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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Pharmaceutical package
Subject:	Pharma package - Replies to the Presidency questionnaire on incentives

Delegations will find in annex a compilation of replies from the Member States to the Presidency questionnaire on incentives.

PRESIDENCY QUESTIONNAIRE

REPLIES FROM THE DELEGATIONS

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AUSTRIA

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	Questions	AT - Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	**YES** - Additionally reduction of protection periods is supported, but framework must be clear and predictable to avoid legal uncertainty and strengthen transparency
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	**YES** - After 2 (3) years, it is known whether the incentive is fulfilled, therefore predictability of the measure is ensured. Additionally some clarification would be helpful: • 81 (2) a) ii) How is "not-for-profit entity" defined and how can this be verified by competent authorities? • Definition for „not-for-profit entity" should be included in Art 4. • 81 (2) a) iii) How is "an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group" defined and how can this be verified by competent authorities? 82 (1) Clarification on what constitutes "sufficient quantity and presentations" AT suggests a public database that provides transparency on the proceedings of applications for reimbursement on national levels in order to know how far advanced these processes are (more transparency to the system).
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES**, an alternative option could be an obligation for MAH to file for reimbursement within 2 (3) years after market authorization, rewarded with 24 months of RDP protection. Additionally, clear definitions and stringent monitoring need be ensured.

	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	**YES** - Clear definitions of UMN necessary, harmonized throughout the regulation and directive. Additionally, an operational definition for UMN is required with respect to (a) the definition of what constitutes a "remaining high morbidity or mortality" in the case of existing treatment alternatives (Art 83 (1) a) and (b) potential misuse of the orphan medicinal product designation for inappropriate disease stratification, which would negatively impact on the goal of affordable access to medicines for all.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES** - If the definition is stringent and targeted enough, a longer reward might be feasible.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	**YES** - Defining the comparator in accordance with authorities might be necessary prior to the start of the clinical development process trials
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES** - Acknowledging the efforts in conducting a comparative trial is important and the length of RDP could be increased to one year
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	**YES** - It should be defined from which date on exactly this period is counted (i. e. "The period of validity shall be 12 months from the date of notification of the Decision or the national equivalent to such a notification"- "dies a quo"). This is a general remark and should be taken into consideration whenever it is about time limits: a « dies a quo » should be determined or precisely determinable.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES** - Given that this incentive applies to products that are already on the market, we find that the proposed 12 months are not proportionate compared to the 6 months reward for true unmet medical needs or comparative trials.

		It might thus be considered to harmonize the rewards for these incentives, given that the general reduction of regulatory protection proposed (6+2) is upheld.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	**YES**, but more clarification on what constitutes a „significant clinical benefit“should be provided.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	**YES**

PUBLIC

BULGARIA

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	If the shortening of the RDP is the only possible tool to stimulate the MAH to ensure equal and timely access of European patients to innovative therapy - in principle yes, but definitely **not under the specified conditions.**
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	No. Simultaneous market entry could lead to a unified pricing across member states, potentially hindering patient access to needed medications due to economic disparities We should explore alternative models to ensure fair distribution and affordability. These conditions are non-enforceable for a number of reasons that are national and multi-factorial, e.g. the health care budget of the various MS, health priorities and infrastructure in the MS, national legislation in the area of pricing and reimbursement, national administrative procedures in the MS. These reasons are largely outside the scope of regulation and we are skeptical that the proposed regulatory framework will have the desired effect of achieving the announced objectives. We also consider as a disadvantage of this proposal the short deadlines, immediately after the issuance of the MA of the new product, which put the MS in a situation of hasty decisions, without the possibility of making a more substantiated assessment of needs and financial possibilities, of opportunities to discuss internal approaches for cooperation in the field of public procurement. We believe that a serious debate on the subject is needed, discussion on alternative approaches - e.g. **providing the initiative to the MS (on demand)**. The satisfied announced wish should be the guarantee for RDP recovery and vice versa.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes but we can be also flexible towards one year.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	

3.a	Do you agree with the conditions for this incentive?	In principle yes, but the concept of UMN should be analyzed in more detail and possibly re-defined.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	In principle yes, but we would rather favor one year. These studies are very important for pricing and reimbursement authorities, and are de facto very expensive and, relative to the incentive offered, become unattractive, especially for the most innovative companies, because the return on investment is in large sales, which is not is the case with ATMPs e.g.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Yes
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	Yes. For a new indication of an innovative product, a one-year incentive is provided, but these are still "old" products, beyond the interest of the pharma companies, and it is good to stimulate the academic circles (champions). However, **Article 84 needs editing and clarification**.

CROATIA

	Questions	HR Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	NO, it is too long. Regulatory protection used to be 8+2+1 years while now it is 10+2 years. This will delay entry of generic medicinal products to the market for additional 1 year plus will prolong ability of generics to apply for MA for 10 years instead of 8. Every year of prolongation of entry of generics on market is burden for national health systems.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	NO, it would be easy for MAH to offer the med. product on extremely high price and then get the non-objection decision from MS without actual supply of medicines. Also, once granted, the prolongation cannot be withdrawn if MAH fails to comply with his obligations.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	It should be deleted.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	We do not agree with cumulating of incentives.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	n/a
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	We do not agree with cumulating of incentives.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	n/a
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	We do not agree with cumulating of incentives.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	As it is now, it should not be in data exclusivity but market exclusivity period as it is now.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	NO, 4 years for repurposed medicines with new indication is too long.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	NO, it is overestimated and over compensated.

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CYPRUS

PUBLIC

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	**YES**
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	**YES.**
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	It is considered that 24 months is proportional.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	YES.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	In principles we agree.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	It is proposed that the RDP is actually prolonged (i.e. 1 year instead of six months) as data from comparative trials may have a beneficial impact downstream such as HTA and reimbursement decisions. Therefore, there may be a need for a better incentive for the industry to undertake relevant comparative studies.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	YES.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	YES.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	YES.

CZECHIA

PUBLIC

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	**YES**
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	**YES,** however clarification is needed as how to provide proof of compliance with 82(1), meaning to safeguard availability of medicines in all Member States.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES,** but conditions should be equal for all MAH, including SME & academia sector. SME etc. may benefit from other tools like waivers, grants etc.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	**YES**
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES**
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	**YES**
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES**
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	**YES**
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	**YES**
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	**YES**
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	**YES**

ESTONIA

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period? D art 81	YES. Estonia supports the modulated approach to regulatory data protection with standrd period of 6 years and the additional conditional periods.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	YES The conditions and criteria of „continuous supply" could be further specified in the Directive to strengthen the application of this provision, ensure better coherence among Member States and legal certainty. It is important that the MAH has taken all the necessary steps to place the product on the market of the MS (readiness for physical delivery). Submission of the application for the reimbursement could be one of the criteria but not the only one. We support the principle that the MS confirms that the conditions have been met, the procedure can be organised in a way that it is not too burdensome.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	YES
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	YES
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	We propose to prolong the reward for comparative studies to **12 months.** Comparative clinical trials are an important and valuable source of information for the relative cost-effectiveness assessments. In situations where it is scientifically justified to carry out a clinical study with a relevant comparator, this should be facilitated.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	

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5.a	Do you agree with the conditions for this incentive?	YES
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	YES
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	YES

PUBLIC

FINLAND

	Questions	FI Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	YES
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	The conditions for this incentive need further discussion and examination. To ensure sufficient predictability it must be clear what bringing to market ("released and continuously supplied into the supply chain") means. It should be understood the same way in every MS. It should also be clear to all actors involved what is meant by "sufficient quantities". The demand varies needs and care practices vary in the Member States. Can the estimation of "sufficient quantity" be tied to the company's own estimate? Predictability is relatively poor when the definition of "sufficient quantity" varies between MSs and depends also on reimbursement status and prices.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	YES. However, it should be ensured that definitions are as clear as possible for all actors (E.g. how is a meaningful reduction defined).
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	YES
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	

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5.a	Do you agree with the conditions for this incentive?	YES
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	YES
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	YES
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	YES However, the 4 years of RDP do not necessarily protect from off label –use with a similar generic.

PUBLIC

FRANCE

The incentives are based on the granting of additional periods of protection to the basic period if certain conditions are met and are associated with a reduction in regulatory data protection from the current 8 years to 6 years.
At this stage, the French authorities have reservations about this proposal and support maintaining the current conditions (8 years) for setting the duration of data protection.
A balance needs to be found between the attractiveness of the European Union, encouraging companies to invest in innovation, and providing access to patients and ensure sustainability of the healthcare system.

Les incitations sont basées sur l'octroi de périodes de protection supplémentaires à la période de base si certaines conditions sont remplies et sont associées à une réduction de la protection réglementaire des données de 8 ans actuellement à 6 ans.
A ce stade, les autorités françaises sont réservées sur cette proposition et soutiennent le maintien des conditions actuelles de fixation de la durée de protection des données (8 ans).
Il convient de trouver un équilibre entre l'attractivité de l'Union européenne, l'encouragement des entreprises à investir dans l'innovation, l'accès aux patients et la soutenabilité du système de soins de santé.

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	The French authorities want to maintain the current situation.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	The French authorities want to maintain the current situation.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	The French authorities want to maintain the current situation.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	The French authorities want to maintain the current situation.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The French authorities want to maintain the current situation.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	The French authorities want to maintain the current situation.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The French authorities want to maintain the current situation.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	

5.a	Do you agree with the conditions for this incentive?	The French authorities want to maintain the current situation.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	The French authorities want to maintain the current situation.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	The French authorities' position on this issue is not yet finalised.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	The French authorities' position on this issue is not yet finalised.

PUBLIC

GERMANY

	Questions	MS Response - DE
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	No. DE is not in favour of shortening the guaranteed achievable data protection period to six years. Thus, the total duration of the data protection period should not deviate from the status quo. The current maximum protection period is a well-established driver of innovation in, and a guarantor for the attractiveness of the EU. This should not be jeopardized, as it would have negative consequences for patients.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	No. The requirement to place medicinal products on the market in all MS in order to obtain the full length of data protection creates a planning gap for the industry, as it is not (solely) up to the MAH whether the market launch will succeed on time. This is because it depends, among other things, on the duration of downstream processes for pricing and reimbursement and the willingness to pay in the various MS. It is also unclear which parameters should be used to measure whether a medicinal product is launched on the market in sufficient quantities in all MS. That determination is the responsibility of the individual MS and could, for example, be rejected due to a lack of listing and reimbursement. However, DE believes that introducing an obligation to apply for pricing and reimbursement can provide a solid basis to address the problem of unequal access to medicinal products.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	See above. The introduction of a mandatory application for pricing and reimbursement could provide a solid basis to address the problem of unequal access to medicinal products.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	No. The total duration of the protection period should not exceed the status quo. (See also answer to question 1).
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	See 3.a
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	

4.a.	Do you agree with the conditions for this incentive?	No. The total duration of the protection period should not exceed the status quo. See also answer to question 1.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	See 4.a
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	It would be proportionate if the guaranteed achievable data protection period remains at eight years.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	Yes.

PUBLIC

HUNGARY

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	No, the maximum protection period should not be longer than today (11 years) as opposed to the COM proposal that allows 12 years (excl. transferable voucher).
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	NO, the proposed system is not predicable neither for payers nor for industry.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	NO. The market launch should not be precondition of RPD length.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	The definition seems to be very restrictive and it is already widely debated. We can consider its introduction but not as a condition of regulatory data protection.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	NO unmet medical need should not be precondition of RPD length
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	YES on the other hand we need to specify the requirements of comparative studies in a way that it remains feasible but useful at the same time.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Comparative studes should be better rewarded. We propose link it with 2 year RDP.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	YES it is basically the current rule (Dir 2001/83 Art 10 (1) third subpara
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	12 month is OK
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	OK
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	OK

PUBLIC

ITALY

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	The legislative proposal extends, through a modular incentive system, the data protection period to a maximum of 12 years from the current 11 years. If all principles of modularity were respected, this would lead to delayed market entry of generics and biosimilars. The reduction of the base period (from the current 8 years to 6) and the modularity of the additional periods should be further discussed instead of focussing on the maximum duration. This mechanism would reduce the predictability of the system for the industry as well as for Member States and competent authorities. In addition, the reduction of the base period would put industrial investments in Europe and in particular in Italy at great risk. Italy is among the major producing countries in Europe. The system provided for in the current legislation strikes the right balance between protecting innovation and ensuring the sustainability of the system through the market entry of generics and biosimilars.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	Italy does not agree with the conditions for the incentive related to market launch. The criteria laid down are unclear, difficult to implement, and would lead to increased workload for the national competent authorities as well as to a high risk of litigation at national level.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	The duration of the reward is not proportionate. The proposed provision should be deleted and other mechanisms should be sought to incentivise the market launch in all MSs.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	The Commission's intention to reward investment in R&D in the area of unmet medical needs is welcomed. However, the discussion on the provisions should be first focused on the definition of unmet medical needs, which should find a common language among States and not be left to the exclusive remit of the EMA. Moreover, this incentive is linked to the further provisions on orphan medicinal products for which a similar modular system of market exclusivity is envisaged. In addition, medicinal products addressing unmet medical needs could benefit of the accelerated regulatory pathway provided by the EMA (such as PRIME, CMA etc.). Research in these areas should be stimulated through other incentives.

		Moreover, the potential meaning of this provision appears quite vague since the EC has the power to adopt implementing measures.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	With reference to duration, the final opinion needs to take into account the discussion on the definition of UMNs and on other incentives.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	The Commission's intention to reward comparative clinical trials is understandable and in principle very welcome. However, it should be noted that it is not always possible to develop new medicines through trials with adequate comparator, especially in the field of rare diseases. Furthermore, the aim of pivotal trials is to demonstrate that the B/R balance is positive. Therefore, such data protection incentive may discourage research in the field of rare diseases. Moreover, the granting of the benefit if the medicine has been developed by comparison with a comparator identified through scientific advice by the EMA alone, is not in line with the current European scenario that will see the HTA Regulation applied from 2025. In fact, the HTA Regulation, as well as the Proposal for a Regulation COM(2023) 193, provides that Joint Scientific Consultations may be conducted between the EMA and the HTA Coordination Group and the respective JSC subgroup. It is therefore considered that these EU bodies should also be involved in the definition of 'adequate comparator'.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	With reference to duration, the final opinion needs to take into account the discussion on the other incentives. Other mechanisms must be envisaged to incentivise the conduction of comparative clinical trials.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	This provision is already included in the current legislation and therefore Italy is in favour of this incentive.

5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	The duration is proportionate.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	In general terms, Italy agrees with the provision but further clarification should be given in relation to the "demonstration that the repurposed medicinal products is of significant clinical benefit".
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	With reference to duration, the final opinion needs to take into account the discussion on the other incentives. Italy reserves the right to further evaluate the related economic impact on the NHS.

LITHUANIA

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	Yes
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	Yes, in principal. However, *the proposal does not provide legal clarity how the implementation of proposed provision and predictability for all actors will be ensured i.e. how the applicants/MAHs and the MSs will obtain data on already issued initial MAs and approved incentives?* *Why is it foreseen that issues of concern to MSs can be discussed in the Pharmaceutical Committee (we believe that this is unnecessary provision)?*
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	Yes *Whether the criteria: „life threatening", „severely debilitating disease", „high morbidity", „mortality meaningful reduction in disease morbidity or mortality" will be clarified in the EMA guidelines?*
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Yes
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes

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5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	Yes

Note: LT is in favour of introduction of variable incentives for medicinal products and can be flexible in respect of duration of data protection periods.

PUBLIC

ROMANIA

	Questions	RO Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	Yes
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	Yes
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes, we consider it is proportionate.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	Yes
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes, we consider it is proportionate.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Yes
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes, we consider it is proportionate.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes, we consider it is proportionate.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	In order to stimulate the research for repurposed medicinal products, we would be in favour of a longer period, for example 5 years, and the posibility to grant a similar regulatory data protection period for the second new therapeutic indication in case of repurposed medicinal products.

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SLOVAKIA

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	Partially. Slovakia fully understands and highlights the key role of Regulatory Data Protection (RDP) in supporting innovation and attracting investments in research and development, which are essential for the development of new and innovative pharmacological interventions in the European Union market. At the same time, we recognize the importance of finding the right balance and synergy between stimulating development, research, and simultaneously making therapy timely and affordably available to EU patients. Extended periods of RDP, despite all indicated and captured positive influencing factors, could also potentially have so-called "side effects" on the current system, such as higher medicines prices, paradoxically reduced number of the clinical trials, or limited access to affordable treatment, which can impact public health and the economy. We believe it is essential to ensure an approach that considers both sides of the coin – supporting innovation while ensuring the availability and affordability of treatment for all. We support the idea of a thorough impact analysis before introducing new RDP rules to ensure we find the best possible way to balance the need to support pharmaceutical development with the necessity of keeping healthcare accessible and affordable. We suggest increasing transparency and predictability in the RDP field, for example, by publishing information about protection extensions in an easily accessible database, and adjusting market exclusivity to reduce legal uncertainty without compromising the motivation for progress in the field of pharmacy. We believe that our goal should be to create a system that is fair and sustainable for all.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	No. Differing principles of the regulatory framework in the area of reimbursement and pricing of medicines across the 27 member states can be a potential barrier to obtaining this incentive. Therefore, the option of granting an additional 2 years of regulatory protection should not be contingent upon an unequal and unpredictable regulatory framework. It is important to ensure fundamental elements of predictability for all stakeholders involved in the process of development, approval, and marketing of new medicines.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	We believe it is essential to find a balance between the need to stimulate innovation and investment in the research and development of new medicines and the need to ensure that medicines are affordable for healthcare payers and patients alike. It is important that such a decision is informed and balanced, reflecting the needs of patients as well as the long-term sustainable goals of the healthcare system and the innovation environment. As a proposal for potential discussion, we note the possibility of a change from the option of extending data exclusivity to modulating the

		duration of market exclusivity by 24 months, which would provide more explicit predictability in the Marketing Authorisation Application (MAA) process for both applicants for the marketing authorisation of original as well as generic and biosimilar medicines. At the same time, for any form and length of the proposed measure, it is necessary that these details be publicly available within a common register, e.g., on the website of the European Medicines Agency (EMA)
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	Yes. The proposed provisions of Art. 81 (2), 1st subparagraph, point (b), and Art. 83 of the Directive, together with Art. 67 of the revised Regulation, adequately capture the necessary regulatory incentives while maintaining a general formulation for medicines addressing unmet needs. We view positively the possibility of adopting European Medicines Agency (EMA) scientific guidelines in relation to the application of Art. 83 of the Directive.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Yes. However, we emphasize that information on the granting of such an incentive, along with other forms of incentives, should be publicly available to ensure transparency and oversight of compliance with the proposed regulatory framework.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed reward is proportionate.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	

6.a	Do you agree with the conditions for this incentive?	Yes.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	We recognize the importance of supporting innovations and the repurposing of existing medicines that can provide significant benefits to patients. The draft of Article 84 reflects a commitment to strengthening data protection and supporting the development of new therapeutic options for medicines that are no longer protected by patent or other forms of protection. However, Slovakia is aware of the challenges associated with economic off-label use and with pricing and reimbursement barriers at the national level, which may limit innovation. In this context, Slovakia supports clear and expanded formulations of the proposed article to encompass all aspects of repurposing that bring significant benefits to patients. By extending the scope of protection to include changes in administration methods, dosing, and pharmaceutical form, it ensures that the regulatory framework effectively supports innovation and contributes to better patient care in Slovakia.

SLOVENIA

	Questions	SI Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	No, compared to the present maximum duration (11 y) it should be shorter, not longer. The present maximum duration (11 y) should not be exceeded.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	We strongly support the concept of awarding an incentive for market launch in all MS. However, a system should be in place to ensure that the product actually stays on the market. Furthermore, positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC **should not be considered as equivalent** to a confirmation referred to in the third subparagraph, point (a). These decisions are not acceptable as proof that the conditions in accordance with Article 82 (1) are met. Measures for monitoring access must be in place that should be matched with affordability. Access could be measured in diiferent levels: mg per capita in the treated indication, mapped Patient flows, duration of treatments. There may be less predictability for generic manufacturers regarding submission of MA application. However, we believe that with this provision the goal of the new legislation to increase availability and access to all EU patients will be achieved, especially in small markets. Regarding predictability, it is important that information on data and market protection are transparent for all actors involved.

2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	The reward could be shorter but should still stimulate access in all MS, e.g. 12 months. Additionally, access in all MS should be awarded with market protection instead of data protection.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	We strongly support the efficient steering of research into areas of UMN. The currently proposed definition is imprecise and could lead to uncertainties (e.g. the notion of "meaningful" and "remaining high morbidity"). Considering the fact that specific scientific guidelines are planned it is therefore premature to give a definite opinion on the conditions.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed reward is not proportionate in comparison with other incentives. It could be longer, e.g. 12 months, on condition that the present maximum duration of the protection period is not prolonged, meaning that other incentives would have to be shortened as proposed in points 5.b and 2.b.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Awarding comparative clinical trials submitted within the MA applications is supported.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	We definitely do not support prolongation to more than 6 months.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	The incentive for additional therapeutic indication (12 months) is not proportionate to other incentives, e.g. for UMN (6 months). Therefore, the reward for a new therapeutic indication should be shorter (see 3.b). Furthermore, market protection should be granted following the addition of a therapeutic indication instead of data protection.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	We agree with the proposal that encourages research and approval of new indications for older active substances (repurposing), but some medicines already have an established off-label use in clinical practice and the granting of a 4-year data protection period would be an excessive reward, as there may be an

		increase in current prices. However, we support an incentive mechanism for a completely new indication (demonstrating that it is of significant clinical benefit) with a shorter data protection period.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	4 years of data protection for repurposed medicinal products seems unproportionally high compared to other incentives. Furthermore, the provision should explicitly state that the award can only be granted to the MAH when adequate non-clinical or clinical studies were carried out by this MAH. Therefore, in cases where research/collecting data was performed by "not-for-profit" stakeholders, data protection should not be rewarded to the MAH.

SPAIN

	Questions	ES Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	Yes. We agree with the 12 years proposed by Commission. We agree with the baseline proposed by the Commission (6 years) and the modulation of incentives. However, we highlight the following three points: 1. The proposed reward (24 additional months of RDP) must be shorter (12 months). 2. Comparative clinical trials: extend from 6 months to 12 months. 3. Unmet Medical Need incentive extended from 6 months to 12 months.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	In principle, we agree with the aim of the article. However, we are skeptical by the way of being implemented.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	No, we find the proposed reward should be shorter (12 months).
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	In principle, we agree. However, the detailed guidelines on concepts such as ´remaining high morbidity or mortality´; `meaningful reduction in disease morbidity or mortality´, `relevant patient population´ should ensure that the aim of the legislation is achived. It is necessary to avoid vague definitions on the guidelines.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed reward (6 additional months of RDP) should be longer (12 months).
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	Yes. This is a way to facilitate the access to medicines by reducing the uncertainty of added clinical value. To support subsequent health technology assessments and decisions on pricing and reimbursement by Member States, consequently, facility the decision making process.

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4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed reward (6 additional months of RDP) should be longer (12 months).
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes. Repurposing is a concept of high value to meet patients needs. It is necessary to avoid vague definitions on the guidelines, such as adequate non `clinical or non clinical´ and `significant clinical benefit´.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	In principle, yes.

PUBLIC

SWEDEN

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	SE believe that the overall objective is to design data protection incentives that is effective, predictable and possible for the companies to fulfil [without being dependent on counter-performances from e.g. national authorities]. Furthermore, the data protection period should be competitive compared to the protection periods in other regions., and therefore should not be shortened as compared to today (i.e. remain 11 years). The proposed system of incentives is complex. How the different incentives should be designed, and relate to each other, remains to be discussed in order to reach a balanced system as a whole.
	Section 2: Different proposed regulatory incentives	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	The proposed conditions are not predictable. The exact meaning of market launch is to unclear and it's debatable whether this incentive will be effective in relation to other factors such as ability to pay. Should such an incentive still be introduced, it must be defined more clearly and each Member state must be able to decide on the need for the product and what constitutes a sufficient quantity of supply.
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed system of incentives is complex, and how the different incentives should be designed and relate to each other remains to be discussed.
	"Unmet Medical Need" incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)	
3.a	Do you agree with the conditions for this incentive?	The proposed definition of UMN, and the corresponding notion of "meaningful reduction in (…) morbidity or mortality" might make consistent regulatory decision-making difficult.
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed system of incentives is complex, and how the different incentives should be designed and relate to each other remains to be discussed.
	"Comparative clinical trials" incentive (Art. 81 (2), 1st subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	No, this incentive will be difficult to apply and evaluate in a transparent,

		equivalent and consistent way, in relation to decisions on what is an awardable comparative trial and what is not. It is therefore questionable if the incentive will have the intended effect.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	The proposed system of incentives is complex, and how the different incentives should be designed and relate to each other remains to be discussed.
	"Additional therapeutic indication" incentive (Art. 81 (2), 1st subparagraph, point (d) Dir.	
5.a	Do you agree with the conditions for this incentive?	Yes
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	Yes, SE believe it is proportionate.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	Yes, however, the obligations of the market authorisation holder with regards to product liability and pharmacovigilance need to be further analysed.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	Yes. It is important that the possibility of off-label use is not restricted, and that the system does not lead to over-pricing of older medicines with currently low costs.

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