Council of the European Union
General Secretariat

Interinstitutional files:
2023/0131 (COD)
2023/0132 (COD)

Brussels, 29 April 2025

WK 5413/2025 INIT

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Pharmaceutical package
Subject:	Pharma package - Comments from the delegations

Delegations will find enclosed comments from delegations on EMA governance and orphans and paediatrics clusters.

COMMENTS FROM THE DELEGATIONS

On EMA Governance and Orphans and paediatrics

DENMARK

DK does not have red lines on the EMA governance cluster. DK would however emphasize that it is the wrong political signal being with the absence of voting rights for patient organizations in the CHMP.

In addition we have some technical comments, DK hopes the Presidency will take into consideration on the EMA governance and Orphans and Paediatrics cluster:

- The added text in art 75R, para 1, letter c: The insertion marked with yellow is superfluous.
- EMA-structure: Art 148R, para 6: We remain reluctant to the insertion as the CHMP should assess the B/R of the product. A WP for environmental matters may be established and the CHMP may seek advice from this group. The added sentence should therefore be deleted. We took note of the fact that the EC agrees to the deletion. "

FRANCE

Following the meeting on April 15, the French authorities are no longer opposed to the proposed compromises concerning orphan and paediatric drugs and EMA governance.

However, the French authorities wish to reiterate their regret regarding the absence of any mention of patients' voting rights at the CHMP, and the lack of any mention of a permanent paediatric working party in the text. They continue to consider these issues as very important. Therefore, they stand by the comments made during the previous consultation conducted by the Presidency.

As a reminder, the comments were as follows:

- **Concerning the provisions relating to paediatric medicinal products** (as set out in article 87 of the compromise on orphan and paediatric medicinal products and article 150 of the compromise on EMA governance): the French authorities maintain their wish to see a permanent, specialized paediatric working party mentioned in article 87 and article 150 of the regulation:
Indeed, the existence of a paediatric working party and its inclusion in legislation is the only way to ensure a specialized approach by guaranteeing the mobilization of experts with country-specific skills in care practices. This would also demonstrate the importance given to paediatric medicines, and the extent to which their specific features are taken into account, particularly with regard to developers.

- Concerning patients' right to vote on the CHMP (provided for in article 148 of the compromise on EMA governance): the French authorities want patient/healthcare professional representatives to be members of the CHMP. These representatives should also have voting rights. The proportion of patient/healthcare professionals on the CHMP needs to be rebalanced.

The current composition of the PRAC seems to be the right format to reproduce, with 2 voting members, one for patients and one for professionals.

The level of representation of these 2 members represents around 5% of the PRAC. A comparable level could also be envisaged within the CHMP, i.e. 2 members (also 1+1). In the same vein, an alignment in proportion of co-opted members could lead to a level of 5 members, with a total composition of 34 members (27 MS + 5 co-opted + 2 (1patient + 1professional) = 34 members).

The deletion of recital 140a, which concerns expert witnesses, and the addition to article 75 1c) do not constitute a blocking point. With regard to article 75 1b) and 1c), the French authorities believe that a broad definition of the term "in the same therapeutic area" should be adopted, given the very specific illnesses that are sometimes outside the traditional therapeutic field, particularly due to the pathophysiological immaturity of newborn babies.

ITALY

MAJOR CRITICALITIES

EMA GOVERNANCE CLUSTER

- Article 148 R

Voting rights to patients and HCP in the CHMP

Italy supports the participation of patients, with their vote, in the EMA's decision-making. This participation has already been experienced in other committees over the past two decades, providing a valuable contribution to scientific discussions and decisions.

However, the representation of Member States at the EMA is expected to be reduced also following the suppression of some of the current committees. A more balanced situation appears necessary at the CHMP level. As a matter of fact, based on the current text of Article 148 R, the next CHMP will consist of 27 Member States, 4 patient representatives, 4 healthcare professional representatives, and 7 co-opted members (as from the PL PCY). So, the "voice" of Member States will be further reduced.

For this reason, 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. For us, it is not a matter of numbers but rather of active and qualifying participation.

Proposal for a 2nd alternate at the CHMP

Italy supports the Commission's proposal to streamline EMA's operations by providing a more efficient and simplified structure, allowing the necessary flexibility to address future challenges as they emerge and avoiding the constraints of rigid legislative provisions.
However, while we champion simplification, we also believe it is essential to uphold the influence of Member States in decision-making, as it is the responsibility of national institutions to implement the EMA's decisions at a local level.

The CHMP we are establishing will differ from the previous one, featuring a broader range of competencies and responsibilities. Consequently, discussions should be supported by more active participation to address complex and multifaceted scientific and regulatory issues.

To enhance the influence and more active participation of Member States in CHMP discussions, Italy proposes **appointing a second alternate member at the CHMP for each Member State.** Having two alternates will enable Member States to bolster discussions in CHMP, also encompassing a wider range of expertise currently present in the committees that will be abolished.

Adding a second alternate to represent the Member States would not alter the voting dynamic (as each Member State will keep counting for one vote) but would have the potential to foster engagement among colleagues, improve capability, enhance rapporteurship uptake, and improve the level of discussions during meetings, all with minimal financial implications. Alternates could follow the discussions remotely or participate in person based on the type of procedures on the agenda.

SLOVENIA

Please find below the response of Slovenia to the amendments to compromise texts of EMA governance and paediatrics cluster.

The amendments to the compromise texts of EMA governance and paediatrics cluster do not represent a red line for Slovenia, yet we would still like to comment on the recital 140a deletion. We would prefer the recital 140a not to be deleted from the text as mentioned in the last WP (15 April 2025) and in addition to the Recital (140a) **SI would like to propose to include new para 3 to Art 147, since a proper legal basis is necessary (we are of the opinion that a recital is not sufficient), as follows**:

3. Where specific expertise can only be provided by individuals who have competing interests incompatible with paragraph 1 of this article, and where it is in the interest of public health and to ensure getting the best possible scientific opinion, these individuals shall be permitted to act as expert-witness and provide written or oral testimony before a scientific committee, working party or other bodies of the Agency.

The expert witness must provide their testimony according to their best knowledge. They shall under no circumstances be considered a member or expert of the respective Agency body and be permitted to participate in the discussions nor in the deliberations and conclusions of said Agency body. The testimony of an expert-witness is subject to the discretion of the CHMP. Willfully telling an untruth or making a misrepresentation before CHMP can be prosecuted as perjury. In cases where the scientific opinion of an expert-witness has been taken into consideration in the decision-making process of the CHMP, this should be summarized in the EPAR.

SPAIN

Please find below ES's comments on the EMA's governance cluster and on orphan and paediatric medicines.

EMA Governance:

- ***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 ~~may participate~~ shall have ~~with~~ voting rights.

  From ES we consider as red line that in the deliberations of the CHMP patients and health professional associations must have the right to vote as well as they also bring knowledge to the Committee. However, we are flexible on the number: 2+2 or 1+1.

- ***Article 150: Scientific working parties and scientific advisory groups***

  The Committee 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.

  From ES we prefer it to be a less flexible provision, we prefer a "shall" rather than a "may" provision to ensure the effective creation of the working groups related to paediatrics medicines and orphan medicinal products.

Orphans medicines and Pediatrics medicinal products:

On recital (110) we considers that the updated proposal better reflects our views and internal discussion on the grounds for the waiver. However, limiting the use of the mechanism of action tool to support the paediatric development "WITHIN the same therapeutic area in children than the one for which the specific medicinal product or class of medicinal products is intended for in the adult population." will lead to the exclusion of neonates. Neonates constitute a very particular group of paediatric subjects as they are affected by very specific diseases with systemic manifestations that can be difficult to attribute to a single therapeutic area. The concept of the therapeutic area may not be fully applicable to them. Therefore, the definition and understanding of the same therapeutic area

should be deficiently broad as to be inclusive rather than exclusive of (e.g.) neonates, the age group with the highest need of therapeutic alternatives (high unmet medical need) and where the off-label use of medicines is the highest putting them a at high risk of undesirable effects (also due to the use of harmful excipients) and medication errors (dilution of adult formulations etc.)

Pharmacovigilance:

No comments.

SWEDEN

EMA GOVERNANCE

SE has no opinion regarding the deletion of recital 140 a) of the Regulation.

Art. 148 R: SE supports the compromised text in its current wording. Members representing healthcare professionals' organisations or patient organisations **shall not** have voting rights.

Art. 149 R: SE supports the compromise text in its current wording.

Art. 150.2 R: SE strongly suggest that the text should be amended so that The Committee **shall** establish working parties with the scientific expertise on paediatric medicinal products and orphan medicinal products. SE proposes that this text is placed in a separate subparagraph than the text regarding Environmental Risk Assessment working party which still can contain a may-provision.

ORPHANS AND PEADIATRICS

SE supports the amendments in art. 75 of the Regulation and the consequential changes in recital 110.

SE would like to see an additional amendment, as previously proposed by SE, for a PIP waiver for Article 48 repurposed paediatric indications, in those cases where someone else has performed the studies and PIP is deemed not relevant. This would clarify for Industry and constitute a regulatory simplification. The proposal that has been sent in by SE consists of an additional paragraph in

article 75: “1 a The Agency may also decide that the production of the information referred to in Article 6(5) point (a), of [revised Directive 2001/83], shall be waived for products subject to a variation to update the product information in accordance with article 48 (2).