorities on request.[951] [952]

SECTION 1 – VIGILANCE[953]

Article 59

Reporting of serious incidents and field safety corrective actions

1. Manufacturers of devices***, made available on the Union market,*** other than investigational devices, shall report, through the electronic system referred to in Article ~~60~~ ***64a,*** the following:
   (a) any serious incident ***involving*** ~~of~~ devices made available on the Union market;
   (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

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[951] **UK** suggestion contained in the response to **IT Pcy** Questionnaire

[952] **DE** Manufacturers shall submit reports by means of the electronic system referred to in Article 62 for devices in all class of risk

[953] This heading is moved back to where it was in the Commission proposal - compare doc. 10146/14.

1a. As a general rule, the time period for reporting shall take account of the severity of the serious incident. [954]

1b. Manufacturers shall ~~make~~ ***provide*** ~~the~~ report ***any serious incident as*** referred to in ***point (a)*** ~~the first subparagraph~~ ~~without delay, and no later than 15 days after they have become aware of the event and~~ ***immediately after the manufacturer has established*** the causal relationship with their device or that such causal relationship is reasonably possible***, and ~~in~~ not ~~case~~ later than 15 ~~30~~ days after they have become aware of the event***.

~~The time period for reporting shall take account of the severity of the~~ ***~~serious~~*** ~~incident.~~ [955]

1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and ~~in~~ not ~~case~~ later than 2 ~~calendar~~ [956] ***days after awareness by the manufacturer of this threat.***

1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship ~~link~~ between the device and the event but not later than 10 elapsed ~~calendar~~ days following the date of awareness of the event.

1e. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

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954 **DE** timescale recommended in MEDDEV 2.12-1 Rev.8

955 This sentence is retained in paragraph 1a.

956 **Cion** homogenize the time references

1f. ***If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer shall submit a report*** ~~***within the timeframe required for that type of incident***~~ ***within the timeframe required for that type of incident.*** [957] *958*

1g. ***Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay,*** [959] ***the manufacturer shall*** ~~***provide the***~~ ***report the field safety corrective action referred to in paragraph 1, point (b)*** ~~***the second subparagraph***~~ ***in advance of the field safety corrective action being undertaken.***

2. For similar serious incidents [960] occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented ***or where the incidents are common*** [961] *962* ~~***expected***~~ ***and well documented***, ***the*** manufacturers~~s~~ may provide periodic summary reports instead of individual ***serious*** incident reports, on condition that the ***coordinating competent authority referred to in Article 61(6), in consultation with the*** competent authorities referred to in points (a), (b) and (c) of Article ~~62a~~***64a***~~62~~(5)**,** ***has*** ~~have~~ agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. ***Where a single competent authority is referred to in points (a), (b) and (c) of Article 64a(5), the manufacturer may provide periodic summary reports on agreement with that competent authority.*** [963]

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[957] **IT Pcy** Questionnaire:
4) Does your delegation agree that in Art. 61 serious incident reports timeline should be in agreement with MEDDEV 2.12.1-Rev.8 and consequently agree with the following text?

YES	NO	Neutral	Comments / Alternative proposal
20	**4**	**1**	Respondent Member States: 25/28

[958] **PT** suggests reintroducing "within the timeframe required for that type of incident"
[959] **Pcy** Added on the basis of debate WP on 13 June 2014.
[960] **DE** similar serious incident has not been defined
[961] **Pcy** Added on the basis of debate WP on 13 June 2014 (**DS2046/13 UK**)
[962] DK suggests reintroducing expected
[963] **UK** Suggestion: **DS 2046/13** Rationale*:* The UK would also propose a less burdensome process for agreeing to periodic summary reporting across multiple competent authorities, with this more explicitly being led by the coordinating competent authority in line with in Article 63(7)(c).

3. The Member States shall take ~~all~~ appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities***, to the manufacturer and, where appropriate, to the authorised representative***[964] [965] [966] suspected serious incidents referred to in point (a) of paragraph 1. They shall record ~~such~~ reports ***that they receive*** centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the ***suspected***[967] ***serious*** incident.

The manufacturer of the device concerned shall provide to the ~~responsible~~ competent authority of the Member State where the event occurred ~~an initial~~ a report[968] ***on the serious incident in accordance with paragraph 1 and ensure the appropriate follow-up; if the manufacturer considers that the event is ~~does~~ not ~~fulfil the definition of~~***[969] ***a serious incident, it shall provide ~~or~~ an explanatory statement ~~why the incident is not a serious incident and~~*** ~~The manufacturer shall ensure the appropriate follow-up~~.

~~The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.~~[970]

~~*3a.*~~ ***If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with this article ~~paragraph 1~~ and to take the ~~that the manufacturer takes~~ appropriate ~~follow-up~~ corrective action.***[971]

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964 **DK, DE, FR, AT, PT** object to inclusion of "*authorised representative*".

965 **FR, PT, AT** Delete "to the manufacturer and, where appropriate, to the authorised representative"

966 **NL** Replace "to the manufacturer and, where appropriate, to the authorised representative" with "to the distributor"

967 Based on suggestion during the WP held on 13 May 2014.

968 Cion suggestion during 11-12 November meeting

969 **DE** suggestion included in **DS 2046/13** has been reinstated

970 Moved to Article 66 point (ba).

971 **DE** suggestion included in **DS 2046/13**.

~~*3c. The Commission shall ensure that the electronic system referred to in Article 64a allows direct reporting from Member States' databases of any reports received pursuant to paragraph 1.*~~ [972]

~~4. Manufacturers of custom-made devices shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available~~ [973]~~.~~

[972] **DS 2046/14**: **UK** suggestion. Rationale:
The UK would propose amending the language in the second sub-paragraph to give Member States greater flexibility in the development of tools to support reporting by healthcare professionals and users. In the UK, for example, we are exploring the development of a single portal for reporting of problems with pharmaceuticals and medical devices. The UK would also propose adding a specific provision to ensure that reports from healthcare professionals and users to competent authorities can be directly and simply uploaded to the EU-wide electronic system on vigilance from national databases.

[973] **NL, DK, SE** suggest to reintroduce paragraph 4

*Article ~~64~~ **59a***

Trend reporting [974] [975] [976] *– ~~**and periodic safety update reports by manufacturers**~~*

1. Manufacturers ~~of devices classified in class C and D~~ shall report ~~to~~ ***by means of*** the electronic system referred to in Article ~~60~~ ***64a*** any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections ***I.***1 and ***I.***5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period ~~as established in **accordance with** the manufacturer's **post market surveillance obligations pursuant to Article 60a(1)** conformity assessment~~. ***The manufacturer shall define how to manage this events and the methodology used for determining any statistically significant increase in the frequency or severity of this events, as well as the observation period, in the post-market surveillance plan pursuant to article 58b.*** Article 61 shall apply.[977]

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[974] IT Questionnaire:
5) Does your delegation agree that Art. 61 (Trend reporting and periodic safety update reports by manufacturer) should be divided in two articles: Art. 61a (Trend reporting) to be included in Section 1- Vigilance and Art.61a bis (Periodic safety update reports) to be included in Section 0-Post-Market Surveillance?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
15	0	10	0	Respondent Member States: 25/28

[975] IT Questionnaire:
6) Art. 61 establishes that manufacturers shall report by means of the electronic system referred to in Article 66a any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Annex I. Does your delegation agree that this article has to be kept in the Regulation?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
17	2	5	1	Respondent Member States: 25/28

[976] **NL** questions the need for trend reporting.

[977] IT Questionnaire:
6.1) Does your delegation agree that in Article 61 a specific reference to the Post-market Surveillance Plan should be done establishing provisions for the management of this events and for the methodology to be used for determining any statistically significant increase in the frequency or severity of incidents as well as the observation period?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
14	1	5	5	Respondent Member States: 25/28

1a. The competent authorities[978] *may*[979] *conduct their own assessments on the trend reports referred to in ~~the first~~ paragraph 1 and adopt appropriate measures in accordance with the present regulation in order to ensure the protection of public health and patient safety. The competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.* [980]

~~*2. Manufacturers of devices falling within class D shall submit, by means of the electronic system referred to in Article 66a, periodic safety update reports including:*~~

~~*(a) summaries of data relevant to the benefits and risks of the in vitro diagnostic medical devices, including results of all studies with a consideration of their potential impact on the certificate and the vigilance summary referred to in Article 59 (1);*~~

~~*(b) a scientific evaluation of the risk-benefit ratio of the device;*~~

~~*(c) all data relating to the volume of sales of the devices including an estimate of the population exposed to the device.*~~

~~*Manufacturers shall submit safety update reports annually during the period of validity of the first certificate. In case of certificate renewal, these reports shall be transmitted every two years.*~~[981]

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978 **DE** The activities referred to here is the responsibility of manufacturers, not of competent authorities.

979 **IE** replace "*may*" by "*shall*".

980 IT Questionnaire:
9) Does your delegation agree that only paragraph 2a of Article 64 (Follow.up of Trend reporting by competent authorities – and periodic safety update reports) should be kept?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
13	8	3	1	Respondent Member States: 25/28

Paragraph 1a of Article 61a is the former Article 64(2a).

981 Pcy: Deleted See art. 60c Periodic safety update report

~~Article 59b~~[982]

***~~Updating technical~~** ~~Documentation~~ **~~based on~~** ~~of vigilance data~~*

~~Manufacturers shall update their technical documentation **listed in Annex IIa** with **vigilance data**:~~

~~(a)~~ ~~information on incidents received from **competent authorities**, healthcare professionals, patients, and users, **and any other economic operators;**~~

~~(b)~~ ***~~reports on~~*** ~~serious incidents, field safety corrective actions, **and** periodic summary reports referred to in Article 59 **and trend reports referred to in article 59a**,~~

~~(c)~~ ~~trend reports referred to in Article 62 and field safety notices referred to in Article 61(5).~~

~~They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.~~

~~Article 79 59c~~ [983]

~~Device registers~~

~~The Commission and the Member States shall take all appropriate measures to encourage the establishment of **and co-operation and interoperability between** registers for specific types of devices to gather post-market experience related to the use of such devices **in a systematic manner**. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices~~

984

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982 **Pcy** This article is replaced by 60a(4) and Annex IIa.

983 **Pcy** On the basis of debate WP on 13 June 2014 this article should remain in Chapter VIII.

984 In document 10146/14 all articles before article 61d where part of the section "*Post-market surveillance*". Following the discussion in the Working Party on 13 June 2014 it is proposed to include Articles 61, 61a and 61b in the section "*Vigilance*".

~~*Article 59d*~~[985] [986]

~~***Manufacturers' obligation to cooperate with the competent authorities as regards risk evaluation***~~

~~***1. The manufacturer shall conduct without delay all investigations necessary to assess the risk of any device in respect of which a serious incident was reported to him or a field safety corrective action was taken and inform the competent authorities of the Member States where the incident occurred about the outcome. However, the manufacturer shall consult the competent authority before performing any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident.***~~

~~***1a. The manufacturer shall provide a final report about its findings, by means of the electronic system referred to in Article 64a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.***~~

~~***2. Upon request by a competent authority, the manufacturer shall provide all documents necessary for a risk evaluation, particularly relevant parts of the risk analysis and the clinical evaluation for the device concerned by electronic means.***~~

~~*Article 60*~~

~~*Electronic system on vigilance*~~[987]

~~1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:~~

~~(a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1);~~

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[985] IT Questionnaire:
3) Does your delegation agree with the UK proposal DS1285/14 which include Art. 61d (Manufacturers' obligation to cooperate with the competent authorities) in Article 63 (Analysis of serious incidents and field safety corrective actions)?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
19	1	3	2	Respondent Member States: 25/28

[986] In accordance with document DS 1285/14, presented by the UK, the provisions of Article 61d are incorporated into Article 63.

[987] This Article has been moved and is now Article 66a.

(b) the periodic summary reports by manufacturers referred to in Article 59(2);

(c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(1);

(d) the reports by manufacturers on trends referred to in Article 62;

(e) the field safety notices by manufacturers referred to in Article 61(5);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(4) and (7).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on serious incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:

(a) the Member State where the incident occurred;

(b) the Member State where the field safety corrective action is being or is to be undertaken;

(c) the Member State where the manufacturer has his registered place of business;

(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.

Article 61

Analysis of serious incidents and field safety corrective actions[988]

0. Following the reporting of a serious incident pursuant to Article 59(1), the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. The manufacturer shall co-operate with the competent authorities and where relevant with the concerned notified body*[989] *during these investigations and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident prior to informing the competent authorities of such action.

[988] **DS 1285/13: UK**: *As highlighted at the Working Party meeting on 13 June, the UK believes that the provisions in Article 61d of the Presidency's proposed text in document 10146/14 should be incorporated into Article 63 to very clearly set out the respective roles and responsibilities of manufacturers and authorised representatives in relation to the investigation of serious incidents and implementation of field safety corrective actions. To this end, the UK has proposed the following changes to Article 63 paragraphs 1 and 2 which would allow the corresponding deletion of Article 61d.*

[989] Based on an **NL** suggestion.

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer***, and, where relevant, with the notified body concerned***.[990]

~~If, in the case of reports received in accordance with Article 59 (3), the competent authority ascertains that the reports relate to a serious incident, it shall notify without delay those reports to the electronic system referred to in Article *64a* 62, unless the same incident has already been reported by the manufacturer.~~[991]

2. ***In the context of the evaluation referred to in paragraph 1, the*** ~~The~~ national competent authorities shall***, in cooperation with manufacturers and notified bodies, evaluate the risks arising from*** ~~carry out a risk assessment with regard to~~[992] reported serious incidents and field safety corrective actions~~,~~ taking into account criteria[993] such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of ***direct or indirect*** harm and severity of ***that*** harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action***, in particular taking into account the principle of inherent safety laid down in Annex I***.

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990 **NL** doesn't agree. Risk analysis evaluation should be in charge to the manufacturer (proposal MDEV – 65 circulated during 11-12 November meeting)

991 **DS 1004/14: DE** has suggested to delete this paragraph. Rationale*: This is not the task of the CA but manufacturers responsibility (see proposed changes in Article 61(3)). In case the event does not qualify the serious incident definition, there is no need to put these user reports into the central database. User reports are usually made in the national language and, therefore, of reduced benefit for the other CAs. In case the MANUFACTURER qualifies the event to fulfil the serious incident definition, the manufacturers report shall be uploaded*.

992 **NL** this is manufacturer's responsibility.

993 **DE** these criteria are not clear

2a. ~~They~~ ***The national competent authorities*** shall monitor the manufacturer's investigation of ~~the~~ ***a serious*** incident.[994] ***Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.***

Upon request by a competent authority, the manufacturer shall provide all documents necessary for a risk assessment.

2b. The manufacturer shall provide a final report setting out its findings by means of the electronic system referred to in Article 64a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

3. In the case of devices referred to in the first subparagraph of Article 1(3) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the second subparagraph of Article 40(2).

[994] **FR** delete this sentence

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article ***64a*** ~~60~~, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment. ~~***In all other cases, the evaluating competent authority shall provide to the manufacturer and, where applicable, to the reporting users and to the electronic system referred to in Article 64a, a final report on the outcome of its assessment.***~~[995]

[995] DS 1004/14: DE proposal. *Rationale: CAs have to provide a final report to manufacturers and users, if necessary.* Based on the debate at the Working Party meeting on 13 June 2014, the paragraph has been deleted

5. The manufacturer shall ensure that ~~the users of the device in question are informed without delay of~~ ***information about*** the ***field safety*** corrective action taken ***is brought without delay to the attention of users of the device in question*** by means of a field safety notice ~~***in an official Union language which can be easily understood by the affected user or patient***~~[996]. ***The field safety notice shall be edited in the official language or in one of the official languages of the Member State where the field safety corrective action is taken or in another language which the Member State has indicated that it can accept.***[997][998] Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 6 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

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[996] Pcy: New text on the basis of similar provision

[997] Similar wording provided in Council Regulation (EC) No 1206/2001 on cooperation between the courts of the Member States in the taking of evidence in civil or commercial matters.

[998] **ES, FI** The Field Safety Notice should be edited in the language which the Member State, where the FSCA is taken, has indicated that can accept

~~*The field safety notice shall, in particular,*~~

~~*(a) identify the affected device, indicating the following elements: type of device, model name and number, batch/lot or serial numbers and part or order number,*~~

~~*(b) describe the deficiencies or malfunctions as well as, where identified, their causes;*~~

~~*(c) describe the product's risks and the facts on which the risk assessment is based,*~~

~~*(d) clearly explain the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person*~~

~~*(e) clearly indicate the necessary corrective measures,*~~

~~*(f) indicate a contact person or a contact point for further questions;*~~

~~*(g) indicate any additional useful information.*~~

The field safety notice shall allow the correct identification of the device or devices involved and of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without playing down the level of risk, [999] ***the reasons for field safety corrective action with reference to the device deficiency or malfunction and associated risks for patient, user or other person and shall clearly indicate all the actions to be taken by users.***

~~*The manufacturer shall omit any comments or description that attempt to play down the level of risk in an inappropriate manner.*~~

The manufacturer shall enter the field safety notice in the electronic system referred to in Article ~~60~~ ***64a*** through which that notice shall be accessible to the public.

~~*460459604*~~

[999] Pcy proposal on suggestion of Cion during the 11-12 November meeting

6. [1000]The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph ~~2~~ ***2a*** in the following cases:

(a) where ***there is concern regarding a particular*** ~~similar~~ serious ***incident or cluster of serious*** incidents related to the same device or type of device of the same manufacturer ~~occur~~ in more than one Member State;

(b) where the ***appropriateness of a*** field safety corrective action ***that is proposed by a manufacturer is in question***. ~~is being or is to be undertaken in more than one Member State.~~

Unless otherwise agreed between the competent authorities, ~~t~~***T***he coordinating competent authority shall be ~~the one of~~ the Member State where the manufacturer ***or the authorised representative*** has his registered place of business.~~[1001][1002]~~

The competent authorities shall actively participate in a coordination procedure. This procedure shall include the following:

- designation of a coordinating authority on a case by case basis, when required;

- a definition of the coordinated assessment process;

- tasks and responsibilities of the coordinating authority and the involvement of other competent authorities

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[1000] IE Proposal working doc. N° MDEV – 64 circulated 11-12 November meeting

[1001] DS 2046/13: DE proposal*: : In the following cases: (a) where similar serious incidents related to the same device or type of device of the same manufacturer occur in more than one Member State (b) where a competent authority has concerns or intends to modify the corrective action proposed by the manufacturer the competent authorities shall actively participate in a coordination procedure developed by the MDCG. This procedure should include the following:*
- the designation of a coordinating authority on a case by case basis
-a definition of the coordinated assessment process, tasks and responsibilities of the coordinating and the other competent authorities in this process
Rationale: the proposed coordination mechanism is unclear and not mature enough to be acceptable for MS yet. in the future appropriate mechanism in the cooperation of MS in the field of vigilance have to be developed.

[1002] IT questionnaire:
8) Does your delegation agree that MDCG should be involved in the procedure of identifying the coordinating competent authority for the analysis of serious incidents and FSCA?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
5	12	8	0	Respondent Member States: 25/28

~~The competent authorities shall actively participate in a coordination procedure developed by the MDCG. This procedure should include the following:~~

~~- the designation of a coordinating authority on a case by case basis~~

~~- a definition of the coordinated assessment process, tasks and responsibilities of the coordinating and the other competent authorities in this process~~

The coordinating competent authority shall~~,~~ ~~inform~~ ***through the electronic system referred to in Article ~~60~~ 64a, inform*** the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

7.[1003] ~~The coordinating competent authority shall carry out the following tasks:~~

~~(a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken;~~

~~(b) to consult with the notified body that issued a certificate in accordance with Article 43 for the device in question regarding the impact of the serious incident on the certificate;~~

~~(c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 60 64a(5) on the format, content and frequency of periodic summary reports in accordance with Article 59(2);~~

~~(d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action;~~

~~(e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 60 64a, of the progress in and the outcome of its assessment.~~

The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

[1003] It is felt that the level of detail on the tasks of the coordinating competent authority is best described in an Implementing Act. However, if it is necessary to retain this detail within the proposed text then we request an amendment to the first paragraph to read: 'The coordinating competent authority shall carry out the following tasks, where relevant'.

8. The Commission shall provide ~~secretarial~~ ***~~logistical~~ administrative***[1004] support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

~~*Article 62*~~ [1005]

~~*Trend reporting*~~

~~Manufacturers of devices classified in class C and D shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 61 shall apply.~~

~~*Article 63*~~[1006]

~~*Documentation of vigilance data*~~

~~Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports referred to in Article 61, trend reports referred to in Article 62 and field safety notices referred to in Article 61(5). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.~~

[1004] This word has been suggested by many Member State at the Working Party meeting on 13 June 2014.

[1005] This article is moved to Article 61a - Trend reporting.

[1006] This article is replaced by 60a(4) and Annex IIa.

Article 63a

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 64a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns. [1007]

When a previously unknown [1008] ***risks*** ~~***s***~~ ***is identified or the*** ~~***a***~~ ***frequency*** ~~***'s increasing***~~ ***of an anticipated risks*** ~~***that***~~ ***significantly and adversely changes the risk-benefit determination*** ~~***ratio***~~***, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, who shall take the necessary corrective actions*** ~~***inform users in accordance with Article 61(5).***~~ [1009]

[1007] **DS 2046/13 UK** Rationale: *The UK believes it is important to include a new Article in both Regulations that ensures that the EU-wide vigilance system is not simply a repository for vigilance information, but rather that the data included in the system is proactively interrogated to be able to identify wider safety signals. It is important to coordinate this activity to avoid duplication of activities by individual Member States.*

1008 Compare Article 72.

[1009] IT Questionnaire:
11.1) Does your delegation agree with the following text: "When previously unknown risks or a frequency's increasing of anticipated risks significantly and adversely change the risk-benefit ratio, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer who should take the necessary corrective actions"?

YES	NO	Neutral	No Answer	Comments / Alternative proposal
12	**5**	**3**	**4**	Respondent Member States: 25/28

Article 64

Implementing acts[1010]

The Commission may[1011] [1012], by means of implementing acts, ***and after consultation of the MDCG***[1013]***,*** adopt the modalities and procedural aspects necessary for the implementation of Articles ~~59***d 61***~~ to 63***a and 64a*** as regards the following:

(a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;[1014]

(b) ~~harmonised forms for~~ the reporting of serious incidents and field safety corrective actions, ***field safety notices,*** periodic summary reports***, periodic safety update reports***[1015] and trend reports by manufacturers as referred to in Articles ***58c,*** 59, ***59a*** and ***61*** ~~64~~;

(ba) standard web-based structured forms including a minimum data set for electronic reporting of serious incidents by healthcare professionals, users and patients;[1016]

(c) timelines for the reporting of ~~serious incidents and~~ field safety corrective actions, periodic summary reports***,*** ~~and~~ trend reports ***and periodic safety update reports*** by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 59 and ***58c*** ~~62~~;

[1010] **DS 2046/13 DE** Article 66 should be deleted. Rationale: Article 66 not necessary. Harmonised forms will be developed through the design of the EUDAMED module on vigilance

[1011] **DS1204/14 DK** "*shall*" instead of "*may*". Rationale: We propose to use the word « shall » instead of « may » in order to oblige the Commission to adopt implementing acts otherwise this is only a possibility.

[1012] **DK, PT** "shall" instead of "may".

[1013] This procedure enables the adoption of a legal requirement ("minimum data set"), whilst fully involving the MS, the MDCG and the Commission.

[1014] **DS 2046/13 SE** ~~*. typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;*~~. Rationale: We need a clarification what is intended by Sub section 66(a) and in particular the wording “typology”. We would prefer this Sub section to be deleted.

[1015] **DS 1204/13 DK** we propose to insert « and the periodic safety update reports » in indent (b) in order for the Commission to launch a harmonised format for PSUR.

[1016] **DS 2046/13 UK** *The Member States shall coordinate between them and with the Commission the development of* ~~*standard web-based structured forms*~~ *a minimum data set for electronic reporting of serious incidents by healthcare professionals, users and patients.* Rationale: The UK would propose amending the language to give Member States greater flexibility in the development of tools to support reporting by healthcare professionals and users.

(d) harmonised forms for the exchange of information between competent authorities as referred to in Article 61.

(e) **procedures for designation of a coordinating competent authority; the coordinated assessment process; tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.** [1017]

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

*Article ~~60~~ **64a***

Electronic system on vigilance[1018] ***~~Vigilance module in EUDAMED~~***

1. The Commission shall, in collaboration with the Member States, ~~set up and manage an electronic system to~~ collate and process the following information ***by means of the electronic system set up pursuant to Article 23 including a link to the product information in accordance with article ~~21~~ 23.***

   (a) the ***~~initial and final~~*** reports by manufacturers on serious incidents and field safety[1019] corrective actions referred to in Article 59(1) ***and Article 61 (1)***;

   (b) the periodic summary reports by manufacturers referred to in Article 59(2);

   ~~(c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(1);~~

   (d) the reports by manufacturers on trends referred to in Article ~~62~~59a;

   (da) the periodic safety update reports referred to in Article ~~59a~~ 58c

   (e) the field safety notices by manufacturers referred to in Article 61(5);

   (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(4) and (7).

[1017] See footnote 73

[1018] This text is reinstated since the original wording would be preferable. It is necessary to ensure consistency with other similar articles like for example Article xx Chapter VI.

[1019] Text reinstated in accordance with the provisions of article 61

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies ~~***that issued a certificate for the device in question in accordance with Article 41***~~.[1020]

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

[1020] **DS 2046/13 BE** "*The electronic system shall allow, where appropriate, the transmission of the information mentioned to the notified body that issued a certificate in accordance with Article 45 for the device in question.*".

5.[1021] The reports on serious incidents and field safety corrective actions referred to in points (a) ~~and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on serious incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62~~ ***to (e) of paragraph 1*** shall be automatically transmitted**,** upon receipt**,** ~~via~~ ***through*** the electronic system, to the competent authorities of the following Member States:

[1021] **DS 2046/13 DE, (PT and UK** agree):

"5. The reports on serious incidents ~~and field safety corrective actions~~ referred to in points (a) ~~and (b)~~ of Article 61(1)~~, the periodic summary reports referred to in Article 61(2),~~ and the reports on serious incidents referred to in the second subparagraph of Article 63(~~1~~2) ~~and the trend reports referred to in Article 64~~ shall be automatically transmitted upon receipt via the electronic system to the competent authority**v**~~ies~~ of the ~~following~~ Member State~~s:~~

~~(a) the Member State~~ where the incident occurred;

~~(b) the Member State where the field safety corrective action is being or is to be undertaken;~~

~~(c) the Member State where the manufacturer has his registered place of business~~;

~~(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.~~

6. The reports on corrective actions referred to in point (b) of Article 61(1) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:

(a) the Member State where the field safety corrective action is being or is to be undertaken;

(b) the Member State where the manufacturer or his authorised representative has his registered place of business.

7. The periodic summary reports referred to in Article 61(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:

(a) the Member State that agreed on the periodic summary report ;

(b) the Member State where the manufacturer or his authorised representative has his registered place of business. "

Rationale: Alignment to the currently functioning EU vigilance system. CION Proposal would mix the responsibilities etc. point b) is about Field Safety Corrective Actions and not related to serious incident therefore we suggest to split the paragraph and bring it into alignment with the MEDDEV

(a) the Member State where the incident occurred;

(b) the Member State where the field safety corrective action is being or is to be undertaken;

(c) the Member State where the manufacturer ***or his authorised representative*** has his registered place of business;

(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.

5a. The information referred to in paragraph 5 shall be automatically transmitted, upon receipt, through the electronic system ~~referred to in Article 60~~, to the notified body that issued the certificate for the device in question in accordance with Article 43. [1022]

SECTION 2 – MARKET SURVEILLANCE

Article 65[1023] [1024]

Market surveillance activities ~~at national level~~[1025]

1. The competent authorities ***~~for in vitro diagnostic medical devices~~*** shall perform appropriate checks on the ***~~conformity~~*** characteristics and performance[1026] of ***~~the~~*** devices ***~~with the applicable legal requirements,~~*** including, where appropriate, ***~~clinical evaluation,~~*** review of ***~~technical~~*** documentation and physical or laboratory checks on the basis of adequate samples. They shall***, in particular,***[1027] take account of ***~~(a)~~*** established principles regarding risk assessment and risk management, ***~~(b)~~*** vigilance data and ***~~(c)~~*** complaints.

[1022] **DS 2046/13: BE** "*The electronic system shall allow, where appropriate, the transmission of the information mentioned to the notified body that issued a certificate in accordance with Article 45 for the device in question.*"

[1023] **Question 13**: 10 Member States agree on the detailed description of the inspections referred to in article 67, paragraph 1a, letter b; 9 not agree; 4 neutral

[1024] **Question 14**:11 Member States prefer to let Member States themselves free to organize their own inspection activity according to the national needs and procedures; 10 not agree; 2 neutral

[1025] **DK, PT, EL:** Delete "*at national level*"

[1026] Reinstated words from the Cion proposal.

[1027] **IE** add "*in particular*"; **ES, FR, UK** support

1a. The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 77.

1b.[1028] ***For the purpose referred to in the previous paragraph,*** The competent authorities may***, inter alia:***

a) require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where ~~***necessary and***~~ justified, ~~enter the premises of economic operators and take~~ ***provide*** the necessary samples of devices ***free of charge;***

[1028] This paragraph is based on paragraph 1a in document 10146/14. Here only changes to the Cion text are, however, indicated. Paragraph 1a in that document read:

"***1a***. ~~The competent authorities may require e~~ ***For the purposes of paragraph 1,***

a) economic operators ***shall*** ~~to~~ make available the documentation and information necessary ~~for the purpose of carrying out their activities~~ and, where ~~necessary and~~ justified, ~~enter take~~ ***provide*** the necessary samples of devices ***free of charge***.

(b) according to a risk based proactive market surveillance plan, or reactively based on information from paragraph 1, the competent authorities shall carry out both announced ~~and~~ or, if necessary for control purposes, unannounced inspections of the premises of economic operators ***as well as suppliers and/or subcontractors,*** and***, where necessary, at the facilities of professional users ~~health care professionals~~.***

To that purpose, they shall designate a sufficient number of competent inspectors who shall be empowered to carry out inspections of the premises of economic operators whose devices are intended to be made available on the Union market. These inspectors may be assisted by experts appointed by the competent authorities.

Following each market surveillance operation carried out, the competent authority shall draw up a report on compliance by the concerned economic operator with this regulation and on any corrective actions needed.

The competent authority which carried out the operation shall communicate the content of this report to the economic operator concerned. Before adopting the report, the competent authority shall give the economic operator concerned the possibility to submit comments. The final report shall be made accessible to other Member States through the electronic system referred to in Article 75b."

b) carry out both announced and, if necessary for control purposes [1029]***, unannounced inspections of the premises of economic operators whose devices are intended to be made available on the Union market, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users*** [1030]***.*** ~~***To that purpose, they shall designate a sufficient number of competent inspectors.***~~ [1031]

1c. The Competent Authorities shall prepare a summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 73b. [1032] [1033] [1034] [1035]

1d. [1036] ***The competent authorities*** ~~They~~ may ***confiscate,*** destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary ***in the interest of the protection of public health***.

[1029] **PT** delete "*if necessary for control purposes*"; **DK** opposed.

[1030] **Question 27**: 15 Member States prefer the wording "*professional users*" instead of "*healthcare professionals*" in Article 67, point 1a, letter b; 6 not agree; 4 neutral.

[1031] **LU, LT, DK, ES**: Concerns about lack of recourses

[1032] **Question 16**: 7 Member States agree drawing up a report following each market surveillance operation carried out; 14 not agree; 3 neutral

[1033] **Question 17**: 18 Member States agree on circulating, through the electronic system, a summary report of their own surveillance plans; 5 not agree; 3 neutral

[1034] **Question 18**: 10 Member States agree on identifying only selected cases to be made accessible to other Member States through the electronic system;9 not agree; 3 neutral

[1035] Many Member States concerned about too detailed provisions; that could lead to unnecessary restrictions for competent authorities.

[1036] This paragraph is the former paragraph 1b in document 10146/14.

2.[1037] The Member States shall ~~periodically~~ review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public ***by means of the electronic system referred to in Article 73b***.

3.[1038] The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof***, ~~by means of the electronic system referred to in Article 73b~~ to provide for a harmonized high level of market surveillance in all Member States***.

[1039]

[1037] This paragraph is substantially changed compared to paragraph 2 in document 10146/14. Here only changes to the Cion text are, however, indicated. Paragraph 2 in that document read:
"2. The ***competent authorities of*** Member States shall ~~periodically~~ review and assess the functioning of their surveillance activities at least every ***three*** ~~four~~ years. ***They shall draw up annual surveillance plans covering their planned surveillance activities, ~~as well as the~~ and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 80.*** ~~Such reviews and assessments shall be carried out.~~ ~~and~~ ***The Member States shall communicate*** the results ~~there~~of ***the reviews and assessment*** ~~shall be communicated~~ to the other Member States and the Commission***, as well as***~~. The Member State concerned shall~~ make a summary of the results accessible to the public ***electronically by means of the system described in Article 75b ~~68~~.***"

[1038] This paragraph is substantially changed compared to paragraph 3 in document 10146/14. Here only changes to the Cion text are, however, indicated. Paragraph 3 in that document read:
"3. The competent authorities of the Member States shall coordinate their market surveillance activities ***following the market surveillance program drawn up by the MDCG according to Article 80,,*** cooperate with each other and share with each other and with the Commission the results thereof, ***by means of the electronic system referred to in Article 75b ~~68~~***.
The competent authorities shall implement and maintain a quality management system in accordance with principles developed by the MDCG. The quality management system shall provide for ~~ensure~~ a harmonised high level of market surveillance in all Member States.
Where appropriate, the competent authorities of the Member States shall agree on work-sharing, ***joint market surveillance activities*** and specialisation."

[1039] **Question 23**: 13 Member States agree on the implementation by Member States of a mandatory quality management system; 8 not agree; 4 neutral.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing***, joint market surveillance activities*** and specialisation.

4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

5. ***Where appropriate, t***~~T~~he competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

~~***Without prejudice to any agreements between the EU and third countries, the inspections referred to in paragraph 1a may also take place in the premises established in a third country where the device is intended to be made available on the EU market.***~~ [1040]

6. The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this article as regards the good practices for market surveillance, particularly for inspection.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3). [1041] [1042]

[1040] **Question** 28: 13 Member States agree on adding in Art. 67 the provision concerning inspections in the premises established in a third country in the MDR; 8 not agree; 3 neutral.

[1041] Based on FR intervention at the WP meeting on 26 February.

[1042] **Question 15**: 8 Member States agree with the inspection activity to be regulated by the Commission by means of implementing acts; 10 Member States do not agree; 7 neutral.

~~*Article 66*~~

~~*Electronic system on market surveillance*~~[1043]

~~1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:~~

~~(a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6);~~

~~(b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 68(2);~~

~~(c) information in relation to formal non-compliance of products referred to in Article 71(2);~~

~~(d) information in relation to preventive health protection measures referred to in Article 73(2).~~

~~2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.~~

[1043] This article is replaced by Article 75b.

Article 67[1044] [1045]

Evaluation regarding ***suspected non-compliant*** *devices* ~~***suspected to***~~ *presenting a****n*** ~~***unacceptable***~~ *risk to health and safety at national level*

Where the ~~***Member State***~~ competent authorities of a Member State[1046], based on ***data obtained by*** vigilance ***or market surveillance activities*** ~~data~~ or other information, have ~~sufficient~~ reason to believe that a device ***may*** present~~s~~ a***n unacceptable*** risk to the health or safety of patients, users or other persons, ***or to other aspects of the protection of public health, or otherwise does not comply with the requirements laid down in this Regulation,*** they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by ***or non-compliance of*** the device. The relevant economic operators shall cooperate ~~as necessary~~ with the competent authorities.

~~*Article 68*~~[1047]

~~*Procedure for dealing with non-compliant devices presenting a risk to health and safety*~~

~~1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.~~

[1044] **Question 24**: 15 Member States agree on adding the wording "unacceptable risk"; 8 do not agree; 2 neutral.

[1045] Articles 69-74 based on **UK** suggestion in **DS 1367/14**.

[1046] The words highlighted in grey are reinstated.

[1047] This article is taken from the Commission proposal 14499/12.

~~2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 66.~~

~~3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.~~

~~4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate provisional measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.~~

~~They shall notify the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 66.~~

~~5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.~~

~~6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 66.~~

~~7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.~~

~~8. All Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the device concerned.~~

Article 69

*[1048]Procedure for dealing with ~~non-compliant~~ devices presenting a**n unacceptable** risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device ***~~according to that evaluation~~***, ~~which~~ presents a***n unacceptable*** risk to the health or safety of patients, users or other persons, ***or to other aspects of the protection of public health and does not comply with the requirements laid down in this Regulation***[1049], they shall without delay require the ***manufacturer of the devices concerned, his authorised representatives and all other*** relevant economic operator***s*** to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to ~~prohibit or~~ restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk ***or non-compliance***. ***~~The Competent Authority of the Member State in which the manufacturer of the concerned device is located shall be informed.~~***

[1048] **ES** suggests to combine article 70 to article 69

[1049] Pcy: Text reintroducing on the basis of the debate at 11-12 November 2014 Working Party

2. ~~Where t~~ ***T***he competent authorities ~~consider that non-compliance is not restricted to their national territory, they~~ shall ~~inform~~ ***notify*** the Commission***,*** ~~and~~ the other Member States ***and the notified body that issued a certificate in accordance with Article 43 for the device concerned*** of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article ***73b*** ~~66~~.

3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate ~~provisional~~ measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

   They shall notify the Commission***,*** ~~and~~ the other Member States ***and the notified body that issued a certificate in accordance with Article 43 for the device concerned***, without delay, of those measures, by means of the electronic system referred to in Article ***73b*** ~~66~~.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification ***and tracing*** of the non-compliant device ~~***if available by means of the electronic system referred to in Article 23***~~, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall**,** without delay**,** inform the Commission and the other Member States***, by means of ~~through~~ the electronic system referred to in Article 73b, ~~(a)~~*** of any additional ***relevant*** information at their disposal relating to the non-compliance of the device concerned and[1050] ***~~(b)~~*** of any measures adopted by them in relation to the device concerned.

~~6a.~~ In the event of disagreement ***~~of a Member State~~*** with the[1051] ***~~a~~*** notified national measure ***~~referred to in paragraph 4 or in point (b) of paragraph 6~~***, they[1052] ***~~the Member State~~*** shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article ***73b*** ~~66~~.

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a***ny*** ~~provisional~~ measure***s*** taken by a Member State, ~~that~~ ***those*** measure***s*** shall be deemed ***to be*** justified.

8. ~~All~~ ***Where paragraph 7 applies, all*** Member States shall ensure that appropriate restrictive ***or prohibitive*** measures***, withdrawing, recalling or limiting the availability of the device on their national market*** are taken without delay in respect of the device concerned.

[1050] The word highlighted in grey is reinstated.
[1051] The word highlighted in grey is reinstated.
[1052] The word highlighted in grey is reinstated.

Article 71

Procedure ***for evaluating national measures*** *at Union level*

1. Where, within two months of receipt of the notification referred to in Article 68(4) ~~***and point (b) of 68(6)***~~, objections are raised by a Member State against a ~~provisional~~ measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall***, after consulting*** ~~***the MDCG,***~~[1053] ~~***and***~~ ***the*** ~~***national***~~ ***concerned competent authorities and, where necessary, the concerned economic operators,*** evaluate the national measure. On the basis of the results of that evaluation, the Commission ~~shall~~ ***may*** decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).

2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. ***In the absence of a Commission decision the national measures shall be considered to be justified.***

1053 Pcy:Text reintroducing on the basis of the debate at 11-12 November 2014 Working Party

2a. Where~~, in the situations referred to in Articles 68 and 70,~~ a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).

~~3. On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2*a* in accordance with the procedure referred to in Article 86(4).~~

~~*Article 70*~~[1054] [1055]

~~*Procedure for dealing with compliant devices presenting a* **an unacceptable** *risk to health and safety*~~

~~1. Where, having performed an evaluation pursuant to Article 67, a Member State finds that although a device has been legally placed on the market or put into service, it presents a **previously unknown unacceptable** risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall**, if it considers that the risk-benefit ratio has deteriorated to such an extent that the risk has become unacceptable,** require the relevant economic operator or operators to take all appropriate provisional measures **corrective actions** to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.~~

[1054] **Question 19**: 13 Member States agree on the provision of separated procedures for surveillance actions on non compliant products and high risk compliant products, as recommended by the Commission; 5 do not agree; 5 neutral

[1055] **Question 20**: 9 Member States agree on a unique procedure (and on the removal of Article 72); 10 do not agree; 1 neutral

~~2.~~ ~~The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 66. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.~~

~~2a.~~ ~~The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market.~~

~~3.~~ The Commission shall evaluate the ~~provisional~~ ~~national measures taken. On the basis of the results of that evaluation, the Commission~~ shall ***may*** ~~decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 86(4).~~

~~4.~~ ~~Where the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.~~ ***In the absence of a Commission decision the national measures shall be considered to be justified.***

~~5.~~ ~~The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.~~

Article 71[1056] [1057]

Formal non-compliance

1. ***Where, having performed an evaluation pursuant to Article 67,*** ~~***Without prejudice to Article 68,***~~ [1058] ~~***where***~~ ***the competent authorities of*** a Member State ***find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they*** shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance***.*** ~~where it makes ***at least*** one of the following findings***, related to formal non-compliance***:~~

   ~~(a) that the CE marking has been affixed in violation of the formal requirements laid down in Article 16;~~

   ~~(b) that the CE marking has not been affixed to a device contrary to Article 16;~~

   ~~(c) that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not covered by this Regulation;~~

   ~~(d) that the EU declaration of conformity has not been drawn up ***in conformity with this Regulation and the requirements set out in Article 15 and Annex IV in particular*** or is not complete;~~

[1056] **Question 21**: 6 Member States agree on the need for a more detailed list of formal non-compliances described in Article 73; 14 do not agree; 3 neutral.

[1057] **Question 22**: 9 Member States agree with the completeness of the list of formal non-compliances described in Article 73; 9 do not agree; 2 neutral.

[1058] ES suggests to delete "*without prejudice to Article 70*"

~~(e) that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not~~ ***~~in conformity with this Regulation and the requirements set out in Annex I Section III in particular~~*** ~~complete or not provided in the language(s) required;~~

~~(f) that the technical documentation, including the clinical evaluation, is not available or not complete~~ ***~~in conformity with this Regulation and the requirements set out in Article 57and Annex XIII in particular;~~***

~~(g) that a conformity assessment according to Article 40 has not been carried out~~~~.~~

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article ***73b*** ~~66~~.

3. The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).

Article 72

Preventive health protection measures

1. Where a Member State, after having performed an evaluation***, which indicates a potential*** ~~[1059]~~ ***previously unknown unacceptable risk related to a device or a specific category or group of devices*** considers that***, in order to protect the health and safety of patients, users or other persons or other aspects of public health,*** the making available on the market or putting into service of ~~such~~ ***a*** device or ***a*** specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled ~~in order to protect the health and safety of patients, users or other persons or other aspects of public health~~, it may take any necessary and justified ~~provisional~~ measures.

2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article ***73b*** ~~66~~.

3. The Commission***, in consultation with the MDCG and, where necessary, the concerned economic operators,*** shall assess the provisional national measures taken. The Commission ~~shall~~ ***may*** decide, by means of implementing acts, whether the national measures are justified or not. ***In the absence of a Commission decision the national measures shall be considered to be justified.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).

~~On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 86(4).~~

1059 ES suggests to reintroduce "*potential risk*"

4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission ~~shall be empowered to~~ ***may*** adopt ~~delegated~~ ***implementing*** acts in accordance with ***the examination procedure referred to in*** Article ~~87~~ ***86(3)*** to take the necessary and duly justified measures.

~~Where in this case imperative grounds of urgency so require, the procedure provided for in Article 90 shall apply to delegated acts adopted pursuant to this paragraph~~.

Article 73

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law ***or the administrative practice*** of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator's being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. Any ***provisional*** measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.

4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall ***by means of the electronic system referred to in Article 73b*** inform the relevant notified body ***and the authority responsible for the notified body*** of the measure taken.

Article 73a[1060]

Hazard alerts

~~***Competent authorities shall alert patients and health professionals within the territory of their***~~ ***Member States shall put in place appropriate mechanisms, in accordance with national law and administrative practice, with a view to ensuring that patients and health professionals within their territory are alerted within an adequate timeframe of hazards they have identified relating to any device*** ~~***so as to avoid any injury or other damage***~~***. Member States shall be free to decide on what they consider to be the most appropriate manner of complying with this article.***

[1060] **Question 25**: 14 Member States agree on adding the following wording in Article 75a: "*Member State shall put in place appropriate mechanisms, in accordance with National law and administrative practice, with a view to ensuring that patients and health professionals within their territory are alerted within an adequate timeframe of hazards they have identified relating to any device. Member State shall be free to decide on what they consider to be the most appropriate manner of complying with this article.*"; 6 do not agree; 5 neutral.

*Article **73b** ~~66~~*

Electronic system on market surveillance[1061] ***~~Market surveillance module in EUDAMED~~***

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to[1062] collate and process the following information: ***~~by means of the electronic system referred to Article 25~~***.

   (aa) summaries of the results of the surveillance activities referred to in Article 67(1c);

   (a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6);

   ~~(b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 70(2);~~

   (c) information in relation to formal non-compliance of products referred to in Article 71(2);

   (d) information in relation to preventive health protection measures referred to in Article 72(2)***;***

   (e) summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in 65(2).

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned ***and, where applicable, to the notified body that issued a certificate in accordance with Article 43 for the device concerned*** and be accessible to the Member States and to the Commission.

3. Information exchanged between Member States shall not be made public when this may impair market surveillance activities and co-operation between Member States.[1063]

[1061] The words highlighted in grey are reinstated.
[1062] The words highlighted in grey are reinstated.
[1063] 19 Member States agree to adding point 3 in Article 75b; 3 do not agree; 2 are neutral. This paragraph, which was suggested for deletion in document 10146/14 is therefore reinstated.

Chapter VIII[1064]

Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

Article 74

Competent authorities

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation.[1065] The Member States shall communicate ***the names and contact details of*** the competent authorities ~~***responsible for the implementation of this Regulation***~~ to the Commission which shall publish a list of competent authorities.[1066]

2.[1067] ~~***By way of derogation from paragraph 1,*** For ***for*** the implementation of Articles 48 to 58, the Member States may designate a national contact point other than a national ***competent*** authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.~~ [1068]

[1064] The text of this chapter comes from document DS 1539/14.

[1065] BG, DK, IE: Delete "*resources, equipment and knowledge*". Cion: This text is based on Regulation (EC) No 765/2008, compare *e.g.* Article 16(3).

[1066] DE: The requirement in the last sentence is impossible - DE has 80 competent authorities. AT, PT: Authority list needed *e.g.* for market surveillance.

[1067] DE, PT, UK: Delete this paragraph - there is no reference to "*national contact point*" elsewhere in the text. ES: Reservation. AT: Contact point needs powers so the paragraph is problematic. Need for contact point for clinical investigations. Cion: Similar provision in Clinical trials regulation

[1068] FR: Reservation on deletion of this paragraph.

Article 75

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission **which shall provide for the organisation of exchanges of** [1069] ~~and exchange with each other the~~ information necessary to enable this Regulation to be applied uniformly.[1070]

2. Member States ***shall with the support of*** ~~and~~ the Commission ~~shall~~ participate***, where appropriate***[1071]***,*** in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.[1072]

Article 76

Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78, **81a** ***and 82***[1073] of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.

[1069] Following MD proposal

[1070] DE, AT: The following text based on part of Article 20a in Directive 93/42/EC is missing: "*The Commission shall provide for the organisation of an exchange of experience between the competent authorities ~~responsible for market surveillance~~ in order to coordinate the uniform application of this Directive.*"

[1071] **DS 1138/13** UK: add "*where appropriate*".

[1072] DE, AT;IE, PT: Important that all Member States can participate - therefore Cion should support MS.

[1073] Presidency proposal in response to FR request (see footnote on Article 82 in the MD Regulation).

Article 77

Tasks of the MDCG [1074]

The MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV; [1075] [1076] [1077]

(b) ~~***to adopt opinions***~~[1078] ~~***to be provided to notified bodies as part of the***~~ to contribute to the scrutiny of certain[1079] conformity assessments pursuant to[1080] ~~***for devices listed in***~~ Article 42[1081] [1082];

(c) to contribute to the development[1083] of[1084] guidance aimed at ensuring effective and harmonised implementation[1085] of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements[1086] and conduct of[1087] the clinical[1088] evaluation[1089] [1090] ~~investigations~~ by manufacturers***,*** ~~and~~ the[1091] assessment by notified bodies ***and the vigilance activities***[1092];

[1074] CY, SE: Questions whether it is possible for the MDCG to take on all the tasks listed here. NL, UK: This article requires more discussion in order for the tasks to be sufficiently clear.

[1075] AT: Important provision.

[1076] IE, IT: Add coordination tasks here.

[1077] UK: Is this really a MDCG task?

[1078] DE: Unclear what this means, in particular in relation to MDCG role regarding guidelines.

[1079] The underlined words come from the Cion proposal and are reinstated.

[1080] The underlined words come from the Cion proposal and are reinstated.

[1081] CZ, DK, IE, IT, LT, NL, AT, PL, SK, SE, UK: Scrutiny reserve until discussion on Article 42 finalised.

[1082] **DS 1483/13** DE: Replace points (b) to (f) with an aim to strengthen market surveillance.

[1083] **DS 1190/13** AT: add "*and maintenance*"

[1084] DE, NL, AT, SK: Replace "*contribute to the development of*" with "*develop*".

[1085] AT: add "*including classification*".

[1086] Following MD proposal

[1087] PT: Add "*post-market surveillance,*"

[1088] SE: Need for coordination of clinical data.

[1089] The underlined word come from the Cion proposal and is reinstated.

[1090] **DS 1190/13** AT: add "*, including PMCF*"

[1091] **DS 1190/13** AT: add "*related*"

[1092] Pcy addition based on the forthcoming proposal on chapter VII concerning the designation of Coordinating Competent Authority (Art. 63)

(ca) to continuously monitor the technical progress and assess whether the essential requirements on safety and performance provided in this Regulation and Regulation (EU) No […/…] [on medical devices] are appropriate to ensure safety and performance of in vitro diagnostic medical devices and identify the need to amend Annex I;[1093] [1094]

[1093] DK: This task had better be allocated to the Commission due to the need for resources. NL, SE: Heavy task.

[1094] FR, IT, AT: Add reference to Annex VII (on classification).

1095 **DS 1483/13** DE add:

"~~*(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;*~~

~~*(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;*~~

~~*(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;*~~

~~*(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;*~~

~~*(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.*~~

(b) to continuously monitor the technical progress and assess whether the essential requirements on safety and performance provided within this Regulation are appropriate to ensure safety and performance of in vitro diagnostic medical devices and identify the need to amend Annex I;

(c) to develop guidelines on clinical evaluation of certain in vitro diagnostic medical devices

(d) to contribute to the development of in vitro diagnostic medical devices standards;

(e) to contribute to the development of Common Technical Specifications (CTS)

(f) to develop and maintain a framework for a European market surveillance program;

(g) to develop minimum requirements on a quality management system for national market surveillance authorities .

(h) to organise joint market surveillance and joint testing projects;

(i) to organise training programmes and exchanges of national officials on market surveillance, on notified bodies designation and monitoring and on clinical investigations;

(j) to organise information campaigns and joint visit programmes;

(k) to provide an opinion on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices according to Article 41 paragraph 3 within six months

(l) to provide at the Commission's request an opinion on a the classification of a device, or category or group of devices according to Article 41 paragraph 4

(m) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation."

1096 **DS 1024/14** NL: does not agree with points g, h, i, j, k, l & m suggested by DE delegation.

(cb) to contribute to the development of in vitro diagnostic medical devices standards and of Common Specifications[1097] [1098] [1099]***;***

(d) to assist the competent authorities of the Member States in their coordination activities **in particular** [1100]in the fields of ***classification and regulatory status***[1101] ***of in vitro diagnostic medical devices,*** clinical performance studies, vigilance and market surveillance ***including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 65 ~~67~~***[1102] [1103];

(e) to provide advice ~~and assist the Commission~~, ***either on its own initiative***[1104] ***or*** at ~~its~~ request ***of the Commission***, in ~~its~~ ***the*** assessment of any issue related to the implementation of this Regulation;[1105]

(f) to contribute to harmonised administrative practice with regard to *in vitro* diagnostic medical devices in the Member States.

[1106]

1097 FR, AT: CTS should be main task, standards less important for MDCG.
1098 SE: Heavy task.
1099 DK, NL: Support for this point.
1100 Following MD Proposal
1101 ES, IT, NL, AT, PT, UK: Add "*and qualification*". PL: Opposed to this addition. ES: Give MDCG a role in the decision on the regulatory status of products (Article 3). Cion: Article 3 is on implementing acts, so there is already a committee assisting the Commission in those decisions. Pcy consider that MDCG can give comments useful to decide the classification or the regulatory status of a product; the Committee assisting the Commission on implementing acts has a different role.
1102 DK, LT, PL, SE: Scrutiny reserve until discussion on Article 67 (MD) finalised.
1103 IE, IT, SK: This point must be further elaborated.
1104 SE: Questions if this is legally possible.
1105 DK, FR: Support for the changes to this point.
1106 UK: Add "*contribute to the development of EUDAMED*".

Article 78

European Union reference [1107] *laboratories* [1108] [1109] [1110] [1111] [1112]

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre[1113] have submitted an application for designation.[1114]

[1107] **DS 1256/14** UK Add : "*and testing*"

[1108] FR: Strong support for EU reference laboratories.

[1109] AT: The procedure for appointing EU reference laboratories must seek to find such laboratories covering all types of IVDs and avoid to "over-establish" laboratories for certain tasks.

[1110] General support for creating EU reference laboratories for IVDs.

[1111] DE: Need for clear rules for reference laboratories for IVDs. Results must be comparable and reliable. (See following footnotes on this article.)

[1112] UK: Proposal for introducing a new concept of 'EU testing laboratories' that would replace the unclear 'national reference laboratories' proposed by the Commission. They would be managed by the JRC and work closely with reference laboratories to ensure high standards.

[1113] BE: What exactly is the role of the JRC here?

[1114] **DS 1484/13** DE: Replace this paragraph with:

"*1. For devices of class D a network of European Union reference laboratories shall be established. The Commission shall designate, by means of implementing acts, European Union reference laboratories as members of the network described in the first sentence, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.*"

AT support

2. [1115] Within the scope of their designation, the EU reference laboratories[1116] shall, where appropriate, have the following tasks[1117]:

(a) to verify compliance of class D **and class C** [1118]devices with the applicable C~~T~~S, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2)[1119];

(b) to carry out appropriate[1120] tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;

(c) to provide scientific and technical assistance to the Commission, ***the MDCG***[1121]**,** the Member States and notified bodies [1122] in relation to the implementation of this Regulation;

(d) to provide scientific advice regarding[1123] the state of the art in relation to specific devices, or a category or group of devices;

[1115] **DS 1256/14** UK**:** Delete points (a) and (b) and add subparagraphs 2a. e 2b. (testing laboratories – see following footnotes)

[1116] SE: Question regarding use of private-owned laboratories and their duties as regards confidentiality.

[1117] IT: The tasks are too broad.

[1118] Cion proposal (Working Party September 30th) – AT, BE support

[1119] **DS 1484/13** DE: Replace: "*when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2).*" by "*. The laboratory evaluation according to Annex VIII and IX shall focus on the analytical and clinical sensitivity and specificity.*".

[1120] **DS 1484/13** DE: Add: "*laboratory*".

[1121] SE: Delete this addition. Cion: The MDCG has no budget. Therefore it is not meaningful to add it here.

[1122] **DS 1484/13** DE: Delete: "*and notified bodies*".

[1123] **DS 1484/13** DE: Replace: "*regarding*" by " *and technical assistance regarding the definition of* ".

(e) to set up and manage a network of national reference laboratories[1124] ***after consulting with the national authorities***[1125] [1126] and publish a list of the participating national reference laboratories[1127] and their respective tasks;[1128]

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures[1129] and market surveillance;

(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;[1130]

(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;

(i) to contribute to the development of standards at international level;[1131]

(j)[1132] to provide scientific opinions[1133] in response to consultations by notified bodies in accordance with this Regulation ***and publish them by electronic means after consideration of national provisions on the respect of confidentiality***[1134]

[1135]

[1124] **DS 1256/14** UK Replace "*national reference laboratories*" by "*EU testing laboratories*"

[1125] NL: Delete this addition. Cion: Same position.

[1126] **DS 1256/14** UK Add **"***in collaboration with the Joint Research Centre which shall"*

[1127] **DS 1256/14** UK Replace "*national reference laboratories*" by "*EU testing laboratories*"

[1128] **DS 1484/13** DE: Replace this paragraph with: "*to contribute to a network of national reference laboratories in particular by developing common principles, best practices and participating in ring testings;*".

[1129] **DS 1484/13** DE: Add: "*, for batch verification and*".

[1130] **DS 1484/13** DE: Delete this point.

[1131] **DS 1484/13** DE: Replace this point with: "*to contribute to the development of common technical specifications (CTS) as well as of international standards;* ".

[1132] **DS 1484/13** DE: Replace this point with: "*to provide scientific opinions in response to consultations by the competent authorities of the Member States.*".

[1133] UK: What exactly are scientific opinions?

[1134] DK: unclear what this addition means.

[1135] **DS 1256/14** UK add :

"2a. EU testing laboratories shall have the following tasks:

(a) to verify compliance of class D devices with the applicable CTS, where available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2);

(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;"

[1136]

3. EU reference[1137] laboratories shall satisfy the following criteria:

(a) to have ***adequate and*** appropriately qualified staff with adequate knowledge and experience in the field of the medical devices for which they are designated;[1138]

(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) to have the necessary knowledge of international standards[1139] and best practices;

(d) to have an appropriate administrative organisation and structure;

[1136] **DS 1256/14** UK Add :
"2b. Laboratories may be designated as both EU reference laboratories and EU testing laboratories. In such cases the laboratories must have in place clear and separate governance structures."

[1137] **DS 1256/14** UK Add : "*and testing*"

[1138] **DS 1484/13** DE: Replace this point with:
"*(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated. Appropriate knowledge and experience shall be based on*
- *experience of assessing high-risk IVDs and of carrying out the relevant laboratory tests;*
- *in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies;*
- *proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or institution, national reference laboratory for class D devices, quality control of in-vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house;*
- *knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs;*
- *knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs;*
- *knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the Common Technical Specifications (CTS), applicable harmonized standards, product-specific requirements and relevant guidance documents;*
- *participation in relevant external and internal quality assessment schemes organised by international or national organisations.*"
AT support

[1139] **DS 1484/13** DE: Add "*, common technical specifications and*".

(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;

(f) to act in the public interest and[1140] in an independent manner;

(g) to ensure that their staff do not have financial or other interests in the in vitro diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the in vitro diagnostic medical device industry and update this declaration whenever a relevant change occurs.

[1141]

4. EU reference laboratories may[1142] be granted a Union financial contribution.
The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

[1140] **DS 1484/13** DE: Delete "*in the public interest and*".

[1141] **DS 1484/13** DE: Add the following paragraph:
"*3a. The network of European Union reference laboratories shall satisfy the following criteria and the reference laboratories in the network should coordinate and harmonise their working methods as regards testing and assessment. This involves:*
a) applying coordinated methods, procedures and processes;
b) agreeing on the use of same reference materials and common test samples and seroconversion panels;
c) establishing and common assessment and interpretation criteria
d) using common testing protocols and assessing the test results using standardised and coordinated evaluation methods;
e) using standardised and coordinated test reports;
f) developing, applying and maintaining a peer review system
g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results).
h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures (SOPs);
i) coordinating the introduction of testing methods for new technologies and according to new or amended CTS;
j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by the European Commission or a Member State"
AT support

[1142] **DS 1484/13** DE: Replace "*may*" with "*shall*".

5. Where notified bodies or Member States[1143] request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially[1144] cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

6.[1145] The Commission shall ***specify*** ~~be empowered to~~ ***by means of*** ~~adopt delegated~~ ***implementing*** acts in accordance with Article 8***4***~~5 for the following purposes~~:

(a) ~~amending, or supplementing~~ ***detailed rules to facilitate the application*** ~~the tasks of EU reference laboratories referred to in~~ ***of*** paragraph 2 and ***detailed rules to ensure compliance with*** the criteria ~~to be satisfied by EU reference laboratories~~ referred to in paragraph 3***;***

(b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies ***and Member States*** in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.

7. EU reference[1146] laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts[1147], shall take appropriate measures, including the ***restriction, suspension or*** withdrawal of the designation.

~~***8. The implementing acts referred to in this article shall be adopted in accordance with the examination procedure referred to in Article 84(3).***~~[1148]

[1143] DE, ES: The assistance for Member States should be free of charge.
[1144] **DS 1484/13** DE: Delete "*wholly or partially*".
[1145] **DS 1484/13** DE: Delete this paragraph.
[1146] **DS 1256/14** UK add : "*and testing*"
[1147] **DS 1484/13** DE: Move "*by means of implementing acts*" to the end of the sentence.
[1148] Pcy: Following MD Proposal

Article 79

Device registers ***and data banks*** [1149] [1150]

The Commission and the Member States shall take all appropriate measures to encourage[1151] [1152] the establishment of[1153] ~~***and co-operation and interoperability between***~~ registers **and data banks** for specific types of devices ~~to gather post-market experience related to the use of such devices ***in a systematic manner***~~ **setting common principles to collect comparable information** [1154]. Such registers **and data banks** shall contribute to the independent evaluation of the long-term safety and performance of devices.[1155]

[1149] SE : doubts on IVD registers . Cion : registers could be useful for certain pathologies (eg.Diabetes). DE IVD data banks more useful than IVD registers

[1150] ES: It should be made clear that Cion should finance device registers. AT: Device registers should be financed by manufacturers.

[1151] The underlined word comes from the Cion proposal and is reinstated.

[1152] SE, UK: Prefer original text. Not appropriate to regulate here who should create device registers and who should finance them. DE, AT: Similar views. Rules are needed to make registers compatible and facilitate joint data evaluation. Cion: Rules on compatibility important. Cion can not finance these registers.

[1153] The underlined words comes from the Cion proposal and are reinstated.

[1154] Following MD Proposal

[1155] NL: Doubts on this article. How does it link to market surveillance and how does it link to EUDAMED?
DS 1262/13 IT: Also has concerns about how meaningful this provision is. Made other suggestion.

Chapter IX[1156]

Confidentiality, data protection, funding, penalties

Article 80

Confidentiality[1157] [1158]

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on ~~medical~~ [1159]confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

   (a) personal data in compliance with ***Article 85*** ~~Directive 95/46/EC and Regulation (EC) No 45/2001~~;[1160]

[1156] The text of this chapter is based on that in document 15118/14 but has been updated by **IT Pcy** following the meeting of the Working Party on 11 and 12 September 2014.

[1157] **DS 1006/14 IE** General comment: Appropriate provisions around confidentiality of information are a critical topic. These provisions should strike a balance between an appropriate level of transparency on information about the performance and safety of medical devices and the need to protect commercially sensitive proprietary information.

In particular, Article 80(1)(b) should seek to protect primarily intellectual property such as design, materials and manufacturing details (although it is important to demonstrate the technical, biological and clinical equivalence in accordance with Annex XII). Other information, such as information obtained through vigilance and market surveillance systems should not be subject to the same level of confidentiality provisions.

It is also critical to ensure that the European legislation is sufficiently clear to ensure that information on emerging safety and regulatory issues can be shared and dealt with effectively between competent authorities on a confidential basis. Practical experience with the variety of national freedom of information provisions across Europe has led to some difficulties with the exchange of information between authorities.

[1158] **BE, IE, PT** suggested that, in order to avoid duplication of communication systems, it should be envisaged to restrict the visibility of some information contained in the unique electronic system to the Member States and the Commission.

[1159] **SE, DK, FI, DE** delete "*medical*".

[1160] The Presidency proposals regarding this point are simply an alignment with what was proposed for article 84 of the Medical Device Regulation in doc. 6804/14.

(b) commercial interests ***and trade secrets***[1161] of a natural or legal person, including intellectual property rights [1162] **unless disclosure is necessary for reasons of public health**;

(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.[1163]

2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall ~~remain confidential unless~~ ***shall not be disclosed without prior consultation with*** the originating authority ~~has agreed to its disclosure~~.[1164] [1165] [1166]

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

[1161] **DS 1006/14 DE** adding "*commercial interests and business secrets of a natural or legal person, including intellectual property rights;*" Changed to "*trade secrets*" by **Pcy**. Comment: Should there be a clarification that confidentiality could only be claimed by CAs and Cion for information concerning vigilance cases or aspects of product safety as far as the protection of the legal interests mentioned in paragraph 1 (a) and(b) is concerned?

[1162] **SE, IR; DK; DE; PT; ES; UK** add ", *unless disclosure is necessary for reasons of public health*".

[1163] The Presidency proposal to reinstate this point is simply an alignment with what is proposed for article 84 of the Medical Device Regulation.

[1164] The Presidency proposal for changes to this paragraph is simply an alignment with what is proposed for article 84 of the Medical Device Regulation.

[1165] **IE** maintain this point. **UK** scrutiny reservation on deletion of this point in previous documents. **SE**, **PL** reservation

[1166] **SE** replace "*shall remain confidential unless the originating authority has agreed to its disclosure*" with "*shall not be disclosed without prior consultation with the originating authority*". **DK, PT** support. Transparency/Confidentiality must be based on objective reasons.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 81

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 82[1167]

Levy of fees[1168]

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. ~~They~~

2. ***Member States*** shall inform the Commission and the other Member States at least three [1169]months before the structure and level of fees is to be adopted.

[1167] The Presidency proposals regarding this article are simply an alignment with what was proposed for article 86 of the Medical Device Regulation in doc. 6804/14.

[1168] **DS 1006/14 IE** General comment: The ability of a national authority to levy fees to fund all of its medical device activities is a critical provision and is very much welcomed. Ideally a common mechanism and structure for fees could be developed for use by some or all of the medical device authorities. This would be simpler, more transparent and less of an administrative burden for the medical device industry.

We suggest that careful consideration is given to other areas of the Proposals to ensure that they facilitate the collection of fees. For example, notification of economic operators and medical devices in the European databank may be a step for which a fee may be charged. National validation of this data may also be of benefit to the overall quality of the data in the databank. This topic should be very carefully considered by the group of experts who will develop the European databank described in these Proposals.

[1169] **FR** due to national decision making procedures one month is more appropriate

Article 83

Penalties

The Member States shall[1170] lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [*3 months prior to the date of application of the Regulation*] and shall notify it without delay of any subsequent amendment affecting them.

[1170] **DS 1006/14 DE** "*may*" instead of "*shall*". According to our legal understanding Member States could only be obliged to lay down penalties for infringements if the infringements that shall be subject to penalties are listed in this Article (principle of legal certainty). The proposed wording leaves it uncertain whether Member States have to lay down penalties for all infringements or only for those they consider as necessary.

It is to be discussed if there should be a list of infringements of provisions of this Regulation that should subject to penalties in each Member State in order to ensure a level playing field.

Pres.: standard provision that can also be found in Article 87 of Regulation (EU) No 528/2012 (biocidal products); Article 24 of Directive 2011/83 (consumer rights); Article 37 of Regulation (EC) No 1223/2009 (cosmetic products); Article 11 of Regulation (EC) No 595/2009 (motor-vehicles); Article 94 of Regulation (EU) No 536/2014 (clinical trials) (OJ L158/2014 p. 1. 27.5.2014). *etc*.

Chapter X[1171]

Final provisions

Article 84

Committee procedure

1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [*Ref. of future Regulation on medical devices*].

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.[1172] [1173]

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

[1171] The text of this chapter comes from document 15118/14.

[1172] The Presidency proposal regarding this paragraph are simply an alignment with what was proposed for article 88 of the Medical Device Regulation in doc. 6804/14.

[1173] **DS 1008/14 DE** Rationale: Article 5 (4) second subparagraph point (b) of Regulation (EU) No182/2011 foresees the option to lay down in the basic act that the Commission cannot adopt the draft implementing act in the absence of an opinion from the committee. This option should be used.
Doing so, different opinions on whether the act in question concerns the protection of the health or safety or definitive multilateral safeguard measures according to Article 5 (4) second subparagraph point (a) could be avoided.

Article 85

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles[1174] 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) is conferred on the Commission subject to the conditions laid down in this Article. ***When adopting those delegated acts, the Commission shall follow its usual practice and carry out consultations with experts, including Member States' experts.***[1175]

2. The delegation of power referred to in Articles[1176] 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) shall be conferred on the Commission for ~~an indeterminate period of time~~ ***a period of five years*** from the date of entry into force of this Regulation. ***The Commission shall draw up a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***[1177]

3. The delegation of power referred to in Articles[1178] 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

[1174] The references in this article are subject to revision depending on the discussion of each specific delegation of power.

[1175] **Pcy** addition of text approved by Coreper. The text in question is subject to discussion in ongoing informal trialogues on other proposals.

[1176] The references in this article are subject to revision depending on the discussion of each specific delegation of power.

[1177] Standard provision - see *e.g.* Regulation (EU) No 536/2014 on clinical trials. (OJ L158/2014 p. 1. 27.5.2014).

[1178] The references in this article are subject to revision depending on the discussion of each specific delegation of power.

1179

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. **1180**

5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of ~~two~~ ***three*** **1181** months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by ~~two~~ ***three*** months at the initiative of the European Parliament or the Council.

1179 **FR, UK** Add the following paragraphs from doc. 6774/14:
"*3a. Before the adoption of a delegated act, the Commission shall consult the MDCG. For this purpose, the Commission shall submit its draft delegated act to the MDCG. Except in duly justified cases, it shall convene a meeting not less than 14 days from submission of the draft delegated act and of the draft agenda to the MDCG. The MDCG shall be given the opportunity to comment on all major changes of the draft delegated act before it is adopted by the Commission.*

The MDCG shall adopt an opinion on the draft delegated act. As far as possible, the MDCG shall adopt its opinions by consensus. In the event of a vote, the outcome of the vote shall be decided by a simple majority of the members. The Commission shall inform the MDCG of its preliminary reactions and how it intends to proceed and shall give the MDCG the opportunity to react.

3b. When adopting a delegated act, the Commission shall take the utmost account of the opinion delivered by the MDCG.

A summary of the consultation shall be drafted by the Commission and adopted by [the expert group]. In case the Commission does not act in accordance with the opinion delivered by [the expert group], it shall set out its reasons for this in the summary."

1180 **FR, UK** Add "*Along with the delegated act, the Commission shall transmit the summary of the consultation.*". (Text from document 6774/14)

1181 Based on recent experience, the Presidency proposes to prolong the time periods in this paragraph in order to make sure that Member States also when delegated acts are notified in July get a chance to properly scrutinize them. Please note that there is also an urgency procedure laid down in Article 86.

~~*Article 86*~~[1182]

~~*Urgency procedure for delegated acts*~~

~~1.~~ ~~Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.~~

~~2.~~ Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 85. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.

Article 86a[1183]

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 87

Transitional provisions[1184]

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.

[1182] **Pcy** proposes to delete this article since the (only) reference to the urgency procedure for delegated acts (in Article 72(4)) will be deleted in analogy to what is done in the Medical Device Regulation.

[1183] **Pcy** follow up to discussion in the Working Party on 16 September.

[1184] **DS 1008/14 DE** Comment: This article requires serious discussion and agreement when general agreement on the other articles is achieved. Many of the provisions in this current article are insufficient and inappropriate however a discussion on this makes only sense if we know the final wording of the related provisions in this regulation. ***Pcy*** agrees that an overview of the timing related to the transitional provisions is necessary.

2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation.

   Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.

4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23(2) and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.

6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.

Article 88

Evaluation

No later than five years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of the Regulation including an assessment of resources required to implement this Regulation.

Article 89

Repeal

Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [*date of application of this Regulation*] with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from [*18 months after date of application*].

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV.

Article 90

Entry into force and date of application

1 This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union*.

2. It shall apply from [*five years after entry into force*].

3. By way of derogation from paragraph 2 the following shall apply:

(a) Article 23(2) and (3) and Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];

(b) Articles 26 to 38 shall apply from [*six months after entry into fo*rce]. However, prior to [*date of application as referred to in paragraph 2*], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.[1185]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, ~~26.9.2012~~

For the European Parliament	*For the Council*
The President	*The President*

[1185] **DS 1008/14 DE** Comment: There is a need to check the compatibility with transitional measures in 87(1).