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LIMITE

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CONTRIBUTION

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

Delegations will find enclosed comments related to the meetings of the Working Party on Pharmaceuticals and Medical Devices on 22 and 25 September 2025.

Written contributions from delegations

AUSTRIA

Please find below AT's written comment on Art 37 (2).

- AT comment on Art. 37(2) in the Directive (Pharma Package): In light of patient views that may provide valuable insights, AT can accept the EP position and remains flexible.

BELGIUM

As asked in the working party, these are our comments on art. 37 (2) of the Directive about representatives of patients in the **Coordination group.**

The EP is in favour of a representative of patient organisations, but we think there is a need to clarify this proposal of the Parliament. As it stands it is not clear what are the conditions of participation of this representative, it is not clear whether they will have a voting right.

We are wondering where this proposal is coming from, a large part of the work of the coordination group is on regulatory questions (such as interpretation of the legislation) which is of no interest to patient representatives.

This said, we are **not opposed in principle** to having a representative of patients organisations as an observer.

CZECH REPUBLIC

Despite some concerns, CZ supported mandate of the Council of the EU on Pharmaceutical Package. Taking into account the fragile balance achieved at the Council level, CZ believes that any possible concessions to the European Parliament proposals should be balanced by acceptance of the Council´s proposals in other parts of the Directive and Regulation Proposals.

EMA governance: voting rights for representatives of patients and healthcare professionals in the CHMP:

Article 148 para 3b of the Regulation Proposal

CZ fully supports mandate of the Council of the EU and respects the reasons why voting rights have been limited for representatives of patients and healthcare professionals. We would like to emphasize that the CHMP is the top scientific committee of EMA, and its opinion should be based on scientific evidence. While representatives of Member States have support from national teams of assessors and high scientific erudition that enable them to adopt qualified decisions on the tasks on the CHMP agenda, such scientific background is not provided for representatives of civil societies. Moreover, representatives of patients and healthcare professionals cannot take up the role of rapporteurs and co-rapporteurs. Their opinion could be influenced by a particular diagnosis or missing alternative of treatment. Extension of members in CHMP by other 8 representatives of civil societies could pose a significant risk of shifting the current decision-making practice of CHMP towards tendence decision-making.

However, CZ understands the political dimension of the European Parliament proposal and is prepared to contribute to reach a compromise at a later stage of negotiations. The following discussion could be focused on limitation of the number of representatives, alternatively on limitation of their voting right to one vote or on exclusion of their votes from the quorum of decision-making as it is currently in the case of votes of representatives EEA countries.

EMA governance: the number of representatives of patients and healthcare professionals in PRAC Committee:

Article 149 para 2 of the Regulation Proposal

CZ fully supports the mandate of the Council of the EU. We consider representation of patients and healthcare professionals in PRAC Committee important, but we are of the opinion that it is sufficient to include one representative for each group. We are concerned that increasing the number of representatives could lead to influencing from pharmaceutical companies on the voting process.

EMA governance: scientific working and advisory parties of EMA:

Article150 para 2 and 3a of the Regulation Proposal

CZ supports maintaining the initial proposal of the Commission, i.e. "may" clause, instead of "shall", as regards the obligation to create scientific working parties within EMA. We are of the opinion that larger flexibility should be given to establishing working parties within EMA according to the immediate needs of EMA. The possible representation of patients and healthcare professionals should correspond to the technical character of such working party of EMA.

In this context, we would like to point out that within EMA, there have already been Working Party on patients and consumers and Working Party on healthcare professionals established for a long time. Therefore, we propose to reflect these facts in this para. Please see the changes in wording proposed:

- The Committee ~~***shall***~~ **may** establish an ***ad hoc*** Environmental Risk Assessment working party and other scientific working parties, as necessary.
- **Representatives of patients, caregivers, clinicians and academia ~~shall~~ may be included as members of the working parties as appropriate.**

Representation of patients in the Coordination Group on decentralised and mutual recognition procedures (CMDh):

Article 37 para 2 of the Directive Proposal

CZ could be flexible regarding inclusion of the representatives of patients in the CMDh when questions with the direct impact on patients are concerned. For example, topics such as update of information about medicinal product and practical questions on implementation of PRAC Committee recommendation on referrals or PSUSA procedures are concerned. However, regarding standard membership in the CMDh, we would like to point out that the primary agenda are procedural, regulatory and technical questions and disagreements of Member States on assessment of applications in particular to generic, hybrid medicines, as well as WEU applications. In this context, we would like to ask why the European Parliament considers it important to include representatives of patients into the CMDh, respectively why patient organisations wish to participate in the CMDh.

CZ is also of the opinion that the possible participation of patients should not be aligned with voting right from the technical point of view. The CMDh has a mandate to vote bindingly only on referrals related to nationally authorised medicines and on recommendations of PRAC Committee on PSUSA procedures while within these procedures representatives of patients have already voted at the level of PRAC Committee.

Periods for assessment of application on marketing authorisation of medicines:

Article 6 para 6 of the Regulation Proposal and Article 30 of the Directive Proposal

CZ has already supported shortening of periods from 210 to 180 days during the negotiation at the working level of the Council of the EU and we can be flexible also in the case of the European Parliament proposal.

Scope of assessment of risks on environment (ERA):

Article 4 para 3 and Article 22 of the Directive Proposal

CZ supports mandate of the Council of the EU. Regarding the European Parliament proposal, we are concerned about potential excessive administrative burden and influence on medicines availability while the practical impact on the environment will be minimal in this case.

ESTONIA

EE comments on Art 27 para 2 Directive in the aftermath of the WP on 25 September

Estonia is not sure about the added value a patient's representative could bring to this technical coordination group as the discussions regarding questions relating to marketing authorisations of medicinal products (mainly generics) are primarily based on regulatory issues. Therefore, at the moment we support the Council's mandate or, for the sake of the compromise, in case it is needed, it could be exchanged for other provisions that hold the highest value for the Council.

FINLAND

WPPMD 22 September / Pharma Package / FI written comments

Pharmacy Exemption (article 1(5) and 1(6) Directive)

Finland supports the Council position.

However, in our view and for the nature of directive it is important that products with marketing authorisation should always be prioritised before any other alternatives.

This principle should be included at least in the corresponding recitals e.g. 20b after references to internal market. This view seems to be included in the position of the Parliament as well.

We propose to add new sentence in the end of Recital 20 (b); "**Products with marketing authorisation should always be prioritised before any other alternatives.***"*

Reference to the Court cases: C-544/13 *and C-545/13 and* C-276/15.

Shortage and defence exemption (Article 3 (1a) Directive)

Finland supports the Council position.

However, with the existing text there is an increased risk for supply issue, which is not what was the purpose of this provision**.** We should ensure that use of authorised products is always priority. Simultaneously we need to ensure that in exceptional case both manufacturing and use of unauthorised product is possible.

Thus we propose to add words "**or used**" in article 3(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 the specific needs of the patients in that Member State in a situation marketing authorisation holder has withdrawn the marketing authorisation of a medicinal product for reasons unrelated to quality, safety or efficacy or to address a situation, where there is an authorised medicinal product with a marketing authorisation which does not cover the specific strength, pharmaceutical form or formulation needed to address the specific needs of patients in that Member State.*

Additionally, the term **'or using'** should be added to the corresponding recital (20b).

Pharma package - FI comments on Art 37 para 2 Directive in the aftermath of the WP on 25 September

Please find below FI comments on article 37 para 2 Directive.

Although the presence of patient organizations is supported and considered highly important in other committees, the nature of the coordination group differs. The coordination group deals with procedure-related issues that require extremely deep procedural understanding, which cannot reasonably be expected from a representative of a patient organization.

FRANCE

Objet : commentaires des autorités françaises suite au groupe de travail « produits pharmaceutiques et dispositifs médicaux » du 22 septembre 2025.

Hospital exemption ATMP (cross-border) (Article 2 (8a) in the Directive).

The current Article 3.7 of Directive 2001/83 does not allow the import or export of these products, nor does the version of the Council mandate. The amendment could therefore meet needs that are not currently covered at Member State level, for those who wish to do so, since the word “may” is used in the Parliament's wording.

However, it is essential that the European provision allows Member States to submit advanced therapy medicinal products (ATMPs) under hospital exemption from another Member State to a product authorisation issued by the Member State receiving the product, so that these imported products meet national requirements. The aim is to prevent unauthorised products from competing with products that have been prepared and duly evaluated and authorised in accordance with requirements similar to those required for a marketing authorisation.

In fact, only the manufacture of MITs under hospital exemption is authorised in most Member States, as the finished product itself is not authorised. In order to ensure a level of quality and traceability equivalent to the European standards applicable to ATMPs subject to marketing authorisation, France, for example, has provided for authorisation of the finished product after assessment of the individual risk-benefit ratio and the quality of the product

The French authorities cannot accept the amendment of the Parliament as it stands. However, if needed, it could be amended to provide for stricter supervision.

In order not to undermine the basic principle of hospital exemption (MTI-PPs in France), NCA must be given the means to monitor that production remains ‘limited’ (in terms of volume, since it will no longer be geographical), otherwise there could be opportunities to circumvent the centralised marketing authorisation requirement.

Therefore, France suggests the following drafting amendment:

8a. By way of derogation from paragraph 1, Member States may authorise the cross-border exchange of advanced therapy medicinal products prepared under hospital exemption in justified cases of medical need and in the absence of other solutions for the individual patient. ***The Member State receiving the advanced therapy medicinal products prepared under hospital exemption might authorise it based on clinical, quality and security data****. A second medical practitioner and a hospital pharmacist in the receiving Member State shall be designated for the* ~~***exclusive***~~ *professional responsibility of the use and collection of follow-up data for the advanced therapy medicinal product. Information about the cross-border exchange shall be submitted to the competent authorities of both Member States, and shall be shared in the public repository referred to in paragraph 6 by the competent authority of the Member State of origin of the advanced therapy medicinal product.*

Objet :commentaires des autorités françaises suite au groupe de travail « produits pharmaceutiques et dispositifs médicaux » du 25 septembre 2025.

National procedures - representation of patient groups within the coordination group (Article 37(2) of the Directive)

The relevance of this participation in the CMDh (coordinating group) may be questioned, as the CMDh deals mainly with regulatory issues and generic marketing authorisation procedures.

However, this proposal may be accepted by the French authorities, particularly by analogy with our positions on the CHMP and PRAC. The Parliament's amendment thus may be supported.

Parliament's 'Transparency' amendment to the 'Advertising' section of the Directive.

The Parliament amendment (lines 1722a to 1723) adds paragraphs 4a to 4c to Article 186 of the Directive.

We would like to raise the following point regarding this amendment and we ask that this amendment be discussed.

In principle, the French authorities support greater transparency in promotional practices.

However, the amendment considers transparency from an advertising perspective only, whereas the French authorities adopt a much broader approach. This proposal from Parliament aims to regulate the promotion of medicines and ensure transparency in commercial practices across the EU (which is more akin to a law regulating benefits). However, our national definition of transparency goes far beyond advertising alone. It encompasses all links of interest between a company producing health products and a healthcare professional or organisation (hospital, patient association, healthcare professional association, etc.).

The Parliament's amendment would allow the 'medical' divisions of pharmaceutical companies without medical representatives or sales forces to easily circumvent the transparency requirement. As a result, medical research contracts would be exempt from transparency requirements, despite being a key pillar of our national legislation on conflicts of interest.

The French authorities therefore cannot support this amendment as it stands. If it were to be discussed during the trilogues, it would be essential either to reject it or to amend it. Drafting proposals would be shared if necessary.

GERMANY

As requested during the meeting by you, please find below written comments on ***Art. 37 para 2 Directive:***

DE opposes the position of the European Parliament and asks for a strong defence of Council mandate. For national, decentralized or mutual recognition authorisation procedures, which involve either known/proven substances or generic hybrid applications, patient participation does not offer a balanced cost-benefit ratio. This is because, due to strict regulatory requirements and evaluation criteria based on the reference medicinal product, patient representatives have little influence in practice. This is offset by considerable effort that is not balanced by corresponding benefits.“

GREECE

concerning the article 37 par. 2 of the Directive: **EL** supports the current Council Mandate taking into account that the CMDh is a purely scientific-regulatory body aiming to facilitate national regulatory procedures and thus the participation of patient representatives does not add to the process.

IRELAND

Please find below the IE comments on art. 37(2):

- As the nature of the CMDh is significantly more regulatory and procedural in nature than both the CHMP and PRAC, IE questions whether there would be added value in requiring patient representation in the coordination group. However, we remain flexible on this matter.

NETHERLANDS

Please find below the NL comments on art. 37(2):

The nature of the discussion in the CMDh is highly regulatory procedural and almost exclusively on generic medicinal products. Therefore, we feel that these discussions are not very relevant nor understandable for patients. Having said that the NL can be flexible towards a representative from patient organisations in the CMDh, as long as no voting rights are granted.

SLOVENIA

Please find below the **SI** comments on art. 37(2):

SI *is of the opinion that the inclusion of one representative from patients' organisations in the coordination group is not necessary. CMDh questions relating to a marketing authorisation of a medicinal product are mainly based on regulatory issues in connection with the Mutual Recognition and Decentralised Procedures.*

However, **SI** can remain flexible in a way that having a representative of patients organisations as an observer or

alternatively, the model currently followed by the CHMP could be used to invite patient representatives to topics and hearings of particular interest to them.

SWEDEN

Please find below SE´s written comment on Art 37 (2):

- Sweden can accept the European Parliament's amendment that the coordination group should also include a representative from patient organisations.

SPAIN

Regarding the latest discussions on the Pharmaceutical Package, I am sharing two comments for now:

- Antimicrobial resistance (AMR): Special information requirements (Directive Article 69/lines 808-812b), *where the Council removes the proposal for the 'awareness card' (line 810), while the Parliament maintains it. The Council introduces the global AMR symbol and additional information on the package leaflet as an alternative to the awareness card.*

> **Spain supports maintaining both the global AMR symbol and the awareness card, as both tools are complementary in raising awareness. <u>However, we consider the inclusion of the global AMR symbol on the package leaflet to be fundamental</u>.**
>
> In this regard, Spain, as part of the EU-JAMRAI project, is actively promoting the inclusion of the AMR symbol on antimicrobial package leaflets. To this end, I am attaching a document from EU-JAMRAI with the key arguments.
>
> **The symbol is fundamental** to ensure that **patients** know they are taking an **antimicrobial**. When receiving treatment, **they are often unaware** whether their medicine is an antibiotic or not. For example, in Spain and France, amoxicillin with clavulanic acid ("Augmentine") is among the most prescribed medicines in the community, **yet** studies show that most of the population does not know it is an antibiotic. **The AMR symbol visible on the package leaflet would address this knowledge gap immediately and universally.**

- "National procedures - representation of patient groups within the coordination group

(Article 37(2) of the Directive)

> **Spain supports the French comment:** *"The relevance of this participation in the CMDh (coordinating group) may be questioned, as the CMDh deals mainly with regulatory issues and generic marketing authorisation procedures. However, this proposal may be accepted by the French authorities, particularly by analogy with our positions on the CHMP and PRAC. <u>**The Parliament's amendment may thus be supported**</u>."*

EU-JAMRAI Joint Action Antimicrobial Resistance and Healthcare-Associated Infections

Pharma Legislation Review

Special info requirements for antimicrobials to raise awareness of their prudent use

***

AMR Symbol inclusion
Key arguments for Trilogue discussions

1. Proven power of symbols

Simple visual tools such as the AIDS Red Ribbon or the Pink Ribbon for breast cancer transformed awareness worldwide. The AMR Symbol, born within an EU initiative and already recognised at high-level meetings (UNGA, World Health Summit, ministerial events), has the same potential **if patients encounter it consistently**.

2. Why include it on antimicrobials leaflet with an awareness card

This combination ensures **maximum patient reach and visibility**. The leaflet is the official document every patient is expected to read, and the awareness card reinforces the message with additional context about the importance of proper handling and disposal of these precious medicines. Together, they guarantee **universal access and repeated exposure**. This two-layer approach **maximises the chance of behaviour change**.

3. Consistency with other health warnings

Medicines already carry visible warnings in the leaflet (pregnancy, driving, etc.). **AMR is a serious public health threat and should receive the same treatment**.

4. AMR Symbol is not sufficiently known

- Similar public health symbols, like the Red Ribbon for HIV/AIDS, were not universally recognised at first but became powerful awareness tools. Including the AMR Symbol on antimicrobial packaging accelerates this process and creates a **standardised, global approach to AMR awareness**.
- **Recognition takes time**, but the AMR Symbol was created within EU-JAMRAI (a project uniting all 27 EU Member States), is gaining traction among policymakers, scientists, and institutions, and has been **prominently used at major events** (UNGA, Ministerial AMR Meeting, World Health Summit).
- **It is not a standalone solution.** Efforts and campaigns to increase its recognition across target groups (general public, healthcare workers, veterinarians, farmers, policymakers) are ongoing. The **next campaign will target public reference hospitals in all Member States**.
- EU-JAMRAI 2 continues to receive **many requests from organisations wishing to use the Symbol**. A recent example came from the agency promoting the major **HBO/BBC production Superbug**.
- We now have the **opportunity to accelerate this process and consolidate it as a European initiative**.

Co-funded by the European Union

5. Unique opportunity for legitimacy and standardisation

Placing the AMR Symbol in the leaflet makes it an **official, EU-endorsed tool. Standardisation builds recognition and trust across Member States and avoids confusion with other pictograms.**

6. Minimal burden for industry

The symbol is **small**, uses **only two colours**, and requires negligible space.

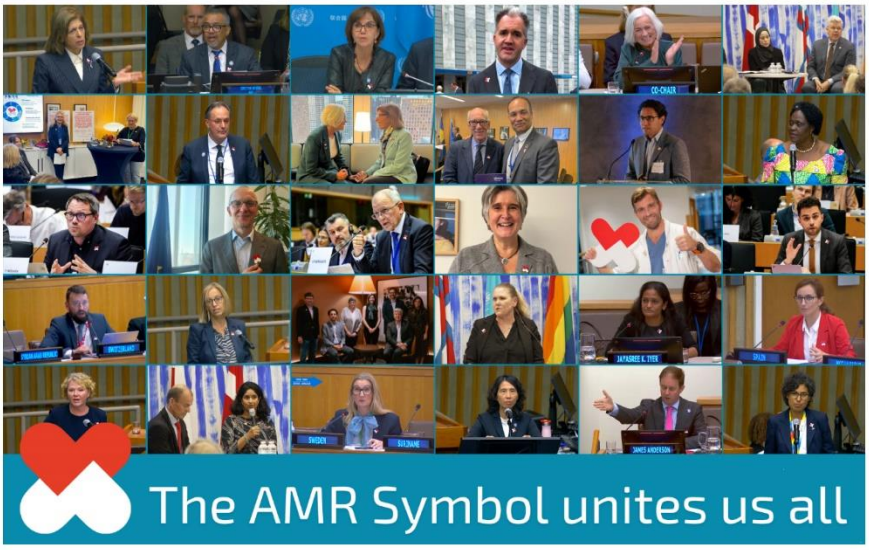
- It is a **simple measure** that will not increase production costs.
- **This is a public health initiative, not a restriction or a burden on industry.**

7. Space limitations in multilingual packaging

- We acknowledge the constraints, especially in small packs.
- The AMR Symbol is a simple, space-efficient visual element. Similar warnings already coexist without affecting legibility or availability.

8. Cost–benefit logic

AMR costs the European Economic Area more than €11 billion annually and causes around 1.3 million deaths globally each year. **The negligible implementation cost is fully justified by the potential to raise awareness and reduce misuse.**



More info about the AMR Symbol at

https://eu-jamrai.eu/raise-awareness/antimicrobial-resistance-symbol/

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