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LIMITE

SAN **VETER**
PHARM **ENV**
MI **RECH**
COMPET **CODEC**
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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 13037/24).

Incentives_13037_24 Deadline: ***26 September 2024***

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

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

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

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

Thank you for your cooperation!

Presidency comrpomise	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 comrpomise	Suggested adaptations to the text and Comments
ADAPTED FRAMEWORKS	
Chapter II **Application requirements for national and centralised marketing authorisations**	
Section 5	
Adapted dossier requirements	IT (Comments): ***IT COMMENT: It supports the amendments provided by the PCY.***
Article 28	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 specific scientific or regulatory requirements due to the characteristics or methods inherent to the medicinal product ***or category of medicinal products***, when:	
(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	

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Presidency comrpomise	Suggested adaptations to the text and Comments
from characteristics or methods inherent to the medicinal product ***or category of medicinal products***; and	
(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.	EE (Suggested adaptations to the text): EE (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~~. EE (Comments): EE 'patient care' does not fall under the scope of this Directive and should be therefore left out since specific requirements will be elaborated only on medicinal products.

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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.	RO (Comments): RO agrees with the proposed changes.
3. The Commission **~~may adopt implementing acts~~** is empowered to adopt ~~delegated~~ **implementing** acts ~~in accordance with Article~~ 215 **214** ~~to supplement this Directive~~ by laying down~~:~~	RO (Comments): RO agrees with the proposed changes.

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Presidency comrpomise	Suggested adaptations to the text and Comments
~~(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;~~	AT (Suggested adaptations to the text): AT: (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; AT (Comments): AT: This would be a problematic reduction of Commission power towards supervision EE (Suggested adaptations to the text): EE (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; EE (Comments): EE Should be reinstated for alignment in para 4 and 5.

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Presidency comrpomise	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.	EE (Suggested adaptations to the text): EE (b) the technical documentation to be submitted by applicants for marketing authorisations for medicinal products **or category of medicinal products** referred to in paragraph 1. EE (Comments): EE "or category of medicinal products" should be added for alignment in para 3(a).

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Presidency comrpomise	Suggested adaptations to the text and Comments
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, 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**	LT (Comments):

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an adaptation, enhancement, waiver or deferral from the requirements laid down in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007. ~~The **specific** detailed rules referred to in paragraph 3, point (a), shall be proportionate to the risk and impact involved. These may entail adapted, enhanced, waived or deferred requirements.~~ Any **adaptation, enhancement,** waiver or deferral shall be limited to the extent strictly necessary, proportionate and duly justified by the characteristics or methods inherent to the medicinal product **or category of medicinal products**, and shall be regularly reviewed and evaluated **by the Commission** ~~**by the Agency**~~. Apart from the **specific** ~~detailed~~ rules referred to in paragraph 3, point (a), all other rules laid out in this Directive shall apply.	LT: We pay attention to the reference to paragraph 3 point (a) – it is deleted. NL (Suggested adaptations to the text): **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 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

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	specific ~~detailed~~ ~~**rules**~~ **requirements** referred to in **paragraph 3a**, ~~**point (a),**~~ all other rules laid out in this Directive shall apply. NL (Comments): We propose to replace 'rules' by requirements to align the text with para 3a. In addition, the reference to para 3 should now read para 3a. IT (Suggested adaptations to the text): 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 requirements.~~ Any **adaptation, enhancement,** waiver or deferral shall be limited to the extent strictly necessary, proportionate and duly justified by

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	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~~. IT (Comments): ***IT COMMENT: please delete the sentence "Apart from the specific ~~detailed~~ rules referred to in paragraph 3, point (a), all other rules laid out in this Directive shall apply." since appears not in line with the amendments provided above.***
5. Until the adoption of **specific** ~~detailed~~ rules for ~~specific~~ medicinal products **or category of medicinal products** listed in Annex VII	NL (Suggested adaptations to the text):

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Presidency comrpomise	Suggested adaptations to the text and Comments
pursuant to paragraph 3, an application for a marketing authorisation for that medicinal product may be submitted in accordance with Article 6(2).	Until the adoption of **specific** ~~detailed~~ ~~**rules**~~ **requirements** for ~~specific~~ medicinal products **or category of medicinal products** listed in Annex VII pursuant to ~~**paragraph 3**~~ **paragraph 3a**, an application for a marketing authorisation for that medicinal product may be submitted in accordance with Article 6(2). NL (Comments): We propose to change the wording 'rules' to 'requirements' and to change the reference to para 3a, in line with our remarks in para 4.
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	

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Presidency comrpomise	Suggested adaptations to the text and Comments
sandbox established in accordance with Article 115 of the [revised Regulation (EC) No 726/2004].	
REGULATORY DATA PROTECTION, UNMET MEDICAL NEEDS, REWARDS FOR PAEDIATRICS	
Chapter VII **Regulatory protection, unmet medical needs and rewards for paediatric medicinal products**	FR (Comments): Scrutiny reservations The French position cannot change at present because of the political context.
Article 80	AT

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): AT (general remark): AT has supported the initial commission proposal to reduce RDP to 6 years combined with the new approach to modulate incentives. AT still strongly supports the reduction of the baseline RDP to 6 years in combination with incentives, but sees movement towards a compromise in the dossier as vital. AT welcomes the new compromise text by the presidency and supports the proposal made by NL in the working party: to remain at 6 years baseline + one more easily obtainable incentive (R&D in Europe/production in Europe if no infringement with international trade laws.) + selection of incentives as suggested by the presidency. However, in the spirit of moving towards a compromise, AT remains open to discussions.
Regulatory data and market protection	DE (Comments): DE continues to advocate the retention of the current protection periods. A total period of protection of 11 years must not be exceeded. PT

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): Scrutiny reservation
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').	
2. A medicinal product concerned by a subsequent marketing authorisation referred to in paragraph 1 shall not be placed on the market	RO (Comments):

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for a period of two years after the expiry of the relevant regulatory data protection periods referred to in Article 81.	RO supports the amendment of para 2, removing the reference to the fact that, in the case of a new therapeutic indication, the applicant must demonstrate that the study reports specific to the new indication did not exist at time of initial authorization , and is consistent with our previous observations.
	IE (Suggested adaptations to the text): 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. **This period shall not apply in Member States that have not been supplied by the original marketing authorisation holder, in accordance with article 56a** IE (Comments): IE does not believe that market protection should automatically apply in all member states given that under article 56a, market protection will not

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	apply in a member state if a company does not comply with the supply obligations. To this end, we are concerned that the current text here automatically grants market protection across all member states that then must be taken away if obligations are not met. IE therefore proposes to clarify in this paragraph, that market protection should only apply where a product is supplied to a member state in line with the new supply obligations under 56a, and therefore allow generics to be placed on the market before the 2 years if the 56a supply requirements have not been met.
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	AT (Suggested adaptations to the text): AT: 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

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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.~~	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 support the condition of non-existence of data at time of MA when applying for an extension in order to avoid ever-greening methods. This could be controlled through the submission of clinical trial protocols or "last patient, last visit". AT is however also open to a deletion as suggested by the presidency on July 19th. CZ

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	(Suggested adaptations to the text): **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 the applicant shall demonstrate that the clinical study reports specific to the approval of the new indication were not available at the time of the submission of the initial authorisation application.** CZ (Comments): In accordance with its previous comments CZ supports tightening of the incentive on new therapeutic indication of medicine as was proposed by HU PRES in the previous text in this matter. CZ prefers maintaining this part of the text as proposed as explanation of provability of this provision

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	considers sufficient. Moreover, CZ is of the opinion that timeframe of study conducted on support of new indication is sufficiently mentioned in report on clinical trials as well as in European database on clinical trials which is publicly available. Apart from that CZ considers it important that burden of proof is on MAH as included in this proposal. Please see the change in wording. LT (Comments): LT: We agree with the deletion of MAH's obligation to demonstrate 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. NL (Comments): The NL delegation supports the proposed changes in Para 2. PT

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	(Comments): We can agree with the deletion as it is less restrictive of the data to be taken into account IT (Comments): ***IT comment: IT supports the amendment provided by the PCY.***
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.	

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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 **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 insofar as the compulsory licence requires, ~~and during~~ **for** the duration **and the territory of the Member States for which** ~~period of~~ the compulsory licence **has been granted**.	NL (Comments): The NL delegation supports the changes in para 4. SE (Suggested adaptations to the text): 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**~~ **as 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 **licensee** insofar as the compulsory licence requires, ~~and during~~ ~~**for** the~~ **during the period for which** ~~ation~~ ~~**and the territory of the Member States for which** period of~~ the compulsory licence **has been granted in that Member State**. SE (Comments):

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	We appreciate the intentions. We feel the para needs to be more precise about the temporary and restricted nature of a compulsory license, hence we suggest some changes and simplifications of the text. It should be clear that it is not a general suspension of data protection
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.	EE (Comments): EE To be reviewed in connection with Art 56a para 5

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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.~~**	AT (Suggested adaptations to the text): AT: 5a. The marketing authorisation holder The Agency 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]. 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**~~ AT (Comments):

[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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	AT: To be supported. It is however crucial to keep the term "supporting documentation" in order to maintain a certain burden of proof for the MAH. CZ (Comments): CZ is in favour of adding emphasis that information should be up-to date and clear as it is important to have the information on data and market periods publicly available for centrally and nationally authorised medicines as well. This kind of information is crucial for applicants, pharmaceutical industry and NCA as well. However, the process of validation of data in database which is managed by EMA should be clarified. Moreover, it should be specified if it is the same database which is managed by EMA or not. NL (Comments): The Netherlands fully supports that the article 138(1)(n) database is used to make transparent the applicable periods of data and market protection.

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	However, we do not fully support the proposed wording in newly added para 5a and para 5b. Although we do understand the wish for clarity on roles and responsibilities for MAHs and NCAs when it comes to including and validating the data on regulatory protection periods in the art. 138 database, information on responsibilities, roles and tasks should not be included here. We believe instead this should be added to article 138(1)(n), for the following reasons: • First, any information related to maintaining the data in the database does not belong here but should be included under article 138(1)(n). • Second, the art. 138 database will contain a lot more data than just regulatory protection periods. Where possible, it is desirable to have a single process (including who does what and within how many days and who corresponds with whom) for inclusion and qualification of data for the different types of data included in the database. • Third, EMA and NCAs, through the ROG PMS optimisation group falling under the HMA, are currently jointly working on further detailing such processes for the Product Management Service (PMS), which in the future will form the basis for the article 138 database. To

Presidency comrpomise	Suggested adaptations to the text and Comments
	now include details on who is responsible for what in how many days interferes with this very important and careful process. • Fourth, functionalities of the database, interoperability with other databases and the needs and wants for its use may change in the future. Including in this Directive the level of detail as proposed in para 5a and 5b may obstruct or get in the way with progress / desired changes. It is therefore better to further detail tasks, responsibilities, deadlines and processes into a delegated act which can be amended more readily. We realise that article 138 is not within the scope of this cluster. However we would already flag this point. Text proposals will follow. RO (Comments): MAHs for centrally and nationally authorized medicinal products are responsible for transmitting and updating information related to data protection and market protection, information that will be entered in the database referred to in art. 138 para. 1 letter (n) of REG. reviewed. This article in the revised REG mentions that the EMA is responsible for

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	creating and maintaining a database for medicines for human use, which is updated and managed independently of the pharmaceutical companies. RO considers that the EMA is responsible for the information on data protection and market protection for centrally authorized medicinal products that are entered into this database and we propose that paragraph 5a be completed as follows, taking into account also the introduction of paragraph 5b which provides obligations for ANC in the case of medicinal products authorized through national procedures: *"In case of medicinal products covered by centralized marketing authorization , the Agency should ensure that information provided by the MAHs on data and market protection periods is correct ".* In addition, we consider it necessary to update art. 138 para. 1 letter (n) to correctly reflect this assignment of the EMA and the data protection and market protection information that will be accessible through this database. SI (Comments): SI is of the opinion that it should be clarified who validates the information provided by MAHs and which information submitted by MAHs are to be accepted.

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	SI would like to see that the relevant database includes interfaces between different databases information about regulatory protection periods and information regarding patents.
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 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	AT (Comments): AT: AT support this provision, but would like to remark, that any additional bureaucracy should be avoided. With respect to the experiences made with the Article 57-database in the past, it would be even better if the database was provided with validated data by the Agency and the NCAs. CZ (Suggested adaptations to the text): **In case of medicinal products covered by a national marketing authorisation, the national competent authorities that granted the**

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approved under this paragraph, the data related to data and market protection periods indicated in the database shall remain unchanged.	**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~~ 15 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.** CZ (Comments): CZ suggests extending the period of time to 15 days, instead of 8 days. Please see the change in wording. CZ would like to point out that each Member State can confirm only the date from which the marketing authorisation is valid in the particular Member State. In this context, it is necessary to have in mind that in case when medicines are nationally authorised via MRP/DCP procedures Member States issue the decision on a different date. Therefore, the

Presidency comrpomise	Suggested adaptations to the text and Comments
	decisive date should be clarified. Apart from that it should be specified who will be responsible for the correctness of data, MAH or NCA. Additionally, the communication between NCA and MAH via database should be clarified, including adding the possibility of having notifications. It is not clear whether failure to comply with such obligations stipulated in para 5a and 5b of this Article is a reason for imposing sanctions, and if so, who will impose them. Last but not least, Article 138 para 1 letter n) should be in accordance with the final version of text in this provision. ES (Suggested adaptations to the text): ~~**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 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**~~

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	~~**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.**~~ ES (Comments): Is it really necessary to detail the procedure in the Directive? ES considerS that paragraph 5a proposed by PRES HU is sufficient and that it should be referenced that the Agency (EMA) will manage the Database for CAPs and NAPs and ensure that the information on protection periods is correct before the data is published. We understand that the database being referred to is currently managed by the EMA, PMS (Product Management System), where the roles and responsibilities of the MAHs (Marketing Authorization Holders) and NCAs (National Competent Authorities) have not yet been established FR (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	The proposed additional measure requiring each national authority to check, in addition to a notification, that the laboratory has filled in the European database on this subject represents an additional workload. France has a rather negative opinion for this. If it is not deleted, the 8-day time limit should be reviewed to set a more reasonable time limit, of the order of 30 days for example, given that there is no urgency to verify this information. LT (Comments): We agree with the proposed concept of validation procedure, according to which the information submitted by the MAH to the database referred to in Article 138 must be validated prior to the publication. However, the MAH shall be responsible for the correctness of the data. We also support the proposal expressed by some MSs that the MAH should also submit the data on patents and supplementary protection certificates in the database. NL

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): The NL delegation wants to express their concern on the administrative burden and workload this article places on the NCA's. The article demands additional requirements and relatively short deadlines of the NCA's. We are not yet convinced this is currently sufficiently safeguarded in article 138. Furthermore, we would like to see additional assurances on the legal standing of the database. Any confusion on the protection period can lead to unwanted litigation. PT (Suggested adaptations to the text): **5b. In case of medicinal products covered by a national marketing authorisation, the first national competent authority~~ies~~ 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**

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Presidency comrpomise	Suggested adaptations to the text and Comments
	the Agency on its objection within 10 working ~~8~~ days, the data shall be published in the database. In case of objection, the national competent authority shall invite ~~without undue delay~~ the marketing authorisation holder to make a correct submission within 8 working days. 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. PT (Comments): Support for the transparency principle; however, we have concerns on the quality of data, its eventual legal consequences, interoperability with other systems namely national and administrative burden. Deadline of 8 day is too short and a deadline for the MAH to correct the submission should also be included for predictability. For a national reference medicinal product, only the first national authorisation is considered for counting the regulatory protection. Therefore, only that MS should confirm the information included in the database.

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Presidency comrpomise	Suggested adaptations to the text and Comments
	RO (Comments): We propose to replace the term of 8 days with 15 days or 10 working days. SE (Suggested adaptations to the text): **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~~ 15 working days, the data shall be published in the database. In case of objection, the national competent authority shall invite without undue delay the** SE (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	We suggest to extend the timeline to three weeks for NCA to assess and communicate with all parties, hence 15 working days. We are flexible to extend to one month. We also suggest the MAH should submit patent data. IT (Suggested adaptations to the text): **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 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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Presidency comrpomise	Suggested adaptations to the text and Comments
	IT (Comments): ***IT comment: the paragraph proposed by the PCY, that provides for the obligation of NCAs to verify the information entered by the MAH, may place a disproportionate burden on NCAs, which would have to verify the information within 8 days and contact the MAH. Moreover, such an obligation could lead to perceive the information in the register as having legal effects.***
Article 81	DE (Comments): DE continues to advocate the retention of the current protection periods. A total period of protection of 11 years must not be exceeded. SI (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	- SI supports the modulation model, which we believe could be predictable and transparent
Regulatory data protection periods	ES (Comments): Spain supports a modulation of incentives. We would like to thank the efforts of the Presidency as it is a basis to start negotiating. However, with regard to the 4 proposed incentives, we consider that, taking into account that the margin of years of modulation is shortening, the number of incentives proposed should also be limited. The aim is to achieve a meaningful modulation system. Otherwise, there would be a risk that companies would opt for easy incentives, such as R&D, and not strive for incentives that are really necessary, such as UMN. On the other hand, as far as Access is concerned, it is also very important for ES so we would like to continue working on Article 56 a in order to try to achieve the greatest possible Access through an obligation.

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Presidency comrpomise	Suggested adaptations to the text and Comments
1. The regulatory data protection period shall be ~~six~~ **seven** ~~**eight**~~ years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	AT (Suggested adaptations to the text): AT: 1. The regulatory data protection period shall be **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 AT (Comments): AT: We support the initial proposal to reduce baseline RDP to 6 years and in our opinion this is still the preferred option. However, in order to reach a compromise, we remain open for discussion.

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Presidency comrpomise	Suggested adaptations to the text and Comments
	Our reasoning: Starting with a lower baseline and then having the possibility of receiving additional protection periods is a higher incentive. Some of the newly suggested incentives (research and production) in our opinion are quite easy to obtain, but the will send a signal that RDP will not be granted unconditionally. This in our opinion is one of the essential changes in the system that we still strongly support. CZ (Suggested adaptations to the text): The regulatory data protection period shall be **six** ~~**seven**~~ 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):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	CZ considers it important to stipulate six years as the basics of data protection and does not support the current change in proposal made by HU PRES. The detailed CZ opinion is expressed below in accordance with the proposal we have already submitted. Please see the change in wording. EE (Suggested adaptations to the text): EE 1. The regulatory data protection period shall be **six** ~~**seven eight**~~ years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union. EE (Comments): EE

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Presidency comrpomise	Suggested adaptations to the text and Comments
	We propose to keep six years baseline and focus on the two most important incentives, that have emerged from the discussions so far and are important for the majority of countries. Taking the baseline 6 years, the two incentives that could be maintained would be 1 year for UMN or CCT and 1 year for market launch. This way, we could keep the modulation system that would be meaningful and make it as objective and simple as possible, without creating excessive burden. If both conditions would be defined in a way that they are attainable, this would in practice result in maintaining the status quo of 8 years for the companies. IE (Comments): IE have concerns that the new criteria to modulate RDP is very achievable and as a result may not be meaningful. We are concerned that as 2(c) and 2 (d) are achievable it may lead to unmet need not being addressed. We support the proposal of NL at the meeting that suggested a baseline of six years and modulating additional years

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(a)12 months for R&D or manufacture and (b) 12 months for comparator trials or unmet need We consider this would bring a balance to make the proposal achievable while addressing innovation and public health needs. We also see merit in the proposal of EE to award 1 year of RDP if the marketing authorisation holder demonstrates that a valid pricing and reimbursement application has been submitted within 2 years from the marketing authorisation in interested member states upon request This suggestion is in line with industry's commitment in this area. However, if there isn't sufficient support within the working party for this link between RDP and market launch, we will continue to work on the requirements to make available and supply within article 56a. see further comments in this article. LT

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): With the aim of reaching a compromise, we could support the proposed 7-years regulatory data protection period. MT (Comments): This proposal which deliberately includes conditions which are easy to attain, to retain the status quo when it comes to RDP does not provide much added value. One can hardly define this as an incentive. NL (Suggested adaptations to the text): The regulatory data protection period shall be ~~six~~ **six** ~~**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. NL (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	We propose to keep the baseline at six years, combined with meaningful modulation. See our detailed comments below. PT (Comments): Support for the 7 years baseline but with flexibility in consideration of the need to balance incentives and access in an integrated way. RO (Comments): RO can support any form of modeling of the incentive system within the 8 years of data protection, but we want to find in these proposals also an incentive for putting it on the market. We believe that the inclusion of a marketing incentive will increase the interest of pharmaceutical companies in all EU markets and can be a tool to increase access to necessary treatments for all patients. Our main objective, and what we expect from the review of pharmaceutical legislation, is to increase the access of EU patients to innovative treatments, and we believe that providing an incentive for placing on the market in the EU, in all Member States, can be instrumental in achieving this objective. SE (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	SE is opposed to the shortening to 7 years and to the proposed modulation coupled to requirements in this proposal. We will comment on some of the details below. SI (Suggested adaptations to the text): The regulatory data protection period shall be **six**~~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. SI (Comments): SI proposes the baseline of regulatory data protection to remain at 6 years as under the current scenario where the comulative duration of data protection is set to 8 years there is too little stimulous for MAH to choose more than one (out of 4) option that prolongates the data protection.

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	In second scenario we still support the idea of (based on WP discussions) incentive of 1 year for market launch. The other should be 1 year for UMN or CCT (6Y+1Y+1Y=8Y). If market launch is not linked to incentive, medicinal products will most likely not be put on the market of small MS. 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).***

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Presidency comrpomise	Suggested adaptations to the text and Comments
	IT believes that the provisions regarding the regulatory data protection should be clear, straightforward and ensure transparency.
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:~~**	CZ (Comments): CZ is not in favour of the changes proposed by HU PRES and would like to apply scrutiny reservation on Article 81 para 2. Moreover, CZ proposal is expressed in detail below, including changes in wording. We are of the opinion that with this modulation system of incentives the MAH could very easily obtain an additional year of regulatory data protection. Apart from that, there is no option to fulfil all the conditions which we consider crucial. In this concept, we are at the max limit of 8 years without motivation for MAH to fulfil all of these conditions.

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	Additionally, we are of the opinion that burden of proof, meaning that all conditions have already been fulfilled, should remain on MAH, instead of Member State.
~~(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities:~~	
~~(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;~~	
~~(ii) entities not engaged in an economic activity ('not-for-profit entity'); and~~	

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~~(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.~~	
~~**Option A)**~~	
~~**(e)(a) 12 months if**~~	
~~**(i) the marketing authorisation holder demonstrates that a significant substantial share of research and development, including**~~	

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~~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, or .~~	
~~(ii) the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator taking into account the scientific advice provided by the Agency;~~	
~~(b)~~ **12 months if** ~~six months, where~~	

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~~**(i)** the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;~~ **or**	
~~(c~~**ii**~~) six months for medicinal products containing a new active substance, where~~ **for medicinal products containing a new active substance, where** ~~the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with~~**taking into account the** ~~scientific advice provided by the Agency;~~	
~~(d) 12 months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit in comparison with existing therapies.~~	

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~~**Option B)**~~	
~~**(a) 12 months if the marketing authorisation holder demonstrates that a substantial share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in collaboration with public entities, including university hospital institutes health centres, centres of excellence or bioclusters located in the Union.**~~	
~~**(b) 12 months if**~~	

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~~**(i) the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;**~~	
~~**or**~~	
~~**(ii) the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator taking into account the scientific advice provided by the Agency;**~~	

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~~**Option C)**~~	AT (Comments): AT welcomes the proposal by the presidency, it might prove to be preferable to merge lit. c and d, depending also on whether d) is compatible with international trade laws.
The data protection period referred to in paragraph 1 shall be prolonged by the following periods ~~**not exceeding 8 year in total**~~ **by:**	PT (Comments): Support for the modulated system that has to be balanced, objective, proportional, enforceable and seen as a whole to stimulate innovation and competitiveness and address public health objectives. IT (Suggested adaptations to the text): ~~**The data protection period referred to in paragraph 1 shall be prolonged by the following periods not exceeding 8 year in total by:**~~

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(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;**~~ CZ (Comments): We propose to remove the incentive covering UMN. While we find the concept very important, we are missing a clear consensus on its definition, making it an unpredictable criterion, exceedingly difficult to be incentivized through the regulatory data or market protection. Moreover, it is not clear how to assess UMN in time. We suggest focusing the debate on other types of incentives when it comes to this criterion. Please see the changes in wording. EE (Suggested adaptations to the text): EE

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	(a) 12 months if **(i) the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83 paragraph 1 (a); or** EE (Comments): EE We could work around the concept proposed by the NL to better delineate the UMN criteria by limiting it to the "first-in class" products in the context of RDP, possibly by referring to Art 83 p 1 (a). We believe that the additional clinical benefit aspect (art 83 1 (b)) could be covered under the comparative clinical trials incentive, effectively combining the two incentives. On the assumption that all new products will fit either under UMN (being first-in class) or CCT category (providing important information on the added clinical benefits as a basis for the EU HTA and national reimbursement decisions), the 1-year extension of RDP would be realistically attainable for the companies.

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	ES (Comments): Scrutiny reservation. PT (Comments): Support for UMN; definition need to be objective and clear for effectiveness of the incentive SE (Comments): We will comment on article 83 later. 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;**~~

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(b) ~~12~~ 6 months for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice ~~provided~~ by the Agency;	AT (Suggested adaptations to the text): AT: 12 months for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency; AT (Comments): AT: In light of the requirements under the Regulation on health technology assessment as well as Member State efforts to strengthen pricing and reimbursement policies, the use of a relevant and evidence-based comparator in clinical trials has, and will continue to, gain in importance for HTA processes and ensueing national reimbursement decisions. It would therefore be **strongly advisable** to keep the incentive for using the relevant comparator as a prolongation of 12 months to the data protection period because using the relevant comparator in clinical trials will facilitate the efficient and timely conduct of the HTA, pricing and reimbursement decision-making processes.

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	CZ (Suggested adaptations to the text): **6 months, 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): CZ would like to precise that the incentives related to the substantial share of research and development in the EU and the relevant and evidence-based comparator in the clinical trial supporting the initial marketing authorization application are meant to further support investment in the EU and increase our competitiveness. Therefore, please see the changes in wording proposed. DE (Comments):

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	We await COM's explanations as to what proportion of the marketing authorisations in the last five years contained comparative clinical trials in the marketing authorisation dossiers and what proportion of the marketing authorisations in the last five years would have fulfilled the criterion of relevant R&D in the EU. EE (Suggested adaptations to the text): EE ~~**(b) 12 6 months for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;**~~ **(ii) the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator taking into account the scientific advice provided by the Agency;** EE (Comments):

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	EE We propose to combine the CCT incentive with the UMN incentive, provided that the UMN incentive could cater for "first-in class" products and for other products CCT incentive would be applicable. These two incentives could effectively be complementary. ES (Comments): Scrutiny reservation. PT (Comments): Even tough clinical trials with relevant comparators are considered as the gold standard, there will be more benefit to medicines safety and effectiveness when being marketed. This proposal can allow for a beneficial interplay between regulators and HTA bodies. It is particularly relevant the need to ensure adequate collaboration between the Agency and HTA bodies in order to have a common framework for assessing the conditions as considered in n.3

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	SE (Suggested adaptations to the text): ~~**(b) 12 6 months for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;**~~ SE (Comments): Randomised clinical trials, with a comparator, is the gold standard design. We think having (b) might signal that this is not the case. Scientific advice is consultative and non-binding and not obligatory. Therefore *"in accordance with"* should be exchanged by *"taking into account"*. IT (Suggested adaptations to the text):

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	~~**(b) 12 6 months for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;**~~
	EE (Suggested adaptations to the text): EE **(b) 12 months if the marketing authorisation holder demonstrates that a valid pricing and reimbursement application has been submitted within 2 years from the marketing authorisation in interested Member States upon request.** EE (Comments): EE We propose to foresee a reduced and simplified condition for market launch as part of the RDP scheme to make it more predictable for the companies. In our proposal, the submission of a P&R application at the

Presidency comrpomise	Suggested adaptations to the text and Comments
	request of the Member States (keep opt-in principle) would be the sole requirement to the MAH in order to receive a 1-year RDP extension. This could replace the concept of sufficient and continuous supply, which has been difficult to establish. Submission of a P&R application would not be unreasonably difficult to fulfil for the MAHs (also relying on joint EU clinical assessments under the new HTA regulation). It would be factually easy to establish and entirely in the hands of the company. It is also in line with EFPIA's voluntary commitment to submit P&R application within 2 years in all MSs. If no P&R process is foreseen in the MS or for some products – it should be possible to work around by demonstrating that the product has been actually launched and is in use in a particular MS. It would also need to be seen in combination with Article 56a in terms of actual supply, following a mixed approach with rewarding the companies under the RDP scheme and dealing with actual supply under art 56a. In our experience, the time we have to wait after marketing authorisation for the submission of the P&R application is much longer than the time it takes to negotiate and reach a price agreement after the submission (in 2023 it took on average 738 days for the submission vs

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	295 days to reach the price agreement). Therefore, it is important to incentivise companies to at least enter negotiations upon the request from the MS within reasonable timeframe. SE (Suggested adaptations to the text): **(bb) A derogation from performing randomised confirmatory clinical trials should be justified by the applicant.** SE (Comments): We suggest to insert somewhere that a deviation from RCT (late clinical phase) should be justified by an applicant. There are instances where they cannot be used.
(c) ~~12~~ 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal product has been done within the Union and at least partly in collaboration with public entities, including university hospital	AT (Comments): AT: We prefer the original option of the last compromise text, however we can accept splitting up the incentive in R&D as well as production in Europe. These incentives should be as precise as possible

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institutes health centres, centres of excellence or bioclusters located in the Union.	Two parts of this proposed text are too unspecific, namely "a significant share of research and development…" and, "partly in collaboration with…". What counts as a 'significant' share of research and development that has taken place in the Union (will a share threshold be specified, for example as percentage of the overall R&D costs or other resources?)? 'Significant' in terms of patient numbers enrolled in trials and/or in terms of staff and financial resources that have gone into R&D of the product in question? How will this be determined if a share of the research was originally conducted by another entity such as a public research institution or a smaller biomedical company? What does 'partly' in collaboration mean? Would peer review activities or an academic exchange on ongoing research already count as a collaboration (we think it should not because these are expected best practice activities for ensuring excellence in research. CZ (Suggested adaptations to the text): **6 months, where the marketing authorisation holder demonstrates that a substantial share of research and development, including**

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	clinical studies, related to the medicinal product has been done within the Union; CZ (Comments): Please see the comment above. In accordance with CZ previous comments, we are not in favour of adding part "at least partly in collaboration with public entities". Apart from that, we do not support adding preclinical studies as we believe that MAH or applicant is to fulfil this condition easily without any significant benefit for patients in the EU. Therefore, please see the changes in wording proposed. DE (Comments): See above; We also await the Legal Services explanations on whether an incentive for production and R&D in the EU would be compatible with international law. EE

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	(Suggested adaptations to the text): EE ~~**(c) 12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal 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.**~~ EE (Comments): EE The added elements in (c) and (d) in our view are not clear and instead add complexity to the RDP scheme. These elements could be seen as contradicting the international trade agreements and potentially impeding joint global R&D ventures. ES (Comments):

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	Scrutiny reservation. NL (Suggested adaptations to the text): **(c) ~~12~~ 6 months where the marketing authorisation holder demonstrates at time of the initial marketing authorisation application 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.** NL (Comments): The Netherlands remains of the opinion that a modulated system of incentives will achieve a better balance between rewarding companies for innovation, and ensuring policy objectives that matter to patients. We previously made the constructive suggestion to keep the baseline at 6

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	years, but to provide 1 year of additional protection that can be easily attained in a predictable manner. We believe that by merging the requirements in (c) and (d), this can be attained. A company will then receive 12 months of additional protection when R&D and/or manufacturing takes places in the EU. This means in practice that all European firms will have a baseline of 7 years, while rewarding a bigger footprint in the EU for non-European firms. However, we understand that the Council Legal service adviced negatively on (d). We will analyse this point before the next CWP . An additional 12 months can then be awarded for either meeting UMN or performing comparative clinical trials, capping the protection at 8 years. We furthermore note that there should be a time specified when the MAH should demonstrate whether **it** is eligible for this incentive. This will prevent the MAH claiming this incentive years after the initial marketing authorisation. PT

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	(Suggested adaptations to the text): **c) ~~12~~ 6 months where the marketing authorisation holder demonstrates at the time of the initial marketing authorisation that a ~~significant~~ majority 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** PT (Comments): Concerns on the meaningfullness of the incentive considering its requirements . May be too easy to achieve and inhibit the pursuit of more important incentives (UMN). SE (Suggested adaptations to the text): **~~(c) 12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development,~~**

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	~~**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.**~~ IT (Suggested adaptations to the text): ~~**(c) 12 6 months where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical studies, related to the medicinal 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.**~~
(d) 6 months where the marketing authorisation holder demonstrates that the medicinal product or the active substance was	AT (Comments):

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manufactured in the European Union, excluding import related processes.	AT: A definition for "manufacturing within the EU" is required in order to confine at what stage an active substance or a MP is regarded as manufactured in the EU. AT generally supports this incentive depending on whether international trade laws are not infringed. CZ (Suggested adaptations to the text): **12 months, where the marketing authorisation holder demonstrates that the medicinal product is manufactured within the Union and the production of that medicinal product is sufficient to meet the Union market demand.** CZ (Comments): **CZ finds the manufacture in the EU the most beneficial additional regulatory data protection incentive for the EU and the Member States.** In general, incentivising manufacture in the EU will have a major impact on the security of supply of medicines for patients in the EU, while increasing competitiveness of the EU. This incentive should lead to a return

Presidency comrpomise	Suggested adaptations to the text and Comments
	of investments, back into the economy and revenues of the Member States, thus at least slightly mitigating the fact that regulatory incentives are financed through national reimbursement systems. The incentive will ensure that funds from which regulatory incentives are financed, will be returned to the benefit of the patients. The Czech proposal has been incorporated in letter d) of this para by HU PRES, however, in changed wording. **We are not in favour of the changes proposed by HU PRES. CZ also proposes that the manufacture in the EU should be rewarded with an additional one-year data protection period.** Additionally, we are not in favour with adding of API. In general, it should **also** be clarified whether, on the basis of the current text, every medicinal product for the EU market should be manufactured in the EU in order to fulfil this condition. The incentives we propose will ensure a clear and predictable environment, and at the same time we will simplify the modular system and avoid alternative solutions where it is not possible for the marketing authorisation holder to get additional regulatory data protection for all specified situations. Please see the changes in wording proposed. DE

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	(Comments): What if the MAH doesn't have a production site while obtaining the marketing authorization and also gets it later on. Is it then possible to take advantage of this incentive, too? EE (Suggested adaptations to the text): EE ~~**(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.**~~ EE (Comments): EE (d) related to EU manufacturing raises questions on the usefulness and criteria to be used taking into account the global nature of manufacturing and pharmaceutical supply chains. This wording is very broad and leaves a lot of room for interpretation. The production of the active substance

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	and the final product does not take place in one company, but often in stages: for example, intermediate products (granules, active intermediate products, etc.) are produced in different production sites. ES (Comments): Scrutiny reservation. LT (Comments): In general, we support a new incentive for manufacture of the medicinal product or the active substance in the EU. However, the meaning of formulation "*import related processes*" should be clarified in the Directive. There is also the question of how the case will be assessed when the manufacturer obtains the active substance both from the MS and from a third country. NL (Suggested adaptations to the text): **d) 6 months where the marketing authorisation holder demonstrates at time of the initial marketing authorisation**

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	application that the medicinal product or the active substance was manufactured in the European Union, excluding import related processes. NL (Comments): The Netherlands remains of the opinion that a modulated system of incentives will achieve a better balance between rewarding companies for innovation, and ensuring policy objectives that matter to patients. We previously made the constructive suggestion to keep the baseline at 6 years, but to provide 1 year of additional protection that can be easily attained in a predictable manner. we understand that the Council Legal service adviced negatively on (d). We will analyse this point before the next CWP . An additional 12 months can then be awarded for either meeting UMN or performing comparative clinical trials, capping the protection at 8 years.

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	We furthermore note that there should be a time specified when the MAH should demonstrate whether it is eligible for this incentive. This will prevent the MAH claiming this incentive years after the initial marketing authorisation. PT (Comments): Although we agree on the principle, we have concerns on the meaningfullness of the incentive considering the requirements as drafted. May be too easy to achieve and inhibit the pursuit of more important incentives (UMN). In addition, and according to CLS, it does not seem compatible with WTO rules. ~~international and competitiveness rules need to be verified;~~ some medicines have extensive and global manufacturing chains. What will it take to fulfil the requirement? First manufacturer in Europe? Manufacturing of a single batch? SE (Suggested adaptations to the text):

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	~~**(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.**~~ SE (Comments): We await Legal Council Service's further reflection on this. We suggest this is deleted. We think this may distort and deter global companies from the EU market, even if it is desirable to support production in the EU. SI (Comments): SI supports the EU manufacturing, but we still have some issues with the text as it stands now. Main issues are, that the actual manufacturers can not be determined/ identified also based on the fact that manufacturers can be changed during the lifecycle of the product. There are too many variables and we see it will be difficult to implement current provision. IT

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	(Suggested adaptations to the text): ~~**(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.**~~
The cumulative duration of data protection for a medicinal product shall not exceed eight years from the date the initial marketing authorisation was granted.	CZ (Comments): CZ supports the maximum of 8 years of data protection. However, based on the CZ proposal the text is unnecessary. ES (Comments): Scrutiny reservation. IE (Comments):

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	IE agrees with the max cap of eight years LT (Suggested adaptations to the text): **The cumulative duration of data protection for a medicinal product shall not exceed eight years and six months from the date the initial marketing authorisation was granted.** LT (Comments): We believe that it is particularly important to ensure the balance between the availability of medicinal products for patients and the research and development of innovative medicinal products. For a compromise, we believe it is appropriate to take into account the proposals of the European Parliament and consider capping the maximum data protection period to 8.5 years instead the proposed 8 years. We think that more flexible options for extending the regulatory data protection period will encourage the pharmaceutical industry to meet several conditions in order to obtain more than one incentive and to develop innovative medicinal products in the EU.

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	SE (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.**~~ SE (Comments): See our initial comment on data protection. IT (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.**~~

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In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the ~~prolongation~~ **condition** referred to in the first subparagraph, point (b), shall ~~only apply~~ **be considered as met** if, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.	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), 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.~~
~~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**~~	

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~~**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**) ~~**(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 assessment as referred to in Regulation (EU) 2021/2282**.	CZ (Suggested adaptations to the text): The Agency shall set the scientific guidelines referred to in paragraph 2, point (c), 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 assessment as referred to in Regulation (EU) 2021/2282**~~. CZ

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	(Comments): CZ does not consider adding the link to HTA bodies necessary as they have been already mentioned among others in Article 162. Therefore, we are in favour of deleting this part of provision. However, it is not a crucial comment. Please see the change in wording. SE (Comments): We support references to scientific guidelines in more technical matters, but we have objections to the current proposal of this article, hence scrutiny reservation for 3. here. Please see elaborations on article 83 and the reference to guidelines, where HTA bodies also are mentioned. There need not be several guidelines. IT (Suggested adaptations to the text): ~~3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c~~**b**~~)~~ **(ii)**~~, on criteria for proposing a comparator for a~~

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	~~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 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.	CZ (Suggested adaptations to the text): **The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement paragraph 2, point (b), in order to set specific criteria for the designation of a substantial share of research and development done within the Union.** CZ (Comments): Please see the comment below as 4a para of this Article is proposed.

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	IT (Suggested adaptations to the text): ~~**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**~~
	CZ (Suggested adaptations to the text): **4a. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement paragraph 2, point (a), in order to set specific criteria for the manufacturing process and for the designation of sufficiently meeting the Union market demand.** CZ (Comments): CZ would like to ask for addition of option to stipulate via delegated acts the particular conditions in order to fulfil manufacturing of medicines in

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	the EU incentive, meaning in the same way as it is proposed for the substantial share of research and development. Please see the changes in wording.
~~*Article 82*~~	AT (Comments): AT: in light of the feasibility of a compromise in the incentives cluster AT supports the striking of this provision in order to implement a general obligation to supply the MS as suggested in Article 56a. CZ (Comments): CZ is in accordance with deleting of Article 82 as proposed by HU PRES. The specified explanation in this matter is mentioned in Article 56a, please see the comment below. DE (Comments): Decoupling is welcomed. The combination of EU-wide marketing with data protection period is systematically misguided. IE

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	(Comments): IE preference was to link access to modulation but as we stated at the meeting last week we are open to working with the presidency proposal on a solution to access based on 56a. SE (Comments): We support the omission of this article, suggest we finetune article 56 a.
~~*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~~	

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~~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.~~	
~~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.~~	

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~~2. To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.~~	
~~The application for a variation shall be submitted between 34 and 36 months after the date when the initial marketing authorisation was granted, or for entities referred to in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.~~	

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~~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 purpose of the prolongation.~~	

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~~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 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.~~	

~~[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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~~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 accordance with the decentralised procedure, the competent authorities of~~	

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~~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	
Article 56a	CZ

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	(Comments): CZ would like to apply a scrutiny reservation on Article 56a. In general, we can support stipulating an obligation for MAH to ensure supplies of medicines to markets in all Member States instead of incentivising pharmaceutical industry. However, there are several parts in new HU PRES proposal which should be more clarified and that raise concerns of an excessive administrative burden. CZ also believes that it should be the initiative of the MAH to enter the markets of all Member States. Otherwise, it is not clear how MAH would be contacted by a Member State. In addition, this provision should be in accordance with Regulation on HTA. EE (Comments): EE We have been reluctant before to the idea that merely imposing supply obligations on the MAH would be an effective way to tackle equal access, our preference is still to work via incentives. However, combining the RDP reward under art 81 with a supply obligation in Art 56a, could be a way forward, if this obligation would be enforceable in practice. In

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	principle, we could consider the PRES proposal, which would lead to the loss of market protection in case the original product is not supplied in a particular MS within 5 years. However, we have difficulties with the text as it too heavily relies on the Member States making the request as opposed to the responsibility of MAHs LT (Comments): The actual supply of new innovative medicinal products (market access) is particularly important issue to us, as Lithuania is one of MSs facing delays of supplies of medicinal product. We could preliminarily agree with the proposed concept of Article 56a. As well, we could be flexible as to whether a market access should be regulated as part of an incentive system or as an obligation under Article 56a. SE (Comments): We appreciate the efforts, but the article needs more finetuning. We support the idea.

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	It is important to balance MAH's and MS' responsibilities. There is a need for guidance on how to interpret "good faith" in negotiations. Pricing is beyond the scope for this legislation and a national issue. We await the Danish suggestion of MS going in joint tenders. SI (Comments): Slovenia, is in favour that Market launch is linked with incentives, and not as obligation. We already act in a very similar way nowadays (asking MAH to start procedures for coming on the market), however most of the time without a success. It is of our opinion, that current proposal should necessarily be combined with incentives. For small countries, without a combination of incentives, MAH will have no interest in entering the market. It is also of our believe, that the current text too heavily relies on the Member States making the request as opposed to the responsibility of MAHs

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	IT (Comments): ***IT comment: IT does not agree with the new article proposed by the PCY. The provision continues to be complex and difficult to implement and may lead to potential litigations. Indeed, the wording appears unclear with reference "sufficient quantities", "meeting procedural obligations", "good faith". In addition, the reference to "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.***
Specific requirements ~~Obligation to~~ on making available ~~market launch~~ and continuously supplying of a medicinal product ~~on the market~~ in a Member State	AT (Comments): AT: AT supports the introduction of a general obligation, but would support a stronger more binding wording. We support further work on

Presidency comrpomise	Suggested adaptations to the text and Comments
	making sure that access for smaller MS is actually improved and are open for further strengthening of the text in this regard. The timelines should be fixed as much as possible and the penalties should be real and enforceable. DE (Comments): DE is sceptical of the conditions and penalties laid out in this cluster. At the same time, DE recognizes that there should be an obligation for companies to enter into negotiations with the relevant actors if asked to do so by Member States. In detail: 1. DE rejects any financial penalty for not making available medicinal products in all Member States as this would severely curtail the economic freedom enjoyed by the private sector. 2. DE is also sceptical of cutting marketing protection periods in case a medicinal product is not available in a Member States within five years of the request. This does not address the root problem, as in most cases of new medicinal products not entering smaller markets there is no generic

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	industry even after all protection periods run out. This measure would therefore likely be not effective. In addition, this seems to lead to high fragmentation within the European market. 3. DE favours an obligation for companies to make an offer or enter into negotiations at the request of the Member State. ES (Comments): ES supports the Presidency proposal: to maintain that "Access/market access" should not be an incentive, but an obligation. We agree with the PRES HU proposal because it takes into account the current and different casuistry of Member States regarding access. LT (Comments): We agree with the deletion of the term "market launch". PT (Comments):

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	Scrutiny reservation. Support for the principle but needs to be enforceable to effectively increase access. SE (Suggested adaptations to the text): ***Specific requirements to ~~Obligation to on making available market launch~~ and continuously supply~~ing of~~ a medicinal product ~~on the market~~ in a Member State*** SE (Comments): We suggest a simpler wording 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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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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 (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 8~~10(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 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): CZ considers changes proposed by HU PRES in this para positive as the text is clearer compared to the previous text. However, we find it very important to clarify that the access to a medicinal product is related to a

Presidency comrpomise	Suggested adaptations to the text and Comments
	medicinal product covered by the regulatory data protection in accordance with Article 81 (from day one after authorisation of such medicinal product), not only to medicinal products covered by marketing protection or additional market exclusivity. The medicinal products need to be accessible in all Member States already during the regulatory data protection. Therefore, please see the change in wording proposed. Additionally, we do not support this proposal as MAH should initiate the process, instead of Member States. Please see explanation to our comment above in the general comment on Article 56a. IE (Comments): At the meeting Legal Services suggested that the wording previously used in 2001/83/EC Art 81 in terms of the obligation to supply "within the limits of their responsibility" should be included here. IE have found that this provision did not work as the interpretation of "within the limits of their responsibility" was interpreted broadly. While IE accept that the obligation to supply cannot be an absolute one, we consider that other

Presidency comrpomise	Suggested adaptations to the text and Comments
	wording, closer to force majeure should be used. Suggested wording might be "excluding events that are outside the control of .."
	MT (Comments): It is unclear how this provision would work in practice when it comes to products other than with a centralised MA. Whilst we understand that there is an opt-in possibility for these products, the MA holder may withdraw the MA in some MS providing one year notice. It is unclear whether the sanctions may be enforced if the MA holder exercises its rights to withdraw the MA.
	NL (Comments): The NL delegation is concerned that wordings such as 'available' and 'sufficient quantities' are not well defined when it comes to potential litigation. Also, the NL delegation wonders whether provisons should be included that ensure that a company can make a profit and not suffer losses in trying to meet the requirements.

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	SE (Suggested adaptations to the text): **. With a view to facilitate~~ing~~ 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 guarantee ~~to make it available and continuously~~ supply ~~on~~ the market of that Member State. The supply should be 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.** SE (Comments): "Within their territories" may mislead to include all authorisations. We support that it is restricted to protected products only. We suggest other simplifications of the text.

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	For para 1 and 2, it will be important to ensure that we do not end up with a different interpretation and solution in each MS, so wording needs to be clear, and guidelines necessary. 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 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.**~~

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Presidency comrpomise	Suggested adaptations to the text and Comments
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:	CZ (Comments): CZ appreciates that the Member State may specify the obligations to MAH based on each given case. DE (Comments): The requirements are rather broad and should be further narrowed down/clarified in order to clarify the request for the MAH. SE (Comments): We would like to turn to the Council's legal service about this para. Is 2. appropriate and/or necessary here (National competence)? 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:**~~

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Presidency comrpomise	Suggested adaptations to the text and Comments
a) meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;	EE (Suggested adaptations to the text): EE **a) ~~meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;~~** submit an application for pricing and reimbursement concerning that medicinal product; EE (Comments): EE Previous compromise text was much clearer; we suggest reverting to the previous version. It is not clear what is meant under procedural obligations for pricing and reimbursement. It is self-evident that the MAHs have to follow the procedures foreseen in the national law, for this MS do not need a mandate to request it. IE (Suggested adaptations to the text):

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	a) submit a valid pricing and reimbursement application within 2 years from marketing authorisation in interested Member States upon request IE (Comments): Market launch and therefore access is only possible when an application is complete/adequate with all the necessary data submitted. IE considers 5 years too long to wait to see if an MAH have fulfilled obligations within article 56a and would request a P&R application within 2 years. This is also in line with the commitment from industry in this area. IT (Suggested adaptations to the text): **~~a) meeting procedural obligations on marketing authorisation holders for pricing and reimbursement;~~**
b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;	EE (Suggested adaptations to the text): EE

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	b) ~~fulfilling specific requirements for marketing authorisation holders in procurement procedures;~~ participate in any procurement procedures necessary to meet the needs of the patients in that Member State pursuant to national law implemented; EE (Comments): EE Previous compromise text was much clearer; we suggest reverting to the previous version. IT (Suggested adaptations to the text): **~~b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;~~**
c) establishing a supply plan.	EE (Comments): EE

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	The possibility to request and agree on the supply plan is a useful addition that could be strengthened even further. We find the IE proposals very helpful in this regard, possibly linking it also to the national HTA procedures to determine the necessary quantities etc. LT (Comments): This paragraph provides the requirement to establish a supply plan, but the following provisions do not provide the requirement to implement this plan. We believe that it is very important to amend this Article in this aspect. We note that in the previous compromise document the obligation to implement a supply plan was provided. We propose to accordingly amend paragraph 3 of this Article (see below). PT (Comments): Wording could be changed to “access and supply plan” to avoid confusion with the supply plan applicable to shortages. SE (Comments):

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	There is need for a guidance on the contents of the supply plan. IT (Suggested adaptations to the text): ~~**c) establishing a supply plan.**~~
Such requirements shall be proportionate to the objective pursued and in compliance with Union law.	CZ (Comments): CZ is of the opinion that the period for fulfilment of requirements expressed in para 2 letter a), b), c) or alternatively the other obligations should be more specified. IT (Suggested adaptations to the text): ~~**Such requirements shall be proportionate to the objective pursued and in compliance with Union law.**~~
3. The supply plan referred to in paragraph 2, point (c), shall include information about the supply of the medicinal product by the	AT (Comments):

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marketing authorisation holder over a given period in the Member State concerned. The supply plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the supply plan.	AT: The provision for the submission of a supply plan is welcomed, but the conditions under which a Member State can require the marketing authorisation holder to update the supply plan need to be specified (possibly in an implementing act) in order to allow for adjustments should the Member State consider the supply plan to be insufficient to facilitate patient access. DE (Comments): This seems to be an unproportionable high burden on MAH. It also cannot be expected that the MAH can provide supply plans for several years in advance. ES (Comments): How will the proposal for the supply plan be what does it refer to? The mechanics will be: first plan and then ask for a review and if we see that the plan is not adequate, what happens with protection? LT (Suggested adaptations to the text):

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	The supply 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 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 regularly update and implement the supply plan. LT (Comments): For the argumentation of this proposal, see paragraph 2, point c above. Also, we have a question what the wording "over a given period" means: the whole data protection period or a shorter period of 5 years after the marketing authorisation of the medicinal product. IT (Suggested adaptations to the text): ~~**3. The supply 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**~~

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	~~**State concerned. The supply plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the supply plan.**~~
4. When a Member State decides to avail itself of the obligation in paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within one year from the marketing authorisation for that medicinal product.	LT (Comments): We think it is important to enable the MS to set specific terms within which the MAH of the medicinal product must complete the actions specified in the MS's request, taking into account the nature of specific obligation. MT (Suggested adaptations to the text): When a Member State decides to avail itself of the obligation in paragraph 1, it shall communicate it to the marketing authorisation

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	holder, together with the modalities referred to in paragraph 2, ~~within one year from~~ following the marketing authorisation for that medicinal product. MT (Comments): The one-year timeline from the granting of marketing authorisation, for Member States to inform MAHs that the Member State has decided to avail itself of the obligation in this paragraph, may be too restrictive, especially in the case of drugs which involve low patient numbers such as orphan drugs or ATMPs. We suggest increased flexibility with regards to timelines in these cases. SE (Suggested adaptations to the text): **4. When a Member State decides to avail itself of the obligation in paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within ~~one~~ two years from the marketing authorisation for that medicinal product.**

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	SE (Comments): We are not sure about the timeline in this para. One year may be too short a time, national treatment recommendations do not change that quickly. New indications may be approved later. Within two years? We assume that this para regards for instance where the MS is in no need of the product, the patient group is not present, like for some orphan medicinal products? IT (Suggested adaptations to the text): ~~**4. When a Member State decides to avail itself of the obligation in paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within one year from the marketing authorisation for that medicinal product.**~~

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5. Where within 5 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously within that period in a sufficient quantities and in the presentations necessary to cover the needs of patients in a Member State that made a request in accordance with paragraph 1, the market protection for that medicinal product in accordance with Article 80(2), and, if applicable, the prolongation of the market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004] shall not apply within that Member State.	AT (Suggested adaptations to the text): AT: 5. Where within 5 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously **within a period of minimum one year** 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. AT (Comments): AT: Depending on whether the continuous supply must be established during the 5 year period, AT suggests that if that is not the case, to

Presidency comrpomise	Suggested adaptations to the text and Comments
	implement a minimum period where continuous and sufficient supply needs to be documented. CZ (Comments): CZ would like to apply a scrutiny reservation on para 5 of this Article. We would like to ask for clarification how cancelation of market protection or market exclusivity in one Member State is to be applied in practice, especially, in the case of centralised marketing authorisations of medicines. DE (Comments): We reject this clause, see explanation above. IE (Suggested adaptations to the text): **Where within 3/4 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available or 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**

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	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. IE (Comments): **IE considers that 5 years is too long to wait to see if access obligations are being met by the MAH. We suggest 3 years and modulating to 4 years for SMEs.** LT (Comments): Also, we need clarification why the 5-year period is proposed and how this provision will be applied in practice. MT (Comments):

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	The loss of a two-year period of market protection for a product without a Marketing Authorisation, does not provide earlier access to the generic version in practice in those MS in which the originator version was not launched. Consequently, it does not really constitute much of deterrent / incentive to launch the product on the smaller market in which the originator is clearly not interested. The period is just too short to have any impact. It would be much better to have a 6 year RDP period and a 4 year Market protection which may be waived when products are not launched. NL (Comments): The NL delegation has some questions and concerns with regard to para 5 of this article. We fear this para might contribute to creating a patch-work of protection within the EU, which does not align with the set goal of creating a strong single market. Secondly, we question how effective this new rule will be, as data protection is still in place. With both the generic MA application and, where required, P&R procedure taking significant time, we foresee that generic entry into the market will hardly be

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	improved compared to the status quo. Finally, this article could devaluate the incentive of one year additional market protection for the addition of a new indications. PT (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** PT (Comments):

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	Deadline of 5 years seems too long; consider whether it should be reduced. On the other hand, there are no guarantees of generic submission. RO (Comments): We propose establishing a shorter term, of 3 years, from obtaining the APP, in which the MAH can put the medicine on the market, at the request of the ANC. SE (Suggested adaptations to the text): **5. Where within 5 years after the marketing authorisation of the medicinal product has been granted, and the MS has requested supply, the marketing authorisation holder has not agreed to ~~made~~ supply or failed to supply 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 according to paragraph 1, the Member State may start an inquiry process with the Marketing Auhtorisation Holder. Insofar**

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	the Member State's inquiry concludes that the MAH will not provide the medicinal product in adquate quantities, the Member State may revoke the market protection 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. SE (Comments): We would like this para to be reconsidered in a new draft. We suggest some changes. Perhaps there are two more paras needed. It should be stated somewhere that the MAH needs to respond to why it has not provided if there is a supply plan and an early dialogue with the MS of the need.

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	The idea about losing the market protection is fine, but it should be predictable and be communicated in due time for generics to enter. There should be a clear SPOC-function for these activities. The SPOC level /organisation may vary between MS. SI (Suggested adaptations to the text): **Where within 3 years after the…** SI (Comments): If the market protection is not in force, this doesn't mean that generics are free to enter the market because the procedures for issuing a MA takes at least 2 years. From availability and affordability perspective and competitive internal market, generics and biosimilars must have mechanisms to have medicines on the market from day 1.

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	SI proposes to change 5 years to 3 or 4 years. IT (Suggested adaptations to the text): ~~**5. Where within 5 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously within that period in a sufficient quantities and in the presentations necessary to cover the needs of patients in a Member State that made a request in accordance with paragraph 1, the market protection for that medicinal product in accordance with Article 80(2), and, if applicable, the prolongation of the market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004] shall not apply within that Member State.**~~
	IE (Comments): **While IE appreciates the PRES position that this article introduces a new obligation on MAH that was not previously there, the main**

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	concern the IE has with this article we do not consider that it is likely to increase access to medicines in practice. **The purpose of market protection is to allow submission of the generic application and allow it to be assessed and granted but not to access the market. Removing market protection, still only allows the generic application to be submitted at the end of data protection period and given that it takes a minimum of 18 months from submission to market access, at most this gives 6 months access to the generic but could be less. Therefore while penalties are in place for an MAH that does not comply, IE cannot see how it will increase access to the medicine or generic for the MS.** **For article 56a to increase access generic should be enabled to launch at the start of the market protection period.** **If the originator does not wish to market there is also a question as to whether a generic will want to market the product.**

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6. The Member State shall make this information publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.	CZ (Comments): CZ would like to ask for clarification of what information should be made publicly available. EE (Suggested adaptations to the text): EE **6. The Member State shall make ~~this~~ 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.** EE (Comments): EE Added reference to para 5 LT (Comments): It is not clear where information about the non-application of the market protection period or, in the case of orphan medicinal products, the market

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	exclusivity period will be made public. Will it be a database in accordance with Article 138 of the Directive, which provides for the publication of information received from marketing authorization holders about data and market protection periods, or another place, such as the websites of the competent authorities of the MSs? If it is the database according to Article 138 of the Directive, and the MAH have an obligation to submit this information, what will be done in those situations where the MAH does not submit the information about a non-application of the market protection period to the database? NL (Comments): In our view, it is not clear from the article how and where this should be made publicly available. Does the presidency intend to link this para to article 138? If this is the case, we worry about placing the responsibility on the NCA's, because of the possible administrative workload it places on the already overburdened NCA's SE

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	(Comments): Support, see comment above. IT (Suggested adaptations to the text): ~~**6. The Member State shall make this information publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.**~~
7. This Article is without prejudice to Member States' legislation and procedures aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation.	EE (Suggested adaptations to the text): EE ~~**7. This Article is without prejudice to Member States' legislation and procedures aiming at making available and continuously**~~

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	~~**supplying the medicinal product concerned within their territory at any time following the marketing authorisation.**~~ EE (Comments): EE We do not understand the need for these clauses. As was explained by CLS, this wording would annul the normative value of this Article. SE (Suggested adaptations to the text): **7. This Article is without prejudice to Member States' legislation and procedures ~~aiming~~ with the objective to ~~at making available and continuously~~ supply~~ing~~ the medicinal product concerned in adequate quantities to cover patients needs within their territory at any time following the marketing authorisation.** SE (Comments): Just simplifying. IT (Suggested adaptations to the text):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	~~**7. This Article is without prejudice to Member States' legislation and procedures aiming at making available and continuously supplying the medicinal product concerned within their territory at any time following the marketing authorisation.**~~
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.	EE (Suggested adaptations to the text): EE ~~**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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Presidency comrpomise	Suggested adaptations to the text and Comments
	EE (Comments): EE See comment above. 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.**~~
In the course of the application of this Article, the Member States and the marketing authorisation holder shall cooperate in good faith.	EE (Suggested adaptations to the text): EE ~~**In the course of the application of this Article, the Member States and the marketing authorisation holder shall cooperate in good faith.**~~

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Presidency comrpomise	Suggested adaptations to the text and Comments
	EE (Comments): EE See comment above. LT (Comments): We have concerns about the evaluative term "in good faith" and about the practical implementation of this provision in national law. 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.**~~
~~**1. Pursuant to Article 56 paragraph 1, for medicinal products authorised in accordance with this Directive and the [revised**~~	

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

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~~(b) participate in any procurement procedures necessary to meet the needs of the patients in that Member State pursuant to national law implemented in accordance with the national legislation ; or~~	
~~(c) make the product otherwise available on the market offer the medicinal product to designated supply chain operators.~~	
~~For the purpose of letter c, Member States shall designate the operators whose supply is deemed necessary to meet the needs of the patients in that Member State. The designation shall be carried out in a proportionate manner.~~	

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~~**2. For the application of paragraph 1, the Member States shall may make communicate the requestsrequirements set out in paragraph 1 at the earliest latest one three years before the end of the regulatory data protection period, pursuant to Article 80(1), for that medicinal product or, if the marketing authorisation holder is an SME within the meaning of Commission Recommendation 2003/361/EC, two years after the granting of the marketing authorisation. The requirements shall include a deadline for the marketing authorisation holders to comply with the actions pursuant to paragraph 1.**~~	
~~**3. For the application of paragraph 1, the Member State shall indicate the a deadline for submission or participation, which shall be no shorter than 3 months. In addition, the Member States shall**~~	

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~~**indicate the minimum quantity of the authorised medicinal product, that it considers as sufficient to meet the needs in that Member State.**~~	
~~**4. When complying with the relevant obligations in accordance with paragraph 1During the application or the participation referred to in paragraph 1, the marketing authorisation holder shall apply make its offer under reasonable terms. The terms shall be considered reasonable if, taking into account all circumstances, they the marketing authorisation holder prove the intention of the marketing authorisation holder to**~~	
~~**(a) make, within the limits of its responsibility, the medicinal product available on the market concerned and continuously supply it the quantity indicated by the Member State under paragraph (2),**~~	

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~~**during the whole period of the protection provided by patent protection, regulatory data protection or market exclusivityin that Member State.**~~	
~~**(b) applyies, overall, conditions that are not unjustifiably more disadvantegous than the conditionsto those applied in another Member State in a similar situation, taking into account, among others, the Purchasing Power Parities set out in Regulation (EC) No 1445/2007 of the European Parliament and of the Council of 11 December 2007 establishing common rules for the provision of basic information on Purchasing Power Parities and for their calculation and dissemination.**~~	
~~**5. With a view to comply with the obligations laid down in Article 56(3), the Member State may require the marketing authorisation holder to establish, regularly update and implement a supply plan for the given medicinal productUnless waived by the Member State, for**~~	

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~~**the application of point (a), the marketing authorisation holder shall present and implement a supply plan as a part of its application or participation referred to in paragraph 1that will ensure that, within the limits of the resopnsibility of the marketing authorisation holder, the medicinal product is continuously supplied into the supply chain in a sufficient quantity,. within the timelines laid down in paragraph 2.**~~	
~~**6. Where the marketing authorisation holder does not comply with its obligations in accordance with this Article in a Member State, Article 80, paragraph 2, shall not apply within that Member State. conditions set out in paragraph (1) and (4) are not met:**~~	

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~~**The Member State may communicate the name of the marketing authorisation holder subject to this paragraph to the Agency, which shall make this information public.**~~	
~~**(a) the protection referred to in Article 80 paragraph (2) does not apply in the Member State concerned,**~~	
~~**(b) the Member State may also apply penalties, such as the penalties set out in Article 206 (4) to (6).**~~	
Recital:	IT (Comments): ***IT comment: Please see comment above.***
Access to medicinal products in all Member States and guaranteeing a stable, reliable and high-quality supply of medicinal products is an	IE (Suggested adaptations to the text):

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Presidency comrpomise	Suggested adaptations to the text and Comments
essential objective to achieve an overall high level protection of human health in the Member States, thus contributing to the protection of human health and human life in the Union. The responsibility of ensuring an adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is granted, the medicinal product is placed on the market by the marketing authorisation holder on its own initiative. Practice shows, however, that in certain Member States the behaviour of marketing authorisation holders results in the placing on the market of authorised medicinal products is delayed or in quantities that do not correspond to the needs of those Member States. Therefore, Member States should be enabled to require to the MAHs specific actions with a view to comply with their market launch and supply obligations pursuant to this Directive. To this aim, Member States should be able to request the marketing authorisation holder to submit an application for pricing and reimbursement or to participate in any	**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 adequate, timely 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 be enabled to choose to be included in a marketing authorisation holder's market launch and supply strategy ~~require to the MAHs specific actions~~ with a view to ensuring ~~comply~~ compliance**

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Presidency comrpomise	Suggested adaptations to the text and Comments
relevant national procurement procedures or make the product available in the supply chain. Member States should base their request on the grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition. Member States should also be able to request the submission and implementation of a supply plan that ensures sufficient and continuous supply to meet the needs of the patients in that Member State.	**of the market authorisation holder with their market launch and supply obligations pursuant to this Directive. To this aim, Member States should be able to decide if they wish to be supplied with a medicinal product and notify the ~~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 in that product available in the supply chain in that Member State. Member States should base their decision in this regard ~~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 and marketing authorisation holders should also agree a supply plan ~~be able to request the~~ which should be submitted~~ssion~~ and implemented~~tation of a supply plan that~~ to ensures sufficient and continuous supply to meet the needs of the patients in that Member State.** SE (Suggested adaptations to the text):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	Access to medicinal products in all Member States and guaranteeing a stable, reliable and high-quality supply of medicinal products is an essential objective to achieve an overall high level protection of human health in the Member States, thus contributing to the protection of human health and human life in the Union. The responsibility of ensuring an adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, 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~~ by its own initiative. Practice shows, however, that in certain Member States the ~~behaviour of~~ marketing authorisation holders do not ~~results in the~~ place ~~ing~~ the authorised medicinal product on the market, or ~~of authorised medicinal products~~ market entry is delayed or provided in inadequate quantities ~~that do not correspond~~ to meet the needs of those Member States. Therefore, Member States should be enabled to require to the MAHs specific actions with a view to comply with their

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	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.~~ 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. SE (Comments): See some suggestions. On the "pricing and reimbursement" text we ask the Council's Legal Service to take a look, just as in para 2 above, should it be stated explicitly? We should act in good faith.

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Presidency comrpomise	Suggested adaptations to the text and Comments
	IT (Suggested adaptations to the text): ~~**Access to medicinal products in all Member States and guaranteeing a stable, reliable and high-quality supply of medicinal products is an essential objective to achieve an overall high level protection of human health in the Member States, thus contributing to the protection of human health and human life in the Union. The responsibility of ensuring an adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is granted, the medicinal product is placed on the market by the marketing authorisation holder on its own initiative. Practice shows, however, that in certain Member States the behaviour of marketing authorisation holders results in the placing on the market of authorised medicinal products is delayed or in quantities that do not correspond to the needs of those Member States. Therefore, Member States should be enabled to require to the MAHs specific actions with**~~

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Presidency comrpomise	Suggested adaptations to the text and Comments
	~~**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. 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.**~~
Article 166	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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.	DE (Comments): DE upholds the question to the Council Legal Service if this proposal would conflict with the basic economic liberties. ES (Comments): ES supports Presidency´s proposal. SE (Comments): Support in principle. It depends on where article 56 a goes. IT (Suggested adaptations to the text): ~~**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**~~

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Presidency comrpomise	Suggested adaptations to the text and Comments
	~~**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.**~~
Article 216	
Report	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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.	AT (Comments): AT: AT supports the suggested evaluation. DE (Comments): DE is in favour of such an evaluation clause if a workable mechanism can be agreed. EE (Comments): EE Follow-up actions should be added in case based on the review the legislation has not been fit for purpose.

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Presidency comrpomise	Suggested adaptations to the text and Comments
	ES (Comments): ES supports Presidency´s proposal. IE (Suggested adaptations to the text): **By [OP please insert the date = 6 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the to the European Parliament and the Council on the application of Article 56a. The report shall include an assessment whether the rules provided for in that Article ensures timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article and suggest any further legislative change required.** IE (Comments): The review should not just include an assessment but also suggest any further action required. LT (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	We support this amendment. NL (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 shall present a report ~~to the~~ to the European Parliament and the Council on the application of Article 56a. The report shall include an assessment whether the rules provided for in that Article ensures timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article.** PT (Suggested adaptations to the text): **. By [OP please insert the date = ~~6~~ 5 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the to the European Parliament and the Council on the application of Article 56a. The report shall include an assessment whether the rules provided for in that Article ensures**

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Presidency comrpomise	Suggested adaptations to the text and Comments
	timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article PT (Comments): Support. Relevant to see if system has achieved its objective. Need to take in consideration the deadline in n.5 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 shall present a report to the to the European Parliament and the Council on the application of Article 56a. The report shall include an assessment whether the rules provided for in that Article ensures timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article.**~~

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Presidency comrpomise	Suggested adaptations to the text and Comments
Chapter XVI **General provisions**	
Article 206	EE (Comments): EE Further explanations from CLS would be welcome to better understand whether legally MSs would be in a position to impose penalties on MAHs in cases where the MAH has not entered the market and is not legally represented on the territory of the MS. MT (Comments): Penalties at EU level as we have in competition law are much more effective than penalties at MS level. Infractions to this article should be

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	listed in annex 2 of the regulation. Failure to list in annex 2 would be sending the wrong message, both to industry and also to patients. Obligations are only complied with if there are serious consequences and unfortunately that is not the case with the current text.
Penalties	
2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:	NL (Comments): This paragraph refers to para 1, which is not included in this proposal. We would like to know whether this reference is an omission.
(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;	

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(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.	DE (Comments): See introductory remarks to Article 56a SE (Comments): Scrutiny reservation (positive). 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.**~~
(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;	

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(c) non-compliance with the provisions laid down in this Directive on the use of excipients;	
(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	
(e) non-compliance with the provisions laid down in this Directive on advertising.	
~~**4. Without prejudice to the national rules on penalties referred to in paragraph 1, Wwhere the marketing authorisation holder fails to comply withinfringes the its obligations set out pursuant to set outpursuant to in Article 56a, including, if applicable, the**~~	AT (Suggested adaptations to the text): **AT: 4. Without prejudice to the national rules on penalties referred to in paragraph 1, Where the marketing authorisation holder fails to**

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Presidency comrpomise	Suggested adaptations to the text and Comments
~~**implementation of the supply plan, Member States may decide to impose a administrative fines not exceeding theup to 5% of the marketing authorisation holder's Union annual turnover within the Union in the business year preceding the date of that decisionof the preceding financial year.**~~	**comply withinfringes the its obligations set out pursuant to set outpursuant to in Article 56a, including, if applicable, the implementation of the supply plan, Member States may decide to impose a administrative fines not exceeding theup to 5% of the marketing authorisation holder's Union annual turnover within the Union in the business year preceding the date of that decisionof the preceding financial year.** AT (Comments): AT: We would support the reintroduction of the penalties. The initially proposed extent of penalties is also reasonable
~~**5. Without prejudice to the national legislation on financial penalties, whereWhere the marketing authorisation holder continues to fail to complyrepeatedly infringes the obligations set out pursuant to with its obligations referred to in Article 56a, the Member State may decide to impose, until the day of compliance and until the expiry of the patent protection, regulatory data protection or market**~~	AT (Suggested adaptations to the text): **AT: 5. Without prejudice to the national legislation on financial penalties, whereWhere the marketing authorisation holder continues to fail to complyrepeatedly infringes the obligations set out pursuant to with its obligations referred to in Article 56a, the Member State**

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~~**exclusivity, periodic penalty payments per day not exceedingup to 2,5 % of the marketing authorisation holder's average daily Union turnover within the Union of the preceeding financial year. in the business year preceeding the date of that decision.**~~	**may decide to impose, until the day of compliance and until the expiry of the patent protection, regulatory data protection or market exclusivity, periodic penalty payments per day not exceedingup to 2,5 % of the marketing authorisation holder's average daily Union turnover within the Union of the preceding financial year. in the business year preceding the date of that decision.**
~~**Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Member State decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in Article 56, paragraphs 1 and 3 has been brought to an end.**~~	AT (Suggested adaptations to the text): **AT: Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Member State decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in Article 56, paragraphs 1 and 3 has been brought to an end.**

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~~**6.**~~ ~~**Member States may send the Agency their decision referred to paragraphs 4 and 5, and the Agency shall make this decision public.**~~	
Chapter VII	
Regulatory protection, unmet medical needs and rewards for paediatric medicinal products	

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Presidency comrpomise	Suggested adaptations to the text and Comments
Article 83	
Medicinal products addressing an unmet medical need	IT (Comments): ***IT comment: IT suggests that the criteria for identifying an UMN should be specified separately and not linked to the incentives. Medicinal products addressing an UMN authorised via centralised procedure benefit from multiple regulatory incentives, such as the eligibility for the EMA Priority Medicines scheme (PRIME), the conditional authorisation procedure, and the accelerated assessments. Such procedures entail the acceptance of a higher level of evidence uncertainty to allow faster access to therapies. As a result, it could potentially increase pressure on MSs by patients and MAHs to recognise the value (higher prices) and ensure a faster market access, even if there is no certainty of the evidence produced. In addition, this***

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	could have potential negative effects on HTA and pricing and reimbursement procedures, with a consequent delayed patient access to medicinal products. Finally, there are no references to the quality of evidence and the magnitude of the clinically meaningful effect.
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:	FR (Comments): France supports the return to the Commission's version at 1a in view of the Presidency's clarification. SE (Comments): We provide with basic elements here. We have omitted orphan MPs (2.). They may or may not be addressing UMN, according to the definition.

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Presidency comrpomise	Suggested adaptations to the text and Comments
	SE is of the opinion that it is important to refer to regulatory, scientific/clinical guidelines for the final identification of UMN. Also, UMN (including as orphan conditions) will be present in most therapeutic areas. Appropriate expertise should decide further. UMN will be moving targets as the medical needs will be fulfilled with time, so it is important to be able to update guidelines (more often than EU legislation).
(a) there is no medicinal product authorised in the Union **~~satisfactory method of diagnosis, prevention or treatment in standard of care~~** for such disease, or, where despite **~~the existence of a satisfactory method of diagnosis, prevention or treatment in standard of care~~** medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;	AT (Suggested adaptations to the text): AT: (a) there is no **~~medicinal product authorised in the Union~~** **satisfactory method of diagnosis, prevention or treatment in standard of care** for such disease, or, where despite **the existence of a satisfactory method of diagnosis, prevention or treatment in standard of care** **~~medicinal products being authorised for such disease in the Union~~**, the disease is associated with a remaining high morbidity or mortality AT

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	(Comments): AT: The initial wording, in our view, better reflected the aim of this article. CZ (Comments): CZ can support deleting of the text in para 1 letter a) as proposed by HU PRES. We considered the previous text unprecise as it raised questions and allowed a wide interpretation of such provision. However, we would like to point out that healthcare standards are not harmonized at the EU level. Additionally, please see comment on Article 81 para 2 letter a). DE (Comments): DE in general welcomes the return to this phrasing. The final assessment hinges on what incentives are connected with this definition. ES (Comments): ES supports Presidency´s proposal. LT (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	Since there are no common standards of care for diagnosis, prevention and treatment at the EU level, we support the proposal to return to the original version of the Commission, as it is clearer and is associated with the absence of an authorised medicinal product in the EU. NL (Suggested adaptations to the text): (a) there is no medicinal product authorised in the Union **~~satisfactory method of diagnosis, prevention or treatment in standard of care~~** for such disease, or, where despite **the existence of a satisfactory method of diagnosis, prevention or treatment in standard of care** medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality; NL (Comments): The NL delegation wonders why in paragraph 1(a), the wording on 'the existence of satisfactory methods of diagnosis, prevention or treatment in standard of care' was deleted. In determining and Unmet Medical Need, it

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Presidency comrpomise	Suggested adaptations to the text and Comments
	is important to also look at non-medicinal treatment such as for instance surgery. It is not self-evident that a medicinal treatment is preferable. PT (Comments): Agreement with the definition as proposed. SE (Suggested adaptations to the text): (a) there is no medicinal product authorised in the Union **~~satisfactory method of diagnosis, prevention or treatment in standard of care~~ for the corresponding use in the target** ~~such~~ disease **or population**, or, **if there are authorized products or alternative methods,** ~~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 SE (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	"High" is difficult word to assess and describe here, but that should be made clear from the therapeutic area and corresponding regulatory guidelines.
(b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population. **The meaningful reduction in disease morbidity or mortality for the relevant patient population ~~may~~ shall be demonstrated, where possible and appropriate, with data from comparative clinical ~~trials~~ studies ~~that use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency~~.**	AT (Comments): AT: We would advise to keep the original wording in order to strengthen the importance of evidence based comparators also for OMPs. CZ (Comments): In accordance with the comment on para 1 letter a) CZ can support this provision. ES (Comments): ES supports Presidency´s proposal. FR (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	France believes it is important to take into account the agency's scientific opinion. PT (Comments): Support. For most of the orphan medicinal comparative clinical trials are not often the path to provide evidence. This sentence allows flexibility to use indirect comparisons. SE (Suggested adaptations to the text): (b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population. **The meaningful reduction in disease morbidity or mortality for the relevant patient population ~~may~~ shall be demonstrated, ~~where possible and appropriate,~~ with data from comparative clinical ~~trials~~ studies ~~that use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency,~~.**

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Presidency comrpomise	Suggested adaptations to the text and Comments
	Derogations from performing randomized clinical trials should be justified by the applicant. IT (Suggested adaptations to the text): (b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population. **The meaningful reduction in disease morbidity or mortality for the relevant patient population ~~may~~ shall be demonstrated, where possible and appropriate, with data from ~~comparative~~ clinical ~~trials~~ studies that use a relevant and evidence-based comparator ~~in accordance with scientific advice provided by the Agency~~.** IT (Comments): ***IT comment: IT does not support the deletion of the reference to the use of the relevant and evidence-based comparator.***

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Presidency comrpomise	Suggested adaptations to the text and Comments
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.	SE (Suggested adaptations to the text): ~~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.~~ SE (Comments): Orphan medicinal products may not be considered UMN by default. Orphan MPs enjoy designation and once approved, market exclusivity, by other articles. We therefore suggest to deletion here, and lean on the guidelines in 3, see also our initial comments.

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Presidency comrpomise	Suggested adaptations to the text and Comments
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].	PT (Suggested adaptations to the text): "The Agency shall adopt scientific guidelines to support the application of this Article, **with the involvement of CHMP. ~~To this end~~ It shall also** consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]. PT (Comments): Support. The involvement of CHMP (depending on the decision on the future restructuring of the Agency committees) in the drafting of the scientific Guidelines is important to promote a common definition and common principles for the assessment of orphan medicinal products. SE (Comments): Support.
Article 84	

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Presidency comrpomise	Suggested adaptations to the text and Comments
Data protection for repurposed medicinal products	
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:	AT (Comments): AT: We suggest the data protection for repurposed products should be listed in the Article 138/ 1(n) of the revised regulation.
(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	NL (Suggested adaptations to the text): (a) adequate ~~non-clinical~~ **and** ~~or~~ clinical studies **and, where relevant, non-clinical studies or tests** were carried out in relation to the

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	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 protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	AT (Suggested adaptations to the text): AT: (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 protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned. AT (Comments): AT: In order to efficiently prevent misuse by the initial MAH (i.e. originator manufacturers), it is crucial to keep this initial wording. CZ (Comments): In general, CZ supports the concept of repurposing of medicines and agrees with deleting the text in para 1 letter b). Crucial is also the reference to

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Presidency comrpomise	Suggested adaptations to the text and Comments
	Article 48. Moreover, new indication should clinically differ from the indications authorised so far and not only within the existing indications´ group of such medicine. Therefore, this provision should be more clarified. IE (Suggested adaptations to the text): (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 protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned. IE (Comments): The purpose of this text was to prevent the use of this provision for 'autogenerics' from the originator company and IE considers that this text should be retained.

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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

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): AT general remark: AT supports a broad and clear definition of Bolar and would very much appreciate to hear the opinion of the Council legal service and its view of procurement bids and tenders in the context of bolar. SE (Comments): SE will come back with comments on this article when dealt with in the WP.
Exemption to the protection of intellectual property rights	DE (Comments): From DE's perspective, there is still a considerable need for clarification in some details. We uphold a scrutiny reservation and await the opinion of the Council Legal Service. This applies in particular to the planned extension of the scope of the Bolar provision to include HTA and pricing and reimbursement, both of which we view critically. Furthermore, we share the Commission's view that paragraphs 1a and 1c are not necessary.

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Presidency comrpomise	Suggested adaptations to the text and Comments
	Instead, they tend to contribute to legal uncertainty and should therefore be deleted. This applies equally to the additions in Recital 65.
1. Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when a ~~reference~~ **patented product, or process, design or invention** ~~medicinal product~~ is used for the purposes of:	NL (Comments): It is not clear why a limitation is placed here by limiting said text to generic, biosimilar, hybrid or bio-hybrid medicinal products. In light of the goal of further harmonisation, any such limitations should be avoided. The current wording will still result in inconsistency within the EU, as some member states have included all types of medicinal products, including innovative ones.

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

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Presidency comrpomise	Suggested adaptations to the text and Comments
(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.	FR (Comments): To clarify the b, and in order to do so, French authorities have thought of an idea worth exploring: b) the activities conducted exclusively for the purposes set out in point (a), may *include,* **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 *used for demonstrating the capacity to produce on an industrial scale and in quantities exceeding those sufficient for trials purposes,* including by third party suppliers and service providers. This exception shall not cover the placing on the market of the medicinal products resulting from such activities NL (Suggested adaptations to the text): (b) the activities conducted exclusively for the purposes set out in point (a), may cover**, where ~~relevant~~ necessary,** the submission of the application for a marketing authorisation and the offer, manufacture, sale,

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	supply, storage, import, use and purchase of ~~patented~~ medicinal products or processes, including by third party suppliers and service providers. NL (Comments): We propose to replace 'relevant' with 'necessary'. Necessity gives a better framework for this para than relevance.
This exception shall not cover the placing on the market of the medicinal products resulting from such activities.	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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).	CZ (Suggested adaptations to the text): 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). CZ (Comments): In general, CZ supports extending of Bolar exemption. However, we would prefer to keep the procurement bids in the text, meaning to keep the previous BE PRES proposal. Possibility of participation in procurement bids can represent a tool how to improve availability of medicines right before the end of the market protection and support sustainability of financial budgets as well. We are of the opinion that supply chains of medicines should be more diversified as in the case of the sole medicines´ supplier MAH may not be able to safeguard the fluent supplies of

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	medicines for the whole EU. Therefore, the change in wording is proposed and the CLS opinion is expected as well. IE (Comments): IE position is to retain all 3 paragraphs 1a /1b/ 1c here. This will ensure clarity in the application and interpretation of the Bolar exemption across the EU, which is the intention of this legislation and will ultimately ensure day one entry of generic medicines. NL (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 procurement bids and decisions on applications referred to in paragraph 1 point (a).**~~ NL (Comments):

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	We remain hesitant to include paragraphs 1a and 1c. In our view, these 'clarifying' legal provisions are unnecessary. We are concerned that these additions may introduce ambiguity and create legal uncertainty.
~~**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.**~~	AT (Suggested adaptations to the text): AT: ~~**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.** AT (Comments): AT: We suggest keeping this paragraph for clarity. IE (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

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	which, as such, are independent from the enforcement of intellectual property rights. IE (Comments): Paragraph 1b was introduced to provide legal certainty that MAA, HTA, and P&R procedures and decisions were not affected by IP rights, and so we would advocate fort this test to be retained
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	AT (Suggested adaptations to the text): AT: **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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submit an application of pricing and reimbursement.~~, when those 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~~** AT (Comments): AT: AT acknowledges that some MS would need to make changes in their reimbursement systems. A link to availability is however, a proxy for IPR and this addition, in our view, would manifest patent linkage, which is deemed undesirable if not illegal by the EC. We suggest to delete the second sentence of this paragraph. If it is to apply generally that price fixing and reimbursement procedures do not constitute patent infringement, the phrase "national rules concerning" should be omitted. A reference to "national" seems likely to lead to a fragmentation of the law, since - depending on the national rules or case law - a patent infringement may or may not exist FR

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(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 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.~~ FR (Comments): The addition of this paragraph brings confusion to the article. To date, several European countries have already adopted different approaches to applying the Bolar exemption, particularly concerning HTA evaluations and price and reimbursement (P&R) applications before the expiration of a patent. For that matter, it is clear the European framework allows for some flexibility in interpreting the directive, and that the application for P&R by generic companies does not constitute a violation of patent rights

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	to the originator. In that regard, France believes that additional provisions may be unnecessary, beyond the objective of harmonisation, since it is already clear from the current directive that such practices are permitted. Moreover, the second sentence of the paragraph brings confusion to the scope of harmonisation, and should therefore be removed to limit misinterpretation. IE (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 medicinal product on the market of that Member State conditional to submit an application of pricing and reimbursement., when those**~~

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	~~**rules concern the applicant's activities that can be indirectly affected by intellectual property rights.**~~ IE (Comments): IE would ask for the PRES / CLS opinion on the implications of the newly added text; **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., -** IE is concerned that this new text will be used to negate the application the BOLAR clause or lead to less clarity in its application. NL (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**~~

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	~~related to the procedures referred to in paragraph (1) and (1a). This paragraph is without prejudice to national rules concerning pricing and reimbursement procedures that make the availability of a medicinal product on the market of that Member State conditional to submit an application of pricing and reimbursement., when those rules concern the applicant's activities that can be indirectly affected by intellectual property rights.~~ NL (Comments): We remain hesitant to include paragraphs 1a and 1c. In our view, these 'clarifying' legal provisions are unnecessary. We are concerned that these additions may introduce ambiguity and create legal uncertainty.
Recital 65	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 valid ground to refuse or suspend decisions related to pricing and reimbursement or health technology assessment procedures. However, Member States should remain free to introduce a national requirement to prove the availability of a medicine on the market of that Member State at the date of submission of the application for pricing and reimbursement.**	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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	

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Regulation (EC) No 726/2004] shall be used for the purposes of applying paragraph 1.	
3. Where the procedures laid down in Chapter III, Sections 3 and 4, have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.	
4. In the case of an application for new **paediatric** therapeutic indications, ~~including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of authorised medicinal products~~ **for a medicinal product** which ~~are~~ **is** protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a	DE (Comments): We would like to understand why this change was made – is any different legal effect intentioned or is it just streamlining the Paragraph without effecting substantial legal change? NL

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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).	(Comments): We fully support the amendmentment of data protection to market protection to keep in line with the compromised text in article 80(2).
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	

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

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

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Presidency comrpomise	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*~~	ES (Suggested adaptations to the text): *Article 70* ES

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): ES supports come back to Commission`s proposal. We have an opportunity NOW to make a difference among all the marketing authorisation applications we receive for orphan drugs for treatment of unmet medical needs that we consider to provide a significant benefit by bringing an EXCEPTIONAL therapeutic improvement. We have in our hands the opportunity to reward those companies that are committed to medicines for HUMN and as the COM told us, in our experience, an exceptional therapeutic improvement is only expected to occur in 2-3 cases per year. As a consequence, we propose to maintain also Arti 71.2 (b) (10 years HUMN) and 72.2.
~~*Orphan medicinal products addressing a high unmet medical need*~~	ES (Suggested adaptations to the text): *Orphan medicinal products addressing a high unmet medical need*

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Presidency comrpomise	Suggested adaptations to the text and Comments
~~1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following requirements:~~	ES (Suggested adaptations to the text): 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;~~	ES (Suggested adaptations to the text): (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 comrpomise	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.~~**	ES (Suggested adaptations to the text): (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.~~	ES (Suggested adaptations to the text):

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	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.
~~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.~~	ES (Suggested adaptations to the text): 3. The Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162.
Article 71	AT (Comments): AT: AT agrees with the return to the current provision (10 year market exclusivity). However, this is contingent on the re-introduction of the

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	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 would substantially relieve pressure on health budgets by allowing an earlier market start for a generic or similar orphan product. DE (Comments): DE proposes the following in connection with the orphan designation, which would also have to be included in Article 63 of the Draft Regulation: Five years after marketing authorisation, the sales of orphan medicinal products should be reviewed. To this end, marketing authorisation holders should provide information on EU-wide sales.

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	If a certain threshold, which is yet to be defined, is exceeded, the medicinal products should lose their orphan status. This would ensure that orphan medicinal products that generate high sales and place a burden on healthcare systems do not benefit from the same incentives as medicinal products that are only slightly profitable. To determine a possible threshold, we ask COM to present an analysis of the annual sales of the drugs on the market and those with market exclusivity.
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**~~	LT (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
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.	We support the proposal to return to the Commission's proposal to use the term "extend" instead of "extension of indication", as the latter does not correspond to the currently valid Regulation (EC) No. 1234/2008 ("Variations Regulation").
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);	IE (Suggested adaptations to the text): 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) IE

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Comments): Typo corrected SI (Comments): SI considers that baseline protection for orphan medicinal products should stay 9 years.
~~(b) ten years for orphan medicinal products addressing a high unmet medical need as referred to in Article 70;~~	ES (Suggested adaptations to the text): **(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].	IE (Suggested adaptations to the text): (c) (b) 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 comrpomise	Suggested adaptations to the text and Comments
	IE (Comments): Typo corrected
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.	

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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:	
(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.	

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

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Presidency comrpomise	Suggested adaptations to the text and Comments
~~**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.	6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for **or granting** **of** a marketing authorisation ~~**for, a medicinal product**~~ ~~**or granting a marketing authorisation,**~~ **including to extend an existing marketing authorisation for a new therapeutic indication**~~**or an extension of an existing marketing authorisation**~~ ~~for~~**of** a similar medicinal product, including generics and biosimilars, where the remainder of the duration of the market exclusivity is less than two years. SI (Suggested adaptations to the text): The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for marketing authorisation **or its granting** ~~a marketing authorisation …~~ SI (Comments): SI suggestion. IT (Comments):

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	IT comment: the change provided by the PCY, inserting "or granting", is not clear and it seems to be in contrast with paragraph 1 of 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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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.~~	IE (Comments): IE understands the rationale for the deletion here but noting same, there is now no supply requirements for OMPs. IE would therefore **ask for PRES position on how the legislation will ensure equitable supply of OMPs across the EU, as was proposed by the Commission,** noting the nuances that must be accounted for in relation to these products and the

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	fact that measures set out in article 56a would therefore not be appropriate.
~~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**~~.	AT (Suggested adaptations to the text): AT: 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

Presidency comrpomise	Suggested adaptations to the text and Comments
	different orphan condition **where such data were not available when the initial marketing authorisation was submitted.** AT (Comments): AT: It remains unclear, why the condition stating that the extension would not be granted if the data underpinning the authorisation of a new indication was available at the time of submission for application leading to the original marketing authorisation, only applies to regular products and not to OMPs. As above in the context of regular products, it is crucial that the burden of proof does not lie within the responsibility of the Competent authorities. After all, it is the MAH who profits from any extension of protection periods, especially in case of market exclusivity See above: this is crucial to avoid ever-greening and misuse of the prolongation. ES

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(Suggested adaptations to the text): 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. ES (Comments): See comments in article 70 (High Unmet Medicinal Needs). SI (Suggested adaptations to the text): … therapeutic indications for a different orphan condition **where such data were not available when the initial marketing authorisation was submitted**. SI (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	SI proposes to keep last sentence.
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].	

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Presidency comrpomise	Suggested adaptations to the text and Comments
4. Article 71(3) equally applies to the prolongations of market exclusivity referred to in paragraph~~s 1 and~~ 2.	
REPURPOSING BY ANOTHER ACTOR ('CHAMPION')	

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Presidency comrpomise	Suggested adaptations to the text and Comments
CHAPTER IV **POST-MARKETING AUTHORISATION MEASURES**	
Article 48	AT (Comments): AT: general remark: AT has submitted comments to this article with the document 13038/24, these comments are included in this version (and for the sake of clarity we would be grateful if the presidency could try to consolidate the various documents under the relevant clusters.
Scientific opinion on data submitted from not-for-profit entities for repurposing of authorised medicinal products	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

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	guidelines will be made to clarify the process, including the involvement of MAHs. Furthermore: we would like to address a new issue and discuss whether we could expand this article to gain even more benefits for patients. • In practice, we see that academics and other third parties also perform dose and treatment optimisation studies. • We believe that patients can benefit from post authorisation studies for treatment optimisation. These can minimise harmful side effects and reduce the overall burden of treatment, while maintaining the therapeutic benefits. • This is also recognized by the Commission with the option to impose post authorisation studies on a MAH as laid out in the proposed REG Article 12 (4h). • We would like to discuss whether it is desirable to also include these types of studies in this Article. • This would lead to an assessment of the studies by the Agency. In cases where the opinion is positive, the MAH would be obligated to include this new information into its product information. • We believe that this potentially will result in benefits for patients throughout the Union.

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	• We are also open to discuss other possibilities to promote studies that can reduce the burden of treatment for patients. RO (Comments): As a general observation, RO supports the elimination of the condition of " unmet medical need " to be fulfilled by the new therapeutic indication and proposes greater involvement of MAHs for the purpose of submitting additional safety and efficacy data to support or supplement the data submitted by non-profit entities. We believe that the request addressed to MAHs to provide data in this type of procedure can bring benefits both by providing additional data that they have at their disposal or can later characterize in additional studies, as well as in the implementation of the targeted changes and the fulfillment of the obligations deriving from they

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Presidency comrpomise	Suggested adaptations to the text and Comments
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~~.	AT (Comments): AT: Allowing not-for-profit- entities to submit evidence for the repurposing of an authorised medicinal products is a significant and commendable new avenue to identify therapies that address an unmet medical need. AT would like to remark, that it is unclear, what extra resources (staff and otherwise) might be necessary in the Agency or competent authorities of Member States to support this new route to variation of an authorisation. This should be considered and thought given on how best to support this new route. CZ (Suggested adaptations to the text): 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.** CZ (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	CZ expresses support to the initial EC text which narrows using Article 48 only to UMN. Please see the change in wording. ES (Suggested adaptations to the text): 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.** ES (Comments): ES supports to come back to Commission´s proposal. IE (Comments): **IE continue to have reservations with the use of the phrase "not engaged in economic activity" as not consistent with other legislation although acknowledge that "not-for-profit" gives the sense of the intention.** LT (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	We agree with the broader scope of application of the provision - i.e. that the EMA's scientific opinion be provided to not-for-profit entities for any new therapeutic indication without linking it to an unmet medical need. This provision is important in encouraging non-profit entities to develop new therapeutic indications.
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.~~	AT (Suggested adaptations to the text): AT: 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, **including any additional evidence that may be submitted by the marketing authorisation holders of the medicinal products concerned,** 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. AT (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	AT: Inclusion of new data/indications developed by a third-party under a repurposing framework needs careful consideration and consultation with marketing authorisation holders, well ahead of implementation. Additionally, regulatory standards for marketing authorisation should be the same for all entities. The expertise, capacity and deep product knowledge of the MAH should be considered when implementing labelling changes CZ (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.** CZ (Comments): Please see the comment above. ES (Suggested adaptations to the text):

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	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.** ES (Comments): ES supports to come back to Commission´s proposal. NL (Comments): The NL delegation notes that it is important to include MAHs in the process. The MAH may have information that can influence the benefit-risk. RO (Suggested adaptations to the text): **National Competent Authority of a Member State or** the Agency may, at the request of a Member State **or** the Commission, or on its own initiative and on the basis of all available evidence make a scientific

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	evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication. RO (Comments): Paragraph **1** states that non-profit entities can submit evidence for a new therapeutic indication both to the Agency (EMA) and to an MS NCA. We propose to complete the second subparagraph from paragraph 1 with the mention of the Competent National Authority of the Member State. We consider that ANCs can also evaluate these data in the case of medicines authorized through national procedures.
The opinion of the Agency shall be made publicly available and the competent authorities of the Member States shall be informed.	AT (Suggested adaptations to the text):

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	AT: The opinion of the Agency shall be made publicly available and the competent authorities of the Member States **and the marketing authorisation holders** shall be informed. LT (Suggested adaptations to the text): The opinion of the Agency shall be made publicly available and the competent authorities of the Member States **and the marketing authorisation holder** shall be informed. LT (Comments): We propose to provide that not only the competent authorities of the Member States shall be informed about the opinion of the EMA, but also the MAH of the medicinal product must be informed about it.

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 Article 47~~.	CZ (Suggested adaptations to the text): In cases where the opinion is favourable~~,~~ ~~and the new therapeutic indication addresses an unmet medical need,~~ ~~on the request of the Agency the Agency shall inform Member States and the Commission and request~~ 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 Article 47~~. CZ (Comments): If the current text is kept, CZ does not support the changes proposed by HU PRES that narrow down the obligation for MAH to submit a variation of marketing authorisation only in case of UMN. We are of the opinion that in the moment when non-profit organisation has already submitted data and EMA has made risk and benefit assessment on scientific basis with a positive result of such assessment, it is not possible to narrow the obligation of MAH only to UMN. Additionally, we are of the opinion that proposed changes in para 2 od this Article precise the EMA process in question of

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	positive assessment in some way, however, the situation should still be more specified. Please see the changes in wording. CZ would like to point out that in the case when the link on UMN is moved to para 2 of this Article, it is not clear whether the assessment concerning if the medicinal product fulfils an-UMN or not should become a part of the EMA opinion or not. Moreover, who is to make such decision and when should it be established that the medicinal product fulfils an UMN is to be clarified. Apart from that it is not clear whether MAH has an option to comment on the EMA assessment or not. Could MAH reject submission of a variation of medicine? We would like to emphasize a risk that MAH could ask for withdrawal of such marketing medicine authorisation. This situation should be specified. Especially, it should be made clear who is responsible for optional adverse effects of use in such indication in the case when MAH is not in accordance with EMA scientific assessment in this matter. DE (Comments):

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	We continue to take a critical view of the pharmaceutical company's obligation to apply for a change to the marketing authorisation as set out in paragraph 2. This interferes with the company's entrepreneurial freedom. In our opinion, it is also not certain that the marketing authorisation holder has sufficient expertise in the area if it is a completely new area of application. LT (Comments): We agree that in cases where the MAH receives a positive scientific opinion and a new therapeutic indication is related to "an unmet medical needs", at the request of the EMA, he shall submit a variation to update the product information with the new therapeutic indication. NL (Suggested adaptations to the text): 2. In cases where the opinion is favourable~~,~~ **and** ~~**the new therapeutic indication addresses an unmet medical need,**~~ **on the request of the Agency** ~~**the Agency shall inform Member States and the Commission**~~

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	~~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 Article 47~~**. NL (Comments): We would like to clarify why paragraph 2 lists Unmet Medical Need as a requirement for this procedure? It is our contention that this action should not be limited in scope. SI (Suggested adaptations to the text): In cases where the opinion is favourable, **and the new therapeutic indication ~~addresses an unmet medical need,~~ on the request of the…** SI (Comments): SI is of the opinion that the scope of this article should be broader and not limited to UMN. Therefore, we propose to delete »**addresses an unmet medical need”**.

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	IT (Comments): ***IT comment: It's not clear what happens in case a positive B/R ratio is established for a medicine not addressing an UMN.*** ***If a marketing authorisation cannot be imposed to the MAH, there might be cases in which another Applicant can submit a hybrid application for a new brand (possibly highly expensive for the public) relying on the positive opinion already released based on data produced by not-for-profit entities. Or an off-label use can be envisaged. All situations that would render access to this new alternative therapeutic option more difficult. More therapeutic options might represent a benefit per se even in situations where there is no UNM.*** ***So, if scientific evaluations to assess the B/R are to be released by the Agency also for therapeutic indications with no unmet need further discussions are needed to explore other regulatory options. This regulatory outcome should to be envisaged also considering that the assessment of evidence submitted by not-for-profit entities would entail an increase in the workload for NCAs.***

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3. Article 8**0**~~1~~(2), **2nd subparagraph** ~~point (~~**~~de~~**~~)~~ **and Article 84(1)** of [revised Directive 2001/83/EC] shall not apply for variations under this Article.	IE (Comments): IE notes that UMN is removed form para 1 but reintroduced in para 2. This will have the effect of only mandating a variation where a positive opinion is issued for a new indication which addresses a UMN. **IE's question is therefore what will happen in the case of other new indications.**
Article 4 (Directive)	

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Presidency comrpomise	Suggested adaptations to the text and Comments
Definitions	
(52) 'entity not engaged in an economic activity' means any legal or natural person that is not engaged in an economic activity and that:	
(a) is not an undertaking or controlled by an undertaking; and,	
(b) has not concluded any agreements with any undertaking concerning sponsorship or participation to the medicinal product development;	
PRE-AUTHORISATION REGULATORY SUPPORT	

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Presidency comrpomise	Suggested adaptations to the text and Comments
CHAPTER V	
PRE-AUTHORISATION REGULATORY SUPPORT	
Article 58	

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
Scientific advice	
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].	

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
2. In the preparation of the scientific advice referred to in paragraph 1 and upon request by undertakings or, as relevant, not-for-profit entities that requested the scientific advice, the Agency may consult experts of the Member States with clinical trial or medical device expertise or the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745.	
3. In the preparation of the scientific advice referred to in paragraph 1 and in duly justified cases, the Agency may consult authorities established in other Union legal acts as relevant for the provision of the	

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Presidency comrpomise	Suggested adaptations to the text and Comments
scientific advice in question or other public bodies established in the Union, as applicable.	
4. The Agency shall include in the European public assessment report the key areas of the scientific advice once the corresponding marketing authorisation decision has been taken in relation to the medicinal product, after deletion of any information of a commercially confidential nature.	
Article 59	
Parallel scientific advice	

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
1. Undertakings or, as relevant, not-for-profit entities established in the Union may request that the scientific advice referred to in Article 58(1) takes place in parallel to the joint scientific consultation carried out by the Member State Coordination Group on Health Technology Assessment, in line with Article 16(5) of Regulation (EU) 2021/2282.	DE (Comments): This should be extended to all companies who ask for such a parallel scientific advice
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	

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

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
Enhanced scientific and regulatory support for priority medicinal products ('PRIME')	IE (Comments): Clarification is requested as to whether orphan medicinal products could also seek to enter PRIME via options (a) or (c). 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 and 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.
1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain	AT (Suggested adaptations to the text):

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Presidency comrpomise	Suggested adaptations to the text and Comments
medicinal products that, based on preliminary evidence submitted by the developer fulfil **at least one of** the following conditions:	AT: 1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil **at least two of** the following conditions: AT (Comments): AT: PRIME also enables accelerated assessment, hence, more strict criteria are needed to avoid an increase of MA based on limited evidence. IT (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):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(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)~~;	AT (Comments): AT: The term "exceptional therapeutic advancement" is unclear. The different terms like "significant benefit" and "exceptional therapeutic advancement" need definitions/explanations and if indeed a different meaning is intended, the differences between the terms need to be clarified ES (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);**

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Presidency comrpomise	Suggested adaptations to the text and Comments
	ES (Comments): ES support maintain article 70. LT (Comments): We believe that for legal clarity the criteria "likely to bring exceptional therapeutic advancement" should be defined in this Regulation or in the guidelines adopted by the European Commission. NL (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)~~; NL (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. IT

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Presidency comrpomise	Suggested adaptations to the text and Comments
	(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);~~
(c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3)**;** ~~.~~	
(d) are likely to adress a neglected tropical disease (NTD).	DE (Comments): We request clarification from COM whether neglected tropical diseases always fall under the rubric of "unmet medical need" as a matter of definition or whether there are exceptions to this rule. ES (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	ES supports Presidency´s proposal.
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.	NL (Comments): The NL delegation wonders why para 3 refers to criteria mentioned in para 1a and 1b of this article, but not to the criteria in 1c (and 1d). Indeed,

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Presidency comrpomise	Suggested adaptations to the text and Comments
	also in case those criteria are not met, it is desirable that PRIME can be stopped to save resources.
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.	AT (Comments): AT: It should be noted that already the applicability of Article 60(1) of the proposed Regulation will imply the submission of a dossier to apply for PRIME designation (bureaucratic). Once granted, it is necessary to demonstrate continued eligibility to maintain the designation. This may not always be feasible from neither MAH nor EMA perspective. Consideration should be given to what level of demonstration of eligibility should be achieved – AT suggests to give further guidance like this in a guideline.

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
REGULATORY SANDBOXES	
CHAPTER IX **REGULATORY SANDBOX**	
Article 113	
Regulatory sandbox	CZ

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
	(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 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.

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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.	

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Presidency comrpomise	Suggested adaptations to the text and Comments
	AT (Suggested adaptations to the text): AT: **new (1a) Medicinal products that are eligible for a regular marketing authorisation procedure are excluded from a regulatory sandbox.** AT (Comments): AT: It is crucial to avoid that a sandbox does not open up an "easier" route for manufacturers to obtain eventually MA.
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,	CZ (Comments): CZ supports deleting link on Regulation of the European Parliament and the Council of the EU on clinical assessment as proposal by HU PRES.

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[revised Directive 2001/83/EC]**,** ~~**or**~~ Regulation (EC) 1394/2007 ~~**or Regulation (EU) 536/2014**~~ under the conditions set out in Article 114.	
A regulatory sandbox shall take effect under direct supervision of the competent authorities of the Member States concerned with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member State legislation concerned by the sandbox. Any violation of the conditions set out in the decision referred to in paragraph 6 and the identification of any risks to health and to environment shall be immediately notified to the Commission and to the Agency.	
3. The Agency shall monitor the field of emerging medicinal products and may request information and data from **the national competent**	

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Presidency comrpomise	Suggested adaptations to the text and Comments
authorities of the Member States, marketing authorisation holders, 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 sandbox plan referred to in paragraph 1.	

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Presidency comrpomise	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)	CZ (Comments): Please see the comment on para 2 of this Article.

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Presidency comrpomise	Suggested adaptations to the text and Comments
1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The **sandbox** plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory **sandbox**.	
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).	

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Presidency comrpomise	Suggested adaptations to the text and Comments
7. Decisions establishing a regulatory sandbox under paragraph 5 shall be limited in time and shall set out detailed conditions for its implementation. These Decisions shall:	
(a) include the proposed sandbox plan;	
(b) include the duration of the regulatory sandbox and its expiry;	
(c) include as part of the sandbox plan the requirements of this Regulation and of [revised Directive 2001/83/EC]**, Regulation (EC) 1394/2007 ~~or Regulation (EU) 536/2014~~** that cannot be complied with and shall include appropriate measures to mitigate potential risks to health and to the environment.	CZ (Comments): Please see the comment on para 2 of this Article.

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Presidency comrpomise	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.	

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Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).	
Where the Agency receives information that one 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	CZ (Comments): CZ supports added link on para 7 and 8 of this Article as proposed by HU PRES.

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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 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, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	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 comrpomise	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.~~	

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	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.	
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).	

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Presidency comrpomise	Suggested adaptations to the text and Comments
6. The Commission shall immediately vary the marketing authorisation to take account of the mitigation measures taken in accordance with Article 115.	
Article 115	
General sandbox provisions	

From: AT, CZ, DE, EE, ES, FR, IE, LT, MT, NL, PL, PT, RO, SE, SI, IT **Updated: 04/10/2024 10:22**

Presidency comrpomise	Suggested adaptations to the text and Comments
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).	
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.	

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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	CZ (Comments): CZ would like to point out that Recital 135 should be changed accordingly with text in Article 113.

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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**	NL (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~~ 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 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~~ standards for quality, safety and efficacy as other medicinal products. Products approved under a regulatory sandbox receive the same period of regulatory protection periods as other**

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holders, applicants for marketing authorisation, or any entities involved in the lifecycle of the medicinal product.	**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**. NL (Comments): In previous Council Working Parties, the Commission clarified when the regulatory data protection and market protection will be in force. Since it is not clear from the legal text, we propose to clarify this in the recitals, to prevent future possible confusion on this point. 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

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	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 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**

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Presidency comrpomise	Suggested adaptations to the text and Comments
	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. 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.***

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Presidency comrpomise	Suggested adaptations to the text and Comments
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 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 comrpomise	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].	
	AT (Suggested adaptations to the text): AT: **new (Article 116)** **This Chapter shall apply 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 set up a total of 10 sandboxes in accordance with this Chapter, whichever date is the earliest** AT (Comments):

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Presidency comrpomise	Suggested adaptations to the text and Comments
	AT: It is important to establish a pilot phase to test the regulatory sandboxes, since they are a complex new mechanism, which has not yet been tested in this form; thus, their impact is unpredictable. In addition to a timeline, an evaluation of the sandboxes should take place and the results have to be published.
CHAPTER III **INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'**	FR (Comments): Scrutiny reservations LT (Comments): We maintain the general scrutiny reservation regarding the transferable data exclusivity voucher. IT (Comments): ***IT comment: IT would like to reiterate its concerns over the proposed voucher system and its reserve for examination.***

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Presidency comrpomise	Suggested adaptations to the text and Comments
	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).***
Article 40	AT (Comments): AT: AT remains critical of the voucher, but is open to discuss. We suggest reducing the number of possible vouchers from 10 in 15 years to 5 in 10 years. EE (Comments): EE

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	We can support the AMR voucher only if more specific conditions would be set on its use and would be supportive of a blockbuster clause. In addition, possibly we could consider whether it would be necessary and feasible under art 40 to request more information on the planned use of the voucher already at the stage of the application (f.ex financial analysis of expected revenues and costs).
Granting the right to a transferable data exclusivity voucher	CZ (Comments): CZ does not support the proposed text related to TEV which is suggested in the context of unavailability of antimicrobials. **CZ is of the opinion that this proposal raises concerns about 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. Moreover, on the basis of EC proposal, there is no guarantee that such medicine will be in fact developed, based on TEV. **CZ is of the opinion that HU PRES proposal does not bring explanation on the**

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	TEV proposal, even though, there is a proposal on blockbuster as there are still unpredictable consequences on budgets of payers of healthcare services of Member States. Therefore, reasons and consequences of TEV should be clarified on the relevant data based on evidence. The focus should be given on transparency. We consider it important to open a discussion on other options how to motivate pharmaceutical companies to research and develop new antimicrobial medicines in order to safeguard safety of patients within the EU. DE (Comments): In our view, the voucher is still an inefficient approach to promoting research into antimicrobial medicines. In our view an incentive similar to the orphan drug incentive would be appropriate. With regards to the blockbuster clause, it must be verified whether and how this rule can be operationalised. It must be taken into account that the market coverage of medicines is only fully achieved after a few years. The period under review must therefore not be too short. We also ask the Commission to

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	assess whether the incentive effect could be compromised by the exclusion of blockbuster medicines. ES (Comments): ES thinks the proposed derisking approach deserves further examination. The Commission should carry out, together with the EMA, an analysis of the molecules that are potential candidates for the Voucher. We need to know the real scenario in order to make this decision. According to an analysis carried out by EFPIA at the end of 2019, the number of candidates, within the top 50 products of 2018, was 19 molecules, which already represents a limited number of candidates. We could support this proposal if we had an estimate of the potential candidates. IE (Comments): 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 implications

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	for national health budgets which these vouchers may have, both in terms of costs, and delaying the entry into the market of generic / biosimilars. It is also difficult to support a model where a company which has not themselves developed or contributed to the development of a novel antimicrobial would derive significant financial benefit and it would be more cost-effective to ensure that funding in this area is targeted specifically at antimicrobial developers. We await the proposals of the taskforce set up in this area to derisk the vouchers before commenting further PT (Comments): Consider EP proposals as well. SE (Comments): We think that the voucher articles 40-43 need major adjustments. We have concrete ideas. We will contribute to the task force.

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	We think the final wording of the concept of the voucher should be well reflected in a preamble. The voucher is just one tool of several needed to get Priority antimicrobial substances, "PAS" (MPs). There should be a direction towards use of the voucher in the service of public health. The processes should be efficient and there is a need for a longer perspective to be able to reach the objective, to have more priority antimicrobials on the market. The current perspective of either 15 years or 10 vouchers risk to bring uncertainty and unwillingness to invest in research, so does an evaluation after 2 vouchers. There should be a more balanced risk sharing between engaged parties. There should also be more of entrepreneurial flexibility where it is possible, and more regulatory support procedures, where possible.

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	There must be predictability and the program long enough for stakeholders to yield priority antimicrobials. Generic industry must know when they can engage time and money. Some of the adjustments of the voucher will be dependent on the baseline data protection periods.
1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	RO (Comments): RO proposes that the definition of priority antimicrobial drugs be revised, in the sense that it is specified that at least one of the conditions listed in letters (a)-(c) to be fulfilled, so that the drug is considered " priority. " anitimicrobial "and for which the provisions of art. 40-43. We believe that the definition should be correlated with the WHO list of priority pathogens pathogens list " for research and development (R&D) of new antibiotics and that the current proposed criteria, by choice, will be easy to meet and

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	will not address the issue of developing new antibiotics for the pathogens of interest.
2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection for one authorised medicinal product.	
3. An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:	

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(a) it represents a new class of antimicrobials;	
(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;	
(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.	
In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into	

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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:	
(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.	
	PL (Suggested adaptations to the text): (c) demonstrate that the application for granting marketing authorisation of the priority antimicrobial has been first submitted at Union level or has not been submitted later than 90 days after the

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	submission of the application for the first marketing authorization outside the Union. PL (Comments): Given the potentially greater burden on health systems resulting from granting the right to a transferable data exclusivity voucher we should ensure that the submission of the application for granting the marketing authorisation in the EU will not be excessively delayed comparing to other markets outside the Union.
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. 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.	AT (Comments): AT: Strongly supported. NL (Suggested adaptations to the text): ~~**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.**~~ NL

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	(Comments): We recognize the effort of the Presidency to better safeguard the cost of the voucher, but do not support the amendment. The aim of a pull incentive model – whether it is a voucher or a different type model – should be to incentivise companies and investors to invest in R&D of novel antimicrobials. If we adopt this article, we will increase the administrative burden, making for a less attractive investment landscape. This, next to the lack of specificity in this article, makes that we cannot give our support at this moment.
Article 170	
Evaluation	

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(…)	
6. The Commission shall, following the use of two vouchers pursuant to Article 41, paragraph 2, carry out an evaluation of Chapter III of this Regulation and present a report on the main findings of that evaluation to the European Parliament and the Council. The evaluation shall include an assessment of the effectiveness of the measures to address the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the actual and expected costs. The Commission shall, if appropriate, present a legislative proposal, based on the evaluation, in order to amend this Regulation.	AT (Comments): AT: Strongly supported. 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. DE (Comments):

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	It should be clarified in the text that the evaluation also includes the effectiveness of the instrument. We also welcome the reduction of the number of products as ES mentioned. NL (Comments): As stated previously, we do not support the voucher system. However, we are in favour of evaluating any pull incentive. We would like to keep a scrutiny reservation on the specific conditions and time periods mentioned in the article, as these are closely interlinked with any potential pull incentive model that may be adopted. PT (Comments): Support
Article 41	CZ (Comments):

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	Please see the comment on Article 40.
Transfer and use of the voucher	RO (Comments): We support PRES HU's idea to limit the transfer of the voucher to medicines that are considered " blockbuster " drugs" and which, by delaying the marketing of generic/ biosimilar medicines, can increase the costs for health systems. Regarding the proposed text, we express our reservation for a more in-depth analysis.
1. A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	AT (Comments): AT: Strongly supported.

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A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection **and its average annual gross sales in the Union during the Y years preceding the use of the voucher does not exceed X million euros.**	AT (Comments): AT: The blockbuster clause is welcomed, but the implementation and operationalisation of it needs more thought. Is there a Union-wide way to measure and compare the sales data given country-specific processes and foci for collecting (and sharing) such data? Which agency / competent authority would monitor the sales data? AT remains open to the discussion of these aspects. CZ (Comments): CZ finds it important to prevent that the TEV is used for blockbuster medicinal products. However, the added text does not solve the fact that the TEV is not transparent etc. CZ is also not sure how will the gross sales

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	be counted across the EU. Please see CZ general comments related to TEV above. DE (Comments): To provide the gross annual sales should be an obligation for the authorisation holder and not MS. In DE the sales numbers for ambulatory and hospital sectors are not available for quite a while, around two years so there would be no possibility to give an amount in the time needed. MT (Comments): Malta supports the efforts of the Presidency to address concerns of the MS through the inclusion of safeguards. It should also be considered to include within the mechanism the legal possibility for the EU to purchase the voucher itself at the price of the highest bidder if it considers it more feasible, such as the price paid was too low considering the projected cost to the MS health systems. NL (Suggested adaptations to the text):

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	A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection ~~and its average annual gross sales in the Union during the Y years preceding the use of the voucher does not exceed X million euros.~~ NL (Comments): We do not support the inclusion of the blockbuster clause. While we do not oppose the potential budget implications of an effective pull incentive, any financial expenditure towards AMR R&D must be transparent, predictable and in a direct manner, ensuring access to the antimicrobials, and in a way that does not inhibit competition and generics entering the market. We would like to stress that France has previously proposed to invite DG HERA to give a presentation about revenue guarantee models. Many members states had indicated their wish to explore alternative models. It is our contention that we should take adequate time to consider alternative

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	pull incentive systems before we continue to discuss a voucher system that does not seem to carry wide support, and ask the Presidency to take this into consideration. PT (Comments): Positive but needs to be workable. Consider EP proposals as well.
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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3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.	AT (Suggested adaptations to the text): AT: A voucher may be transferred **the earliest after 2 years** and only **if the criteria of Article 56a of [the revised Directive 2001/83/EC] have been fulfilled** to another marketing authorisation holder and shall not be transferred further. AT (Comments): AT: In our view, including an element of availability after transfer of the voucher to another MAH is crucial. Hence, the transfer should be linked to the provisions of Art. 56a of the revised Directive.

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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**.	
Article 42	
Validity of the voucher	CZ (Comments): Please see the comment on Article 40.

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1. A voucher shall cease to be valid in the following cases:	FR (Comments): Scrutiny reservations The French position cannot change at present because of the political context.
(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.	

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2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.	AT (Suggested adaptations to the text): AT: The Commission may revoke the voucher ~~***prior to its transfer as referred to in Article 41(3)***~~ if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled ***within a reasonable timeframe.*** AT (Comments): AT: If the Commission can only revoke the voucher prior to its transfer, the vouchers will simply be transferred as soon as possible. After the transfer, the Commission would not have any leverage to prevent the antimicrobial from being removed from the market. The addendum “within a reasonable timeframe” will give the marketing authorisation holder of the antimicrobial some time to fulfil its obligations. The buyer can avoid being stuck with an unusable voucher by adding suitable clauses in the purchase contract.

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3. Without prejudice to patent rights, or supplementary protection certificates[4], 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].	AT (Suggested adaptations to the text): AT: ***~~Without prejudice to patent rights, or supplementary protection certificates,~~*** **I**f 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] ***as well as the expiry of patent rights or supplementary protection certificates***, those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference.

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

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Article 43	
Duration of application of Chapter III	
This Chapter shall apply 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.	

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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): CZ would like to apply a scrutiny reservation on the definitions in Article 4.

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(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**;	FR (Comments): Scrutiny reservation SE (Comments): Support.