MEDTECH & PHARMA
PLATFORM

Directorate-General for Health and Food Safety
Medicines: Policy, authorization and monitoring (SANTE.D.1)
European Commission
1049 Brussels
Belgium

Basel, 13 October 2023

MPP input to the European Commission public consultation on the proposals to review the EU pharmaceutical, orphan and pediatric legislation

To whom it may concern,

The Medtech & Pharma Platform Association (MPP) is writing to you to share its views on the European Commission's proposals revising the EU pharmaceutical, orphan and pediatric legislation.

The MPP welcomes the proposals' objectives to improve the availability and accessibility of medicinal products throughout the EU and support industry competitiveness.

We would like to propose amendments on points which are of importance for products combining medicines and medical devices including *in-vitro* diagnostics and therefore all under the scope of both the medicinal product and medical devices legislation in the EU.

The MPP advocates for a better alignment of the text of the proposals with the applicable medical devices legislation, i.e. Regulation 2017/745 (MDR) and Regulation 2017/746 (IVDR), on various aspects including definitions, in order to avoid divergences and legal uncertainties. Additionally, the MPP calls for clarifications on several points which are not sufficiently specified or may lead to conflicting interpretations. This includes the information supporting medical device/IVD compliance with the MDR's/IVDR's requirements which can be requested by the competent authorities as part of marketing authorization and variation applications or a pediatric investigation plan, the assessment of the risks linked to the medical device/IVD or the labelling and information requirements of combined products*.

The MPP recommends incorporating measures in the legislation that would allow Notified Bodies to provide an opinion on medical device technology platforms which are part of drug device combinations covered by the EU medicinal product legislation. This will prevent work duplication in the review of the information relating to the platform, as the notified body opinion on the platform would be considered when assessing specific combinations.

Furthermore, proposed amendments aim to ensure that Notified Body expertise is considered during the scientific advice procedure for medicinal products used with a medical device. Additionally, the role of medical device expert panels and the scope of their intervention should be clearly defined in the proposals.

We recommend amending the proposals to clarify that products intended for the sterilization of packaging, specifically ethylene oxide, are covered by the medicinal product legislation, provided they are manufactured on a site holding a manufacturing authorization, in line with the position communicated by the European Commission in the first half of 2023.

An overview of the MPP's specific feedback in relation to the proposed legislation is provided in the Annex appended to this letter.

The MPP continuously seeks dialogue with relevant stakeholders to create an appropriate framework for combined products that fosters innovation, reduces time to market, and addresses patients' needs. We thank you for considering our position and the proposals outlined in this document.

I remain at the European Commission's disposal for further dialogue and collaboration.

Yours sincerely,

Shayesteh Fürst-Ladani
MPP President
association@medtech-pharma.com

* The MPP Association defines combined products as combined use of a medicinal product with a device or diagnostic, and/or e-/m-health products for a medical purpose, without necessarily forming an integrated unit.

About the Medtech & Pharma Platform Association

The Medtech & Pharma Platform Association (MPP) draws together companies from the pharmaceutical, medtech, diagnostics, and tech sectors and provides opportunities to exchange knowledge and to collaborate in technology and regulatory areas related to combined products.

The MPP's objectives are:

- To enhance synergies between the pharma, medtech, diagnostics, and ICT industries,
- To establish new collaboration models to ensure and accelerate market access for safe and innovative treatment options,
- To contribute to developing a balanced and proportionate legislative and regulatory framework for combined products including connected combined products.

Annex

Reference	Content	MPP suggested amendments	MPP proposal
Proposal for a Directive of The European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC			
Recital 83	To ensure that the competent authorities have all the information needed for their assessment in the case of integral combinations of a medicinal product with a medical device or of combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product with the medical device or of the combination of a medicinal product with the other product. The competent authority should assess the benefit-risk balance of the integral combination taking into account the suitability of the use of the medicinal product together with the medical device or the other product.	To ensure that the competent authorities have all the information needed for their assessment in the case of integral combinations of a medicinal product with a medical device or of combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product with the medical device or of the combination of a medicinal product with the other product. The competent authority should assess the benefit-risk balance of the integral combination taking into account the suitability of the use of the medicinal product together with the medical device or the other product. **By way of derogation from Article 6(2), Article 9 to 14 of the Directive, and the Regulation (EU) 2017/745 applies for the applicant for a marketing authorisation, for integral combinations of a medicinal product with a medical device or of combinations of a medicinal product with a product other than a medical device, containing a medicinal substance and/or a medical device responding to the criteria of an abridged application.**	MPP suggests the addition of a new paragraph to preamble 83. The current text is subject to interpretation and may lead to debate between Manufacturers and Competent Authorities, delaying EU patient's access to new medicines. This addition clarifies that abridged applications may also be applicable to integral combination of a medicinal product with a medical device or of combinations of a medicinal product with a product other than a medical device.
Recital 85	The Directive also clarifies that a medical device that is part of an integral combination has to	The Directive also clarifies that a medical device that is part of an integral combination has to	MPP suggests a wording change for clarity on the mode of action and alignment with wording of

Reference	Content	MPP suggested amendments	MPP proposal
	comply with the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council. A medical device in exclusive use with a medical device needs to meet all of the requirements of Regulation (EU) 2017/745. A medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004] taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745.	comply with the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council. **A medicinal product in exclusive use with a medical device and which has an action that is not ancillary to that of the medical device** […]	MDR 2017/745, Art. 1 (here and throughout the text of the complete directive).
Recital 86	For all these products (integral combinations of a medicinal product and a medical device, medicinal products in exclusive use with medical devices and combinations of a medicinal product with a product other than a medical device) the competent authority should also be able to request the marketing authorisation applicant to transmit any additional information needed and the marketing authorisation applicant should be bound to submit any such information requested. For medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device, the marketing authorisation applicant shall also, upon request from the competent authority, submit any additional information related to the medical device taking into account its use with the medicinal product and that is relevant for the postauthorisation monitoring of the medicinal product, without prejudice to the specific		A more specific wording regarding the information requested would be appreciated: MPP is concerned that the current wording can lead to duplicate review since the conformity assessment for the device part is performed by the medical device manufacturer and, where applicable, with the involvement of a notified body. Furthermore, feedback from EMA/CA could be conflicting to e.g. the notified body assessment which would be difficult for the MAA to resolve. In addition, the EUDAMED will give the authorities additional information regarding the medical device being used with the medicinal product.

Reference	Content	MPP suggested amendments	MPP proposal
	requirements of the [revised Regulation (EC) No 726/2004]		
Article 4 paragraph 25	'medicinal product in exclusive use with a medical device' means a medicinal product presented in a package with a medical device or to be used with a specific medical device, as defined by Regulation (EU) 2017/745, and referenced in the summary of product characteristics;		Further guidance from EMA suggested to help interpret the expectations for labeling/SmPC in case a medicinal product is '*used with a specific medical device"*, especially for co-packaged devices Specific guidance from EMA requested to enable the requirement "with a specific medical device, as defined by Regulation (EU) 2017/745, and referenced in the summary of product characteristics" to be satisfactorily implemented.
Article 4 paragraph 26	'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745) and where the two are intended for use in the given combination in accordance with the summary of product characteristics	'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745 **and Regulation (EU) 2017/746**) and where the two are intended for use in the given combination in accordance with the summary of product characteristics	This definition is very broad /vague, the specific reference to also exclude IVDR is important, to avoid confusion that in vitro diagnostics (including CDx) are not within this definition.
Article 4 paragraph 35	'risks related to use of the medicinal product' means any risk: (a) relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health; (b) of undesirable effects on the environment posed by the medicinal product; (c) of undesirable effects on public health due to the release of the medicinal product in the environment including anti-microbial resistance;		MPP proposes to consider amending the definition with a view to include the risks from the drug-device component and its interaction.

Reference	Content	MPP suggested amendments	MPP proposal
Article 4 paragraph 41	'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35), subpoint (a);		The MPP proposes to consider amending the definition with a view to include the risks from the drug-device component and its interaction.
Article 4 paragraph 43	'package leaflet' means information for the user that accompanies the medicinal product;		The MPP proposes to consider amending the definition or to add a new definition in order to clarify, in the case of co-packaged products, the need to add the IFU or the device-relevant information in the SMPC of the product. It is currently not regulated.
Article 18 paragraph 3	The application for a marketing authorisation for an integral combination of a medicinal product with a medical device shall include the documentation supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	The application for a marketing authorisation for an integral combination of a medicinal product with a medical device shall include the ~~**documentation**~~ **evidence** supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 ~~in **accordance with Annex II, including**~~, or where relevant, the conformity assessment by a notified body **for a platform technology**.	MPP proposes to delete the requirements of Annex II: The MDR in Article 117 requires that, in the case of integral combinations of medicinal products with medical devices, the device part must only comply with the relevant Annex I requirements, compliance with Annex II is not required according to the MDR Article 117 and should therefore not be required here. Justification to delete conformity: To differentiate from the conformity assessment described for Medical Devices in the MDR, which is different to what is required for integral products, where only Annex I compliance is required. Justification for changed wording on conformity assessment report: To create consistency with MDR Art 117 wording and improve clarity on the notified body involvement applicable to device part of integral DDCs. A lot of integral drug-device combinations are based on the same medical device technology
Annex II, paragraph 3.2 (12)	Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (10), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's	Where […] Directive, the **application for a** marketing authorization ~~**dossier**~~ **for an integral combination of a medicinal product with a medical device** shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.	

Reference	Content	MPP suggested amendments	MPP proposal
	EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device. If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.	If the **~~dossier~~ application** does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, **~~the authority shall require the applicant to provide~~** an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question. **Where the medical device part of such integral combination of a medicinal product with a medical device is based on a medical device technology platform, the opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I of EU-MDR issued by a notified body may also be issued for a medical device technology platform when requested by the medical device manufacturer. A Marketing Authorization Holder for a specific integral combination of a medical product with a medical device using a platform medical device part may not provide an opinion if duly justified based on a risk assessment. If a specific opinion is required for the specific integral combination of a medical product with a medical device using a platform medical device part, the Notified Body establishing the opinion needs to consider by**	platform, i.e. pre-filled syringes, injection pen, autoinjectors, inhalers. The current regulation and guidance leads to repeated reviews of the same platform information over and over again without adding any benefit for the patient. MPP proposes the regulation to allow to split the necessary review into a “medical device technology platform” review and a review of the information related to the specific integral combination. This would lead to a streamlined process without adding additional costs and delay of supply of therapy to the patients.

Reference	Content	MPP suggested amendments	MPP proposal
		ways of gap assessment the Notified Body Opinion for the platform device.	
Article 18 paragraph 4	In its evaluation of the integral combination of a medicinal product with a medical device concerned, the competent authorities shall recognise the results of the assessment of compliance of the medical device part of that integral combination with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	In its evaluation of the integral combination of a medicinal product with a medical device concerned, the competent authorities shall recognise the results of the assessment of compliance of the medical device part of that integral combination with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment**(s)** by a notified body.	
Article 19 paragraph 3	The application for a marketing authorisation for a medicinal product in exclusive use with a medical device shall include the documentation supporting the compliance of the medical device with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report issued by a notified body.	The application for a marketing authorisation for a medicinal product in exclusive use with a medical device shall include the documentation supporting the compliance of the medical device with the general safety and performance requirements ~~**as referred to in paragraph 2 in accordance with Annex II**~~, including, where relevant, the ~~**conformity assessment report**~~ **certificate** issued by a notified body **or EU Declaration of Conformity**.	The co-packed /referenced medical devices device used for the delivery of the drug are often CE-marked devices and with that the technical documentation documents are owned by the legal manufacturer and not the MAA applicants. The results of the conformity assessment process is documented in Declaration of Conformity /CE certificates, These documents should be enough to demonstrate the compliance of the device with the requirements of the MDR.
Article 19 paragraph 4	In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the results of the assessment of compliance of the medical device concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the results of the assessment of compliance of the medical device concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 ~~**including, where relevant, the results of the assessment by a notified body.**~~	Please kindly refer to the above cell.

Reference	Content	MPP suggested amendments	MPP proposal
Article 19 paragraph 6	If the action of the medicinal product is not ancillary to that of the medical device, the medicinal product shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004], taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745. In this case, the marketing authorisation applicant shall, upon request from the competent authorities, submit any additional information related to the medical device, taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific requirements of the [revised Regulation (EC) No 726/2004].	If the action of the medicinal product is **principal and** not ancillary to that of the medical device, the medicinal product shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004], taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745. In this case, […] requirements of the [revised Regulation (EC) No 726/2004].	This change is proposed to ensure alignment of the wording with MDR Article 1(8).
Article 41	Scientific evaluation by the Committee for Medicinal Products for Human Use in a referral procedure		The MPP would propose clarifying the variation process for drug-device combination products. Specifically, the question of how to classify the changes on the combination product as significant or non-significant.
Annex IV, (o)	o) for medicinal products other than radiopharmaceuticals referred to in Article 67(1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:		The text could benefit from a clarification: It is not clear if the device section in the last line is related to point (o) or it is new topic to be considered for the device. Does this allow for repackaging as foreseen in MDR Article 16? Should an additional leaflet to accommodate for information of the outer packaging be placed?

Reference	Content	MPP suggested amendments	MPP proposal
	(i) verify the authenticity of the medicinal product, and (ii) identify individual packs, • as well as a device allowing verification of whether the outer packaging has been tampered with.		
Not included in current proposals	-	**Products specifically intended for the sterilisation of packaging - intended for medicinal products, but without the product itself being present during sterilisation - are covered by this Directive, provided that the activities are performed on a site holding a manufacturing authorisation.**	MPP suggests including specific wording on ethylene oxide sterilization into the Directive, following the feedback from EU commission received.

Reference	Content	MPP suggested amendments	MPP proposal
Proposal for Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006			
Recital 21	In order to allow for advice that is more informative and an exchange of information between different bodies, scientific advice provided by the Agency should sometimes take place in parallel to scientific advice provided by other bodies. This should be the case for the joint scientific consultation carried out by the Member State Coordination Group on Health Technology Assessment foreseen in Regulation (EU) 2021/2282 of the European Parliament and		It is suggested to clarify Recital 21: It would be worth clarifying if a reference should be made to the expert panels or the advisory board in this section. The expert panels are not an advisory board as understood by pharma companies. The expert panels are providing a scientific opinion on the clinical trial of the high-risk devices/implantable (IVDs and medical devices) under development as required by the medical device/IVD legislation. The

Reference	Content	MPP suggested amendments	MPP proposal
	of the Council8 and, in cases of medicinal products involving a medical device, the consultation of the expert panels as described in Article 106 of Regulation (EU) No 2017/745 of the European Parliament and of the Council9. Where parallel scientific advice consultation mechanisms are established under other relevant Union legal acts, a similar mechanism should apply.		procedure is clearly defined and involves notified bodies and manufacturer.
Article 58	1. Undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 138(1), second subparagraph, point (p), from the Agency. Such advice can also be requested for medicinal products referred to in Articles 83 and 84 of [revised Directive 2001/83/EC] 2. In the preparation of the scientific advice referred to in paragraph 1 and upon request by undertakings or, as relevant, not-for-profit entities that requested the scientific advice, the Agency may consult experts of the Member States with clinical trial or medical device expertise or the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745. 3. In the preparation of the scientific advice referred to in paragraph 1 and in duly justified cases, the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in	3. In the preparation of the scientific advice referred to in paragraph 1 and in duly justified cases, the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in question or other **~~public~~** bodies **~~established in the Union~~**, as applicable.	3. Changes introduced to ensure that Notified Bodies can be included as expertise in advice procedures.

Reference	Content	MPP suggested amendments	MPP proposal
	question or other public bodies established in the Union, as applicable.		
Article 59	2. In case of medicinal products involving a medical device, undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 58(1) in parallel with the consultation of the expert panels referred to in Article 61(2) of Regulation (EU) 2017/745. 3. In the case of paragraph 2, the scientific advice, as referred to in Article 58(1), shall involve exchanges of information between the respective authorities or bodies and, where applicable, have synchronised timing, while preserving the separation of their respective remits.		It is suggested to consider including a reference to IVDs and to the relevant section of the IVDR.
Article 74	A paediatric investigation plan shall specify the timing and all the measures proposed to assess the quality, safety and efficacy of the medicinal product in all subsets of the paediatric population that may be concerned. In addition, it shall describe any measures to adapt the pharmaceutical form, the strength, the route of administration and the eventual administration device of the medicinal product so as to make its use more acceptable, easier, safer or more effective for different subsets of the paediatric population. 2. By derogation from paragraph 1, in the following cases an applicant may submit only an		It would be great to clarify which device-related details should be added in the pediatric investigation plan (PIP).

Reference	Content	MPP suggested amendments	MPP proposal
	initial paediatric investigation plan as referred to in the second subparagraph: (a) when the active substance concerned is not yet authorised in any medicinal product in the EU and is intended to treat a novel paediatric condition; (b) following the acceptance by the Agency of a justified request from an applicant in accordance with paragraph 3. An initial paediatric investigation plan shall contain only the details and the timing of the measures proposed to assess the quality, safety and efficacy of the medicinal product in all subsets of the paediatric population that may be concerned, that are known at the moment of the submission of the request for agreement mentioned in Article 76(1). This initial paediatric investigation plan shall also provide a precise timing of when updated versions of the paediatric investigation plan are to be submitted and when a final paediatric investigation plan complying with all the particulars described in paragraph 1, is expected to be submitted to the Agency. 3. When it is not possible, on the basis of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1)		

Reference	Content	MPP suggested amendments	MPP proposal
	an applicant may submit a justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal. 4. On the basis of the experience acquired as a result of the operation of this Article or of scientific knowledge, the Commission is empowered to adopt delegated acts in accordance with Article 175 to amend the grounds for		
Article 83	Waivers during a public health emergency 1. The decision by the Agency referred to in Article 6(5), point (e) of [revised Directive 2001/83/EC] shall concern only medicinal products intended for the treatment, prevention or medical diagnosis of a serious or life-threatening disease or condition which are directly related to the public health emergency. 2. The decision mentioned under paragraph 1 shall include the grounds for providing such derogation and its duration. 3. At the latest at the date of expiry of the derogation referred to in paragraph 2, the applicant shall submit to the Agency a paediatric investigation plan or an application for a waiver with a request for agreement in accordance with the provisions of Article 76(1).		The relation with Article 18 of Regulation (EU) 2022/123 could be clarified: It could be useful to clarify, in the case of drug-device combinations, whether the notified body would be involved in the assessment of a temporary emergency marketing authorization.

Reference	Content	MPP suggested amendments	MPP proposal
Article 139	1. The Agency shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other Union bodies and agencies carrying out similar tasks in relation to issues of common concern. 2. Where the Agency identifies a potential source of divergence, it shall contact the body or agency in question to ensure that all relevant scientific or technical information is shared and in order to identify potentially contentious scientific or technical issues. 3. Where a substantive divergence over scientific or technical issues is identified and the body concerned is a Union Agency or a scientific committee, the Agency and the body concerned shall cooperate to resolve the divergence, and inform the Commission without undue delay. 4. The Commission may ask the Agency to conduct an assessment as regards specifically the use of the substance concerned in medicinal products. The Agency shall make public its assessment stating clearly the reasons for its specific scientific conclusions. 5. To enable coherence between scientific opinions and to avoid duplication of tests, the Agency shall make arrangements with other	1. The Agency shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other ~~Union~~ bodies and agencies carrying out similar tasks in relation to issues of common concern. 2. Where the Agency identifies a potential source of divergence, it shall contact the body or agency in question to ensure that all relevant scientific or technical information is shared and in order to identify potentially contentious scientific or technical issues. 3. Where a substantive divergence over scientific or technical issues is identified ~~and the body concerned is a Union Agency or a scientific committee~~, the Agency and the body concerned shall cooperate to resolve the divergence, and inform the Commission without undue delay. 4. The Commission may ask the Agency to conduct an assessment as regards specifically the use of the substance concerned in medicinal products. The Agency shall make public its assessment stating clearly the reasons for its specific scientific conclusions. 5. To enable coherence between scientific opinions and to avoid duplication of tests, the Agency shall make arrangements with other bodies or agencies ~~established under Union law~~ for cooperation on	The proposed edits to remove text in subparagraph (1), (3) & (5) are addressing the need to ensure that, within the scientific advice procedure when associated with medicinal products used with a medical device, notified bodies can specifically be included to provide expertise.

Reference	Content	MPP suggested amendments	MPP proposal
	bodies or agencies established under Union law for cooperation on scientific assessments and methodologies. The Agency shall also make arrangements for the exchange of data and information on relevant substances with the Commission, Member States' authorities and other Union Agencies, in particular for environmental risk assessments, non-clinical studies and maximum residue limits. These arrangements shall seek to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection	scientific assessments and methodologies. The Agency shall also make arrangements for the exchange of data and information on relevant substances with the Commission, Member States' authorities and other Union Agencies, in particular for environmental risk assessments, non-clinical studies and maximum residue limits. These arrangements shall seek to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection	