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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

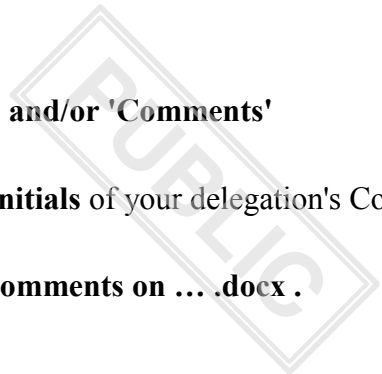
Delegations will find enclosed comments from the Danish delegation on incentives (ST 13037/24).

Please add your contributions in the table below, only in the columns '**Drafting**' and/or '**Comments**'

Name of document: please rename the MS Word document by adding the **two initials** of your delegation's Country followed by a space.

Only then you may add any text to the file name, for example, for Austria: **AT comments ondocx .**

Thank you for your cooperation!



Presidency compromise	Suggested adaptations to the text	Comments
<u>General comments</u>		DENMARK
<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>		
ADAPTED FRAMEWORKS		

Presidency compromise	Suggested adaptations to the text	Comments
Chapter II Application requirements for national and centralised marketing authorisations		
Section 5		
Adapted dossier requirements		
<i>Article 28</i>		
<i>Adapted frameworks due to the characteristics or methods inherent to the medicinal product <u>or category of medicinal products</u></i>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>1. Medicinal products <u>or category of medicinal products</u> listed in Annex VII shall be subject to specific scientific or regulatory requirements due to the characteristics or methods inherent to the medicinal product <u>or category of medicinal products</u>, when:</p>		
<p>(a) it is not possible to adequately assess the 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 characteristics or methods inherent to the medicinal product <u>or category of medicinal products</u>; and</p>		
<p>(b) the characteristics or methods <u>inherent to the medicinal product or category of medicinal products</u> positively impact the</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>quality, safety and efficacy of the medicinal product or category of medicinal product or provide a major contribution to patient access to prevention, diagnosis, or treatment or any other form of patient care.</p>		
<p>2. Based on a recommendation by After having consulted the Agency, tThe Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the list of medicinal products or categories of medicinal products listed in the list of areas of adapted frameworks under Annex VII in order to take account of scientific and technical progress.</p>		
<p>3. The Commission may adopt implementing acts is empowered to adopt</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>delegated implementing acts in accordance with Article 215 214 to supplement this Directive by laying down:</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>		
<p>(b) — the technical documentation to be submitted by applicants for marketing authorisations for medicinal products referred to in paragraph 1.</p>		
<p><u>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><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 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>It is still not entirely clear to us how para 3 and para 3a differ from each another.</p>
<p><u>4. The Commission shall, taking into account a scientific assessment by the Agency, specify whether those requirements</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>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. The 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.</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>5. Until the adoption of specific detailed rules for specific medicinal products or category of medicinal products 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>"Paragraph 3" should be replaced by "paragraph 3a".</p>
<p>6. When adopting implementing and delegated acts or implementing acts 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>		

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>		
1. The data referred to in Annex I, originally submitted with the view to obtaining a		

Presidency compromise	Suggested adaptations to the text	Comments
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').		
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.		We suggest "referred to in Article 81" instead of "referred to in paragraph 1". Paragraph 1 refers to Article 81 (the regulatory data protection period).
<p><u>The period shall be extended to three years if, during the regulatory data protection period referred to in paragraph 1, the marketing authorisation holder concerned obtains an authorisation for one or more new</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>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> 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 marketing authorisation was submitted.</p>		
<p>3. By way of derogation from paragraph 1, the marketing authorisation holder concerned</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 <u>under conditions laid out in Union or national law</u> to address a public health emergency, the <u>relevant</u> data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during <u>for</u> the duration <u>and the territory of the Member States for which</u> period of the compulsory licence <u>has been granted</u>.</p>		

Presidency compromise	Suggested adaptations to the text	Comments
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><u>5a. 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</u></p>		

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<p>(n) of the [revised Regulation (EC) No 726/2004].¹ <u>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>		
<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</u></p>		<p>For practical reasons all DCPs equivalent to today's article 8(3), 10a, 10b and 10c (full dossier) could be automatically transferred to the table from CTS provisionally with the date of EoP (Day 210). It would then be in the MAH's interest to submit the real date of</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.

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<p><u>with paragraph 5a. If the National competent authority does not inform the Agency on its objection within 8 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 paragraph, the data related to data and market protection periods indicated in the database shall remain unchanged.</u></p>		<p>earliest MA. All MS concerned (RMS+CMS) would have to be notified to confirm the date entered by the MAH, i.e. to check that the national MA was not granted at an earlier date in their MS.</p> <p>For purely National MAs that MS would be responsible for notifying EMA?</p> <p>8 days is a very short deadline and doesn't match that at least initially it will be used to calculate an expiry of data protection [x] years later.</p> <p>A non-answer may not be sufficient to establish the data protection period. Active confirmation by the MS concerned is considered more appropriate</p>
<p><i>Article 81</i></p>		<p>Our position is unchanged from the Council meeting in June when it comes to the data</p>

Presidency compromise	Suggested adaptations to the text	Comments
		<p>protection period. The current 8 year period provides the necessary foresight and stability to ensure a predictable framework for investments in the European lifes science industry and will ensure that European patients will have access to the newest and best treatments available.</p> <p>The proposed modulated system will be too complex and unpredictable and will probably lead to legal disputes. Modulation should not be a goal in itself. If it is we risk ending up with the same bureaucratic nightmare as we have with the MDR/IVDR which is damaging access to medical devices in the EU. Better access to medicines must be addressed in the package in a new article if we are to ensure a balanced compromise in the final text. DK is working on a suggestion that we hope can contribute to better access without moving into national competencies.</p>

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<i>Regulatory data protection periods</i>		
<p>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 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: The data protection period</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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:</p>		
<p>(a) — 24 months, where the marketing authorisation holder demonstrates that the 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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 establishment of the undertaking or the group, whichever is earliest.</p>		
<p><u>Option A)</u></p>		
<p><u>(c)(a) 12 months if</u></p>		
<p><u>(i) the marketing authorisation holder demonstrates that a significant substantial share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in collaboration</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union, or.</p>		
<p>(ii) the clinical trials supporting the initial marketing authorisation application use a relevant and evidence based comparator taking into account the scientific advice provided by the Agency;</p>		
<p>(b) 12 months if six months, where</p>		
<p>(i) 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; or</p>		

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<p>(cii)— six months for medicinal products containing a new active substance, where for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with taking into account the scientific advice provided by the Agency;</p>		
<p>(d)— 12 months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit in comparison with existing therapies.</p>		
<p><u>Option B)</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>(a) — 12 months if the marketing authorisation holder demonstrates that a substantial share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union,</p>		
<p>(b) — 12 months if</p>		
<p>(i) — the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<u>medical need as referred to in Article 83;</u>		
<u>or</u>		
<u>(ii) the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator taking into account the scientific advice provided by the Agency;</u>		
<u>Option C)</u>		
<u>The data protection period referred to in paragraph 1 shall be prolonged by the following periods not exceeding 8 year in total by:</u>		

Presidency compromise	Suggested adaptations to the text	Comments
<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>		
<p><u>(b) 12-6 months for medicinal products containing a new active substance, 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) 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</u></p>		

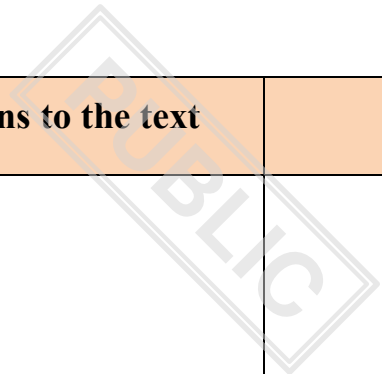
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>product has been done within the Union and at least partly in collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union.</u></p>		
<p><u>(d) 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>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>		

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 (b), shall only apply be considered as met 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</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>marketing authorisation was granted. [This 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) (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>		

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 of specific criteria for the designation of significant substantial share of research and development is done within the Union.</u></p>		
<p><i>Article 82</i></p>		
<p><i>Prolongation of the data protection period for medicinal products supplied in Member States</i></p>		
<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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.</p>		
<p>2. To receive a prolongation referred to in</p>		



Presidency compromise	Suggested adaptations to the text	Comments
<p>Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.</p>		
<p>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.</p>		
<p>The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:</p>		

Presidency compromise	Suggested adaptations to the text	Comments
(a) — confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or		
(b) — waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation.		
Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC ² shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a).		

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).

Presidency compromise	Suggested adaptations to the text	Comments
<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 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>		

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<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.</p> <p>For medicinal products granted a marketing 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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>Committee established by Council Decision 75/320/EEC³ ('Pharmaceutical Committee').</p> <p>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.</p>		
<p>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).</p>		

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

Presidency compromise	Suggested adaptations to the text	Comments
Chapter V		
Obligations and liability of the marketing authorisation holder		
<u>Article 56a</u>		<p>Denmark fully agrees that we must ensure that all member states can access the medicines they want access to and we acknowledge the presidency’s attempt to strengthen access to medicines across the EU. However, we see many legal challenges in the Presidency’s approach that we have highlighted below. We have to bear in mind, that access is a very complex matter that is very much linked to the national framework of individual Member States. There is also the question of what</p>

Presidency compromise	Suggested adaptations to the text	Comments
		constitutes making a product available? What if an agreement cannot be reached on price? Will this mean that the company is not in compliance?
<p><i><u>Specific requirements</u> Obligation to-on making available market launch and continuously supplying of a medicinal product on the market in a Member State</i></p>		
<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</u></p>		<p>Firstly, Denmark has severe doubts if para 1 this is legally possible and therefore kindly ask the Council Legal Service of its opinion.</p> <p>Secondly, we are unsure what is meant by “make available” and when a “supply” is fulfilled.</p> <p>Thirdly, if we assume the approach to be legally sound we still have severe concerns how this</p>

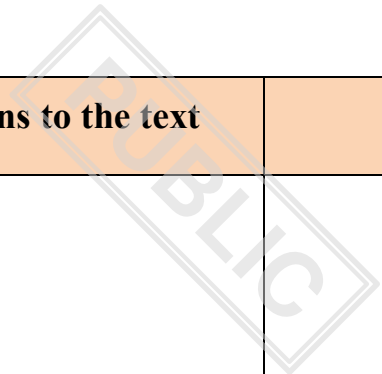
Presidency compromise	Suggested adaptations to the text	Comments
<p><u>request the marketing authorisation holder of that medicinal product to make it available and continuously supply on the market of that Member State in a sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as specified by that Member State.</u></p>		<p>provision should be enforced in practice and if it is at all possible.</p> <ul style="list-style-type: none"> • Lastly, we are highly concerned that the requirement would be counterproductive and thus lead to the entirely opposite effect.
<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>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 supply plan.</p> <p>However, we believe that the provision could be written in a more straight forward way providing Member States with a mandate according to which they may require the marketing authorisation holder to apply for</p>

Presidency compromise	Suggested adaptations to the text	Comments
		pricing and reimbursement. This is on condition that such obligation is not linked to regulatory protection.
a) <u>meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;</u>		
b) <u>fulfilling specific requirements for marketing authorisation holders in procurement procedures;</u>		
c) <u>establishing a supply plan.</u>		
<u>Such requirements shall be proportionate to the objective pursued and in compliance with Union law.</u>		We believe that this sentence should be deleted, as any requirement should always be proportionate and in compliance with Union law.
3. <u>The supply plan referred to in</u>		We are uncertain what happens in case of

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>paragraph 2, point (c), shall include information about the supply of the medicinal product by the marketing authorisation holder over a given period in the Member State concerned. The supply 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 plan.</u></p>		<p>disagreement a Member State and a MAH.</p>
<p><u>4. When a Member State decides to avail itself of the obligation in paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within one year from the marketing authorisation for that medicinal product.</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>5. Where within 5 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 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>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>6. The Member State shall make this information 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>		
<p>7. This Article is without prejudice to Member States' legislation and procedures aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation.</p>		



Presidency compromise	Suggested adaptations to the text	Comments
<p><u>This Article shall also not affect the right of marketing authorisation holders to release 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.</u></p>		
<p><u>1. Pursuant to Article 56 paragraph 1, for medicinal products authorised in accordance with this Directive and the [revised</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>Regulation (EC) No 726/2004], when a Member State considers it necessary for the purpose of making a medicinal product available on its market, guaranteeing an appropriate and continued supply of a specific medicinal product to the patient in that Member State, that Member State shall require that the marketing authorisation holder of that medicinal product to carriesy out at least one or more of the following: In case of medicinal products granted a centralised marketing authorisation in accordance with [revised Regulation (EC) No 726/2004] of the Regulation, or that have been granted a national marketing authorisation through the decentralised procedure, as referred to in Chapter III, Section 3, the marketing authorisation holder shall, in accordance withas the requested of by a Member State,</p>		

Presidency compromise	Suggested adaptations to the text	Comments
(a) — submit an application for pricing and reimbursement concerning that medicinal product; or		
(b) — participate in any procurement procedures necessary to meet the needs of the patients in that Member State pursuant to national law implemented in accordance with the national legislation ; or		
(c) — make the product otherwise available on the market offer the medicinal product to designated supply chain operators.		
For the purpose of letter c, Member States shall designate the operators whose supply is deemed necessary to meet the needs of the		

Presidency compromise	Suggested adaptations to the text	Comments
<p>patients in that Member State. The designation shall be carried out in a proportionate manner.</p>		
<p>2. — For the application of paragraph 1, the Member States shall may make communicate the requestsrequirements set out in paragraph 1 at the earliest latest one three years before the end of the regulatory data protection period, pursuant to Article 80(1), for that medicinal product or, if the marketing authorisation holder is an SME within the meaning of Commission Recommendation 2003/361/EC, two years after the granting of the marketing authorisation. The requirements shall include a deadline for the marketing authorisation holders to comply with the actions pursuant to paragraph 1.</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>3. For the application of paragraph 1, the Member State shall indicate the a deadline for submission or participation, which shall be no shorter than 3 months. In addition, the Member States shall indicate the minimum quantity of the authorised medicinal product, that it considers as sufficient to meet the needs in that Member State.</p>		
<p>4. When complying with the relevant obligations in accordance with paragraph 1 During the application or the participation referred to in paragraph 1, the marketing authorisation holder shall apply make its offer under reasonable terms. The terms shall be considered reasonable if, taking into</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>account all circumstances, they the marketing authorisation holder prove the intention of the marketing authorisation holder to</p>		
<p>(a) — make, within the limits of its responsibility, the medicinal product available on the market concerned and continuously supply it the quantity indicated by the Member State under paragraph (2), during the whole period of the protection provided by patent protection, regulatory data protection or market exclusivity in that Member State,</p>		
<p>(b) — applies, overall, conditions that are not unjustifiably more disadvantageous than the conditions to those applied in another Member State in a similar situation, taking into account, among others, the Purchasing</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>Power Parities set out in Regulation (EC) No 1445/2007 of the European Parliament and of the Council of 11 December 2007 establishing common rules for the provision of basic information on Purchasing Power Parities and for their calculation and dissemination.</u></p>		
<p><u>5. — With a view to comply with the obligations laid down in Article 56(3), the Member State may require the marketing authorisation holder to establish, regularly update and implement a supply plan for the given medicinal product Unless waived by the Member State, for the application of point (a), the marketing authorisation holder shall present and implement a supply plan as a part of its application or participation referred to in paragraph 1 that will ensure that, within the limits of the responsibility of the marketing authorisation holder, the</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>medicinal product is continuously supplied into the supply chain in a sufficient quantity, within the timelines laid down in paragraph 2.</p>		
<p>6. — Where the marketing authorisation holder does not comply with its obligations in accordance with this Article in a Member State, Article 80, paragraph 2, shall not apply within that Member State. conditions set out in paragraph (1) and (4) are not met:</p>		
<p>The Member State may communicate the name of the marketing authorisation holder subject to this paragraph to the Agency, which shall make this information public.</p>		
<p>(a) — the protection referred to in Article 80</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<u>paragraph (2) does not apply in the Member State concerned.</u>		
<u>(b) — the Member State may also apply penalties, such as the penalties set out in Article 206 (4) to (6).</u>		
<u>Recital:</u>		
<u>Access to medicinal products in all Member States and guaranteeing a 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 an adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests,</u>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is 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 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 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</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>procurement procedures or make the product available in the supply chain. 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 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>		
<i>Article 166</i>		Scrutiny reservation in view of our comments to Article 56a.
<i>Obligations of the wholesale distribution authorisation holder</i>		

Presidency compromise	Suggested adaptations to the text	Comments
<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 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>		
<i>Article 216</i>		Scrutiny reservation in view of our comments to Article 56a.

Presidency compromise	Suggested adaptations to the text	Comments
<i>Report</i>		
<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 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>2. <u>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 include an assessment whether the rules provided for in that Article ensures timely availability and continuous supply of</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>medicinal products in a sufficient quantity in all Member States that have applied that Article.</u></p>		
<p>Chapter XVI General provisions</p>		
<p><u>Article 206</u></p>		
<p><u>Penalties</u></p>		
<p>2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:</p>		
<p>(a) the manufacturing, distribution, brokering,</p>		

Presidency compromise	Suggested adaptations to the text	Comments
import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;		
<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>		In view of our comments to Article 56a, Denmark cannot support this provision. Moreover, supply is national competence. Sanctions are therefore equally a national matter.
(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;		
(c) non-compliance with the provisions laid down in this Directive on the use of excipients;		
(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;		

Presidency compromise	Suggested adaptations to the text	Comments
(e) non-compliance with the provisions laid down in this Directive on advertising.		
<p><u>4. Without prejudice to the national rules on penalties referred to in paragraph 1, Where the marketing authorisation holder fails to comply withinfringes the its obligations set out pursuant to set outpursuant to in Article 56a, including, if applicable, the implementation of the supply plan, Member States may decide to impose a administrative fines not exceeding theup to 5% of the marketing authorisation holder’s Union annual turnover within the Union in the business year preceding the date of that decisionof the preceding financial year.</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>5. <u>Without prejudice to the national legislation on financial penalties, where the marketing authorisation holder continues to fail to comply repeatedly infringes the obligations set out pursuant to with its obligations referred to in Article 56a, the Member State may decide to impose, until the day of compliance and until the expiry of the patent protection, regulatory data protection or market exclusivity, periodic penalty payments per day not exceeding up to 2,5 % of the marketing authorisation holder's average daily Union turnover within the Union of the preceding financial year. in the business year preceding the date of that decision.</u></p>		
<p><u>Periodic penalty payments may be imposed</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>for a period running from the date of notification of the relevant Member State decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in Article 56, paragraphs 1 and 3 has been brought to an end.</u></p>		
<p><u>6. Member States may send the Agency their decision referred to paragraphs 4 and 5, and the Agency shall make this decision public.</u></p>		
<p>Chapter VII</p>		
<p>Regulatory protection, unmet</p>		

Presidency compromise	Suggested adaptations to the text	Comments
medical needs and rewards for paediatric medicinal products		
<i>Article 83</i>		
<i>Medicinal products addressing an unmet medical need</i>		
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 the following conditions are met:		

Presidency compromise	Suggested adaptations to the text	Comments
<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>		
<p>(b) the use of the medicinal product results in 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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
with scientific advice provided by the Agency.		
2. Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as addressing an unmet medical need.		
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].		
<i>Article 84</i>		

Presidency compromise	Suggested adaptations to the text	Comments
<i>Data protection for repurposed medicinal products</i>		
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 for the active substance(s) , provided that:		
(a) adequate non-clinical and or clinical studies and, where relevant, non-clinical studies/tests were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and		
(b) the medicinal product is authorised in accordance with Articles 9 to 12, with a		

Presidency compromise	Suggested adaptations to the text	Comments
<p>different marketing authorisation holder than the reference medicinal product and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.</p>		
<p>2. The data protection period referred to in paragraph 1 may only be granted once for any given medicinal product.</p>		
<p>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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
additional therapeutic indication.		
<i>Article 85</i>		
<i>Exemption to the protection of intellectual property rights</i>		
<p>1. Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument 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>		

Presidency compromise	Suggested adaptations to the text	Comments
(a) studies, trials and other activities conducted to generate data for an application, <u>which are necessary</u> for:		
(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;		
(ii) health technology assessment as defined in Regulation (EU) 2021/2282;		
(iii) pricing and reimbursement.		
(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		

Presidency compromise	Suggested adaptations to the text	Comments
and purchase of patented medicinal products or processes, including by third party suppliers and service providers.		
This exception shall not cover the placing on the market of the medicinal products resulting from such activities.		
<p><u>1a. Patent rights, or supplementary 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).</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>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.</u></p>		
<p><u>1c. The protection of intellectual property rights shall not be a valid ground to refuse, suspend, delay, withdraw or revoke decisions 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</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>application of pricing and reimbursement, when those rules concern the applicant's activities that can be indirectly affected by intellectual property rights.</u></p>		
<p><u>Recital 65</u></p>		
<p>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><u>While this corresponds to the current application of the regulatory framework of</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>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 of a medicine on the market of that Member State at the date of submission of the application for pricing and reimbursement.</u></p>		
<p><i>Article 86</i></p>		
<p><i>Rewards for paediatric medicinal products</i></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<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>		
<p>The first subparagraph shall also apply where 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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
appropriate, in the package leaflet of the medicinal product concerned.		
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.		
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.		
4. In the case of an application for new		Note that reference should be made to Article

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 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>		80(2).

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 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</p>		
<p>ORPHAN INCENTIVES</p>		

Presidency compromise	Suggested adaptations to the text	Comments
Chapter II GENERAL PROVISIONS AND RULES ON APPLICATIONS		
Section 2		
Marketing authorisation decisions		
<i>Article 29</i>		
<i>Regulatory protection periods</i>		
Without prejudice to the law on the protection		

Presidency compromise	Suggested adaptations to the text	Comments
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 regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC].		
CHAPTER VI ORPHAN MEDICINAL PRODUCTS		
<i>Article 70</i>		As said during our previous discussion of this article, we don't agree with the deletion of this article as we support the intention of the Commissions' proposal to promote development of orphan medicinal products that address a high

Presidency compromise	Suggested adaptations to the text	Comments
		unmet medical need.
<i>Orphan medicinal products addressing a high unmet medical need</i>		
<p>1. An orphan medicinal product shall be 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>		

Presidency compromise	Suggested adaptations to the text	Comments
<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 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>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>3. Where t<u>The Agency shall</u> adopts scientific guidelines for the application of this Article. <u>To this end</u>, 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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>extension of indication to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product for the duration of market exclusivity set out in paragraph 2.</p>		
<p>2. The duration of market exclusivity shall be as follows:</p>		
<p>(a) nine ten years for orphan medicinal products other than those referred to in points (b) and (c);</p>		
<p>(b) ten years for orphan medicinal products addressing a high unmet medical need as referred to in Article 70;</p>		
<p>(c) five years for orphan medicinal products</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].</p>		
<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 granted, for the same therapeutic indication, to a</p>		

Presidency compromise	Suggested adaptations to the text	Comments
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.		
5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 or granting a marketing authorisation for, a medicinal product or granting a marketing authorisation, including to extend an existing marketing 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</p>	<p>The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for or granting a marketing authorisation for, a medicinal product or granting a marketing authorisation, including to extend an existing marketing 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</p>	<p>We have a proposal to make the article more precise.</p>

Presidency compromise	Suggested adaptations to the text	Comments
of the market exclusivity is less than two years.	<p>two years. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for a marketing authorisation with the same therapeutic indication for a similar medicinal product, including generics and biosimilars, or the submission, validation and assessment of an application (variation) for the addition of the same therapeutic indication to an existing marketing authorisation for a similar medicinal product, where the remainder of the duration of the market exclusivity of the orphan medicinal product is less than two years.</p>	
7. Where the Agency adopts scientific guidelines for the application of paragraphs 1 and 4, it shall consult the Commission.		

Presidency compromise	Suggested adaptations to the text	Comments
<i>Article 72</i>		
<i>Prolongation of market exclusivity</i>		
<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>		

Presidency compromise	Suggested adaptations to the text	Comments
<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>		
<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>We welcome the deletion of the text (“where such data were not available when the initial marketing authorisation was submitted”)</p>
<p>Such a prolongation may be granted twice, if the</p>		

Presidency compromise	Suggested adaptations to the text	Comments
new therapeutic indications are each time for different orphan conditions.		
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 80 4 (2); point (d) , of [revised Directive 2001/83/EC].		
4. Article 71(3) equally applies to the prolongations of market exclusivity referred to in paragraphs 1 and 2.		

Presidency compromise	Suggested adaptations to the text	Comments
REPURPOSING BY ANOTHER ACTOR (‘CHAMPION’)		
CHAPTER IV POST-MARKETING AUTHORISATION MEASURES		
<i>Article 48</i>		
<i>Scientific opinion on data submitted from not-for-profit entities for repurposing of authorised medicinal products</i>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>1. An entity not engaged in an economic 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>We 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 in question to vary a marketing authorisation in view of an unmet medical need considering that the company's autonomy.</p>

Presidency compromise	Suggested adaptations to the text	Comments
The opinion of the Agency shall be made 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 to shall submit a variation to update the product information with the new therapeutic indication <u>in accordance with Article 47.</u></p>		
3. Article 80 1 (2), <u>2nd subparagraph</u> point		

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

Presidency compromise	Suggested adaptations to the text	Comments
(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		
<i>Article 58</i>		

Presidency compromise	Suggested adaptations to the text	Comments
<i>Scientific advice</i>		
1. Undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 138(1), second subparagraph, point (p) , from the Agency.		
Such advice can also be requested for medicinal products referred to in Articles 83 and 84 of [revised Directive 2001/83/EC].		
2. In the preparation of the scientific advice		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 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.</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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.</p>		
<i>Article 59</i>		
<i>Parallel scientific advice</i>		
<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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
Member State Coordination Group on Health Technology Assessment, in line with Article 16(5) of Regulation (EU) 2021/2282.		
2. In case of medicinal products involving a medical device, undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 58(1) in parallel with the consultation of the expert panels referred to in Article 61(2) of Regulation (EU) 2017/745.		
3. In the case of paragraph 2, the scientific advice, as referred to in Article 58(1), shall involve exchanges of information between the respective authorities or bodies and, where		

Presidency compromise	Suggested adaptations to the text	Comments
applicable, have synchronised timing, while preserving the separation of their respective remits.		
<i>Article 60</i>		
<i>Enhanced scientific and regulatory support for priority medicinal products ('PRIME')</i>		
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		During previous meetings we have discussed the draw on resources in a PRIME context. If the conditions a to c are no longer cumulative access to PRIME will be broadened. We wonder if this is feasible.

Presidency compromise	Suggested adaptations to the text	Comments
conditions:		
(a) are likely to address an unmet medical need as referred to in Article 83(1) of [revised Directive 2001/83/EC];		
(b) are orphan medicinal products and are likely to bring exceptional therapeutic advancement and are likely to address a high unmet medical need as referred to in Article 70(1);		
(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);		
(d) are likely to address a neglected tropical		

Presidency compromise	Suggested adaptations to the text	Comments
<u>disease (NTD).</u>		
<p>2. The Agency, at the request of the Commission and after consulting the EMA 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</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<u>serious cross border health threats</u> to the anticipated extent.		
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.		
REGULATORY SANDBOXES		
CHAPTER IX		

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 medicinal products due to scientific or regulatory challenges arising from</p>		

Presidency compromise	Suggested adaptations to the text	Comments
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 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)		

Presidency compromise	Suggested adaptations to the text	Comments
1394/2007 or Regulation (EU) 536/2014 under the conditions set out in Article 114.		
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 environment shall be immediately notified to the Commission and to the Agency.		
3. The Agency shall monitor the field of emerging medicinal products and may request information and data from <u>the national</u>		

Presidency compromise	Suggested adaptations to the text	Comments
<p><u>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 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 sandbox plan referred to in</p>		

Presidency compromise	Suggested adaptations to the text	Comments
paragraph 1.		
The Agency shall not recommend to set up a regulatory sandbox for a medicinal product that is already advanced in its development programme.		
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		

Presidency compromise	Suggested adaptations to the text	Comments
<p>Regulation, [revised Directive 2001/83/EC], Regulation (EU) 536/2014 and Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The sandbox plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory sandbox.</p>		
<p>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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
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 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.		

Presidency compromise	Suggested adaptations to the text	Comments
<p>8. The Commission may, by means of implementing acts, suspend or revoke a regulatory sandbox at any time. in any of the following cases:</p>		
<p>(a) the requirements and conditions laid down in paragraphs 6 and 7 are no longer met;</p>		
<p>(b) it is appropriate to protect public health.</p>		
<p>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).</p>		

Presidency compromise	Suggested adaptations to the text	Comments
Where the Agency receives information that one of the cases referred to in the first subparagraph may be fulfilled, it shall inform the Commission accordingly.		
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		

Presidency compromise	Suggested adaptations to the text	Comments
sandbox by means of implementing acts. Those 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		

Presidency compromise	Suggested adaptations to the text	Comments
sandbox, Member States shall take the sandbox plan referred to in Article 113(1) into consideration.		
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.		
3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include		

Presidency compromise	Suggested adaptations to the text	Comments
<p>derogations from the requirements set out in this Regulation and [revised Directive 2001/83/EC], Regulation (EC) 1394/2007 or Regulation (EU) 536/2014. 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>These derogations shall not cover the ethical assessment organised pursuant to Article 8, paragraph 4 of Regulation (EU) 536/2014.</p>		
<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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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>		
<p>6. The Commission shall immediately vary the marketing authorisation to take account of the mitigation measures taken in accordance</p>		

Presidency compromise	Suggested adaptations to the text	Comments
with Article 115.		
<i>Article 115</i>		
<i>General sandbox provisions</i>		
<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 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>		

Presidency compromise	Suggested adaptations to the text	Comments
<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 the medicinal product concerned, shall remain is <u>without prejudice to rules related to liability</u> 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 <u>Entities implementing the sandbox</u> shall inform the Agency without undue delay of any information which might entail the amendment of the regulatory sandbox or concerns the quality,</p>		

Presidency compromise	Suggested adaptations to the text	Comments
safety or efficacy of products developed as part of a regulatory sandbox.		
<u>Recital 135</u>		
<p>The establishment of a regulatory sandbox should be based on a Commission implementing Decision, following a recommendation of after having consulted 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 maycould be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox are capable of should informing future changes to the legal framework in order to fully integrate the particular innovative aspects into the medicinal product</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).</p>		
<p>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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
available by the Commission.		
<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>The fight against AMR is a high priority for the Danish government. Targeted measures to promote development of new antibiotics should be addressed at a European level. It is key that we strike the right balance in order to ensure predictability and balanced costs.</p> <p>We are skeptical about the proposed “transferable exclusivity voucher”, as we are concerned that the voucher could entail</p>

Presidency compromise	Suggested adaptations to the text	Comments
		<p>unpredictable costs for Member States that do not necessarily match the benefits.</p> <p>We would therefore prefer to explore alternative options for new targeted incentives for new antibiotics. But we are open to discuss proposals to improve the voucher model.</p>
<i>Article 40</i>		
<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</p>		

Presidency compromise	Suggested adaptations to the text	Comments
<p>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 12 months of data protection for one authorised medicinal product.</p>		
<p>3. An antimicrobial shall be considered ‘priority antimicrobial’ if 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>		

Presidency compromise	Suggested adaptations to the text	Comments
(a) it represents a new class of antimicrobials;		
(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.		

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.		
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		

Presidency compromise	Suggested adaptations to the text	Comments
the Agency.		
<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 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>		

Presidency compromise	Suggested adaptations to the text	Comments
<i>Article 170</i>		
<i>Evaluation</i>		
(...)		
<p><u>6. The Commission shall, following the use of two vouchers 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 that evaluation to the European Parliament and the Council. The evaluation shall include an assessment of the effectiveness of the measures 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</u></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<u>evaluation, in order to amend this Regulation.</u>		
<i>Article 41</i>		
<i>Transfer and use of the voucher</i>		
1. A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.		
A voucher shall only be used once and in		

Presidency compromise	Suggested adaptations to the text	Comments
<p>relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection <u>and its average annual gross sales in the Union during the Y years preceding the use of the voucher does not exceed X million euros.</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>		
<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>		

Presidency compromise	Suggested adaptations to the text	Comments
<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 available <u>on its webpage</u>.</p>		
<p><i>Article 42</i></p>		

Presidency compromise	Suggested adaptations to the text	Comments
<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 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, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.		

Presidency compromise	Suggested adaptations to the text	Comments
<p>3. Without prejudice to patent rights, or supplementary protection certificates⁴, 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], 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].</p>		

⁴ Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).

Presidency compromise	Suggested adaptations to the text	Comments
<i>Article 43</i>		
<i>Duration of application of Chapter III</i>		
<p>This Chapter shall apply until [<i>Note to OP: insert the date of 15 years after the date of entry into force of this Regulation</i>] 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>		

Presidency compromise	Suggested adaptations to the text	Comments
<i>Article 4</i>		
<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> ;		Denmark has a scrutiny reservation on this definition.