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## WORKING DOCUMENT

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

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Subject: Pharma package - Replies to the Presidency questionnaire on incentives

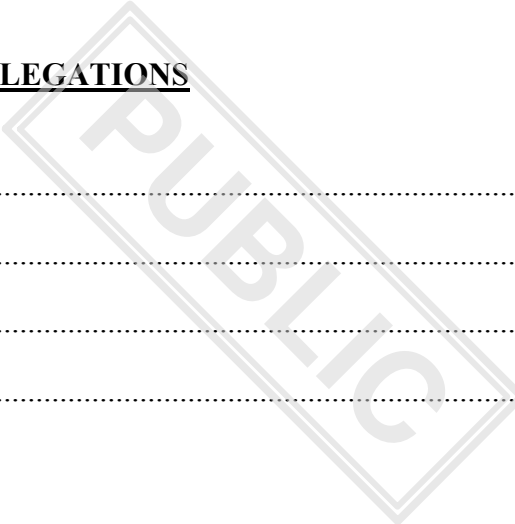
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Delegations will find in annex a compilation of replies from the Member States to the Presidency questionnaire on incentives.

**PRESIDENCY QUESTIONNAIRE**

**REPLIES FROM THE DELEGATIONS**

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## DENMARK

	Questions	DK response
Section 1: Nature of the incentives		
1	Do you agree with the proposed maximum duration of the protection period?	<p>We do not agree with the reduction of the data protection period from 8 to 6 years. The overall regulatory protection periods should not be reduced or weakened compared to today.</p> <p>We find it important to implement initiatives that promote innovation of important new medicines for unmet medical needs and better access to medicines across the EU. However, any regulatory incentives should be predictable and effective in order to ensure investments in development and marketing of new medicines to patients. We fear that the reduction of the data protection period could create uncertainty for companies, which would result in a reduction of development and availability of new important medicines.</p>
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)?	<p>No. We are concerned that the proposed condition may not solve the problem of lack of and delayed access to medicines in some Member States, and that it will create uncertainty for companies thereby reducing the incentive to develop of new medicines, which will have negative impacts for patients.</p> <p>It may not solve the problems of access, since the launch of a new medicine is also dependent on national procedures such as pricing and reimbursement decisions which companies cannot control. Further, the incentive may only have a short-term effect on access, since a company may discontinue the supply once the extra two years of RDP have been granted.</p> <p>It will introduce uncertainty for companies for several reasons:</p> <ol style="list-style-type: none"> <li>1) It is unclear when the condition to release and continuously supply a product in a sufficient quantity is fulfilled. Increase in legal disputes may be foreseen.</li> <li>2) It will be very difficult (if not unrealistic) for companies to release and supply a product in all Member States within 2 years (or 3 years for SMEs etc.).</li> </ol> <p>It may not be possible for companies to launch in all Member States within the time limit, as some Member States require the product to be launched beforehand in other Member States, e.g. due to external reference pricing.</p>

		<p>Further, it may be difficult for companies, especially SMEs, to upscale their production in order to supply in the EU-quantities needed. It may also be difficult to anticipate the quantity needed, and the opt-in provision in the decentralised procedure could potentially lead to further uncertainty.</p> <p>Instead, we propose an obligation or incentive to file for pricing and reimbursement in all Member States, where the medicine is authorized, as this could improve availability across the EU and at the same time be more predictable for both companies and Member States.</p>
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	<p>Since DK does not favor the market launch provision for the reasons stated above, the question on proportionality in terms of the RDP becomes redundant.</p> <p>As mentioned above, we propose an obligation or incentive to file for pricing and reimbursement in all Member States, where the medicine is authorized. An incentive could be 6 months of RDP.</p>
“Unmet Medical Need” incentive ( Art. 81 (2), 1 <sup>st</sup> subparagraph, point (b) and 83 Dir.)		
3.a	Do you agree with the conditions for this incentive?	From our perspective, we believe that the definition of “unmet medical need” should be broader to promote development of new medicines that address “unmet societal needs”, e.g. medicines for treatment of serious chronic diseases and diseases with high burden on society. Preferably, an “unmet societal needs” category should be introduced (alongside “unmet medical needs”).
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	It depends on how the regulatory protection system as a whole is designed. The reward should be stronger to have sufficient effect, e.g. 12-24 additional months of RDP.
“Comparative clinical trials” incentive (Art. 81 (2), 1 <sup>st</sup> subparagraph, point (c) Dir.)		
4.a.	Do you agree with the conditions for this incentive?	Yes. It is relevant to promote comparative clinical trials to support the development of evidence for HTA assessment.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	It depends on how the regulatory protection system as a whole is designed. For the benefit of HTA comparative clinical trials are important and thus the RDP extension could be longer.
“Additional therapeutic indication” incentive (Art. 81 (2), 1 <sup>st</sup> 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?	In principle yes, but depends on how the regulatory protection system as a whole is designed.
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.

## IRELAND

A stakeholder consultation re Incentives is underway in Ireland. As such, our responses are preliminary, and incomplete, and those provided may be subject to amendment once all stakeholder comments have been received.

The final IE working position on incentives will be agreed in early March.

	Questions	MS Response
	<b>Section 1: Nature of the incentives</b>	
1	Do you agree with the proposed maximum duration of the protection period?	<p>IE believes that the proposed reduction of the baseline RDP and its further modulation needs further analysis and discussion, and we welcome the opportunity to engage in these discussions at upcoming WPMMD meetings. IE remains focused on the need to support the competitiveness of the EU pharma ecosystem, while achieving and maintaining the critical balance between access and innovation.</p> <p>Should any of the modulated data protection conditions be amended, including those related to market access, the overall maximum duration should be reconsidered accordingly to ensure that equality of access and promotion of innovation remain as key objectives while also ensuring abridged applications are not unduly delayed.</p>
	<b>Section 2: Different proposed regulatory incentives</b>	
	<b>Market launch” incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)</b>	
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	<p>Ireland supports the intention to enhance market access, however there are remaining concerns that the current proposal may inadvertently lead to lack of predictability for manufacturers and will ultimately impact on patient access. Delays and uncertainty are detrimental to both innovator and generic manufacturers, as well as health systems. The</p>

		<p>practical implications of the current proposal should be considered further with proposed amendments addressing concerns re predictability while still addressing current inequalities in market access across the EU, particularly in relation to centralised medicines which are approved for use on an EU wide basis.</p>
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	This reward should be amended in line with response to 2.a
“Unmet Medical Need” incentive ( Art. 81 (2), 1 <sup>st</sup> subparagraph, point (b) and 83 Dir.)		
3.a	Do you agree with the conditions for this incentive?	<p>IE is supportive of the intention to incentivise the development of medicines that address unmet medical need (UMN).</p> <p>In relation to the proposed definition, where existing authorised treatments exist, the assessment of whether a new medicine addresses UMN should not exclusively focus on morbidity and mortality and the impact on health-related quality of life should also be taken into account.</p> <p>Further consideration should be given re incentives that are available for products with demonstrated ability to address UMN as opposed to products which have the potential ability to address UMN. We believe that it would be preferable if demonstrated ability to address UMN was based on criteria defined via parallel joint scientific consultations involving both EMA and HTA, with developers being incentivised to generate data addressing regulatory and HTA aspects (similar to the approach taken for comparative studies in Art 81 (d) where scientific advice provided by the EMA is</p>

		obligatory).
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	While IE is not suggesting extending the maximum potential RDP period of 12 years, the proposed 6-month period may not be sufficient to incentivise the development of medicines addressing unmet medical needs and should be considered further.
	“Comparative clinical trials” incentive (Art. 81 (2), 1 <sup>st</sup> subparagraph, point (c) Dir.)	
4.a.	Do you agree with the conditions for this incentive?	IE supports this proposal and the link between this incentive and the associated requirement for the use of a relevant and evidence-based comparator in accordance with scientific advice provided by the EMA. Depending on the capacity within the HTA network, we would suggest that a link could also be made to the parallel scientific advice with the joint scientific consultation carried out by the Member State Coordination Group on HTA (as provided for in Art 59 of the draft Regulation). This would help to ensure that the subsequent comparative clinical trials are suitable for both regulatory and HTA purposes thereby reducing the potential for delays in access in the event of positive outcomes to such studies.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	IE believes that additional RDP granted for comparative trials could be longer than the six months currently proposed to further incentivise the measuring of the efficacy of medicines.
	“Additional therapeutic indication” incentive (Art. 81 (2), 1 <sup>st</sup> subparagraph, point (d) Dir.)	
5.a	Do you agree with the conditions for this incentive?	IE supports the inclusion of an incentive for additional therapeutic indications and notes that the provision is similar to a provision in

		existing legislation.
5.b	Is the proposed reward (12 additional months of RDP) proportionate? If not, should it be longer or shorter?	IE has no objection to the proposed reward period.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	IE supports the inclusion of an incentive for repurposing medicinal products.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	While we have no objection in principle to the proposed 4-year data protection period, this seems significant compared to the data protection periods associated with other topics (e.g. in Art 81). Consideration should be given as whether a reward period of this length could encourage off-label (unauthorised) use of other medicines with the same active substance(s).

## THE NETHERLANDS

	Questions	MS Response
	Section 1: Nature of the incentives	
1	Do you agree with the proposed maximum duration of the protection period?	<p>NO</p> <p>We support a more graduated system of incentives in which the baseline regulatory protection is reduced and extra protection can be granted for specific achievements.</p> <p>However, we propose a cap of 11 years for the maximum duration of the protection period in line with the current maximum duration of protection. This to prevent that the legislative revision will lead to higher medicine expenditure.</p>
	Section 2: Different proposed regulatory incentives	
	<p><b>General comment on the modulation of incentives:</b></p> <p>Although we generally support a more modulated approach, as stated above, we would like to underline that such an approach may come with a potential risk of legal disputes following the validation of new generic applications for a marketing authorisation. Generic applications may only be submitted to the authorities after the data protection of the reference medicinal product has elapsed. If a generic application is submitted prematurely, the relevant competent authority must reject the application. If it fails to do so, it will face a legal dispute from the marketing authorisation holder of the reference product. For both the competent authorities and innovative and generic industry alike, the system should therefore be transparent and predictable so that no doubt exists on the duration of data protection awarded to each individual innovative product. Furthermore, the conditions for obtaining additional regulatory protection must be feasible for both Member States and industry, and have a positive effect on industry's willingness to invest in research and development and thus availability to patients. The (non-)acceptance of a more graduated system of incentives thus depends on the type of measures put in place to ensure transparency and oversight as well as practicability and feasibility. In our view, a discussion on how to revise the system of incentives can therefore not be held in isolation, but should take place in conjunction with a discussion on the set-up of a system for oversight and on measures needed to operationalise the conditions for all stakeholders involved.</p>	
	Market launch" incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)	
2.a	Do you agree with the conditions for this	NO

	incentive (predictability for different actors involved)?	<p>The Netherlands welcomes the Commission’s efforts to promote equal access to medicines in all Member States. Linking this to the duration of regulatory protection could be an option to improve EU-wide access and could benefit the functioning of the single market for medicines.</p> <p>However, we do have several thoughts and concerns that we would like to discuss further.</p> <p>First, we believe that the proposed reduction of the baseline protection period contributes more to the availability, accessibility and affordability of medicines than the proposed incentive as this reduction allows earlier generic market entry.</p> <p>In addition, we have concerns about the feasibility, certainty and practicability for Member States (including consistency with national regulatory healthcare and reimbursement systems) and industry regarding this “market launch” incentive. Many conditions are currently unclear, e.g. in regards the requirement for continuous monitoring of supply. This proposal needs to be developed in more detail before these concerns can be addressed.</p> <p>We further note that due to the concept of global marketing authorisation (GMA), this incentive will not provide a push for companies towards EU-wide market entry of any variations to their original product, for instance products with an additional therapeutic indication or different route of administration, because such developments are not awarded by an additional protection period. To avoid any doubt, we fully support the concept of GMA because it avoids abuse of the system of incentives. The point we wish to make though is that due to this concept, as well as due to our already mentioned concerns about practicality and feasibility, the proposed incentive in itself may not be as successful as hoped in achieving its objective. In our view, other measures that fall outside of the scope of this legislation may (also) be needed to promote EU-wide access, such as cooperation under the HTA Regulation.</p>
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	<p>The reward should be proportional to the effort required of companies. Until the discussion concerning point 2a has crystallised more, we feel it is premature to make a statement on the proportionality of the proposed additional duration of data protection that can be earned for EU-wide market entry.</p>
“Unmet Medical Need” incentive ( Art. 81 (2), 1 <sup>st</sup> subparagraph, point (b) and 83 Dir.)		
3.a	Do you agree with the conditions for this	NO

	incentive?	<p>We fully support the Commission’s effort to strive for a more patient-centred, demand-driven system. Awarding additional regulatory data protection to products that meet an unmet medical need can be a way to achieve this.</p> <p>However, in our view, the discussion on the proportionality of the proposed conditions and duration of the reward cannot be held in isolation. After all, the success of this incentive in achieving its objective of a more needs-driven system depends on the definition and criteria for unmet medical need. On the one hand, these should be distinctive enough to ensure that only medicines that truly satisfy an unmet need are rewarded. Indeed, if (almost) all innovative medicines qualify for this incentive, its objective to steer innovation towards unmet medical needs will not be achieved. Additionally, affordability and availability of medicines will be negatively impacted because generic entry will be widely delayed. On the other hand, an important factor for success is creating (and keeping) an attractive environment for businesses to continue investing in development. If the definition and criteria for meeting an unmet medical need are set too narrow, this incentive may prove too difficult to obtain for companies and may thus fail to reward medicines that truly meet an unmet medical need, again hampering our striving for a more needs-driven system. Hence, the discussion on the proportionality and appropriateness of the proposed incentive needs to go hand in hand with the discussion on the definition and criteria for unmet medical need.</p>
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	<p>NO</p> <p>As indicated before, we fully support the Commission’s effort to strive for a more demand-driven system, and awarding additional regulatory data protection to products that satisfy an unmet medical need can be a way to achieve this.</p> <p>However, we feel that a blanket reward for all medicines that meet an unmet need may not be proportional nor suitable in relation to its objective. First, an extended period of monopoly as compared to the current situation can only be justified if needed to ensure return of investment and when justified form a public health need. This means that we need to look at the underlying cause for the unmet need before we can decide on the appropriate incentive.</p> <p>For instance, in areas where lack of scientific knowledge is the cause of lack of treatment but where at the same time lots of research already takes place and where a future breakthrough</p>

		<p>medicine will be used for a large group of patients, such as for Alzheimer’s disease, an extended period of data protection is neither needed nor proportionate. After all, no incentive is needed to stimulate companies to steer innovation towards that particular unmet need, and extending the period of monopoly on a blockbuster product negatively impacts availability and affordability for patients and national health systems.</p> <p>On the other hand, in areas where the underlying reason for the lack of treatment is related to insufficient return of investment, the proposed reward of an additional period of data protection seems justified. For such products, this period may even need to be longer than the proposed 6 months in order to have a true effect.</p> <p>Having said this, we believe that additional measures are needed to stimulate development of therapies in particular areas and to provide industry with more direction and certainty. In our view, a successful measure could be an EU record listing the therapeutic areas or conditions recognised as representing the highest unmet need. This list will be linked to, among other things, willingness to pay. Such a measure may in the end prove more successful in achieving more demand-driven innovation and is more transparent and predictable for industry than a reward in the form of additional data protection.</p>
“Comparative clinical trials” incentive (Art. 81 (2), 1 <sup>st</sup> subparagraph, point (c) Dir.)		
4.a.	Do you agree with the conditions for this incentive?	<p>YES/NO</p> <p>In principle, we support the Commission’s effort to accelerate and improve patient access. A specific reward for the submission of comparative clinical trials as part of the application for a marketing authorization may be a way to achieve this. However, we have a few concerns that need further discussion.</p> <p>First, medicinal products that fulfil an unmet medical need will not be able to meet this condition because there is no comparator due to lack of treatment. In such cases, clinical studies can only be performed with placebo. This incentive therefore leads to unfair competition. Second, we feel that whenever a comparator (reference treatment) is available during the</p>

		development phase, it should be the standard approach that clinical studies are not just performed with placebo but also with a comparator. At this stage, we are unsure whether a desired standard approach should be incentivized or simply expected.
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	We feel it is premature to discuss the proportionality of the proposed duration before having discussed in more detail the appropriateness and effectiveness of the incentive and its conditions.
	“Additional therapeutic indication” incentive (Art. 81 (2), 1 <sup>st</sup> 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 12 months of additional protection proportionate.
	Incentive for repurposed medicinal products (Art. 84 Dir.)	
6.a	Do you agree with the conditions for this incentive?	NO  We argue that this incentive is explicitly decoupled from the proposed Article 48 in the Regulation. This article provides that not-for-profit entities can submit data to the regulatory authorities for the repurposing of authorised medicines. In case of a positive opinion of the EMA, one or more indications will then be added to existing products. However, the MAH of those products have not put any effort into collecting the underlying data. They should therefore explicitly not be eligible to the 12 months additional protection for new indications under Article 81.2(d) or the 4 years additional protection under Article 84.1 of the Directive.  In addition, the conditions should explicitly state that adequate non-clinical or clinical studies were not only <u>carried out</u> but also <u>provided</u> as part of the application for repurposing. We refer to the wording elsewhere in the proposed directive, e.g. Article 6.2 for full dossier applications and Article 81.2(d) for the addition of a new indication, where the wording is more clear.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	NO  We believe that the extension of the duration of data protection from the current 1 year to 4

		<p>years is insufficient to stimulate drug repurposing. As this article is restricted to products authorised in accordance with Articles 9 to 12 and that not previously benefitted from data protection, or where the initial marketing authorisation was granted more than 25 years ago, we believe that the duration of the incentive can be extended from the proposed 4 years to 5 years. We believe that such an extension for these categories of products is more proportionate to the efforts and will lead to more affordable innovation, with a balance of benefits for patients and societal costs.</p> <p>Although this article provides a necessary tool to encourage companies to invest in drug repurposing, we would like to remark that in order to be fully successful in achieving its objective additional measures in pricing and reimbursement within national healthcare systems are required. Without these, companies may not be compensated properly for their investments into research and development for repurposing. We do believe this article provides a solid fundament for Member States to possibly adjust their national systems to pursue earlier access to affordable medicines through repurposed products.</p>
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## PORTUGAL

	Questions	
<b>Section 1: Nature of the incentives</b>		
1	Do you agree with the proposed maximum duration of the protection period?	<p>We support the revision of the current system that adopts a modulated approach creating a more balanced and proportional incentive framework aligning public health interests, namely patient access, and needs-driven innovation with a reward for the promotion of R&amp;D.</p> <p>We highlight the importance of having a clear and predictable framework for all relevant stakeholders, industry and innovators, national competent authorities, and payers. The conditions for accessing new RDP incentives need to be carefully tuned to ensure such a goal.</p> <p>In relation to the total length of protection period, it should not be disproportionate and needs to be balanced with faster access to medicines by broader and underserved populations with particular focus on unmet medical needs, generics and biosimilars. The financial sustainability of health systems is also a criterion to be considered.</p> <p>All the above conditions being met, the total duration of the protection period should not extend beyond the proposed one.</p>
<b>Section 2: Different proposed regulatory incentives</b>		
<b>Market launch” incentive (Art. 81 (2), 1st subparagraph, point (a) and 82 Dir.)</b>		
2.a	Do you agree with the conditions for this incentive (predictability for different actors involved)?	<p>We support the prolongation of protection for product launch.</p> <p>However, the system must not be too complex and should not lead to unnecessary increase of the regulatory burden for industry and NCAs (particularly regarding the need to apply for a variation in order to obtain confirmation of supply in a MS).</p> <p>Further clarification of the actual procedure needs to be added on the practical application of the provision.</p> <p>Additionally, how can we assure that the supply will be maintained after the granting of the 2 additional years?</p> <p>There is a need to clarify also the concept of ‘market launch’ i.e. submission of a pricing &amp; reimbursement application ?</p> <p>We could agree with the principle but we would need to identify a procedure that should not compromise the objectives of such incentive.</p>
2.b	Is the proposed reward (24 additional months of RDP) proportionate? If not, should it be longer or shorter?	We agree with the proposed reward, but products granted conditional market authorisation should be excluded.
<b>“Unmet Medical Need” incentive (Art. 81 (2), 1st subparagraph, point (b) and 83 Dir.)</b>		
3.a	Do you agree with the conditions for this	We agree that additional incentives are given for medicines addressing on unmet medical needs if the conditions are met.

	incentive?	It is particularly relevant the need to ensure adequate collaboration between the Agency and HTA body in order to have a common framework for assessing the conditions as considered in Article 83(3).
3.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	As stated above there should be proportionality in the modulation of incentives.
“Comparative clinical trials” incentive (Art. 81 (2), 1 <sup>st</sup> subparagraph, point (c) Dir.)		
4.a.	Do you agree with the conditions for this incentive?	<p>We consider this proposal a beneficial interplay between regulators and HTA bodies.</p> <p>It is particularly relevant the need to ensure adequate collaboration between the Agency and HTA body in order to have a common framework for assessing the conditions as considered in Article 82(3).</p> <p>However, it should be clarified in which circumstances this incentive could be granted, namely if previous scientific advice is mandatory.</p>
4.b	Is the proposed reward (6 additional months of RDP) proportionate? If not, should it be longer or shorter?	<p>As clinical trials with relevant comparators are considered as the gold standard, there will be more benefit to medicines safety and effectiveness when being marketed.</p> <p>Therefore we can accept 6 months.</p>
“Additional therapeutic indication” incentive (Art. 81 (2), 1 <sup>st</sup> subparagraph, point (d) Dir.)		
5.a	Do you agree with the conditions for this incentive?	<p>We agree.</p> <p>However, it is important to have a common understanding of ”significant clinical benefit”.</p>
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?	We agree with rewarding repurposing of medicines. It is an area that needs special provisions and incentives in order to be attractive and bring products to the market.
6.b	Is the proposed reward (4 years of RDP) proportionate? Are the efforts adequately compensated?	We support the proposal as per its wording.