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WORKING DOCUMENT

From:	Presidency
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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 2 (Support to regulatory system) to be discussed at the meeting of Working Party on Pharmaceuticals and Medical Devices on 3 July 2026.

Articles 4, 4a, 51 to 51b MDR as well as Articles 3, 3a, 47 to 47b IVDR will be examined as part of cluster 5. Article 100 IVDR will be discussed together with cluster 6.

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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ANNEX

Amendments to Regulation (EU) 2017/745

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

(…)

(80) the title of Chapter VIII is replaced by the following:

'COOPERATION BETWEEN MEMBER STATES, THE MDCG, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS, CONFLICTS OF INTEREST AND INTERNATIONAL COOPERATION;'

(81) after the title of Chapter VIII, the following title is inserted:

'SECTION 1

Cooperation between Member States, the MDCG, expert panels, expert laboratories and device registers and conflict of interests;'

(82) Article 101 is replaced by the following:

'Article 101

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge **necessary** to effectively and efficiently perform their tasks pursuant to this Regulation**, in practice**. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.;'

(82a) In Article 102, paragraph 1 is replaced by the following:

*'1. The competent authorities of the Member States shall cooperate with each other**,** ~~and~~ with the Commission **and with the Agency**. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.'*

(83) in Article 102, paragraph 2 is deleted;

(84) Article 103 is amended as follows:

(a) in paragraph 2, second subparagraph, the second sentence is replaced by the following: 'They shall represent the competent authorities of the Member States and the authorities responsible for notified bodies of the Member States, as applicable.;'

(b) paragraph 7 is replaced by the following:

'7. The MDCG shall establish ~~a sub-group with members representing the authorities responsible for notified bodies and may establish other~~ standing or temporary sub-groups**, including the subgroup defined in Article 105a**.

Where appropriate, representatives of the coordination group referred to in Article 49 and organisations representing the interests of the medical device industry, ~~in particular of~~ **including** micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to the MDCG and its sub-groups in the capacity of observers.;'

(c) paragraph 9 is replaced by the following:

'9. The MDCG shall have the tasks laid down in Article 105 of this Regulation.;'

(85) ~~in~~ Article 104~~, the second sentence is deleted;~~ **is replaced by the following:**

'The Commission shall support the functioning of the cooperation between national competent authorities ***and between authorities responsible for notified bodies****.*

It shall, in particular, provide for the organisation of exchanges of experience between competent authorities and between authorities responsible for notified bodies and provide support to the MDCG and its sub-groups.

*It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.***'**

PUBLIC

(86) ~~Articles 105 and 106 are~~ **Article 105 is** replaced by the following:

'Article 105

Tasks of the MDCG

~~In addition to the tasks assigned to it in other provisions of~~*Under this Regulation* ~~and Regulation (EU) 2017/746~~, *the MDCG shall* ~~in particular assist the Commission in the assessment of any issue related to the implementation of those Regulations and contribute to the development of guidance aimed at ensuring their effective and harmonised implementation.~~*have the following tasks**:***

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49, ***including endorsement of the work programme and technical guidance developed by that group;***

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices;

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(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States;

(i) to advise the Commission and competent authorities regarding international regulatory cooperation in accordance with Articles 108a to 108c;

(j) to conduct horizon scanning to identify technological, legal or external sectoral changes or developments which may impact the regulatory system and propose solutions;

(k) to support and oversee international initiatives aimed at improving harmonisation of regulatory operations and activities;

(l) [to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;]'

PUBLIC

(86a) A new Article 105a is inserted as follows:

'Article 105a

Notified Body Operations subgroup

The Notified Body Operations subgroup (NBO) shall assist the MDCG on issues relating to notified bodies and conformity assessments, with the aim of consistent, effective and harmonised application and implementation of this Regulation with respect to notified bodies.

The NBO shall be composed of members representing the authorities responsible for notified bodies.

Under this Regulation and under the supervision of the MDCG, the NBO shall have the following tasks:

(a) to develop draft best practice documents relating to the activities of the authorities responsible for notified bodies, for endorsement of the MDCG;

(b) to develop draft guidance documents for notified bodies in relation to the implementation of this Regulation, for endorsement of the MDCG;

(c) to initiate the draft work programme, the draft common templates and the draft technical guidance elaborated by the coordination group of notified bodies as established pursuant to Article 49;

(d) to contribute to develop training and qualification of the experts referred to in Article 40;

(e) to be consulted by the Commission on the composition of the joint assessment team referred to in Article 36;

(f) to monitor the conformity assessment activities of notified bodies;

(g) to monitor the designation and the surveillance activities of designating authorities;

(h) to provide the MDCG with proposals for improving harmonisation of practices amongst notified bodies and harmonisation of practices amongst designating authorities;

(i) to consider and draw from the exchange of experience referred to in Article 48 and to cooperate with the coordination group referred to in Article 49.

PUBLIC

Where appropriate, representatives of the coordination group referred to in Article 49 shall be invited in the capacity of observers.'

(86b) Article 106 is replaced by the following:

' *Article 106*

Expert panels

1. The Commission shall, by means of implementing acts and following consultation with the MDCG, make provision for expert panels to be designated to provide scientific, clinical, technical or regulatory opinions and advice in relation to the implementation of this Regulation and of Regulation (EU) 2017/746 to the Commission, the MDCG, Member States, notified bodies or manufacturers.

   Expert panels may be designated on a standing or temporary basis.

2. Expert panels shall consist of experts with proven up-to-date clinical, scientific, technical or regulatory expertise ~~in~~**relevant to** the field of medical devices or in vitro diagnostic medical devices reflecting the diversity of scientific and clinical approaches in the Union.

   Experts shall be appointed**, in consultation with the MDCG,** following publication of a call for expressions of interest. Depending on the type of task and the need for specific expertise, experts may be appointed to the panels for a maximum period of three years and their appointment may be renewed.

   When expert panels are requested to provide ~~an opinion~~**clinical, scientific or technical advice [to the MDCG]** on the regulatory status of a product which involves aspects concerning the borderline with other types of products, experts with expertise in the field of the relevant other products shall be involved.

PUBLIC

2a. The activities of the expert panels shall facilitate effective, harmonised and evidence-based application of this Regulation and Regulation (EU) 2017/746. Experts from national competent authorities shall be appropriately integrated within the expert panel structure either through involvement in specific panels, establishment of a standalone regulatory panel or both.

3. The experts shall observe the principles of highest scientific competence and perform their tasks with impartiality, objectivity and transparency. They shall neither seek nor take instructions from notified bodies ~~or~~**,** manufacturers **or other economic operators**. Each expert shall draw up a declaration of interests, which shall be made publicly available.

3a. The Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest during the appointment of experts.

4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals' associations.

5. Experts may be included on a **central** list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panels as needed.

6. Experts from notified bodies shall not be involved in the clinical evaluation consultation procedure provided for in Article 54(1).

An individual expert from a notified body shall not be involved in the provision of advice on a specific device for which the expert or their notified body have been involved in the conformity assessment. An expert from a notified body shall not be involved in the conformity assessment activities regarding a specific device for which the expert was involved in the provision of advice from an expert panel.

PUBLIC

7. In addition to the tasks assigned to them in other provisions of this Regulation and of Regulation (EU) 2017/746, the expert panels ~~may~~**shall support the MDCG and the Commission and** have the following tasks:

   (a) to provide scientific, clinical, technical and regulatory advice to the Commission, the MDCG, Member States or notified bodies in relation to the implementation of this Regulation or Regulation (EU) 2017/746;

   (b) to contribute to the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation or Regulation (EU) 2017/746;

   (c) to **support the MDCG and** contribute to the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

   (d) to contribute to the identification of concerns and emerging issues concerning the safety and performance of medical devices, including in vitro diagnostic medical devices.

8. When adopting their opinions or advice, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the opinion or advice shall mention the divergent positions and the grounds on which they are based.

9. The Commission shall require manufacturers and notified bodies to pay fees for opinions and advice provided by expert panels. The structure and the level of the fees, as well as the scale and type of recoverable costs, shall be established by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

PUBLIC

The fees referred to in the first subparagraph shall be established in a transparent manner and on the basis of the costs for the services provided. The fees shall be reduced for manufacturers which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, including in the case of a clinical evaluation consultation procedure initiated in accordance with Section 5.1, point (c), of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC. The fees related to the opinions and advice provided by expert panels are payable to **the Agency**~~EMA~~[1] pursuant to Article 30, point (f), of Regulation (EU) 2022/123.

10. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 7 of this Article by adding, adapting or removing tasks from the list of tasks of the expert panels.;'

(87) the following Articles 106a and 106b are inserted:

'Article 106a

Expert laboratories

1. The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in the field of testing of medical devices, such as physico-chemical characterisation, microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing **and any other type of testing or assessment considered relevant for the evaluation of the safety, performance or regulatory compliance** of specific devices, categories or groups of devices.

The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

[1] Lawyer-linguists will make the change throughout the Regulations.

2. Expert laboratories shall satisfy the following criteria:

(a) have adequate and appropriately qualified staff with adequate knowledge and experience ~~in the field of~~**related to** the devices **or in the type of laboratory testing** for which they are designated;

(b) have at their disposal the necessary equipment **and reference materials** to carry out the tasks assigned to them;

(c) have the necessary knowledge of international standards and best practices;

(d) have an appropriate administrative organisation and structure;

(e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks;

(f) act in the public interest and in an independent manner~~.~~**;**

(g) ensure that their staff do not have financial or other interests in the medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs.

3. Expert laboratories may have the following tasks:

(a) to provide scientific and technical assistance to the Commission, the MDCG, the **Agency**~~EMA~~, Member States and notified bodies in relation to the implementation of this Regulation**, including at the request of the Commission or the MDCG and, the performance of appropriate tests, assessments or other evaluations necessary to support the assessment of the safety and performance of any device**;

(aa) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices in the field of laboratory testing for which they are designated, on the basis of comparative test results or other studies;

(b) to ~~contribute to~~**support the MDCG in** the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation;

(c) to ~~contribute to~~**support the MDCG in** the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

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(ca) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and for market surveillance;

(d) to ~~contribute to~~**support the MDCG in the** identification **and investigation by laboratory testing** of concerns and emerging issues on the safety and performance of medical devices;

(e) to provide scientific and technical assistance**, including independent investigations of devices,** to Member States and the Commission in vigilance and market surveillance activities.

4. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 3 of this Article by adding, adapting or removing tasks from the list of tasks of the expert laboratories.

4a. The expert laboratories may establish a network in order to coordinate and harmonise their working methods with regards to testing and assessment.

5. The expert laboratories may charge fees in accordance with predetermined and transparent terms and conditions for scientific and technical assistance provided to the **Agency**~~EMA, Member States~~ or notified bodies for carrying out the requested task. For the provision of services within the public interest on request of the Commission or the MDCG, the expert laboratories may be granted a Union financial contribution. **Member States may request, through the MDCG, testing from the expert laboratories.**

PUBLIC

5a. A financial allocation may also be made available from the general budget of the Union for the expert laboratories.

Article 106b

*Support by the **Agency**~~EMA~~*

1. The **Agency**~~EMA~~ shall~~, on behalf of the Commission,~~ provide scientific, technical and administrative support to **facilitate cooperation and coordination and exchange of experience between** the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 to facilitate the exchange of experience, cooperation and coordination **on operational regulatory activities among them and with the Commission,** with a view to ensuring a uniform **practical** application of such Regulations, in particular in the following areas:
   (a) **[**regulatory status of products and classification of devices in accordance with Articles 4, 4a, 51, 51a and 51b of this Regulation and Articles 3, 3a, 47, 47a and 47b of Regulation (EU) 2017/746;**]**
   (b) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746;
   (c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746;
   (d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including**, but not limited to, the** support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746**;**~~.~~

PUBLIC

(e) assessment of whether criteria set out in paragraph 2 or paragraph 3 of Article 52a, as applicable, are fulfilled.

1a. The Agency shall report to the MDCG about the exchange of experience, cooperation and coordination between competent authorities in accordance with paragraph 1 and seek MDCG's guidance on strategic priorities and unresolved issues.

2. The **Agency**~~EMA~~ shall provide scientific, technical and administrative support to the Commission for the establishment of Union regulatory sandboxes in accordance with Article 59c of this Regulation and Article 54c of Regulation (EU) 2017/746.

2a. The Agency shall provide support to the national competent authorities and expert panels in coordinating their Union activities, and when requested by the MDCG, in order to promote consistent, predictable and harmonised application across Member States.

3. The **Agency**~~EMA~~ shall set up a support scheme for manufacturers of medical devices and in vitro diagnostic medical devices, which are micro, small and medium-sized within the meaning of Recommendation 2003/361/EC, regarding the requirements of this Regulation and of Regulation (EU) 2017/746.

4. The **Agency**~~EMA~~ shall have access to Eudamed and any electronic system referred to in Article 33(2) of Regulation (EU) 2017/745 or in Article 30(2) of Regulation (EU) 2017/746 that is not included in Eudamed.;

PUBLIC

5. The Agency shall have sufficient resources and knowledge in the area of medical devices and in-vitro diagnostics to effectively and efficiently perform its tasks pursuant to this Regulation.'

(88) in Article 107(1), the fourth and fifth sentences are replaced by the following:
'The declaration of interests shall be made publicly available **on the Commission or the Agency website**. This Article shall not apply to the representatives of stakeholder organisations participating in the MDCG or its sub-groups.;'

(89) in Article 108, the first sentence is replaced by the following:
'The Commission, the Member States and the **Agency**~~EMA~~ shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices, where appropriate including in vitro diagnostic medical devices, setting common principles to collect comparable information.;'

(89a) Article 110 is replaced by the following:

'1. *Member States shall apply* ***Regulation (EU) 2016/679*** *to the processing of personal data carried out in the Member States pursuant to this Regulation.*

2. *Regulation* ***(EU) 2018/1725*** *shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.'*

(91) the following Article 110a is added:

'Article 110a

Submission of information or documents

The submission of information or documents in accordance with this Regulation shall take place electronically.;'

PUBLIC

(92) ~~in~~ Article 111~~, paragraph 1 is replaced by the following~~ **is amended as follows**:

(a) paragraph 1 is replaced by the following:

'1. This Regulation shall be without prejudice to the possibility for Member States and the Commission to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.;'

(b) **in paragraph 2, second sentence, the words '*on request*' are deleted*;***

(93) **[**Article 112 is deleted;**]**

Amendments to Regulation (EU) 2017/746

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

(…)

(66) the heading of Chapter VIII is replaced by the following:

'COOPERATION BETWEEN MEMBER STATES AND EU REFERENCE LABORATORIES;'

(67) in Article 96, the first and second sentences are replaced by the following:
'The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge necessary for the effective and efficient performance of their tasks pursuant to this Regulation**, in practice. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.**;'

(68) in Article 97, paragraph 2 is deleted;

(69) Articles 98 and 99 are deleted;

PUBLIC

(71) Article 101 is deleted;

(72) Article 103 is amended as follows:

‘(a) in paragraph 1, the reference to ‘Directive 95/46/EC’ is replaced by ‘Regulation (EU) 2016/679’;

(b) in paragraph 2, the reference to ‘Regulation (EC) No 45/2001’ is replaced by ‘Regulation (EU) 2018/1725 of the European Parliament and of the Council*********.

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********* Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).’

(73) the following Article 103a is inserted:

‘Article 103a

Submission of information or documents

The submission of information or documents in accordance with this Regulation shall take place electronically.’

(74) Article 104 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. This Regulation shall be without prejudice to the possibility for Member States and the Commision to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.;’

(b) in paragraph 2, second sentence, the words ‘on request’ are deleted;

(75) Article 105 is deleted;

Amendments to Regulation (EU) 2022/123

Article 30 of Regulation (EU) 2022/123 is amended as follows:

(1) the first subparagraph is replaced by the following:

'The Agency shall provide the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the 'expert panels') and shall provide the support necessary to ensure that those expert panels can efficiently perform the tasks set out in that Regulation and in Regulation (EU) 2017/746.;'

(2) the second subparagraph is amended as follows:

(a) the introductory wording is replaced by the following: 'The Agency shall, in particular,':

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

'(a) select and appoint the experts in accordance with Article 106(2) and (5) of Regulation (EU) 2017/745 and provide administrative and technical support to the expert panels for the provision of opinions and advice;'

(c) points (c), (d) and (e) are replaced by the following:

'(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3) and Article 107 of Regulation (EU) 2017/745. For that purpose, the Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest;

(d) maintain and regularly update a webpage for the expert panels and make all necessary information not already publicly available in Eudamed publicly available on that webpage;

(e) publish the opinions of the expert panels in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746, while ensuring confidentiality in accordance with Article 109 of Regulation (EU) 2017/745 or Article 102 of Regulation (EU) 2017/746;'

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(d) in point (f), the reference to ‘Article 106(14)’ is replaced by the reference to ‘Article 106(10)’;

(e) the following point (i) is added:

‘(i) submit to the Commission a substantiated recommendation for the fees to be paid by manufacturers or notified bodies for the opinions or advice provided by expert panels, as referred to in Article 106(9) and (10) of Regulation (EU) 2017/745.’

PUBLIC