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CONTRIBUTION

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

Delegations find enclosed comments related to the Working Party on Pharmaceuticals on 28 April 2025.

COMMENTS FROM THE DELEGATIONS

WP OF 28 APRIL 2025

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FRANCE

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Objet :commentaires des autorités françaises suite au groupe de travail « produits pharmaceutiques et dispositifs médicaux » du 28 avril 2025.

English version:

Article 119R ***(Obligations on the marketing authorisation holder)***

119(3a) provides for an obligation for the company to carry out a risk assessment for medicinal products outside the scope of SPP and to put in place the necessary measures.

According to the interpretation of the French authorities, this measure is already implied in the obligations of Article 56 (obligation to ensure a continuous and proportionate supply). Its introduction raises the question of control by the competent authority. The French authorities therefore propose that the document should be provided at the request of the competent authority.

"(*3a) In case of medicinal products that are not subject to the obligation of preparing a shortage prevention plan the marketing authorisation holder shall carry out a regular documented risk assessment of potential supply chain risks and, where necessary, take mitigating measures ~~in order to fulfil its obligations set out in Article 56, paragraph 3 of the [Revised Directive 2001/83/EC].~~*

The national competent authority of the Member State or the Agency may request the marketing authorisation holder to submit that document at any time.

The marketing authorisation holder shall submit that copy at the latest two days after receipt of such request*."*

Article 131R ***(The Union List of Critical Medicinal Products)***

With regard to the EU list of critical medicinal products, in connection with Articles 127 and 130, we would point out that it is necessary to clarify in the text the link between the EU list of critical medicinal products and the work on supply chain vulnerabilities, given the consequences of these works in terms of obligations for pharmaceutical companies and national authorities.

In particular, the delegation supports the evaluation of the vulnerability of the supply chain for medicinal products in order to build the Union list at European level by the MSSG, as referred to in Article 130(1)(bb). This centralised process will improve the quality of the assessment by drawing on the contributions and aggregated information of all the national agencies concerned, enriched by the elements provided for in Article 130 (2). This vulnerability evaluation would also be carried out on "medicinal products at risk" in several Member States, following the application of the methodology referred to in Article 130(1)(a), allowing the inclusion of "medicinal products at risk" with proven supply chain vulnerability to the Union List of medicinal products. This approach would also be consistent with the current text of the CMA.

In link with the German proposal regarding Articles 127, 130 and 131, the French authorities propose the following changes:

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

1. **~~For the purposes of establishing the Union list of critical medicinal products referred to in Article 131 (1),~~** The competent authority of the Member State shall identify critical medicinal products in that Member State**~~, using~~ using** the methodology set out in Article 130(1), point (a). **~~The Member State shall make public a list of the critical medicinal products identified pursuant to this subparagraph. In addition to the first subparagraph, the Member State may establish a national list of critical medicinal products using a national methodology or the methodology set out in~~** ~~Article 130 (1), point (a).~~
2. The competent authority of the Member State acting through the working party referred to in Article 121(1), point (c), shall report to the Agency the critical medicinal products in that Member State **identified ~~identified~~** pursuant to the paragraph 1, first subparagraph, **and the data on supply chains vulnerabilities** as well as the information received from the marketing authorisation holder ~~as defined in Article 116(1).~~

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Article 130 - Role of the Agency

1. The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following:
    a. develop a common methodology to identify critical medicinal products **on the basis of their therapeutic relevance and availability of appropriate alternatives,** ~~including the evaluation of vulnerabilities with respect to the supply chain of those medicines,~~ in consultation, where appropriate, with relevant stakeholders;
    b. specify the procedures and criteria for establishing and reviewing the Union list of critical medicinal products referred to in Article 131;
    bb. **~~develop a methodology for~~work with the MSSG to develop a methodology evaluating vulnerabilities of critical medicinal products ~~on the basis of active pharmaceutical ingredients~~ with respect to the supply chains of those medicinal products, in consultation, where appropriate, with relevant stakeholders;**

Article 131 - The Union List of Critical Medicinal Products

1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c). ~~**In addition, the MSSG shall then evaluate the vulnerability with respect to the supply chains of the critical medicinal products identified according to Article 127 paragraph 1 subparagraph 1, using the methodology set out in Article 130(1), point (bb).**~~ Based on this consultation ~~**and the supply chain vulnerability evaluation**~~, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which **the** coordinated Union level action **foreseen in this chapter** is necessary ("the Union list of critical medicinal products").
2. **Following the completion of the "vulnerability evaluation" referred to in Article 130(1)(bb), concerning "medicinal products at risk" identified pursuant to the methodology set out in Article 130(1)(a), the MSSG add to the Union list of critical medicinal products those "medicinal products at risk" in several Member States and for which a supply chain vulnerability has been identified.**
3. The MSSG may propose updates to the Union list of critical medicinal products to the Commission, where necessary.

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Article 134R (*Role of the Commission)*

We point out that a harmonious link needs to be established between the measures put in place by the Member States to combat shortages and the decisions and actions taken at EU level by the MSSG or by the Commission, for example with regard to emergency stocks.

At this stage, the French authorities believe that Article 134 and the related recitals contain red lines or give rise to strong scrutiny reservations, and would like to underline the following points:

- The French authorities are not in favour of paragraph 2 and the powers conferred on the Commission with regard to stocks as well as recitals 136 and 138a.
- The French authorities would like paragraph 2 to be deleted, as proposed by the German delegation.
- The current wording of recitals (136) and (138a) acknowledges that national practices have caused difficulties for certain Member States and created inequalities within the EU. The French authorities would like these additions, which call into question specific national measures without any direct causal link having been established, to be deleted.
- European coordination is essential. This is currently provided by the EMA via its working groups, and seems appropriate to ensure fair management between Member States.
- Stock levels and obligations designed to ensure continuous market supply may need to be adapted to the structure of the national market and its specific characteristics.
- As it stands, the extent of the powers conferred on the Commission seems disproportionate, whereas the measures should allow Member States to draw up their own legislation in accordance with their specific characteristics, particularly with regard to the level of stock required to ensure adequate supplies, and using the solidarity mechanism where necessary.

Article 162(2a)D *(Wholesale distribution of medicinal products)*

With regard to parallel imports, the French authorities have comments and proposals for major changes to the Presidency's proposal.

- The French authorities have no objection to the reference to common origin.
- On the other hand, it seems insufficient to characterise parallel imports solely by the 3 criteria ‘common origin + same composition in active substance + same pharmaceutical form’. The delegation will therefore propose adding 3 other criteria (concerning excipients, final quantity of medicinal product per box and clinical information).

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- It is important to exclude differences in excipients that have a significant effect or that could potentially have an impact on patients. It is also particularly important, for patient safety reasons, that the imported speciality does not contain a quantity of active substance in excess of a maximum dose per box established in the country of destination (for example, 8g of paracetamol per box in France) in order to limit the risk of overdosing.

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

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

b) ***they have the same qualitative and quantitative composition in terms of excipients, except if different excipients or the same excipients in different quantities have no therapeutic impact and present no risk to public health;***

c) they have the same pharmaceutical form

d) ***package contains same weight, volume or number of dosage units;***

e) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation.

f) ***clinical information from the Member state of destination is applied."***

<u>Article 85D</u> (*Exemption to the protection of intellectual property rights*)

- The French authorities strongly opposes extending the Bolar exemption to include tender submissions before patent or SPC expiry.
- To ensure that participation in procurement tenders remains legally compliant under the patent framework and does not constitute an unlawful offer for sale, the tender documents or the bid must expressly state that no supply commitment will take effect until after the expiry of intellectual property so it would not infringe the exclusive rights of the patent holder under Article 28 of TRIPS. However, such an extension creates major uncertainties:

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- Extending the exemption to commercial tendering activities, even if conditional, risks blurring the distinction between lawful regulatory preparation and unlawful commercial acts prohibited during patent protection. Tender submissions, even if framed as "conditional," may still be construed as offers for sale under patent law, especially if national courts interpret procurement offers as legally binding or conferring preferential rights. It would undermine the reliability of procurement processes, introducing uncertainty about product availability and potentially disrupting essential medicine supply, with serious public health risks.
- Accepting bids that are conditional on the expiry of patent rights creates uncertainty about the availability of products, the risk that awards cannot be executed if legal challenges occur (patent litigation, extensions), and administrative and operational disruptions in medicine supply.
- It would also weaken patent protection, eroding the exclusivity guaranteed to innovators and threatening the integrity of the patent system.
- Critically, there is no demonstrated need for this extension: the existing Bolar framework already fully enables rapid market entry post-expiry by covering all necessary regulatory steps (clinical studies, marketing authorisations, HTA, pricing and reimbursement submissions). Authorising pre-expiry tender submissions would not add meaningful benefits but would seriously destabilise the legal and commercial environment in Europe.

Article 40R (***Granting the right to a transferable data exclusivity voucher)***

- The French authorities are not in favour of the exclusivity vouchers proposed by the Commission, as they do not constitute a cost-effective mechanism. Although the 'blockbuster' clause may reduce costs in absolute terms, it does not make it possible to determine whether the investment is profitable.
- Furthermore, the benefits that the developer of the antimicrobial can expect depend on uncertain external factors, including market concentration at the time of resale and the 'perceived value' of the medicine for the purchaser. The timing of the resale and use of the voucher further reduces its value. As the benefit that could be derived from the voucher is not known to the antibiotic company, it could be underestimated and therefore have less impact on the investment. At the national level, national healthcare systems will in any case have to bear the additional costs associated with the late entry of generic medicines.

- The French authorities support the emergence of an alternative solution. They consider that the transferable priority review voucher (guaranteeing access to PRIME and accelerated assessment of marketing authorisation) is more interesting. In this regard, the French authorities wish to relay the proposal already made by Denmark on this subject. This proposal aims to support the development of new priority antimicrobials and pave the way for market mobilisation to raise financial resources at an early stage of development and thus attract investors.

The principles are as follows:

- Application for designation of a developer of a priority antimicrobial at an early stage (i.e. before the marketing authorisation application) and criteria for designation;
- Designation and granting of an exclusivity voucher with a right to PRIME and a 120-day accelerated assessment;
- Right to transfer the voucher to another developer.

- Moreover, it is important to explore other solutions with the support and coordination of the European Commission, allowing for the decoupling of volume and revenue and/or a system of early payments at key stages of development prior to marketing authorisation for targeted needs. The Belgian delegation made some interesting proposals in this area, which are supported by the French authorities. The use of a Target Product Profile to anticipate eligibility for the mechanism enhances its predictability for innovators and sends a positive signal to potential investors at early stages. n addition, the direct financial contribution from Member States ensures immediate benefits upon integration into the subscription programme, offers stable liquidity over time, and provides a direct and stable source of funding, independent of commercial sales, thereby supporting the long-term development and establishment of the company.

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Addition to intervention by SE during CWP April 28 2025, SE proposal to add therapeutic radiopharmaceuticals in Annex VII (Directive):

Annex VII - *Areas for adapted frameworks referred to in Article 28*

"Phage-containing medicinal products, in cases where the medicinal product has a variable composition depending on the specific clinical context."'

"Therapeutic radiopharmaceuticals"

The rationale for adding therapeutic radiopharmaceuticals is because they fulfil the criteria stipulated in Article 28 1. (a) and (b) (compromise text from December 18, 2024), see below

Article 28.1 in the Directive describes the requirements on medicinal products to be included in Annex VII. Please find below each letter in the Article there is one or more technical argument(s) why therapeutic radiopharmaceuticals need to be included in Annex VII:

Article 28.1 (text from compromise proposal)

(a) "it is not possible to adequately assess the medicinal product or category of medicinal products applying the applicable requirements set out in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007 due to scientific or regulatory challenges arising from objective and scientific characteristics or methods inherent to the medicinal product or category of medicinal products; and."

SE rationale for that therapeutic radiopharmaceutical fulfil the criterium to be in Annex VII:

1. Therapeutic radiopharmaceuticals are a regulatory challenge because of the combined regulation from the Euratom Basic Safety Standards Directive (2013/59) and the pharmaceutical legislation. The former demands individual optimization of the treatment (as described in recital 19 of the introduction to the proposal for pharma directive), which is not part of the pharma legislation. On a scientific level, said optimization is methodologically complex, the methods are constantly evolving and they differ from one type of radiopharmaceutical to another (e.g. alpha-emitters vs beta-emitters).

Article 28.1 (text from compromise proposal)

(b) "the characteristics or methods inherent to the medicinal product or category of medicinal products positively impact the quality, safety and efficacy of the medicinal product or category of medicinal product or provide a major contribution to patient access to prevention, diagnosis, or treatment or any other form of patient care.

SE rationale for that therapeutic radiopharmaceutical fulfil the criterium to be in Annex VII:

1. The mechanism of action of therapeutic radiopharmaceuticals depend to an equal extent on the radioactive isotope which delivers the ionizing radiation, and the targeting molecule which ensures that the radiation is delivered in a targeted way. As with all types of radiation therapy, the amount of delivered radiation will affect the size of the biological effect. This is true for both the anti-tumor effect and for the toxic effects on normal tissues and organs. It is possible to estimate the amount of radiation delivered to both tumors and risk organs during therapy e.g. through imaging, and adjusting subsequent treatment cycles to ensure a sufficient radiation dose to tumors and a radiation dose to risk organs with an acceptable level of toxicity. The result of such a process is an optimized efficacy vs safety, i.e. benefit/risk.

2. Optimization of the radiation dose has the added potential of optimizing resource use in healthcare. Properly used, it enables us to appropriately select the patients that will have the greatest chance of benefit, while excluding those that will not be able to receive the therapy with an acceptable balance of efficacy vs toxicity. Such optimization of resource use would reduce the environmental hazards of inadvertent radiation exposure in the whole chain from production to transport to hospitals to home. Last but not least, therapeutic radioisotopes are a scarce resource under a steadily increasing demand. We therefore need to ensure that their use is optimized from an early point in time.

3. If the regulatory authorities continue to allow a non-optimized use of this class of drugs, patient access may be hampered by a non-optimized resource use in the healthcare institutions of the Member States. On the other hand, to demand full optimization (i.e. full adherence to the Euratom Directive) from one day to another would completely stall patient access except at a few selected sites in a few selected Member States. The development of a regulatory framework for this class of drugs must therefore be done in a context that allows some level of flexibility and modifications over time, to a larger extent than what is possible in the core legal text.

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