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LIMITE

SAN **VETER**
PHARM **ENV**
MI **RECH**
COMPET **CODEC**
PI

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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 delegations

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

Incentives 15044_24 Deadline: ***20 November 2024***

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Guidelines to be followed

Please kindly provide your contributions in the table below.

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

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

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

Thank you for your cooperation!

Presidency compromise	Suggested adaptations to the text and Comments
General comments	
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	

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Presidency compromise	Suggested adaptations to the text and Comments
ADAPTED FRAMEWORKS	
Chapter II **Application requirements for national and centralised marketing authorisations**	
Section 5	
Adapted dossier requirements	

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Presidency compromise	Suggested adaptations to the text and Comments
Article 28	
Adapted frameworks due to the characteristics or methods inherent to the medicinal product ***or category of medicinal products***	
1. Medicinal products **or category of medicinal products** listed in Annex VII shall be subject to **adapted** ~~specific~~ scientific or regulatory requirements **('adapted framework')** due to the characteristics or methods inherent to the medicinal product **or category of medicinal products~~,~~. A medicinal product or category of medicinal products shall be listed in Annex VII** when:	

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(a) it is not possible to adequately assess the medicinal product or category of medicinal products applying the applicable requirements **set out in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007** due to scientific or regulatory challenges arising from **objective and scientific** characteristics or methods inherent to the medicinal product **or category of medicinal products**; and	NL (Suggested adaptations to the text): (a) it is not possible to adequately assess the medicinal product or category of medicinal products applying the applicable requirements **set out in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007** due to scientific or regulatory challenges arising from ~~**objective and scientific**~~ characteristics or methods inherent to the medicinal product **or category of medicinal products**; and NL (Comments): Could the Presidency clarify why it added “objective and scientific” in PARA1(a)? We feel this addition is redundant. We suggest to delete this.

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(b) the characteristics or methods **inherent to the medicinal product or category of medicinal products** positively impact the 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.	
2. ~~**Based on a recommendation by**~~ **After having consulted the Agency, t**~~T~~he 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.	

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Presidency compromise	Suggested adaptations to the text and Comments
3. The Commission ~~**may adopt implementing acts**~~ is empowered**, after having consulted the Agency,** to adopt delegated ~~**implementing**~~ acts in accordance with Article 215 ~~**214** to supplement this Directive~~ by laying down **the adapted framework for one or more medicinal products or categories of medicinal produts listed in Annex VII.**	
The adapted framework may entail adapted, enhanced, waived or deferred requirements from those set out in this Directive. The adapted framework shall be proportionate to the risk and impact involved. In particular, any waiver or deferral from the ~~**standards of**~~	IT (Suggested adaptations to the text): The adapted framework may entail adapted, enhanced, waived or deferred requirements from those set out in this Directive, **the [revised**

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Presidency compromise	Suggested adaptations to the text and Comments
requirements for quality, safety and efficacy set out in this Directive shall be limited to the extent strictly necessary, proportionate and duly justified by the characteristics or methods inherent to the medicinal product, and shall be regularly reviewed and evaluated by the Commission. Apart from the detailed rules set out in the delegated act, all other rules laid out in this Directive shall apply. The delegated act shall also contain the technical documentation to be submitted by marketing authorisation applicants for the medicinal product or category of medicinal products for which the adapted framework is laid down. ~~:~~	**Regulation (EC) No 726/2004] or Regulation 1394/2007.** The adapted framework shall be proportionate to the risks and impact involved. In particular, any waiver or deferral from the requirements for of quality, safety and efficacy set out in this Directive**, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007** 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. Apart from the detailed rules set out in the delegated act, all other rules laid out in this Directive**, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007** shall apply. The delegated act shall also contain the technical documentation to be submitted by marketing authorisation applicants for the medicinal product or category of medicinal products for which the adapted framework is laid down
~~(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;~~	

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

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~~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.~~	
~~4.~~ **~~The Commission shall, taking into account a scientific assessment by the Agency, specify whether those requirements entail an adaptation, enhancement, waiver or deferral from the requirements laid down in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007.~~** ~~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~~	

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Presidency compromise	Suggested adaptations to the text and Comments
~~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.~~	
5. Until the adoption of **specific** **adapted** ~~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).	NL (Suggested adaptations to the text): 5. Until the adoption of **specific** **adapted** ~~detailed~~ ~~rules~~ **requirements** 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

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Presidency compromise	Suggested adaptations to the text and Comments
	submitted in accordance with Article 6(2). NL (Comments): We suggest "requirements" in line with PARA 3.
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].	
REGULATORY DATA PROTECTION, UNMET MEDICAL NEEDS, REWARDS FOR PAEDIATRICS	

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Presidency compromise	Suggested adaptations to the text and Comments
Chapter VII **Regulatory protection, unmet medical needs and rewards for paediatric medicinal products**	AT (Comments): AT (general remark): AT thanks the presidency for their work on this chapter. We are a supporter of the reduction to 6 years of RDP, but we remain open for a compromise and welcome the new proposal for the incentives. It is well structured and predictable. AT can support this option.
Article 80	SI (Comments): SI: We

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Presidency compromise	Suggested adaptations to the text and Comments
Regulatory data and market protection	ES (Comments): As in previous written comments and as is well known, ES supports modulated incentive system.
1. The data referred to in Annex I, originally submitted with the view to obtaining a marketing authorisation shall not be referred to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81 (‘regulatory data protection period’).	

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Presidency compromise	Suggested adaptations to the text and Comments
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.	
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 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. ~~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.~~	AT (Comments): AT: We still advise to keep the currently deleted text in order to avoid evergreening or intentional slicing of indications. Moreover, it would be in line with the current proceedings at EU level, see recent sanctions against Teva for pay-for-delay strategies.

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Presidency compromise	Suggested adaptations to the text and Comments
3. By way of derogation from paragraph 1, the marketing authorisation holder concerned may grant the marketing authorisation applicant for another marketing authorisation a letter of access to its data submitted under Annex I, as referred to in Article 14.	
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a ~~party~~ **licensee** **under conditions laid out in Union or national law** ~~to address a public health emergency~~, the **relevant** data and market protection shall be suspended with regard to that ~~party~~ **licensee** insofar as	

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the compulsory licence requires, ~~and during~~ **for** the duration **and the territory of the Member States for which** ~~period of~~ the compulsory licence **has been granted**.	
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.	
5a. National competent authorities shall make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory data or	AT (Comments): AT: Very much appreciated! To know the end of the protection period is

Presidency compromise	Suggested adaptations to the text and Comments
market protection together with the date of the end of the protection period. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.	crucial for efficient pricing and reimbursement decisions/negotiations. CZ (Suggested adaptations to the text): ~~**National competent authorities shall make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory data or market protection together with the date of the end of the protection period. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.**~~ **The marketing authorisation holder shall submit and keep up to date the information on data and market protection periods for both centrally authorised medicinal products and medicinal products that have been granted a national marketing authorisation in the database referred to in Article 138 paragraph 1, point (n) of the [revised Regulation (EC) No 726/2004].** CZ (Comments): CZ is not in favour of the HU PRES proposal that would decentralise the

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Presidency compromise	Suggested adaptations to the text and Comments
	data on regulatory data protection and market protection. We consider it important to have such information publicly available in the EMA database. It would be also possible to publish the date of the marketing authorisation of the medicinal product and the regulatory data and market protection periods that the MAH obtained for the medicinal product (and not the end date of the regulatory data and market protection). Such kind of information is considered really crucial for applicant of marketing authorisation of generic medicines, pharmaceutical industry and NCAs as well. The use of the EMA database would make the related regulatory environment much clearer and user-friendly. Please see the change in wording as we support the previous wording to this para. MT (Comments): MT would prefer a more centralized system, yet it takes note of the discussions and the diverging views. In this regard it may accept the Presidency compromise. It is important that there is also a hyperlink to the agency link for centralized products.

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Presidency compromise	Suggested adaptations to the text and Comments
	NL (Suggested adaptations to the text): ~~**5a. National competent authorities shall make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory data or market protection together with the date of the end of the protection period. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.**~~ NL (Comments): We do not agree with the proposal of the PRES. We propose to use the database from article 138(n) as one central place of all information on medicinal products. This database includes both centrally and nationally authorised products. Having one central database instead of 27 fragmented places for information will enhance the attractiveness of the EU and reduces administrative burden as compared to this compromise proposal. As stated before in during the discussions on article 138(n) from the EMA-governance cluster,

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	we propose to exclude details on the management of the database from this legislation. The Product Management System (PMS) which is currently under development, will become the new Art. 138(n) database. Currently there are discussions on how PMS should be maintained and updated and by whom. We therefore propose not to set these details in text here but propose a delegated act within article 138(n). IT (Suggested adaptations to the text): ~~**5a. National competent authorities shall make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory data or market protection together with the date of the end of the protection period. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.**~~ IT (Comments):

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	IT comment: It is IT opinion that the proposed art 80 par. 5a should be deleted. Reporting RDP from the NCAs could result in inaccurate data collection, taking into account the complexity to verify any previous authorised medicinal products in every single Country belonging to the same Global Market Authorisation. Moreover, IT would like to highlight that the usefulness of such published data is questionable also compared to the burden requested to the NCAs. ES (Comments): ES cannot support this amendment. EE (Comments): We have some hesitations in view of future proof legislation, to set out a technical solution based on a compilation of hyperlinks. Perhaps, a more user-friendly solution could be still found in the future within the Union Register, to have this information available across the EU in one database. This information is necessary not only for the industry but also NCAs. Information on protection periods could be added in the Union

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	Register (in art 16 p.1) or to the EMA database (art 138 p. 2), as considered more appropriate. When considering updates of the Union Register, the Commission could consider whether additional data fields could be added without creating excessive administrative burden (could be spelled out in REG Art 16 p. 1). Furthermore, in case of national authorisations using DCP and MRP, coordinated approach is needed, since the date of granting the initial marketing authorisation is of importance to calculate the protection periods. Possibly the EMA Product Management Service could offer a solution. SI (Comments): SI: We would support the proposal to have data in one data base, namely in Article 138, where the Union registry is defined. LT

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	(Comments): LT: To compromise, we agree that the information on data and market protection periods should not be published in the database referred to in Article 138 paragraph 1, point (n) of the Regulation, but could be in hyperlinks to national websites published by the EMA. However, we believe that it would be appropriate to entitle the Commission to prepare a template of unified information that should be published by MSs. The use of a common template would ensure the completeness of the information and facilitate access to it. DE (Comments): DEU welcomes the reintroduction of an overview of data and marketing protection. In order to avoid that companies need to "collect" the information from the websites of at least 27 authorities, a joint list would be more user-friendly. Consideration should also be given to who could maintain and publish this list. In any case, it should be made clear that a corresponding list only

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	includes those medicinal product authorizations that are granted from the date of transposition of the directive into national law, i.e. not retroactively.
~~**5a. The marketing authorisation holder The Agency shall include submit and keep up to date the information on data and market protection periods for both centrally authorised medicinal products and medicinal products that have been granted a national marketing authorisation in the database referred to in Article 138 paragraph 1, point (n) of the [revised Regulation (EC) No 726/2004].**~~[1] ~~**The marketing authorisation holder shall notify the Agency with supporting documentation whenever the information published concerning the relevant regulatory and market protection periods is missing, not accurate or outdated.**~~	

[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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~~**5b. In case of medicinal products covered by a national marketing authorisation, the national competent authorities that granted the authorisation shall be informed through the database without delay on any submissions and updates made in accordance with paragraph 5a. If the National competent authority does not inform the Agency on its objection within 8 30 days, the data shall be published in the database. In case of objection, the national competent authority shall invite without undue delay the marketing authorisation holder to make a correct submission. Until a new submission is not made and approved under this paragraph, the data related to data and market protection periods indicated in the database shall remain unchanged.**~~	

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Article 81	CZ (Comments): CZ proposes changes in incentives as mentioned below which will ensure a clear and predictable environment, and at the same time simplify the modular system to avoid alternative solutions where it is not possible for MAH to get additional regulatory data protection for all specified situations. The only exception should remain running the evidence based-clinical comparator clinical trial vs. meeting the UMN criterion, that cannot both be fulfilled at the same time. Please see more details below in the particular paras of this Article relating to incentives themselves.
Regulatory data protection periods	NL (Comments): The Netherlands is of the opinion that we can achieve a better balance between rewarding companies for innovation, and ensuring policy

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	objectives that matter to patients. We want to thank the PRES for its hard work on this cluster. We see article 81 and article 56a in conjunction. Our commitment on this article, will be dependent on the discussions in article 56a. For now, we see that the proposal of the PRES moves in the right direction. We agree with the cap on 8 years. We see **meaningful modulation** by linking the modulation to UMN and Comparative Clinical Trials (CCT) However, we propose to keep the **baseline at 6 years.** ES (Comments): ES thinks that this text proposed by the Presidency is a step in the right direction towards achieving a meaningful modulation system. ES welcomes two aspects of this Presidency´s proposal: 1) 12 months of prolongation of RDP for UMN and 2) 8-years cap as limit for RDP. EE

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	(Comments): We maintain our reservations on deleting the market launch condition under this Article. We are of the view that incentives would be a win-win for the industry and the patients, and also the most effective from the economic point of view. Our final position will depend on whether a workable solution can be found under Article 56a to give us the tools for timely launch and supply of medicinal products on all markets where there is a need.
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	AT (Comments): AT: welcomes the proposal of the presidency, will be supportive of a compromise if it is feasible. CZ

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authorisation was granted in the Union.	(Suggested adaptations to the text): 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. CZ (Comments): CZ considers it crucial to maintain 6 years as the basic regulatory data protection period and disagrees with the current HU PRES proposal on 7 years. Please see the change in wording. The more detailed position is expressed in the upcoming paras of this Article. MT (Comments): Access to innovative drugs remains an essential aim of the current revision. Therefore, MT may support the modulation as proposed by the

Presidency compromise	Suggested adaptations to the text and Comments
	presidency, as long as another effective tool is included to address access. IT (Suggested adaptations to the text): The regulatory data protection period shall be **eight** ~~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. IT (Comments): ***IT Comment: IT does not support the amendments as provided by the PCY and calls for reinstating the status quo (8 years).*** ***IT believes that the provisions regarding the regulatory data protection should be clear, straightforward and ensure transparency.*** ***Furthermore, the second criteria, as proposed by the PCY, that grouped***

Presidency compromise	Suggested adaptations to the text and Comments
	3 previous separated criteria, is difficult to reach and this makes the proposal even more from the status quo. SI (Suggested adaptations to the text): 1. The regulatory data protection period shall be ~~six~~ ~~**seven eight**~~ **six** 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. SI (Comments): **SI**: We remain optimistic, that we will be able to agree to a period that will be acceptable to all MS. Yet, we still believe that the regulatory data protection period should be 6 years, with a cap on 8 years. IE (Comments): IE welcomes the rationalisation of the modulation the data protection period (RDP)

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	We consider this new proposal creates more meaningful modulation including addressing **unmet medical need**. and we welcome the maximum cap of **8 years**, We consider this article and article 56a as a package dealing with incentives and facilitating access LT (Comments): LT: We agree with a standard data protection period of 7 years. For a compromise, in principle we support the incentives proposed by the Presidency regarding the extension of the data protection period. We agree with the cap principle, but we have a scrutiny reservation regarding the specific deadline. DE (Comments): Our position has not changed. The current protection periods have proven and should be retained, but should not be exceeded. Against the background of the compromise text that has now been presented, it is

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	once again particularly important for DEU to ensure predictability for the industry. Ultimately, this also benefits patients in the EU, who profit from the development of innovative medicinal products.
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 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:~~**	
~~(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,~~	

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~~within three years from that date for any of the following entities:~~	
~~(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;~~	
~~(ii) entities not engaged in an economic activity ('not-for-profit entity'); and~~	
~~(iii) undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.~~	

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The regulatory data protection period referred to in paragraph 1 shall be prolonged by the following periods ~~not exceeding 8 year in total~~ by:	AT (Comments): AT: can support this proposal. IT (Suggested adaptations to the text): **~~The regulatory data protection period referred to in paragraph 1 shall be prolonged by the following periods not exceeding 8 year in total by:~~**
(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;	CZ (Suggested adaptations to the text): **~~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;~~** **6 months, where the clinical trials supporting the initial marketing**

Presidency compromise	Suggested adaptations to the text and Comments
	authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency or where the medicinal product addresses an unmet medical need; CZ (Comments): CZ is of the opinion that prerequisite for a successful agreement between the Member State and MAH is the existence of data that the NCA in the Member States needs for the evaluation of the medicinal product. We want to encourage pharmaceutical companies to carry out comparative clinical studies early in the lifecycle of the medicinal product to provide the data necessary for evaluation. Any pharmaceutical company should approach EMA for scientific advice as part of the early dialogue and, if a suitable medicine for the comparative clinical study exists, it will be identified. If such medicinal product is not identified within EMA scientific advice, it would be possible to classify this medicinal product as fulfilling UMN condition. Data from such a comparative clinical study, or information on fulfilling UMN condition, will help Member States to

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	make an informed decision on whether to allow such a medicinal product to enter their market and increase availability of such treatment to patients. Relevant and evidence-based comparator in the clinical trial or the fulfilment of UMN condition should be rewarded with six months of additional regulatory data protection for that medicinal product. This proposal is suggested also in the context that UMN has not been defined so far. Therefore, we propose to define UMN negatively in the context of comparator in the clinical trial. Thus, we suggest changing conditions expressed in letter (a) and (b) (i) of this para via one condition. Please see the changes in wording. IT (Suggested adaptations to the text): ~~**(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;**~~ ES (Comments):

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	ES welcomes the inclusion of a 12-months extension for UMN.
or	IT (Suggested adaptations to the text): ~~**or**~~
(b) 12 ~~6~~ months for medicinal products containing a new active substance~~,~~ if they meet all of the following conditions:	AT (Comments): AT: We welcome the change that ALL these options have to be fulfilled for 1 additional year. CZ (Comments): CZ considers it the right step to stipulate an obligation for MAH to fulfil all the conditions for obtaining one extra year of data protection. IT (Suggested adaptations to the text): ~~**(b) 12 6 months for medicinal products containing a new active**~~

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	~~substance, if they meet all of the following conditions:~~
i) where appropriate, ~~where~~ the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;	CZ (Suggested adaptations to the text): **~~where appropriate, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;~~** CZ (Comments): Please see the changes in letter (a) above which represent also the CZ comment and changes to this letter b) (i) of this para. Therefore, we propose to delete this para. Please see the changes in wording. Apart from that, we would like to ask for clarification of the term where appropriate at the beginning of condition in letter (b) (i) on comparative studies in this matter. We find such wording very broad. IT

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	(Suggested adaptations to the text): ~~**i) where appropriate, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;**~~
~~**(c) ii) 12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union.**~~ **the marketing authorisation applicant carried out clinical trials evaluating the efficacy of the medicinal product and used for the marketing authorisation were conducted in at least two Member States of the European Union.**	CZ (Suggested adaptations to the text): ~~**12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union.**~~ **for the purpose of the marketing authorisation the marketing authorisation applicant carried out clinical trials evaluating the efficacy of the medicinal product also in the Union and at least 30 % of all patients**

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	enrolled in the clinical trials were from the Union **or** **for the purpose of the marketing authorisation the marketing authorisation applicant carried out clinical trials evaluating the efficacy of the medicinal product, such clinical trials were conducted in at least two Member States and at least 30 % of the patients enrolled in the clinical trials were from the Union** CZ (Comments): CZ is of the opinion that requirement to carry out a substantial part of research and development of a medicinal product in the EU represents another major step towards increasing the accessibility of modern therapies for patients. In our opinion, we should focus in particular on the phases II and III of clinical trials. This should also allow greater involvement of healthcare providers and doctors, which will result in their greater erudition, but also have a positive impact on the financing of

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	healthcare. Related to HU PRES proposal, we do not consider sufficient to stipulate only two Member States where clinical trials are to be conducted. Therefore, we propose to reward MAH with additional regulatory data protection if at least 30 % of all (globally) enrolled patients are from the EU. The other possibility is mentioning combination of Member States and percentage of EU patients enrolled in clinical trials. By this step transparency of the whole process should be reached. We are also of the opinion that this criterion should be aligned to the final phases of clinical trials as we should avoid the situation when the sufficient number of subjects are enrolled in clinical trials, however, it cannot be stipulated that treatment will be provided. Please see the changes in wording aimed at better clarity. IT (Suggested adaptations to the text): ~~**c) ii) 12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in**~~

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	~~**collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union. the marketing authorisation applicant carried out clinical trials evaluating the efficacy of the medicinal product and used for the marketing authorisation were conducted in at least two Member States of the European Union.**~~
~~**(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.**~~	CZ (Suggested adaptations to the text): **12 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, and the production of that medicinal product is sufficient to meet the Union market demand.** CZ (Comments): **CZ fundamentally does not agree with deleting of the proposal on manufacture in the EU (previous letter (d)). CZ finds especially the**

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	manufacture in the EU the most beneficial additional regulatory data protection incentive for the EU and the Member States. We refer to our proposal, and moreover, we do not agree with changes made by HU PRES in the previous version of the text as API is not to be included from our point of view. We are of the opinion that it is absolutely essential for the strategic safety and availability of innovative treatments to incentivise pharmaceutical manufacturers to produce medicinal products within the EU. Current system of pharmaceutical innovation protection in the EU, both regulatory data protection and market protection, is ultimately funded by national systems of solidarity health insurance. This funding, derived from the outcomes of all citizens to secure provision of healthcare is, however, used under European legislation to provide incentives for the innovative pharmaceutical industry to increase the profitability of their investment in the development of new medicinal products. Despite that, these innovations remain inaccessible for many patients in the EU, as some pharmaceutical companies are delaying their launches especially on smaller markets, or otherwise not affordable due to ever increasing prices. In the Czech Republic alone, a medium-sized country with a population

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	of ten million, each additional year of such regulatory data or market protection costs almost EUR 126 million from the public health insurance budgets and, much more importantly, each year of such protection reduces the availability of innovative treatments for more than 20 000 patients. Tying incentives to manufacture of medicinal products within the EU represents a way how to recoup finances provided back to the EU. Our efforts should be aimed at strengthening the EU's competitiveness, increasing employment and the high added value production that the manufacturing of innovative medicinal products certainly brings. **We propose to reward manufacturing within the EU intended for the benefit of European patients with one year of additional regulatory data protection**. It is important to emphasize that the innovative medicines which manufacture has not been established are considered. Eligible manufacturing capacities should cover the needs of the entire EU market. Last but not least, one of the aims of this incentive should be to prevent medicines shortages in the future. Please see the changes in the wording.

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~~(e) iii) 6 months if~~ the marketing authorisation applicant ~~holder~~ demonstrates that the ~~application for granting~~ marketing authorisation application has been first submitted to the competent authority in the Union or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the Union.	CZ (Suggested adaptations to the text): ~~**6 months if the marketing authorisation applicant holder demonstrates that the application for granting marketing authorisation application has been first submitted to the competent authority in the Union or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the Union.**~~ CZ (Comments): CZ does not support HU PRES on stipulating of incentive expressed in letter iii) of this para. We have concerns of unpredictable consequences related to different and in many cases uncomplete data which are provided for authorisations of medicinal products (and in some countries may be sufficient) due to the differences between health systems at the global level. Apart from that we are of the opinion that the amount of conditional market authorisations of medicines should not be increased only with the purpose to fulfil this condition. Therefore, deleting of this

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	letter is proposed. Please see the changes in wording. IT (Suggested adaptations to the text): ~~**(e) iii) 6 months if the marketing authorisation applicant holder demonstrates that the application for granting marketing authorisation application has been first submitted to the competent authority in the Union or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the Union.**~~
The cumulative duration of data protection for a medicinal product shall not exceed eight years from the date the initial marketing authorisation was granted.	NL (Comments): We would like to note that this PARA might restrict the possible additional regulatory data protection of the voucher. IT

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	(Suggested adaptations to the text): **~~The cumulative duration of data protection for a medicinal product shall not exceed eight years from the date the initial marketing authorisation was granted.~~**
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~~**a**), 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.	IT (Suggested adaptations to the text): ~~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~~~~**a**~~~~), 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.~~

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~~The prolongation referred to in the first subparagraph, point (d), may only be granted once.~~ **~~The cumulative duration of data protection for a medicinal product shall not exceed eight years from the date the initial marketing authorisation was granted. [This limitation does not apply in the case of Article 40 of [revised Regulation (EC) No 726/2004].]~~**	
3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (~~c~~**b**) **(i)** ~~**(ii)**~~, on criteria for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004]**, in particular bodies responsible for health technology**	IT (Suggested adaptations to the text): ~~3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c**b**) **(i)** **(ii)**, on criteria for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of~~

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assessment as referred to in Regulation (EU) 2021/2282.	~~consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004]~~**, in particular bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282**~~.~~
~~4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement paragraph 2 point (ba) c in order to determine situations in which a set specific criteria for the designation of significant substantial share of research and development is done within the Union.~~	

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~~*Article 82*~~	
~~*Prolongation of the data protection period for medicinal products supplied in Member States*~~	
~~1. The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid.~~	

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~~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.~~	
~~2. To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.~~	

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~~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.~~	
~~The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:~~	
~~(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~~	

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~~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).~~	
~~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~~	

~~[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).~~

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~~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.~~	
~~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.~~	
~~For medicinal products granted a centralised marketing authorisation the Commission shall vary the marketing authorisation pursuant to Article 47 of [revised Regulation (EC) No 726/2004] to prolong the data protection period. For medicinal products granted a marketing authorisation in~~	

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~~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.~~	
~~5. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC[3] ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.~~	

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

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~~6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt implementing measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).~~	
Chapter V	
Obligations and liability of the marketing authorisation holder	
	MT

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	(Comments): MT holds that this should be a directly applicable provision and should be shifted to the Regulation.
Article 56a	AT (Comments): AT: Supports the general obligation for market launch in all MS, over the incentive option. We hope to reach a compromise that offers clear and binding provisions, including sanctions on Union level. CZ (Comments): In general, CZ would like to point out that the situation regarding the accessibility of new medicinal products across the EU has not only improved but has rather worsened in recent years. The data published by the pharmaceutical industry itself (W.A.I.T report)[4] clearly show this trend. It therefore seems essential that a medicinal product that obtains a centralised marketing authorisation should be offered by MAH to all Member States for evaluation and approval within a comparable period

[4] https://efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf

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	of time. It should be then up to each Member State to decide whether to let the medicinal product enter into its reimbursement system or conclude a different agreement with MAH. We consider this to be a natural step. NL (Comments): • The Netherlands supports measures that will promote equal access of medicinal products throughout the EU. • However, we do need to find a balance to keep the EU-market **attractive for new medicinal products to enter.** • We try be open and constructive on this to gain an effective, predictable and enforceable instrument. IT (Suggested adaptations to the text): ~~***Article 56a***~~ SI (Comments): SI: We would prefer access as an incentive compared to the obligation

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	outlined in Article 56a, but we are willing to work towards a compromise solution, that will achieve the goal, that is to provide access of medicinal products. We believe that the article could be further involved insofar as the obligation to supply the medicine should be on the MAH, not on the competent authority to ask the MAH to provide the medicinal product. We would however welcome a modification of the provision, where market protection would be lifted in all MS, when supply is not met in one or more MS. This would be a stronger motive for the innovator, to meet the demand in all MSs where the medicine is needed. DE (Comments): General scrutiny reservation
Specific requirements ~~Obligation to~~ on making available ~~market launch~~ and continuously supplying of a medicinal product ~~on the market~~ in a Member State	IT (Suggested adaptations to the text): ***~~Specific requirements Obligation to on making available market launch and continuously supplying of a medicinal product on the market in a Member State~~***

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	IT (Comments): ***IT comment: Although IT agrees with the principle of making medicinal products available to all patients in the EU, the article proposed by the PCY is not supported. The provision continues to be complex and difficult to implement and may lead to potential litigations. Indeed, the wording appears unclear with reference to the phrases "sufficient quantities", "meeting procedural obligations", "good faith". In addition, the phrase "fulfilling specific requirements for marketing authorisation holders in procurement procedures" raises certain concerns. Moreover, it may be noted that the application of pecuniary sanctions may make Europe unattractive and may not be the most suitable instrument to grant patient access within the EU.*** ES (Comments): Market access is no longer an incentive, but an obligation, so it is only fair to strengthen Art 56a. Some delegations consider that the current system works and is attractive, but that modulation and the obligation of

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	Art 56a will make the European market less attractive. The truth is that the European market is currently attractive, but not equally attractive in all Member States, so it is time to improve the *status quo* with a modulated system and an access obligation to make the market in all 27 Member States equally attractive, to achieve equal access for patients in all 27. IE (Comments): Access provisions are very important to IE. We consider the obligations on the MAH to provide access to Member States should be strengthened in this article and have made a number of suggestions in the following paragraphs on this. LT (Comments): LT: We support the proposed concept of the Aricle 56a. However, in order to reach a compromise, we could also agree that making available of medicinal products on the market would be part of the incentive‘s

Presidency compromise	Suggested adaptations to the text and Comments
	system. DE (Comments): DE is in favour to address access problems by regulating an obligation to file for Pricing and reimbursement in all MS. A linkage between market launch and data protection period should be avoided. Regarding the detailed construction we still need clarification.
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	CZ (Suggested adaptations to the text): **With a view to facilitating access to a medicinal product covered by a valid marketing authorisation within the ~~their~~ territories of the Member States subject to regulatory protection pursuant to Article**

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may request the marketing authorisation holder of that medicinal product to make it available and continuously supply, within the limits of its responsibility, on the market of that Member State in ~~a~~ sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as specified by that Member State.	**80 (1) and (2), or, if applicable, the ~~prolongation of the~~ market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004], a Member State may request the marketing authorisation holder shall offer of that medicinal product make it available and continuously supply, within the limits of its responsibility, on the market of that Member State in a sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as specified by that Member State.** CZ (Comments): In general, we support stipulating an obligation for MAH to ensure supplies of medicines to markets in all Member States instead of incentivising pharmaceutical industry. If the Member State has to request the medicinal product from the MAH, it is important that there is a system that would allow to do so (for example a system at EMA level through which all the related communication between the Member State and the MAH would run or at least a database with MAH contacts so that it is clear for the Member State who to contact).

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	CZ is also of the opinion that it is important that the text clearly states that **the Member State may request the medicinal product from the MAH** to make it available and continuously supply, within the limits of its responsibility, on the market of that Member State in a sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as specified by that Member State, **already during the RDP**. Please see the changes in wording. MT (Comments): The scope of this requirement should be widened to also include products covered by a supplementary protection certificate. It is important that this obligation of continuous supply remains under generic entry of the product. Taking note of the opinion of the CLS, MT still holds that medicines are not to be considered as ordinary goods and there is a public health dimension to require all products to be covered by this provision. The special status of these products is reflected in the incentives awarded to these products and also the extended patent protection. Furthermore, the

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	development of these products is often supported by public funds and different stages of their development. NL (Comments): We are happy with the inclusion of "within the limits of its responsibilities" in the PARA. We propose to add recitals to make clear that suffering losses will fall within "the limits of responsibility", since this article could lead to litigations. IT (Suggested adaptations to the text): ~~**1. With a view to facilitating access to a medicinal product covered by a valid marketing authorisation within their territories subject to regulatory protection pursuant to Article 80(2), or, if applicable, the prolongation of the market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004], a Member State may request the marketing authorisation holder of that medicinal product to make it available and continuously supply, within the limits of its responsibility, on the market of that Member State in a**~~

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	~~sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as specified by that Member State.~~ EE (Comments): "within the limits of its responsibility" leaves too much room for interpretation and needs to be clarified in the text, possibly as a separate subparagraph or in the recitals, for example referring to *force majeur*. IE (Suggested adaptations to the text): **With a view to facilitating access to a medicinal product covered by a valid marketing authorisation within their territories subject to regulatory protection pursuant to Article 80(2), or, if applicable, the ~~prolongation of the~~ market exclusivity in accordance with Article 72~~(2)~~ of [revised Regulation 726/2004], a Member State may request the marketing authorisation holder of that medicinal product to make it available and continuously supply, excluding circumstances**

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	outside the control of the MAH, 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. IE (Comments): IE have found that the use of the phrase "within the limits of their responsibility" in the existing supply obligation in Art 81 of Directive 2001/81/EC has contributed to difficulties in applying such obligation as it was interpreted too broadly. While IE accept that the obligation to supply cannot be an absolute one, we consider that other wording, closer to force majeure should be used. We suggest "excluding events that are outside the control of .." DE (Comments): DE agrees with the deletion.

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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:	IT (Suggested adaptations to the text): ~~**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:**~~ EE (Comments): It should be further considered how to better define the scope of specific requirements in this Article. A well-defined scope linked to market launch would facilitate more effective enforcement, which should be brought to the EU level (e.g EU penalties).
a) meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;	MT (Comments): It should also be possible to meet this requirement in a number of

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	Member States through a joint negotiation / joint procurement mechanism led by the Commission. This would be beneficial to the Member State and to the Market Authorisation holder. It is up to the Market Authorisation holder to decide whether it would like to negotiate with Member States individually or collectively. A hybrid approach may also be possible, through which the Market Authorisation holder files a pricing and reimbursement application with some Member States individually and opts for collective negotiations with another group of Member States. Additional modalities may be considered when the concerned Member State would rather opt for a different option other than that selected by the Market Authorisation holder. IT (Suggested adaptations to the text): ~~**a) meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;**~~ EE (Suggested adaptations to the text):

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	a) submit a valid pricing and reimbursement application in accordance with national legislation within 2 years from marketing authorisation in interested Member States upon request EE (Comments): It is not clear what is meant by procedural obligations, a more straightforward language is needed. IE (Suggested adaptations to the text): **a) submit a valid pricing and reimbursement application within 18 months from marketing authorisation, or 24 months for an SME, in an interested Member States upon request** IE (Comments): IE considers that the current obligation in 2a is too general in nature and feel this article would be stronger if we include a specific obligation on an MAH to submit a P&R application, on request.

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Presidency compromise	Suggested adaptations to the text and Comments
	Market launch and therefore access is only possible when an application is complete/adequate with all the necessary data submitted. This is a clear obligation and it will be possible to determine if an MAH has fulfilled obligations within article 56a. This is also in line with the clear commitment and proposal from industry in this area to launch in all markets within 2 years of authorisation
b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;	IT (Suggested adaptations to the text): ~~**b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;**~~
c) establishing a~~n access~~ roll-out ~~supply~~ plan.	MT (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
	If a joint negotiation mechanism is opted for, a roll out plan should still be drafted for all participating Member States. IT (Suggested adaptations to the text): ~~**c) establishing an access roll-out supply plan.**~~
~~**Such**~~ **The arrangements to implement the requirements referred to in this paragraph shall be proportionate to the objective pursued and in compliance with Union law.**	MT (Suggested adaptations to the text): ~~**Such The arrangements to implement the requirements referred to in this paragraph shall be proportionate to the objective pursued and in compliance with Union law.**~~ IT (Suggested adaptations to the text): ~~**Such The arrangements to implement the requirements referred to in this paragraph shall be proportionate to the objective pursued and in compliance with Union law.**~~ EE (Suggested adaptations to the text):

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Presidency compromise	Suggested adaptations to the text and Comments
	~~**The arrangements to implement the requirements referred to in this paragraph shall be proportionate to the objective pursued and in compliance with Union law.**~~ EE (Comments): This is a general principle and it is not clear why it needs to be emphasised specifically in the context of this Article. It is already covered under the accompanying recital, which is more appropriate and should not be repeated here.
2a. Upon request by a Member State in accordance with paragraph 1, the marketing authorisation holder concerned shall carry out the actions referred to in paragraph 2 as relevant.	IT (Suggested adaptations to the text): ~~**2a. Upon request by a Member State in accordance with paragraph 1, the marketing authorisation holder concerned shall carry out the actions referred to in paragraph 2 as relevant.**~~ DE (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
	We still consider para 2a obsolete
3. The ~~supply~~ ~~access~~ roll-out plan referred to in 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~~ ~~access~~ roll-out plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the ~~supply~~ ~~access~~ roll-out plan.	MT (Suggested adaptations to the text): 3. The supply access roll-out plan referred to in paragraph 2, point (c), shall include ~~information~~ commitments to the supply of the medicinal product by the marketing authorisation holder over a given period in the Member State concerned. The supply access roll-out plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the supply access roll-out plan. IT (Suggested adaptations to the text): **~~3. The supply access roll-out plan referred to in paragraph 2, point (c), shall include information about the supply of the medicinal~~**

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	~~**product by the marketing authorisation holder over a given period in the Member State concerned. The supply access roll-out plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the supply access roll-out plan.**~~
4. When a Member State ~~decides to avail itself of the obligation in~~ applies paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within one year from the marketing authorisation for that medicinal product. The communication under this paragraph shall contain explicit reference to this Article.	MT (Comments): This one-year period should only apply to trigger article 5. The obligation should subsist if the conditions in article 1 apply, and failure to abide by the obligation should trigger the penalties. There should also be a time limit after the request of the Member States within which the Market Authorisation holder should either submit a

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	request for pricing and reimbursement to start the process or to request for a joint negotiation through the Commission. IT (Suggested adaptations to the text): ~~**4. When a Member State decides to avail itself of the obligation in applies paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within one year from the marketing authorisation for that medicinal product. The communication under this paragraph shall contain explicit reference to this Article.**~~
5. Where within ~~5~~ 4 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not	CZ (Suggested adaptations to the text): **Where within ~~5~~ 4 years after the marketing authorisation of the**

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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.	**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.~~** CZ (Comments): CZ proposes to delete "within that Member State" at the end of this para 5 to strengthen this para as it would motivate the MAH to supply the medicinal product in all Member States. Please see the change in wording. NL (Comments): We note that this PARA might lead to taking away market protection and

Presidency compromise	Suggested adaptations to the text and Comments
	exclusivity when there is a shortage, out of the control of the MAH, which is undesirable. IT (Suggested adaptations to the text): ~~**5. Where within 5 4 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not 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.**~~ EE (Comments): We support in principle p. 5 and p. 5b however we are concerned that loss of market protection in only a few smaller markets is not a sufficient

Presidency compromise	Suggested adaptations to the text and Comments
	measure to enforce the supply requirement or to get generics earlier to the market. Thus, more effective EU-wide mechanisms are needed. As a minimum, it needs to be considered how the Commission could be given a more prominent role, in cases where the companies are not fulfilling the market launch and supply obligations (f.ex possibilities for penalties at the EU level). LT (Comments): LT: It is important for Lithuania to receive newly authorised medicinal products without delay, so as not to wait for the supply until almost the end of 4 years. We support the concern raised by the Croatian delegation at the last meeting of WP and are in favour of the Commission's proposal regarding wording "**at the latest** within 4 years." DE (Comments): Negative scrutiny reservation: DE is concerned that sanctions are linked to the mandatory placing on the market. A sanction mechanism would have a deterrent effect on the industry and could cause it to avoid the

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	European market.
5a. The Member State shall make the information referred to in paragraph 5 publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.	IT (Suggested adaptations to the text): **~~5a. The Member State shall make the information referred to in paragraph 5 publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.~~** IE (Suggested adaptations to the text): **The Member State shall make ~~this~~ the information referred to in paragraph 5 publicly available without undue delay. The Member State shall also notify the Commission. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.**

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	IE (Comments): IE considers that a provision to provide for the MS to also inform the Commission should be included here. This will provide EU wide visibility on the compliance with the requirements of article 56a and any access issues that MS are encountering. This also assists the timely preparation of the report in Article 216. As the information will be publicly available, we don't envisage such a notification will be a problem. DE (Comments): What is the purpose of that information? Is it essentially about informing other market participants, especially generics manufacturers, that marketing protection has been suspended for a particular medicinal product? Is our assessment correct that details of the procedure regarding the design of the public announcement, for example individual deletion periods, remain within the competence of the MS in the course of

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	implementation of the Directive? We would like to ask COM and HUN Pres for their assessment in this regard.
5ba. By way of derogation from Article 81, a marketing authorisation application may be validated and assessed by the national competent authorities or the Agency six years after the start of the data protection period of the reference medicinal product, where the medicinal product is a generic or biosimilar medicinal product to a reference medicinal product and where a Member State has made publicly available information with regard to that reference medicinal product in accordance with paragraph 6. The marketing authorisation validated and assessed in accordance with this paragraph shall not be granted prior to the expiry of the regulatory data protection period.	AT (Comments): AT: We welcome the opportunity for earlier starts of authorisation procedures for generics and biosimilars. Additionally, "paragraph 6" should be changed to "paragraph 5". IT (Suggested adaptations to the text): ~~**5ba. By way of derogation from Article 81, a marketing authorisation application may be validated and assessed by the national competent authorities or the Agency six years after the start of the data protection period of the reference medicinal product, where the medicinal product is a generic or biosimilar medicinal product to a reference medicinal product and where a Member State has made publicly available information with regard to that**~~

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Presidency compromise	Suggested adaptations to the text and Comments
	~~**reference medicinal product in accordance with paragraph 6. The marketing authorisation validated and assessed in accordance with this paragraph shall not be granted prior to the expiry of the regulatory data protection period.**~~ IT (Comments): ***IT comment: The possibility of losing market protection only in some MSs, as envisaged by the proposed mechanism, further fragments a system already fragmented by the art.81 proposal. It is difficult to understand how the system will work, and this does not contribute to creating a competitive European system.***
~~**6. The Member State shall make this the information referred to in paragraph 5 publicly available without undue delay. For medicinal**~~	

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~~**products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.**~~	
7. This Article shall not affect ~~is without prejudice to Member States'~~ the application of national legislation and procedures, including pricing and reimbursment, public procurement and any other procedures, aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation, where a request in accordance with paragraph 1 has been made by that Member State.	IT (Suggested adaptations to the text): ~~**7. This Article shall not affect is without prejudice to Member States' the application of national legislation and procedures, including pricing and reimbursment, public procurement and any other procedures, aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation, where a request in accordance with paragraph 1 has been made by that Member State.**~~ EE (Suggested adaptations to the text): **Without prejudice to this Article, Member States may foresee other**

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	measures and procedures in their national legislation aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation. EE (Comments): The drafting of this paragraph is not clear and is in contradiction with the aim of this Article to allow Member States to foresee measures as outlined in para 2 (that would need to be transposed to the national legislation). We understand this Article should not prevent Member States from taking any other measures they consider necessary to ensure availability and continuous supply and it does not affect the way pricing and reimbursement procedures are set up. We propose to reformulate to provide clarity and to include further explanations in a recital.

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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.	CZ (Comments): CZ would like to ask for clarification of the term best efforts in the context of this provision. CZ is of the opinion that this provision is not in accordance with the general aim to stipulate an obligation for MAH to supply medicines to all Member States. This part should be more clarified. IT (Suggested adaptations to the text): ~~**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.**~~

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In the course of the application of this Article, the Member States and the marketing authorisation holder shall cooperate in good faith and undertake best efforts to making available and continuously suppling the medicinal product concerned in the concerned Member State.	MT (Comments): This should be placed in a separate sub article, referring to text in the below recital. IT (Suggested adaptations to the text): ~~**In the course of the application of this Article, the Member States and the marketing authorisation holder shall cooperate in good faith and undertake best efforts to making available and continuously suppling the medicinal product concerned in the concerned Member State.**~~
8. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC[5]	AT (Comments): AT: supportive. CZ

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

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('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	(Comments): CZ is in favour with such kind of consultations. However, it is a question whether it is necessary to stipulate this general idea in the Directive. NL (Comments): We are wondering whether the Pharmaceutical Committee is the right forum for this matter. We note that the pharmaceutical committee might not be the right forum to coordinate the notifications. But from the CWP we understood that this was not the intention. IT (Suggested adaptations to the text): **~~8. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC~~**[6] **~~('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing~~**

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

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	~~**and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.**~~ IT (Comments): ***IT comment: The reference to HTA bodies as referred to in the HTA Regulation is unclear. Does it refer to the national HTA agencies or to the Coordination Group? If it refers to the Coordination Group, it should be noted that the Coordination Group is not competent for supply and market access at the national level; moreover, by this time the JCA report, according to HTAR, will already be public and the CG will have effectively completed its task; it will then be up to the national agencies (HTA and P&R) to assess any requests.*** EE (Comments): It is a positive addition, but it needs to be further explored to give the Commission a more prominent role in the monitoring and enforcement of this Article. For example, interventions at EU level could be triggered upon request, in cases where the companies are not fulfilling the market

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	launch and supply obligations and more than one Member State is concerned. We are also interested in further exploring EU penalties. We would appreciate advice from the CLS on the elements that would need to be considered in order to make it legally feasible. To move this Article to Regulation could also be an option to be considered, since it is concerning mostly centrally authorised products. IE (Comments): IE welcomes the opportunity to provide visibility at an EU level on issues being experiences at a national level on the application of Article 56a and gaining access to medicines DE (Comments): Scrutiny reservation. Which bodies are meant regarding HTA?

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The Pharmaceutical Committee may coordinate the notifications by the national competent authorities in agreement with Article 56b points 3 and 5.	CZ (Suggested adaptations to the text): ~~**The Pharmaceutical Committee may coordinate the notifications by the national competent authorities in agreement with Article 56b points 3 and 5.**~~ CZ (Comments): CZ would like to point out that Article 56b is not a part of the HU PRES compromise text. Therefore, this part is proposed to be deleted. IT (Suggested adaptations to the text): ~~**The Pharmaceutical Committee may coordinate the notifications by the national competent authorities in agreement with Article 56b points 3 and 5.**~~ EE (Comments): Reference to 56b points 3 and 5 is not clear, probably needs to be corrected DE

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	(Comments): This reference to Art. 56b points 3 and 5 appears to be an editorial error.
Recital:	CZ (Comments): In general, CZ is of the opinion that the text of recital 56a should be discussed when the final version of the text of Article 56a is reached. IT (Suggested adaptations to the text): ~~***Recital:***~~ IT (Comments): ***IT comment: Please see comment above.***
Access to medicinal products in all Member States and guaranteeing a timely, stable, reliable and high-quality supply of medicinal products is an essential objective to achieve an overall high level	MT (Comments): It should be clarified that article 56A supplements the obligations of the

Presidency compromise	Suggested adaptations to the text and Comments
protection of human health in the Member States, thus contributing to the protection of human health and human life in the Union. The responsibility of ensuring a~~n~~ timely, adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is granted, the medicinal product is placed on the market by the marketing authorisation holder on its own initiative. Practice shows, however, that in certain Member States ~~the behaviour of marketing authorisation holders results in~~ the placing on the market of authorised medicinal products is delayed or in quantities that do not correspond to the needs of those Member States. Therefore, Member States should, based on grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition, be enabled to require to the MAHs specific actions with a view to comply with their market launch and supply obligations pursuant to this Directive. To this aim, Member States should be able	Market Authorisation holder under other provisions of union law such as competition law. It should be recalled that under competition law there is an obligation to supply when there is a dominant position. IT (Suggested adaptations to the text): ~~**Access to medicinal products in all Member States and guaranteeing a timely, stable, reliable and high-quality supply of medicinal products is an essential objective to achieve an overall high level protection of human health in the Member States, thus contributing to the protection of human health and human life in the Union. The responsibility of ensuring an timely, adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is granted, the medicinal product is placed on the market by the marketing authorisation holder on its own initiative. Practice shows,**~~

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to request the marketing authorisation holder to submit an application for pricing and reimbursement or to participate in any relevant national procurement procedures or ~~make the product available in the supply chain~~ draw up and implement ~~an access~~ roll-out plan that is acceptable for that Member State. The implementation of the ~~access~~ roll-out plan should ensure sufficient and continuous supply to meet the needs of the patients in that Member State. ~~Member States should base their request on the grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition. Member States should also be 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.~~	~~**however, that in certain Member States the behaviour of marketing authorisation holders results in the placing on the market of authorised medicinal products is delayed or in quantities that do not correspond to the needs of those Member States. Therefore, Member States should, based on grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition, be enabled to require to the MAHs specific actions with a view to comply with their market launch and supply obligations pursuant to this Directive. To this aim, Member States should be able to request the marketing authorisation holder to submit an application for pricing and reimbursement or to participate in any relevant national procurement procedures or make the product available in the supply chain draw up and implement an access roll-out plan that is acceptable for that Member State. The implementation of the access roll-out plan should ensure sufficient and continuous supply to meet the needs of the patients in that Member State. Member States should base their request on the**~~

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	~~**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.**~~
Article 166	
Obligations of the wholesale distribution authorisation holder	
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	IT (Suggested adaptations to the text): ~~**5. In respect of a medicinal product where the protection referred**~~

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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.	~~**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.**~~ IT (Comments): ***IT comment: Please see comment above.***
Article 216	

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Presidency compromise	Suggested adaptations to the text and Comments
Report	
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.	
2. By [OP please insert the date = 6 years following ~~18 months~~ ~~after~~ the date of entering into force of this Directive], the Commission shall present a report ~~to the~~ to the European Parliament and the Council on the application of Article 56a. The report shall, based	IT (Suggested adaptations to the text): **~~2. By [OP please insert the date = 6 years following 18 months after the date of entering into force of this Directive], the Commission~~**

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among others, on information provided by Member States, include an assessment whether the rules provided for in that Article ensures timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article. The Commission shall, if appropriate, present legislative proposals based on that evaluation in order to amend this Directive or make further proposals.	**~~shall present a report to the to the European Parliament and the Council on the application of Article 56a. The report shall~~, based among others, on information provided by Member States, include an assessment whether the rules provided for in that Article ensures timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article. The Commission shall, if appropriate, present legislative proposals based on that evaluation in order to amend this Directive or make further proposals.~~**
Article 219	
Transposition	

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Presidency compromise	Suggested adaptations to the text and Comments
1. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [18 months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission.	
1a. Member States shall apply those measures from [18 months after the date of entering into force of this Directive].	CZ (Suggested adaptations to the text): **Member States shall apply ~~those~~ measures referred to in paragraph 1 from [18 months after the date of entering into force of this Directive].** CZ (Comments): CZ would like to ask for clarification of the terms “those measures” used

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	in para 1a and 2 of this Article, otherwise the reference to para 1 should be added if the term "laws, regulations and administrative provisions" is considered. Please see changes in wording. IT (Suggested adaptations to the text): ~~**1a. Member States shall apply those measures from [18 months after the date of entering into force of this Directive].**~~
However Member States may apply Article 56a from an earlier date in respect of medicinal products authorised after the date of entering into force of this Directive. In case of a medicinal product authorised between the entry into force and the date of application of this Directive, the second subparagraph of Article 10 (1) of the Directive 2001/83 shall not apply in the member state that made a request in	CZ (Suggested adaptations to the text): **However, Member States may apply Article 56a from an earlier date in respect of medicinal products authorised after the date of entering into force of this Directive. In case of a medicinal product authorised between the entry into force and the date of application of this**

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accordance with Article 56a, if the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously in that Member State in accordance with that Article.	**Directive, the second subparagraph of Article 10 (1) of the Directive 2001/83 shall not apply in the member state that made a request in accordance with Article 56a, if the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously ~~in that Member State~~ in accordance with that Article.** CZ (Comments): CZ appreciates the addition proposed by HU PRES concerning market protection in the period before Directive comes into force. However, similarly to Article 56a para 5 we support not to use "within that Member State" to strengthen this para as it would motivate the MAH to supply the medicinal product in all Member States. Please see the changes in wording. MT (Comments): Article 56a should be in the regulation. IT (Suggested adaptations to the text):

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Presidency compromise	Suggested adaptations to the text and Comments
	~~**However Member States may apply Article 56a from an earlier date in respect of medicinal products authorised after the date of entering into force of this Directive. In case of a medicinal product authorised between the entry into force and the date of application of this Directive, the second subparagraph of Article 10 (1) of the Directive 2001/83 shall not apply in the member state that made a request in accordance with Article 56a, if the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously in that Member State in accordance with that Article.**~~ IT (Comments): ***IT comment: The amendments proposed by the PCY make the European system even more complicated and unattractive. The application of Article 56a before the implementation of the directive could create many problems.*** IE (Comments): It should be considered whether for legal clarity there is a need to specify

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Presidency compromise	Suggested adaptations to the text and Comments
	here that Art 56a can be applied to medicinal products authorised under the Regulation as the majority if not all medicinal products to which it will be applied will be authorised via the centralised procedure which is provided for in the Regulation.
2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.	CZ (Suggested adaptations to the text): When Member States adopt ~~those~~ measures **referred to in paragraph 1**, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to

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	be formulated. CZ (Comments): Please see the CZ comment on para 1a of this Article above. Therefore, the changes are proposed in this para as well.
3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive.	
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	

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Presidency compromise	Suggested adaptations to the text and Comments
Chapter XVI **General provisions**	
Article 206	
Penalties	
2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:	MT (Comments): Article 56A should be shifted to the regulation and failure to comply with the main elements of the provision, such as the submission of the Pricing and reimbursement application in all Member States requesting it within the prescribed timeframes, should be subject to union penalties.

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	Furthermore, certain elements related to the joint negotiation procedure should also be subject to union penalties.
(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;	
(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.	AT (Comments): AT: supported. IT (Suggested adaptations to the text): ~~**(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.**~~ ES (Comments):

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	ES supports this provision. EE (Comments): Based on the explanations given by the Council Legal Service, it would be necessary to further consider whether national penalties in case of no supply would actually be legally possible to enforce. We would be interested to explore the EU penalties and what the legal mechanisms could be to bring the liability to the EU level and to give the investigational powers to the Commission. Having sanctions at the EU level would have bigger leverage than individual Member States.
(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;	

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(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	
(e) non-compliance with the provisions laid down in this Directive on advertising.	
Chapter VII	
Regulatory protection, unmet medical needs and rewards for paediatric medicinal products	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
Article 83	
Medicinal products addressing an unmet medical need	CZ (Comments): In general, CZ refers to its previous comment on Article 81 and its proposal how to define UMN. We are of the opinion that if a comparator is not identified within EMA scientific advice, it would be possible to classify this medicinal product as fulfilling UMN condition meaning that comparator for a comparative clinical study has not been identify. Please see our comment on Article 81 above. NL (Comments):

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	We have a positive scrutiny reservation on this article. We see that the PRES has made the UMN definition more predictable for the modulation. However we are working further on the proposal of the PRES' text and will come back with a detailed text proposal.
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and **either of** the following conditions are met:	
(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**	IT (Suggested adaptations to the text): (a) there is no medicinal product authorised **and no satisfactory**

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Presidency compromise	Suggested adaptations to the text and Comments
~~**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~~;	**method of diagnosis, prevention or treatment in standard of care authorised** in the Union ~~satisfactory method of diagnosis, prevention or treatment in standard of care~~ for such disease **and the medicinal product being authorised results in a meaningful reduction in disease morbidity or mortality for the relevant patient population**~~, 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~~; IT (Comments): ***IT comment: IT considers that for point (a) to be acceptable as the sole condition to be met for considering a medicinal product as addressing an unmet need, the whole therapeutic armamentarium should be considered and there must be the demonstration of an impact on the disease.*** DE (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
	Point (a) is supported in the current version. According to our opinion it also provides for legal certainty.
(b) the use of the medicinal product **for such a disease** results in **clinically relevant advantage ~~a greater~~ in efficacy, or ~~greater~~ in safety with a non-inferior efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union** ~~a meaningful reduction in disease morbidity or mortality for the relevant patient population.~~ **~~The meaningful reduction in disease morbidity or mortality for the relevant patient population may shall be demonstrated, where possible and appropriate, with data from comparative clinical trials studies that use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency.~~**	CZ (Comments): CZ would like to ask for clarification of the term "clinically relevant advantage" in the context of this provision. CZ is of the opinion that it represents too general and wide definition. From our perspective, it should be at least add that the clinical relevant advantage is represented by clinically relevant endpoint in a clinical study, which has an impact on the quality of life, and e.g., there was at least a 30% improvement in comparison with the current treatment or there was a significant positive difference in survival time or time to progression. This part should be more clarified. IT (Suggested adaptations to the text): (b) **despite medicinal products being authorised for such disease in the Union the disease is associated with remaining high morbidity or**

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	mortality, and the use of the medicinal product for such a disease results in clinically relevant advantage ~~a greater~~ in efficacy, or ~~greater~~ in safety with a non-inferior efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union ~~a meaningful reduction in disease morbidity or mortality for the relevant patient population. The meaningful reduction in disease morbidity or mortality for the relevant patient population may shall be demonstrated, where possible and appropriate, with data from comparative clinical trials studies that use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency~~. IT (Comments): ***IT comment: IT would propose an amendment to highlight the existence of an unmet need despite the existence of already authorised medicinal products.*** ES (Comments): ES supports this letter b as proposed by the PRES.

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	IE (Suggested adaptations to the text): b) the use of the medicinal product for such a disease results in clinically relevant advantage in efficacy, or in safety with a non-inferior efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment ~~authorised~~ **commonly used** in the Union IE (Comments): IE considers the wording of Art 83 improved but in relation to para 1(b)- if the reference to other methods of diagnosis, prevention and treatment authorised in the union is intended to take into account other products, such as medical devises or SoHo, different wording should be used here as not all such products will be 'authorised' e.g. medical devices are registered/certified and individual SoHOs are not necessarily authorised on a product-by-product basis. We have suggested the use of the phrase 'commonly used' instead which is used in a COM notice providing guidance on the content of applications for the designation of orphan

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Presidency compromise	Suggested adaptations to the text and Comments
	medicinal products where a similar consideration arises. DE (Suggested adaptations to the text): (b) the use of the medicinal product **for such a disease** results in **clinically relevant ~~advantage~~ ~~a greater~~ ~~in~~ efficacy, or ~~greater~~ in safety with a non-inferior efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union** ~~a meaningful reduction in disease morbidity or mortality for the relevant patient population.~~ **~~The meaningful reduction in disease morbidity or mortality for the relevant patient population may shall be demonstrated, where possible and appropriate, with data from comparative clinical trials studies that use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency.~~** DE (Comments): We do not support introducing a value judgement in the context of

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	authorization. Value judgements ("clinically relevant **advantage**") should remain purely on the national level. This is also reflected in the HTA regulation, where joint clinical assessments shall **explicitly not** contain value judgements, as this interferes with national competences. In addition, the supply situation and treatment practice differ in the individual MS, thus the operationalization would be difficult. Overall, the definition ultimately depends on which incentives are linked to the term. This requires further examination.
1a. The applicant shall demonstrate the improvement in efficacy or safety referred to in paragraph 1(b) with data from clinical trials that use, where possible and appropriate, a relevant and evidence-based comparator. ~~In the case of paragraph 1(b), the applicant shall demonstrate the greater efficacy or safety with data from clinical~~	AT (Comments): AT: Since incentives are tied to UMN, comparators suggested by HTA-Bodies/Payers in scientific advice should be taken into account. CZ

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~~**trials that use a relevant and evidence-based comparators.**~~	(Suggested adaptations to the text): **The applicant shall demonstrate the improvement in efficacy or safety referred to in paragraph 1(b) with data from clinical trials that use, where possible and appropriate, a relevant and evidence-based comparator in accordance with advice from the Agency. ~~In the case of paragraph 1(b), the applicant shall demonstrate the greater efficacy or safety with data from clinical trials that use a relevant and evidence-based comparators.~~** CZ (Comments): Please see the CZ comment above on para 1 letter b) of this Article. We are of the opinion that adding comparator is a step forward, however, it should be done in accordance with advice from the Agency. Please see the changes in wording proposed.
~~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.~~	

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3. ~~Where t~~**T**he Agency **shall** adopt~~s~~ 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].	
Article 84	
Data protection for repurposed medicinal products	

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Presidency compromise	Suggested adaptations to the text and Comments
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 different marketing authorisation holder than the reference medicinal product~~ and has not previously benefitted from data	IE (Suggested adaptations to the text): b) the medicinal product is authorised in accordance with Articles 9 to

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Presidency compromise	Suggested adaptations to the text and Comments
protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	12**, with a 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 IE (Comments): IE are of the view that the deleted text should be reinstated to prevent possible 'evergreening' practices. We would note that as per the remainder of the article, this provision (which provides for 4 years data protection for a new indication) was never intended to apply to medicines that have benefitted from data protection within the past 25 years and that for such medicines there are other options to obtain incentives for new indications.

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2. The data protection period referred to in paragraph 1 may only be granted once for any given medicinal product.	
3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	
Article 85	AT (Comments): AT welcomes and strongly supports the current proposal for the Bolar provision, including the addition of procurement tenders. We look forward to more precision in that clause as suggested by the commission (including limiting procurement tenders to such procedures where patent

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	provisions have expired after the tendering period has ended), as discussed in the working party. Additionally, we welcome a rephrasing that recognizes that the goal of these procedures is to "obtain" a marketing authorisation. DE (Comments): Scrutiny reservation.
Exemption to the protection of intellectual property rights	
1. **The protection provided by p**~~P~~atent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be	

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regarded as infringed when a ~~reference~~ **patented product~~,~~ or process~~,~~ ~~design or invention~~** ~~medicinal product~~ is used for the purposes of:	
(a) studies, trials and other activities conducted to generate data **necessary** for an application~~, which are necessary~~ for:	AT (Comments): AT: preferable wording "to obtain".
(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;	NL (Comments): We like to reiterate our point. From our national experts on intellectual property we understood that the exemption to the protection of intellectual property rights could be applied broader than these category of products. We propose to change "generic, biosimilar, hybrid or bio-hybrid medicinal products to "medicinal products" to prevent possible confusion.

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(ii) health technology assessment as defined in Regulation (EU) 2021/2282;	DE (Comments): We still do not see any need to extend the Bolar provision to HTA and pricing and reimbursement. We have circulated a question to the MS and the Commission in this regard in advance of the previous WP. Namely, to what extent HTA procedures and procedures for pricing and reimbursement are not carried out in MS due to conflicting patents. None of the MS replied. We were also unable to find any substantiated findings on this in the impact assessment, so that an extension appears questionable.
(iii) pricing and reimbursement.	
(aa) application on procurement tenders are submitted, in compliance with Union and national law,	CZ (Comments): CZ supports the extension of the Bolar exemption. We welcome the addition of the procurement bids in the text as proposed by HU PRES. It

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	represents a possibility of participating in procurement bids and improving availability of medicines right before the end of the market protection and supporting sustainability of financial budgets of payers as well. NL (Comments): During the CWP the CLS clarified that procurement bids are possible, but a clearer wording is needed. The CLS also confirmed that the Dutch ruling will be overruled. We place a scrutiny reservation to formulate a position on this addition. IT (Suggested adaptations to the text): ~~**(aa) application on procurement tenders are submitted, in compliance with Union and national law,**~~ IT (Comments): ***IT comments: As already stated, the procurement tenders could represents a commercial use of a product particularly when competing***

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	one product with another covered by a patent. IT reserves the right to assess this point further and maintains a scrutiny reservation. ES (Comments): ES supports this Presidency´s proposal. IE (Comments): We note the comments of the CLS and CION on this provision and await revised wording DE (Comments): We are critical of the reintroduction of procurement tenders. In our view, this represents a commercial activity which the Bolar exemption is not intended to facilitate.

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(b) the activities conducted exclusively for the purposes set out in point (a), may cover**, where relevant,** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of ~~patented~~ medicinal products or processes, including by third party suppliers and service providers.	DE (Comments): Point (b) appears to us to be systematically misguided in conjunction with point (a). We are working on an alternative formulation and a new structure.
2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.	IT (Suggested adaptations to the text): ~~**2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.**~~ DE (Comments): The main content seems to be taken from paragraph 1a. We continue to advocate deletion for the known reasons (above all legal certainty).

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3. This exception **provided for in this Article** shall not cover the placing on the market of the medicinal products resulting from such activities.	DE (Comments): We welcome the fact that this essential content has been given its own paragraph in the legal system.
~~**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).**~~	IT (Suggested adaptations to the text): **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**

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	procurement bids and decisions on applications referred to in paragraph 1 point (a).
~~**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.**~~	IT (Suggested adaptations to the text): **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.**
~~**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 application of pricing and reimbursement., when those**~~	IT (Suggested adaptations to the text): **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**

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~~**rules concern the applicant's activities that can be indirectly affected by intellectual property rights.**~~	**medicinal product on the market of that Member State conditional to submit an application of pricing and reimbursement., when those rules concern the applicant's activities that can be indirectly affected by intellectual property rights.**
Recitals 63-65	
(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without	CZ (Comments): CZ would like to ask for clarification whether the new proposal of this recital is in accordance with Article 85 para 1 subpara 1 letter (aa). Otherwise, we consider it important to add a possibility of submitting of applications into procurement bids into this recital as well. This part

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this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process**, even in the cases of procurement tenders**.	should be more clarified. IT (Suggested adaptations to the text): (63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing

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	reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process**, ~~even in the cases of procurement tenders~~**. DE (Comments): In our opinion, the last sentence needs to be clarified in order to fully reflect the regulatory content (exclusion of commercial use) provided for in Art. 85 (3). We are working on an alternative proposal. Regarding the reference to "procurement tenders", please see our comment for Article 85 para. 1 point aa).
(64) It will allow, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations	

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during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.	
(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product. ~~**While this corresponds to the current application of the regulatory framework of medicinal products, it seems appropriate to clarify it in this Directive for the avoidance of doubt. Similarly, the protection of intellectual property rights shall not be a**~~	CZ (Comments): CZ would like to ask for clarification of HU PRES proposal in this recital, respectively, which national requirements are meant. This part should be more clarified. IT (Suggested adaptations to the text): (65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities

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~~valid ground to refuse or suspend decisions related to pricing and reimbursement or health technology assessment procedures.~~ ~~However,~~ Member States should remain free to introduce a national requirement to prove the ~~availability~~ readiness to supply ~~of~~ a ~~medicine~~ medicinal product on the market of that Member State for the period when the patent and SPC has expired~~at the date of submission of the application for pricing and reimbursement~~.	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. **While this corresponds to the current application of the regulatory framework of medicinal products, it seems appropriate to clarify it in this Directive for the avoidance of doubt. Similarly, the protection of intellectual property rights shall not be a valid ground to refuse or suspend decisions related to pricing and reimbursement or health technology assessment procedures. However, Member States should remain free to introduce a national requirement to prove the availability ~~readiness to supply~~ of a ~~medicine~~ medicinal product on the market of that Member State ~~for the period when the patent and SPC has expired~~ at the date of submission of the application for pricing and reimbursement.** DE (Comments): We welcome the deletion in order to avoid legal uncertainty. However, we don't fully understand the reasons for the latest additions and kindly ask for further explanations in this respect.

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Article 86	
Rewards for paediatric medicinal products	
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	

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to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	
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 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.	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
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 **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	

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Presidency compromise	Suggested adaptations to the text and Comments
- 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).	
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	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
ORPHAN INCENTIVES	
Chapter II **GENERAL PROVISIONS AND RULES ON APPLICATIONS**	
Section 2	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
Marketing authorisation decisions	
Article 29	
Regulatory protection periods	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC].	
CHAPTER VI **ORPHAN MEDICINAL PRODUCTS**	
~~*Article 70*~~	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
~~*Orphan medicinal products addressing a high unmet medical need*~~	
~~1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following requirements:~~	
~~(a) there is no~~ **~~satisfactory method of diagnosis, prevention or treatment in standard of care~~** ~~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;~~	

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Presidency compromise	Suggested adaptations to the text and Comments
~~(b) the use of the orphan 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 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.~~**	
~~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.~~	

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Presidency compromise	Suggested adaptations to the text and Comments
~~3. Where t~~**~~T~~**~~he Agency~~ **~~shall~~** ~~adopts scientific guidelines for the application of this Article~~**~~. To this end~~**~~, it shall consult the Commission and the authorities or bodies referred to in Article 162.~~	
Article 71	AT (Comments): AT agrees with the return to the current provision (10 year market exclusivity). However, this is contingent on the re-introduction of the profitability aspect in the context of a regular re-evaluation for maintaining market exclusivity, including an assessment whether the volume of sales have exceeded a predefined threshold. This would reflect the initial aim of the OMP Regulation, namely to incentivise the development in disease areas where the cost of development would not be recovered by the expected sales of the medicinal product (see also Recital 1 of the current OMP Regulation). When an orphan product is proven to be profitable, market exclusivity should be revoked or reduced. This

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Presidency compromise	Suggested adaptations to the text and Comments
	would substantially relieve pressure on health budgets by allowing an earlier market start for a generic or similar orphan product
Market exclusivity	
1. Where an orphan marketing authorisation is granted and without prejudice to intellectual property law, the Union and the Member States shall not grant a marketing authorisation or **~~extension of indication to~~** extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product for the duration of market exclusivity set out in paragraph 2.	

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Presidency compromise	Suggested adaptations to the text and Comments
2. The duration of market exclusivity shall be as follows:	
(a) ~~nine~~ **ten** years for orphan medicinal products other than those referred to in point~~s (b) and~~ (c);	
~~(b) ten years for orphan medicinal products addressing a high unmet medical need as referred to in Article 70;~~	
(c) five years for orphan medicinal products which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].	

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Presidency compromise	Suggested adaptations to the text and Comments
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.	
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 similar medicinal product if:	

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Presidency compromise	Suggested adaptations to the text and Comments
(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 authorisation for a generic or biosimilar product to the reference medicinal product for which market exclusivity has expired, shall not be prevented by the	NL (Suggested adaptations to the text): 5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing authorisation for a

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Presidency compromise	Suggested adaptations to the text and Comments
market exclusivity of a similar product to the reference medicinal product.	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 **medicinal** product to the reference medicinal product. NL (Comments): We have a text proposal for clarification
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	AT (Comments): AT: If this is kept, the relation between Article 71(1) and this para (6) should be addressed in the wording of at least one of the provisions. NL

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Presidency compromise	Suggested adaptations to the text and Comments
medicinal product, including generics and biosimilars, where the remainder of the duration of the market exclusivity is less than two years.	(Suggested adaptations to the text): 6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for **or the granting of** a marketing authorisation **~~for, a medicinal product~~** **~~or granting a marketing authorisation,~~** **including the extension of 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 two years. NL (Comments): We have a text proposal for clarification. IT (Comments): ***IT comment: The change provided by the PCY, by inserting "or granting", is not clear and seems to be in contrast with paragraph 1 of***

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Presidency compromise	Suggested adaptations to the text and Comments
	article 71, providing that "Where an orphan marketing authorisation is granted and without prejudice to intellectual property law, the Union and the Member States shall not grant a marketing authorisation ~~or extension of indication to~~ extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product for the duration of market exclusivity set out in paragraph 2.".
7. Where the Agency adopts scientific guidelines for the application of paragraphs 1 and 4, it shall consult the Commission.	

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Presidency compromise	Suggested adaptations to the text and Comments
Article 72	
Prolongation of market exclusivity	
~~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(1**a**) [of revised Directive 2001/83/EC] are fulfilled.~~	

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Presidency compromise	Suggested adaptations to the text and Comments
~~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.~~	
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**~~.	

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Presidency compromise	Suggested adaptations to the text and Comments
Such a prolongation may be granted twice, if the 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 8**0**~~1~~(2)~~, point (d),~~ of [revised Directive 2001/83/EC].	
4. Article 71(3) equally applies to the prolongations of market exclusivity referred to in paragraph~~s 1 and~~ 2.	

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Presidency compromise	Suggested adaptations to the text and Comments
REPURPOSING BY ANOTHER ACTOR ('CHAMPION')	
CHAPTER IV **POST-MARKETING AUTHORISATION MEASURES**	
Article 48	NL

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Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): In practice, we see that academics and other third parties also perform dose and treatment optimisation studies to ensure safe and effective use of medicinal products. Could the Commission clarify whether these studies could also be handed in under this article?
Scientific opinion on data submitted from not-for-profit entities for repurposing of authorised medicinal products	
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~~.	IE (Comments): We await the CLS view on this description of a 'not-for-profit entity' and the associated definition of an 'entity not engaged in an economic

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Presidency compromise	Suggested adaptations to the text and Comments
	activity’
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.~~	NL (Suggested adaptations to the text): 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.~~. The Agency shall draw up guidance on the consultation process. NL (Comments): As previously stated, the Netherlands supports this article. The Commission confirmed during the prior council working party that involvement of the MAH is foreseen. The Commission clarified this could be clearer in text. We would propose to add in legal text that guidelines will be made to clarify the process, including the involvement of MAHs.

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Presidency compromise	Suggested adaptations to the text and Comments
The opinion of the Agency shall be made publicly available and the competent authorities of the Member States shall be informed.	
2. In cases where the opinion is favourable~~,~~ **and the new therapeutic indication addresses an unmet medical need,** ~~on~~ **on the request of the Agency** ~~the Agency shall inform Member States and the Commission and request~~ the marketing authorisation holders of the medicinal products concerned ~~to~~ shall submit a variation to update the product information with the new therapeutic indication ~~in accordance with~~	IT (Comments): ***IT comment: IT reiterates the comments already provided to Incentive Cluster 13037*** IE (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
~~**Article 47**~~.	As per previously discussed changes to paragraph 1 of this article its overall scope was extended to go beyond UMN. However, the proposed changes to this paragraph would limit the scope of mandatory variations following a positive COM opinion to indications addressing an UMN. We would like to clarify the rationale for having different scopes in paragraphs 1 and 2 and understand what will happen in the event of a positive scientific opinion for an indication that does not address UMN. We also note that it may be difficult to strictly require not-for-profit entities to carry out comparative CTs to demonstrate UMN when there is an existing authorised medicine for the same indication.
3. Article 8**0**~~1~~(2), **2nd subparagraph** ~~point (~~**dc**~~)~~ **and Article 84(1)** of [revised Directive 2001/83/EC] shall not apply for variations under this Article.	

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Presidency compromise	Suggested adaptations to the text and Comments
Article 4 (Directive)	
Definitions	CZ (Comments): CZ would like to ask a general scrutiny reservation on Article 4 and definitions.
(52) ‘entity not engaged in an economic activity’ means any legal or	IE

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Presidency compromise	Suggested adaptations to the text and Comments
natural person that is not engaged in an economic activity and that:	(Comments): See comment on Art 48 above.
(a) is not an undertaking or controlled by an undertaking; and,	
(b) has not concluded any agreements with any undertaking concerning sponsorship or participation to the medicinal product development;	
PRE-AUTHORISATION REGULATORY SUPPORT	
CHAPTER V	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
PRE-AUTHORISATION REGULATORY SUPPORT	
Article 58	
Scientific advice	

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

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Presidency compromise	Suggested adaptations to the text and Comments
that requested the scientific advice, the Agency may consult experts of the Member States with clinical trial or medical device expertise or the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745.	
3. In the preparation of the scientific advice referred to in paragraph 1 and in duly justified cases, the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in question or other public bodies established in the Union, as applicable.	

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Presidency compromise	Suggested adaptations to the text and Comments
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.	
Article 59	
Parallel scientific advice	
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	

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Presidency compromise	Suggested adaptations to the text and Comments
by the 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	

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Presidency compromise	Suggested adaptations to the text and Comments
respective authorities or bodies and, where applicable, have synchronised timing, while preserving the separation of their respective remits.	
Article 60	
Enhanced scientific and regulatory support for priority medicinal products ('PRIME')	
1. The Agency may offer enhanced scientific and regulatory support,	IT

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Presidency compromise	Suggested adaptations to the text and Comments
including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil **at least one of** the following conditions:	(Comments): ***IT comment: IT would like to amend the text of this article in order to better reflect the requirements for accessing the PRIME scheme. The amendment follows the EMA guideline on enhanced early dialogue to facilitate accelerated assessment of PRIority MEdicine.***
(a) are likely to address an unmet medical need as referred to in Article 83(1) of [revised Directive 2001/83/EC];	IT (Suggested adaptations to the text): (a) are likely to address an unmet medical need as referred to in Article 83(1) of [revised Directive 2001/83/EC] **to a significant extent based on the potential to bring a major therapeutic advantage to patients through a clinically meaningful improvement of efficacy or improving the morbidity or mortality of the disease;**
(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)~~;	NL (Comments): We want to reiterate our point.

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Presidency compromise	Suggested adaptations to the text and Comments
	• The Netherlands remains of the opinion that all orphans should be eligible for PRIME and the wording 'and are likely to bring exceptional therapeutic advancement' should be deleted. • This is beneficial for the EU-competitiveness. Our experts performing PRIME, agree that PRIME is more resource intensive, but see that PRIME saves more resources in the process afterwards. • In order to future proof the article, we propose to add a sentence stating that the scope will be determined in guidance, combined with an evaluation of the scope and possible adaptation. Thus allowing for greater flexibility. IT (Suggested adaptations to the text): ~~(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);~~ IE (Comments): Clarification is requested as to whether orphan medicinal products could

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Presidency compromise	Suggested adaptations to the text and Comments
	also seek to enter PRIME via options (a), (c) or (d). Given the added text in (b), if only option (b) applies for an orphan medicinal product it would seem like the requirement for an orphan medicinal product to enter PRIME (likely to bring exceptional therapeutic advancement) would be higher that option (a) unmet medical need or (c) major interest from a public health perspective. It is considered that the criteria for orphan medicinal products to enter PRIME should not be more stringent than for other types of medicinal products.
(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)**;-**	

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Presidency compromise	Suggested adaptations to the text and Comments
(d) are likely to adress a neglected tropical disease (NTD).	
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.	
3. The Agency may stop the enhanced support if it is established that the medicinal product will not address the identified unmet medical need **or does not have the potential to enhance preparedness and response to serious cross border health threats** to the anticipated extent.	AT (Comments): AT: This possibilty to stop the enhanced support should be aligned with para (1) points (a) to (d) and para (2).

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Presidency compromise	Suggested adaptations to the text and Comments
	It should only apply to cases of • para (1) point (a), where support is only granted because of an unmet medical need, if such need will not be met, or • para (2), where support is initially granted in view of a serious cross border health threat, if preparedness an response cannot be enhanced. In other cases of para (1), it should not be possible to stop the enhanced support based on the reasons listed in para (3). NL (Comments): Could the Commission and the Presidency clarify why in para 3 only the criteria in 1a and 2 are listed and not those from 1c? Being: will not be of major interest from the point of view of public health (para 1c)

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Presidency compromise	Suggested adaptations to the text and Comments
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	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
REGULATORY SANDBOX	
Article 113	CZ (Comments): CZ supports the general idea of the regulatory sandbox and considers it important, in particular in emergency situations, when it is not possible to reach a solution in the current EU legal framework, but it is crucial to allow innovations to be implemented. However, we have some questions in order to clarify the provision in this matter. What mechanism will be used to establish regulatory sandbox? What role will be given to EMA and NCA, including a control task? On what legal basis will medicines become a part of the regulatory sandbox? How will the recommendations of EMA be reviewed? How will the related implementing acts be specified? Moreover, the form of act on which basis regulatory sandbox will be established should be specified. In the initial EC proposal of Regulation implementing acts are mentioned, however, in other parts of the text there

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Presidency compromise	Suggested adaptations to the text and Comments
	is an EC decision. Additionally, HU PRES proposes to use the wording implementing decision in the recital. This situation should be clarified because of the legal certainty. Opinion of CLS is expected in this matter.
Regulatory sandbox	
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:	
(a) it is not possible to develop the medicinal product or category of **medicinal** products in compliance with the requirements applicable to	

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Presidency compromise	Suggested adaptations to the text and Comments
medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;	
(b) the characteristics or methods referred to in point (a) positively and distinctively contribute to the quality, safety or efficacy of the medicinal product or category of products or provide a major ~~advantage~~ contribution to patient access to treatment.	
2. The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1 under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, [revised Directive 2001/83/EC]**,** ~~or~~ Regulation (EC) 1394/2007 **~~or~~**	

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Presidency compromise	Suggested adaptations to the text and Comments
~~**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 **the national competent authorities of the Member States,** marketing authorisation holders,	

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Presidency compromise	Suggested adaptations to the text and Comments
developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions.	
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**,** ~~**,**~~ **following appropriate consultations including consultation with the competent authorities of the Member States,** provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the **recommended** sandbox plan referred to in paragraph 1.	

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Presidency compromise	Suggested adaptations to the text and Comments
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 **including consultation with competent Authorities of the Member States**. The **sandbox** plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC]**, ~~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	

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

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Presidency compromise	Suggested adaptations to the text and Comments
(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.	

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

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Presidency compromise	Suggested adaptations to the text and 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 **referred to paragraphs 7 or to restart the sandbox following a suspension under paragraph 8** by means of implementing acts. The Commission may also prolong the duration of a regulatory sandbox by	

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Presidency compromise	Suggested adaptations to the text and Comments
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.	
Article 114	
Products developed under a sandbox	

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
1. When authorising a clinical trial application for products covered by a regulatory 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.	

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Presidency compromise	Suggested adaptations to the text and Comments
3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation and [revised Directive 2001/83/EC]**, 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.	
~~These derogations shall not cover the ethical assessment organised pursuant to Article 8, paragraph 4 of Regulation (EU) 536/2014.~~	

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Presidency compromise	Suggested adaptations to the text and Comments
4. For medicinal products developed as part of a regulatory sandbox for which a marketing authorisation has been granted in accordance with paragraph 2 and where appropriate paragraph 3, the summary of product characteristics and the package leaflet shall indicate that the medicinal product has been developed as part of a regulatory sandbox.	NL (Suggested adaptations to the text): 4. For medicinal products developed as part of a regulatory sandbox for which a marketing authorisation has been granted in accordance with paragraph 2 and where appropriate paragraph 3, the summary of product characteristics and the package leaflet shall indicate that the medicinal product has been developed as part of a regulatory sandbox. **This conditions applies for the duration of the regulatory sandbox.** NL (Comments): We would like to reiterate our point. We understand that transparency towards patients is needed when the medicinal product is still part of a regulatory sandbox. However, we do not think it is necessary and desirable for patients to mention that the medicinal product has been a sandbox product, once the sandbox has been terminated and a "normal" marketing authorisation has been granted to the product. We therefore

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Presidency compromise	Suggested adaptations to the text and Comments
	propose to restrict PARA 4 to when the regulatory sandbox is "active".
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).	
6. The Commission shall immediately vary the marketing authorisation to take account of the mitigation measures taken in accordance with Article 115.	

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Presidency compromise	Suggested adaptations to the text and Comments
Article 115	
General sandbox provisions	
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).	

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Presidency compromise	Suggested adaptations to the text and Comments
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.	
2. Participants in **~~T~~**the regulatory sandbox**~~, in particular the marketing authorisation holder of the medicinal product concerned,~~** shall remain **~~is~~ without prejudice to rules related to** ~~liable~~ **~~liability~~** under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the testing taking place in the sandbox. **~~2a.~~**They **~~Entities implementing the sandbox~~** shall inform the Agency	

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Presidency compromise	Suggested adaptations to the text and Comments
without undue delay of any information which might entail the amendment of the regulatory sandbox or concerns the quality, safety or efficacy of products developed as part of a regulatory sandbox.	
Recital 135	
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 ~~may~~**could** be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox **are capable of** ~~should~~ inform**ing** future changes to the legal framework **in order** to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted	IT (Suggested adaptations to the text): 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 ~~may~~could 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

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Presidency compromise	Suggested adaptations to the text and Comments
frameworks ~~may~~**could** be developed by the Commission on the basis of the results of a regulatory sandbox. **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 authorision holders, applicants for marketing authorisation, or any entities involved in the lifecycle of the medicinal product**.	framework in order to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks ~~may~~could be developed by the Commission on the basis of the results of a regulatory sandbox. ~~**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 authorision holders, applicants for marketing authorisation, or any entities involved in the lifecycle of the medicinal product**~~ **Medicinal products developed under a sandbox should comply with the same regulatory principles of quality, safety and efficacy as any 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 authorision holders, applicants for marketing authorisation, or any entities involved in the lifecycle of the medicinal product.**

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Presidency compromise	Suggested adaptations to the text and Comments
	IT (Comments): ***IT comment: IT agrees with the amendment that specifies the need to comply with the regulatory principles of quality, safety and efficacy. However, IT expresses concern over the phrase "Marketing authorisations under a sandbox" because this should not refer to a different kind of marketing authorisation. Therefore, IT proposes its deletion.***
3. The modalities and the conditions of the operation of the regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing	

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

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Presidency compromise	Suggested adaptations to the text and Comments
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].	
CHAPTER III **INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'**	IT (Comments): ***IT comment: IT would like to reiterate its concerns over the proposed voucher system and maintains a scrutiny reservation.*** ***IT considers that this system poses problems in terms of sustainbaility for the NHS due to the high costs, and for the lack of predictability in terms of effectiveness of the proposed solution.*** ***In light of the above, in order to combat AMR, other incentives having the potential to encourage the development of 'priority antimicrobials' should be evaluated instead of the voucher (e.g. through the involvement of HERA, by stimulating R&D of new products, by direct financial incentives or by adopting incentive mechanisms similar to those used for rare diseases).***

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Presidency compromise	Suggested adaptations to the text and Comments
	LT (Comments): LT: We maintain the general scrutiny reservation regarding all transferable data exclusivity voucher provisions. DE (Comments): Scrutiny reservation: we are concerned about the cost burden.
	IE (Comments): IE has a scrutiny reservation on Articles 40 & 41 IE acknowledges the need to find appropriate measures to address the evolving threat of AMR and fully supports this ambition. However, IE still has concerns in relation to the proposed TEVs even with a derisking approach. These concerns centre around the potential

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Presidency compromise	Suggested adaptations to the text and Comments
	implications for national health budgets which these vouchers may have, both in terms of costs, and delaying the entry into the market of generic / biosimilars.
Article 40	AT (Comments): AT: We remain convinced that other solutions (especially outside the pharmaceutical legislation) may be a better avenue to stimulate research in the development of novel antibiotics. However, considering the discussions in the working party AT supports the current provisions for the voucher. CZ (Comments): CZ does not support the proposed text related to TEV which is suggested by EC. Moreover, we are not in favour with the changes proposed by HU PRES. Particularly, **the idea of transferability of the voucher is not supported**. TEV is proposed in the context of unavailability of antimicrobial medicines. However, **it raises concerns about**

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Presidency compromise	Suggested adaptations to the text and Comments
	unpredictable consequences on budgets of payers of healthcare services in Member States. Especially, in the case if the TEV is used for a medicine which is considered attractive on the market. **CZ fundamentally does not support to finance TEV from healthcare insurance system, respectively from healthcare systems of Member States.** Moreover, on the basis of EC proposal, there is no guarantee that such medicine will be in fact developed based on TEV. In general, CZ can support the tool of a voucher (e.g. reward for developing an antimicrobial) provided there is not a transferable voucher, meaning TEV itself. We consider it important to open a discussion on other options how to motivate pharmaceutical companies to research and develop new antimicrobial medicines. The basis is to safeguard safety of patients within the EU and not to finance this kind of tool from healthcare systems of Member States. There are the other options such as Horizon Europe Programme.
Granting the right to a transferable data exclusivity voucher	NL (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
	The Netherlands agrees that the current system of regulatory incentives does not encourage the development and availability of antimicrobials. However, we have expressed our concerns with the **transferable exclusivity vouchers (TEV)** during previous Council Working Parties and pleaded to delete the TEV. Our primary concern is that the TEVs are indirect and non-transparent with unpredictable costs. However, we acknowledge that deleting the TEV is difficult with the Council's position and understand we will keep discussing the TEV. We have several questions on this article to further formulate a position on the TEV.
1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4	

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based on a scientific assessment by the Agency.	
2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection **within the meaning of Article 80 paragraph 1 of [revised Directive 2001/83/EC]** for one authorised medicinal product.	NL (Comments): We'd like to flag that legal text clarification is needed on whether the exclusivity with a voucher is excluded from the cap of 8 years RDP in article 81. IT (Comments): ***IT comment: It should be clarified whether it refers to the base RDP or to the maximum duration under Article 81.***

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3. An antimicrobial shall be considered 'priority antimicrobial' if **it addresses a multi-drug resistant organism and serious or a life-threatening infection, the** preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:	AT (Comments): AT: To be supported. CZ (Comments): CZ would like to ask for clarification of consequences and feasibility of HU PRES proposal in this provision. The purpose of this text should be more clarified. ES (Suggested adaptations to the text): 3. An antimicrobial shall be considered 'priority antimicrobial' if ~~**it addresses a multi-drug resistant organism and serious or a life-threatening infection, the**~~ preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:

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	ES (Comments): ES proposes to come back to the Commission´s proposal.
(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~~.	ES (Suggested adaptations to the text): (c) it contains an active substance not previously authorised in a medicinal product in the Union-that addresses a multi-drug resistant organism **~~and~~ or serious or life threatening infection.** ES (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
	ES considers ´and´ serious or life threatening infection makes the text more complex. There is a WHO list of priority pathogens for which most institutions and NCAs agree that new antibiotics are needed. This list is based on multi-resistance criteria and global impact (burden disease, transmissibility, readability and prevention).
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.	
4. To be granted the voucher by the Commission, the applicant shall:	

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(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.	
(c) demonstrate that the application for granting a marketing authorisation of the priority antimicrobial has been first submitted to the Agency or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the European Union.	CZ (Suggested adaptations to the text): ~~demonstrate that the application for granting a marketing authorisation of the priority antimicrobial has been first submitted to the Agency or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the European Union.~~ CZ (Comments):

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	Apart from the general CZ comment on TEV, CZ is of the opinion that HU PRES proposal on the other condition does not bring explanation on the TEV proposal in the question of transparency and predictability. Therefore, this condition is not considered important and is proposed to be deleted. Please see the changes in wording. ES (Comments): ES supports this provision.
Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.	

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5. Once the marketing authorisation is granted, the Agency shall inform without undue delay the MSSG, in accordance with Article ~~130~~ 131 paragraph 2~~, second subparagraph, to initiate the procedure~~ with a view to propose a ~~for~~ the potential inclusion of the priority antimicrobial on the Union list of critical medicinal products~~, in agreement with the procedure set out in Article 131 of the Regulation~~.	CZ (Comments): CZ can support that MSSG should take into consideration inclusion of priority antimicrobial medicines on the Union list of critical medicines. Concerning the new HU PRES proposal, we have no comments in this matter. NL (Comments): Could the PRES clarify on PARA 5 why this PARA is needed in legislation? We feel that this might be redundant.

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~~**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.**~~	
Article 170	CZ (Comments): CZ would like to apply a scrutiny reservation on Article 170. We are of the opinion that the process of evaluation of TEV after two successful TEV should be more specified. It is not clear whether the process of TEV themselves would be possible during the evaluation or should be stopped in this case. We would like to ask for the clarification of this situation.

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Presidency compromise	Suggested adaptations to the text and Comments
Evaluation	
(…)	
6. The Commission shall, following the use of two vouchers or every 5 years pursuant to Article 41, paragraph 2, carry out an evaluation of Chapter III of this Regulation and present a report on the main findings of that evaluation to the European Parliament and the Council. The evaluation shall include an assessment of the effectiveness of the voucher as a measures, taking into account also other existing Union level market incentives for authorised priority antimicriobials, 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,	NL (Comments): We interpretate that his article allows evaluation after each 5 years. Is our assumption correct that the PRES also foresees to evaluate each time after two vouchers has been used? How the PARA is now phrased, we see that for evaluation after a voucher has been used, will only happen once.

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Presidency compromise	Suggested adaptations to the text and Comments
present a legislative proposal, based on the evaluation, in order to amend this Regulation.	
Article 41	
Transfer and use of the voucher	IT (Comments): ***IT comment: IT would like to reiterate its concerns over the proposed voucher system and maintains a scrutiny reservation. Specifically, the proposed calculation for defining a blockbuster is complex and there is a high risk of non-sustainability of the healthcare system if this value does not have the ability to avoid transferability to such products.***

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Presidency compromise	Suggested adaptations to the text and Comments
1. A voucher may be used to extend the data protection for a period of 12 months **within the meaning of Article 80 paragraph 1 of [revised Directive 2001/83/EC],** of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	NL (Comments): This PARA restrict the use of the voucher to the fifth year. This could be too restrictive. Has the PRES considered a time frame, for example fourth and fifth year, instead of 1 year? IT (Comments): ***IT comment: please see comment on art.40.***
A voucher can be transferred at any time before its use. A voucher **may** ~~shall~~ ~~only~~ be used once **only** and in relation to a single centrally	AT (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
authorised medicinal product**.** ~~and only if that product is within its first **six** four years of regulatory data protection.~~	AT: New wording accepted. CZ (Comments): CZ is of the opinion that HU PRES proposal on TEV does not bring **more transparency and explanation on the TEV proposal as there are still unpredictable consequences on budgets of payers of healthcare services of Member States,** even thought, there is the blockbuster clause proposal. In general, provisions to TEV should be more clarified. ES (Comments): ES supports the provision referring a the transfer of the voucher at any time before use.
In case of a medicinal product other than the priority antimicrobial concerned~~, while the the voucher can be transferred any time before the use~~, the use of the voucher can take place only in the fifth ~~sixth~~ year of the regulatory data protection period and if the marketing authorisation holder demonstrates that the ~~and its average~~ annual	IT (Comments): ***IT comment: IT believes that the financial impact for Member states due to the non-entry of generics, as explained by the PCY during the last working party, is underestimated because the percentage of price***

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Presidency compromise	Suggested adaptations to the text and Comments
gross sales of ~~the~~ that medicinal products ~~s~~ in the Union during any of the ~~Y years~~ preceding four years ~~the use of the voucher does not~~ have not exceeded ~~X~~ 490 million euros.	***decrease due to the entry of generics could be higher. Therefore, the financial impact due to lost savings may be greater.*** ES (Comments): ES has scrutiny reservation on the value of X as established in 490 million euros.
~~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.~~	
1a. The marketing authorisation holder shall demonstrate that information about the annual gross sales referred to in para (1) is	IT (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
accurate and complete and that it has been audited by an independent external auditor.	***IT comment: It is IT opinion that further information on the external auditor should be given.***
~~**The additional data protection period shall not apply if the annual gross sales of the medicinal product concerned in the Union exceeds the amount referred to in point 1 of this Article.**~~	CZ (Comments): CZ can agree with the deletion of this provision as proposed by HU PRES as it represents duplication of the legislative text mentioned above.
~~**The Commission is empowered to adopt delegated acts in accordance with Article 175 of this Regulation to adjust this amount with the rate of the inflation.**~~	CZ (Comments):

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Presidency compromise	Suggested adaptations to the text and Comments
	CZ can agree with deleting of this provision as proposed by HU PRES.
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.	
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.	

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Presidency compromise	Suggested adaptations to the text and Comments
3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.	MT (Comments): The new structure of the article may be misleading. This paragraph should be integrated in para 1 which also regulates the transfer.
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 **on its webpage**.	

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Presidency compromise	Suggested adaptations to the text and Comments
Article 42	
Validity of the voucher	
1. A voucher shall cease to be valid in the following cases:	

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Presidency compromise	Suggested adaptations to the text and Comments
(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 **by any Member State or the Commission**, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.	NL (Comments): Could the PRES or CIE elaborate on how it sees PARA 2 if there are shortages out of the responsibilities of a MAH? Is it then possible or desireable to revoke the voucher?

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Presidency compromise	Suggested adaptations to the text and Comments
3. Without prejudice to patent rights, or supplementary protection certificates[7], 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].	

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

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
Article 43	
Duration of application of Chapter III	
This Chapter shall apply**, ~~subject~~ taking ~~to~~ into account of the outcome of the evaluations referred to in Article 170 paragraph 6,** until [*Note to OP: insert the date of 15 years after the date of entry into force of this Regulation*] or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.	NL (Suggested adaptations to the text): This Chapter shall apply**, ~~subject~~ taking ~~to~~ into account ~~of~~ the outcome of the evaluations referred to in Article 170 paragraph 6,** until [*Note to OP: insert the date of 15 years after the date of entry into force of this Regulation*] or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
	NL (Comments): We have an editorial suggestion to delete “of”.
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	
Article 4	
Definitions	CZ (Comments):

From: AT, CZ, MT, NL, IT, ES, EE, SI, IE, LT, DE **Updated: 25/11/2024 14:44**

Presidency compromise	Suggested adaptations to the text and Comments
	CZ would like to ask a general scrutiny reservation on Article 4 and definitions.
(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 **and antiprotozoals**;	NL (Comments): We flag that during the previous CWP, the Commission proposed to use antiparasites instead of antiprotozoals. This should be consistent.