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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 and Medical Devices on 12 May 2025.

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COMMENTS FROM THE DELEGATIONS

Working Party on Pharmaceuticals and Medical Devices 12 May 2025

BELGIUM

Fyi, the Belgian counterproposal. The idea is to solve the discussion we had on excipients and clinical information by leaving this to the MS ('at least').

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 essentially similar with the medicinal product already authorised in the destination Member State. Medicinal products are considered to be essentially similar if they fulfil at least the following conditions:

(a) they have the same qualitative and quantitative composition in terms of active substance(s) ~~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.~~

Our main issue with the IE proposal is how the NCA/member state will be able to illustrate/demonstrate that the PT would not respect the rules, i.e. how should the member state demonstrate that the wholesaler intends to circumvent the rules of the directive?

*"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 w****ould 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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Following the discussion on our **borderline proposal** during Tuesday's CWP and based on constructive comments by COM, which we received after the CWP, we have adapted our proposal.

We have made considerable changes in the spirit of collaboration and pragmatism. We owe the MS that supported the need for a mechanism during the WP a realistic and operational proposal.

Below you can find

1. The adapted proposal
2. How we changed the proposal to respond to the relevant comments by COM.

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1. The proposal

New Recital Directive

(15B) In order to take account of the growing number of so-called 'borderline' products between the medicinal products sector and other health sectors such as medical devices, in vitro diagnostic medical devices and substances of human origin, a mechanism to clarify the regulatory status of a product is required. To ensure efficiency and scientific consistency between the relevant Union legislation and coherence with the different regulatory status mechanisms established under other Union legislation this mechanism should build on the opinions of a regulatory status advisory committee. When a borderline product that may fall under the definition of a medicinal product, a medical device, an in vitro diagnostic medical device or a substance of human origin may also fall under the legislation of other Union legislations, the advisory committee shall consult with the competent European Agencies and advisory bodies set up under the relevant legislation.This Committee should be empowered to give scientific opinions on whether a product meets the scientific criteria to be a medicinal product or should be regulated under another legislative framework. Such an advisory mechanism would address questions related to borderline cases with other areas.

Adaptation of the Directive art. 201

Cooperation with other authorities and determination of regulatory status

1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States shall consult the relevant competent authorities designated under other Union legislation referred authorities established under that Regulation.

1. **(1A) In all cases where questions arise as to the regulatory status of a product which are either under development or products already on the market in the EU or an EU Member State and which may fall under the definition of an medicinal product that cannot be resolved at national level, or where different Member States have a different view with regard to the regulatory status of the same product, the national competent authorities may consult the regulatory status advisory committee provided for in article 201A for an opinion on the regulatory status of the product. The regulatory status advisory committee shall issue its opinion within 90 days following the request.**

New article 201A under the directive

Determination of regulatory status

1. **A regulatory status advisory committee is hereby established.**

2. **The Committee shall be responsible for the examination and drawing up an opinion where questions arise as to the regulatory status of a substance or product upon request of a national competent authority in accordance with article 201 (1A).**

The Committee shall be responsible for the examination of any question relating to the regulatory status of a substance or product upon request of a national competent authority in accordance with article 201 (1a) and the

– the adoption of opinions or recommendations relating to the regulatory status of a substance or product.

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3. **The committee shall be composed of representatives of the Agency and representatives appointed by Member States.**

Each Member State shall appoint to this committee for a three-year term which may be renewed, one member and one alternate with expertise in the qualification and classification of substance or products under this Directive, [new Regulation] and other related Union legislation, such as and not limited to Regulation (EU) 2017/745, Regulation (EU) 2017/746 and Regulation (EU) 2024/1938. The members shall represent the competent authorities of the member States within these legislations.

Within the same conditions, The Agency shall appoint to this committee for a three-year term which may be renewed, one member and one alternate.

The alternates shall represent and vote for the members in their absence.

4. **The Committee shall use its best endeavors to reach consensus. If such consensus cannot be reached, the Committee shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the Committee's position.**

5. **The Committee shall be chaired by a representative of the Commission. The chair shall not take part in votes of the Committee.**

6. **The committee shall consult, where appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. The committee may also invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.**

7. **The committee shall establish its rules of rules of procedure, which shall, in particular, lay down procedures for the following:**

- **The adoption of opinions or recommendations or other positions;**
- **The delegation of tasks to reporting or co-reporting members;**

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8. **The Commission shall publish summaries of the opinions issued in accordance with paragraph 2, after deletion of all information of a commercially confidential nature.**

In recitals of the proposed regulation :

(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the regulatory status advisory committee for medicinal products, medical devices and SoHO-products, established by [new Directive].

In articles 61 and 62 of the proposed regulation:

Article 61

Scientific recommendation on regulatory status

1. For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer or a competent authority of the Member States may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product', including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council.
   The Agency shall deliver its recommendation within 60 days of receiving such a request, which shall be extended by an additional 90 days where a consultation in accordance with paragraph 2 is required.

   2.When forming the recommendation referred to in paragraph 1, the Agency shall consult **the regulatory status advisory committee set in the Article 201a of the revised Directive and**, where appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. IThe advisory or regulatory bodies consulted shall reply to the consultation within 90 days of receipt of the request.

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The Agency shall publish summaries of the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.

Article 62

Decision on regulatory status

1. In the case of duly substantiated disagreement with the Agency's recommendation, in accordance with Article 61(2), a Member State may request the Commission to decide whether the product is a product referred to in Article 61(1).

   The Commission may initiate the procedure referred to in the first subparagraph on its own initiative.

2. The Commission **shall consult the regulatory status advisory committee set in the Article 201a of the revised Directive** where a Member State's request raises new questions of a scientific or technical nature or on its own initiative.

3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure referred to in Article 173(2), taking into account the opinion of the **regulatory status advisory committee**.

2. How the new proposal responds to COM-comments

Commission comments in black, our responses in green.

Organisational:

- The **regulatory status advisory committee** (RSAC) will be part of which structure? Commission, and Commission should take the chair of the committee. This also follow the obligation for COM publishes summaries of the opinions.
- Who will finance it and provide a secretariat? Commission.

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Composition:

- How many members will the committee have? Who will nominate the representatives? For how long? 27+1+1 (MS, Agency, COM (not voting but chair)
- The draft refers to the SCB, MDCG and coordination group? Are the nominated experts representing those groups or acting indepdently? See above – has been abandoned.
- Is it a fixed composition or a variable composition depending on the issue, i.e. if a question relates to the borderline between medicinal products and medical devices can the representative of the SCB participate in the discussion/vote and influence the outcome? Fixed, and possibility if necessary to consult other in additional/consults; a fixed composition could encourage the knowledge building and expertise, consistency, etc. representatives can consult domain-specific experts MS-internally.
- What will be the weight of the votes? See also below on opinion forming. See below.

Mandate and accountability:

- What is the task of the RSAC? The Committee shall be responsible for the examination and drawing up an opinion where questions arise as to the regulatory status of a substance or product upon request of a national competent authority
- May it give only a recommendation on whether a product is a Medicinal product or not or potentially, positively recommend whether it is seen as a MP, MD, IVD or a SoHO (or even food, biocidal products etc.). If it is the latter, on which basis can the RSAC give a scientific classification on other legal frameworks practically and legally (through a legislation the scope of which is restricted to medicinal products). We have changed this and removed the formal link with the other frameworks (SoHO, MD, IVDR). We focus MP vs. other products/not-MP. Nevertheless, next to a clear answer to the question whether a product should be classified as a MP, there seems to be no objection that such an opinion could also provide a 'soft' indication on what the regulatory status possibly could be (MD, etc.)?
- What will be the legal value of the recommendation and can it be challenged? If yes, by whom? Recommendation/opinion, not binding. We provide no possibility to challenge the opinion, but do provide the possibility to ask the opinion of third parties (the developer, the MAH).

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Process:

- Who can initiate the process of a recommendation? MS? The Commission? Developpers? NCA (within the context of the new Directive, i.e. MP-NCAs) (article 201, new 1A); Developers can use the route of art. 61 Regulation. For those products that are under development (= pre-market) and that may fall within the scope of the centralised procedure, an NCA or a developer may request advice/recommendation from the EMA on whether or not the product qualifies as such a medicinal product. Consultation of the Committee by EMA is also foreseen in the Article 61, etc., procedure. There is, fundamentally, no hierarchy or precedence between the two advisory procedures (committee and 61), which means that an NCA could also go through the Committee (instead of first using the Article 61-62 procedure) for, let's say, Article 61 products.

- Are there any criteria for initiation? below
- The proposed Article 201, specifies **that *In all cases where questions arise as to the regulatory status of a product which are either under development or products already on the market in the EU or an EU Member State and which may fall under the definition of medicinal product, of a Medical device, an in vitro diagnostic medical devices or a substance of human origin (SoHO) cannot be resolved at national level, or where different Member States have a different view with regard to the regulatory status of the same product, the national competent authorities shall consult the regulatory status advisory committee.*** Who raises the questions?

  Not explicitly identified and this to maintain flexibility, openness, no limitations on 'source'… questions that have arisen in the context of market surveillance, national scientific advice applications, questions of companies, complaints, etc.

  The 'shall' would only be triggered when there is an unresolvable discussion in the MS or between MS. But we can give more discretion to the MS by choosing a 'may' – and that is what we do in this new proposal.

  - How/when, from the moment that a company raises the question in one or more MSs, a MS will decide that they shall escalate the matter to the advisory cttee? in other words when and by whom the issue is considered not resolved? Discretion of the NCA

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- Will there be coordination among MS? Hence, committee. The goal is streamlining the coordination.

- Will a company indicate that there is a problem? This is not clear from this provision. This could be one of the 'cases where questions arise', i.e. company asking the NCA, NCA not able to resolve and therefore escalating to committee.

- Is it limited to products under development or can also include products already placed on the market (i.e. developed under a specific framework)? Both.
- Are there specific timelines for forming a recommendation? Yes, within 90 days following the request (art. 201 (1a), 2nd subpara).
- Can the committee ask for additional information on the product? Yes, possibility to consult other advisory bodies + third parties
- How will an overload of the committee avoided? Only a NCA can initiate a request, not developers.

Opinion forming:

- Will the recommendation be adopted by consensus or majority? If majority, what will be the threshold? See new proposal, rules were added, similar to MDCG, CMDh.
- What will be the weight of votes of the representatives of the different fields? Will experts in medicines have the same weight of votes in deciding whether a product is a medicine with experts in other fields with no expertise in medicines and in medicines legislation? No such weight in votes is foreseen.
- What happens when there is divergence opinion between the experts? What will be included in the opinion that the cttee shall issue within 90 days following the request? If No opinion is reached What happens then? Divergent voices can ask for their opinion to be published.

Relation to other classification mechanism

- What is the link between the recommendation and the MD mechanism, the SoHO mechanism and the proposed classification mechanism? If it is a non-binding recommendation, we assume other classification decision may still be taken Yes, remains a recommendation.

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- Given that the proposed mechanism is open to all products including SOHO and medical devices how will it be ensured that it clear which path should be followed for the classification of a product? In practice what would be the path for eg a borderline between medicinal product and medical device? the classification mechanism of MDs or the advisory cttee should be followed?
- According to the proposed mechanism for medicines the advisory cttee will need to consult other relevant advisory or regulatory bodies established in other Union legal acts, even if these bodies are already represented within the committee. What is the purpose of the double consultation? In the reverse case, under the SOHO and the MDR will the relevant bodies consult the Agency or the advisory cttee when there is borderline with medicinal products? How this will be clarified?

  (on last two questions) MDCG and SoHO mechanisms remain independent "gateways" for borderline questions —questions such as whether a product qualifies as a medical device (MD) or a medicinal product (MP) can also be addressed through these mechanisms. The starting point for determining which mechanism applies is the initial "qualification" of the product. Consultation could potentially be ensured by explicitly referencing Article 201a in the MDR and SoHO regulations. However, this does not currently appear to be under consideration, as the relevant legislative frameworks are not being reopened.

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FINLAND

FI comments – Recitals and Annexes - follow up to CWPPH 12th May 2025

Recitals (Directive)

(20b) In exceptional cases, the Directive allows Member States to exclude medicinal products from the scope to fulfil special needs of individual patients. In addition, to effectively mitigate shortages, it is important to address the patients' needs on population level and allow the preparation or use of medicinal products, under strict conditions. Such exceptions should never be aimed at distorting competition and should be interpreted narrowly, and only used to mitigate or resolve a shortage or in a situation where there is no relevant authorised product on the market.

We propose to add **"or use"** to recital (20b). This has been reasoned in our comments regarding Article 3.

(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based **alone** on the patent or SPC status of the reference medicinal product. **From these rules it also stems that the protection of intellectual property rights does not represent a valid ground to refuse or suspend decisions related to relevant pricing and reimbursement, ~~or~~ health technology assessment procedures, or where applicable, application for procurement tenders ~~procedures~~. Member States remain free to introduce rules to ensure the readiness to supply a medicinal product on the market of that Member State for the period when the patent and SPC have expired**.

We propose to delete the new sentence relating to pricing and reimbursement. This is not correctly aligned with article 85.

(147) On the basis of the opinion of the Agency, the Commission should adopt a decision on the referral by means of implementing acts. In justified cases, the Commission may return the opinion for further examination or deviate in its decision from the opinion of the Agency.

Taking into account the need to make medicinal products swiftly available to patients, it should be acknowledged that the chairperson of the Standing Committee for Medicines for Human Use will use the available mechanisms under Regulation 182/2011 and notably the possibility to obtain the committees opinion in written procedure and within expeditious deadlines which, in principle, will not exceed 10 calendar days.

In recital 50 of the proposed version of the Regulation is included 15 calendar days. This should be harmonized and should preferably be 15 calendar days.

ANNEX VI

CONTENTS OF PACKAGE LEAFLET

(3) a list of information that is necessary before the medicinal product is taken:

(a) contra-indications;

(b) appropriate precautions for use;

(c) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, food **and herbal products** ~~**preparations**~~) that may affect the action of the medicinal product;

We propose the clarification of text in brackets. Annex VI (3) (c) 'Herbal preparation' is defined in Article 4 Definitions 1. (66) as 'preparations obtained by subjecting herbal substances...' and means different issue than 'herbal preparations' under Annex VI (3) (c). To avoid misunderstandings, the text 'herbal preparations' (in brackets) should be changed into form '**herbal products**'.

Latest compromise texts 12.5.2025

Regulation Article 134

FI cannot support this article in current form..

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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

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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.

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New Article 3d

FI supports the proposal of FR include emergency/pandemic stocks in Article 3.

Article 3 Exceptions under certain circumstances

3.1.

FI fully supports this modified version of paragraph 1 of Article 3, since it more clearly allows patient specific special permits and possibly also institution-specific special permits.

3.1a

We suggest the following additions (or used) to 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.

Justification:

The proposed paragraph 1a, in our view, do not necessarily allow for a clear continuation of our current special permit procedures (more specifically fixed-term special permits) and batch-specific exemption permit procedures. Paragraph 1a still emphasizes preparation for situations of shortages and the word "prepared" is repeated. Paragraph 1a should also clearly 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.

Article 4 Definitions

4a The directive should clearly establish **at which point a medicinal product subject to a decentralised manufacturing turns from an "intermediate (medicinal) product" to a "finished medicinal product".**

Justification: This is essential for the implementation of rules concerning i.e labelling - including satety features -, QP certification etc.

The directive therefore does not regulate essential matters regarding decentralized manufacturing, and it is very unclear how the QP release, packaging of medicines (including the addition of safety features) is carried out at a decentralized manufacturing site.

Recital 67a

New text proposal for 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 but not limited to processing, filling, sterilisation, assembly, immediate and outer packaging and repackaging, storage, quality control testing, **certification in accordance with Art 153 by the Qualified Person referred to in Art 151 paragraph 1** and release of the medicinal product;

Justification:

The QP certification is the significant difference between the definitions of 'manufacturing of medicinal products' and 'manufacturing of active substances', so the difference should also be reflected in these definitions.

Furthermore, the manufacturer where the QP certification and batch release takes place, is the only manufacturer whose name and address is available for the users and prescribers of medicinal products.

Article 26a Medicinal products concerned with decentralised manufacturing

See comments under Art 4 Definitions. The Directive should define at which point of the manufacturing process a product approved for the decentralised manufacturing process turns from an 'intermediate 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 83 Medicinal products addressing an unmet medical need

83.1b

We suggest to add **major contribution to patient care** here. If we use only "improved efficacy or safety", many of the currently conditionally approved products will not be approved (criteria are too challenging.), and EU will not any more provide early access to e.g. cancer products. Many nowadays conditionally approved products will be approved years later in the EU compared to e.g. USA.

Alternatively the simplifying the terminology and use "**significant clinical benefit**" also here.

It is used in several other Articles where comparisons with other products are needed (Art 84/ repurposed medicine incentive; Art 80/ new indication incentive; Art 86/ paediatric incentive).

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Justification:

Currently the requirement "major therapeutic advantage, MTA" in the conditional approval legislation (when there are other existing treatments, to meet unmet medical need) has been interpreted to include: **improved efficacy or safety <u>or "major contribution to patient care"</u>**. Substantial part of these CMA- comparisons have concluded MTA based on this "major contribution to patient care" *(e.g. a new cancer medicine with no improved efficacy or safety, but being an oral treatment compared to existing intravenous treatments and hence allowing treatment at home; or compared to very complicated ATMP-products which are not off the shelf products; or a new medicine allowing treatment holiday for cancer patients).*

Article 105 Recording and reporting of suspected adverse reactions by the marketing authorisation holder

6.This Article shall apply *mutatis mutandis* to undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2**.**

As we have commented earlier: 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.

Justifications: 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 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. 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.
Justification: The vast and fragmented case-law of the ECJ should absolutely be codified into the legislation in order to prevent inconsistency between different Member States. This proposed wording clarifies that the products must share a common origin, but also leaves some room of interpretation for the Member States. It also prevents situations, where the marketing authorisation system would be undermined.

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Article 217 Repeals

The time should be 24 months also here as it is in Article 218.

Article 218 Transitional provisions

To avoid possible loopholes, we suggest following wording:

6b *Medicinal products placed on the market prior to [24 months after the date of entering into force of this Directive] which do not comply with the requirements of this Directive**, but comply with the requirements of Directive 2001/83/EC**, may be marketed until the stocks of the medicinal products are exhausted.*

REGULATION

Article 171 Market exclusivity

The wording is not aligned with Paragraph 1 and could create a situation where the authorisation is granted before the period mentioned in Paragraph 1 has ended. After that, there seems to be no provision that would prevent the new marketing authorisation holder from entering the market. Thus this could lead to a situation that the exclusivity period intended in Paragraph 1 is not fully covered,

GERMANY

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General comment

Our comments are preliminary on the PRES changes of 12 May 2025. See our comments on the last compromise text from 6 May for more detailed argumentation. See these comments as well for our position on Articles 22, 44, 47, 68, 83, 164, 177, 188, 189, 193, 218, 219 and Annexes V and VI Directive and Articles 6, 26, 40-43, 46, 54, 60, 117, 119, 120 Regulation. The same goes for the recitals.

We did not have sufficient time to check all the changes made, e.g. in Articles 36 Directive and Article 52 Regulation, and therefore reserve our position on the changes.

I. Comments on RDP and Access

1. Regulatory Data Protection: DE insists on maintaining 8 years of RDP without modulation for reasons of EU competitiveness and predictability for companies.

2. Access:

Directive:

- There must not be financial penalties for not bringing a medicinal product to all Member States.
- 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 5a cannot be accepted. 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 5a, this provision is entirely unacceptable. There must not be financial penalties for failing to launch in all interested Member States. Such a sanction is legally questionable and would be economically disastrous.

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.
- 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 in comments from 6 May.

Article 1 Directive – Subject matter and scope

- 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.
- Paragraph 6: Thank you for changing the wording in para 5a. For reasons of coherence, in para 6 the text should also refer to "medical instructions" instead of prescriptions.

Article 3 Directive – Exceptions under certain circumstances

- Our position remains unchanged. The amendments proposed by the Commission in the WP of 12 May is rejected.

Article 51 Directive – Medicinal products subject to medical prescription

- DE rejects the deletion in para 1(e), we strongly prefer the previous version. According to our understanding in the previous WPs the preceding proposal was widely agreed amongst MS.

Article 85 Directive - Bolar provision

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.

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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

- Art. 85 (1) lit. ad) further refers to "procurement offers" / 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 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.
- More background/arguments for the DE position:
    - The deletion means an obligation to record and document all non-prescription medicines for all customer groups. As a rule, this can only be done manually, resulting in enormous additional personnel, time, infrastructure and financial costs. This would also go far beyond the current requirements of Chapter 4.2, Paragraph 10 of the GDP Guidelines.
    - An extension of batch documentation to all medicinal products, including OTC, would only be meaningful and acceptable if the same digital and machine-readable batch identification and coding requirements for all medicinal products were established uniformly across the EU and implemented by pharmaceutical companies.
    - However, not all packs of OTC and non-prescription medicines currently have a machine-readable and standardised Data Matrix code. As a result, mandatory batch recording is likely to mean that largely automated processes in the RX area will have to be carried out manually. This applies not only to picking, but also to the recording of incoming goods. **Overall, this would result in significant additional costs and would run counter to the administrative simplification aimed at by the pharmaceutical package.**
- We therefore again ask all MS for their consideration and support. We would like to point out that with the current wording of Directive 2001/83 and the COM's proposal for the revised Directive, MS could already require batch documentation for all medicinal products in their MS. However, in DEU we do not consider this necessary (see arguments above).

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Regulation

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.

PUBLIC

AUSTRIA

AT strongly supports DE on re-introducing the deleted part for Art. 166 Para 1 lit. g (v).

IRELAND

PUBLIC

We just wanted to draw your attention again to our comment on Art 1 (5) (a) and our concern about the deletion of prescription and its replacement with "instruction". We would suggest the following -

Article 1 Para 5 (a) of the Directive:

5. The Directive shall not apply to:

(a) medicinal products prepared in a pharmacy in accordance with a medical prescription ~~**instruction**~~ **of a doctor or of another authorised healthcare professional** for an individual patient ('magistral formula');

Comment: We consider the reference to an 'instruction' as opposed to a medical 'prescription' is too imprecise and could potentially be interpreted as exempting medicinal products from the Directive in the event that any healthcare professional (not just those who are allowed prescribe) issues an instruction for an individual patient. 'Medical prescription' is currently included in the definitions of the Directive so there is a clear and common understanding of the circumstances to when the exemptions applies and it is linked to the prescribing authority within a MS. There is no common understanding for the new terminology 'medical instruction of a doctor or of another healthcare professional' and is considered too wide for such an exemption.

MALTA

PUBLIC

Further to the working party on the 12 May, as instructed, I resend the comments on the text which are very sensitive to MT.

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

SPAIN

PUBLIC

Please, find below ES red lines following the Working Party held on 12 May:

Directive:

1. Modulation of incentives and market access compulsory, not as an incentive: 11 years as maximum protection.
2. Article 1: Subject matter and scope:

   p1: Member States may allow the supply of officinal formula or magistral formula by the pharmacy to a hospital it serves, subject to the approval of the competent authority concerned.

   We cannot support supply limitation to hospitals only to officinal formula. Magistral formula should be included as well.

3. 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.

Regulation:

1. Regulatory incentives (vouchers) for the development of priority antimicrobials.
2. 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.

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.

3. 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.

PUBLIC

SWEDEN

PUBLIC

SE comments – recitals and Annexes - follow up to CWP May 12 2025

Recitals (Directive)

Recital 20b

SE suggests some minor but important changes to recital 20b.

(20b) In exceptional cases, the Directive allows Member States to exclude medicinal products from the scope to fulfil special needs of individual patients. In addition, to effectively mitigate shortages, it is important to address the patients' needs on population level and allow the preparation of medicinal products, under strict conditions. Such exceptions should never be aimed at distorting competition and should be interpreted narrowly, and only used to mitigate or resolve a shortage or in a situation where there is no relevant authorised product *available* on the market *in that Member State*.

Recital 63

Together with DE and FR, SE has proposed a new wording of recital 63. We are not in favour of including HTA and P&R in the Bolar exemption and which to see an adjustment in accordance with the following text:

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

~~obtained for the purposes of the regulatory approval process, even in the cases of procurement tenders.~~

Recital 64.

Similarly with the comments to recital 63 SE does not want the inclusion of HTA and P&R in the polar exemption and suggests the following wording of the recital:

(64) It will allow, inter alia, to conduct studies to support ~~pricing and reimbursement as well as~~ the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Recital 65

As suggested in the joint proposal DE+FR+SE we are not in favour of an extension of the Bolar exemption. SE suggest the following changes to recital 65:

(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product. *While this corresponds to the current application of the regulatory framework of medicinal products, it seems appropriate to clarify it in this Directive for the avoidance of doubt. Similarly, the protection of intellectual property rights shall not be a valid ground to refuse or suspend decisions related to pricing and reimbursement or health technology assessment procedures.* ~~However,~~ Member States should remain free to introduce a national requirement to prove the ~~availability~~ readiness to supply ~~of~~ a ~~medicine~~ medicinal product on the market of that Member State for the period when the patent and SPC has expired ~~at the date of submission of the application for pricing and reimbursement~~.

PUBLIC

Annex VII (Directive)

SE has previously commented that therapeutic radio pharmaceutical should be added to Annex VII as they fulfil the requirements laid down in Article 28 (adaptive frameworks).

There are several reasons for this. It is a regulatory challenge to deal with these products as also other legislation than pharmaceutical legislation apply. See Council Directive 2013/59/EURATOM Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. According to that directive each treatment shall be adapted to each individual that is exposed to ionising radiation and that is not expressed in the pharmaceutical legislation. It is also scientifically complex to optimize the dose and the methods for constantly changes and is dependent on the type of radio pharmaceutical. Therapeutical radio pharmaceuticals have been of great importance for patients and the optimization of doses also lead to an optimization of resources in health care and reduces the environmental impact. Today it is not possible to use this kind of pharmaceuticals in the most optimal way and consequently adapted rules are needed.

SE has previously submitted a proposal in writing.

Recitals (Regulation)

Recital 36

The recital needs to be revised. Presently it gives the impression that external experts can exceed the total number of experts from the Member States. It is also a risk of brain drain from national competent authorities to external experts in EMA working parties. The following wording is suggested.

The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and~~,~~ *if necessary,* of external experts.

Recital 36a

SE has previously commented that the recital is too detailed and risk not being future proof. The following wording is suggested:

(36a) It is crucial that the expertise of experts is not only preserved within working groups, working parties, and a pool of experts, but also that the relevant expertise is expanded to cover emerging technologies, incorporates expertise from a broader range of Member States, and enables the Agency to continue fulfilling its obligations at the highest scientific level. It is also essential that experts can share knowledge, expand their skills through training programs.

The rest of the sentence can be deleted. (Dvs. resten av meningen därefter (exempel på training

Recital 84

SE can support the recital vb with the following wording:

"The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament and the Council upon proposal by the Commission on the basis of the experience acquired"

Recital 136

SE is of the view that the recital relating to Articles 126 and 134 about the Commission role in Chapter X should be adjusted and partly deleted, particularly the addition of the role of the member states.

~~**"Member States, depending on their situation, have addressed this in different ways. Due to a lack of coordination to 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."**~~

Recital 138a

The recital that corresponds with Article 134 should be deleted and/or adapted as SE strongly opposes the current and previous wording of Article 134.

Annex I (Regulation)

Annex I, paragraph 3:

Annex I, point 3 currently states:

"Medicinal products for human use containing a new active substance which on [date of application of this Regulation] was not authorised in the Union, excluding allergen medicinal products or herbal medicinal products."

SE is of the view that an applicant with an innovative medicinal product should apply for a centralised authorisation even if the product is a herbal medicinal product. The following wording is suggested:

"Medicinal products for human use containing a new active substance which on [date of application of this Regulation] was not authorised in the Union, excluding allergen medicinal products or traditional herbal medicinal products."

PUBLIC