Council of the European Union
General Secretariat

PUBLIC

Brussels, 08 May 2025

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

WK 5450/2025 ADD 3

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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

PUBLIC

CROATIA, CZECH REPUBLIC, FRANCE, GERMANY, ITALY, THE NETHERLANDS

PUBLIC

On behalf of Croatia, Czech Republic, France, Germany, Italy, the Netherlands, you will find enclosed a background paper on incentives for priority antimicrobials ahead of our WP discussions next week.

To sum it up:

- We are maintaining our reservations on the exclusivity vouchers proposed by the Commission which is not a cost-efficient mechanism according to us. Even if the 'blockbuster' clause may reduce the cost in absolute terms, it does not really answer the issue that this investment is not cost-effective.
- We question the efficiency of the TEV, particularly as the profit that the developer of the antimicrobial can expect to make depends on uncertain external factors, including market concentration at the time of resale and the 'perceived value' of the buyer's drug. The timing of the resale as well as of the use of the voucher further reduce its value. As the profit that could be made from the voucher is not known for the antibiotic laboratory, it could be underestimated and therefore have a lesser effect on the investment. At the same the national health care systems will need to bear the additional costs of the belated generic entry anyway.
- We trust other alternatives that provide sufficient support to pay Europe's fair share, while being cost-effective and incentivising stewardship should be considered.

Pharmaceutical package: background paper on incentives for priority antimicrobials

Summary / key points:
We are maintaining our reservations on the exclusivity vouchers proposed by the Commission which is not a cost-efficient mechanism according to us. Even if the 'blockbuster' clause may reduce the cost in absolute terms, it does not really answer the issue that this investment is not cost-effective.

We question the efficiency of the TEV, particularly as the profit that the developer of the antimicrobial can expect to make depends on uncertain external factors, including market concentration at the time of resale and the 'perceived value' of the buyer's drug. The timing of the resale as well as of the use of the voucher further reduce its value. As the profit that could be made from the voucher is not known for the antibiotic laboratory, it could be underestimated and therefore have a lesser effect on the investment. At the same the national health care systems will need to bear the additional costs of the belated generic entry anyway.
We trust other alternatives that provide sufficient support to pay Europe's fair share, while being cost-effective and incentivising stewardship should be considered.

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Why do we consider that the transfer exclusivity voucher (TEV) is not the adapted tool to incentivize the development of new antimicrobials?

1. The TEV is a mechanism that is not cost-effective:

We are maintaining our reservations on the exclusivity vouchers proposed by the Commission, given their impact on healthcare spendings, despite the 'blockbuster' clause. Even if this clause reduces the cost in absolute terms, it does not really answer the issue that this investment is not cost-effective. In the end, the real beneficiary will be the buyer as he will receive an additional year of data protection, however the buyer will never pay the worth he associates with this additional year of data protection to the developer. Thus the national health care system will need to bear high costs which eventually will benefit the buyer most.

2. Several doubts regarding the efficiency and attractiveness of the TEV are identified:

We also have doubts about the efficiency of the TEV, particularly as the profit that the developer of the antimicrobial can expect to make is fairly small:

First, the actual value of the voucher is a source of uncertainty. It depends on uncertain external factors, including market concentration at the time of resale. The resale of the voucher depends on the 'perceived value' of the buyer's drug. The price at which a pharmaceutical company would be prepared to buy the voucher depends on the commercial value of the product to which it can be applied. If the buyer market is small, the value of the voucher will fall sharply. The 'blockbuster' clause increases this risk as the beneficiary drug must not have had average annual sales in excess of €490 million, which severely limits the number of would-be buyers and therefore reduces competition for the voucher.

Second, the timing of the resale as well as of the use of the voucher further reduce its value. The sale of the voucher will take place in year 5, while the term of protection will begin at the end of year 10 (or 11 if there is an additional indication), i.e. 5 or 6 years later (in the Commission's version, this period was estimated at only 2 years). The time lag between the investment and the benefit implies the application of a discount rate (10% to 12% per year). This means that at least 40% of the possible profit will be 'deducted' when estimating the profit made by the purchasing laboratory when setting the purchase price of the voucher, i.e. the same amount of loss for the laboratory selling the voucher. **As the profit that could be made from the voucher is not known in advance, the antibiotic laboratory could underestimate it, lessing the primary investment and therefore the incentive's effectiveness.**

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3. Other alternatives should be considered:

In light of the above, we trust other alternatives that provide sufficient support to pay Europe's fair share, while being cost-effective and incentivising stewardship, should be considered such as:

- a transferable priority review voucher (guarantying an access to PRIME and a fast-track market authorization evaluation);
- prolonged data exclusivity for antibiotics;
- the implementation of EU-financed incentives allowing for volume-revenue de-linkage with the support and coordination of the European commission;
- a system of early payments at key stages of development prior to marketing authorization for targeted needs.

SPAIN

Spain can also support the reservations on the TEVs expressed in the non-paper by CZ, DE, FR, HR, IT, and NL, and we are therefore open to exploring other alternative options set out in the non-paper.

However, we would not be totally opposed to combining alternative proposals with TEVs, as long as they are developed in a controlled environment".

FINLAND

PUBLIC

RED LINE FOR FI

Regulation

Article 134

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

Justification:

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

Directive:

Article 3

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Justification:

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

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

Article 4

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

Article 49

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

Justification:

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

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

Article 56

para 2a: this section should be completely deleted.

Justification:

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

Arikle 93a

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

Justification:

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

PUBLIC

Article 103

para 6: We propose to change the para accordingly:

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

Justification:

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

Article 135

para 1: We propose to change this para accordingly:

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

Justification:

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

Article 141

para 1 point d) : should be changed accordingly:

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

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Justification:

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

Article 151

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

Article 162

Point 2a

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

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

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

(b) they have the same pharmaceutical form; and

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

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

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

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

Article 219

Para 1: should be changed accordingly:

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

Justification:

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

Regulation

Article 45

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

Justification:

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

Article 90

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

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

Justification:

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

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

PUBLIC

Article 134

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

Justification:

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

PUBLIC

FRANCE

PUBLIC

In view of the WP of next week, you will find hereafter some elements for your consideration concerning the French position on the Bolar exemption:

We are firmly opposed the extension of the Bolar exemption to public procurement tenders prior to the expiry of the patent or supplementary protection certificate (SPC).

To ensure that participation in tenders remains legally compliant with the patent framework and does not constitute an unlawful offer for sale, the bid must explicitly state that no commitment to supply will take effect before the expiry of intellectual property rights. This ensures that such actions do not infringe upon the exclusive rights of the patent holder under Article 28 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

However, this extension introduces major uncertainties:

- Extending the exemption to commercial tendering activities, even conditionally, risks blurring the line between the lawful preparation for market entry and prohibited commercial acts during the term of patent protection. Bids, even when presented as "conditional," can still be interpreted as offers for sale under patent law—particularly if national courts consider tender submissions to be legally binding or conferring preferential rights. This would undermine the reliability of procurement processes, create uncertainty regarding product availability, and risk disrupting the supply of essential medicines, with serious public health consequences;
- Accepting bids conditional upon the expiry of patent rights creates uncertainty regarding product availability, the risk that awards cannot be implemented in case of legal disputes (e.g., patent litigation, extensions), and operational and administrative disruptions in the medicines supply chain;
- It would also weaken patent protection, erode the exclusivity guaranteed to innovators, and threaten the integrity of the patent system;
- This extension is not necessary: the current Bolar framework already enables swift market entry upon patent expiry, covering all necessary regulatory steps (clinical trials, marketing authorisations, health technology assessments, pricing and reimbursement applications). Allowing tender submissions before expiry would not bring meaningful benefits but would significantly destabilise the legal and commercial environment in Europe.