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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 find enclosed comments related to the Working Party on Pharmaceuticals on 5-6 May 2025.

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COMMENTS FROM THE DELEGATIONS

Working Party on Pharmaceuticals and Medical Devices 5-6 May 2025

BULGARIA

As mentioned, we reserve our position on a couple of issues, until we have more clarity on legal and practical consequences, esp. by the CLS. This goes in particular for the Regulation:

Article 5 (1a) from the Regulation is partially overlapping with Art. 56a from the Directive, however it is quite vague. Given that it is related to sanctions, we may favor a deletion of Art. 5 (1a), subject to legal analysis.

Chapter IX of the Regulation (Regulatory sandboxes): Articles 113, 114 и 115, where a more limited/framed empowerment of the Commission is appropriate.
We also request to **restore the deleted text in Art. 115 (2)**: this concerns the liability, which should remain for the MAH:
Participants in the regulatory sandbox, ~~in particular the marketing authorisation holder of the medicinal product concerned, ,~~ in particular the marketing authorisation holder of the medicinal product concerned, shall remain liable 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. They 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.

At this stage we reserve our position on further proposals, such as redispensing of pharmaceuticals, overarching committee on borderline products etc., discussed at the last WP, which appear to require careful assessment of legal and practical consequences, and can benefit from scrutiny both by the COM and the CLS.

Beyond that:

Art. 134. In case contingency stocks are kept in the text, we would need clarity that this concerns only MAH (no impact on government reserves). We refer to our proposal ("*obligations on MAH or wholesales, as appropriate, to hold a certain amount of contingency stocks").*

Art. 148 (6) We request if not deletion, at least shifting the words "*This expertise shall also cover the environmental risk assessment"* before the last sentence, so that it is clear that this concerns the expertise of CHMP, not of each of its members.

6. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed on the basis of their relevant expertise in the assessment of medicinal products which should cover all types of medicinal products covered by [revised Directive 2001/83/EC] and this Regulation and which include medicinal products for rare and paediatric diseases, advance therapy medicinal products, biological and biotechnological products, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. ~~***This expertise shall also cover the environmental risk assessment.***~~ *The Member States shall cooperate in order to ensure that the final composition of the Committee for Medicinal Products for Human Use provides appropriate and balanced coverage of all scientific areas relevant to its tasks taking into account scientific developments and new types of medicinal products. This expertise shall also cover the environmental risk assessment.For this purpose, Member States shall liaise with the Management Board* ~~a~~

Art. 150 (2) "ATMP" could be added to orphan and paediatric scientific groups.

Recital (136) the words „~~*Due to a lack of coordination of measures taken at national level these efforts resulted in a fragmented response leading to a jeopardy of the availability of medicines across the European Union*~~" should preferably be deleted as they appear as severe self-criticism not backed by data. This statement is also irrelevant for the SPP, which is the purpose of this recital: „.~~ Therefore, all m~~Marketing authorisation holders should have shortage prevention plans in place for certain products, to prevent or mitigate shortages".

We understand that major political issues remain for Coreper; at this stage we just flag that **Art. 56a (5)** of the Directive and in particular the loss of ME should be carefully reflected.

I take the occasion to flag our flexibility in case the Presidency would consider re-instating **Art. 162 (2a)** as suggested by Ireland, with one addition:

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Art. 162 (2a)

For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') is identical or essentially similar with the medicinal product already authorised in the destination Member State. This can be ensured by demonstrating that the medicinal products share a common origin ***in accordance with national rules***. A destination member state can refuse to permit the parallel trade of a medicinal product by a wholesale distributor from another Member State in case they consider that permitting such parallel trade would not respect the marketing authorisation rules established in this Directive and Regulation [726/2004], including the procedure for mutual recognition of national marketing authorisations.

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CZECHIA

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Directive Proposal:		
INCENTIVES:		
Article 80		
para 5a (new)		CZ still considers it important to have the exact data on the end of regulatory data protection related to centrally and nationally authorised medicines publicly available in the EMA database. Such kind of information is considered really crucial for pharmaceutical industry such as applicant of marketing authorisation of generic medicines, and NCAs as well. Instead of the list of links on websites of the individual NCA of Member States as it is proposed in Article 80 para 5, we promote as easier and more practical solution to stipulate the already mentioned information within EMA database on the basis of Article 138 para 1 letter n), alternatively within PMS. We refer to EC competence to adopt delegated acts by which it is possible to add the other information included in EMA database and

		to specify rules on their update – reference to Article 138 para 2 subpara 4.
Article 81		
para 1		CZ can support EC initial proposal to maintain 6 years as the basic regulatory data protection period with the possibilities on prolongment on the particular conditions. **However, we can express such kind of flexibility in the case when one condition is to be aligned to support medicine manufacture within the EU.**
para 2		**CZ fundamentally does not agree with deleting of the proposal on medicine manufacture in the EU** as the proposed changes in protection data period do not bring motivation and possibility to MAH to fulfil all conditions. **CZ finds the manufacture in the EU the most beneficial additional regulatory data protection incentive for the EU and the Member States**. Within the upcoming negotiation of Pharmaceutical Package, we would like to emphasize that the actual geopolitical situation should be taken into consideration as even the mere mention of

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		potential change within international trade could lead to announcements by pharmaceutical manufacturers that they will relocate the medicine manufacture outside the EU. Therefore, we are of the opinion that it is absolutely essential to ensure safety of the EU market and medicine availability for EU patients in the future. Moreover, the other aim of this incentive is to restrict the dependence of the EU on the third countries. **We have submitted the proposal to reward manufacturing within the EU intended for the benefit of European patients with one year of additional regulatory data protection**. However, despite the support of this proposal of several Member States this proposal is not the integral part of the Pharmaceutical Package. In the context of the already mentioned changes in geopolitical situation and the necessity to ensure safe medicines supplies in the future to the patients in the EU, we would like to ask for reconsideration and addition of such incentive into Directive Proposal. In this matter, we would like to refer to our non-paper on

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		incentives which has been shared before the meeting.
para 2 letter b) i)	**~~where appropriate, where~~ the clinical trials supporting the initial marketing authorisation application use, where possible ~~and appropriate,~~ a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency;**	In this context of incentive on comparative studies, CZ is of the opinion that it should be sufficient to mention only "possible" in order to clarify the text. Please see the changes in wording proposed.
para 2 letter b) ii)		CZ is still of the opinion that condition on clinical studies should be stipulated that clinical trial should be conducted at least in two Member States and at least 30 % of subjects included into clinical should be from the EU. In this context, the meaning of "several Member States" is not clear, respectively how many Member States are to be concerned. From our perspective, criterion should be aligned to the final phases of clinical trials as we should avoid the situation for applicant when the sufficient number of subjects are enrolled in clinical trials in order to receive the additional data protection, however, it cannot be stipulated that treatment will be provided, moreover such patients could be excluded from the clinical trials in the meantime.

para 2 letter b) iii)		CZ is not in favour of stipulating incentive on submission of marketing authorisation applications until 90 days from submission of the first application within the EU. We have concerns of consequences related to different and in many cases uncomplete data which are provided for medicine marketing authorisations (and in some countries may be sufficient) due to the differences between health systems of states at the global level. Apart from that we are of the opinion that the amount of conditional market authorisations of medicines should not be increased only with the purpose to fulfil this condition.
para 2 subpara 3	**In the case of prolongation of data protection in accordance with first subparagraph point ~~2~~(a), the applicant shall demonstrate the improvement in efficacy or safety of the medicinal product referred to in Article 83 paragraph 1(b) with data from clinical trials that use, where possible ~~and appropriate,~~ a relevant and evidence-based comparator.**	Please see the CZ comment on para b) letter b) i) above. We are of the opinion that it would be sufficient to use "possible". Please see the changes in wording proposed.
Regulation Proposal:		
Article 56a		In general, we support stipulating an obligation for MAH to ensure supplies of medicines to

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		markets in all Member States instead of incentivising pharmaceutical industry on which basis the addition year of data protection is to be received. If the Member State has to request the medicinal product from the MAH, it is important that there is a system that would allow to do so (for example a system at EMA level through which all the related communication between the Member State and the MAH would run or at least a database with MAH contacts so that it is clear for the Member State who to contact).
para 4		CZ would like to ask for clarification of contact persons of MAH in the case when MAH is asked on the basis of such provision. We are of the opinion that it is necessary to stipulate contact persons of MAH to be provided, for instance via database of contact person of MAH.
para 5	**Where within 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**	CZ proposes to delete "within that Member State" at the end of this para 5 to strengthen this para as it would motivate the MAH to supply the medicinal product in all Member States. In the case when MAH does not fulfil the obligation of four years from marketing authorisation to

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	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.**~~	launch such medicine on the market and continuously supplies it should be cancelled data protection of such medicine in all Member States. We are of the opinion that the period of four years is sufficient long or it could be alternatively shorter. Please see the change in wording.
Article 219		
para 1	**if the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously** ~~**in that Member State**~~ **in accordance with that Article.**	CZ similarly to Article 56a para 5 proposes to delete "within that Member State" to strengthen this para as it would motivate the MAH to supply medicines in all Member States. Please see the changes in wording.
Directive Proposal:		
MEDICINE SHORTAGES:		
Article 3		
para 1 letter b)	**medicinal products supplied in response to unavailability of the medicinal product due withdrawal, suspension, cessation of marketing or shortages, if the unavailability or the shortage cannot be prevented or resolved through Union coordination in accordance with chapter X of [revices directive 2001/83]**	CZ is not in favour of deleting of the previously proposed text and the alternative solution expressed in para 1a of this Article. We would like to ask for maintaining of this text proposed in the previous version of the text. Please see the other comment related to this provision as well

		on para 1a below. Please see the changes in wording proposed.
para 1a	**In justified cases a Member State may temporarily exclude from the scope of this Directive medicinal products prepared to mitigate or resolve a shortage in that Member State or to address a situation, where no authorised medicinal product is available in that Member State or another Member State.** **The exception referred to in this paragraph shall apply only when no suitable medicinal product is authorised and available within that Member State or can be supplied in accordance with paragraph 1, and in the case of shortage, when the shortage in the relevant Member State cannot be resolved at that time through Union coordinated actions.** **For medicinal products prepared in accordance with this paragraph Member States shall ensure that:** **(a) the preparation of the medicinal product is approved by the national competent authority on the basis of a risk assessment;** **(b) the approval under point (a) is revoked when the shortage is resolved or the medicinal product can be supplied in accordance with paragraph 1;**	In the context of the CZ comment on para 1 letter b) above, we are not in favour of this provision as in such case it would be possible from Member State side to allowed to only preparation of such medicine in shortage that could not be sufficient solution of the row of situations in the case of unavailability of such authorised medicine. Please see the changes in wording proposed.

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	(c) in the case of no authorised medicinal product, that the approval is assessed annually for the necessity of the exemption; **(d) appropriate oversight by the national competent authority is in place and in particular any issues with regards to quality and safety are monitored and evaluated;** **(e) the facility preparing the medicinal product complies with the requirements equivalent to the Good Manufacturing Practices referred to in Article 160;** **(f) the quality, safety and efficacy of the medicinal product is confirmed by the national competent authority, or the medicinal products is prepared in accordance with a pharmacopeia or national monograph;** **(g) the product is supplied to patients under the supervision of an authorised healthcare professional;**	
Article 205		In the context of Article 3 para 1a CZ could not consider sufficient addition into Article 205 para 1 meaning such as the need to ensure access, availability or security of supply as on the basis of the current practice condition on public health protection is to be fulfilled only in the case in the particular situations. In such case it would not be

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		for instance possible to allowed to use oncologic medicine as private interest is concerned of individual or individuals, and therefore, the case of on public health protection case is not concerned.
para 1		
Directive Proposal		
Article 56		
para 3 subpara 1	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate **stock levels** and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the member state in question are covered. **The marketing authorisation holder shall not prioritize any Member State if he is not able to cover the needs of patients.**	In the context of the aim to ensure the equal access to all Member States from MAH side, CZ proposes to add to the end of this subpara an obligation to not prioritise the particular Member State in the case of unavailability or shortage of medicine. Please see the changes in wording proposed.
Similarly, it should be changed Article 167 para 2 as well	**The wholesale distributor shall not prioritize any Member State if he is not able to cover the needs of patients.**	Apart from that, we propose to add the similar obligation into the part related to distributors as well, meaning in Article 167, at the end of para 2. Please see the changes in wording proposed.
LABELLING		

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Article 69		In general, we are not in favour of the global AMR resistance symbol as we are of the opinion that any AMR symbol does not exist under such term, therefore this term is considered unclear.
para 2	The marketing authorisation holder shall include in ~~the beginning of~~ the package ~~ing leaflet~~ of antimicrobials a ~~document~~ **section** that contains specific information about the medicinal product concerned ~~and that is made available to the patient in addition to the product leaflet (“awareness card”)~~ **and** ~~with~~ information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.	CZ does not support addition of „the beginning of“ as it is too detailed for the Directive and this issue should be solved in QRD template (Quality Review of documents). Please see the changes in wording proposed.
para 2 subpara 2 (new)	~~In the case of electronic version of the package leaflet, the information referred to in the previous subparagraph shall be made available to patients electronically in a distinct and immediately visible way.~~	CZ proposes to delete this subpara as details of ePIL layout should be specified at the level of QRD template. Please see CZ comment above. Please see the changes in wording proposed.
Article 74		
para 1	The particulars ~~for labelling~~ listed in Articles 64 ~~and~~ **to** 65 ~~-~~**6**, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State**, as well as in the English language in the electronic version of the** ~~package leaflet~~ **product information**.	CZ proposes replacing the „package leaflet“ with „product information“ as we consider the extension to include an English version of SmPC to become a key part with the aim to ensure availability of medicines in Member States. Please see the changes in wording proposed.
SHORTAGES OF MEDICINES		

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Article 83		
para 1 letter b)		CZ proposes to add the clinically relevant advantage represented by percentual ratio in order to increase transparency of such method. Concretely, it is proposed that clinically relevant advantage is to be represented by relevant endpoint in a clinical study which has an impact on the quality of life. The example could be 30% improvement in comparison with the current treatment or there was a significant positive difference in survival time or time to progression.
Article 85		In general, CZ supports extending of Bolar exception. We welcome changes proposed by PL PRES which bring clarification of such provision. Related to application of Bolar exception, we have concerns of the previous expressed proposals on narrowing of the initial EC proposal only on providing of clinical studies for the purpose of marketing authorisation granting or variation of medicine. CZ has been supported measures on strengthening soon launching of generic and biosimilar medicines on the EU

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		market for a long time, including extending and harmonisation of Bolar exception which is considered as a measure that can indirectly enable price and reimbursement decision of such medicine at the national level. CZ also prefers to maintain addition of the PL PRES text on procurement bids as possibility of participating in procurement bids right before the end of the market protection represents a tool how to improve availability of medicines and supporting sustainability of financial budgets of payers as well.
Article 144		
para 1 subpara 3 (new)	~~By way of derogation from the second subparagraph, in justified cases, th inspection may be carried out after the manufacturing authorisation has been granted.~~	CZ still applies the already mentioned comment as the new sentence of this provision "in justified cases" enables to grant approvement of medicine manufacture and afterwards to provide inspection. Therefore, this sentence is proposed to be deleted. When it is necessary to follow this procedure, e.g., in emergency situations related to protection of public health such as pandemics, therefore, reference on the particular EU legislation should be added, Otherwise, this

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		sentence is to be deleted as term "in justified cases" is considered wide. Please see the changes in wording proposed.
Article 162		
para 2a (new)	**For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') share a common origin is essentialy similar with the medicinal product already authorised in the destination Member State. Medicinal products are considered to be sharing a common originessentially similar if they fulfil all the following conditions:** **(a) they have the same qualitative and quantitative composition in terms of active substances and excipients;** **(b) they have the same pharmaceutical form;** **(c) they have the same clinical information; and** **(d) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation**	CZ does not support deleting of para 2a and would like to ask for clarification of PL PRES as at WPPMD on 28th April 2025 the majority of Member States was in favour of this Article, respective to maintain letter c) as well. CZ assists on stipulating EUI legislative framework on parallel import. We can accept deleting of requirement on the same excipient from letter a), however, we would like to ask for restoring letter c). From our perspective, deleting of condition on the same clinical information in letter c) is confusing as it can evocate that parallelly imported medicine could have the different indication or target population. Please see the changes in wording proposed.
Article 188		

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para 14	the competent authority of the Member State concerned shall issue a statement of non-compliance ~~and may shall revoke the certificate of compliance with good manufacturing practice or good distribution practice fully or partially, as appropriate~~.	CZ is not in favour of the proposed change of "may" to "shall" in comparison to the previous version of the text. CZ is of the opinion that the initial EC proposal should be maintained without any change. We are of the opinion that stipulating an obligation to cancel GMP certificate in case when NCA finds out indifferences with GMP during inspection could lead to serious impacts on medicine availability, especially, in case of only one available producer of such medicine. Moreover, we are of the opinion that NCA should assess all circumstances and the potential options of correction and inform the other Member States before the last solution which represents just cancellation of GMP certificate. Therefore, this part of the text is proposed to be deleted. Please see the changes in wording proposed.
Article 217		On basis of obligations for Member States stipulated in Article 219 to reach accordance with Directive within 24 months from entry into force, CZ is of opinion that this provision should be clarified and changes as well.
Article 218		Please see the CZ comment on Article 217 above.

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Article 219		
para 7 letter b)		CZ would like to ask for clarification of the changes proposed by PL PRES. We are not in favour of the temporary provision which stipulates that ePIL are to be obligatory for part of medicines after 3 years of entry into force of national legislations (meaning 24 months + 3 years, therefore 5 years). We consider it key to ensure that ePIL becomes the integral part of all medicines in the most sooner time, similarly to the other provisions, meaning 24 months of entry into force of Directive. Apart from that, we would like to point out that the proposal is not in accordance with legal rules related to the difference of Regulation and Directive which is not to entries into application as on the contrary is implemented via national legislations. This part should be more clarified and changed.
Regulation Proposal		
Article 40		CZ does not support the proposed text related to TEV, which is suggested by EC, including changes proposed by HU PRES. Particularly, the

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		idea of transferability of TEV based on the current conditions is not supported. TEV is proposed in the context of unavailability of antimicrobial medicines. However, it 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. CZ fundamentally does not support to finance TEV from healthcare insurance system, respectively from healthcare systems of Member States. Moreover, on the basis of EC proposal, there is no guarantee that such medicine will be in fact developed based on TEV. CZ would like to ask for clarification of transparency and feasibility of TEV which represent the crucial questions for us. The consequences of TEV should be clarified on the basis of the relevant data with focus on guarantee of transparent transferability of TEV. In general, CZ can support the tool of a voucher provided there is not a transferable voucher,

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		meaning TEV itself. We consider it important to open a discussion on other options how to motivate pharmaceutical companies and promote research and development of new antimicrobial medicines. The basis is to safeguard safety of patients within the EU and not to finance this kind of tool from healthcare systems of Member States, however, from other resources. There are the other options such as milestone payments within phase 1 and phase 2 of the clinical trials, accelerated assessment of the priority antimicrobials or potentially extending the regulatory data protection of the priority antimicrobials. These parts are to be relevant to be discussed within the Pharmaceutical Packages negotiations. CZ would like to ask whether the other discussion on this matter will follow as this topic represent the crucial part of this legislative proposal as these parts should be more discussed. CZ can also support FR background paper on TEV as it is necessary to focus on the other alternatives on support of antimicrobial

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		substances within the upcoming phase of Pharmaceutical Package negotiations.
Article 113		CZ supports the regulatory sandbox as considers it useful tool, 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 for which the current EU legal framework has not been stipulated. The question of the upcoming implementation process of this provision should be more clarified. In general, Chapter IX should be more clarified concerning mechanism of regulatory sandbox establishment, role of EMA and NCA in this matter, including a control task or on which legal basis medicines are to become a part of the regulatory sandbox. Moreover, it should be clarified how the recommendations of EMA will be reviewed and how the related implementing acts are to be specified etc.
Article 117		
para 1		CZ is of the opinion that in the context of changes on the market list of medicines in shortage on the basis of Article 123 para 2a could be relatively

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		changeable. From this reason, it is a question whether in the context of determined periods of time for SPP preparation the obligation is to be in the particular time in all cases relevant. This part should be more clarified.
Annex IV, Part V		
para 1 letter i)	**(i) Pack size(s);**	CZ considers pack size of medicine crucial part of SPP which should be mentioned in this list as otherwise, it is not possible to concretely identify such medicine. Please see the changes in wording proposed.
para 1 letter j)	Details of authorisation: procedure type (national (including Member State(s) involved)/centralised marketing authorisation) and ~~reference~~ **~~marketing authorisation number~~ national code.**	CZ still promotes to mention on such list of SPP the national code as well which is to concretely identify such medicine as this proposal has already been expressed on previous WP meeting and is in accordance with Article 120. We are of the opinion that addition of reference marketing authorisation number is not for identification of such medicine sufficient. Please see the changes in wording proposed. Alternatively, it could be maintained the EC initial proposal on reference number, or potentially product code (PMS).

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Article 120		In general, CZ supports stipulating of harmonised EU framework on parallel trade. On previous WP meetings, we considered it necessary in this matter to distinguish between case of availability and unavailability of such medicine in order to avoid of outflow of the smaller markets in Member States. Moreover, it should be emphasized that unreasonable barriers should not be created within the EU. It is considered priority to ensure availability of medicines in accordance with needs of Member States. Apart from that, option for Member States to adopt measures at the national level should be maintained as well, therefore, it is not possible to allow that harmonisation of this area at the EU level is to bring worsening of the current position of Member States in the question of ensuring availability of medicines on the market of the particular Member State.
Article 134		
para 2		In general, CZ concerns that division into subpara in para 2 is confusing and should be edited in order to clarify this provision.

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CZ Proposal	**Safeguards related to Member States' contingency stocks requirements and other security of supply measures** **1. Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for public or private entities to hold contingency stocks.** **2. Member States shall ensure that any requirements they impose on public or private entities in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.**	CZ supported addition of the EC option to stipulate the uniform requirements related to contingency stock. We are not in favour of deleting of this part and would like to ask for alternative solution of harmonisation on contingency stocks. We are of the opinion that from the perspective of the current state of unharmonized national measures in medicine stocks it is important to stipulate within Pharmaceutical Package a complex system which will strengthen cooperation between Member States and harmonisation of such area and support principle of solidarity. Therefore, we propose to set principles for medicine stock area into the Pharmaceutical Package and not into CMA act concerning all medicinal products, not only critical medicines and medicines of common interest which are integral part of medicine stock, and both public and private entities that keep medicine stock. In order to secure a high level of transparency between Member States, a database that would collect up to date information on the current level

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		of contingency stock should be created, including information such as API, pack size, ATB group and quantity of stock. Moreover, possibility to share such medicinal product with other Member States in the case of need based on the principle of solidarity should be concerned as well. With the aim to regulate in more detail medicines stocks area, it is needed to set a definition on contingency stock of medicines. The option is to stipulate this area in the separate Article within the Pharmaceutical Package.
para 2 subpara 2		CZ would like to ask for clarification of impacts of criteria adopted by EC on national measures which have already been adopted, however, would not be in accordance with such EC criteria.
HMA BE proposal on Article 200		CZ would like to point out that the question on legal recognition of the Heads of Medicines Agencies network (HMA) at the EU level has already been discussed many times within HMA meetings, however, without any significant results of such discussions. HMA network has been worked on the informal basis for a long time. The regular meetings have been always

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		organised by the current Presidency of the Council of the EU. In the meantime, HMA Management Group and Permanent Secretariat are in function of HMA management. CZ is of the opinion that mutual cooperation, information exchange and coordination have already worked at the level of directors of such agencies and HMA working parties as well, including processes setting and common multi-year strategy. Therefore, we consider the current cooperation setting sufficient, and we do see the significant benefit of legal recognition of HMA network, meaning via stipulating such provision in Article 200 of Pharmaceutical Package. Apart from that, financial impacts of BE proposal on legal recognition of HMA are not clear, especially, whether HMA secretariat should be provided via EMA. In this context, CZ is of the opinion that informal HMA setting represents advantages as it brings flexibility and independence of HMA meetings. Moreover, it should be point out that human and veterinary agencies are included and the

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		participation of Member States in HMA is at director´ level who are very busy. From these reasons, CZ is not in favour of this BE proposal.

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ESTONIA

Comments from ESTONIA on the EU Pharmaceutical Package (ST 8311/25)

DIR Art 1 p.5 and p. 6a

Text proposal:

Member States may allow the supply of officinal formula by the pharmacy to a ~~hospital~~ **healthcare provider** it serves **according to national law**, ~~subject to the agreement of the competent authority concerned.~~

In Estonia a hospital pharmacy is allowed to dispense medicines to the hospitals and also to other healthcare providers, i.e. a hospital or emergency service provider that does not have its own hospital pharmacy. This proposed amendment is important to maintain our national system and continue to supply medicines to all healthcare providers as provided by national law.

~~"Where pharmacies operate in a Member State under common ownership, a Member State may allow the preparation of officinal formula at a central pharmacy, provided that the principles of subparagraph 1 are respected"~~

Member States may allow the supply of medicinal products prepared under officinal formula from one pharmacy to another pharmacy for dispensing directly to their patients, under specific conditions to be set by national law, provided that the principles of subparagraph 1 are respected.

We request a more general wording in the last subparagraph. The current wording is too specific and not taking into account the national arrangements regarding pharmacy services. Flexibility is needed for one pharmacy to prepare medicines for another pharmacy, even if they are not under common ownership. Common ownership of pharmacies is very limited in Estonia. Nevertheless, it is very important to have the possibility that one pharmacy can, for example on a contractual basis, supply other pharmacies, since not all pharmacies have the capacity. This is necessary to maintain access to treatments across the country, and support smaller or rural pharmacies that lack the capacity to prepare such medicines themselves. Alternatively, the text could be broadened to cover also contractual basis (under common ownership or on a contractual basis).

~~6a. Member States may allow the supply of medicinal products referred to in paragraph 5, point (b), by the pharmacy to a hospital it serves for dispensing directly to that hospital's patients, subject to the approval of the competent authority concerned~~

We propose to delete p.6a as it is covered in p. 5

DIR Art 3 p. 1

Text proposal:

medicinal products supplied in response to a bona fide unsolicited order **or anticipated bonafide unsolicited order**, ~~prepared~~ **formulated** in accordance with the specifications of an authorised healthcare professional and for use ~~by~~ **to fullfil the needs of** ~~an~~ individual patient**s** under their direct personal responsibility.

*We propose to revert to the existing wording in the current Directive (art 5) and replace **'prepared'** with **'formulated'**. The change compared to the wording in the current Directive is not clear and in light of the ECJ case law might open up new interpretations, which should be . Referring to the "preparation process" is creating confusion, as it could be interpreted that the product has to be prepared for an individual patient, not the order. This exception should cover also the use of unauthorised products that are imported from third countries (f.ex situations where existing authorised medicines have not provided the desired treatment result, but the patient could receive help from a medicine that has a marketing authorisation and is available from third countries).*

DIR Art 36 p. 5 (mutual recognition)

We request to revert to the original COM proposal:

5. If the competent authorities of the Member States concerned so require, the marketing authorisation holder shall request the competent authority of the reference Member State for the mutual recognition procedure to update the assessment report drawn on the medicinal product concerned by the application. In that case, the reference Member State shall update the assessment report within 90 days after validation of the application. If the competent authorities of the Member States concerned do not require the update of the assessment report, the reference Member State shall provide the assessment report within 30 days.

PUBLIC

It is very important that Article 36(5) maintains the possibility of receiving an assessment report within 30 days without the requirement to update an assessment report. This could facilitate the MRP with a view to get older medicinal products to our market. In some cases for older products updating assessment reports is considered an unnecessary burden, especially if the concerned Member State really needs a medicine on its market. At the same time, the possibility to have an updated assessment report should also not be completely omitted, which could be drafted by the reference Member State within 90 days. This has been the proposal of the European Medicines Regulatory Network and has been long sought for. There is no need to exclude this option, which aims to simplify the procedure to facilitate availability of medicinal products.

DIR Art 51 p. 5 (medical prescription)

We would request to include paragraph (e) to allow the competent authorities to waive the medical prescription status.

5. A competent authority may waive application of **criteria set out in** ~~the~~ paragraphs 1 **(a), (b), (c), (d), (e) and (f)** , 3 and 4 **regarding the medical prescription,** having regard to:

(a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; or

(b) other circumstances of use that it has specified

DIR Art 218 p. 7 (transitional provisions)

Text proposal:

(b) for medicinal products authorised before [OP please insert the date the date of entering into force of this Directive] and medicinal products for which the application for marketing authorisation was submitted before [OP please insert the date of entering into application], it shall apply on [OP please insert the date = 3 years after the date of entering into **force** ~~application~~ of this Directive], unless a markeing authorisation holder chooses to comply with the requirement earlier and provided that the implementing act mentioned in Article 63(6) is adopted.

The transition period for the electronic package leaflet for already authorised medicinal products should be applied 3 years from the date of entering into force of the Directive and not from the date of application.

FINLAND + FRANCE

In order to prepare for and to mitigate the occurrence of a sanitary crisis (typically a pandemic or CBRN events), it is critical to maintain "insurance" stockpiles of crisis-related products so that the response can be immediate. The topic discussed here is not related to shortage of routinely used products and the related contingency stockpile.

Several national and EU "insurance" stockpiling initiatives have been intensified since the Covid-19 crisis. The Commission endeavors to ease the cooperation between these stockpiles so that products can circulate within the EU in case of a cross-border sanitary crisis.

In order to facilitated the stockpile constitution, maintenance and (when needed) deployment, some exemption to the general regulations applying to all medicines would greatly facilitate these activities.

Typically, the packaging obligations could be waived as regards languages, blue box or serialisation since the concerned products will remain in "sleeping" stockpiles and used only in case of declared sanitary crisis. Outside such a crisis, they are not to circulate within the market of the health care system. It would allow facilitated procurement and exchanges during a crisis.

Such measures and others have been discussed under the aegis of DG HERA between MSs representatives in charge of "insurance" stockpiling and discussed with EMA. EMA issued a paper describing more precisely the current difficulties and the expected benefit of the regulatory amendment proposed here.

To be included in Article 3:

"In the event of a serious national health threat requiring emergency measures or in the event of an exceptional health situation or any event likely to involve a large number of victims or in the event of a cross-border public health emergency declared by the Council as mentioned in EC 2022/2371, and for the preparedness activities conducted to be able to face such events before a sanitary crisis occurs, as regards medicinal products likely to be used in such situations and stockpiled for that purpose, a Member State may derogate from all or part of the provisions of this [Directive or Regulation].

PUBLIC

Such measures shall be strictly proportionate to the risks anticipated or involved, and the Commission shall be informed immediately. Within this framework, the Member State may derogate in particular from the provisions relating to the labelling and package leaflet of medicinal products, and to their shelf life and storage conditions."

PUBLIC

FINLAND

RED LINE FOR FI

Regulation

Article 134

FI cannot support the proposed article. We have made the common compromise proposal with SE.

Justification:

The proposal is in conflict with, in particular, the principles of subsidiarity and proportionality. In addition, the empowerment is too extensive and does not meet the requirement of specificity. It is not clear from the text of the article, what is the exact purpose of the Commission empowerment. We cannot support any binding uniform criteria for measures concerning security of supply set to the Member States that don't take into account different national needs and circumstances. SE and FI have presented a compromise proposal that would solve these issues.

Directive:

Article 3

para 1 and !a, we propose to change the text accordingly:

1. A Member State may, in order to fulfil special needs, exclude from the scope of this Directive:

~~(a)~~ medicinal products supplied in response to a bona fide unsolicited order or anticipated bonafide unsolicited order, prepared **or used** in accordance with the specifications of an authorised healthcare professional and for use ~~by~~ to fullfil the needs of ~~an~~ individual patients under their direct personal responsibility.

~~(b) medicinal products supplied in response to unavailability of the medicinal product due to a critical shortage in the Member State due to withdrawal, suspension, cessation of marketing or shortages, prepared under the direct supervision of a pharmacist in accordance with a European pharmacopeia or with the pharmacopeia of a Member State or national monographs, if the unavailability or the shortage in the Member State cannot be prevented or resolved through Union coordination in accordance with cChapter X of [revisedces dDirective 2001/83] of authorised medicinal products and for as long as the critical shortage in the Member State is not resolved~~.

However, in such case~~s~~ Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.

~~Member States shall ensure that medicinal products referred to in point (b) are prepared in a facility that complies with the requirements equivalent to the good manufacturing practices referred to in Article 160.~~

~~The exception of point (b), first subparagraph shall not apply to medicinal products listed in points 1 and 2 of Annex I of [revised Regulation (EC) No 726/2004] that have been included, either directly or as part of a category of medicinal products, on a list published by the Agency, of medicinal products or categories of medicinal products that, when prepared under the conditions of point (b), first subparagraph, are reasonably likely to lead to a negative impact on the safety or efficacy of the medicinal product or category of medicinal products, taking into account their specific characteristics and the benefits and risks to patients~~.

For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.

1a. In justified cases a Member State may temporarily exclude from the scope of this Directive medicinal products prepared **or used** to mitigate or resolve a shortage in that Member State or to address a situation, where no authorised medicinal product is available in that Member State or another Member State.

The exception referred to in this paragraph shall apply only when no suitable medicinal product is authorised and available within that Member State or can be supplied in accordance with paragraph 1, and in the case of shortage, when the shortage in the relevant Member State cannot be resolved at that time through Union coordinated actions.

For medicinal products used in accordance with this paragraph Member States shall ensure that:

(a) the use is approved temporarily by the national competent authority on the basis of a risk assessment or the special needs of the patients;

(b) the approval under point (a) is revoked when the shortage is resolved or the medicinal product can be supplied in accordance with paragraph 1;

(c) the use of medicinal product is based on the assessment of a healthcare professional, or the medicine is otherwise critical for the treatment of a specific patient group;

(d) the facility preparing the medicinal product complies with the requirements equivalent to the Good Manufacturing Practices referred to in Article 160 or the national competent authority has assessed the quality, safety, and efficacy of the medicinal product

~~For medicinal products prepared in accordance with this paragraph Member States shall ensure that:~~

~~(a) the preparation of the medicinal product is approved by the national competent authority on the basis of a risk assessment;~~

~~(b) the approval under point (a) is revoked when the shortage is resolved or the medicinal product can be supplied in accordance with paragraph 1;~~

~~(c) in the case of no authorised medicinal product, that the approval is assessed annually for the necessity of the exemption;~~

~~(d) appropriate oversight by the national competent authority is in place and in particular any issues with regards to quality and safety are monitored and evaluated;~~

~~(e) the facility preparing the medicinal product complies with the requirements equivalent to the Good Manufacturing Practices referred to in Article 160;~~

~~(f) the quality, safety and efficacy of the medicinal product is confirmed by the national competent authority, or the medicinal products is prepared in accordance with a pharmacopeia or national monograph;~~

~~(g) the product is supplied to patients under the supervision of an authorised healthcare professional;~~

Justification:

The proposed Article 3, paragraphs 1 and 1a, in our view, do not necessarily allow for a clear continuation of our current special permit and exemption permit procedures. The article emphasizes preparation for situations of shortages and, for example, requires authorities' approval for the preparation of the medicinal product, as well as confirmation by the national competent authority of the quality, safety, and efficacy of the medicinal product. The word "prepared" is repeated in several sections of the article. It is therefore unclear whether the exception in the article is intended more for situations where manufacturing is carried out nationally. The article 3 should clearly also cover situations where medicinal products are imported from another Member State or third countries or deviate in some way from marketing authorisation's demands, and the authority grants permission for releasing the medicinal products for consumption. It must be ensured that our current special permit procedures and batch-specific exemption procedures can be maintained.

The use of medicinal products that possess marketing authorisation in the Member State is consistently the primary option in pharmacotherapy. In circumstances where an authorised medicine is unavailable to ensure public health due to the authorised medicine not being marketed in Member State or experiencing a supply disruption, it becomes necessary to use a medicinal product that is authorised in another Member State or third country.

Article 4

- Para1 point 4a and 4b: Finland supports both definitions.
- point 67 a (’manufacture of medicinal products’): certification by qualified person is an essential part of the manufacturing and control process and should be mentioned specifically on this point.
- point 67b (decentralised manufacturing’: The directive should clearly establish at which point a medicinal product subject to decentralised manufacturing turns from an ”intermediate (medicinal) product” to a ”finished medicinal product”. This is essential for the implementation of rules concerning i.e labelling - including satety features -, QP certification etc.

Article 49

Para 1 point a): the results of all ~~clinical~~ studies, conducted in compliance with an agreed paediatric investigation plan as referred to in Article 6(5), point (a), shall be included, **if appropriate**, in the summary of product characteristics and, ~~if appropriate~~, in the package leaflet, or
We propose to change the place of ”if appropriate” to refer also to SmPC, not only package leaflet.

Justification:

PIPs include often numerous studies, like numerous pharmacokinetic modelling studies, which would be never allowed in the SmPC via normal assessment, as they are not relevant for prescribers (such belong to EPARs=European public assessment reports, but not the SmPCs). Some studies may also have major weaknesses (GCP-problems, methodological uncertainties, etc), that they would not be considered relevant information for doctors, but instead very confusing and misleading.

Adding all these PIP-studies by default will make SmPCs very long. There is ongoing major work in the CHMP to try to streamline the SmPCs and make them more relevant for prescribers, to include only concise, most relevant information. This statement of adding "all paediatric studies within PIP to the SmPC" (regardless if they are relevant or not) is completely against the current CHMP-efforts here, and not at all scientifically sound request.

Article 56

para 2a: this section should be completely deleted.

Justification:

The proposal could lead to a large number of products being released on the market just before the marketing authorisation is withdrawn. This could meant that products being on the market for a long time after the marketing authorisation has been withdrawn and marketing authorisation would not obtein theres oblibations properly. For excamle Marketign authorisations would not could not provide any safety changes to the medicinal product.

Arikle 93a

Point 4a: Would be more correct to modify to: On that basis, if the additional evidence has a **significant** impact on **how to use the product safely and effectively**, the Agency may recommend…

Justification:

To have an "impact on benefit-risk balance" would need to result in a formal referral, if BR-balance is questioned. Thus, it would be more correct to modify as presented above.

Article 103

para 6: We propose to change the para accordingly:

Undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2, shall without delay forward to the MAH located in the EU/ETA OR to the competent authority of the Member State any notification they receive regarding suspected adverse effects relating to those medicinal products.

Justification:

It seems unreasonable to demand that distributors have systems capable of reporting directly to the EV database. However, medicine wholesalers/distributors and marketing authorisation holders often have agreements for exchanging information about adverse reaction reports among themselves. Therefore, it is suggested that the distributor should report adverse reactions to the EU/EEA-area marketing authorisation holder, or if there is none, to the national authority (but not both, to avoid duplicates).

Article 135

para 1: We propose to change this para accordingly:

The ~~applicant and the the~~ holder of the ~~**homeopathic**~~ **traditional herbal** medicinal product simplified registration ~~registration holder of the traditional-use herbal medicial product registration holder~~ shall be established in the Union.

Justification:

Section 2 relates to traditional herbal medicinal products. Under Article 135, point 1. 'The holder of the **homeopathic** medicinal product simplified registration shall be established in the Union.' needs to be corrected into form 'The holder of the **traditional herbal** medicinal product simplified registration shall be established in the Union.' (Article 127, point 1 relates to homeopathic medicinal products.)

Article 141

para 1 point d) : should be changed accordingly:

where a matter concerning medicinal products containing herbal substances **or herbal preparations**, other than ~~the~~ traditional-use medicinal products, ~~other medicinal products containing herbal substances~~ is referred to the Agency under Chapter III, Section 5, or Article 95, to give an opinion on the herbal substance, where appropriate.

Justification:

This is because quite often not only herbal substances but also herbal preparations are used in medicinal products. In addition, both 'herbal substance' and 'herbal preparation' have been defined under Article 4 Definitions (65) and (66).

Article 151

point 3: It remains unclear at what stage the batch release is performed and who is responsible for it in decentralized manufacturing. Is it carried out at the centralized manufacturing site before delivery to the decentralized site, where further manufacturing activities take place? The QP, however, is not present on-site to perform batch releases at the decentralized manufacturing location. Likewise, it is not evident whether the final packaging of the medicinal product must be completed at the decentralized site. Furthermore, it is unclear whether all the same packaging labeling and language requirements applied to other authorised medicinal products are also applicable to the medicinal products produced in decentralized manufacturing.

Article 162

Point 2a

This paragraph should not be removed. For the functioning of internal market, it is essential to codify the broad case-law of the ECJ to the legislation. Finland supports the wording suggested by Sweden earlier, with the additional requirement that the marketing authorisation of the product in the destination member state must be currently valid when applying the licence for parallel trade:

For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') share a common origin with the medicinal product currently authorised in the destination Member State. Medicinal products are considered to be sharing a common origin if they fulfil all the following conditions:

(a) they have the same qualitative and quantitative composition in terms of active substances

(b) they have the same pharmaceutical form; and

(d) they have been manufactured by the same manufacturer of finished product or by a manufacturer working under license according to the same formulation.

Member States may decide that the medicinal products also must have the same clinical information.

For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') share a common origin with the medicinal product currently authorised in the destination Member State. **Destination Member State** ***may implement a restriction that parallel trade can be started only if the marketing authorisation of the medicinal product sharing a common origin with the parallel traded product is currently valid in the destination Member State when the application or notification for parallel trade is submitted."***

Justification: Assessment needed to process applications for parallel trade should be kept separate from the assessment required for actual marketing authorisations, which requires thorough clinical evaluation of the benefit-risk -ratio. In a situation where the marketing authorisation has not been in force for quite a long time in the destination member state, the processing of a new application for parallel trade referring to that withdrawn marketing authorisation would require an actual new and updated clinical assessment of the benefit-risk -ratio by the destination member state. Even if the B/R-ratio was considered positive a long time ago, it does not mean it would necessary be considered positive by today´s standards. This means that the process for parallel trade licence would actually start to resemble a process for mutual recognition of a marketing authorisation.

Article 219

Para 1: should be changed accordingly:

Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [**36**~~24~~18 months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission. Member States shall apply those provisions from [**36** ~~24~~ months after the date of entering into force of this Directive].

Justification:

Member states need more time to implement so large legislation to the national legislation.

Regulation

Article 45

point 4a: Would be more correct to modify to: On that basis, if the additional evidence has a **significant** impact on **how to use the product safely and effectively**, the Agency may recommend…

Justification:

To have an ”impact on benefit-risk balance” would need to result in a formal referral, if BR-balance is questioned. Thus, it would be more correct to modify as presented above.

Article 90

Para 1 point a): the results of all ~~clinical~~ studies, conducted in compliance with an agreed paediatric investigation plan as referred to in Article 6(5), point (a), shall be included, **if appropriate**, in the summary of product characteristics and, ~~if appropriate~~, in the package leaflet, or

We propose to change the place of ”if appropriate” to refer also to SmPC, not only package leaflet.

Justification:

PIPs include often numerous studies, like numerous pharmacokinetic modelling studies, which would be never allowed in the SmPC via normal assessment, as they are not relevant for prescribers (such belong to EPARs=European public assessment reports, but not the SmPCs). Some studies may also have major weaknesses (GCP-problems, methodological uncertainties, etc), that they would not be considered relevant information for doctors, but instead very confusing and misleading.

Adding all these PIP-studies by default will make SmPCs very long. There is ongoing major work in the CHMP to try to streamline the SmPCs and make them more relevant for prescribers, to include only concise, most relevant information. This statement of adding “all paediatric studies within PIP to the SmPC” (regardless if they are relevant or not) is completely against the current CHMP-efforts here, and not at all scientifically sound request.

Article 134

FI cannot support the proposed article (red line for FI). We have made the common compromise proposal with SE.

PUBLIC

Justification:

The proposal is in conflict with, in particular, the principles of subsidiarity and proportionality. In addition, the empowerment is too extensive and does not meet the requirement of specificity. It is not clear from the text of the article, what is the exact purpose of the Commission empowerment. We cannot support any binding uniform criteria for measures concerning security of supply set to the Member States that don't take into account different national needs and circumstances. SE and FI have presented a compromise proposal that would solve these issues.

PUBLIC

GERMANY

PUBLIC

COMMENTS FROM GERMANY ON the Revision of the EU Pharmaceutical Package – examination of full text

following the Working Party on the 5 and 6 May 2025

General comment

Our statements are subject to change, given the fact that German government has not been formed yet.

I. Comments on RDP and Access

1. Regulatory Data Protection:

- It is crucial for DE to maintain the current protection periods. We firmly believe that they are a key means of driving innovation. The current terms of protection periods are also a guarantee of the attractiveness of the EU as an important business location.
- This is all the more true in the current geopolitical situation. It would be a serious geostrategic mistake to recklessly jeopardise EU's competitiveness. The EU must work to ensure that intellectual property rights protection systems and pharmaceutical protection periods are not further weakened. This would be a fatal signal as it would lead to a decline in investment with negative consequences for EU patients. This must be avoided at all costs.

2. Access:

Directive:

- There must not be financial penalties for not bringing a medicinal product to all Member States. Article 56a(1) in conjunction with Article 206(1) is therefore unacceptable.
- A penalty for not placing a product on the market would be in serious conflict with Article 16 of the EU Charter of Fundamental Rights. The right to set prices freely and the principle of private autonomy expressed therein would be infringed upon under the current proposal.

- Moreover, in the current global context, such a sanction mechanism would send a devastating signal to industry. Applicants would have to think very carefully about the products they wish to place on the European market. The penalty mechanism would create significant financial risk and uncertainty for companies. This also directly harms patients in Europe.
- In contrast to financial penalties, the suspension of marketing protection as proposed in Article 56a(5) might be a reasonable compromise and a good way to increase access together with regulatory simplifications.
- In Article 166(5), it must be made clear that not only wholesalers, but also mail-order pharmacies or any other entity may not deliver the generic medicines to other MS. We suggest the following alteration: "… the wholesale distribution holder **or any person or entity engaged in sale at a distance of medicinal products**...". Otherwise pharmacies might exploit this loophole.

Regulation

- Article 5(1a) should be deleted. The provision in Article 56a is sufficient, and having corresponding provisions in both Directive or Regulation would raise complex legal questions.
- Annex II point 8a: Combined with Article 5(1a), this provision is entirely unacceptable for the reasons given regarding the Directive. Such a sanction is legally questionable and would be economically disastrous. In addition, it is impossible for companies to predict the amount of the sanction, which makes investment decisions much more difficult.

II. Further comments

Directive

Recitals

- 17: We request the deletion of the addition to the principle of voluntary and unpaid donations. It is incomprehensible why this one principle is randomly emphasised here. Furthermore, the addition is incorrect, as the aforementioned principle from the SoHO Regulation does not refer to bodies. The general reference to the SoHO Regulation should therefore be retained.

PUBLIC

- 18b new: We propose the insertion of a new recital 18b: With regard to the health aspects of the pharmaceutical package, a horizontal recital referring to Article 168 TFEU should be included. This is a common practice, see e.g. Regulation (EU) 2021/522, Regulation (EU) 2025/327 and Regulation (EU) 2024/1938.
- EG 63-65: see comments on Art. 85
- EG 70: see comments on Art. 47

Article 1 Directive – Subject matter and scope

- Paragraph 5 letter a - request for addition: EG 20a refers to 'instructions' by healthcare professionals, which can form the basis of a 'formula magistralis' preparation. However, this modality is not reflected in point (a). It should therefore be supplemented accordingly. Proposal: 'instructions of a qualified healthcare professional'.
- Paragraph 5 letter b - Amendment request: The previously envisaged provision should be retained with regard to the listing (i/ii/iii), sentences 3 and 4 should be deleted accordingly. In our view, paragraph 5 should essentially continue to define a framework for exceptions to the Directive and not create any further conditions for individual cases in the Directive. It goes without saying that a hospital pharmacy supplies its hospital with medicinal products and should not require any additional authorisation, even with regard to preparations manufactured in the pharmacy.
- Paragraph 5 letter d: We repeatedly call for the addition that SoHO should be covered by the Directive if they fall under the definition of a homeopathic medicinal product. It is incomprehensible why homeopathic medicinal products manufactured from SoHO should not be regulated, unlike all other homeopathic medicinal products. Proposed wording has already been submitted. This is an important issue for Germany.
- Paragraph 6a: see comment on paragraph 5 letter b; this proposal is duplicated here. It is self-evident that a hospital pharmacy supplies its hospital with medicinal products and should not require any additional authorisation, even with regard to preparations manufactured in the pharmacy

Article 3 Directive – Exceptions under certain circumstances

- Paragraphs 1-1b: In paragraph 1a, subparagraph 1, the words 'in that Member State or another Member State' should be deleted at the end. According to the second subparagraph, it is the availability in the Member State concerned that is important. As we understand it, the statement in subparagraph 1 contradicts this statement and should therefore be deleted.

PUBLIC

- We also suggest moving the new paragraph 1b to Article 1 paragraph 5.

Article 4 Directive – Definitions

- Number 39: The English language version refers to ‘medicinal prescription’ here, while the rest of the text refers to ‘medical prescription’. This was already the case in Directive 2001/83 and is probably simply an editorial error. In the DEU and FRA language versions of both Directive 2001/83 and the draft directive, the terms are congruent in the definition and in the regulatory section (‘medical prescription’, ‘prescription médicale’).

Article 9 Directive – Applications concerning generic medicinal products

- Paragraph 2: We ask once again for consideration of our amendment request that it should be a scientific justification as to why certain studies are not carried out.

Article 22 Directive – Environmental risk assessment and other environmental information

- Paragraph 7: We call for the proposal from the previous compromise text to be retained. Medicinal products authorised in accordance with Art. 9-12 should also be able to refer to ERA studies of medicinal products that are not the reference medicinal product but contain the same active substance.

Article 36 Directive – Mutual recognition procedure for national marketing authorisations

- Paragraph 4: Request for addition. For reasons of consistency with Article 34, we would like to point out once again that the following clarifying sentence should be included at the end of paragraph 4: ‘The Member State that requests to enter the mutual recognition procedure under this paragraph shall be considered as Member State concerned.’

Article 44 Directive – National marketing authorisation subject to conditions

- See Art. 47

Article 47 Directive – Refusal of a national marketing authorisation

- Regarding the environmental impact assessment: we have submitted a proposal together with the NL. It looks extensive, but does not deviate much from the previous proposal in terms of content and offers more legal certainty.

PUBLIC

- As stated in the previous WP, we believe that a MA should only be refused if deficiencies in the environmental risk assessment are not sufficiently substantiated. Instead, authorisation should be granted with the condition that the deficiencies must be rectified within a reasonable period of time.
- In our view, our proposal can ensure that authorisations are not delayed, but that the environmental risk assessment can still be demanded with the required binding force.

Article 51 Directive – Medicinal products subject to medical prescription

- Paragraph 2: For reasons of consistency, not only PBT substances, but also vPvB, PMT and vPvM substances should be mentioned in paragraph 2, analogous to paragraph 1 (f) (i) to (iv). We support the solution proposed by the Commission to include a reference to paragraph 1.

Article 68 Directive – Labelling and instruction leaflet of radionuclides and radiopharmaceuticals

- Paragraph 2: Sentence 1 should be deleted, as Article 65 is already applicable under the first sentence of Article 68(1). Sentence 2, which then becomes sentence 1, should be introduced with the words "In addition to Article 65...". The insertion "where necessary" should be deleted, as the information on the level of activity is always required.
- Paragraph 4: It should be clarified that the reference to Article 64 does not only concern its paragraph 1. To this end, sentence 2 should be deleted. Sentence 3, which then becomes sentence 2, should be introduced with the words "In addition to Article 64...".
- As in the heading, the term "instruction leaflet" is now used here, whereas the term "package leaflet" is used in Articles 63 and 64. The wording should be consistent.
- Addition to Annex V paragraph 13 (new): We propose the inclusion of a new paragraph 13:

  (13) for radiopharmaceuticals,

  1. the physical name of all radionuclides including radionuclide impurities contained in the radiopharmaceutical, their activity concentration and the time of determining the activity concentration, if relevant for disposal including clearance in accordance with Article 30 Council Directive 2013/59/Euratom, as appropriate, or
  2. the period of time after the date of calibration, after which the radiopharmaceutical including its potential maximum amount of radionuclide impurities can be cleared in accordance with Article 30 Council Directive 2013/59/Euratom, as appropriate.

PUBLIC

Justification:

- The new paragraph is intended to ensure that all accompanying nuclides are also declared in relation to radiopharmaceuticals. Although these are not relevant from a clinical point of view, they play an important role in correct disposal. The addition provides users with additional information.

Article 83 Directive – Medicinal products addressing an unmet medical need

- Paragraph 1: It should be clarified that a medicinal product only covers an unmet medical need if the disease is associated with a high morbidity or mortality. In this respect, the following should be added to the sentence: ‘relates to a life threatening or severely debilitating disease with a high morbidity or mortality’.
- Paragraph 1 letter (b): The letter should be deleted, as we want to avoid interference with HTA procedures. The danger is that a medicinal product addresses a high unmet medical need but cannot provide any comparative data. These would then no longer fall under the provisions' scope. The criterion of lack of availability mentioned in para. 1 point a is simpler, legally certain and should be sufficient.

Article 85 Directive - Bolar provision

Our position on the reform of the Bolar rule has not changed. The extension of the scope should be reversed. We fear that the Council text will create legal uncertainty. Moreover, given the current geopolitical situation, the competitiveness of the EU should not be jeopardised by further weakening of the level of protection of intellectual property.

We therefore reiterate our strong support for the adoption of the amendments we proposed during the last RAG Pharma.

From our point of view, it is particularly important that the Bolar rule does not refer to commercial activities and that legal certainty is guaranteed. Against this background, DEU finds it particularly problematic that

a. Article 85(1)(ab) refers to obtaining approval for pricing and reimbursement. We fear that this will (indirectly) influence the price and sales of the originator product during the period of protection, as potential buyers will be attracted to the generic product, which is likely to be cheaper. It is also likely to make it more difficult to assess whether there is a risk of patent infringement. At the very least, the deletion of the terms "obtaining" and "authorisation" in lit. ab) and in EC 63 is therefore essential from a German perspective.

PUBLIC

b. Art. 85 (1) lit. ad) further refers to "procurement tenders" ("submitting an application on procurement tenders, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale of the marketing of the medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate"). In our view, TRIPS compliance remains doubtful. In addition, there is considerable legal uncertainty regarding the assessment of imminent patent infringement. We therefore urgently request the deletion of subparagraph ad) and the corresponding comments in recital 63.

Article 135 Directive – Submission of dossier for traditional herbal medicinal product

- Paragraph 1: The current version does not match the heading. The deleted part of the sentence should be reinserted here.

Article 164 Directive – Requirements for a wholesale distribution authorisation

- Paragraph 2(a) asks for an explanation as to why it was decided to require the applicant to be established in the Member State and not in the Union as in the original text. The reference to the Union should remain here.

Article 166 Directive – Obligations of the wholesale distribution authorisation holder

- Paragraph 1 (g) (5): The COM's original proposal should be retained. The deletion leads to disproportionate effort compared to the benefits. The deletion means an obligation to record and document all non-prescription medicines for all customer groups. As a rule, this can only be carried out manually, resulting in an enormous amount of additional work.

Article 177 Directive – Restrictions on advertising of medicinal products

- In principle, there should be the possibility for MS to prohibit the advertising of particularly environmentally critical medicinal products at national level. A corresponding addition to Art. 177 would be desirable.

Article 188 Directive – System of supervision and inspections

- Paragraph 5 letter a: We request an explanation as to why the applicant for an import licence should not be included here. In our last written comments, we called for a corresponding addition and continue to demand this.

PUBLIC

Article 189 Directive – Cooperation on inspections

- Paragraph 2(b): We request the deletion of the last half-sentence 'unless otherwise ag-reed between the Member States' in order to exclude the possibility of a transfer of sovereignty between Member States.
- Paragraph 9: The paragraph has been moved here from Article 52 of the draft regulation. Please explain the last sentence. Does this mean that the Agency decides whether it supports or undertakes the inspection? If it is meant that it carries out the inspection itself, it must be made clear that this is only a 'last resort' solution, analogous to third country inspections, and that the corresponding conditions apply. We therefore reject the assumption of inspections by the EMA without any restrictions.

Article 193 Directive – Batch control of specific medicinal product by Member States

- Paragraph 1: We again request the inclusion of immunological medicinal products of biological origin, either as a new point (d) or in addition to point (c). For this type of immunological medicinal product, too, the Member States should be given the opportunity to test the quality experimentally by means of national batch testing. This does not impose an obligation on the Member States to implement the directive. Examples of this group of medicinal products are allergens and immune sera of animal origin. Due to their natural biological origin, these are characterised by a high degree of variability combined with a sometimes critical side-effect profile and are therefore particularly critical in terms of quality.

Article 207a new:

- DE can support the proposal submitted by NL.

Legal personality to HMA:

- DE opposes the proposal to give legal personality to HMA.

Article 218 Directive – Transitional provisions

- The monthly data for the period since entry into force should correspond to the data in Article 219.
- In para. 1, the point of reference for the start of validity should not be the validation but the pendency of the authorisation applications. This would be a legally effective connecting factor and would also lead to consistency with para. 2.

PUBLIC

- In our view, paragraph 6b contradicts paragraph 4 and should therefore be deleted.
- Paragraph 8: why is the paragraph necessary? Please provide an assessment COM.

Article 219 Directive – Transposition

- The transposition period should be 36 months. This applies at least to the provisions that require extensive changes to the laws and structures of the Member States.

Annex V + VI

- Annex V: Contents of SPC: If an environmental risk has been identified within the ERA, this information should also be included in the SPC. We request that this be added, e.g. in paragraph 5 (c) non-clinical safety data.
  For radiopharmaceuticals, see addition to Art. 68.
- Annex VI: Contents of Package Leaflet: If an environmental risk has been identified in the ERA that can be minimised by specific instructions for use (e.g. 'wipe instead of wash'), this should be stated in the PI. We request that this be added to paragraph 4 (b). Information on the proper disposal of medicinal product residues should be included not only in the SPC but also in the PI. We therefore request that this be added, e.g. in paragraph 6.
- Justification: The additions serve in particular to clarify matters and are in part already possible today. In our view, however, inclusion in the annex would create more clarity.

Regulation

Article 6 Regulation – Centralised marketing authorisation application

- Paragraph 2: We once again request the reintroduction of this paragraph with the limitation to 'for medicinal products that are intended to be used in relation to potential or declared public health emergency'. In the last WP, there was support for this from some MS and the COM was also in favour of this. We did not note that any MS were explicitly against the reintroduction.

Article 12 Regulation – Committee Opinion

- See Art. 47 Directive

Article 15 Regulation – Refusal of a centralised marketing authorisation

- See Art. 47 Directive

PUBLIC

Article 20 Regulation – Imposed post-authorisation studies

- Paragraph 1 lit. c: For reasons of consistency, the wording should be adapted to the other figurative articles in the draft directive and draft regulation. We have also communicated this in our last written comments and ask here again for examination and adaptation.

Article 26 Regulation – Medicinal products for compassionate use

- Proposed wording in paragraph 8: For reasons of legal certainty, 'during the period between authorisation and placing on the market' should be used instead of 'if necessary until the medicinal product is made available on the market of the Member State concerned'.

Article 40 - 43 Regulation

- DEU supports the FRA proposal for a priority authorisation assessment voucher. In our view, this represents a suitable incentive to promote the research and development of new antibiotics to combat priority pathogens on the WHO list. It may be worth considering adding extended dossier protection to the incentive, provided the antibiotic has received a marketing authorisation. As this is a new tool, an evaluation should take place after three PRVs have been issued. We also believe it is important that a PRV is only awarded once in vitro data proving efficacy against the targeted multi-resistant pathogens is available. It should also be ensured that the voucher can only be used once.

Article 46 Regulation – Variation of marketing authorisation

- Paragraph 1: additional risk minimisation measures should also be mandatory for holders of generic or biosimilar marketing authorisations if they are also mandatory for the reference product. Paragraph 1 should be supplemented accordingly: 'or if additional risk minimisation measures have been imposed concerning the reference medicinal product.'

Article 52 Regulation – Inspection capacity of the Agency

- Para. 6 lit. c: Reference to Directive required: 'in accordance with Article 160 of [revised Directive...]'. WE can support the proposal made by IE (mitigation of brain drain).

Article 54 Regulation – Joint Audit Programme

- Paragraph 1 point b: We are grateful for the partial adoption of our proposals. In our view, it should also be included that the working group supports rather than monitors the MS and the Agency in the follow-up of measures.

PUBLIC

- Paragraph 2: We had proposed an amendment to this, but it did not find its way into the compromise text. We therefore request that it be ensured that the assessment within the framework of the Joint Audit Programme ensures that the associated effort remains proportionate, even in Member States with more than one competent authority, so that the supervisory authorities can perform their routine tasks appropriately. We had submitted a proposal in this regard, which could also be included in a recital.

Article 60 Regulation – Enhanced scientific and regulatory support for priority medicinal products ('PRIME')

- Paragraph 1 lit. b: lit. b should be restricted to the extent that the illness is life-threatening or leads to severe disability. The PRIME procedure should be further limited to specific cases. This is also important in terms of the authorities' capacities. We raised this point last time and received support from many MS.

Article 117 Regulation – The shortage prevention plan

- Paragraph 1a: The preparation of an SPP is very time-consuming for an authorisation holder. A period of 12 months would be appropriate; we therefore request that the compromise text be amended accordingly.

Article 119 Regulation – Obligations on the marketing authorisation holder

- Paragraph 3a: The time limit for submitting the risk assessment to the competent national authority or the EMA is too short. Due to the various company structures and internal communication channels, at least 7 days (instead of 2 days) should be allowed for submission.

Article 120 Regulation – Obligations on other actors

- Paragraph 1a: We again request that the medicinal products be limited to certain medicinal products (Union list) or medicinal products with an SPP obligation (Article 117(1) Draft Regulation).
- Paragraph 1a lit. g: We are still of the opinion that the country of destination should not be mentioned, as this information is irrelevant and cannot be provided with sufficient certainty by the trader at the time of purchase.

PUBLIC

Article 130 Regulation (Role of the Agency) and Article 131 Regulation (The Union List of Critical Medicinal Products)

- The pharmaceutical package and the CMA should be harmonised with regard to the 'vulnerability analysis'. We have already submitted a proposal for this. We request that it be reviewed and adopted again. Other MS have also requested this change.

Article 134 Regulation – Role of the Commission

- We oppose implementing or delegated acts of the Commission. The powers of the MS to deal with shortages must be preserved.
- Technically, this can be implemented by deleting the Article entirely, except for para 1. Alternatively, para 2 can be retained, but with the key change that the Commission only has the right to issue recommendations.

Article 180 Regulation – Transitional provisions

- Paragraph 2: as already explained in the Directive, the connecting factor for the application of the old or the new legal situation should be exclusively the time of submission of the application for authorisation.

Article 181 Regulation – Entry into force

- The effective date should be 36 months after entry into force. For individual articles, such as RDP, an earlier effective date can be specified. For Articles that require adaptation at the national level, 36 months are required due to their complexity.

PUBLIC

HUNGARY

We would appreciate it if the Presidency could take into consideration the comments submitted.

Directive Article 4(36) – Definition of Active Substance Master File (ASMF)

It is possible that an active substance is manufactured at multiple production sites, while there exists only a single Active Substance Master File (ASMF), prepared by an administrative office that is not necessarily located at any of the manufacturing sites. This administrative office should act as the holder of the ASMF and assume ultimate responsibility for the active substance. Therefore, we recommend that the term *"manufacturer of the active substance"* be replaced by *"ASMF holder"* in the definition.

Annex I of the Directive – Point 13 (Information to be provided in the application)

In the absence of the introduction of a dedicated legal basis, such as a new Article "10b", allowing the registration of fixed-dose combinations of known substances under equivalent conditions, such products would fall under Article 6(2) and thus require a full dossier. In such cases, applicants should be allowed to refer to relevant published scientific literature. Accordingly, Annex I should be amended. Applicants cannot reasonably or ethically be expected to repeat animal or human studies solely to reproduce data that already exist and are documented in scientific publications.

Proposed addition to point 13: *"Where relevant, non-clinical and clinical data from other sources may be accepted as evidence, including non-interventional clinical studies, registries, and relevant published literature."*

Directive Article 218(1) and Regulation Article 180 – Transitional provisions

There is an inconsistency between Article 218(1) of the Directive and Article 180 of the Regulation regarding ongoing applications. All ongoing decentralised procedures should be completed under the existing legislation, in line with the approach proposed in the Regulation for ongoing centralised procedures. We recommend aligning the transitional provisions accordingly.

PUBLIC

IRELAND

Draft Directive

Compromise text dated 30/04/25

IE comments

PUBLIC

Article 1 Subject matter and scope

5. The Directive shall not apply to:

(a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula');

(b) medicinal product**s** prepared in a pharmacy ~~**('serving pharmacy') on a non-industrial scale and by a method not involving an industrial process**~~ in accordance with ~~a~~ ~~**European**~~ pharmacopoeia ~~**or with the pharmacopoeia of a Member State**~~ and intended to be supplied directly to ~~**any of the following**~~ the patients served by the pharmacy in question ('officinal formula')**:**~~;~~

~~**i) the patients served by the serving pharmacy in question;**~~

~~**ii) a hospital for dispensing directly to its patients;**~~

~~**iii) another pharmacy for dispencing directly to its patients.**~~

~~**The hospital and pharmacy listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;**~~

The exceptions under p~~**P**~~**oints (a) and (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/20**~~**2**~~**04].**

Member States may allow the supply of officinal formula by the pharmacy to a hospital it serves, subject to the agreement of the competent authority concerned.

~~**Where pharmacies operate in a Member State under common ownership, a Member State may allow the preparation of officinal formula at a central pharmacy, provided that the principles of subparagraph 1 are respected.**~~

……

Comment:

In general we believe significant improvements have been made to this article compared to the previous version. In line with a number of other MSs, we request the deletion of the last paragraph as a distinction based on common ownership of pharmacies in EU legislation is problematic and interferes with national legislation in relation to regulation of pharmacies. We do not agree with including a distinction in the types of activities allowed in pharmacies based on the model of ownership. In addition the reference to the principles of subparagraph 1 in the last paragraph is not clear.

Article 1 Subject matter and scope

1a. In justified cases a Member State may temporarily exclude from the scope of this Directive medicinal products prepared to mitigate or resolve a shortage in that Member State or to address a situation, where no authorised medicinal product is available in that Member State or another Member State.

The exception referred to in this paragraph shall apply only when no suitable medicinal product is authorised and available within that Member State or can be supplied in accordance with paragraph 1, and in the case of shortage, when the shortage in the relevant Member State cannot be resolved at that time through Union coordinated actions.

For medicinal products prepared in accordance with this paragraph Member States shall ensure that:

(a) the preparation of the medicinal product is approved by the national competent authority on the basis of a risk assessment;

(b) the approval under point (a) is revoked when the shortage is resolved or the medicinal product can be supplied in accordance with paragraph 1;

(c) in the case of no authorised medicinal product, that the approval is assessed annually for the necessity of the exemption;

(d) appropriate oversight by the national competent authority is in place and in particular any issues with regards to quality and safety are monitored and evaluated;

(e) the facility preparing the medicinal product complies with the requirements ~~equivalent to~~ the Good Manufacturing Practices referred to in Article 160;

(f) the quality, safety and efficacy of the medicinal product is confirmed by the national competent authority, or the medicinal products is prepared in accordance with a pharmacopeia or national monograph;

(g) the product is supplied to patients under the supervision of an authorised healthcare professional;

Comment:

The proposed text appears to envisage that NCAs take responsibility for medicinal products prepared in accordance with this exemption with references to "appropriate oversight by a national competent authority" and for the NCA to confirm "the quality, safety and efficacy" of the product. we question the feasibility of this approach outside of an authorisation procedure.

In addition, point (e) requires that the facility preparing the medicinal product complies with "requirements equivalent to the GMPs referred to in Art 160. The inclusion of the term 'equivalent' creates uncertainty as to the relevant manufacturing standards. If it is proposed that a site would be temporarily allowed to mass produce medicines to mitigate or resolve a shortage it would seem appropriate to expect the site to comply with relevant GMPs and to remove the term 'equivalent'.

*Article 148 Registration and ~~listing process of~~ **supervision of** decentralised sites*

....

2. The manufacturing authorisation holder of the central site shall request the competent authority of the Member State in which the decentralised site is established, to register the decentralised site.

   The competent authority of the Member State where the decentralised site is located shall not register the decentralised manufacturing site when the conditions set out in Article 26a paragraph 3 or 5 are not met.

Comment:

The reference to Art 26a Para 5 here still means that a decentralised site cannot be registered until a related MA has been granted, which does not seem workable in practice as the MA will only be granted when each manufacturing site is appropriately authorised (in the case of 'standard' manufacturing sites) or registered and included on the MIA for the central site (in the case of decentralised sites).

PUBLIC

Suggested text:

The competent authority of the Member State where the decentralised site is located shall not register the decentralised manufacturing site **until is has been established as part of a marketing authorisation application that the use of decentralised manufacturing is justified in line with Article 26a paragraph 1.** ~~when the conditions set out in Article 26a paragraph 3 or 5 are not met~~.

Article 162 Wholesale distribution of medicinal products

~~**2a. For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') share a common origin is essentially similar with the medicinal product already authorised in the destination Member State. Medicinal products are considered to be sharing a common origin essentially similar if they fulfil all the following conditions:**~~

~~**(a) they have the same qualitative and quantitative composition in terms of active substances and excipients;**~~

~~**(b) they have the same pharmaceutical form;**~~

~~**(c) they have the same clinical information; and**~~

~~**(d) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation.**~~

~~**(a) they consist of the same active substance or the same combination of active substances;**~~

~~**(b) they have the same strength;**~~

~~**(c) they have the same administration route;**~~

~~**(d) they have the same pharmaceutical form or a similar pharmaceutical form where the difference in the form does not result in differences with regard to the therapeutic effect of the medicinal product covered by the marketing authorisation in the destination Member State.**~~

Comment:

As reflected in our previous comments, we do not support the deletion of paragraph 2a. We believe that the discussions have highlighted the importance of bringing more consistency to the criteria applied for parallel trade and that rather than simply removing the paragraph and leaving this to case law, we should be seeking to provide clarity for all stakeholders. In conjunction with like minded MSs we will look to develop an amended proposal which we would kindly ask the PRES to consider.

Article 189 Cooperation on inspections

….

9. Following a request by a Member State, the inspectors of the Agency may provide support to that Member State when it performs inspections referred to in Article 78 of Regulation (EU) 536/2014. The Agency shall take a decision on whether to carry out such inspection.

Comment:

This paragraph has been moved and slightly amended from Article 52 of the Regulation. While we can agree to this provision in principle, we are concerned that the last sentence still reflects the original proposal whereby EMA would decide on the level of its involvement in an inspection and could decide to lead on the inspection even if only requested to assist by the Member State. We would request that this sentence be deleted or amended to be consistent with the revised approach described for other inspections. Clarification is still required in relation to any EMA involvement in GCP inspections.

Suggested text:

9. Following a request by a Member State, the inspectors of the Agency may provide support to that Member State when it performs inspections referred to in Article 78 of Regulation (EU) 536/2014. The Agency shall **consider whether it is in a position to provide the requested support.** ~~take a decision on whether to carry out such inspection.~~

Recital

Recital 18

(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and **then** used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption')…..

Comment:

ATMPs that avail of the hospital exemption are not fully excluded from the scope of the Directive. Art 2 of the Directive applies and includes specific requirements related to such products including a requirement for a hospital exemption approval and to comply with relevant manufacturing, traceability and pharmacovigilance requirements. The text should be amended to reflect the fact that this directive includes provisions which apply specifically in the event that the hospital exemption is used.

Suggested text:

18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and then used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should ~~be excluded from the scope of this Directive~~ **subject to a general exemption, while applying the rules specific to the 'hospital exemption'** ~~whilst at the same time~~ ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption').

Draft Regulation

Compromise text dated 30/04/25

IE comments

Article 6 Centralised marketing authorisation application

…..

2. For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement. The Agency shall inform the applicant accordingly.

…..

Comment:

As previously stated and supported by a number of other MSs, we do not support the complete deletion of paragraph 2 of Article 6 relating to phased reviews, and request that this Article be reinstated with an appropriately limited scope. We do not view the provisions relating to TEMAs as being sufficient in this regard.

Article 26 Medicinal products for compassionate use

…..

2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 or the submission of such application is imminent, or it must be undergoing clinical trials in the same indication.

Comment:

The rationale for the complete deletion of the second sentence of paragraph 2 (which is similar to text in Art 83 Para 2 of the existing Regulation) is unclear. This deletion could be used to significantly extend the timing and duration of compassionate use programmes and without further clarification could undermine the clinical trial and marketing authorisation processes.
If this text is being deleted due to the fact that compassionate use programmes may now cover new therapeutic uses of an authorised medicinal product it would be preferable to amend the text in a manner which addresses this scenario rather than completely delete the second sentence of paragraph 2.

Article 40 Granting the right to a transferable data exclusivity voucher

3. An antimicrobial shall be considered 'priority antimicrobial' if **it addresses a multi-drug resistant organisms** ~~**and**~~ **causing a severe** ~~**serious**~~ **or a life-threatening infection, and for which the** preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:

~~(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 **used either alone or in combination with other active substances** ~~not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.~~

Comment:

We understand from the discussions at the Council WP meeting that the word 'new' will be added immediately prior to 'active substance' in point (c), This will help to clarify the intention of point (c) but we would suggest that the overall intention of the article is considered. As only one of these characteristics currently have to be met, point (b) will become redundant as a new active substance will qualify under point (c) even if its mechanism of action is not distinctly different from that of a currently authorised antimicrobial.

Article 52 ~~*Inspection capacity of the Agency*~~ ***Cooperation between national competent authorities and the Agency for inspections in third countries***

…..

6. The Agency shall ensure that

(a) appropriate resources are made available for the performance of inspection tasks in accordance with the paragraphs 2**1** and 5**3**;

(b) the inspectors of the Agency possess expertise, technical knowledge, and formal qualifications equivalent to those of the national inspectors as detailed in the compilation, published by the Commission, on Union procedures on inspections and exchange of information.

(c) it **shall implement a quality system as provided for in Article 3 paragraph 3 of [the revised Directive 2017/1572], shall comply with principles of good manufacturing and good distribution practices in accordance with Article 160 and** participates as an inspectorate in the Joint Audit Programme and be subjected to periodic audits.

….

Suggested text / Previously proposed point (d):

(d) it reviews the composition of its inspectorate at 2 yearly intervals for the first 6 years after the application of this Regulation to ensure that the provision of appropriate resources is being developed without undermining the national competent authority inspection resources. If the report indicates that the Agency inspectorate is having a negative impact on national competent authority resources, they will develop a plan to ameliorate that impact.

PUBLIC

Comment:

IE along with a number of other MSs has previously expressed its reservations in relation to the proposal to establish an inspectorate within EMA and its potential impact on existing national inspectorates. We acknowledge the considerable improvements that have been made to the text to provide assurances in this regard but we would still have concerns that the establishment of the EMA inspectorate could see experienced inspectors move from national inspectorates to EMA which could lead to resource gaps in national inspectorates.

With this in mind we had proposed the addition of a new subparagraph (d) to Article 52 to ensure that this aspect would be kept under close review and that any negative impacts would be proactively addressed. Despite support from a number of other MSs this text has not been incorporated. We would ask for further consideration to be given as to how assurances can be provided on this important point for national inspectorates (taking into account that the need to avoid undermining national inspection resources is acknowledged in recital 24). We have amended the proposed frequency of the view with a view to avoiding an unnecessary administrative burden

Article 135 Establishment

The ~~functioning of the~~ European Medicines Agency established by Regulation (EC) No 726/2004 (the 'Agency') shall **be replaced and succeeded by the European Medicines Agency (the 'Agency') established by** ~~continue in accordance with~~ the present Regulation.

The Agency shall be responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.

Comment:

The original text was amended for legal reasons but we previously raised the possible need for provisions clarifying that the obligations, liabilities, assets and receivables of the EMA under 726/2004 are carried forward under this legislation We await the outcome of the discussions between the COM and Council legal services.

PUBLIC

Article 138 Objectives and tasks of the Agency

….

(l) ~~conducting~~ **participating in** inspections with Member States **at their request** to verify the compliance with the principles of good manufacturing practice, ~~including issuing GMP certificates~~ and **with** good clinical practice at the request of the Supervisory Authority referred to in Article 50(2) whenever additional capacity is needed to carry out inspection of Union interest including in response of public health emergencies;

…..

Suggested text

(l) participating in inspections with Member States at their request to verify the compliance with the principles of good manufacturing practice **at the request of the Supervisory Authority referred to in Article 50(2)** and with good clinical practice **at the request of the relevant Competent Authority** ~~at the request of the Supervisory Authority referred to in Article 50(2)~~ whenever additional capacity is needed to carry out inspection of Union interest including in response of public health emergencies;

Comment:

Point (l) provides for potential EMA involvement in GCP inspections. The text links this to a request from a supervisory authority but the concept of the supervisory authority in Art 50(2) is linked to imports and depends on the location of the manufacturers responsible for batch certification / release which is not linked to GCP.

We have proposed text to address this specific point but separately clarity is still needed on how any EMA involvement in GCP inspections would operate in practice.

Article 148 Committee for Medicinal Products for Human Use activities

….

4a. In the deliberations of the Committee for Medicinal Products for Human Use the committee shall take into account the opinion of Members appointed under paragraphs 3 (b) and (c), but only the Members appointed under paragraph 3.a. and 4 shall have voting rights.

…

PUBLIC

Comment:

As previously indicated, IE strongly disagrees with the proposal to not allow HCP and patient representatives to have voting rights in CHMP and we have a negative scrutiny reservation in relation to this text. We understand the concerns in relation to proportionality of votes but would consider that this would have been more appropriately addressed by reducing the number of votes for HCP and patient representatives rather than seeking to prevent them having any voting rights. We believe that this position will send the wrong signal in relation to how MSs view the input of HCPs and patients and does not take into account the contribution that such representatives have and continue to make at EMA and at national level.

PUBLIC

Recitals

Recital 26

~~An~~ **The** inspection working group**s**, which provides input and recommendations on all matters relating, directly or indirectly, to **good clinical practice,** good manufacturing practice**,** ~~and~~ good distribution practice **and good pharmacovigilance practice,** irrespective of the marketing authorisation procedure through different reporting lines, should be established within the Agency. In particular, that working group should be responsible for the establishment, development and overall supervision of the joint audit programme.

Suggested text:

An ~~The~~ inspection working group~~s~~, which provide~~s~~ input and recommendations on all matters relating, directly or indirectly, to ~~good clinical practice,~~ good manufacturing practice~~,~~ **and** good distribution practice ~~and good pharmacovigilance practice~~**,** irrespective of the marketing authorisation procedure through different reporting lines, should be established within the Agency. In particular, that working group should be responsible for the establishment, development and overall supervision of the joint audit programme.

Other working groups may be established to provide input and recommendations on all matters relating, directly or indirectly, to good clinical practice and good pharmacovigilance practice.

Comment:

The text of this recital is inconsistent. The first sentence indicates that there will be more than one inspection WG but the second sentence refers to a singular WG.

With thanks to colleagues for their cooperation on this draft on Article 162 (2 a), please see below an alternative approach to Parallel Trade (Art 162 (2a)) incorporating elements of the other proposals that have been made.

Art. 162 (2a)

For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') is identical or essentially similar with the medicinal product already authorised in the destination Member State. This can be ensured by demonstrating that the medicinal products share a common origin in accordance with national rules. A destination member state can refuse to permit the parallel trade of a medicinal product by a wholesale distributor from another Member State in case they consider that permitting such parallel trade would not respect the marketing authorisation rules established in this Directive ~~and Regulation [726/2004],~~ including the procedure for mutual recognition of national marketing authorisations.

PUBLIC

ITALY

Red-lines

A. **Articles 81** of the directive (*Duration of the data protection periods*): the Presidency proposal concerning the data protection periods **is not acceptable for Italy, which supports the status quo**, e.g.: 8 years of data protection, + 2 years pf market protection, +1 years of market protection for new indications → **Total 10 (+1).**

B. **Articles 56 a)** of the directive (*Specific requirements on making available supplying of a medicinal product in a Member State*) and **article 5, paragraph 1 a)** of the regulation (*Submission of applications for marketing authorisations*): the Presidency proposal **is not acceptable for Italy unless penalties will be expunged from the proposal**. Applying article 56 a) without a sanction is a first step towards moral suasion to grant access to medicines. Additionally, any non-compliance thereof may lead to reputational damage, if made public.

C. **Chapter III** of the regulation (*Incentives for the development of "Priority Antimicrobials"*): the Presidency proposal **is not acceptable for Italy**, which has strong concerns over the transferable data exclusivity voucher, that is not an ideal instrument to promote research & development in antimicrobials resistance (AMR). Indeed, Italy is available to evaluate other alternatives, that provide sufficient support to the research & development while being cost-effective.

D. **Article 148** of the regulation (*Committee for Medicinal Products for Human Use activities*): **Italy supports the participation of patients, with their right to vote, in the EMA's decision-making and therefore** the Presidency proposal **is not acceptable**. This participation has already been experienced in other committees over the past two decades, providing a valuable contribution to scientific discussions and decisions. However, since the representation of Member States at the EMA is expected to be reduced also following the suppression of some of the current committees, Italy proposes to reduce the number of patients' and healthcare professionals' representatives with voting rights **from 4 to 2 each**, in order to restore a fair balance. This would be in line with the representation of these actors in the EMA Management Board as well as in PRAC.

PUBLIC

In addition to the above, Italy identified **other remaining aspects** in the proposals that Italy asks to the Presidency to consider.

PUBLIC

Proposal of a directive

Article 1 (*Subject matter and scope)*

With respect to the amendments introduced, Italy has a scrutiny reservation.

Article 3 (*Exceptions under certain circumstances)*

With respect to the amendments introduced, Italy deems that there is a need to strengthen the control mechanisms, clarify the conditions for triggering exceptions and ensure a minimum of consistency between national regulations and EU standards. Only in this way will it be possible to reconcile flexibility and integration, urgency and patient protection.

Article 4 (*Definitions*)

PROPOSED AMENDMENT:

*(20) 'kit **for radiopharmaceutical preparation**' means ~~**any preparation**~~ **a medicinal product** to be ~~reconstituted or~~ combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.*

COMMENT: The definition should be amended as proposed because the kit is one of the four forms of a radiopharmaceutical. Therefore, it can be considered a medicinal product *per se*. It is not correct to refer to a mere reconstitution, since reconstitution is a simple operation that does not change the quality attributes of the medicinal product. Conversely, the marking has such an impact on the medicinal product that it requires the carrying out of a series of regulatory checks that would not be necessary in the case of a mere reconstitution (new specifications, analytical methods, stability data, etc.).

Article 25 (*Active substance master file certificate*)

PROPOSED AMENDMENT:

*1. Marketing authorisation applicants ~~may~~ **should**, instead of submitting the relevant data on a chemical active substance of a medicinal product required in accordance with Annex II, rely on ~~**an active substance master file**~~, an active substance master file certificate granted by the Agency in accordance with this Article ('active substance master file certificate') or a certificate confirming that the quality of the active substance concerned is suitably controlled by the relevant monograph of the European Pharmacopeia.*

~~*Marketing authorisation applicants may only rely on an active substance master file if no certificate exists on the same active substance master file.*~~

2. An active substance master file certificate ~~***may***~~ ***should*** *be granted by the Agency in cases where* ~~***the relevant data on***~~ *the active substance concerned is not already covered by a monograph of the European Pharmacopeia* ~~***or by an active substance master file certificate.***~~

[...]

COMMENT: Italy deems that only **two** options should be allowed regarding the ASMF to avoid duplications of work and potentially differing outcomes:

1. Reference to the Active Substance Master File Certificate issued by the EMA in the case of active substances not included in the European Pharmacopoeia
2. Possibility to refer either to the Active Substance Master File Certificate issued by the EMA or to the CEP issued by EDQM in the case of active substances included in the European Pharmacopoeia.

This approach would contribute to remove an extra layer of complexity, optimise the use of already strained Network resources, and ensure harmonisation.

Article 85 (*Exemption to the protection of the intellectual property rights*)

PROPOSED AMENDMENT:

1. […] ~~***(ad) submitting an application on procurement tenders, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale of the marketing of the patented medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate.***~~ […]

COMMENT: Italy supports the harmonization of the scope of the Bolar clause and the Commission proposal was in line with our legislative framework. Therefore, Italy could support the Presidency proposal provided that the possibility of "submitting an application on procurement tenders", set out by paragraph 1 lett. ad) will be expunged from the proposal.

Article 96 (*Member State pharmacovigilance system*)

PROPOSED AMENDMENT:

1. […] The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards health of the patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with ***medication errors and*** *occupational exposure.*

COMMENT: Italy proposes to insert also the reference to “medication errors" in line with the definition of “adverse drug reactions”.

Article 135 (*Submission of dossier for traditional herbal medicinal product*)

PROPOSED AMENDMENT:

1 The ~~applicant and the~~ **~~the~~ holder of the traditional herbal ~~homeopathic~~ medicinal product registered through the simplified procedure ~~simplified registration~~ registration ~~holder of the~~** ~~traditional use~~ **~~herbal medicial product~~** ~~registration holder~~ shall be established in the Union. […]

COMMENT: Italy proposes a formal amendment to correct the text of the article. Subsequent amendments should be introduced in line with this correction in article 136, paragraphs 2 and 3.

Proposal of a regulation

Article 2 (*Definitions*)

PROPOSED AMENDMENT:

Article 2 - Definitions: *(14) ‘shortage’ means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State* ***for a duration of at least two weeks****.*

COMMENT: Italy proposes to improve the definition of shortage by coordinating the same with other articles of the regulation, such as article 116.

Article 26 (*Medicinal products for compassionate use*)

PROPOSED AMENDMENT:

4. *When compassionate use is envisaged by* ***~~a~~ more than one*** *Member State, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution* ***~~and~~,*** *the patients targeted* ***and the conditions of monitoring****. The opinions shall be updated where necessary. In the preparation of the opinion, the Committee for Medicinal Products for Human Use may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The Committee may also make use of health data generated outside of clinical studies, where available, taking into account the reliability of those data.*

PUBLIC

Article 127 (*Identification and management of critical medicinal products by the competent authority of the Member State*)

PROPOSED AMENDMENT:

1. *The competent authority of the Member State shall identify critical medicinal products in that Member State, **also by** using the methodology set out in Article 130(1), point (a).*

Article 177 (*Amendments to Regulation (EU) No 536/2014*)

PROPOSED AMENDMENT:

If Article 177 cannot be deleted in its entirety, in the spirit of compromise, Italy would request the following amendments to paragraphs 4, 5, and 7.

[…]

*4. The **Committee for Medicinal Products for Human Use (CHMP) referred to in Article 148 (revised Regulation No (EC) 726/2004] Reporting Member State** shall assess the ERA referred to in paragraph 1 in the form of a scientific opinion. The **CHMP RMS** shall submit its opinion to the competent authority of the Reporting Member State within 45 38 days from the validation date referred to in Article 5(3). Where appropriate, the opinion shall include risk mitigation measures. The sponsor shall provide evidence to the Reporting Member State and the Member States Concerned that these measures will be implemented.*

*5. The **CHMP RMS** may request, with justified reasons, via the EU portal (CTIS) additional information from the sponsor regarding the assessment referred to in paragraph 1, which shall be provided only within the period referred to in Article 6, paragraph 5.*

*6. To obtain and review the additional information referred to in paragraph 65, the **Agency RMS** may extend the period referred to in paragraph 5 by a maximum of 31 days. The sponsor shall submit the requested additional information within the period set by the **Agency RMS**. Where the sponsor does not provide additional information within the period set by the **Agency RMS**, the application referred to in paragraph 1 shall be deemed to have expired in all Member States concerned. The **Agency RMS** shall inform the **reporting Member State via the CTIS and the** Member States concerned **via the CTIS** about the extension of the period referred to in paragraph 5 in accordance with this paragraph as well as the period set for the sponsor to submit the requested information.*

PUBLIC

7. In case of first-in-class products or when a novel question arises during the assessment of the submitted ERA as referred to in paragraph 1, the ~~***Agency***~~ ***RMS*** *shall* ~~*may , if as*~~ *necessary**,** consult with bodies that Member States have set up in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the European Parliament and of the Council**. If a consultation is necessary, the technical dossier addressing in sufficient detail the information specified in Annex III to Directive 2001/18/EC should be included to support the ERA where appropriate.*
Please note that Article 138, c.1, point (ca) should be amended accordingly.

COMMENT: This article introduces an extra layer of complexity in a procedure that is already structured enough. It also introduces an additional assessment body (the CHMP) other than the Reporting Member State and concerned Member States. However, it should be noted that such body has no mandate either over clinical trials (for which MSs and not EMA are directly responsible) or academic trials. Additionally, if the provision were to be implemented, a new CTIS functionality should be developed. This would further overload a management system, which is already quite burdened. Italy also considers that CHMP is already heavily overburdened, and will be more so after assuming the competences previously attributed to committees that will be suppressed.

PUBLIC

MALTA

Comments by Malta on the Consolidated version of the Pharmaceutical Package

PUBLIC

Regulation
Article 120(1a)

MT reiterates its reservations on the legal soundness of the proposed Article 120(1a). These doubts were explained in document WK 14978/2024 ADD 2.

MT also has reservations on the legal soundness of the proposed framework. As explain on various occasions Malta has concerns on the fragmented Market in particular, when it comes to the Decentralized Procedure and to the Mutual Recognition procedure. This fragmentation should work for all Member States. In practice this means that all Member States should have access and security of supply to medicines.

The current text appears to direct access of medicines to Malta through Article 205 of the directive, which however falls within the scope of Article 120(1a), thereby undermining the directed source of access to MT.

Considering that MT is the only Member State which appears to have this issue, the following derogation for Malta could be included within the text:-
New paragraph
The information system and the measures introduced under paragraph 1a shall not apply to cross border distribution of products holding a Marketing Authorization issued under article 205 of Directive XXXX to Malta. Malta shall ensure that these products do not leave its territory

Directive
The BREXIT derogation under Directive (EU) 2022/642 was intended to bridge Malta, Cyprus and Ireland to the new pharmaceutical framework. However, the conclusion of the negotiations on the new framework will be at a much later date than envisaged in 2022, when Directive (EU) 2022/642 was negotiated.

The transposition of the new framework is also likely to be longer than the 18 months proposed by the Commission. It is important a viable solution in in place when the derogation comes to an end.

MT holds that the date referred to in Article 211 of the proposed Directive should be aligned with the date of implementation of the new framework.

PUBLIC

THE NETHERLANDS

PUBLIC

We hereby send the additional written comments in light of the discussions during the Council Working Party meetings. For the Netherlands the possibility to redispense medicinal product is a political issue, addressing sustainability and alleviating health budgets. The practice has great support from Dutch patients, pharmacists and prescribers.[1]

We thank the broad support of MS. We would also like to thank the delegations that shared their concerns. We hereby would like to take the opportunity to elaborate on these issues:

- **Safeguards for quality and safety:** multiple measures can be implemented to assure the quality of redispensed medicines, through both the delegated act on EU-level and in additional national requirements:
    - Dispensed medicines are placed in a sealed bag.
    - The sealed bag ensures that the validated temperature logger is always with the dispensed medicinal product to ensure reading the right storage information.
    - The sealed bag ensures that the original package with anti-tampering device of the MAH is intact.
    - The pharmacist checks the sealed bag, temperature logger, the package and the remaining shelf life.
- **Minimal risk for counterfeit medicinal products**:
    - Dispensed medicines are in a sealed bag to ensure the same, untampered medicinal product is given back to the pharmacist, only a medicinal product in an unopened bag can be redispensed.
    - The medicinal product can only go back to the same pharmacist and redispensed from this pharmacist to his own patients: there is a closed loop.
    - The status of the decommissioned unique identifier of the medicinal product will not be reversed in the EMVS: the medicinal product cannot re-enter the distribution chain and stays in the same Member State.
    - Please note that under the proposed alternative of the delegated regulation, products would re-enter the EMVS, and could cross borders.
- **Administrative burden on pharmacists**
    - The support for redispensing from the field, also from pharmacists, is strong.

[1] Please see the supporting position of a multidisciplinary group of representatives of pharmacists, doctors, nurses and patients: Startpagina - Standpunt Heruitgifte van orale oncolytica - Richtlijn - Richtlijnendatabase

- In fact, when expanding the scope of the pilot, a notary had to do a lottery to assign new eligible (hospital)pharmacies, since there were too many pharmacies that signed up.
- Initial experience with the pilot indicates that the extra procedural steps for redispensing that need to be taken by pharmacists, are not viewed as potential barriers by pharmacists.
- Furthermore, exploratory discussions are being held with health insurers, to see how the necessary time investments should be dealt with, for instance through shared savings models. However, this can only be further developed when redispensing is legally allowed.

- **No effect on other Member States:**
  - Our proposal is a "may" provision. We acknowledge that redispensing medicinal products like in the Netherlands is not suitable for all Member States. Member States decide whether or not to allow redispensing in their country.
  - With only amending Delegated Regulation 2016/161 (safety features), a medicinal product will re-enter the distribution chain, with the possibility to go to other MS. As stated before, our proposal limits redispensing to within the same MS.
- **Legal basis**
  - We need a legal basis in EU legislation for national practices, to deviate and supplement to certain articles (DIR 58, 67(2) and 4(1)) to avoid legal actions based on claims of infringement.
  - The route of the delegated regulation is not legally sound, as it is limited to the safety features. Allowing redispensing this way, would effectively be an alteration of <u>essential elements</u> of the basic act, which is not allowed.

Proposal NL: redispensing of specific unopened medicinal products

The Netherlands has shared its proposal on redispensing of unopened medicinal products, limited to specific medicinal products suitable for redispensing. We have taken note of the concerns of other Member States and notes of the Commission and tried to address those in this document.

A. Goal of the proposal

To create a legal basis to allow each Member State to decide on national level whether or not to allow redispensing of specific unopended medicinal products under strict conditions within its own territory. If necessary a Member State can set additional conditions. (See Box 1: Proposed legal text.)

- Redispensing is benificial for the environment due to less medicinal waste, can address shortages and alleviate healthcare budgets.
- The Dutch ROAD-study[2] showed that:
    - Redispensing of oral anticancer drugs reduced waste by 68.1% compared with the standard practice of disposal.
    - Redispensing of unused oral anticancer drugs provides mean net annual cost savings of US $680 to $1.591 per patient**.**

PUBLIC

B. Need to amend Directive 2001/83/EC

Only amending Delegated Regulation 2016/161 (safety features) seems insufficient. That route poses risks *for other Member States*: the status of the decommissioned unique identifier of the medicinal product would be reversed in the European Medicines Verification System (EMVS), and as such the medicinal product would re-enter the distribution chain. That way, returned medicinal products could cross borders. The Netherlands proposes a closed loop at the end of the distribution chain, from pharmacy to patient and back to the same pharmacy with sufficient safety measures (as tested in the ROAD-study[1]).

C. Safety

Safeguards for quality and safety of redispensed medication

The medicinal product is given to the patient:

(1) in the original package with anti-tampering device of the Marketing Authorization Holder (MAH);

(2) labelled with the dispensing date;

(3) in a sealed bag containing a temperature logger.

This way safeguards for the right light, humidity, temperature conditions and prevention of possible tampering are in place. Only returned packages that are still in the unopened sealed bag with the temperature logger are allowed to be redispensed after safety and quality checks by the pharmacist. (See Box 2: Pilot redispensing in the Netherlands.)

Minimal risk of introducing counterfeit medicinal products into the distribution chain

[2] Smale EM, van den Bemt BJF, Heerdink ER, et al. Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs: The ROAD Study. JAMA Oncol. 2024;10(1):87–94. doi:10.1001/jamaoncol.2023.4865

The Netherlands thinks redistribution doesn't increase the risk of introducing counterfeit medicinal products into the redistribution chain. The status of the decommissioned unique identifier of the medicinal product will not be reversed in the EMVS and as such the medicinal product can not re-enter the distribution chain. The involvement of the pharmacist via the closed-loop from the same pharmacy of the initial dispensing and the safety measures and checks further guarantee that counterfeit medicinal products will not enter the distribution chain.

PUBLIC

D. Liability and responsibility

During the ROAD-study that is performed in the Netherlands since February 2021, more than 3.700 patients were included in the trial for 12 months. There have been no complications, thus also no issues of liability. Patients are informed in advance about the procedure and safety and quality checks the pharmacist performs. The pharmacist is responsible for the execution of the protocol and the safety and quality checks.

Box 1: Proposed legal text

Article 207a Directive 2001/83/EC

Redistribution to the public of unused medicinal products

1. By way of derogation from and supplement to Article 58 and the delegated acts referred to in Article 67(2), the Commission shall adopt delegated acts in accordance with Article 215, laying down the conditions under which Member States may designate medicinal products which, after having been supplied to the public and taken back, may be supplied again to the public and shall not be regarded as falsified medicinal products as referred to in Article 4(1), fiftieth subparagraph, introductory sentence and point (c).
2. Medicinal products may only be supplied again to the public in the territory of the Member State where the pharmacy that initially supplied the medicinal product to the public, is established.
3. Member States can set additional restrictive conditions under which medicinal products may be supplied again to the public in their territory.

Explanation

In the delegated acts, the Commission could set conditions like:

1) the authenticity and quality of the product can be guaranteed,

2) the products can only be redispensed to the public by the pharmacy that initially supplied the medicinal product to the public,
3) the member state may set additional conditions, and
4) the products should under no circumstances be allowed to re-enter the regulated pharmaceutical supply chain.

PUBLIC

Box 2: ROAD-study redispensing in the Netherlands

Redispensing is only allowed for a specific group of stable medicinal products which are suitable for safe redispensing (oral anticancer drugs).

Initial dispensation of the medication

- The patients are informed about the intended use of the medication and asked to return the medication to the pharmacy once they no longer use it.
- The patients receive medication in the original package with anti-tampering device, labelled with the dispensing date in a sealed bag together with a time-temperature logger.
- The medication is verified in the EMVS and the unique identifier is decommissioned.

Process after the patient has returned the medication

- Redispensing is only possible through the same pharmacy that initially dispensed the medication.
- The pharmacist checks the returned medication and ascertains that:
    - the primary and secondary packaging is original, unopened and intact
    - the expiration date has not been exceeded
    - the package has been stored under the right conditions by reading the temperature logger.
- If the pharmacist confirms the quality of the returned medication, the medication can be redispensed to another patient who has given his informed consent.

SPAIN

DIRECTIVE

Article 1.5 Subject matter and scope

The new wording is adequate, however, the details of these two texts are unnecessary and not suitable for all countries. We request the ***deletion*** *of them:*

- *Member States may allow the supply of officinal formula by the pharmacy to a hospital it serves, subject to the agreement of the competent authority concerned.*

- *Where pharmacies operate in a Member State under common ownership, a Member State may allow the preparation of officinal formula at a central pharmacy, provided that the principles of subparagraph 1 are respected.*

It should be left for development in national legislation.

Article 2 Advanced therapy medicinal products prepared under hospital exemption

Due to the fact paragraph 3 of article 2 makes reference to good manufacturing practices, traceability and pharmacovigilance, we request to ***delete*** *the word "pharmacovigilance" in order both paragraphs are consistent.*

"4. Member States shall ensure that data on the use, **such as the number of patients and product administrations,** safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported **in an aggregated manner** by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the ~~**pharmacovigilance**~~ requirements referred to in paragraph 3."

Article 4 Definitions

(67a) 'manufacture of medicinal products' means any total or partial operation as part of the process of bringing the active substance(s) and excipient(s) to a medicinal product, including in particularbut not limited to processing, filling, sterilisation, assembly, immediate and outer packaging, and repackaging, storage, quality control testing ***certification,*** ~~***and***~~ *release* ***and import*** *of the medicinal product*

It is important to include in the definition of manufacturing of medicinal product the activities of certification and import because they are part of the guideline of Variations.

Article 74 Requirements on languages

1. The particulars for labelling listed in Articles 64 and **to** 65**6**, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State~~**, as well as in the English language in the electronic version of the package leaflet**~~.

Language requeriment is part of the national procedure and a principle of subsidiarity; it cannot be an obligation for Member States.

Article 162 Wholesale distribution of medicinal products

Art. 162 (2a) For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') is identical or essentially similar with the medicinal product already authorised in the destination Member State. This can be ensured by demonstrating that the medicinal products share a common origin in accordance with national rules. A destination member state can refuse to permit the parallel trade of a medicinal product by a wholesale distributor from another Member State in case they consider that permitting such parallel trade would not respect the marketing authorisation rules established in this Directive and Regulation [726/2004], including the procedure for mutual recognition of national marketing authorisations.

Recital (xx) For the purposes of parallel trade in medicinal products, the wholesale distributor shall ensure that the medicinal product it intends to obtain from a Member State ('source Member State') and distribute in another Member State ('destination Member State') share a common origin. Medicinal products can be considered to be sharing a common origin if they fulfil criteria such as same qualitative and quantitative composition in terms of active substances and excipients; same pharmaceutical form; same or similar clinical information; same manufacturer or a manufacturer working under licence according to the same formulation; same active substance or the same combination of active substances; same strength; same administration route; same pharmaceutical form or a similar pharmaceutical form where the difference in the form does not result in differences with regard to the therapeutic effect of the medicinal product covered by the marketing authorisation in the destination Member State; same legal basis.

Article 200 Competent authorities of the Member States

We support the inclusion of HMA with legal basis status as part of legislation and accordingly to modify Article 162 and 178 of Regulation.

1. Member States shall designate the competent authorities to carry out tasks under this Directive.

2. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].

3. The competent authorities of the Member States shall cooperate with each other and with the Agency and the Commission in the performance of their tasks under this Directive and [revised Regulation (EC) No 726/2004] to ensure proper application and due enforcement. The competent authorities of the Member States shall transmit to each other all necessary information.

3A. ***In order to support and facilitate the cooperation, the coordination, and the exchange of information among the competent authorities, to foster an effective and efficient European medicines regulatory system [and to achieve a high level of public health protection and a high common level of availability and accessibility, of medicinal products in the Union], a Heads of Medicines Agencies Group (the Group) is hereby established.***

3B. The Group shall be composed of representatives of Member States Competent authorities at senior level. Where appropriate, the Group may invite experts, representatives of the Commission, the Agency, the relevant stakeholders, authorities and bodies to participate in its work.

3C. The Group shall be supported by a management group and a permanent secretariat.

3D. The Group shall lay down the arrangements necessary for the functioning of the Group and shall agree on its rules of procedure. The group is supported by working groups and allowed to run or participate to any kind of project.

4. The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.

Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.

4B. The Group may process personal health data from sources other than clinical studies to support and facilitate the cooperation, the coordination, and the exchange of information among the competent authorities and for the purpose of fostering an effective and efficient European medicines regulatory system [and achieving a high level of public health protection and a high common level of availability and accessibility, of medicinal products in the Union].

Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.

Chapter X Homeopathic medicinal products and traditional herbal medicinal products

Our view in general is that these products should not be in the pharmaceutical legislation and rather should be covered under a separate legal act.

We can be flexibles in the triologues and it could be possible to adjust the terminology and to drop ´medicinal´ as in the EP proposal.

REGULATION

Article 6: Centralised marketing authorisation application

1. For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, **are intended to be used in relation to potential or declared public health emergency** the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement. The Agency shall inform the applicant accordingly.

We request this paragraph to be part of the Regulation document as stated in COM proposal. This is a key tool as per experience acquired during COVID pandemia.

Art 25 Duplicate marketing authorisations

1. Only one marketing authorisation may be granted to an applicant for a specific medicinal product.

By way of derogation from the first subparagraph, the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product in either of the following cases:

*(a) if one of its indications or pharmaceutical forms**, methods or routes of administration ~~or any other way in which the medicinal product may be used~~** is protected by a patent or a supplementary protection certificate in one or more Member States;*

*To include the following sentence in order to be consistent with Article 4: "**~~or any other way in which the medicinal product may be used~~** "*

Article 26 Medicinal products for compassionate use

2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product. ~~The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 or the submission of such application is imminent, or it must be undergoing clinical trials in the same indication.~~

It is extremely important to mantain the COM proposal to guarantee having some evidence of safety and efficacy of the compassionate use medicinal product.

Article 50: Supervisory authority

To include this article mantaining the figure of "importer" instead of holder of the manufacturing authorisation because *from a regulatory point of view, a 'holder of the manufacturing authorisation that performs the certification' is equivalent to 'importer'.*

2. In the case of medicinal products imported from third countries, the supervisory authorities for imports shall be the competent authorities of the Member State or Member States that granted the authorisation referred to in Article 142(43) of [revised Directive 2001/83/EC] to the **importer** ~~**or the holder of the manufacturing authorisation**~~, unless appropriate agreements have been made between the Union and the exporting country to ensure that those controls are carried out in the exporting country and that the manufacturer applies

Article 148 Committee for Medicinal Products for Human Use activities

We support "Healthcare Proffesionals`Organisations" and "Patient Organisations" have voting rights but with a more proportionated composition 2+2, according to the EU Pharmaceutical Strategy which aims a competitive and transparent regulatory framework. Patients should have a voice in the regulatory decision-making processes that will empower the system with a multiple perspective, improved transparency and trust and more efficient and equitable health policies.

1. The Committee for Medicinal Products for Human Use shall be responsible for drawing up the opinion of the Agency on any matter concerning the admissibility of the files submitted in accordance with the centralised procedure, the granting, variation, suspension or revocation of an authorisation to place a medicinal product for human use on the market in accordance with the provisions of this Chapter, ~~and~~ pharmacovigilance **and scientific advice**. For the fulfilment of its pharmacovigilance tasks, including the approval of risk management systems and monitoring their effectiveness provided for under this Regulation, the Committee for Medicinal Products for Human Use shall rely on the scientific assessment and recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 142, point (e).
2. In addition to their task of providing objective scientific opinions to the Union and Member States on the questions which are referred to them, the members of the Committee for Medicinal Products for Human Use shall ensure that there is appropriate coordination between the tasks of the Agency and the work of competent national authorities, including the consultative bodies concerned with the marketing authorisation.
3. The Committee for Medicinal Products for Human Use shall be composed of the following:
   (a) one member and one alternate member appointed by each Member State, in accordance with paragraph 6;
   (b) ~~four~~ **two** members and ~~one~~ **four** **two** alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals**' organisations**;
   (c) ~~four~~ **two** members and ~~four~~ **two** alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

4. The Committee for Medicinal Products for Human Use may co-opt a maximum of **seven** ~~five~~ additional members chosen on the basis of their specific scientific competence. Those members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

With a view to the co-opting of such members, the Committee for Medicinal Products for Human Use shall identify the specific complementary scientific competence of the additional member or members. Co-opted members shall be chosen among experts nominated by Member States or the Agency.

~~**4a. In the deliberations of the Committee for Medicinal Products for Human Use the committee shall take into account the opinion of Members appointed under paragraphs 3 (b) and (c), but only the Members appointed under paragraph 3.a. and 4 shall have voting rights.**~~

5. The alternates shall represent and vote for the members in their absence and may also be appointed to act as rapporteurs in accordance with Article 152.
Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human use as appropriate and shall represent the competent authorities of the Member States.

6. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed on the basis of their relevant expertise in the assessment of medicinal products which should cover all types of medicinal products covered by [revised Directive 2001/83/EC] and this Regulation and which include medicinal products for rare and paediatric diseases, advance therapy medicinal products, biological and biotechnological products, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. **This expertise shall also cover the environmental risk assessment.** The Member States shall cooperate in order to ensure that the final composition of the Committee for Medicinal Products for Human Use provides appropriate and balanced coverage of all scientific areas relevant to its tasks taking into account scientific developments and new types of medicinal products. For this purpose, Member States shall liaise with the Management Board ~~and the Commission~~.

PUBLIC

7. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed for a term of th**r**ee years, which may be renewed following the procedures referred to in paragraph 6. The Committee shall elect its chairperson and vice-chairperson from among its members for a term of 3 years, which may be prolonged once.

8. The Committee for Medicinal Products for Human Use shall establish its own rules of procedure.

These rules shall, in particular, lay down:

(a) procedures for appointing and replacing the chairperson;

(b) procedures relating to working parties and scientific advisory groups; and

(c) a procedure for the urgent adoption of opinions, particularly in relation to the provisions of this Regulation on market surveillance and pharmacovigilance.

They shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Article 150: Scientific working parties and scientific advisory groups

The Committee ***shall*** ~~*may*~~ *establish an Environmental Risk Assessment working party*, ***working parties with scientific expertise on paediatric medicinal products and orphan medicinal products*** *and other scientific working parties, as necessary.*

We request a "shall" rather than a "may" provision to ensure the effective creation of the working groups related to paediatrics medicines and orphan medicinal products.

Article 162 Consultation process

In order to guarantee a proportionated and properly regulated wholesale distribution of medicinal product with the European Union and to be alligned with Article 2002 (DIR).

1. The Agency shall establish a consultation process with relevant national authorities or bodies for the exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency, in particular guidelines on unmet medical needs and the design of clinical trials, other studies and the generation of evidence along the life cycle of medicinal products.

PUBLIC

The consultation process shall include **the** ***Heads of Medicines Agencies Group and*** bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 and national bodies responsible for pricing and reimbursement.

The conditions of participation shall be set by the Management Board in agreement with the Commission.

2. The Agency may extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders, as relevant.

Article 178 A (Regulation) Amendments to Regulation (EU) 2019/6

We support the inclusion of HMA with legal basis status as part of legislation and accordingly to modify Article 200 (DIR) and Article 178 (REG) Regulation (EU) No 2019/6 is amended as follows:

1. In Article 137, the following paragraphs are inserted :

‘**3A.** ***In order to support and facilitate the cooperation, the coordination, and the exchange of information among the competent authorities and with a view to foster an effective and efficient European Medicines Regulatory system [and to achieving a high level of protection of animal health, animal welfare and environment and safeguarding public health and a high common level of availability, accessibility, of medicinal products in the Union], a Heads of Medicines Agencies Group (the Group) is hereby established.***

3B. The Group shall be composed of representatives of Member States Competent authorities at senior level. Where appropriate, the Group may invite experts, representatives of the Commission, the Agency, the relevant stakeholders, authorities and bodies to participate in its work.

3C. The Group shall be supported by a management group and a permanent secretariat.

3D. The Group shall lay down the arrangements necessary for the functioning of the Group and shall agree on its rules of procedure. The group is supported by working groups and allowed to run or participate to any kind of project aimed at supporting and facilitating the cooperation, the coordination and the exchange of information among its members and with the Commission, the Agency and other relevant bodies.’

PUBLIC

SWEDEN

PUBLIC

General comments

Red lines for SE

- **Article 81 D: RDP – we want to keep 8 years as basic RDP, status quo.**

- **Article 85 D: Bolar provision. We are aligned with the DE/FR/SE position but it is particularly important that the Bolar it is particularly important that the Bolar exemption does not refer to commercial activities, e.g. procurement, and that legal certainty is guaranteed.**

- **Article 134 R: The role of the Commission in security of supply. We do not support this Article and would like to delete 2. and in particular the empowerment for the Commission to adopt implementing acts. We and FI have provided with two alternative versions, one more extensive version on the coordinating role of the Commission, and a shorter version where the COM can provide with recommendations taking into account the opinion of MS.**

- **Article 56.3 D: para 3, should remain as it is.**

- **Article 56 a D: There needs to be a clear and traceable point of decision in Member States when and if market protection will not be valid in that Member State. SE has provided with suggestions.**

- **162 2a D: Parallel import:** SE can support the proposal regarding article 162.2a (parallel import) that has been sent in by Latvia, Bulgaria and Ireland. SE can also accept that parallel import remains unregulated in the directive or the Swedish proposal that has been sent in previously.

Directive

Art. 1

SE would like to reiterate the need for alignment with the Veterinary Regulation Article 2, p. 9 by this amending in the compromise text:

4a. Nothing in this Regulation shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate regarding narcotic and psychotropic substances.

Art. 9

SE propose two additions in paragraph 2

Proposal

For the purpose of demonstrating the equivalence as referred to in paragraph 1, the applicant shall **for systemically acting products** submit to the competent authorities **bio**equivalence studies, or a justification as to why such studies were not performed and demonstrate that the generic medicinal product meets the relevant criteria set out in the appropriate detailed guidelines. **For locally applied and locally acting products, the applicant shall submit to the competent authorities studies demonstrating therapeutic equivalence as set out in the appropriate detailed guidelines.**

Justification

SE share the concerns of DE that we should not weaken the criteria for generic authorisations. Locally acting/locally applied (LALA) products are today considered under Article 10(3) hybrid application as bioequivalence studies are not applicable. However, we find it logical to include all generic applications for the same active substance, strength and form under Article 9, regardless of the nature of the underlying data for showing equivalence, so we do not agree to mention "bioequivalence" in Article 9(1). To avoid different national interpretations or discussions with applicants, we find it important that the legislation is very clear on this subject. We therefore propose some additional wording to Article 9(2) above.

Art. 13

Herbal medicinal products should continue to be able to apply as "well established use", with maintained requirements for demonstrated efficacy and safety, also when a corresponding medicinal product is already available on the EU market. For herbal medicines that contain extracts as active substances and thus a large number of substances, it is in principle impossible to demonstrate bioequivalence and apply as generics.

Art. 16

SE supports the addition in paragraph 1 (proposal by DE). SE also supports the proposal by DK in para 2.

PUBLIC

Art. 22 D

SE proposes that the first part of the first sentence in paragraph 3 should be deducted ('Where the ERA identifies a risk to the environment). *This was also the opinion of the Commission during the Council Working Party 5-6th of May.*

With the added phrasing in the first sentence, the article loses its original intent. The intent is to harmonise with other legislative frameworks and have a *one substance one assessment* approach. The substances in the directives mentioned in the article, constitutes a problem in the environment. It is therefore reasonable to demand risk mitigation measures from the pharmaceutical industry. When identifying risk in the environmental risk assessment one major component is the amount of use of the pharmaceutical. This may mean that many of the substances listed in the directives mentioned may not constitute a risk in the ERA-assessment. Nonetheless, mitigation measures are justified and needed in all industries including the pharmaceutical industry.

Art. 26

SE is of the opinion that para 2a should be deducted because it limits the scope of possible applications for additional master files.

Art. 40

Strong support for the additions in para 3a and 4!

Art. 44

SE propose that paragraph (ga) should be deleted.

This addition makes it possible for the marketing authorisation holder to not enclose complete environmental risk assessments at the time of application for a centralised marketing authorisation. This is the situation today. Only a few marketing authorisation applications contain a complete environmental risk assessment and when they are incomplete, the national competent authorities can't do anything about it.

PUBLIC

Art. 47

SE propose that all additions in the latest compromised text should be deleted.

The additions make it possible for the marketing authorisation holder to not enclose complete environmental risk assessments at the time of application for a centralised marketing authorisation. This is the situation today. Only a few marketing authorisation applications contain a complete environmental risk assessment and when they are incomplete, the national competent authorities can't do anything about it.

Art. 51

SE **does not** support the amendment of 1 e.

SE proposes that the wording "unless other circumstances of use justify" in paragraph 1 f (iv) is deducted.

A medicinal product with a significant environmental impact may be exempted from being subject to medical prescription only when the use of the medicinal product and the patient safety require otherwise. But "under other circumstances of use" is too vague and open and does not justify an exemption.

Art 56. 3

SE will oppose to any further changes in recitals or in para 3. of this Article, as was much of a debate during the BE presidency. It should remain with the "**or**" persons auhtorised to…", see below.

3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate **stock levels** and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Art. 56a

It is important that the national competent authorities decides when the market protection is not applied and that this decision is subject to judicial review.

Art. 85 - *Exemption to the protection of intellectual property rights*

SE support amendments proposed by DE. It is particularly important that the Bolar exemption does not refer to commercial activities, e.g. procurement, and that legal certainty is guaranteed.

PUBLIC

Art. 81 - *Regulatory data protection periods*

SE supports to maintain the current protection periods (status quo/8 years).

Article 83 D.

If point 1 b. is deleted we suggest to replace it with:

"Any derogations from performing randomised controlled clinical trials should be justified by the applicant."

Art. 105a

Proposal

Wholesale distributors that ~~supply~~ **distribute** medicinal products in accordance with Article **162(3) to (5)** shall record all suspected adverse reactions with regard to those medicinal products which are brought to their attention, whether reported spontaneously by patients or by healthcare professionals, including **suspected** adverse reactions ~~related to the use of the product outside the terms of the marketing authorisation~~ **occuring where the product is used outside the terms of the marketing authorisation**. They shall transmit those reports immediately to the marketing authorisation holder holding the marketing authorisation in the ~~country of origin~~ **source Member State** concerned.

Proposed rewording in accordance with article 162.2a and for harmonisation purposes: a change from "supply" to "distribute".

Proposed rewording in accordance with Article 105 and for harmonisation purposes: a change from "related to the use of the product outside the terms of the marketing authorisation" to "occuring where the product is used outside the terms of the marketing authorisation".

Proposed rewording in accordance with Article 162.2a and for harmonisation purposes: change from "country of origin" to "source Member State".

Also, the references to art. 162 might need to be altered depending on the final wording of that article.

Art 130

For many homeopathic medicinal products, the labelling is the only product information available to the patient. As the patient has no other means of finding out the contents of the product, all excipients must be listed in the labelling, not only the ones known to have a recognised action or effect. The suggested changes to article 130.1(f) and (n) are not supported unless a complete list of active substances and excipients is allowed or required in the labelling.

PUBLIC

Art. 135

Article 135.1 should not refer to homeopathic medicinal products but traditional herbal medicinal products.

Art. 136

Article 136.1(a)(i) should also list point 23 of annex I. GMP-certificates should be part of the application.

In article 136.1(a)(ii) reference is made to "pharmaceutical tests referred to in **point 12(b) of** Annex I;" which is not correct. Point 12(b) in annex I is "(b) non-clinical (toxicological and pharmacological) tests,". The reference should hence be corrected to:
"pharmaceutical tests referred to in **point 12(a) of** Annex I;"

Regarding article 136.1(a)(iii), the sentence "…without the clinical particulars pharmacological properties as specified in Annex V" should also include the addition **", unless necessary for the safe use of the product**".
It is vital that the competent authorities are allowed to require that pharmacological properties are specified in the summary of product characteristics **if they are necessary for the safe use of the product**. This has already been implemented by Member States and is exemplified in the Committee on Herbal Medicinal Products (HMPC) monograph template: https://www.ema.europa.eu/en/documents/template-form/template-european-union-herbal-monograph_en.pdf-1

Art. 140

It is not logical that the entire chapter XV shall apply to traditional herbal medicinal products except article 199(1): "A marketing authorisation of a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive." For easier understanding, it is suggested that the whole chapter XV is included. Article 140.1 should hence read:
Article 1(5), points (a) and (b) and Article 1(10), point (**a**c), Articles 6 **5, 7,** to 8, 29, 30, 44, 46, **56, 61, 89,** 90, **92** 155, 188, paragraphs 1 and 11, Articles 191, 195, 196, **197,** 198, 199(2), 202, 203 and 204 **and 206** and Chapters **IV,** IX, XI, and XII **and XV** of this Directive as well as Commission Directive **(EU) 2017/1572**[43]2003/94/EC[44] shall apply, *mutatis mutandis*, to traditional-use registrations granted under this Section.

Art. 141

Article 141.1 (a)(ii) specifies tasks arising from article 137 as competence of the herbal medicinal products working group. Article 137 in its updated form, however, does not include any assignments for the working group. Article 141.1(a)(ii) may hence be deleted.

Also, throughout the directive, reference is made to ”methods laid down in annex I” and similar phrases. As the suggested annex I regards ”INFORMATION REFERRED TO IN THE APPLICATION” while the suggested annex II regards ”ANALYTICAL, PHARMACOTOXICOLOGICAL AND CLININCAL STANDARDS AND PROTOCOLS IN RESPECT OF THE TESTING OF MEDICINAL PRODUCTS” it is assumed that the reference is erroneous.
Examples (not comprehensive) of articles where the reference should probably be to annex II instead of annex I:
Art 191, last phrase
Art 195.4, last phrase

Art. 162.2a

SE can support the proposal regarding article 162.2a (parallel import) that has been sent in by Latvia, Bulgaria and Ireland. SE can also accept that parallel import remains unregulated in the directive or the Swedish proposal that has been sent in previously.

Art. 218

It seems that para 4 and para 6b are overlapping each other. One of them can be omitted?

Regulation

Art. 15

SE propose that the added text in paragraph 1 d is deleted. This addition makes it possible for the marketing authorisation holder to not enclose complete environmental risk assessments at the time of application for a centralised marketing authorisation. This is the situation today. Only a few marketing authorisation applications contain a complete environmental risk assessment and when they are incomplete, the national competent authorities can’t do anything about it.

PUBLIC

Art. 40 (TEV)

General comment: Sweden is in support of the progress made under the HU Presidency regarding the Transferable Exclusivity Voucher and welcome the idea of a blockbuster clause.

The definition of Priority antimicrobials (voucher):

Minor adjustment to the SE text proposal after comments from other MS and the Commission on WP of April 28 and May 6 (see yellow):

Revised SE text proposal in Article 40 p. 3:

An antimicrobial shall be considered 'priority antimicrobial' if **it addresses a multi-drug resistant organisms causing a severe serious or a life-threatening infection, and for which the** preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:

~~a) it represents a new class of antimicrobial~~

~~b~~ a) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

~~c~~ b) **a new** active substance, **alone or in a combination with other antimicrobial substances** ~~or substance combination~~ not previously authorised ~~in a medicinal product~~ in the Union.

In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.

We also insist on deleting 40 4. (c) as it is counterproductive for SME:s that develop priority antimicrobials, see below:

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.

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

Article 134 - Role of the Commission

The way that this Article is constructed can be interpreted as inflicting on national competence. It is a matter of subsidiarity and division of competences. The mandate in the current text is very broad and unclear, and we oppose to the power of adopting implementing acts on the basis of lack of specificity in its framing, not respecting subsidiarity and national differences when suggesting uniform rules in all Member States.

See the most recent proposal by SE/FI (separate attachment).

Annex I

Para 3a: We are of the opinion that this paragraph can be omitted and that it is sufficient with para 3. If para 3a is kept, SE would like to point out that some of the diseases was added after 2004 (auto-immune diseases and other auto-immune dysfunctions and viral diseases).

Article 134
Role of the Commission

1. The Commission ~~may, where it considers it appropriate and necessary:~~
(a) **shall** take into account the MSSG recommendations ~~and implement the relevant measures~~;

(aa) shall ~~may~~ take, if appropriate, any necessary ~~relevant non-binding~~ actions within the limits of the powers conferred on the Commission, including the development of ~~guidelines~~ recommendations to improve the security of supply;

(ab) may foster coordination of Member State measures aimed at ensuring security of supply within their territories.

(b) **shall** inform the **Member States and the** MSSG of those ~~measures~~ **actions** taken by the Commission.

(c) **may** request the MSSG to provide information or an opinion or further recommendations referred to in Article 132(1).

2. If necessary to ensure the smooth functioning of the internal market and without prejudice to Member States' competences in the areas of national supply systems to public health care services, the Commission **may, taking into consideration the recommendations of the Member States, draw up recommendations for ~~is empowered to adopt~~**, ~~taking into consideration the **recommendations** information or the opinion, referred to in paragraph 1, or MSSG recommendations, may decide to adopt an implementing act to **provide for uniform application and temporary criteria**~~ **national measures** ~~**for national measures aiming at**~~ **to improve the security of supply of medicinal products included in the Union list of critical medicinal**

products ~~or a decision to set uniform and specific requirements, in particular regarding contingency stocks~~.

~~The criteria shall apply in all Member States when they adopt measures to improve security of supply. The criteria shall be aimed at preventing or mitigating fragmentation in the internal market, while pursuing a high level of human health protection.~~

The adoption of these recommendations ~~criteria~~ shall be limited to cases where the Commission identifies a highly likely disruption of the internal market which negatively affects the security of supply of critical medicinal products. They shall take into account:

(a) the severity of the disruption of the internal market, or the risk thereof;

(b) the causes of the disruption to security of supply and the actual or potential emergence of national rules to resolve it;

(c) the existence of other available measures under this Regulation to mitigate or resolve the disruption;

(d) the gravity and scope of risks to public health.

The recommendations ~~criteria~~ shall be based on objective, factual, measurable and substantiated data, including from the Agency and its preparatory bodies, national competent authorities and relevant economic operators. The recommendations ~~criteria~~ shall be proportionate, non-discriminatory and comply with competition rules.

~~The Commission shall clearly define the temporary scope of these criteria.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).~~

~~2a. The implementing powers referred to in paragraph 2 and 2a of this Article shall not affect measures adopted by the Member States, the Council or the Commission pursuant to [EMA revised mandate, HERA Regulation, CBHT] concerning supply of critical countermeasures during a major event or a public health emergency at Union level.~~

~~3. The implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 173(2).~~

PUBLIC