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NOTE

from:	Presidency
to:	Working Party on Pharmaceuticals and Medical Devices
No. Cion prop.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
No. prev. doc.	6516/14 PHARM 16 SAN 76 MI 167 COMPET 111 CODEC 424
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** – *Presidency proposal for Chapter VII*

Delegations will in Annex A find a Presidency draft text for Chapter VII of the proposal on medical devices.

The changes proposed to the Commission proposal should also be applicable to the corresponding articles of the proposal on *in vitro* diagnostic medical devices.

Annex B contains some definitions that are relevant for Chapter VII.

In Annex C some consequential changes to Articles 6 and 8(6) are mentioned and some questions are raised.

Annex D sets out some proposed changes to Annex II of the proposal.

Text Conventions:

Additions to the Commission proposals are indicated in ***bold italics***.

Deletions to the Commission proposal are indicated with ~~strikethrough~~.

Additions of text that are presented for the first time here are set out in ***bold underline italics*** and deletions of text that are presented for the first time here are set out in ~~underline strikethrough~~ or ~~***bold italics underline strikethrough***~~ depending on whether the corresponding text is from the Commission proposal or from the Presidency text set out in document 6516/14.

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Medical Devices Proposal

Chapter VII

Post-market surveillance, v~~V~~igilance and market surveillance

SECTION 0 – POST-MARKET SURVEILLANCE

Article ~~65b~~60a[1]

Post-market surveillance by economic operators ~~the manufacturer~~

1. The manufacturer of a device shall ensure compliance with the provisions of this Regulation throughout the lifecycle ~~entire lifetime~~ of the devices ~~while the devices he has is made available on the market~~ as stated by the manufacturer. If the manufacturer has not stated the length of the lifecycle, this obligation shall apply during the reasonably expected lifetime of the device. To this end, the manufacturer shall ~~plan,~~ continuously ~~conduct and document post-market surveillance to~~ gather and record data about the safety and performance ~~and safety~~ of the device, in accordance with the post-market surveillance plan established pursuant to paragraph 1a.

[1] Based on the previous Article 65b. (See document 6516/14.)

1a.[2] ***The manufacturer shall draw up the post-market surveillance plan which shall be part of the technical documentation as specified in Annex II.***

The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints[3] ***and reports from healthcare professionals, patients or users and from authorised representatives in accordance with Article 9(3)(d), importers in accordance with Article 11(8) or distributors in accordance with Article 12(5) on suspected incidents related to the device. It shall also set out the process for keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, for sample testing of marketed devices. The post-market surveillance plan shall include a plan for post-market clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.***[4]

1b. Data on incidents identified in post-market clinical investigations[5] ***referred to in Article 59(5) shall be treated as data collected pursuant to paragraph 1.***

1c.[6] ***The manufacturer~~s~~ shall establish and annually***[7] ***~~keep~~ update~~d~~ a summary report based on the data recorded in accordance with ~~synthesis of the incidents referred to~~ in paragraph 1. That report shall includ~~eing the~~ an analysis of the seriousness of each type of incident and its number and frequency of occurrence, and shall summarise the implications of the assessment ~~of each type of incident~~. The summary report as updated shall be included in the technical documentation referred to in Annex II, Section 6.1. The recorded data shall also, upon request, ~~the synthesis shall~~ be made available to the notified body that issued the certificate for the device and to the competent authorities***[8] ***~~of the Member States~~.***

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2 This paragraph contains the obligations set out in Article 60a(1) of document 6516/14.
3 BE: Should record all complains, not only incidents. Need a broad database.
4 This is based on Article 8(6) which is substantially shortened, see below.
5 CZ: Replace investigations with studies in line with GHTF.
6 This paragraph is based on Article 60a(2) of document 6516/14.
7 IE: Agree with principles and proposes: "..shall annually summarise…". AT: "Synthesis" not appropriate. DK: "Register" more appropriate than "Synthesis".
8 AT: Delete "of the Member States".

2. The manufacturer shall use ~~and update the gathered data~~ the summary report for at least the following purposes, as applicable:

(a) to update the technical documentation referred to ~~as specified~~ in Annex II, in particular as concerns[9]:

i) the risk/benefit analysis and risk management;

ii) the design and manufacturing information;

iii) the instructions for use;

(b) to update the clinical evaluation;

(c) to identify~~ication of~~ needs for preventive, corrective or field safety corrective action;

(d) to identify~~ication of~~ possibilities to improve the ~~usability,~~ performance and safety of the device, and where relevant, its usability.

3. If in the course of the post-market surveillance the manufacturer identifies a need for corrective action to bring the device in conformity with this regulation ~~is identified~~, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body and the competent authorities concerned. ~~The identification of an incident or a field safety corrective action shall induce actions according to~~ Article 61 shall apply accordingly.

~~4.~~[10] ~~The manufacturer shall establish, document, implement, maintain and update a post-market surveillance plan which shall be part of the technical documentation as specified in Annex II.~~

~~5.~~[11] ~~The manufacturer shall prepare an annual report summarising the implications of analysis of the gathered post-market surveillance data, which shall be part of the technical documentation as specified in Annex II.~~

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9 BE: Move the following points to relevant recitals.

10 Obligation moved to paragraph 1.

11 Obligation moved to paragraph 1a.

Article 60a

Register of incidents

The obligations following from this Article, which was proposed in document 6516/14 have been included in the new Article 60a, which is thus a combination of Articles 60a and 65b of document 6516/14.

~~***SECTION 1 – VIGILANCE***~~[12]

Article 61

*Reporting of **serious** incidents and field safety*[13] *corrective actions*

1. Manufacturers of devices shall report ***in respect of devices made available on the Union market***~~, other than~~ ***including*** custom-made[14] ~~or investigational~~ devices**,** through the electronic system referred to in Article ***66a*** ~~62~~, the following:
   (a) any serious incident of devices made available on the Union market;
   (b) any field safety[15] 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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12 Article 61 as changed and the following fit better under the heading "Post-market surveillance" than under "Vigilance".
13 The text in grey highlight is reinstated following requests by ES, FR, NL.
14 The text in grey highlight is reinstated following requests by delegations.
15 The text in grey highlight is reinstated following requests by ES, FR, NL.

Manufacturers shall make the report referred to in the first subparagraph ~~without delay,~~ ***as soon as possible, and in no case later than 15 days***[16] after[17] they have become aware of the event~~, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible~~. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

Manufacturers shall make the report referred to in the second subparagraph in advance of the field safety corrective action being taken ~~issued~~.

2. For similar serious incidents 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~~ expected and well documented***, ***the*** manufacturer~~s~~ may provide periodic summary reports instead of individual ***serious*** incident reports, on condition that the ***coordinating competent authority referred to in Article 63(6), in consultation with the*** competent authorities referred to in points (a), (b) and (c) of Article ***66a*** ~~62~~(5)**,** has ~~ve~~ 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 66a ~~62~~(5), the manufacturer may provide periodic summary reports on agreement with that competent authority.]*** [18]

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 to the authorised representative*** 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 ***serious*** incident.

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16 The time limit is reinstated following requests by BE, CZ, ES.
17 The text in grey highlight is reinstated.
18 Pcy: Is this addition really needed?

The manufacturer of the device concerned shall provide to the responsible competent authority an initial report on serious incident in accordance with ~~Article 61(1)~~ paragraph 1 or an explanatory statement why the incident ~~does not fulfil the definition of~~ is not a serious incident ~~to the responsible competent authority~~ and ensure the appropriate follow-up.

3a. ***If the competent authority does not agree with the conclusion of the explanatory statement, it may require ~~can request~~ a report in accordance with paragraph 1 and that the manufacturer takes appropriate follow-up action ~~Article 61(1)~~.***

~~The manufacturer shall ensure the appropriate follow-up.~~[19]

~~3b.~~ ~~The~~ Member States ***~~MDGC~~*** ~~shall coordinate between them~~ ***~~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.~~[20]

3c. ***The Commission shall ensure that the electronic system referred to in Article 66a ~~62~~ allows direct reporting from Member States' databases of any reports received pursuant to ~~this~~ paragraph 1.***

~~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.~~

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[19] Moved to the end of paragraph 3.

[20] Moved to Article 66 introductory part and point (ba).

*Article ~~64~~ **61a***

*Trend reporting – **and periodic safety update reports by manufacturers***

1. Manufacturers ~~of devices classified in class IIb and III~~ shall report ~~to~~ ***by means of*** the electronic system referred to in Article ~~62~~ ***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 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)*** ~~***performance follow-up plan***~~ ~~conformity assessment~~. Article 63 shall apply.

2. Manufacturers of implantable devices and devices falling within class III shall ~~transmit~~ submit, by means of the electronic system referred to in Article 66a ~~62~~, periodic safety update reports including:

(a) summaries of data relevant to the benefits and risks of the 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 61 (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.

*Article ~~65~~ **61b***

***Updating technical** Documentation **based on** ~~of~~ vigilance data*

Manufacturers shall update their technical documentation ***listed in Annex II*** with:

(a) information on incidents received from ***competent authorities***, healthcare professionals, patients***,*** ~~and~~ users, ***and any other economic operator;***

(b) ***reports on*** serious incidents, field safety corrective actions~~,~~ ***and*** periodic summary reports referred to in Article 61,

(c) trend reports referred to in Article 64 and field safety notices referred to in Article 63(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.

~~This information shall be part of the technical documentation listed in Annex II.~~

*Article ~~83~~ **61c**[21]*

Device registers[22]

The Commission and the Member States shall take all appropriate measures to ***encourage*** ~~encourage~~[23] 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.[24]

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21 It is suggested to move Article 83 to this chapter. The changes to this article are based on the discussion in the Working Party on 22 May.

22 ES: It should be made clear that Cion should finance device registers. AT: Device registers should be financed by manufacturers.

23 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.~~

24 NL: Doubts on this article. How does it link to market surveillance and how does it link to EUDAMED? IT: Also has concerns about how meaningful this provision is. Made other suggestion (DS 1262/13).

SECTION 1 – VIGILANCE[25]

Article ~~64a~~ 61d

Manufacturers' obligation to cooperate with the competent authorities as regards risk evaluation

1. ***The manufacturer~~s~~ shall conduct without delay all investigations necessary to assess the risk of ~~the~~ any device ~~concerned~~ 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.]***[26]

1a.[27] ~~***Manufacturers shall perform appropriate investigations of the reported serious incident and the involved devices, monitored by the competent authority.***~~ ***The manufacturer shall ~~has to~~ provide a final report about its findings, ~~conclusions and if necessary corrective actions~~ by means of the electronic system referred to in Article 66a ~~62.~~ 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 ~~assessment~~ evaluation, particularly relevant parts of the risk analysis and the clinical evaluation for the device concerned by electronic means.***

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25 Heading moved.

26 Pcy: Why is consultation needed? The part in square brackets Would be better as part of follow-up.

27 This paragraph is based on Article 63(1a) of document 6516/14.

~~*Article 62*~~

~~*Electronic system on vigilance*~~[28]

~~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 referred to in point (e) of Article 27(1) including a link to the product information in accordance with article 23.~~***

~~(a)~~ ~~the~~ ***~~initial and final~~*** ~~reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 61(1)~~ ***~~and Article 63 (1new)~~***~~;~~

~~(b)~~ ~~the periodic summary reports by manufacturers referred to in Article 61(2);~~

~~(c)~~ ~~the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 63(1);~~

~~(d)~~ ~~the reports by manufacturers on trends referred to in Article 64;~~

~~(da)~~ ***~~the periodic safety update reports referred to in Article 65a;~~***

~~(e)~~ ~~the field safety notices by manufacturers referred to in Article 63(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 63(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~~ ***~~concerned~~*** ~~notified bodies~~ ***~~that issued a certificate in accordance with Article 43 of the device in question~~***~~.~~

~~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.~~

[28] This Article has been moved and is now Article 66a.

~~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), the reports on serious incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 *to (c) of paragraph 1* shall be automatically transmitted, upon receipt, via *through* 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.~~

~~*5a. The information referred to in paragraph 5 shall be automatically transmitted, upon receipt, through the electronic system referred to in Article 62, to the notified body that issued the certificate to the concerned device in accordance with Article 45.*~~

Article 63

Analysis of serious incidents and field safety corrective actions

1. ~~The~~ Member States shall take[29] ~~*adopt*~~ the necessary steps ~~*measures*~~ 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 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.
If, in the case of reports received in accordance with Article 61(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 ~~*66a* 62~~, unless the same incident has already been reported by the manufacturer.

[29] Words in grey highlight is reinstated.

~~*1a.*~~ ~~***Manufacturers shall perform appropriate investigations of the reported serious incident and the involved devices, monitored by the competent authority. The manufacturer has to provide a final report about its findings, conclusions and if necessary corrective actions by means of the electronic system referred to in Article 62.***~~[30]

~~*1b.*~~ ~~***Any corrective action performed by the manufacturer must be in accordance to the general safety and performance requirements established in this Regulation.***~~[31]

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or ~~field safety~~ corrective actions, taking into account criteria 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 (xx)***. They shall monitor the manufacturer's investigation of the ***serious*** incident.

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30 This paragraph is moved to Article 61d(1a).

31 Doubts on need for this paragraph so deleted.

3. In the case of devices referred to in the first subparagraph of Article 1(4) and where the serious incident or field safety[32] 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 42(2).

   In the case of devices covered by this Regulation in accordance with point (e) of Article 1(2) and where the serious incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with the third subparagraph of Article 42(2).

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article ***66a*** ~~62~~, 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 66a ~~62~~, a final report on the outcome of its assessment.***

[32] Words in grey highlight is reinstated.

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***. 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.

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 manufacturer shall enter the field safety notice in the electronic system referred to in Article ~~62~~ ***66a*** through which that notice shall be accessible to the public.

6. The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 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 the field safety corrective action is being or is to be undertaken in more than one Member State.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer ***or the authorised representative*** has his registered place of business.

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 ~~62~~ 66a*** the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

7. 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 45 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 ~~62~~ ***66a***(5) on the format, content and frequency of periodic summary reports in accordance with Article 61(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 ~~62~~ ***66a***, 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.

8. The Commission shall provide ~~secretarial~~ ***logistical*** support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 64[33]

Follw-up of *Trend reporting* ***by competent authorities – and periodic safety update reports***

1. ~~Manufacturers of devices classified in class IIb and III 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~~ ***post market performance follow-up plan*** ~~conformity assessment. Article 63 shall apply.~~

2. ***Manufacturers of implantable devices and devices falling within class III shall transmit, by means of the electronic system referred to in Article 62, periodic safety update reports including:***

(a) ***summaries of data relevant to the benefits and risks of the 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 61 (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.

[33] Paragraphs 1 and 2 of this Article (as set out in document 6516/14) have been moved to become Article 61a.

2a.[34] ***The competent authorities may conduct ~~their own~~ assessments of ~~on~~ the trend reports and periodic safety update reports ~~referred to in the first paragraph~~ and ~~to~~ 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 and the other competent authorities through the MDCG as well as the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.***

3. The MDCG may assess the safety update reports regarding devices which undergone the procedure laid down in Article 44a in order to determine whether there are new risks or whether risks have changed, or whether there are changes to the risk-benefit ratio of the medical device.

4. Following the assessment of the periodic safety update reports, the MDCG shall consider whether any action regarding the device concerned is necessary. The MDCG shall inform the notified body ~~in case of unfavourable~~ of the outcome of the assessment. ~~In this case,~~ The notified body shall, taking the assessment into account, decide to maintain, amend, suspend or withdraw the certificate ~~as appropriate~~. The notified body shall inform the MDCG of its decision and the reasons therefor, if the decision is not in accordance with the outcome of the assessment.

~~5. The competent authorities may conduct their own assessment on the reports referred to in the first paragraph and to adopt 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 and the other competent authorities as well as the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.~~

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[34] This paragraph is based on paragraph 5 (in document 6516/14).

6. Where deemed necessary for the protection of public health, ~~the Commission~~ a Member State may, after informing the other Member States and the Commission ~~consultation of the MDCG, determine, by means of implementing acts~~, decide to apply the obligation to submit periodic safety update reports to additional devices or categories of devices~~, other than implantable devices and devices of class III, to which the present article shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(3)~~.

Article 64a

Manufacturer's obligation to cooperate with the competent authorities

This Article has been moved and is now Article 61d in Section 1.

Article 65

Documentation of vigilance data

This Article has been moved and is now Article 61b in Section 0.

Article 65a

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 66a ~~62~~, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns.

When a previously unknown[35] risk that significantly changes the risk-benefit ratio is identified, the competent authority shall inform the manufacturer who shall inform users in accordance with ~~take the measures laid down in~~ Article 63(5).

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35 Compare Article 72.

Article 65b

Post-market surveillance by the manufacturer

This Article has been moved to become Article 60a in Section 0.

Article 66

Implementing acts

The Commission may, by means of implementing acts, ***and after consultation of the MDCG,*** [36] adopt the modalities and procedural aspects necessary for the implementation of Articles 61***d*** to 65***a and 66a*** 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;

(b) harmonised forms for the reporting of serious incidents and field safety corrective actions, periodic summary reports***, periodic safety update reports*** and trend reports by manufacturers as referred to in Articles 61***a*** and 64 ~~***xx and xx***~~;

(ba) standard web-based structured forms including a minimum data set for electronic reporting of serious incidents by healthcare professionals, users and patients; [37]

(c) timelines for the reporting of ~~serious incidents and~~ field safety[38] 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 61 and 64;

(d) harmonised forms for the exchange of information between competent authorities as referred to in Article 63.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

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[36] This procedure enables the adoption of a legal requirement ("minimum data set"), whilst fully involving the MS, the MDCG and the Commission.

[37] Based on the previous Article 61(3b). (See doument 6516/14.)

[38] Words in grey are reinstated.

*Article ~~62~~ **66a***

~~*Electronic system on vigilance*~~ ***Vigilance module in EUDAMED***[39]

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 ~~referred to in point (e) of~~ set up pursuant to Article 27~~(1)~~ including a link to the product information in accordance with article 23.***

   (a) the ***initial and final*** reports by manufacturers on serious incidents and ~~field safety~~ corrective actions referred to in Article 61(1) ***and Article 63 (1)***;

   (b) the periodic summary reports by manufacturers referred to in Article 61(2);

   (c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 63(1);

   (d) the reports by manufacturers on trends referred to in Article 64;

   (da) the periodic safety update reports referred to in Article 61a ~~65a~~;

   (e) the field safety notices by manufacturers referred to in Article 63(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 63(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 ~~***concerned***~~ notified bodies ***that issued a certificate for the device in question in accordance with Article 43 ~~of the device in question~~***.

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.

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39 This Article is the former Article 62 with changes.

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 61(1), the periodic summary reports referred to in Article 61(2), the reports on serious incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64~~ ***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:
   (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.

5a. The information referred to in paragraph 5 shall be automatically transmitted, upon receipt, through the electronic system referred to in Article 62, to the notified body that issued the certificate ~~to~~ for the ~~concerned~~ device in question in accordance with Article 45.

SECTION 2 – MARKET SURVEILLANCE

Article 67

Market surveillance activities ***at national level***

1. The competent authorities ***for medical devices*** shall perform appropriate checks on the ***conformity*** ~~characteristics and performance~~ 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 take account of
   - ***(a)*** established principles regarding risk assessment and risk management;
   - ***(b)*** vigilance data and
   - ***(c)*** complaints.

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.

1b. ***The competent authorities*** ~~They~~ may ***confiscate***, destroy or otherwise render inoperable ***falsified devices or*** devices presenting a serious risk where they deem it necessary ***in the interest of the protection of public health***.

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.***

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.

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 medical device is intended to be made available on the EU market.

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 88(3). [40]

~~*Article 68*~~

~~*Electronic system on market surveillance*~~[41]

~~1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information~~ ***~~by means of the electronic system referred to in point (f) of Article 27(1).~~***

~~(a) information in relation to non-compliant devices presenting a~~ ***~~serious~~*** ~~risk to health and safety referred to in Article 70(2), (4) and (6);~~

~~(b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 72(2);~~

[40] Based on FR intervention at the WP meeting on 26 February.
[41] This article is replaced by Article 75b.

~~(c) information in relation to formal non-compliance of products referred to in Article 73(2);~~

~~(d) information in relation to preventive health protection measures referred to in Article 74(2)~~***;***

~~(e)~~ information of the results of the reviews and assessments of the surveillance activities of the Member-States referred to in 67(2).

~~2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned~~ ***~~and to the notified body that issued a certificate in accordance with Article 45 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.

Article 69

Evaluation regarding devices ***~~presumably~~ suspected to*** *present~~ing~~ a****n unacceptable*** *risk to health and safety at national level*

Where the ***Member State*** competent authorities ~~of a Member State~~, based on ***data obtained by*** vigilance ***or market surveillance activities*** ~~data~~ or other information, have ~~sufficient~~ reason to believe that a device ***may*** 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,*** they shall carry out ***~~a risk assessment~~*** an evaluation[42] in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate ~~as necessary~~ with the competent authorities.

[42] Words highlighted in grey are reinstated.

Article 70

Procedure for dealing with non-compliant devices presenting a risk to health and safety

1. Where, having performed an evaluation[43] ***~~assessment~~*** pursuant to Article 69, 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, 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. ***The Competent Authority of the Member State in which the manufacturer of the concerned device~~s~~ is located shall be informed.***

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 45 for the device concerned*** of the results of the evaluation[44] ***~~assessment~~*** and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article ***75b*** ~~68~~.

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.

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[43] Words highlighted in grey are reinstated.

[44] Words highlighted in grey are reinstated.

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 45 for the device concerned***, without delay, of those measures, by means of the electronic system referred to in Article 68.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification ***and tracing*** ~~***traceability***~~ of the non-compliant device ***if available by means of the electronic system referred to in Article 25***, 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, ***through the electronic system referred to in Article 75b*** ~~***68***~~***,***

(a) of any additional ***relevant*** information at their disposal relating to the non-compliance of the device concerned ~~and~~;

(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~~ **a** notified national measure ***referred to in paragraph 4 or in point (b) of paragraph 6***, ~~they~~ ***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 ***75b*** ~~68~~.

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, th***ose*** measure***s*** shall be deemed ***to be*** justified.

8. ***Where paragraph 7 applies, all*** ~~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.

Article 71

Procedure at Union level

1. Where, within two months of receipt of the notification referred to in Article 70(4) ***and point (b) of 70(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 and the national competent authorities*** ~~***of the Member States in which the manufacturer is located and, where appropriate, 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 88(3).

2. If the national measure is considered justified, Article 70(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.***

2a. Where, in the situations referred to in Articles 70 and 72, 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 88(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 paragraph~~s 1 and~~ 2***a*** in accordance with the procedure referred to in Article 88(4).

Article 72

*Procedure for dealing with compliant devices presenting a**n unacceptable** risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 69, 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.

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 68. 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 88(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 88(4).~~

4. Where the national measure is considered justified, Article 70(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 73

Formal non-compliance

1. Without prejudice to Article 70, a Member State 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 18;
   (b) that the CE marking has not been affixed to a device contrary to Article 18;
   (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 17 and Annex IV in particular*** ~~or is not complete~~;

(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 59and Annex XIII in particular;***

(g) that a conformity assessment according to Article 42 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 ***75b*** ~~68~~.

Article 74

Preventive health protection measures

1. Where a Member State, after having performed an evaluation which indicates a ~~potential~~ ***previously unknown unacceptable*** risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or 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 ***75b*** ~~68~~.

3. The Commission, ***in consultation with the MDCG and, where appropriate 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 88(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 88(4).~~

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 Article ~~89~~ ***88(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~~.

On duly justified imperative urgency related to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

Article 75

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 70 to 74 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 70 to 74 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 75b*** inform the relevant notified body ***and the authority responsible for the notified body*** of the measure taken.

Article 75a

Competent authorities shall alert patients and health professionals within the territory of their Member States within an adequate timeframe of hazards they have identified relating to any device so as to avoid any injury or other damage.

*Article **75b** ~~68~~*

*~~Electronic system on market surveillance~~**Market surveillance module in EUDAMED***

1. The Commission, in collaboration with the Member States, shall ~~set up and manage an electronic system to~~ collate and process the following information ***by means of the electronic system referred to in point (~~f~~g) of Article 27(~~1~~2).***
   (a) information in relation to non-compliant devices presenting a ***~~serious~~*** risk to health and safety referred to in Article 70(2), (4) and (6);
   (b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 72(2);
   (c) information in relation to formal non-compliance of products referred to in Article 73(2);
   (d) information in relation to preventive health protection measures referred to in Article 74(2)***;***
   (e) summaries ~~information~~ of the results of the reviews and assessments of the surveillance activities of the Member-States referred to in 67(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 45 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.~~

Definitions from Article 2 relevant for this Chapter

(48) 'market surveillance' means the activities carried out and measures taken by public authorities to ***check and*** ensure that ~~products~~ ***devices*** 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;

(48a) '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.

(48b) '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 or put into service for the purpose of identifying any need to immediately apply any necessary corrections, corrective or preventive actions.

Consequential changes for other parts of the proposal

Article 6 to be complemented by 5(3) of Directive 93/42/EEC.

Article 8(6) is replaced by:

6. ***Manufacturers shall perform post-market surveillance and, where relevant, take corrective action, in accordance with Article 60a for devices they place on the market.*** ~~Proportionate to the risk class and the type of device, manufacturers of devices, other than custom-made devices, shall institute and keep up to date a 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'. The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients 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 clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.~~

   ~~If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.~~

Outstanding questions:

1. What about Clinical follow-up in Article 8(6)?
2. What about custom-made devices and investigational devices?
3. Recurring topic of time lines for procedures discussed in Articles 69-74

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by the manufacturer shall include in particular the following elements:

1. Device description and specification, including variants and accessories

1.1 Device description and specification

(a) product or trade name and a general description of the device including its intended purpose,

(b) the UDI device identifier as referred to in item (i) of point (a) of Article 24(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria;

(d) principles of operation of the device;

(e) risk class and the applicable classification rule according to Annex VII;

(f) an explanation of any novel features;

(g) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it;

(h) a description or complete list of the various configurations/variants of the device that will be made available;

(i) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(j) a description of the (raw) materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

(k) technical specifications (features, dimensions and performance attributes) of the medical device and any variants and accessories that would typically appear in the product specification made available to the user, e.g. in brochures, catalogues and the like.

1.2 Reference to previous and similar generations of the device

(a) an overview of the manufacturer's previous generation(s) of the device, if such exist;

(b) an overview of the manufacturer's similar devices available on the EU or international markets, if such exist.

2. Information supplied by the manufacturer

(a) a complete set of

- the label(s) on the device and on its packaging;
- the instructions for use;

(b) a list of the language variants for the Member States where the device is envisaged to be marketed.

3. Design and manufacturing information

(a) Information to allow a general understanding of the design stages applied to the device and the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;

(b) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

4. General safety and performance requirements

The documentation shall contain information regarding the solutions adopted to meet the general safety and performance requirements laid down in Annex I. This information may take the form of a checklist identifying

(a) the general safety and performance requirements that apply to the device and why others do not apply;

(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards or CTS applied or other method(s) employed;

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CTS or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. Risk/benefit analysis and risk management

The documentation shall contain a summary of

(a) the risk/benefit analysis referred to in Sections 1 and 5 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.

6. Product verification and validation

The documentation shall contain the results of verification and validation testing and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1 Pre-clinical and clinical data

(a) results of (engineering, laboratory, simulated use, animal) tests and evaluation of published literature applicable to the device or substantially similar devices regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding

- biocompatibility (identifying all materials in direct or indirect contact with the patient or user);
- physical, chemical and microbiological characterisation;
- electrical safety and electromagnetic compatibility;

- software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);
- stability/shelf life.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[45] shall be demonstrated.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous version of the device that has been legally placed on the market or put into service;

(c) the report on the clinical evaluation in accordance with Article 49(5) and Part A of Annex XIII;

(d) the ~~PMCF plan~~ ***the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market clinical follow-up*** and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate.

(e) The summary report referred to in Article 60a.

[45] OJ L 50, 20.2.2004, p. 44.

6.2 Additional information in specific cases

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, referred to in the first subparagraph of Article 1(4), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

(b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are covered by this Regulation in accordance with point (e) of Article 1(2), a statement indicating this fact. In this case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 10.1. or 10.2., respectively, of Annex I.

(c) In the case of devices placed on the market in a sterile or defined microbiological condition a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(d) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(e) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.