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From: General Secretariat of the Council
To: Working Party on Pharmaceuticals and Medical Devices

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No. Cion doc.: 14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1
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Subject: Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
Proposal for a Regulation of the European Parliament and of the Council on **in vitro diagnostic medical devices**
- *Chapter I of the two proposals*

Delegations will find attached texts containing proposals for changes to the Proposal for a Regulation on medical devices and to the Proposal for a Regulation on *in vitro* diagnostic medical devices prepared by the Latvian Presidency. The texts are based on document 16893/1/14 REV 1.

Annex A to this Note sets out the text of Chapter I of the Proposal for a Regulation on medical devices.

Annex B to this Note sets out the text of Annex XV to the Proposal for a Regulation on medical devices.

Annex C to this Note sets out the text of Chapter I of the Proposal for a Regulation on *in vitro* diagnostic medical devices.

Text conventions

Additions of new text to the text in the Commission proposal are set out in ***bold italics***.

Deletions of text in the Commission proposal are set out in ~~strikethrough~~.

Deletions of text in previous Presidency documents are set out in ***bold italics strikethrough***.

Changes compared to document 16893/1/14 REV 1 and text elements to which the Presidency wishes to draw attention are **highlighted in grey**.

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and
Regulation (EC) No 1223/2009

Chapter I
Scope and definitions

Article 1

Scope

1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with~~ ~~by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or ***putting*** into service¹ ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~. ***This regulation also establishes rules to be complied with by sponsors who take the responsibility for applies to clinical investigations and investigational on medical devices conducted in the Union.***^{2 3}

¹ **DS 1639/14 DE** “*putting into service*” should be better defined, **CZ** support.

² **Pcy** the last sentence is subject to revision depending on decisions in other parts of the regulation.

³ **DS 1029/15 DE** Scrutiny reservation on the last sentence. **DE** alternative: replace “*applies to*” by “*lays down rules on*”.

1a.⁴ *This regulation shall also apply to the groups of products without an intended medical purpose that are listed in ~~each section of Annex XV~~ as from the date of entry into force of common specifications covering at least the application of risk management for ~~each group of those products~~, adopted pursuant to Article 7 [~~, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology~~]. ~~for each group of products. The common specifications for a group of products listed in each section of Annex XV shall specifically address application of Section 6 of Annex I in relation to the acceptable risks for that group of products.~~^{5 6}*

The Commission shall adopt the necessary Common Specifications ~~per~~ [for the groups of products listed in ~~each the sections of Annex XV~~] at the latest one year after the date of application of this Regulation.⁷

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⁴ This paragraph replaces the last paragraph of Article 2(1)(a).
⁵ **BE, DK, DE, IE, EL, HR, IT, HU, AT, NL, PL, PT, FI, SE, UK** expressed support for this **Pcy** compromise proposal. For suggested alternative wordings from **DE, HR** see **DS 1029/15**.
⁶ **DS 1403/14 DK** the products listed in Annex XV should not be part of the definition of a medical device and it should be stipulated in Article 1 paragraph 1 if these products fall under the scope of the Regulation on medical devices. **DE, PL, SE** also oppose including aesthetic products into the scope of this regulation.
⁷ **UK** would prefer one year before the date of application of this Regulation. **DK** proposes to rather have a joint MS and **Cion** declaration.
CLS clarified that in case CS are not adopted in time, this regulation is not applicable for aesthetic devices and the current unclear legal situation prevails.
BE, DK, IE, ES, FR, HR, IT, PT, FI expressed that development of CS should not delay the application of the regulation. **Pcy** therefore proposes a deadline.
⁸ **DE DS 1639/14** in addition suggests that Notified Bodies for the relevant conformity assessment procedures should be designated and notified in order for the Regulation to apply to the products in Annex XV. **IE** proposes to address this concern in Annex 6. **IT, EL** supports. This requirement would make the application of the Regulation subject to actions of individual Member States and the **Council Legal Service** therefore has a strong reservation. **Pcy** however invites delegations to give their view on such an addition.
⁹ **FR** and **ES** proposal **DS 1061/15**. **EE, IT, PT, FI** support. **DE, AT** don't support. **CLS** concerns on the delegation of power to the **Cion** to legislate on the application of scope of Regulation, which is substantial part of legislation.

1b. For the purposes of this Regulation, medical devices, ~~and~~ accessories to medical devices **and products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a**¹¹ shall hereinafter be referred to as ‘devices’.

2. This Regulation shall not apply to:

- (a) *in vitro* diagnostic medical devices covered by Regulation (EU) [.../...];
- (b) medicinal products **as defined in** ~~covered by~~¹² Directive 2001/83/EC¹³ ~~and advanced therapy medicinal products covered by Regulation (EC) No 1394/2007~~. In deciding whether a product falls under Directive 2001/83/EC ~~or Regulation (EC) No 1394/2007~~ or under this Regulation, particular account shall be taken of¹⁴ the principal mode of action of the product.

(ba) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;¹⁵

¹⁰ Pcy also proposes to amend Recital (11) as follows:

"(11) Certain implantable and other invasive products for which the manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. ***In order for manufacturers to be able to demonstrate conformity and in order for competent authorities to be able to take action against those devices that pose a risk to their users, the Commission should, where no harmonised standards for such devices exist or where they are not sufficient, be empowered to lay down common specifications on application of risk management and, where appropriate, of other general safety and performance requirements and requirements for clinical evaluation and/or post-market clinical follow-up, applicable to those devices.***"

¹¹ ~~Pcy addition aiming at making the devices in Annex XV subject to all provisions in this Regulation. Builds on interventions by DK, ES, HR, LT, Cion. DE against.~~

¹² ~~Reinstated words from the Cion proposal.~~

¹³ ~~DE, IE, EL, NL, AT support the wording “covered by”. Pcy "as defined in" is a more appropriate legal drafting in point (b) since some medicinal products are excluded from Directive 2001/83, by virtue of Art. 3 thereof (e.g. magistral formula, prepared in pharmacies), but that does not mean that they become "medical devices".~~

¹⁴ ~~Reinstated words from the Cion proposal.~~

¹⁵ Following DE remarks.

- (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market **or put into service**¹⁶ ~~or used in accordance with the manufacturer's instructions~~, such blood products, plasma or cells, except for devices referred to in paragraph 4;
- (d) cosmetic products covered by Regulation (EC) No 1223/2009;
- (e)¹⁷ transplants, tissues or cells of ~~human or~~ animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of ~~human or~~ animal origin, or their derivatives, which are non-viable or are rendered non-viable.

~~However, human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular **any of the manipulations** those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be **covered by this Regulation** considered devices manufactured utilising tissues or cells of human origin or their derivatives;~~¹⁸

¹⁶ **DS 1029/15 AT** add „*or put into service*” to cover in-house blood product production and transfusion.

¹⁷ **DS 1008/15 DK** has presented an alternative wording. **DE** supports **DK** wording. Alternative suggestions also from **DS 1029/15 DE, AT**.

¹⁸ ~~Several Delegations (**DK, DE, ES, FR, NL, AT**) consider unclear the second subparagraph of Article 1(2)(e); during the Working Party meeting on 11-12 September 2014 **Cion** proposed an alternative text included in the **Pcy** proposal. New text seems to be clearer than the previous one. WP 11.11.2014: **BE, IE, FR, NL, AT, SE, UK** not satisfied with the second subparagraph of Article 1(2)(e). **DS 1406/14 UK** delete the entire subparagraph.~~

- (ea)¹⁹ *transplants, tissues or cells of human origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of human origin, or their derivatives, which are non-viable or are rendered non-viable and ~~that fulfil at least one of the following conditions:~~*
- ~~*the cells or tissues*~~ *have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved. The manipulations listed in Annex I of Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations,*
 - ~~*the cells or tissues are not intended to be used for the same essential function or functions in the recipient as in the donor.*~~
- (f) products, *other than those referred to in points (c) and (e)*, that ~~intentionally~~ contain or consist of *viable* biological substances or organisms, ~~other than those referred to in points (c) and (e), that are viable,~~ including living micro-organisms, bacteria, fungi or virus *in order to achieve or support the intended purpose of the product;*²⁰
- (g) food covered by Regulation (EC) No 178/2002.
- ~~(h) *products intended to be ingested, inhaled or administered orally, vaginally or rectally which shall fall under Directive 2001/83/EC.*~~²¹

¹⁹ Wording from **DS 1005/15** UK, IE, EL, ES, IT, NL, AT tentatively support UK text. DE against. FI, SE, Cion support previous Pcy proposal.

PT suggests to delete paragraph (ea) and add a new paragraph (Article 1(1c)):

“1c. This regulation shall also apply to products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action, and which are excluded from the scope of Regulation n° 1394/2007.”.

²⁰ ~~DE DS 1029/15~~ has presented alternative wording.

²¹ Deleted in accordance with the joint suggestion from PT, UK (DS 1518/14).

3. Any device which, when placed on the market or **put into service**²² ~~used~~ in accordance with the manufacturer's instructions²³, incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2 of Regulation (EU) [.../...] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation, ~~unless it is covered by Article 1(3) of that Regulation.~~ The relevant general safety and performance requirements set out in Annex I of that Regulation shall apply as far as the safety and performance of **to** the *in vitro* diagnostic medical device part ~~are concerned.~~^{24 25}

²² **Pcy** compromise based on **DS 1029/15 DE** suggestion to replace "*used in accordance with the manufacturer's instructions*" by "*put into service*".

²³ ~~**DE DS 1029/15** Replace "*used in accordance with the manufacturer's instructions*" by "*put into service*".~~

²⁴ **BE DS 1866/12** 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 pieces of legislation 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. **DE DS 1029/15** against.

²⁵ **BE** suggestion circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57)

4. Where a device, when placed on the market or **put into service and** used in accordance with the manufacturer's instructions²⁶, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation.²⁷

However, if the action of the medicinal substance is **principal**, not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC **or Regulation (EC) No 726/2004, as applicable**. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

5. Where a device is intended to administer a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, that device shall be governed by this Regulation, without prejudice to the provisions of Directive 2001/83/EC **and Regulation (EC) No 726/2004** with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the product shall be governed by Directive 2001/83/EC **or Regulation (EC) No 726/2004, as applicable**. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

6. 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.

²⁶ ~~DE DS 1029/15~~ Replace "*used in accordance with the manufacturer's instructions*" by "*put into service*".

²⁷ **BE DS 1367/13** add "*In this case, the relevant requirements of Annex I of Directive 2001/83/EC shall apply as far as the safety, quality and usefulness of the medicinal product are concerned according to the procedure described in Annex VIII, Chapter II, point 6*".

7. This Regulation shall not affect the application of Council Directive 96/29/Euratom nor of Council Directive 97/43/2013/59/Euratom²⁸.
- 8.²⁹ 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 medical devices may only be supplied on a medical prescription³⁰, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling.*³¹
- 8a. *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.*³²
9. ~~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.~~³³

²⁸ Correction, following a suggestion in **DS 1416/14 AT**.

²⁹ **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.

³⁰ Highlighted text is reinstated.

³¹ Suggestion from **DS 1416/14 AT**.

³² **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57). **FI** support. **NL** Redundant. **DE, IE** scrutiny reservation, concerned of the impact on confidentiality provisions.

³³ **Pcy** proposal based on oral advice from the Council Legal Service in the Working Party.

Article 2

Definitions

1. 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, reagent³⁴,³⁵ ³⁶ material or other article,³⁷ ~~whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,~~³⁸ 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* process or state,
 - ~~control or support of conception,~~³⁹
 - *cleaning*, disinfection or sterilisation of any of the above-mentioned products;

³⁴ Pcy proposes to reinstate “*reagent*” following requests from **ES, AT, PT, Cion. DE** against.
³⁵ **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...”.

³⁶ **DS 1029/15 AT** add “*or other product for in vitro use*”.

³⁷ **DS 1867/12 AT** add “*including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products*”

³⁸ **Pcy** proposal based on **DS 1029/15 DE. DK, IE, IT, HU, AT** Support. **ES, FR, HR, PT, SE, UK** against. For complete **DE** suggestions on Article 2(1)(1) see **DS 1029/15, DS 1639/14**. **Pcy** suggests to address the concerns described in **DS 1029/15 DE** in other parts or the proposal.

³⁹ Indent moved to the next sentence in accordance with **DS 1029/15 DE**

- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*^{40 41}

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 function by such means.

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Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.

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~~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.~~⁴⁴

⁴⁰ **DE DS 1029/15** delete " blood and tissue donations ".

⁴¹ **AT DS 1867/12** 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”.

ES suggests to instead add

“– providing information by means of in vitro examination of specimens derived from the human body, including blood and tissue donations”. **AT** support. **DK, FR** against.

⁴² **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.”

⁴³ **FR DS 1401/14** 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.”

IE, ES, LT, NL, PL, SK, UK delete this subparagraph. **FR** suggest to change the text; **PT** support. **Pcy** suggests addressing the issue in the context of custom-made devices.

⁴⁴ Deletion following the addition of the new paragraph 1a in Article 1. Against deletion: **ES, FR**.

(2)⁴⁵ ‘accessory to a medical device’ means an article which, whilst not being a medical device, is intended by its manufacturer⁴⁶ to be used together with one or several particular medical device(s) to specifically⁴⁷ enable ~~or assist~~⁴⁸ the device(s) to be used in accordance with its/their intended purpose(s) *or to specifically and directly*⁴⁹ *assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)*⁵⁰;

⁴⁵ DK prefers Cion version.

⁴⁶ ES Change to read: "... an article which, whilst not being a medical device, is intended specifically by its manufacturer ...". AT, PL, SE Support.

⁴⁷ ES Delete: "specifically". SE Support.

⁴⁸ ~~DS 1401/14 FR delete "or assist"~~.

⁴⁹ PT add „and directly”. ES, DE, IT, AT, Cion Support.

⁵⁰ ~~DS 1401/14 FR add "or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)"~~.

- (3) ‘custom-made device’ means any device specifically made in accordance with a written prescription of a ~~medical~~ doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications⁵¹ which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient.

However, mass-produced devices which need to be adapted to meet the specific requirements of a ~~medical~~ doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes⁵² in accordance with the written prescriptions of ~~medical~~ doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;⁵³

⁵¹ ~~DK, PL~~ replace with “*other duly qualified person*”.

⁵² AT add „*to be used in the production of custom made devices*”.

⁵³ DS 1205/14 FR replace the second paragraph with
"However, mass-produced devices which need to be adapted “standard processed devices” manufactured on the bases of the anatomical characteristics of each patient to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass produced by means of industrial manufacturing processes shall not be considered to be custom-made devices;

However devices which need to be adapted to meet the specific anatomical characteristics of the patient in accordance with a ~~the~~ written prescriptions of a doctors of medicine, of a dental practitioners or of any other ~~authorised~~ person authorised by national law by virtue of this person's professional qualifications which are manufactured by means of standard process without specific design characteristics shall not be considered to be custom-made devices;".
ES support.

- (4) 'active device' means any device, the operation of which depends on a source of electrical energy or any a source of power *energy*⁵⁴ other than that directly ~~and~~ *intentionally* generated *by the human body for that purpose or* by gravity and which acts by changing the density of or⁵⁵ converting this energy. Devices intended to transmit energy, substances or other elements⁵⁶ between an active device and the patient, without any significant change, shall not be considered to be active devices.^{57 58 59 60}

~~Stand alone software shall be considered an active device;~~^{61 62}

⁵⁴ **PT** change "power" to "energy".

⁵⁵ In order to solve the problem with electrodes not being considered active devices **Pcy** proposes to revert to the original Cion wording here, which was intended to solve that problem. Alternatively the wording "... *acts by transmitting or converting this energy.*" could be used. **FR, PT, Cion** supports alternative proposal.

⁵⁶ **ES** Delete: "*substances or other elements*".

⁵⁷ Suggestion from **UK DS 1295/13**.

⁵⁸ **DE, PL** suggest to revert to 90/385/EEC directive text:

"'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;".

⁵⁹ **ES** opposed to this definition since electrodes will not be considered active devices.

⁶⁰ **ES** suggests the following definition "*'active device' means any device, the operation of which depends on any source of energy other than that directly generated by the human body or by gravity and which acts by transmitting or converting this energy. Devices intended to transmit ~~energy~~, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.*".

⁶¹ **ES** Delete: "*Stand alone software shall be considered an active device;*".

⁶² **LV Pcy** proposes to delete: "*Stand alone software shall be considered an active device;*" and to address this issue in Annex VII, Chapter II, Section 3, which **IT Pcy** proposed to change as follows:

"Software ~~Stand alone software~~, which has a medical purpose and drives a device or influences the use of a device, falls automatically in the same class as the device. If ~~stand alone~~ the software is independent of any other device, it is classified in its own right."

The **IT Pcy** proposal is based on a **DE** suggestion. This would require a new definition: "*'Stand-alone software' means a software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.*"

IT Pcy alternative text

"Software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If the software is independent of any other device, it is classified in its own right.". **FR, SE, UK, Cion** are noted to support this text. **AT** wording should be improved.

- (5) ‘implantable device’ means any device, including those that are partially or wholly⁶³ absorbed, which is intended⁶⁴
- to be totally introduced into the human body or
 - to replace an epithelial surface or the surface of the eye,
- by clinical⁶⁵ intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical⁶⁶ intervention and intended to remain in place after the procedure for at least 30 days shall also be considered an implantable device;
- (6) ‘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;
- (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;

...

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in *Article 1(1a)* ~~the last subparagraph of number (1) of paragraph 1~~, in the light of technical progress, ***in order to protect the health and safety of patients, users or other persons or other aspects of public health,***⁶⁷ and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.

⁶³ DS 1029/15 DE delete "or wholly".

⁶⁴ DS 1416/14 HU add “by the manufacturer”; Pcy it could be considered implied.

⁶⁵ DS 1029/15 DE replace "clinical" by "surgical".

⁶⁶ DS 1029/15 DE replace "clinical" by "surgical".

⁶⁷ Text added following a suggestion from UK. In MDEV-54 it was pointed out that this power touches on the scope of the Regulation, making the list in Annex XV, in principle, an open list. BE, EL, FR, Cion supports. DK, DE, AT delete the paragraph.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to adapt the definition of nanomaterial set out in number (15) of paragraph 1 in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

Article 3

Regulatory status of products⁶⁸

1. ~~The~~ *Without prejudice to Article 2(2) of Directive 2001/83⁶⁹, at a duly substantiated request of a Member State⁷⁰, the Commission may^{shall}⁷¹, at the request of a Member State or on its own initiative ~~and following consultation with~~ *after consulting the MDCG and interested parties⁷²*, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

⁶⁸ **DS-1189/13-IT** replace paragraphs 1 and 2 with:

- "1. ~~The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, representing the opinion of Member States, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~
2. ~~The Commission shall ensure the sharing of expertise between Member States through MDCG, referred to in Article 80(d) in the fields of medical devices, in vitro diagnostic 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."~~

Furthermore add to article 80d:

- "(d) ~~to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance, and market surveillance, and borderline and classifications;"~~

⁶⁹ Pcy proposal in response to issue raised by BE and DK. Cion don't support.

⁷⁰ DE not agree on the wording "at a duly substantiated request"; DK, AT support.

⁷¹ FR Replace: "may" with "shall". SE support. UK Against. DE, AT add a deadline for acting.

⁷² UK Replace: "on its own initiative" with "and following consultation with the MDCG and interested parties".

- 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 referred to in Article 80(d),***⁷³ in the fields of medical devices, *in vitro* diagnostic 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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⁷³ **DK, ES, SE, Cion** delete “*through MDCG referred to in Article 80(d)*”. **DK** suggests to mention European Medicines Agency.

ANNEX XV⁷⁴

LIST OF ~~GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE COVERED BY THE LAST SUBPARAGRAPH OF THE DEFINITION OF 'MEDICAL DEVICE' REFERRED TO IN NUMBER (1) OF ARTICLE 1 2(1a)~~^{75 76 77}

1. Contact lenses ~~or equivalent similar articles~~^{78 79} *intended to be introduced into or onto*⁸⁰ *the eye* ~~with no corrective~~⁸¹ *function;*⁸²

2. ~~Implants~~ *Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of* ~~modification~~ *modifying of the anatomy or fixation of body parts*⁸³ ~~excluding piercings with the exception of tattooing products and piercings;~~⁸⁴

⁷⁴ This annex is based on a suggestion from UK following the discussions in the WP on 16 September.

⁷⁵ The title of this annex is adapted following the introduction of the new paragraph 1a in Article 1 and the removal of aesthetic devices from the definition of medical device.

⁷⁶ IE suggests to add a recital clarifying that products listed in annex XV may have a dual propose. PT supports.

⁷⁷ ES considers the defined product groups as too broad.

⁷⁸ DK, DE, AT, PL concerns on the use of term "equivalent article".

⁷⁹ Pcy proposal in response to Cion that found "articles" too broad and suggested to limit to "contact lenses".

⁸⁰ DS 1029/15 AT add "or onto". Cion support.

⁸¹ Cion replace "corrective" with "medical" RO support. .

⁸² DS 1029/15 DE replace this entry with "Contact lenses with no corrective optical function". DK, ES, NL, PL, RO support.

⁸³ DK delete "fixation of body parts". Paragraph 2 should be better defined, piercings and tattoos should be excluded. Cion supports.

⁸⁴ DS 1029/15 DE replace this entry with "Products intended to be totally or partially introduced into the human body through surgically invasive means for the purposes of modifying the physical appearance of human beings with the exception of tattooing products and piercings.". NL, AT, PL support.

3. *Substances, combinations of substances, or articles intended to be used for facial ~~Facial~~ or other dermal or mucous membrane fillers ~~fillers~~ filling by subcutaneous, **submucous**⁸⁵ or intradermal injection or other introduction, **excluding those for tattooing**;^{86 87 88 89}*
4. *Equipment intended to be used to reduce, remove or destroy adipose tissue⁹⁰, such as equipment for liposuction, lipolysis or lipoplasty;*^{91 92}
- ~~5. Invasive laser equipment intended to be used on the human body;~~
6. *High intensity electromagnetic radiation (infra-red, visible light and⁹³ ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense ~~Intense~~ pulsed light equipment, **for**⁹⁴ skin resurfacing, tattoo⁹⁵ or hair removal **or other skin treatment**;⁹⁶*
- 6a. *Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain;*⁹⁷

⁸⁵ **DS 1029/15 AT** add "*submucous*".

⁸⁶ **DS 1029/15 DE** this entry is redundant. Products covered in entry 2.

⁸⁷ **ES, Cion** there are fillers which are not injected. **ES** therefore replace "*injection*" by "*introduction*". **PL** support.

⁸⁸ **DS 1029/15 AT** add "*or other introduction*".

⁸⁹ **DK** prefers original Cion proposal

⁹⁰ **HR** delete examples from paragraphs 4 and 6.

⁹¹ **DS 1029/15 DE** replace this entry with "*Equipment for not medically indicated liposuction, lipolysis and lipoplasty*";. **NL, RO** support.

⁹² **DK** replace paragraph 4 with "*Equipment for liposuction, lipolysis or lipoplasty*".

⁹³ **DS 1029/15 AT** replace "*and*" by "*and/or*".

⁹⁴ **DS 1029/15 DE** add "*not medically indicated*".

⁹⁵ **DS 1029/15 AT** products for tattooing and piercing must be explicitly excluded. **ES, NL** same request.

⁹⁶ **DK** replace paragraph 6 with: "*invasive laser equipment intended to be used on the human body for skin resurfacing or tattoo removal and intense pulsed light equipment for hair removal*".

AT add "*other skin treatment*"

⁹⁷ **DK, ES, NL, PT, FI** against or reserves on including these products. They raise lots of issues e.g. ethical. **DE, RO** need to clarify wording. **BE, IE, HR, AT, UK, Cion** support the inclusion, these products are already on the market and can be banned based on other provisions if included in the scope of this regulation.

7. ~~*Tooth whitening or bleaching products with a concentration of hydrogen peroxide higher than 6%.*~~⁹⁸

⁹⁸ ~~**DS 1189/13 IT** add to the Annex XV list tooth whiteners with a concentration of hydrogen peroxide higher than 6%.~~

~~“We have some concerns in relation to products with concentrations of hydrogen peroxide higher than 6%, that are still placed on the market with CE marking and EC Conformity Certificates issued by NBs.~~

~~Based on the Italian database we have a lot of products ranging from 6 to 50% of hydrogen peroxide marketed in Italy, manufactured by several European manufacturers and CE marked by different European NBs (list available).~~

~~Although we agree that some of them do not have a medical purpose, our concern is that if they cannot be marketed as medical devices, they could enter the market as free sale products unless a general ban is foreseen. As free sale products, they would elude the vigilance system. The fact that these products are not cosmetics nor medical devices does not exempt us from safeguarding the health of European citizens.~~

~~In order to try to solve this problem we propose to include them in the Annex XV list since other products not provided with a medical purpose (aesthetic implants) have already been included in the recently released MD regulation at Article 2 "Definitions" 1:~~

~~“The implantable or other invasive products, 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.”~~

~~Furthermore, in order to limit their use, and taking into consideration that some of them are invasive, a restrictive use by dentists and other healthcare providers should be considered in the provision.~~

~~This kind of restricted use could be foreseen also for those products provided with a cosmetic purpose beside a medical purpose which could be qualified as medical devices.”~~

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on *in vitro* diagnostic medical devices

Chapter I
Scope and definitions⁹⁹

Article 1

Scope

- 1.¹⁰⁰ 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 putting into service of ***in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices for human use***¹⁰¹ 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 applies to clinical performance studies***¹⁰² ***on in vitro diagnostic medical devices conducted in the Union***¹⁰³.~~
- 1a.¹⁰⁴ 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'.

⁹⁹ This chapter is taken from the consolidated text under preparation by the IT Presidency.

¹⁰⁰ This paragraph is aligned to the wording of the proposed Regulation on Medical Devices.

¹⁰¹ **AT** add “*and performance evaluation devices*”. **IE** support.

¹⁰² **BE, AT** don't limit to clinical performance studies.

¹⁰³ **Pcy** last sentence is subject to revision depending on decisions in other parts of the regulation.
DS 1029 DE Scrutiny reservation on the last sentence. **DE** alternative: replace “*applies to*” by “*lays down rules on*”.

¹⁰⁴ As part of the alignment with the MD proposal a separate number is given to this paragraph.

2. This Regulation shall not apply to:
- (a) products for general laboratory use **or research-use only products**¹⁰⁵, unless such products, in view of their characteristics, are specifically¹⁰⁶ 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.
 - (d) **materials used for external quality assessment schemes;**
 - ~~(e) **research-use only products.**~~¹⁰⁷

¹⁰⁵ Moved from point (e).

¹⁰⁶ NL replace “*specifically*” with “*exclusively*”

¹⁰⁷ UK delete (e), AT support (e), IE add reference to “*research use only*”.

3.¹⁰⁸ Any device which, when placed on the market or **put into service**¹⁰⁹ ~~used~~ in accordance with the manufacturer's instructions¹¹⁰, 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 to **of this** Regulation (EU) [Ref. of future Regulation on medical devices]¹¹¹ shall apply as far as the safety and performance of ~~to~~ the ~~medical device~~¹¹² part ~~that is not an *in vitro* diagnostic medical device~~ are concerned.^{113 114}

¹⁰⁸ ~~Following MD Proposal – BE suggestion circulated during the WP meeting on 11-12 September 2014 (WD MDEV-57).~~

¹⁰⁹ ~~Pcy compromise based on DS 1029/15 DE suggestion to replace "used in accordance with the manufacturer's instructions" by "put into service".~~

¹¹⁰ ~~DS 1029/15 DE Replace "used in accordance with the manufacturer's instructions" by "put into service".~~

¹¹¹ ~~Reinstated text from Cion proposal.~~

¹¹² ~~Reinstated text from Cion proposal.~~

¹¹³ ~~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~~

¹¹⁴ ~~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. DS 1029/15 DE opposes.~~

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**.¹¹⁵
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 **may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense** devices **or that their application must be accompanied by specific professional counselling**.^{116 117}
- 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.**¹¹⁸
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~~¹¹⁹

¹¹⁵ Correction, following a suggestion in **DS 1416/14 AT**.

¹¹⁶ Suggestion from **DS 1416/14 AT**.

¹¹⁷ **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.

¹¹⁸ **SE** suggestion during the WP meeting on 11-12 September 2014 (WD MDEV-57).

¹¹⁹ **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)¹²⁰ ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent^{121, 122} material or other article,¹²³ ~~whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,~~¹²⁴ 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* process or state,
 - ~~control or support of conception~~¹²⁵,
 - ~~cleaning, disinfection or sterilisation of any of the above-mentioned products,~~
 - ~~providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,~~¹²⁶

¹²⁰ HU suggests to replace with a cross reference to the definition of "medical device" in the Medical devices regulation. Pcy will invite the delegations to express views on this idea.

¹²¹ Pcy proposes to reinstate “reagent” following requests from ES, AT, PT, Cion.

¹²² DS 1029/15 AT add “or other product for in vitro use”.

¹²³ DS 1867/12 AT add “including reagents, reagent products, calibrators, control materials, kits or systems for in vitro use, and other products”

¹²⁴ Pcy proposal based on DS 1029/15 DE. DK, IE, IT, HU, AT Support. ES, FR, HR, PT, SE, UK against. For complete DE suggestions on Article 2(1) see DS 1029/15, DS 1639/14.

¹²⁵ Indent moved to the next sentence in accordance with DS 1029/15 DE.

¹²⁶ Alignment with the definition in the MD Regulation.
DS 1029/15 DE delete “blood and tissue donations”.

- ~~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;~~^{127 128 129}

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 and devices for the purpose of control or support of conception shall be considered medical devices.

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¹²⁷ Following MD proposal.

¹²⁸ **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*”

¹²⁹ **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

¹³⁰ **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.*”

~~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.~~^{131 132}

~~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.~~¹³³

- (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 or¹³⁴ 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.

¹³¹ **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.*”

¹³² **IE, ES, LT, NL, PL, SK, UK, Cion** delete this subparagraph; **FR** suggests to change the text; **PT** support. **Pcy:** suggest addressing the issue in the context of custom-made devices.

¹³³ Deletion following the addition of the new paragraph 1a in Article 1 of the MD Regulation.

¹³⁴ **BE** delete "*define or*".

(3)¹³⁵ 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended ¹³⁶ by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically¹³⁷ enable or assist¹³⁸ the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) *or to specifically and directly*¹³⁹ *assist the medical functionality of the medical device(s) in view of 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;~~¹⁴⁰

(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;

¹³⁵ **DK** prefers **Cion** version.

¹³⁶ **ES** add "*specifically*". **AT, PL, SE** Support.

¹³⁷ **ES** delete "*specifically*". **SE** Support.

¹³⁸ **FR** delete "*assist*" in order to avoid inclusion of laboratory generic use devices. **BE, AT, SE** support.

¹³⁹ **PT** add "*and directly*". **DE, ES, IT, AT, Cion** Support.

¹⁴⁰ **BE, FR, NL, AT, UK** delete (3a).

(6) 'companion diagnostic' means a device **which is essential for the safe and effective use of a corresponding medicinal product to:**

- **identify patients who are most likely to benefit from the medicinal product, or;**
- **identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the medicinal product, or;**
- **monitor response to treatment by the medicinal product for the purpose of adjusting treatment to achieve improved safety or effectiveness;**¹⁴¹

specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy;

¹⁴¹ Compromise as a result of cooperation between **BE, DE, FR, UK**. In addition the following recitals shall be added:

"(11a) Companion diagnostics are essential to identify patients for eligibility of treatment with a specific medicinal therapy (e.g. molecule, dose, scheduling) through the determination of a biomarker, either qualitatively or quantitatively, which is specific for a population of responders, non-responders or persons which will develop an adverse response towards this specific therapy. Such biomarker may be present in healthy persons or may be present or induced in the patient due to a condition or pathology.

(11b) It should be clarified that devices monitoring the response to treatment by the corresponding medicinal product are considered companion diagnostics where treatment adjustment to achieve improved safety or effectiveness is essential for the safe and effective use of a corresponding medicinal product, while devices that are used in treatment drug monitoring (TDM) to ensure that the drug concentration in the human body is within the therapeutic window of the drug are not considered companion diagnostics."

...

Article 3

Regulatory status of products¹⁴⁵

1. ~~The~~ Without prejudice to Article 2(2) of Directive 2001/83¹⁴⁶, at a duly substantiated request of a Member State,¹⁴⁷ ~~the~~ Commission ~~may~~ shall¹⁴⁸, at the request of a Member State ~~or on its own initiative and following consultation with the MDCG and interested parties,~~¹⁴⁹ 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.

¹⁴² FR, AT, Cion use FDA definition as basis. UK use Parliament amendment 47 as basis. DE proposal in DS 1029/15, FR proposal in DS 1007/14.

¹⁴³ DS 1007/14 FR replace this definition by:

""Companion diagnostic" means a device specifically ~~intended~~ designed to:

- ~~select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy~~ identify patients who are most likely to benefit from a corresponding medicinal product, or
- identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a corresponding medicinal product, or
- monitor response to treatment by the corresponding medicinal product." IT, PT support. DE, AT on the condition that last indent is reworded.

¹⁴⁴ DE DS 1029/14 replace this definition by:

"companion diagnostic' means a device specifically ~~intended~~ designed to:

~~select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy~~

- identify patients who are most likely to benefit from the treatment with a corresponding medicinal product, or
- identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a corresponding medicinal product;" BE support and will provide text suggestion based on DE text suggestion.

¹⁴⁵ Following MD Proposal Definition from GHTEF/SC/N4/2012 Edition 2.

¹⁴⁶ Following MD Proposal - Pcy proposal in response to issue raised by BE and DK. Cion against.

¹⁴⁷ DE against the wording "at a duly substantiated request". DK, AT support.

¹⁴⁸ FR Replace: "may" with "shall". SE support. UK Against. DE, AT add a deadline for acting.

¹⁴⁹ UK Replace: "on its own initiative" by "and following consultation with the MDCG and interested parties".

2. The Commission shall ensure the sharing of expertise between Member States, ~~through MDCG,~~¹⁵⁰ ~~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.
-

¹⁵⁰ **DK, ES, SE, Cion** delete “*through MDCG referred to in Article 80(d)*”.