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WORKING DOCUMENT

From:	Presidency
To:	Delegations
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- Exchange of views*

Delegations will find in Annex the first Presidency compromise text on Cluster 3 and 4 - Block 4 – (PMS, PSUR, vigilance reporting, reporting of actively exploited vulnerabilities and severe cybersecurity incidents, analysis of vigilance reports, trend reporting) to be discussed at the meetings of Working Party on Pharmaceuticals and Medical Devices on 15-16 July 2026.

Changes compared to the Commission proposal are indicated in ~~strikethrough~~ for deletions and **bold** for new text. Text from the MDR or IVDR not included in the Commission proposal and added to this compromise text is indicated in *italics*. Changes to that text are indicated in ~~*strikethrough*~~ for deletions and ***bold*** for new text.

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Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(…)

(65) in Article 83(4), the first sentence is replaced by the following:

'If in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. **These preventive or corrective actions shall be appropriately documented and, where relevant, included in the reports referred to in Articles 85, 86, 87 and 88. A Member State may request that a manufacturer informs** the competent authorities ~~concerned may request the manufacturer to inform them when~~ **and, where appropriate, the notified body of** such preventive or corrective action ~~is taken~~**, including those not already included in the reports mentioned in Articles 85, 86, 87 and 88,** to reduce a risk that may compromise the safety or performance of the device.';

(66) in Article 84, **the following sentence is added after** the second sentence ~~is deleted;~~**:**

'The post-market surveillance plan shall specify the criteria, and timelines where relevant, for updating the Post-Market Surveillance Report as referred to in Article 85 or the Periodic Safety Update Report as referred to in Article 86.'

(67) Article 86 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:

'Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report ('PSUR') for each device, or where relevant for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article

84, together with a description of any preventive and corrective actions taken, including their rationale.';

(ii) the second and third subparagraphs are replaced by the following:

'Manufacturers of class IIb and class III devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSUR shall be part of the technical documentation as specified in Annex III.

Manufacturers of class IIa devices shall update the PSUR **and in accordance with the criteria set out in the manufacturer's post-market surveillance plan referred to in Article 83, and in any event when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects** ~~when necessary~~. The PSURs shall be part of the technical documentation specified in Annex III.;'

(iii) the fourth subparagraph is deleted.

(b) paragraph 2 is replaced by the following:

'2. For class III devices or class IIb implantable devices, other than well-established technology devices, the notified body shall review the PSUR during the surveillance assessment**, where applicable, or as part of the technical documentation review**. The manufacturer and the notified body shall make such PSURs **available to competent authorities through the electronic system referred to in Article 92.** ~~and the evaluation by t~~ **T**he notified body **shall make its evaluation of such PSURs** available to competent authorities through the electronic system referred to in Article 92.

For all other devices where the PSUR is applicable, the notified body shall review PSURs on a representative basis as part of the surveillance activities in accordance with Section 4.10 of Annex VII or periodic reviews in accordance with Section 4.11 of Annex VII.';

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(68) Article 87 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, point (a) is replaced by the following:

‘(a) any serious incident involving devices made available on the Union market, except expected undesirable side-effects which are clearly documented in the ~~product~~**device** information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;’

(ii) the second subparagraph is replaced by the following:

‘The reports referred to in the first subparagraph shall be submitted ~~without undue delay~~ **in accordance with the timelines specified in this Article** through the electronic system referred to in Article 92.’;

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 30 days after they become aware of the incident.’;

(69) the following Article 87a is inserted:

‘Article 87a

Reporting of actively exploited vulnerabilities and severe incidents related to devices

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 87, the manufacturer of a device shall report to the computer security incident response teams (‘CSIRTs’), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:

(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******* contained in the device;

(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 92 **immediately after and** not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.

3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 87 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

5. In respect of the report referred to in paragraph 1, the competent authorities shall cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.';

_____

******* Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

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~~(70) in Article 88(1), the first sentence is replaced by the following:~~

~~'Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I.';~~

(71) Article 89 is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

'The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.';

(b) paragraph 2 is replaced by the following:

'2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.';

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(c) the following paragraph 3a is inserted:

‘3a. **The competent authorities may exchange information in relation to their assessments in paragraph 3 and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for market surveillance.**

The competent authority may request the notified body that issued a certificate for the device in question in accordance with Article 56 to provide assistance in evaluating a corrective action related to a serious incident or a field safety corrective action**, taking into account the risk management and conformity assessment performed for the device**.’;

(d) paragraph 6 is replaced by the following:

‘6. In the case of devices referred to in Article 1(8), first subparagraph, and where the serious incident or field safety corrective action is confirmed by the manufacturer to 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 9 shall inform the national competent authority or the EMA, which issued the scientific opinion on that substance in accordance with Article 52(9), of that serious incident or field safety corrective action.

In the case of devices falling within the scope of this Regulation in accordance with Article 1(6), point (g), or in accordance with Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for substances of human origin that was consulted by the notified body in accordance with Article 52(10), provided that the serious incident or field safety corrective action is confirmed by the manufacturer to be related to the derivatives of substances of human origin utilised for the manufacture of the device or to the non-viable substances of human origin or their derivatives that have an action ancillary to that of the device.’;

(e) paragraph 7 is replaced by the following:

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‘7. If, after carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.’;

(f) in paragraph 9, the introductory wording is replaced by the following:

‘The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:’;

(72) in Article 91, the first subparagraph is amended as follows:

(a) the introductory wording is replaced by the following:

‘The Commission may, by means of implementing acts, and after consul~~ta~~ting the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 84 to 90 and Article 92 as regards the following:’;

(b) point (b) is replaced by the following:

‘(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 84, 85, 86, 87, 88 and 89 respectively;’;

(73) in Article 92(2), the reference to ‘Article 53’ is replaced by ‘Article 56’;

(…)

(3) in Annex III, Section 2 is replaced by the following:

‘2. The PSUR referred to in Article 86 or the post-market surveillance report referred to in Article 85.’;

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Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(…)

(51) in Article 78(4), the first sentence is replaced by the following:

'If, in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. **These preventive or corrective actions shall be appropriately documented and, where relevant, included in the reports referred to in Articles 80, 81, 82 and 83. A Member State may request that a manufacturer informs** the competent authorities ~~concerned may request the manufacturer to inform them when such~~**and, where appropriate, the notified body of such preventive or corrective** action ~~is taken~~**, including those not already included in the reports referred to in Articles 80, 81, 82 and 83,** to reduce a risk that may compromise the safety or performance of the device.';

(52) in Article 79, **the following sentence is added after** the second sentence ~~is deleted;~~**:**

'The post-market surveillance plan shall specify the criteria, and timelines where relevant, for updating the Post-Market Surveillance Report as referred to in Article 80 or the Periodic Safety Update Report as referred to in Article 81.';

(53) Article 81 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:

'Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale.';

(ii) the second subparagraph is replaced by the following:

‘Manufacturers of class C and class D devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results. **The**~~That~~ PSUR shall be part of the technical documentation specified in Annex III.’;

(b) paragraph 2 is replaced by the following:

‘2. For class D devices, the notified body shall review the PSUR during the surveillance assessment**, where applicable, or as part of the technical documentation review**. The manufacturer and notified body shall make such PSURs ~~and the evaluation by~~**available to competent authorities through the electronic system referred to in Article 87.** The notified body **shall make its evaluation of such PSURs available** to the competent authorities through the electronic system referred to in Article 87.

For all other devices where the PSUR is applicable, the notified body shall review PSURs on a representative basis as part of the surveillance activities in accordance with Section 4.10 of Annex VII or periodic reviews in accordance with Section 4.11 of Annex VII.’;

(54) Article 82 is amended as follows:

(-a) In paragraph 1, first subparagraph, point (a) is replaced by the following:

‘*(a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented ~~and quantified~~ in the ~~product~~* ***device*** *information and* ***quantified*** *in the technical documentation and are subject to trend reporting pursuant to Article 83;*’**;**

(a) in paragraph 1, the second subparagraph is replaced by the following:

‘The reports referred to in the first subparagraph shall be submitted ~~without undue delay~~ **in accordance with the timelines specified in this Article** through the electronic system referred to in Article 87.’;

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 30 days after they become aware of the incident.’;

(55) The following Article 82a is inserted:

‘Article 82a

Reporting of actively exploited vulnerabilities and severe incidents related to devices

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 82, the manufacturer of a device shall report to the computer security incident response teams (‘CSIRTs’), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:

   (a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******** contained in the device;

   (b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 87 **immediately after and** not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.

3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 82 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

5. In respect of the report referred to in paragraph 1, the competent authorities shall cooperate with the CSIRTs designated as coordinators of the Member States in which the device has been made available, and with ENISA.';

******** Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

(56) in Article 83(1), the first subparagraph is replaced by the following:

'Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents, which could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I or of any significant increase in expected erroneous results established in comparison with the stated performance of the device as referred to in Section 9.1, points (a) and (b), of Annex I and specified in the technical documentation and product information.';

(57) Article 84 is amended as follows:

(-a) in paragraph 1, the first subparagraph is replaced by the following:

'*Following ~~the~~ reporting ~~of a serious incident~~ pursuant to Article 82(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include risk assessment of the incident ~~and~~* ***or*** *field safety corrective action taking into account the criteria as referred to in paragraph 3 of this Article as appropriate.***';**

(a) in paragraph 1, the second subparagraph is replaced by the following:

'The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned

in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.';

(b) paragraph 2 is replaced by the following:

'2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 82 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.';

(c) the following paragraph 3a is inserted:

'3a. **The competent authorities may exchange information in relation to their assessments in paragraph 3 and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for market surveillance.**

The competent authority may request the notified body that issued a certificate in accordance with Article 51 for the device in question for assistance in evaluating a corrective action related to a serious incident or a field safety corrective action**, taking into account the risk management and conformity assessment performed for the device.**';

(d) paragraphs 6 and 7 are replaced by the following:

'6. In the case of a companion diagnostic and where the manufacturer confirms that the serious incident or field safety corrective action may affect the safe and efficient use of the corresponding medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which was consulted by the notified body in accordance with the procedures set out in Section 5.2 of Annex IX and Section 3, point (k), of Annex X.

7. If, after carrying out the evaluation in accordance with paragraph 3, the evaluating competent authority identifies the need for additional corrective

actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 87, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying serious incidents and the outcome of its assessment.';

(e) in paragraph 9, the introductory sentence is replaced by the following:

'The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:';

(58) Article 86 is amended as follows:

(a) in the first subparagraph, the reference to 'Articles 80 to 85 and 87' is replaced by 'Articles 79 to 85 and 87';

(b) in the first subparagraph, point (b) is replaced by the following:

'(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 79, 80, 81, 82, 83 and 84 respectively;';

(59) in Article 87(2), second sentence, the reference to 'Article 49' is replaced by 'Article 51';

(…)

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(3) Annex III is amended as follows:

(a) in Section 1, point (a), the sixth indent is replaced by the following:

‘- publicly-available information about similar devices.’;

(b) Section 2 is replaced by the following:

‘2. The PSUR referred to in Article 81 or the post-market surveillance report referred to in Article 80.’;

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