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General Secretariat

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CONTRIBUTION

From: General Secretariat of the Council
To: Working Party on Pharmaceuticals and Medical Devices (Attachés)
Pharmaceutical package

Subject: Pharma package
- Comments from the Danish delegation

Delegations will find enclosed comments from the Danish delegation on incentives (ST 15044/24).

DK comments

Guidelines to be followed

Please kindly provide your contributions in the table below.

To make it feasible to consolidate all contributions, the structure of the table must not be changed, so **no rows can be added or deleted**.

New provisions may only be added in any of the '**existing cells**'.

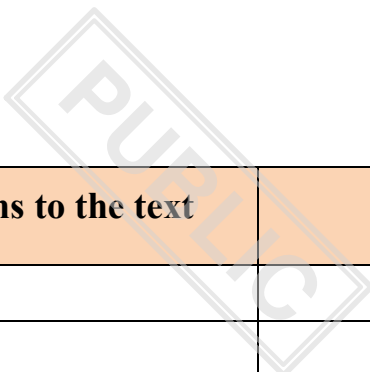
Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments ondocx**

Thank you for your cooperation!



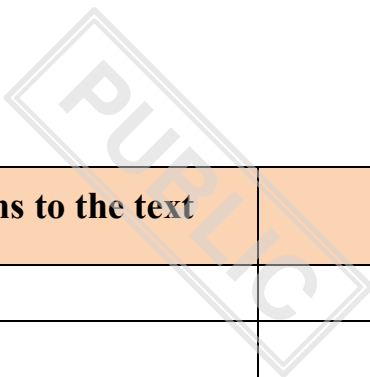
Presidency compromise	Suggested adaptations to the text	Comments
<u>General comments</u>		
<u>Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive</u>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<u>2001/83/EC and Directive 2009/35/EC</u>		
ADAPTED FRAMEWORKS		
Chapter II Application requirements for national and centralised marketing authorisations		
Section 5		
Adapted dossier requirements		
<i>Article 28</i>		

DK comments

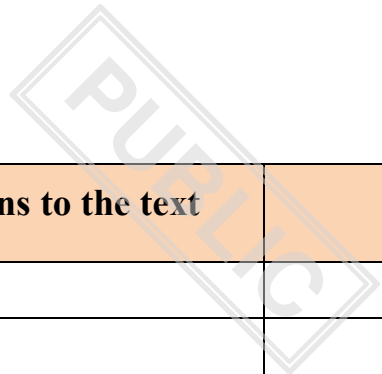


Presidency compromise	Suggested adaptations to the text	Comments
<p><i>Adapted frameworks due to the characteristics or methods inherent to the medicinal product <u>or category of medicinal products</u></i></p>		
<p>1. Medicinal products <u>or category of medicinal products</u> listed in Annex VII shall be subject to <u>adapted</u> specific scientific or regulatory requirements (<u>'adapted framework'</u>) due to the characteristics or methods inherent to the medicinal product <u>or category of medicinal products</u>; <u>A medicinal product or category of medicinal products shall be listed in Annex VII</u> when:</p>		
<p>(a) it is not possible to adequately assess the</p>		<p>The wording “objective and scientific” reiterates</p>

DK comments

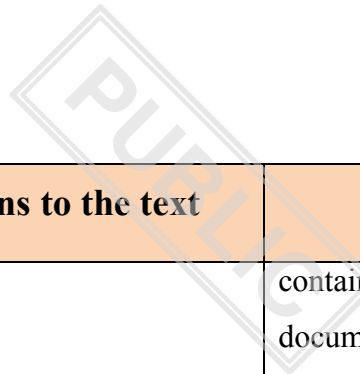
Presidency compromise	Suggested adaptations to the text	Comments
<p>medicinal product or category of medicinal products applying the applicable requirements <u>set out in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007</u> due to scientific or regulatory challenges arising from <u>objective and scientific</u> characteristics or methods inherent to the medicinal product <u>or category of medicinal products</u>; and</p>		<p>what has already been said in para 1. We therefore deem this addition superfluous.</p>
<p>(b) the characteristics or methods <u>inherent to the medicinal product or category of medicinal products</u> positively impact the quality, safety and efficacy of the medicinal product or category of medicinal product or provide a major contribution to patient access <u>to prevention, diagnosis, or treatment</u> or <u>any other form of</u> patient care.</p>		

DK comments



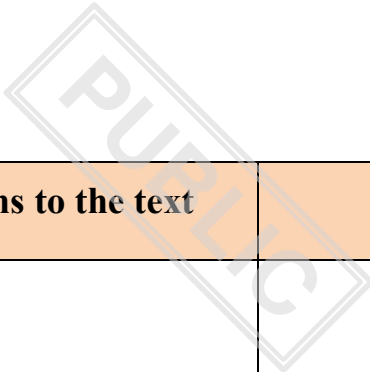
Presidency compromise	Suggested adaptations to the text	Comments
<p>2. Based on a recommendation by After having consulted the Agency, The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend <u>the list of medicinal products or categories of medicinal products listed in the list of areas of adapted frameworks under</u> Annex VII in order to take account of scientific and technical progress.</p>		
<p>3. The Commission may adopt <u>implementing acts</u> is empowered, <u>after having consulted the Agency,</u> to adopt delegated</p>		<p>We suggest to insert "a description of" after "contain" and before "the technical documentation" - "The delegated act shall</p>

DK comments



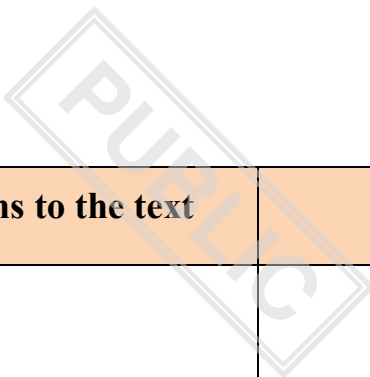
Presidency compromise	Suggested adaptations to the text	Comments
<p>implementing acts in accordance with Article 215 214 to supplement this Directive by laying down <u>the adapted framework for one or more medicinal products or categories of medicinal products listed in Annex VII.</u></p>		<p>contain a description of the technical documentation...".</p>
<p><u>The adapted framework may entail adapted, enhanced, waived or deferred requirements from those set out in this Directive. The adapted framework shall be proportionate to the risk and impact involved. In particular, any waiver or deferral from the standards of requirements for quality, safety and efficacy set out in this Directive shall be limited to the extent strictly necessary, proportionate and duly justified by the characteristics or</u></p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>methods inherent to the medicinal product, and shall be regularly reviewed and evaluated by the Commission. Apart from the detailed rules set out in the delegated act, all other rules laid out in this Directive shall apply. The delegated act shall also contain the technical documentation to be submitted by marketing authorisation applicants for the medicinal product or category of medicinal products for which the adapted framework is laid down.</u></p>		
<p>(a) specific detailed rules for the marketing authorisation and supervision of the medicinal products or category of medicinal products referred pursuant to the criteria referred to in paragraph 1;</p>		

DK comments

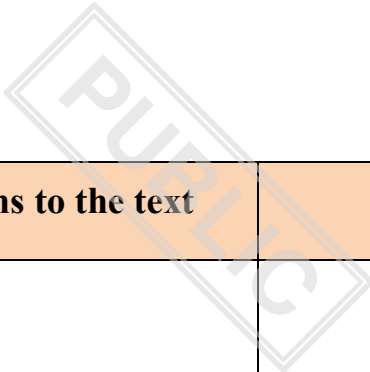


Presidency compromise	Suggested adaptations to the text	Comments
(b) — the technical documentation to be submitted by applicants for marketing authorisations for medicinal products referred to in paragraph 1.		
<u>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).</u>		
<u>3a. The Commission is empowered, after consulting the Agency and when it deems that the conditions set out in paragraph 1 are met, to adopt a delegated act in accordance with Article 215 to specify, for each of the</u>		

DK comments

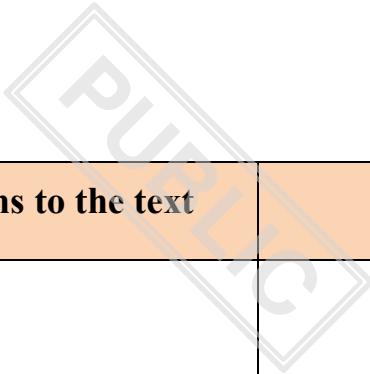
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>medicinal products or category of medicinal products listed in Annex VII, the list of specific scientific or regulatory requirements applicable to that medicinal product or category of medicinal products. The specific applicable requirements shall be proportionate to the risk and impact involved.</u></p>		
<p>4. <u>The Commission shall, taking into account a scientific assessment by the Agency, specify whether those requirements entail an adaptation, enhancement, waiver or deferral from the requirements laid down in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007.</u> The</p>		

DK comments



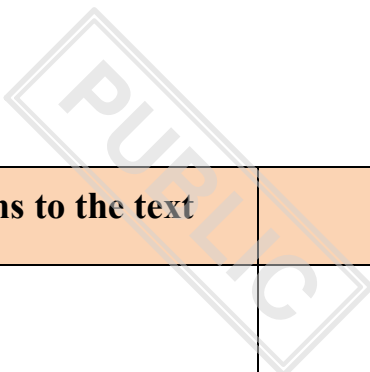
Presidency compromise	Suggested adaptations to the text	Comments
<p>specific detailed rules referred to in paragraph 3, point (a), shall be proportionate to the risk and impact involved. These may entail adapted, enhanced, waived or deferred requirements. Any adaptation, enhancement, waiver or deferral shall be limited to the extent strictly necessary, proportionate and duly justified by the characteristics or methods inherent to the medicinal product or category of medicinal products, and shall be regularly reviewed and evaluated by the Commission by the Agency. Apart from the specific detailed rules referred to in paragraph 3, point (a), all other rules laid out in this Directive shall apply.</p>		
<p>5. Until the adoption of specific adapted</p>		

DK comments



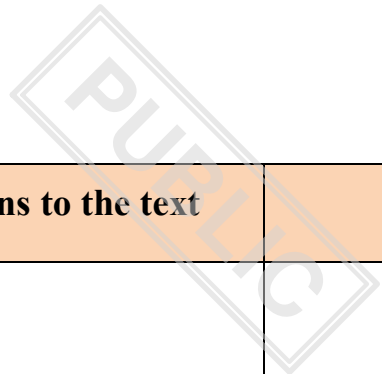
Presidency compromise	Suggested adaptations to the text	Comments
<p>detailed rules for specific medicinal products <u>or category of medicinal products</u> listed in Annex VII pursuant to paragraph 3, an application for a marketing authorisation for that medicinal product may be submitted in accordance with Article 6(2).</p>		
<p>6. When adopting implementing and delegated acts <u>or implementing acts</u> referred to in this Article, the Commission shall take into account any available information resulting from a regulatory sandbox established in accordance with Article 115 of the [revised Regulation (EC) No 726/2004].</p>		
<p>REGULATORY DATA PROTECTION,</p>		

DK comments



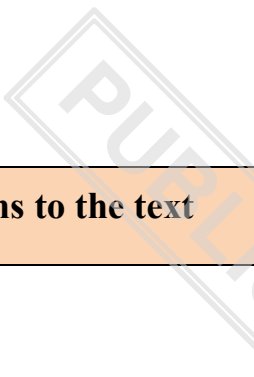
Presidency compromise	Suggested adaptations to the text	Comments
UNMET MEDICAL NEEDS, REWARDS FOR PAEDIATRICS		
Chapter VII Regulatory protection, unmet medical needs and rewards for paediatric medicinal products		
<i>Article 80</i>		
<i>Regulatory data and market protection</i>		

DK comments



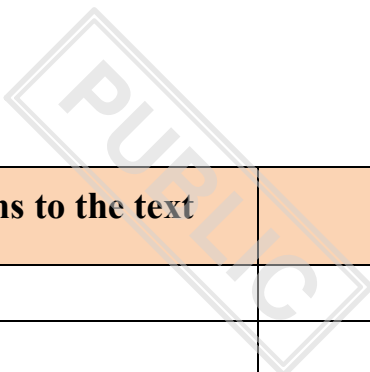
Presidency compromise	Suggested adaptations to the text	Comments
<p>1. The data referred to in Annex I, originally submitted with the view to obtaining a marketing authorisation shall not be referred to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81 ('regulatory data protection period').</p>		
<p>2. A medicinal product concerned by a subsequent marketing authorisation referred to in paragraph 1 shall not be placed on the market for a period of two years after the expiry of the relevant regulatory data protection periods referred to in Article 81.</p>		
<p><u>The period shall be extended to three years if,</u></p>		<p>We suggest to refer to Article 81 instead of para</p>

DK comments



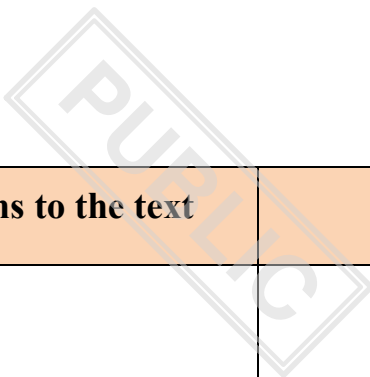
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>during the regulatory data protection period referred to in paragraph 1, the marketing authorisation holder concerned obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation and based on supporting data submitted by the marketing authorisation holder, are held to bring a significant clinical benefit in comparison with existing therapies.</u></p> <p><u>When applying for an extension under this subparagraph and where such data were not available when the applicant shall demonstrates that the clinical study reports results of the clinical trials specific to the approval of the new indication were not available at the time of the submission of the initial authorisation application initial</u></p>		<p>1 as Article 81 concerns the data protection periods.</p>

DK comments



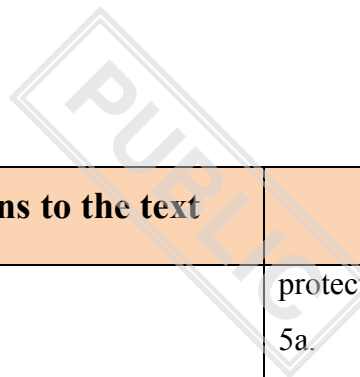
Presidency compromise	Suggested adaptations to the text	Comments
marketing authorisation was submitted.		
<p>3. By way of derogation from paragraph 1, the marketing authorisation holder concerned may grant the marketing authorisation applicant for another marketing authorisation a letter of access to its data submitted under Annex I, as referred to in Article 14.</p>		
<p>4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party licensee under conditions laid out in <u>Union or national law</u> to address a public</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>health emergency, the relevant data and market protection shall be suspended with regard to that party licensee insofar as the compulsory licence requires, and during for the duration and the territory of the Member States for which period of the compulsory licence has been granted.</p>		
<p>5. The data protection period set out to in paragraph 1 shall also apply in Member States where the medicinal product is not authorised or is no longer authorised.</p>		
<p>5a. National competent authorities shall</p>		<p>"...together with the date of the end of the</p>

DK comments



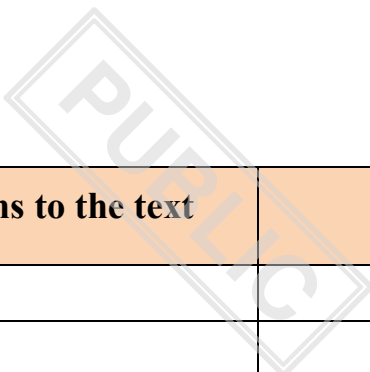
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory data or market protection together with the date of the end of the protection period. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.</u></p>		<p>protection period" should be deleted from para 5a.</p> <p>The NCAs are not able to provide information on the exact dates where the protection periods end as other NCAs may have issued national marketing authorisations at an earlier point in time for the same product.</p> <p>Therefore, the NCAs can only publish the date of granting of a "full application" marketing authorisation in their Member State and inform whether that MA benefits from data and market protection. It'll be up to the generic applicant to consult all the lists and find the earliest date of issue and based on that calculate the expiry of data and market protection, respectively.</p>

DK comments

Presidency compromise	Suggested adaptations to the text	Comments
<p>5a. <u>The marketing authorisation holder</u> <u>The Agency shall include submit and keep up to date the information on data and market protection periods for both centrally authorised medicinal products and medicinal products that have been granted a national marketing authorisation in the database referred to in Article 138 paragraph 1, point (n) of the [revised Regulation (EC) No 726/2004].¹ The marketing authorisation holder shall notify the Agency with supporting documentation whenever the information published concerning the relevant regulatory and market protection periods is missing, not accurate or outdated.</u></p>		

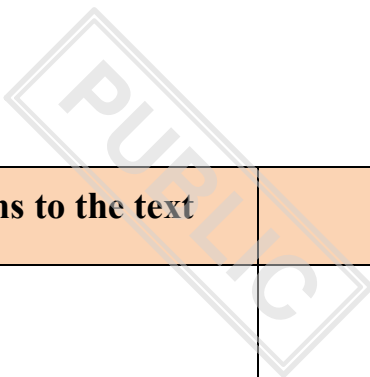
¹ ~~Presidency note: In order to be coherent, it should be specified in Article 16 of the Regulation (on ‘marketing authorisations’) that this information on data and market protection periods should be integrated into the register referred to in Article 138. However, as this Article is a central Article in the ‘authorisations cluster’, we decided not to add it to this cluster.~~

DK comments



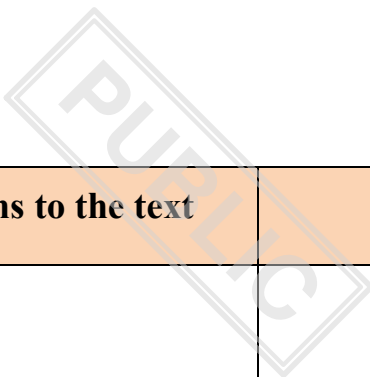
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>5b. In case of medicinal products covered by a national marketing authorisation, the national competent authorities that granted the authorisation shall be informed through the database without delay on any submissions and updates made in accordance with paragraph 5a. If the National competent authority does not inform the Agency on its objection within 8 30 days, the data shall be published in the database. In case of objection, the national competent authority shall invite without undue delay the marketing authorisation holder to make a correct submission. Until a new submission is not made and approved under this</u></p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<u>paragraph, the data related to data and market protection periods indicated in the database shall remain unchanged.</u>		
<i>Article 81</i>		Our position is unchanged. An unmodulated data protection period of 8 years is necessary.
<i>Regulatory data protection periods</i>		
1. The regulatory data protection period shall be six seven eight years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to		

DK comments

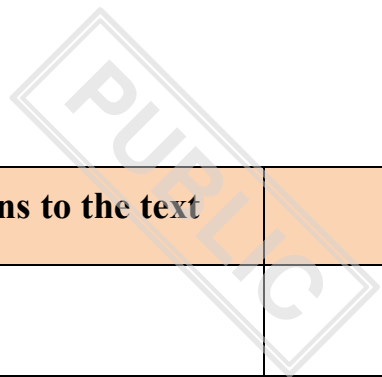


Presidency compromise	Suggested adaptations to the text	Comments
<p>the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.</p>		
<p>2. Subject to a scientific evaluation by the relevant competent authority, the data protection period referred to in paragraph 1 shall be prolonged by: <u>The data protection period referred to in paragraph 1 shall be prolonged by: By way of derogation from paragraph (1) the data protection period shall be 7 years if none of the following conditions is fulfilled:</u></p>		
<p>(a) — 24 months, where the marketing authorisation holder demonstrates that the</p>		

DK comments

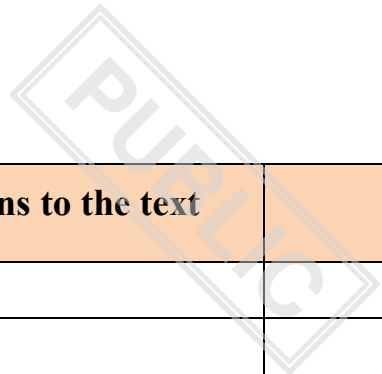
Presidency compromise	Suggested adaptations to the text	Comments
<p>conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities:</p>		
<p>(i) — SMEs within the meaning of Commission Recommendation 2003/361/EC;</p>		
<p>(ii) — entities not engaged in an economic activity ('not for profit entity'); and</p>		
<p>(iii) — undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the</p>		

DK comments



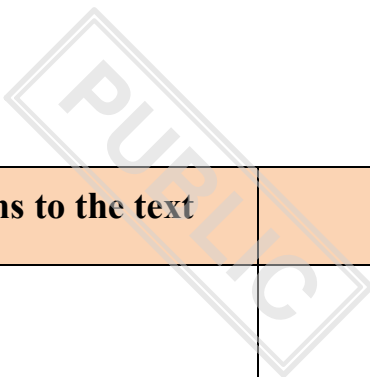
Presidency compromise	Suggested adaptations to the text	Comments
establishment of the undertaking or the group, whichever is earliest.		
<p><u>The regulatory data protection period referred to in paragraph 1 shall be prolonged by the following periods not exceeding 8 year in total by:</u></p>		
<p><u>(a) 12 months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;</u></p>		
<u>or</u>		

DK comments



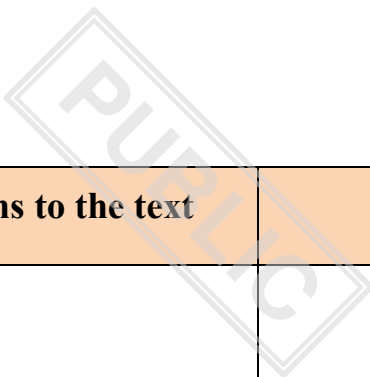
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>(b) 12 6 months for medicinal products containing a new active substance, if they meet all of the following conditions:</u></p>		
<p><u>i) where appropriate, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;</u></p>		
<p><u>(c)—ii) 12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and</u></p>		

DK comments



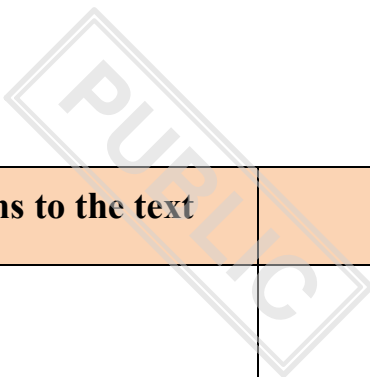
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>at least partly in collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union, the marketing authorisation applicant carried out clinical trials evaluating the efficacy of the medicinal product and used for the marketing authorisation were conducted in at least two Member States of the European Union.</u></p>		
<p><u>(d) — 6 months where the marketing authorisation holder demonstrates that the medicinal product or the active substance was manufactured in the European Union, excluding import related processes.</u></p>		
<p><u>(e) — iii) 6 months if the marketing</u></p>		

DK comments



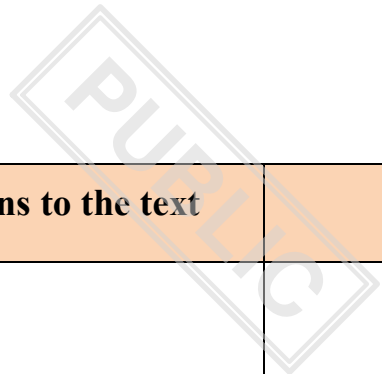
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>authorisation applicant holder demonstrates that the application for granting marketing authorisation application has been first submitted to the competent authority in the Union or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the Union.</u></p>		
<p><u>The cumulative duration of data protection for a medicinal product shall not exceed eight years from the date the initial marketing authorisation was granted.</u></p>		

DK comments



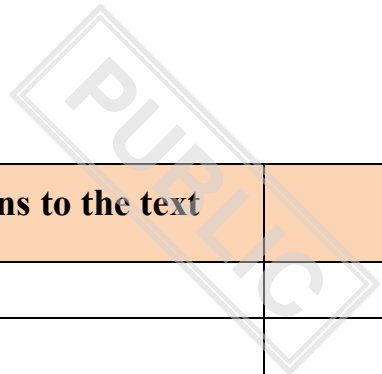
Presidency compromise	Suggested adaptations to the text	Comments
<p>In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation condition referred to in the first subparagraph, point (ba), shall only apply <u>be considered as met</u> if, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.</p>		
<p>The prolongation referred to in the first subparagraph, point (d), may only be granted once. <u>The cumulative duration of data protection for a medicinal product shall not exceed eight years from the date the initial marketing authorisation was granted. [This</u></p>		

DK comments



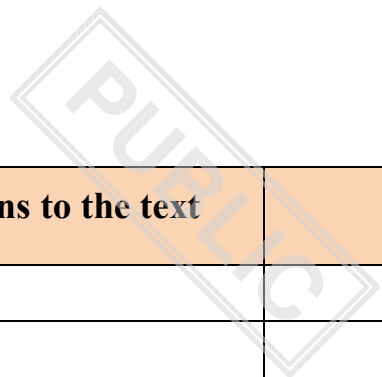
Presidency compromise	Suggested adaptations to the text	Comments
<p>limitation does not apply in the case of Article 40 of [revised Regulation (EC) No 726/2004].</p>		
<p>3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (eb) (i) (ii), on criteria for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004], <u>in particular bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282.</u></p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement paragraph 2 point (ba) c in order to determine situations in which a set specific criteria for the designation of significant substantial share of research and development is done within the Union.</u></p>		
<i>Article 82</i>		
<i>Prolongation of the data protection period for medicinal products supplied in Member States</i>		

DK comments

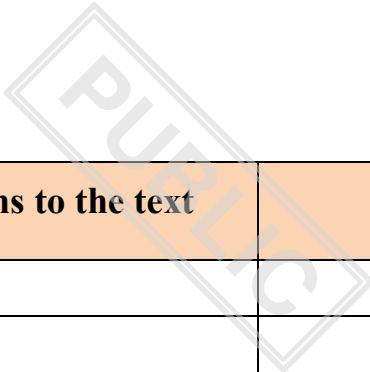


Presidency compromise	Suggested adaptations to the text	Comments
<p>1. The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid.</p>		
<p>The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing</p>		

DK comments

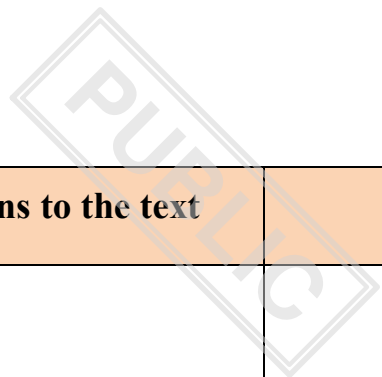
Presidency compromise	Suggested adaptations to the text	Comments
authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.		
2. To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.		
The application for a variation shall be submitted between 34 and 36 months after the date when the initial marketing authorisation was granted, or for entities referred to in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:</p>		
<p>(a) — confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or</p>		
<p>(b) — waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation.</p>		

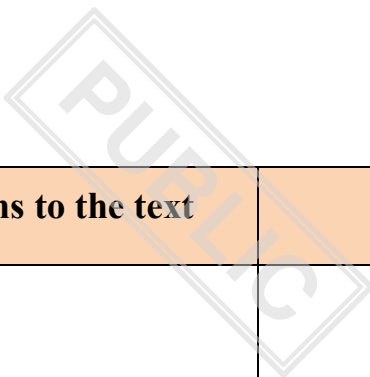
DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC² shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a).</p>		
<p>3- To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the Member State shall issue a confirmation of compliance or, a reasoned statement of non-compliance or</p>		

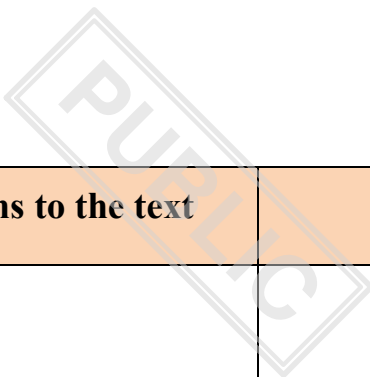
² Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.</p>		
<p>4. In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided.</p>		
<p>For medicinal products granted a centralised marketing authorisation the Commission shall vary the marketing authorisation pursuant to Article 47 of [revised Regulation (EC) No 726/2004] to prolong the data protection period. For medicinal products granted a marketing</p>		

DK comments



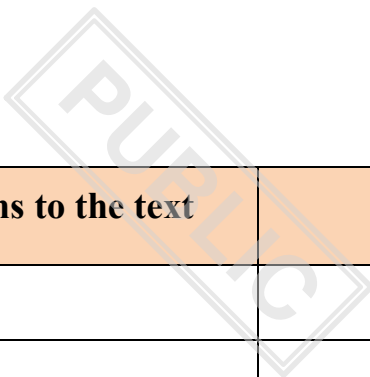
Presidency compromise	Suggested adaptations to the text	Comments
<p>authorisation in accordance with the decentralised procedure, the competent authorities of the Member States shall vary the marketing authorisation pursuant to Article 92 to prolong the data protection period.</p>		
<p>5- Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC³ ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and</p>		

³ Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).

DK comments

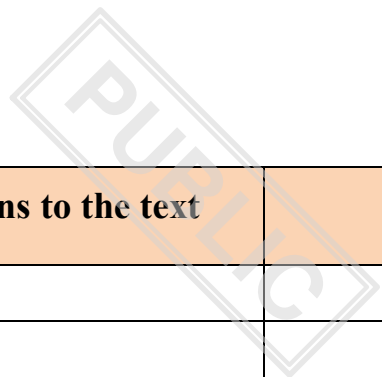
Presidency compromise	Suggested adaptations to the text	Comments
reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.		
6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt implementing measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).		
Chapter V		
Obligations and liability of the		

DK comments



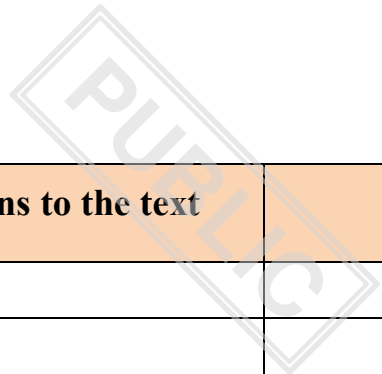
Presidency compromise	Suggested adaptations to the text	Comments
marketing authorisation holder		
<u>Article 56a</u>		<p>We support that Member States may require the marketing authorisation holders to apply for pricing and reimbursement as well as Member States may require a roll-out plan on the launch of the product.</p> <p>However, we remain deeply concerned that the proposal will have serious negative effect, and that it will be very difficult to operationalize in practice.</p>
<p><u>Specific requirements Obligation to-on making available market launch and continuously supplying of a medicinal product-on the market in a Member State</u></p>		

DK comments



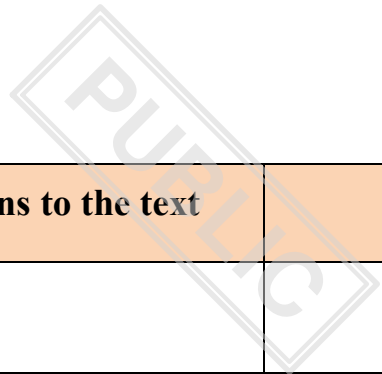
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>1. With a view to facilitating access to a medicinal product covered by a valid marketing authorisation within their territories subject to regulatory protection pursuant to Article 80(2), or, if applicable, the prolongation of the market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004], a Member State may request the marketing authorisation holder of that medicinal product to make it available and continuously supply, within the limits of its responsibility, on the market of that Member State in a sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as</u></p>		<p>We assume that “regulatory protection” means regulatory data protection and market protection pursuant to “Article 80” of the Directive. Therefore, reference should be made to Article 80 in its entirety.</p> <p>The term “within the limits of its responsibility” should be clarified to specify the obligation for the MAH. Does this cover situations, where the MAH is not able to upscale its production to meet the demands in all Member States simultaneously?</p>

DK comments



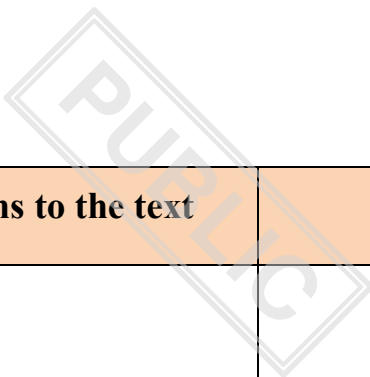
Presidency compromise	Suggested adaptations to the text	Comments
<u>specified by that Member State.</u>		
<p><u>2. For the purposes of paragraph 1, a Member State may require the marketing authorisation holder to carry out specific actions pursuant to national law, including but not limited to, the following:</u></p>		
<p><u>a) meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;</u></p>		
<p><u>b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;</u></p>		

DK comments



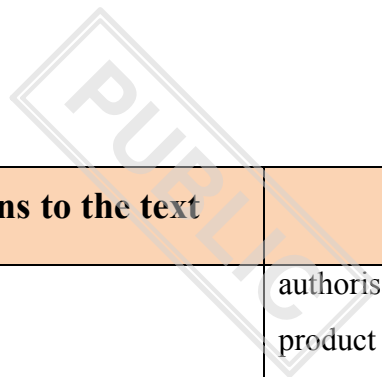
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>c) establishing an access roll-out supply plan.</u></p>		
<p><u>Such The arrangements to implement the requirements referred to in this paragraph shall be proportionate to the objective pursued and in compliance with Union law.</u></p>		
<p><u>2a. Upon request by a Member State in accordance with paragraph 1, the marketing authorisation holder concerned shall carry out the actions referred to in paragraph 2 as relevant.</u></p>		
<p><u>3. The supply access roll-out plan referred to in paragraph 2, point (c), shall include</u></p>		

DK comments



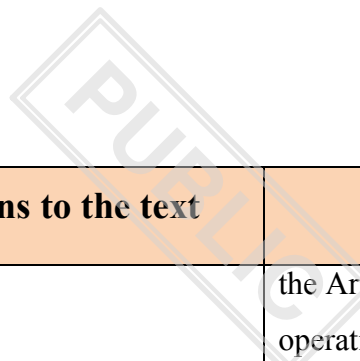
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>information about the supply of the medicinal product by the marketing authorisation holder over a given period in the Member State concerned. The supply access-roll-out plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the supply access roll-out plan.</u></p>		
<p><u>4. When a Member State decides to avail itself of the obligation in applies paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within</u></p>		<p>According to para 4 the Member States' request shall be communicated to the marketing authorisation holder within 1 year from the marketing authorisation.</p> <p>The request can be made to a marketing</p>

DK comments



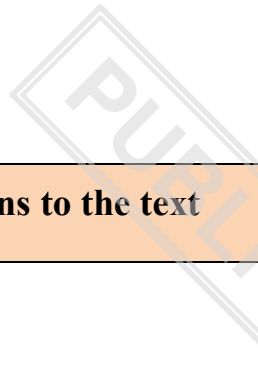
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>one year from the marketing authorisation for that medicinal product. The communication under this paragraph shall contain explicit reference to this Article.</u></p>		<p>authorisation holder of an orphan medicinal product subject to a prolonged market exclusivity period in accordance with Article 72, cf. Article 56a, paragraph 1 (and the reference to Article 72).</p> <p>However, for orphan medicines this will not be possible in practice, because the prolongations in accordance with Article 72 may be granted much later than 1 year from the first/original orphan marketing authorisation.</p>
<p><u>5. Where within 5 4 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not</u></p>		<p>While we sympathize with the fact that all Member States should have increased access to medicines, we do not believe the approach taken is suitable and we remain deeply concerned that it will have severe detrimental effects as well as</p>

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>supplied it continuously within that period in a sufficient quantities and in the presentations necessary to cover the needs of patients in a Member State that made a request in accordance with paragraph 1, the market protection for that medicinal product in accordance with Article 80(2), and, if applicable, the prolongation of the market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004] shall not apply within that Member State.</u></p>		<p>the Article 56a approach is very difficult to operationalize in practice.</p> <p>From a Danish perspective this is a standing invitation to legal disputes as well as it will most likely refrain companies from applying for marketing authorisations within the EU.</p> <p>The provision lacks predictability in its entirety for both marketing authorisation holders as for national competent authorities.</p> <p>For example, it is unclear what constitutes to make a product available and supply continuously? What if an agreement cannot be reached on price between the market authorisation holder and a Member States? Will this mean that the market authorisation holder is not compliant?</p> <p>It is unclear what deadlines the MAH shall meet in regard to make a product available and supply</p>

DK comments

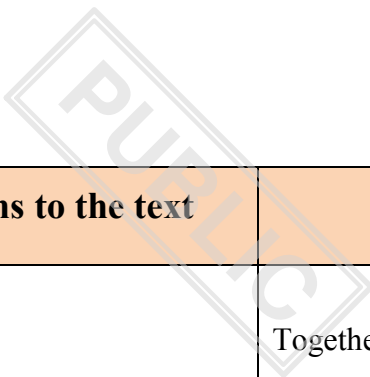


Presidency compromise	Suggested adaptations to the text	Comments
		<p>continuously. What is the deadline for the MAH to comply after a MS has made a request in accordance with para 1? Is the MAH compliant if the product is made available no later than 4 years after the marketing authorisation?</p> <p>This may especially harm SMEs since it may be difficult for them to upscale their production. In addition, we cannot see how this should be enforced in terms of personalized medicines.</p>
<p><u>5a. The Member State shall make the information referred to in paragraph 5 publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the</u></p>		

DK comments

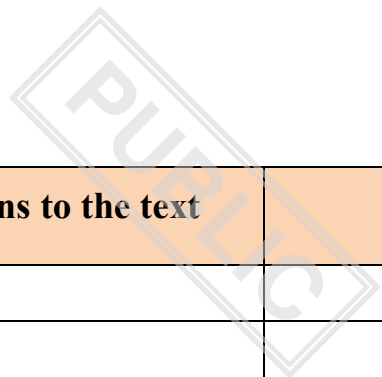
Presidency compromise	Suggested adaptations to the text	Comments
<u>Agency.</u>		
<p><u>5ba. By way of derogation from Article 81, a marketing authorisation application may be validated and assessed by the national competent authorities or the Agency six years after the start of the data protection period of the reference medicinal product, where the medicinal product is a generic or biosimilar medicinal product to a reference medicinal product and where a Member State has made publicly available information with regard to that reference medicinal product in accordance with paragraph 6. The marketing authorisation validated and assessed in accordance with this paragraph shall not be granted prior to the expiry of the regulatory data protection period.</u></p>		<p>We cannot support a weakening of the regulatory data protection. This could potentially be applied in many Member States.</p> <p>Further, we are concerned about the application of this provision for centrally authorized medicinal products. We assume that the inclusion of “the Agency” imply that for centrally authorized medicinal products the regulatory data protection will be reduced in all Member States, if a product has not been made available in at least one Member State. Even though the marketing authorisation shall not be granted prior to the expiry of the regulatory data protection period, this would weaken the data protection in all Member States.</p>

DK comments



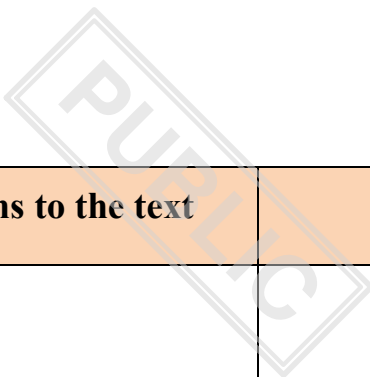
Presidency compromise	Suggested adaptations to the text	Comments
		<p>Together with Article 5, this provision will lead to even more fragmentation of the protection of medicines across the EU, that will make the internal market for medicines even more complicated and may be difficult for companies, authorities and buyers to navigate.</p>
<p>6. — The Member State shall make this the information referred to in paragraph 5 publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.</p>		

DK comments



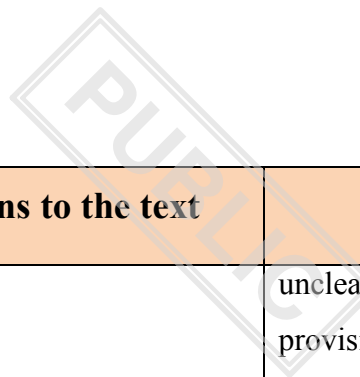
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>7. This Article shall not affect is without prejudice to Member States' the application of national legislation and procedures, including pricing and reimbursement, public procurement and any other procedures, aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation, where a request in accordance with paragraph 1 has been made by that Member State.</u></p>		<p>From a legal perspective we still have difficulties with this provision.</p>
<p><u>This Article shall also not affect the right of marketing authorisation holders to release</u></p>		<p>This provision is very unclear to us.</p>

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>and continuously supply the medicinal product concerned in a Member State by carrying out the relevant procedures pursuant to national law, regardless of whether a request in accordance with paragraph 1 has been made by that Member State.</u></p>		
<p><u>In the course of the application of this Article, the Member States and the marketing authorisation holder shall cooperate in good faith and undertake best efforts to making available and continuously supplying the medicinal product concerned in the concerned Member State.</u></p>		
<p><u>8. Member States representatives may request the Commission to discuss issues</u></p>		<p>From our perspective the procedure in terms of the practical application of article 56a is most</p>

DK comments



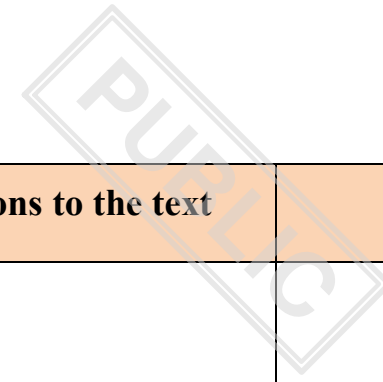
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC⁴ ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.</u></p>		<p>unclear. We have substantial concerns that the provision in its entirety will lead to legal disputes at the costs of Member States</p>
<p><u>The Pharmaceutical Committee may coordinate the notifications by the national competent authorities in agreement with Article 56b points 3 and 5.</u></p>		

⁴ Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).

DK comments

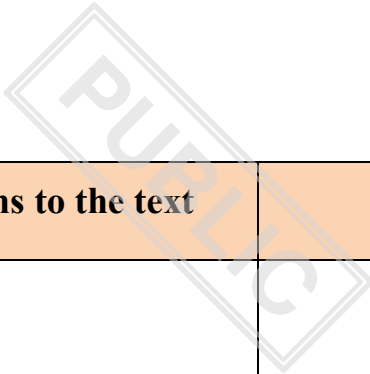
Presidency compromise	Suggested adaptations to the text	Comments
<u>Recital:</u>		Denmark maintains a negative scrutiny reservation in view of our comments to Article 56a.
<p><u>Access to medicinal products in all Member States and guaranteeing a timely, stable, reliable and high-quality supply of medicinal products is an essential objective to achieve an overall high level protection of human health in the Member States, thus contributing to the protection of human health and human life in the Union. The responsibility of ensuring a timely, adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is</u></p>		

DK comments



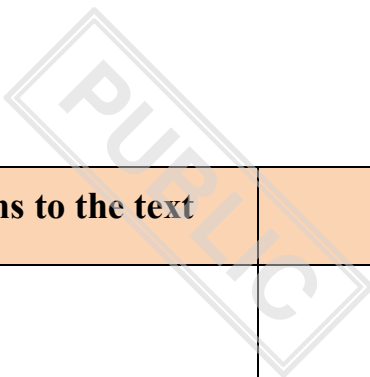
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>granted, the medicinal product is placed on the market by the marketing authorisation holder on its own initiative. Practice shows, however, that in certain Member States the behaviour of marketing authorisation holders results in the placing on the market of authorised medicinal products is delayed or in quantities that do not correspond to the needs of those Member States. Therefore, Member States should, based on grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition, be enabled to require to the MAHs specific actions with a view to comply with their market launch and supply obligations pursuant to this Directive. To this</u></p>		

DK comments



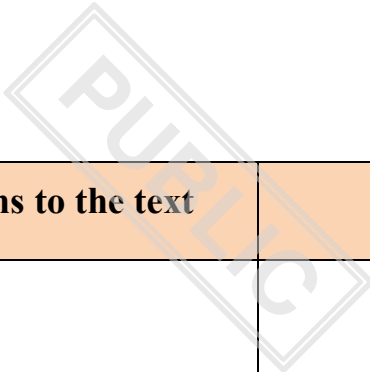
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>aim, Member States should be able to request the marketing authorisation holder to submit an application for pricing and reimbursement or to participate in any relevant national procurement procedures or make the product available in the supply chain draw up and implement an access roll-out plan that is acceptable for that Member State. The implementation of the access-roll-out plan should ensure sufficient and continuous supply to meet the needs of the patients in that Member State. Member States should base their request on the grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition. Member States should also be</u></p>		

DK comments



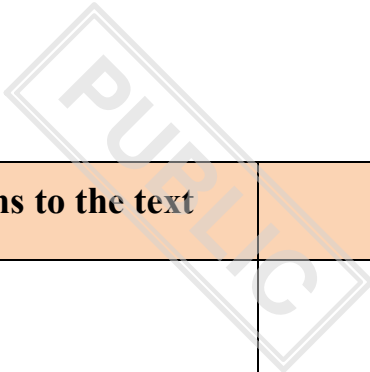
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>able to request the submission and implementation of a supply plan that ensures sufficient and continuous supply to meet the needs of the patients in that Member State.</u></p>		
<p><i>Article 166</i></p>		<p>Denmark maintains a negative scrutiny reservation in view of our comments to Article 56a.</p>
<p><i>Obligations of the wholesale distribution authorisation holder</i></p>		
<p><u>5. In respect of a medicinal product where the protection referred to in Article 80, paragraph (2) or the prolongation referred to in Article 72(2) of [revised Regulation 726/2004] does not apply in a Member State pursuant to Article 56a(5), the wholesale</u></p>		

DK comments



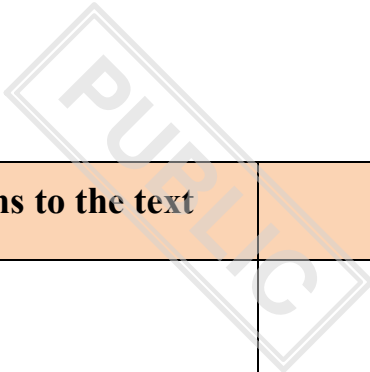
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>distribution holder shall not make the generic, biosimilar, hybrid and biohybrid medicinal product available on the market of another Member State where the protection referred to in Article 80 paragraph (2) and, if applicable, Article 72(2) of [revised Regulation 726/2004] applies, during the period of the protection.</u></p>		
<p><i>Article 216</i></p>		
<p><i>Report</i></p>		
<p>1. By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission</p>		

DK comments



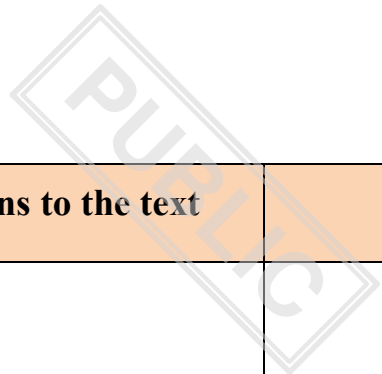
Presidency compromise	Suggested adaptations to the text	Comments
<p>shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it.</p>		
<p><u>2. By [OP please insert the date = 6 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the to the European Parliament and the Council on the application of Article 56a. The report shall, based among others, on information provided by Member States, include an assessment whether the rules provided for in that Article ensures timely availability and</u></p>		

DK comments



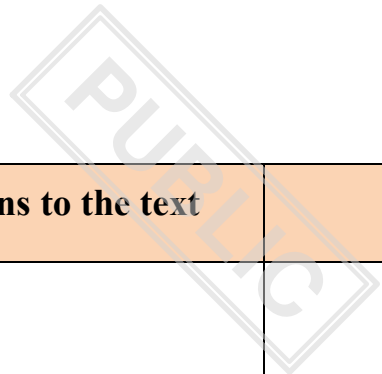
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article. The Commission shall, if appropriate, present legislative proposals based on that evaluation in order to amend this Directive or make further proposals.</u></p>		
<p><i>Article 219</i></p>		
<p><i>Transposition</i></p>		
<p>1. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [18 months after the date of entering into force of this</p>		

DK comments



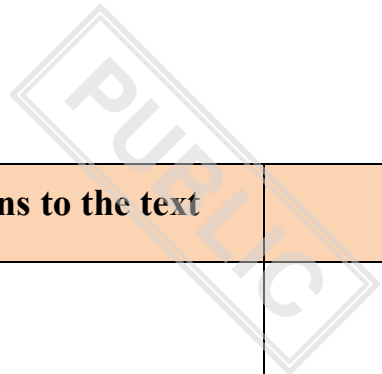
Presidency compromise	Suggested adaptations to the text	Comments
Directive]. They shall immediately communicate the text of those measures to the Commission.		
<u>1a. Member States shall apply those measures from [18 months after the date of entering into force of this Directive].</u>		DK takes a scrutiny reservation. We need to have a better overview of all the elements in the Directive before we can subscribe to this approach
<u>However Member States may apply Article 56a from an earlier date in respect of medicinal products authorised after the date of entering into force of this Directive. In case of a medicinal product authorised between</u>		DK has a negative scrutiny reservation in view of our approach to Article 56a.

DK comments



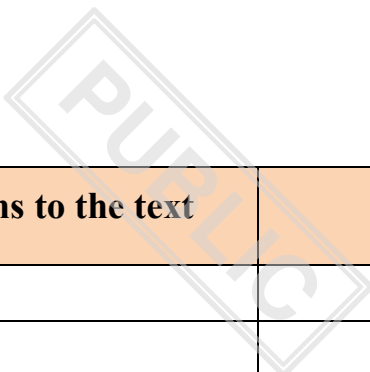
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>the entry into force and the date of application of this Directive, the second subparagraph of Article 10 (1) of the Directive 2001/83 shall not apply in the member state that made a request in accordance with Article 56a, if the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously in that Member State in accordance with that Article.</u></p>		
<p>2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.</p>		
<p>3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive.</p>		
<p><u>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</u></p>		

DK comments

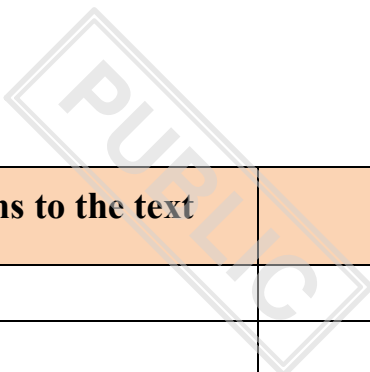


Presidency compromise	Suggested adaptations to the text	Comments
<u>2001/83/EC and Directive 2009/35/EC</u>		
Chapter XVI General provisions		
<u>Article 206</u>		
<u>Penalties</u>		
2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:		
(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;		

DK comments

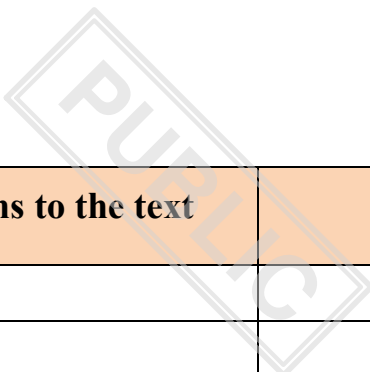
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>(aa) non-compliance with the provisions laid down in this Directive on making available and continuously supply the medicinal product on the market of a Member State.</u></p>		<p>In view of our negative stance towards Article 56a, we cannot support this provision.</p> <p>Since supply is national competence, sanctions should equally be so.</p>
<p>(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;</p>		
<p>(c) non-compliance with the provisions laid down in this Directive on the use of excipients;</p>		
<p>(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;</p>		
<p>(e) non-compliance with the provisions laid</p>		

DK comments



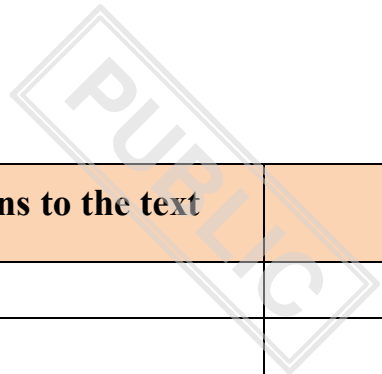
Presidency compromise	Suggested adaptations to the text	Comments
down in this Directive on advertising.		
Chapter VII		
Regulatory protection, unmet medical needs and rewards for paediatric medicinal products		
<i>Article 83</i>		
<i>Medicinal products addressing an unmet medical need</i>		

DK comments



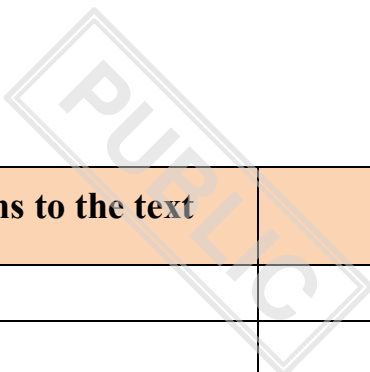
Presidency compromise	Suggested adaptations to the text	Comments
<p>1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and either of the following conditions are met:</p>		
<p>(a) there is no medicinal product authorised in the Union satisfactory method of diagnosis, prevention or treatment in standard of care for such disease, or, where despite the existence of a satisfactory method of diagnosis, prevention or treatment in standard of care medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;</p>		

DK comments



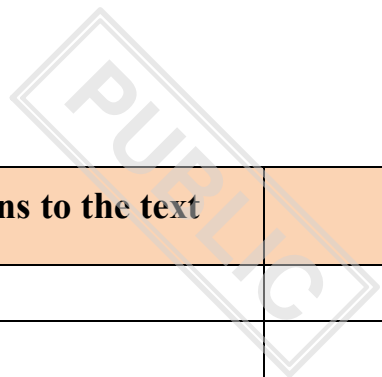
Presidency compromise	Suggested adaptations to the text	Comments
<p>(b) the use of the medicinal product <u>for such a disease</u> results in <u>clinically relevant advantage</u> a greater in efficacy, or greater in safety with a non-inferior efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union a meaningful reduction in disease morbidity or mortality for the relevant patient population. The meaningful reduction in disease morbidity or mortality for the relevant patient population may shall be demonstrated, where possible and appropriate, with data from comparative clinical trials studies that use a relevant and evidence-based comparator in accordance with scientific advice provided by the</p>		

DK comments



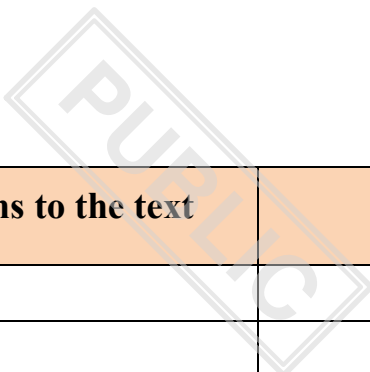
Presidency compromise	Suggested adaptations to the text	Comments
<u>Agency.</u>		
<p>1a. The applicant shall demonstrate the improvement in efficacy or safety referred to in paragraph 1(b) with data from clinical trials that use, where possible and appropriate, a relevant and evidence-based comparator. In the case of paragraph 1(b), the applicant shall demonstrate the greater efficacy or safety with data from clinical trials that use a relevant and evidence-based comparators.</p>		
<p>2. Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as</p>		

DK comments



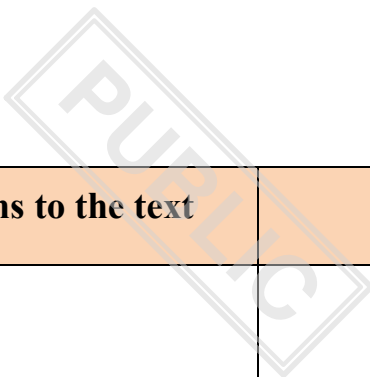
Presidency compromise	Suggested adaptations to the text	Comments
addressing an unmet medical need.		
<p>3. Where †The Agency shall adopts scientific guidelines for to support the application of this Article. To this end, it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].</p>		
<i>Article 84</i>		
<i>Data protection for repurposed medicinal products</i>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union <u>for the active substance(s)</u>, provided that:</p>		
<p>(a) adequate non-clinical <u>and</u> or clinical studies <u>and, where relevant, non-clinical studies/tests</u> were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and</p>		
<p>(b) the medicinal product is authorised in accordance with Articles 9 to 12, <u>with a different marketing authorisation holder than the reference medicinal product</u> and has</p>		

DK comments

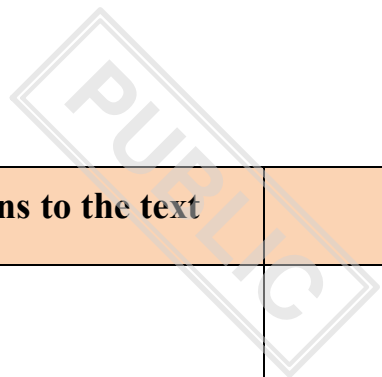


Presidency compromise	Suggested adaptations to the text	Comments
not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.		
2. The data protection period referred to in paragraph 1 may only be granted once for any given medicinal product.		
3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an		

DK comments

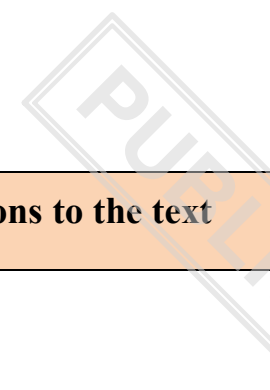
Presidency compromise	Suggested adaptations to the text	Comments
additional therapeutic indication.		
<i>Article 85</i>		Overall, we support that current rules are clarified and patients get access to generics with undue delay when the protection period for innovative medicines expires. This is important to ensure effective competition in the market and lower prices on medicine for patients.
<i>Exemption to the protection of intellectual property rights</i>		
<p>1. <u>The protection provided by p</u>Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument</p>		

DK comments



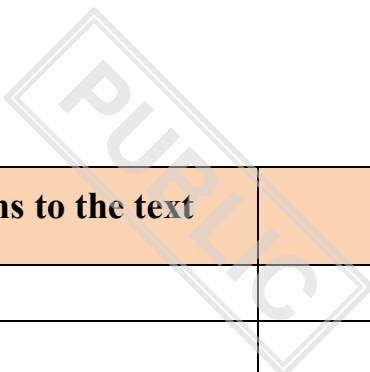
Presidency compromise	Suggested adaptations to the text	Comments
<p>when adopted] shall not be regarded as infringed when a reference patented product, or process, design or invention medicinal product is used for the purposes of:</p>		
<p>(a) studies, trials and other activities conducted to generate data necessary for an application, which are necessary for:</p>		
<p>(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;</p>		
<p>(ii) health technology assessment as defined in Regulation (EU) 2021/2282;</p>		
<p>(iii) pricing and reimbursement.</p>		

DK comments



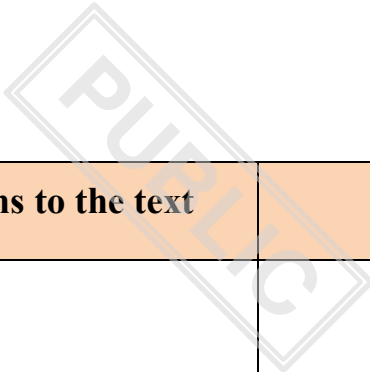
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>(aa) application on procurement tenders are submitted, in compliance with Union and national law,</u></p>		<p>Following comments made by several delegations and the Commission in the working party, it should be clarified under what circumstances an application on procurement tenders can be submitted while not infringing the protection of the patented product.</p>
<p>(b) the activities conducted exclusively for the purposes set out in point (a), may cover, <u>where relevant</u>, the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.</p>		

DK comments



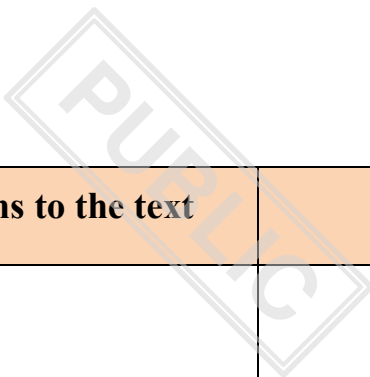
Presidency compromise	Suggested adaptations to the text	Comments
<p>2. <u>Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.</u></p>		
<p>3. This exception <u>provided for in this Article</u> shall not cover the placing on the market of the medicinal products resulting from such activities.</p>		
<p>1a. <u>Patent rights, or supplementary</u></p>		

DK comments



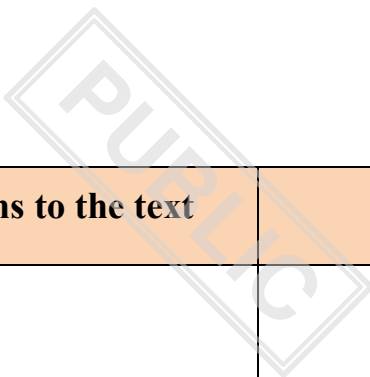
Presidency compromise	Suggested adaptations to the text	Comments
<p>protection certificates under the [Regulation (EC) No 469/2009 – OP please replace reference by new instrument when adopted] shall not be regarded as infringed by procurement bids and decisions on applications referred to in paragraph 1 point (a).</p>		
<p>1b. The procedures and decisions in Paragraph (1) and (1a) shall be considered by Member States as regulatory or administrative procedures which, as such, are independent from the enforcement of intellectual property rights.</p>		
<p>1c. The protection of intellectual property rights shall not be a valid ground to refuse, suspend, delay, withdraw or revoke decisions</p>		

DK comments



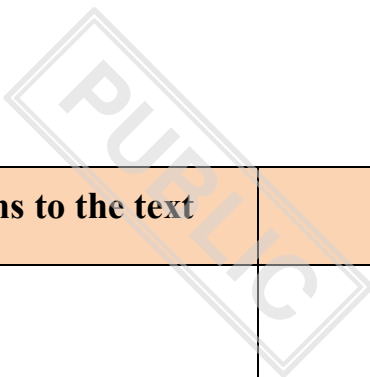
Presidency compromise	Suggested adaptations to the text	Comments
<p>related to the procedures referred to in paragraph (1) and (1a). This paragraph is without prejudice to national rules concerning pricing and reimbursement procedures that make the availability of a medicinal product on the market of that Member State conditional to submit an application of pricing and reimbursement, when those rules concern the applicant's activities that can be indirectly affected by intellectual property rights.</p>		
<p><u>Recitals 63-65</u></p>		
<p>(63) It is currently possible for applicants for marketing authorisation of generic,</p>		

DK comments



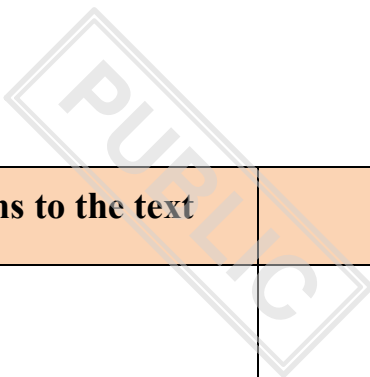
Presidency compromise	Suggested adaptations to the text	Comments
<p>biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be</p>		

DK comments



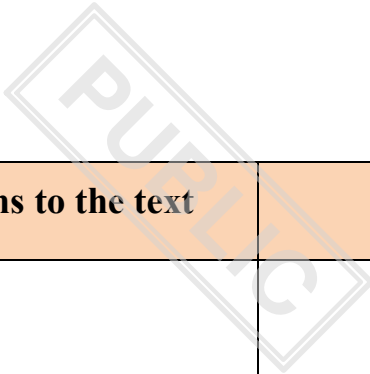
Presidency compromise	Suggested adaptations to the text	Comments
<p>confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process, <u>even in the cases of procurement tenders.</u></p>		
<p>(64) It will allow, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period,</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.</p>		
<p>(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.</p> <p>While this corresponds to the current</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>application of the regulatory framework of medicinal products, it seems appropriate to clarify it in this Directive for the avoidance of doubt. Similarly, the protection of intellectual property rights shall not be a valid ground to refuse or suspend decisions related to pricing and reimbursement or health technology assessment procedures. However, Member States should remain free to introduce a national requirement to prove the availability readiness to supply of a medicine medicinal product on the market of that Member State for the period when the patent and SPC has expired at the date of submission of the application for pricing and reimbursement.</u></p>		

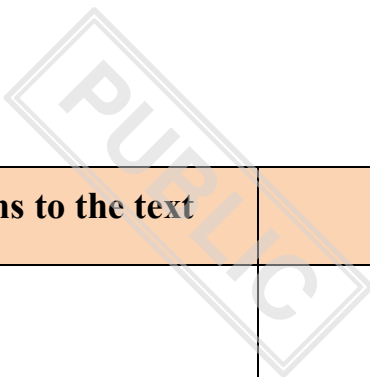
DK comments

Presidency compromise	Suggested adaptations to the text	Comments
<i>Article 86</i>		
<i>Rewards for paediatric medicinal products</i>		
<p>1. Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].</p>		
The first subparagraph shall also apply where		

DK comments

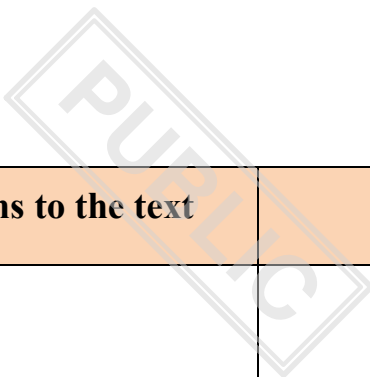
Presidency compromise	Suggested adaptations to the text	Comments
<p>completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.</p>		
<p>2. The inclusion in a marketing authorisation of the statement referred to in Article 49(2) of this Directive or in Article 90(2) of [revised Regulation (EC) No 726/2004] shall be used for the purposes of applying paragraph 1.</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>3. Where the procedures laid down in Chapter III, Sections 3 and 4, have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.</p>		
<p>4. In the case of an application for new paediatric therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of authorised medicinal products for a medicinal product which are is protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies</p>		

DK comments

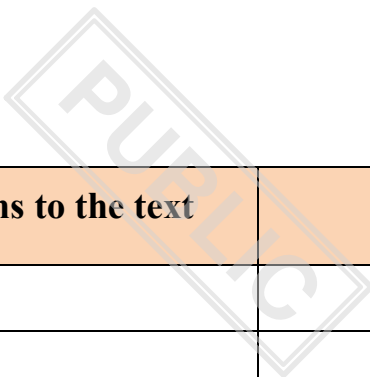


Presidency compromise	Suggested adaptations to the text	Comments
<p>for the granting of the supplementary protection certificate which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of marketing data market protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article 81(2), first subparagraph, point (d).</p>		
<p><u>Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending</u></p>		

DK comments

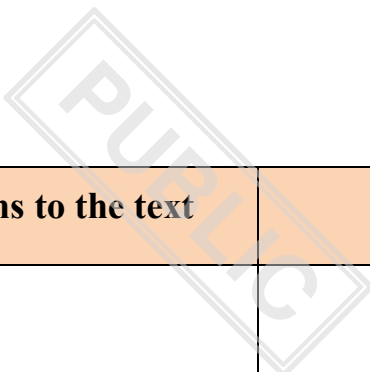
Presidency compromise	Suggested adaptations to the text	Comments
<u>Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006</u>		
ORPHAN INCENTIVES		
Chapter II GENERAL PROVISIONS AND RULES ON APPLICATIONS		

DK comments



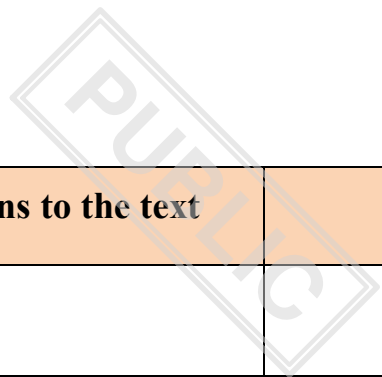
Presidency compromise	Suggested adaptations to the text	Comments
Section 2		
Marketing authorisation decisions		
<i>Article 29</i>		
<i>Regulatory protection periods</i>		
Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of		

DK comments



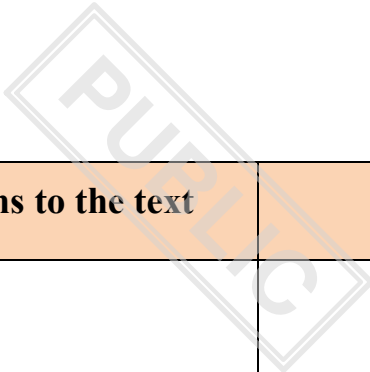
Presidency compromise	Suggested adaptations to the text	Comments
regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC].		
CHAPTER VI ORPHAN MEDICINAL PRODUCTS		
<i>Article 70</i>		
<i>Orphan medicinal products addressing a high unmet medical need</i>		
1. An orphan medicinal product shall be		

DK comments



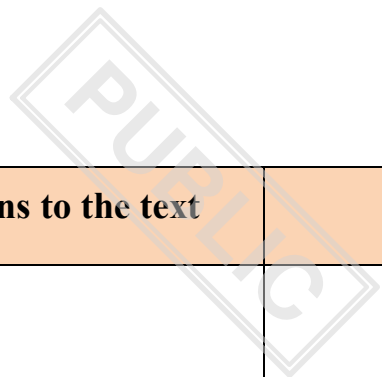
Presidency compromise	Suggested adaptations to the text	Comments
<p>considered as addressing a high unmet medical need where it fulfils the following requirements:</p>		
<p>(a) there is no <u>satisfactory method of diagnosis, prevention or treatment in standard of care</u> medicinal product authorised in the Union for such condition or where, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement;</p>		
<p>(b) the use of the orphan medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population. <u>The meaningful reduction in disease morbidity or mortality for the</u></p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>relevant patient population shall be demonstrated, where possible and appropriate, with data from clinical trials that use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency.</u></p>		
<p>2. A medicinal product for which an application has been submitted in accordance with Article 13 of [revised Directive 2001/83/EC] shall not be considered as addressing a high unmet medical need.</p>		
<p>3. Where t<u>The Agency shall</u> adopts</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>scientific guidelines for the application of this Article. To this end, it shall consult the Commission and the authorities or bodies referred to in Article 162.</p>		
<i>Article 71</i>		
<i>Market exclusivity</i>		
<p>1. Where an orphan marketing authorisation is granted and without prejudice to intellectual property law, the Union and the Member States shall not grant a marketing authorisation or extension of indication to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar</p>		

DK comments

Presidency compromise	Suggested adaptations to the text	Comments
medicinal product for the duration of market exclusivity set out in paragraph 2.		
2. The duration of market exclusivity shall be as follows:		
(a) nine ten years for orphan medicinal products other than those referred to in points (b) and (c);		
(b) ten years for orphan medicinal products addressing a high unmet medical need as referred to in Article 70;		
(c) five years for orphan medicinal products which have been authorised in accordance with		

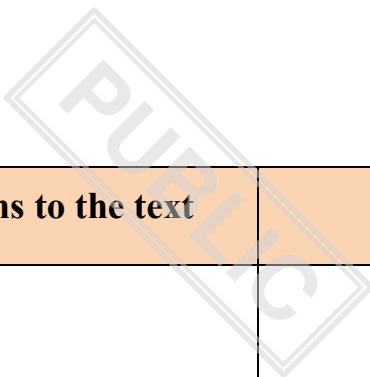
DK comments

Presidency compromise	Suggested adaptations to the text	Comments
Article 13 of [revised Directive 2001/83/EC].		
<p>3. Where a marketing authorisation holder holds more than one orphan marketing authorisations for the same active substance, those authorisations shall not benefit from separate market exclusivity periods. The duration of the market exclusivity shall start from the date when the first orphan marketing authorisation was granted in the Union.</p>		
<p>4. By way of derogation from paragraph 1, and without prejudice to intellectual property law, the marketing authorisation may be</p>		

DK comments

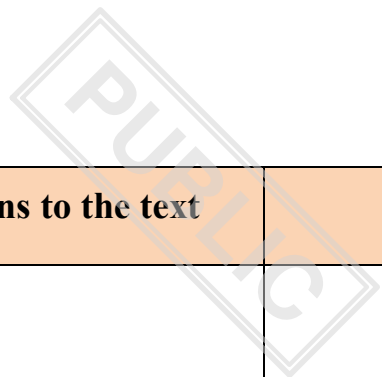
Presidency compromise	Suggested adaptations to the text	Comments
granted, for the same therapeutic indication, to a similar medicinal product if:		
(a) the marketing authorisation holder for the original orphan medicinal product has given consent to the second applicant, or		
(b) the marketing authorisation holder for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or		
(c) the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.		

DK comments



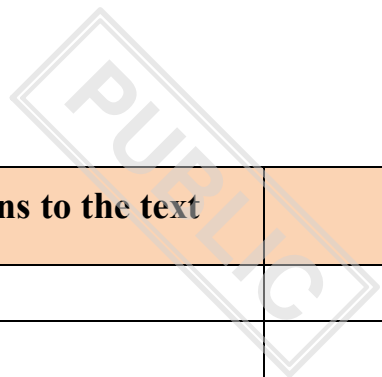
Presidency compromise	Suggested adaptations to the text	Comments
<p>5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing authorisation for a generic or biosimilar product to the reference medicinal product for which market exclusivity has expired, shall not be prevented by the market exclusivity of a similar product to the reference medicinal product.</p>		
<p>6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for <u>or granting</u> a marketing authorisation <u>for, a medicinal product or granting a marketing authorisation,</u> <u>including to extend an existing marketing</u></p>		<p>DK remains hesitant towards the term “granting a marketing authorization” as this is contradictory to the market exclusivity. We’d welcome the views of the Council Legal Service as well of the EC.</p>

DK comments



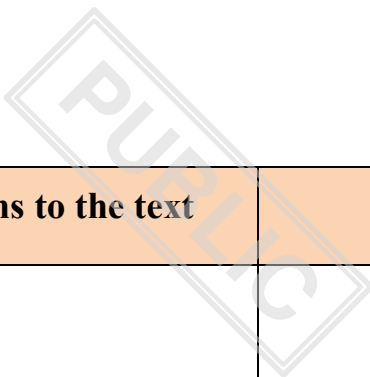
Presidency compromise	Suggested adaptations to the text	Comments
<p>authorisation for a new therapeutic indication or an extension of an existing marketing authorisation for of a similar medicinal product, including generics and biosimilars, where the remainder of the duration of the market exclusivity is less than two years.</p>		
<p>7. Where the Agency adopts scientific guidelines for the application of paragraphs 1 and 4, it shall consult the Commission.</p>		
<p><i>Article 72</i></p>		
<p><i>Prolongation of market exclusivity</i></p>		

DK comments



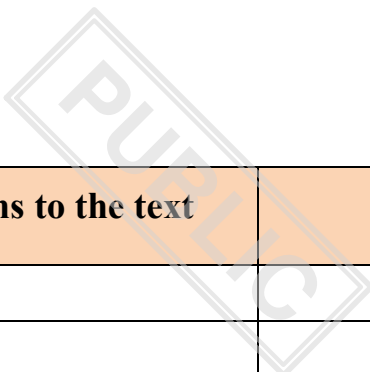
Presidency compromise	Suggested adaptations to the text	Comments
<p>1. — The periods of market exclusivity referred to in Article 71, paragraph 2, points (a) and (b), shall be prolonged by 12 months, where the orphan marketing authorisation holder can demonstrate that the conditions referred to in Article 81(2), point (a), and Article 82(1a) [of revised Directive 2001/83/EC] are fulfilled.</p>		
<p>The procedures set out in Articles 82(2) to (5) [of revised Directive 2001/83/EC] shall accordingly apply to the prolongation of market exclusivity.</p>		

DK comments



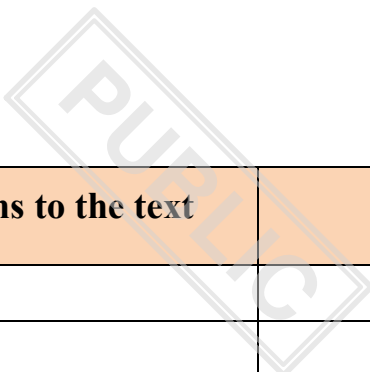
Presidency compromise	Suggested adaptations to the text	Comments
<p>2. The period of market exclusivity shall be prolonged by an additional 12 months for orphan medicinal products referred to in Article 71(2), points (a) and (b), if at least two years before the end of the exclusivity period, the orphan marketing authorisation holder obtains a marketing authorisation for one or more new therapeutic indications for a different orphan condition where such data were not available when the initial marketing authorisation was submitted.</p>		
<p>Such a prolongation may be granted twice, if the new therapeutic indications are each time for different orphan conditions.</p>		

DK comments



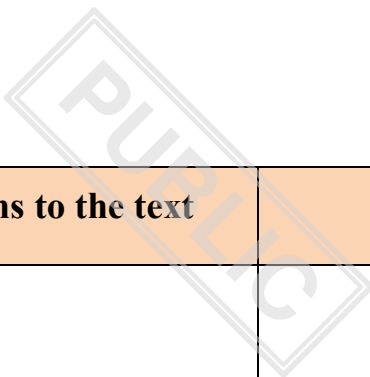
Presidency compromise	Suggested adaptations to the text	Comments
<p>3. The orphan medicinal products which benefit from the prolongation of market exclusivity referred to in the paragraph 2 shall not benefit from the additional period of data market protection referred to in Article 801(2); point (d), of [revised Directive 2001/83/EC].</p>		
<p>4. Article 71(3) equally applies to the prolongations of market exclusivity referred to in paragraphs 1 and 2.</p>		
<p>REPURPOSING BY ANOTHER ACTOR</p>		

DK comments



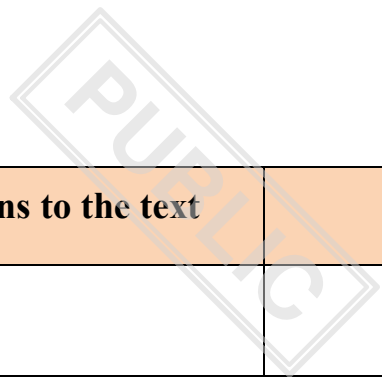
Presidency compromise	Suggested adaptations to the text	Comments
('CHAMPION')		
<p>CHAPTER IV POST-MARKETING AUTHORISATION MEASURES</p>		
<i>Article 48</i>		
<i>Scientific opinion on data submitted from not-for-profit entities for repurposing of authorised medicinal products</i>		
1. An entity not engaged in an economic		

DK comments



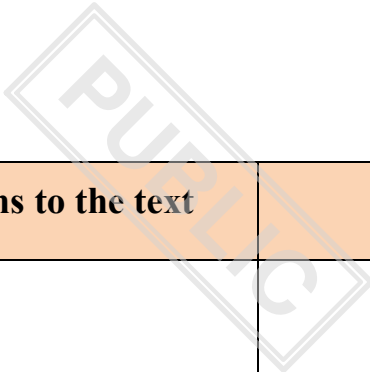
Presidency compromise	Suggested adaptations to the text	Comments
<p>activity ('not-for-profit entity') may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication that is expected to fulfil an unmet medical need.</p>		
<p>The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication that concerns an unmet medical need.</p>		
<p>The opinion of the Agency shall be made</p>		

DK comments



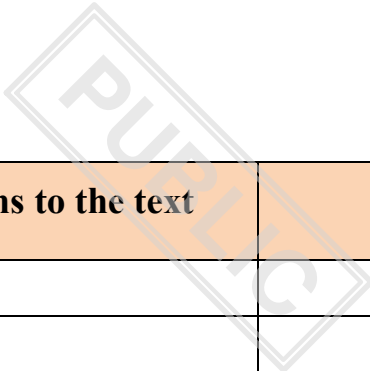
Presidency compromise	Suggested adaptations to the text	Comments
publicly available and the competent authorities of the Member States shall be informed.		
<p>2. In cases where the opinion is favourable, <u>and the new therapeutic indication addresses an unmet medical need, on the request of the Agency the Agency shall inform Member States and the Commission and request</u> the marketing authorisation holders of the medicinal products concerned <u>to</u> shall submit a variation to update the product information with the new therapeutic indication <u>in accordance with Article 47.</u></p>		<p>We still question why the obligation shall be based on a request from EMA in view of the fact that the provision is not limited to centrally authorised products.</p> <p>Secondly, we still wonder if it is legally possible to force the marketing authorisation holder to vary a marketing authorisation in view of an unmet medical need considering the company's autonomy?</p>

DK comments



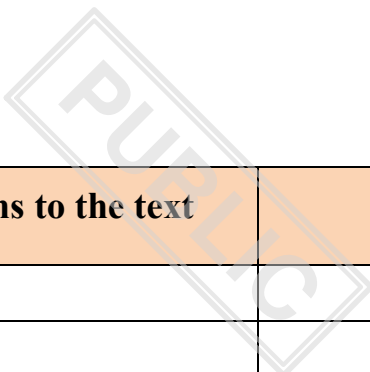
Presidency compromise	Suggested adaptations to the text	Comments
3. Article 80 1 (2), <u>2nd subparagraph</u> point (de) <u>and Article 84(1)</u> of [revised Directive 2001/83/EC] shall not apply for variations under this Article.		
<i>Article 4 (Directive)</i>		
<i>Definitions</i>		
(52) ‘entity not engaged in an economic activity’ means any legal or natural person that is not engaged in an economic activity and that:		
(a) is not an undertaking or controlled by an		

DK comments



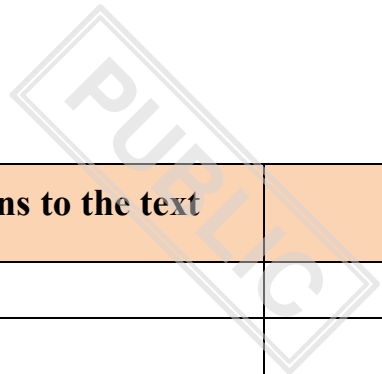
Presidency compromise	Suggested adaptations to the text	Comments
undertaking; and,		
(b) has not concluded any agreements with any undertaking concerning sponsorship or participation to the medicinal product development;		
PRE-AUTHORISATION REGULATORY SUPPORT		
CHAPTER V		
PRE-AUTHORISATION REGULATORY SUPPORT		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<i>Article 58</i>		
<i>Scientific advice</i>		
<p>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.</p>		
<p>Such advice can also be requested for medicinal products referred to in Articles 83 and 84 of [revised Directive 2001/83/EC].</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p>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.</p>		
<p>3. In the preparation of the scientific advice referred to in paragraph 1 and in duly justified cases, the Agency may consult authorities</p>		

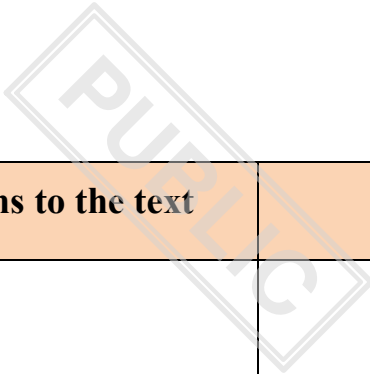
DK comments

Presidency compromise	Suggested adaptations to the text	Comments
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.		
4. The Agency shall include in the European public assessment report the key areas of the scientific advice once the corresponding marketing authorisation decision has been taken in relation to the medicinal product, after deletion of any information of a commercially confidential nature.		
<i>Article 59</i>		
<i>Parallel scientific advice</i>		

DK comments

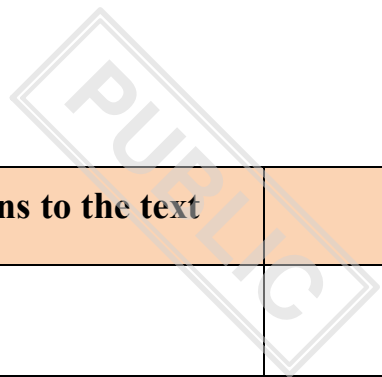
Presidency compromise	Suggested adaptations to the text	Comments
<p>1. Undertakings or, as relevant, not-for-profit entities established in the Union may request that the scientific advice referred to in Article 58(1) takes place in parallel to the joint scientific consultation carried out by the Member State Coordination Group on Health Technology Assessment, in line with Article 16(5) of Regulation (EU) 2021/2282.</p>		
<p>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</p>		

DK comments



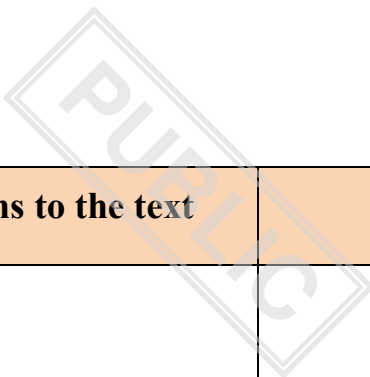
Presidency compromise	Suggested adaptations to the text	Comments
with the consultation of the expert panels referred to in Article 61(2) of Regulation (EU) 2017/745.		
3. In the case of paragraph 2, the scientific advice, as referred to in Article 58(1), shall involve exchanges of information between the respective authorities or bodies and, where applicable, have synchronised timing, while preserving the separation of their respective remits.		
<i>Article 60</i>		

DK comments



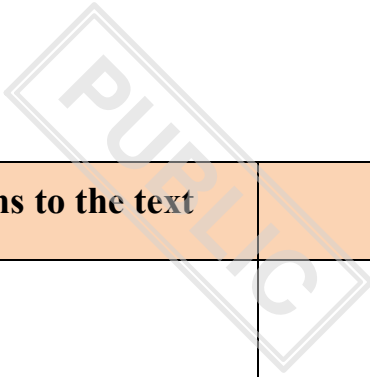
Presidency compromise	Suggested adaptations to the text	Comments
<i>Enhanced scientific and regulatory support for priority medicinal products ('PRIME')</i>		
<p>1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil at least one of the following conditions:</p>		
<p>(a) are likely to address an unmet medical need as referred to in Article 83(1) of [revised Directive 2001/83/EC];</p>		

DK comments



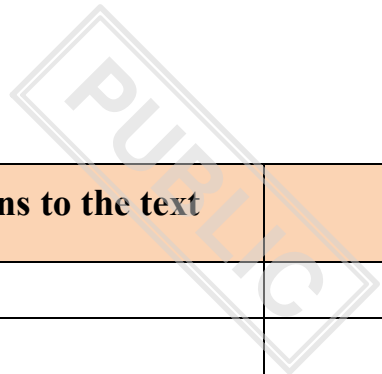
Presidency compromise	Suggested adaptations to the text	Comments
<p>(b) are orphan medicinal products <u>and are likely to bring exceptional therapeutic advancement</u> and are likely to address a high unmet medical need as referred to in Article 70(1);</p>		
<p>(c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3);</p>		
<p><u>(d) are likely to adress a neglected tropical disease (NTD).</u></p>		
<p>2. The Agency, at the request of the Commission and after consulting the EMA</p>		

DK comments



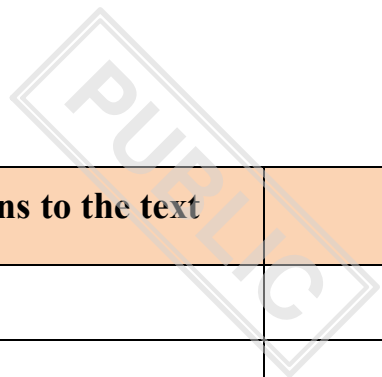
Presidency compromise	Suggested adaptations to the text	Comments
<p>Emergency Task Force, may offer enhanced scientific and regulatory support to developers of a medicinal product preventing, diagnosing or treating a disease resulting from serious cross border threats to health if access to such products is considered necessary to ensure high level of Union preparedness and response to health threats.</p>		
<p>3. The Agency may stop the enhanced support if it is established that the medicinal product will not address the identified unmet medical need <u>or does not have the potential to enhance preparedness and response to serious cross border health threats</u> to the anticipated extent.</p>		

DK comments



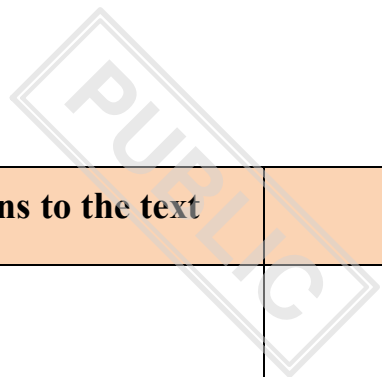
Presidency compromise	Suggested adaptations to the text	Comments
<p>4. The compliance of a medicinal product with the criteria set out in Article 83 of [revised Directive 2001/83/EC] shall be assessed on the basis of the relevant criteria, independently of whether it has received priority medicinal product support under this Article.</p>		
REGULATORY SANDBOXES		
CHAPTER IX		

DK comments



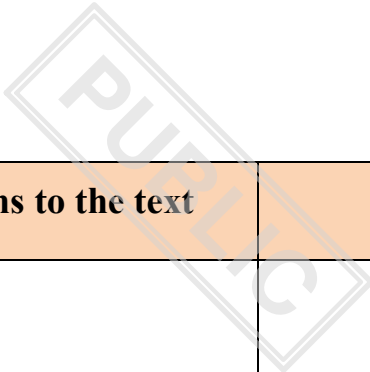
Presidency compromise	Suggested adaptations to the text	Comments
REGULATORY SANDBOX		
<i>Article 113</i>		
<i>Regulatory sandbox</i>		
<p>1. The Commission may set up a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency and pursuant to the procedure set out in paragraphs 4 to 7, where all the following conditions are met:</p>		
<p>(a) it is not possible to develop the medicinal product or category of medicinal products in compliance with the requirements applicable to</p>		

DK comments



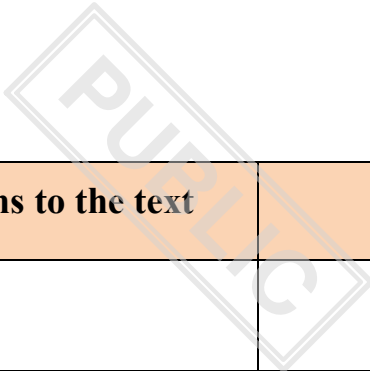
Presidency compromise	Suggested adaptations to the text	Comments
medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;		
(b) the characteristics or methods referred to in point (a) positively and distinctively contribute to the quality, safety or efficacy of the medicinal product or category of products or provide a major advantage contribution to patient access to treatment.		
2. The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1		

DK comments



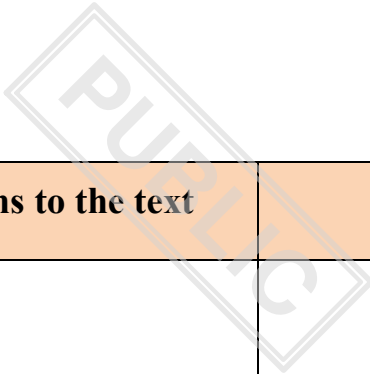
Presidency compromise	Suggested adaptations to the text	Comments
<p>under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, [revised Directive 2001/83/EC], or Regulation (EC) 1394/2007 or Regulation (EU) 536/2014 under the conditions set out in Article 114.</p>		
<p>A regulatory sandbox shall take effect under direct supervision of the competent authorities of the Member States concerned with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member State legislation concerned by the sandbox. Any violation of the conditions set out in the decision referred to in paragraph 6 and the identification of any risks to health and to</p>		

DK comments



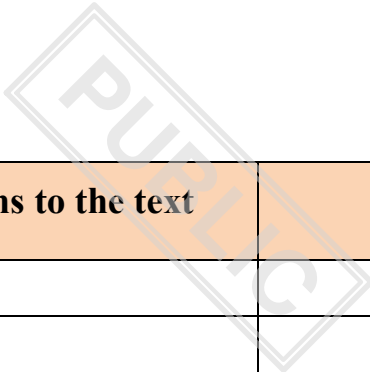
Presidency compromise	Suggested adaptations to the text	Comments
environment shall be immediately notified to the Commission and to the Agency.		
<p>3. The Agency shall monitor the field of emerging medicinal products and may request information and data from <u>the national competent authorities of the Member States,</u> marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions.</p>		
<p>4. Where the Agency considers it appropriate to set up a regulatory sandbox for medicinal products which are likely to fall under the scope</p>		

DK comments



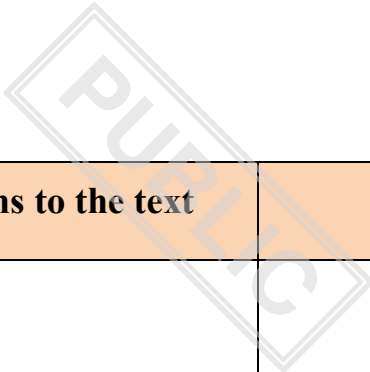
Presidency compromise	Suggested adaptations to the text	Comments
<p>of this Regulation, it shall, <u>following appropriate consultations including consultation with the competent authorities of the Member States,</u> provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the <u>recommended</u> sandbox plan referred to in paragraph 1.</p>		
<p>The Agency shall not recommend to set up a regulatory sandbox for a medicinal product that is already advanced in its development programme.</p>		

DK comments



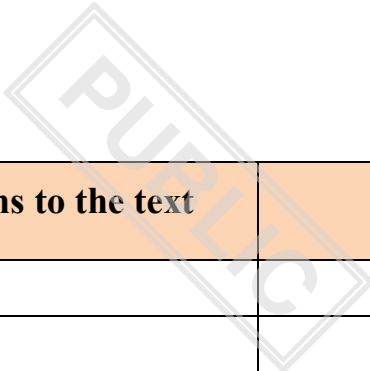
Presidency compromise	Suggested adaptations to the text	Comments
<p>5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations <u>including consultation with competent Authorities of the Member States</u>. The <u>sandbox</u> plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC]₅ <u>Regulation (EU) 536/2014</u> and Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The <u>sandbox</u> plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to</p>		

DK comments



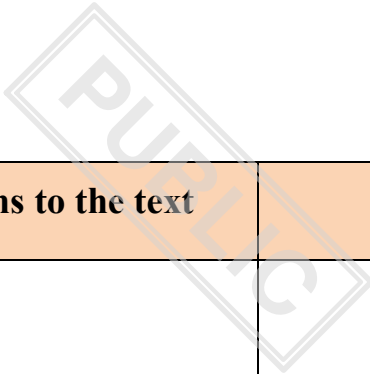
Presidency compromise	Suggested adaptations to the text	Comments
mitigate any possible distortion of market conditions as a consequence of establishing a regulatory sandbox .		
6. The Commission shall, by means of implementing acts, take a decision on the set up of a regulatory sandbox taking into account the recommendation of the Agency and the sandbox plan pursuant to paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).		
7. Decisions establishing a regulatory sandbox under paragraph 5 shall be limited in time and shall set out detailed conditions for its		

DK comments



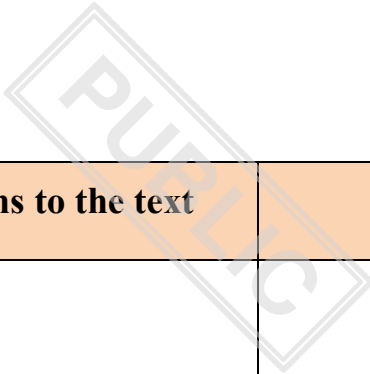
Presidency compromise	Suggested adaptations to the text	Comments
implementation. These Decisions shall:		
(a) include the proposed sandbox plan;		
(b) include the duration of the regulatory sandbox and its expiry;		
(c) include as part of the sandbox plan the requirements of this Regulation and of [revised Directive 2001/83/EC], Regulation (EC) 1394/2007 or Regulation (EU) 536/2014 that cannot be complied with and shall include appropriate measures to mitigate potential risks to health and to the environment.		
8. The Commission may, by means of		

DK comments



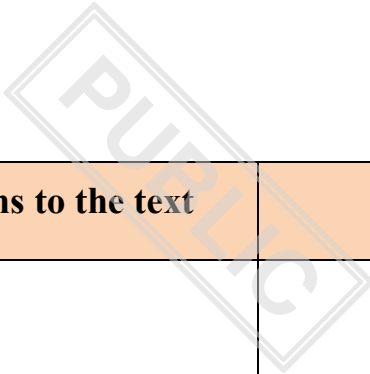
Presidency compromise	Suggested adaptations to the text	Comments
implementing acts, suspend or revoke a regulatory sandbox at any time. in any of the following cases:		
(a) the requirements and conditions laid down in paragraphs 6 and 7 are no longer met;		
(b) it is appropriate to protect public health.		
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).		
Where the Agency receives information that one		

DK comments



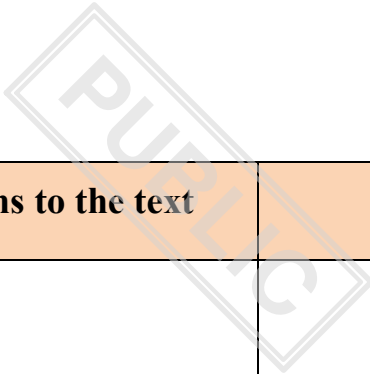
Presidency compromise	Suggested adaptations to the text	Comments
<p>of the cases referred to in the first subparagraph may be fulfilled, it shall inform the Commission accordingly.</p>		
<p>9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by the adoption of supplementary conditions, the Commission may, after consultation of the Agency, amend its decision <u>referred to paragraphs 7 or to restart the sandbox following a suspension under paragraph 8</u> by means of implementing acts. The Commission may also prolong the duration of a regulatory sandbox by means of implementing acts. Those</p>		

DK comments



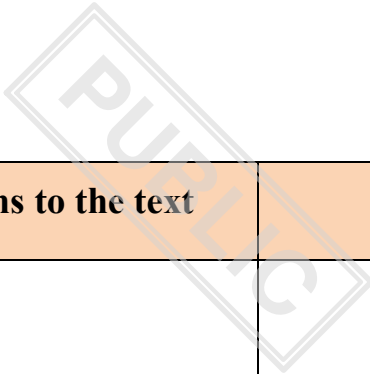
Presidency compromise	Suggested adaptations to the text	Comments
implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).		
10. This Article shall not exclude the setting up of time limited pilot projects to test different ways of implementing the applicable legislation.		
<i>Article 114</i>		
<i>Products developed under a sandbox</i>		
1. When authorising a clinical trial application for products covered by a regulatory		

DK comments



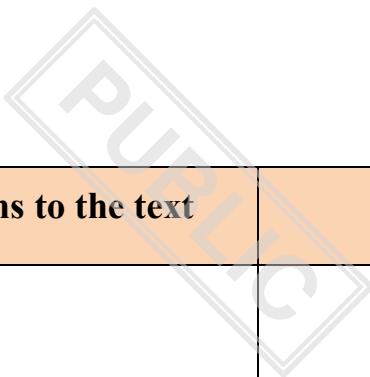
Presidency compromise	Suggested adaptations to the text	Comments
<p>sandbox, Member States shall take the sandbox plan referred to in Article 113(1) into consideration.</p>		
<p>2. A medicinal product developed as part of a regulatory sandbox may shall be placed on the market only when authorised in accordance with Article 5 of this Regulation. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may be prolonged at the request of the marketing authorisation holder.</p>		
<p>3. In duly justified cases, the marketing</p>		

DK comments



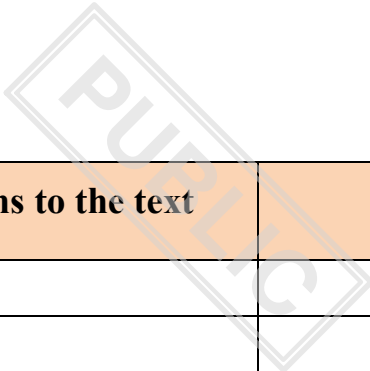
Presidency compromise	Suggested adaptations to the text	Comments
<p>authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation and [revised Directive 2001/83/EC], <u>Regulation (EC) 1394/2007 or Regulation (EU) 536/2014</u>. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation.</p>		
<p><u>These derogations shall not cover the ethical assessment organised pursuant to Article 8, paragraph 4 of Regulation (EU) 536/2014.</u></p>		

DK comments



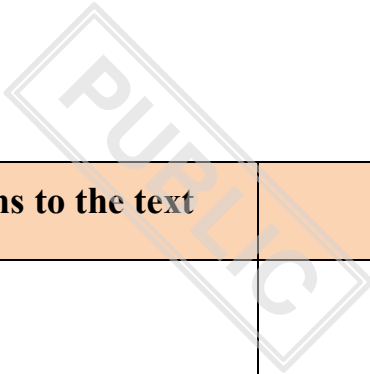
Presidency compromise	Suggested adaptations to the text	Comments
<p>4. For medicinal products developed as part of a regulatory sandbox for which a marketing authorisation has been granted in accordance with paragraph 2 and where appropriate paragraph 3, the summary of product characteristics and the package leaflet shall indicate that the medicinal product has been developed as part of a regulatory sandbox.</p>		
<p>5. Without prejudice to Article 195 of [revised Directive 2001/83/EC], the Commission shall suspend or revoke a marketing authorisation granted in accordance with paragraph 2, where the regulatory sandbox has been suspended or revoked in accordance with Article 113(7).</p>		

DK comments



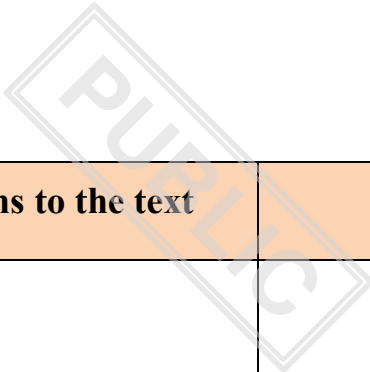
Presidency compromise	Suggested adaptations to the text	Comments
<p>6. The Commission shall immediately vary the marketing authorisation to take account of the mitigation measures taken in accordance with Article 115.</p>		
<p><i>Article 115</i></p>		
<p><i>General sandbox provisions</i></p>		
<p>1. The regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. In case of identification of risks to public health or safety concerns</p>		

DK comments



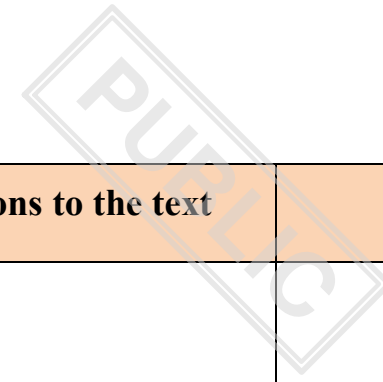
Presidency compromise	Suggested adaptations to the text	Comments
<p>associated with the use of products covered by a sandbox, competent authorities shall take immediate and adequate temporary measures in order to suspend or restrict their use and inform the Commission in accordance with Article 113(2).</p>		
<p>Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place.</p>		
<p>2. Participants in the regulatory sandbox, in particular the marketing authorisation holder of</p>		

DK comments



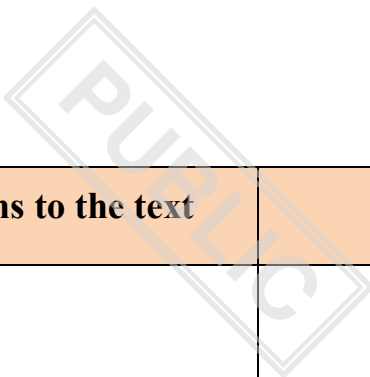
Presidency compromise	Suggested adaptations to the text	Comments
<p>the medicinal product concerned, shall remain is without prejudice to rules related to liability under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the testing taking place in the sandbox. 2a. They Entities implementing the sandbox shall inform the Agency without undue delay of any information which might entail the amendment of the regulatory sandbox or concerns the quality, safety or efficacy of products developed as part of a regulatory sandbox.</p>		
<p><u>Recital 135</u></p>		
<p>The establishment of a regulatory sandbox should be based on a Commission implementing Decision, following a</p>		

DK comments



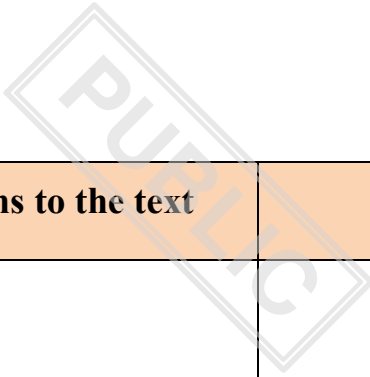
Presidency compromise	Suggested adaptations to the text	Comments
<p>recommendation of <u>after having consulted</u> the Agency. Such decision should be based on a detailed plan outlining the particularities of the sandbox as well as describing the products to be covered. A regulatory sandbox should be limited in duration and may<u>could</u> be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox are capable of <u>should</u> informing future changes to the legal framework <u>in order</u> to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks may<u>could</u> be developed by the Commission on the basis of the results of a regulatory sandbox. <u>Marketing Authorisations under a sandbox should be granted on the basis of the same regulatory principles of</u></p>		

DK comments



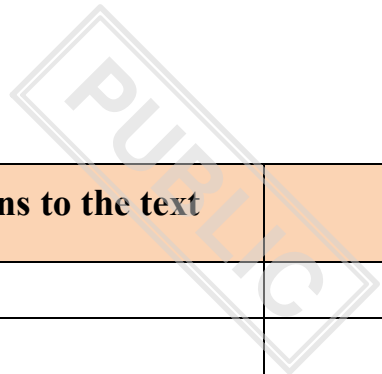
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>quality, safety and efficacy as other medicinal products. The regulatory sandbox should not affect the supervisory and corrective powers of the competent authorities and the liability of the participants, such as clinical trial sponsors, marketing authorisation holders, applicants for marketing authorisation, or any entities involved in the lifecycle of the medicinal product.</u></p>		
<p>3. The modalities and the conditions of the operation of the regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in</p>		

DK comments



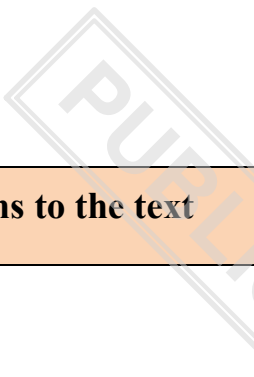
Presidency compromise	Suggested adaptations to the text	Comments
implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).		
4. The Agency with input from Member States shall submit annual reports to the Commission on the results from the implementation of a regulatory sandbox, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legal acts supervised within the sandbox. These reports shall be made publicly available by the Commission.		

DK comments



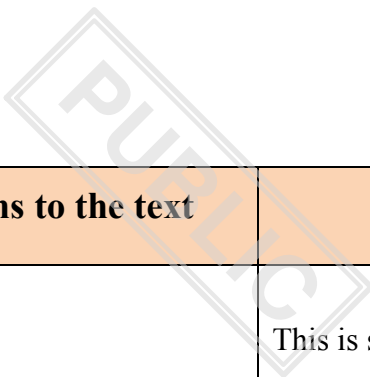
Presidency compromise	Suggested adaptations to the text	Comments
<p>5. The Commission shall review the reports and put forward, as appropriate, legislative proposals with a view to update the regulatory framework referred to in Article 113(2) or delegated acts in accordance with Article 28 of [revised Directive 2001/83/EC].</p>		
<p>CHAPTER III INCENTIVES FOR THE DEVELOPMENT OF ‘PRIORITY ANTIMICROBIALS’</p>		
<p><i>Article 40</i></p>		<p>We acknowledge the Presidency’s attempt to</p>

DK comments



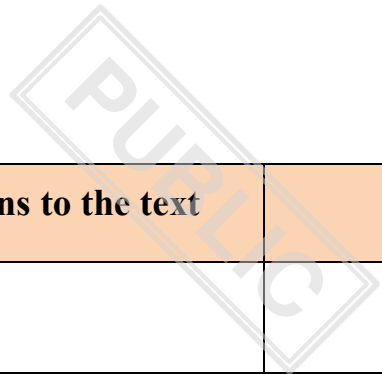
Presidency compromise	Suggested adaptations to the text	Comments
		<p>address the concerns that the proposed transferable exclusivity voucher could entail unpredictable costs for Member States.</p> <p>We have a scrutiny reservation. We are still skeptical whether the proposal will be cost effective.</p> <p>Meanwhile, we have an idea for an alternative voucher model that we would like to discuss further with the Presidency and Member States.</p> <p>We propose that the designation of a developer of a priority antimicrobial gives right to a priority voucher with a legal right to PRIME and accelerated assessment of 120 days. The voucher may be used for any medicinal product and sold to another company.</p>

DK comments



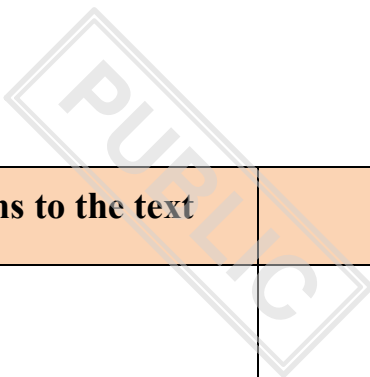
Presidency compromise	Suggested adaptations to the text	Comments
		<p>This is similar to a measure used in the US (FDA's Priority Review Voucher Programs) and it is intended to avoid the cost of the voucher being passed directly to patients and the budgets of our national health systems.</p> <p>We acknowledge that the value of a priority voucher would be less than the data exclusivity voucher. Based on experience from the US, a priority voucher could possibly have a value around 100 million EUR. We still believe that a priority voucher could bring significant funding and thereby promote the development of new antimicrobials. A priority voucher can also work together with other initiatives that can be explored outside the pharmaceutical legislation.</p>

DK comments



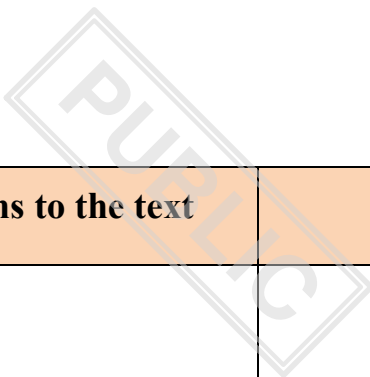
Presidency compromise	Suggested adaptations to the text	Comments
<i>Granting the right to a transferable data exclusivity voucher</i>		
<p>1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a ‘priority antimicrobial’ referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.</p>		
<p>2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional</p>		

DK comments



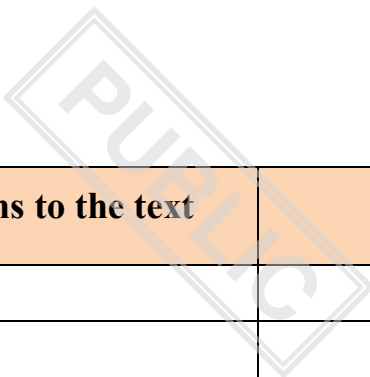
Presidency compromise	Suggested adaptations to the text	Comments
<p>12 months of data protection <u>within the meaning of Article 80 paragraph 1 of [revised Directive 2001/83/EC]</u> for one authorised medicinal product.</p>		
<p>3. An antimicrobial shall be considered ‘priority antimicrobial’ if <u>it addresses a multi-drug resistant organism and serious or a life-threatening infection, the</u> preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:</p>		
<p>(a) it represents a new class of antimicrobials;</p>		

DK comments



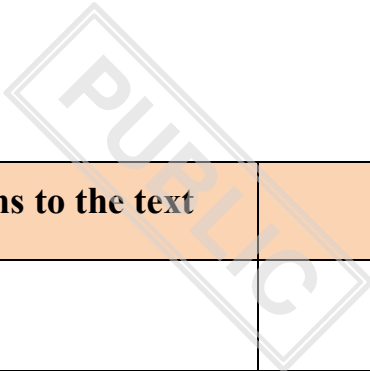
Presidency compromise	Suggested adaptations to the text	Comments
(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;		
(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.		
In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the ‘WHO priority pathogens list for R&D of new antibiotics’, or an equivalent list established at Union level.		

DK comments



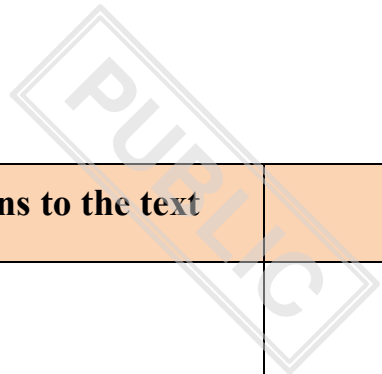
Presidency compromise	Suggested adaptations to the text	Comments
4. To be granted the voucher by the Commission, the applicant shall:		
(a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;		
(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.		
<u>(c) demonstrate that the application for granting a marketing authorisation of the priority antimicrobial has been first submitted to the Agency or has been submitted no later than 90 days after the submission of the application for the first</u>		

DK comments



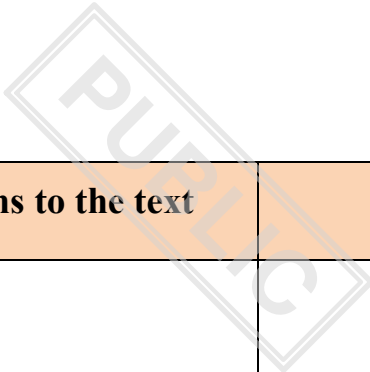
Presidency compromise	Suggested adaptations to the text	Comments
<u>marketing authorisation outside the European Union.</u>		
<p>Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.</p>		
<p><u>5. Once the marketing authorisation is granted, the Agency shall inform without undue delay the MSSG, in accordance with</u></p>		

DK comments



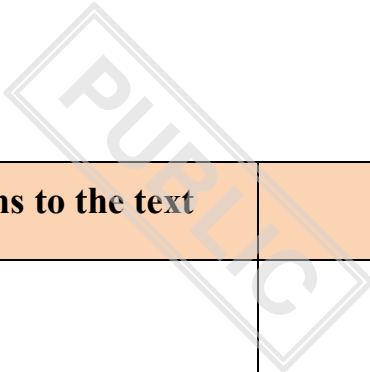
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>Article 130 131 paragraph 2, second subparagraph, to initiate the procedure with a view to propose a for the potential inclusion of the priority antimicrobial on the Union list of critical medicinal products, in agreement with the procedure set out in Article 131 of the Regulation.</u></p>		
<p><u>5. — When adopting the implementing act referred to in paragraph 1, the estimated cost of the voucher, including the actual and expected costs of already used vouchers, and the risk of overcompensation based on the data provided in accordance with paragraph 4(b) shall be considered in addition to the conditions in paragraph 1. In case the</u></p>		

DK comments



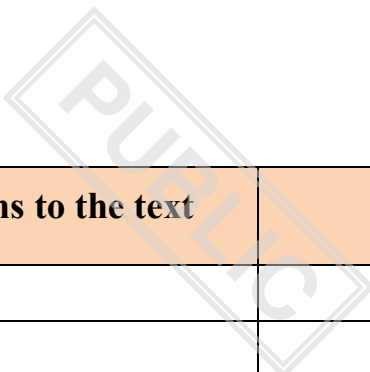
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>estimated cost of the voucher, including the actual and expected costs of already used vouchers, and the risk of overcompensation, overrides the clinical benefit with respect to antimicrobial resistance, the voucher shall not be granted.</u></p>		
<p><i>Article 170</i></p>		
<p><i>Evaluation</i></p>		
<p>(...)</p>		
<p><u>6. The Commission shall, following the use of two vouchers or every 5 years pursuant to Article 41, paragraph 2, carry out an evaluation of Chapter III of this Regulation and present a report on the main findings of</u></p>		

DK comments



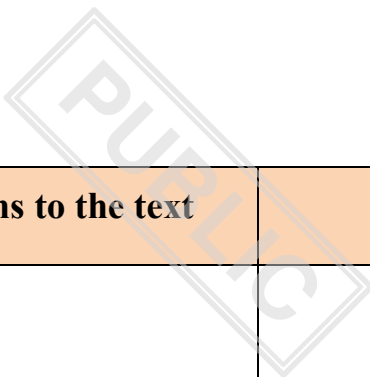
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>that evaluation to the European Parliament and the Council. The evaluation shall include an assessment of the effectiveness of the voucher as a measures, taking into account also other existing Union level market incentives for authorised priority antimicrobials, to address the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the actual and expected costs. The Commission shall, if appropriate, present a legislative proposal, based on the evaluation, in order to amend this Regulation.</u></p>		
<p><i>Article 41</i></p>		

DK comments



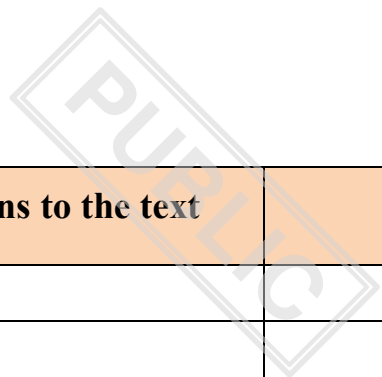
Presidency compromise	Suggested adaptations to the text	Comments
<i>Transfer and use of the voucher</i>		
<p>1. A voucher may be used to extend the data protection for a period of 12 months within the meaning of Article 80 paragraph 1 of [revised Directive 2001/83/EC], of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.</p>		
<p>A voucher can be transferred at any time before its use. A voucher may shall only be used once only and in relation to a single</p>		

DK comments



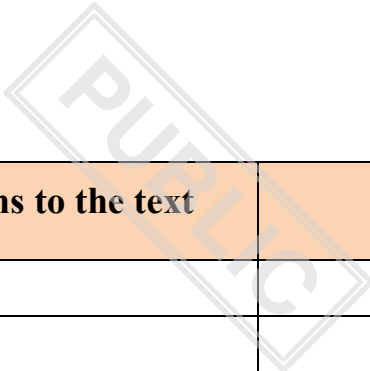
Presidency compromise	Suggested adaptations to the text	Comments
centrally authorised medicinal product, and only if that product is within its first six four years of regulatory data protection.		
<p><u>In case of a medicinal product other than the priority antimicrobial concerned, while the the voucher can be transferred any time before the use, the use of the voucher can take place only in the fifth sixth year of the regulatory data protection period and if the marketing authorisation holder demonstrates that the and its average annual gross sales of the that medicinal products in the Union during any of the Y years preceding four years the use of the voucher does not have not exceeded X 490 million euros.</u></p>		

DK comments



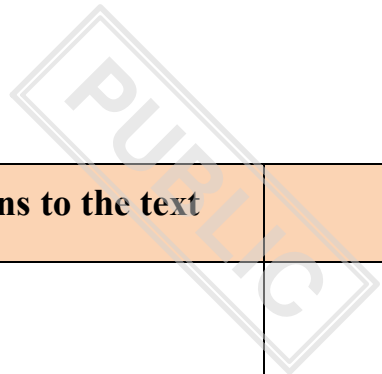
Presidency compromise	Suggested adaptations to the text	Comments
<p>A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.</p>		
<p><u>1a. The marketing authorisation holder shall demonstrate that information about the annual gross sales referred to in para (1) is accurate and complete and that it has been audited by an independent external auditor.</u></p>		
<p><u>The additional data protection period shall not apply if the annual gross sales of the medicinal product concerned in the Union exceeds the amount referred to in point 1 of</u></p>		

DK comments



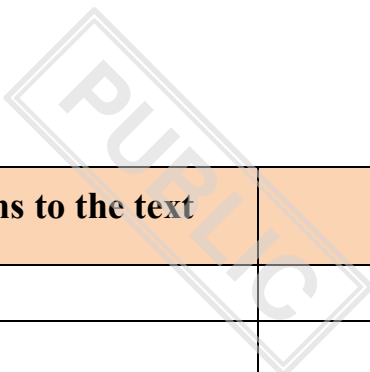
Presidency compromise	Suggested adaptations to the text	Comments
<u>this Article.</u>		
<p><u>The Commission is empowered to adopt delegated acts in accordance with Article 175 of this Regulation to adjust this amount with the rate of the inflation.</u></p>		
<p>A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.</p>		

DK comments



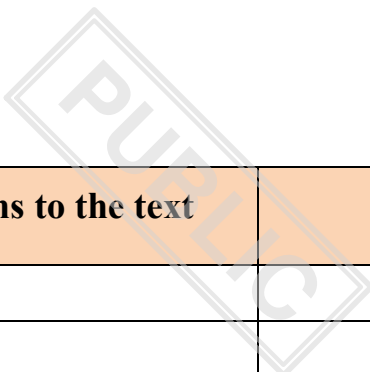
Presidency compromise	Suggested adaptations to the text	Comments
<p>2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.</p>		
<p>3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.</p>		
<p>4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly</p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
available <u>on its webpage</u> .		
<i>Article 42</i>		
<i>Validity of the voucher</i>		
1. A voucher shall cease to be valid in the following cases:		
(a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product;		
(b) where it is not used within 5 years from		

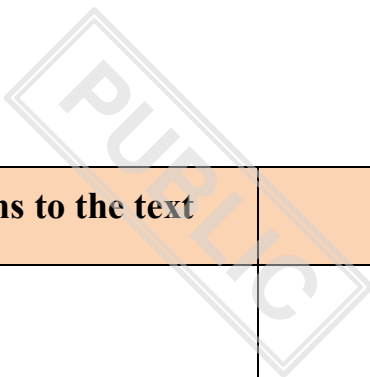
DK comments



Presidency compromise	Suggested adaptations to the text	Comments
the date it was granted.		
2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply <u>by any Member State or the Commission</u> , procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.		
3. Without prejudice to patent rights, or supplementary protection certificates ⁵ , if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC],		

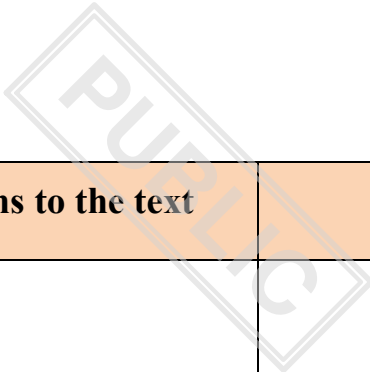
⁵ Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).

DK comments



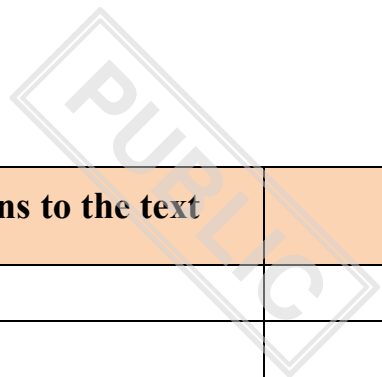
Presidency compromise	Suggested adaptations to the text	Comments
those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II, Section 2 of [revised Directive 2001/83].		
<i>Article 43</i>		
<i>Duration of application of Chapter III</i>		
This Chapter shall apply, subject taking to into		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>account of the outcome of the evaluations referred to in Article 170 paragraph 6</u>, until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.</p>		
<p><u>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</u></p>		
<p><i>Article 4</i></p>		

DK comments



Presidency compromise	Suggested adaptations to the text	Comments
<i>Definitions</i>		
(22) ‘antimicrobial’ means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, and antifungals <u>and antiprotozoals</u> ;		