Council of the European Union
General Secretariat

Brussels, 10 July 2025

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

WK 9567/2025 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 related to the Working Party on Pharmaceuticals and Medical Devices on 24 June 2025.

COMMENTS FROM THE DELEGATIONS

Working Party on Pharmaceuticals and Medical Devices 24 June 2025

AUSTRIA

- General comment: AT prefers to remain with the Council mandate concerning the changes proposed to by the EP regarding antimicrobial resistance. Generally, antimicrobial resistance and various problems in the development of novel antimicrobials are currently sufficiently addressed. We see this as an issue that primarily needs to be addressed outside of the general pharmaceutical legislation. Regarding the suggested alternatives to the voucher, AT also chooses to remain with the Council mandate at this point in time. However, we remain open for a discussion of other alternatives, if there is clear evidence that they can be more effective in incentivizing the development of novel antimicrobials than the current version of the voucher.
- Recital 78a (line 88, etc.) and Article 175a (line 1539 etc.): the re-establishment of HERA under the legal personality of ECDC is a matter that should be dealt with in an open procedure with a public discussion and not via an amendment to the pharmaceutical legislation. To our knowledge the legal location of HERA has been agreed to remain as is, AT supports this.
- Additionally, it is important for AT that the proposal for the General Pharmaceutical Legislation is harmonized with the proposal for the Critical Medicines Act. Any provisions regarding the joint procurement, for example, should be located in the CMA and not in the GPL for that matter.

BULGARIA

As also stated during the WP, our views are similar to those of the German colleagues. We support the Council position on the TEV, which was a difficult comprise reached with the precious aide of the Commission.

No support from our side on subscription models: as mentioned, we have a very critical view on this idea.

CZECHIA

CZ comments on Pharmaceutical Package after WP on 24th June 2025:		
Regulation Proposal:		
TEV:		In general, CZ is of the opinion that the issue of incentives for antimicrobials had not been sufficiently discussed at the Council (technical) level before the mandate of the Council for trilogues was granted. Therefore, it is important to clarify the position of the Council on TEV and potential alternatives before next trilogues. From the beginning of the negotiations, CZ is not in favour of TEV and proposes to delete it and to ensure the support of research and development of antimicrobials via milestone payments, voucher ensuring PRIME, accelerated assessment of priority antimicrobials and the additional data protection for the priority antimicrobials.
Lines 445a-445o, new Article 39a		
Para 2		In general, CZ is in favour of milestone payments for support research and development of a priority antimicrobial. However, it is necessary

		to establish a funding system for the upcoming MFFs in order to ensure the possibility to support research and development within MFF 2028+ and in the future as well.
Para 4		CZ does not agree with the combination of milestone payments and TEV as the problematic elements of the TEV proposal, such as nontransparency and unpredictability, are maintained.
Recital 77b		Additionally, CZ is in favour of setting a milestone for achieving financial support after completion of the phase I of clinical trials (as referred to in Recital 77b).
Lines 445p-445z – new Article 39b		CZ would like to ask for clarification how the EP proposal on subscription model for the joint procurement of antimicrobials is additional to the current EU legislation on joint procurement such as the Regulation of the European Parliament and the Council of the EU on serious cross-border threats to health on which basis, it has already been possible to carry out joint procurement of antibiotics. Moreover, it is important to take into consideration provisions on joint procurement

		stipulated in the proposed Critical Medicines Act in order to ensure that after the adoption of the particular legislative proposals, the complex system on joint procurement will be reached. It is crucial to avoid duplications.
Para 4		In general, CZ supports joining third countries into joint procurement.
Line 449a – new para 2a Article 40		In addition to the general disagreement with TEV, CZ is not in favour of addition of the new para 2a as this provision could create a more unclear environment. Moreover, it is not clear how division of pathogens into three groups could be aligned with definition of the priority antimicrobials.
Line 464a – new para 3a		In addition to the general disagreement with TEV, CZ is not in favour of addition of para 3a as the proposed mechanism is unclear and raises new questions. We consider it inappropriate to impose such an obligation for HERA also due to the fact that there might be changes to its role as the final position of HERA is not clear based on EP proposals. Apart from that, a situation regarding finances which should be transferred to

		HERA would have to be more clarified, especially in the case if the supplies of the priority antimicrobials are not ensured.
HERA		
Lines 1539a-1569bd – new Article 175a		Regarding incorporation of HERA into the structure of the ECDC through a change of the Regulation of the European Parliament and the Council of the EU on ECDC via the Pharmaceutical Package, CZ is not in favour of this proposal. We are of the opinion that competences of HERA should not be set out via the Pharmaceutical Package, despite the fact that we have for a long-time supported discussions on clarification of HERA competences within the whole system. Moreover, we would like to point out that this change is not explained in detail and the consequences of such change are not specified. Furthermore, we are of the opinion that the proposed change could reduce the role and the initial mandate of HERA. CZ would also like to point out that the ECDC is focused on transferable diseases while HERA includes wider branch of activities related to

		cross-border threats to health, including ensuring of access to key health countermeasures such as vaccines, medicines and medical devices. Therefore, CZ believes that incorporation of HERA under ECDC could bring risk of reduction of its options how to react on different potential health crises in the future which is not desirable.

FRANCE

English version follows

Les autorités considèrent que le système de "boîte à outils" du Parlement européen est une approche pragmatique et constructive. En effet, à ce stade, il n'est pas clairement établi quel mécanisme sera le plus efficace, et nous avons des doutes sur le fait que le voucher d'exclusivité transférable soit l'outil le plus adapté, il serait donc préférable de permettre au développeur de sélectionner l'option la plus pertinente pour répondre à leur besoin tout en optimisant le coût de ces incitations.

Le Parlement a introduit des éléments très intéressants sur ce sujet. Nous soutenons sur le principe les ajouts du Parlement des articles 39 bis (système de paiement échelonné de primes) et 39 ter (modèle de souscription en vue de la passation conjointe de marché pour l'achat d'antimicrobiens) qui peuvent être choisi par le développeur, en alternative aux TEV (Transferable Exclusivity Voucher).

Le Priority Review Voucher (PRV) qui n'a pas été intégré dans la version du Conseil, ni dans celle du Parlement européen, est un outil très intéressant en complément du dispositif des early payments (article 39 bis) en réduisant leurs coûts.

Nous estimons qu'il convient d'ajuster la rédaction proposée pour l'article 39 bis afin de ne pas lier son financement à des fonds spécifiques et ainsi, assurer sa pérennité.

L'articulation du modèle de souscription avec le *Critical Medicines Act* (CMA) nous semble être une piste à explorer. Il pourrait être plus pertinent d'intégrer cette mesure dans le CMA afin d'éviter les doublons et de garantir la cohérence entre les textes. En effet, selon les clauses intégrées, les achats conjoints peuvent prendre la forme d'un modèle de souscription.

Enfin, nous souhaitons conserver la définition des antimicrobiens prioritaires issue des travaux du Conseil.

The French authorities consider the European Parliament's "toolbox" system to be a pragmatic and constructive approach. Indeed, at this stage, it is not clear which mechanism will be the most effective, and we have doubts as to whether the transferable exclusivity voucher is the most suitable tool, so it would be preferable to allow the developer to select the most relevant option to meet their needs, while optimizing the cost of these incentives.

The European Parliament has introduced some very interesting elements on this subject. We support in principle the Parliament's additions of articles 39 bis (staggered premium payment system) and 39 ter (subscription model for joint procurement of antimicrobials), which can be chosen by the developer as an alternative to the Transferable Exclusivity Voucher (TEV).

The Priority Review Voucher (PRV), which was not included in either the Council or European Parliament versions, is a very interesting tool to complement the early payment mechanism (article 39 bis) by reducing their costs.

We believe that the proposed wording of Article 39 bis needs to be adjusted to ensure that its financing is not tied to specific funds and that it is sustainable.

We believe that linking the subscription model to the Critical Medicines Act (CMA) is an avenue worth exploring. It might be more appropriate to integrate this measure into the CMA in order to avoid duplication and ensure consistency between texts. Indeed, depending on the clauses incorporated, joint purchases may take the form of a subscription model.

Lastly, we wish to retain the definition of priority antimicrobials resulting from the Council's work.

Recitals

Rows	*Position*
1. row 87 –recital 77.	Reservations to the adding of antimicrobial research and development (R&D) is hampered by the low commercial value of the antimicrobial medicinal product market. It refers to national prices.
2.row 87a– new recital 77a.	Support to the introduction of alternatives solutions such as market entry rewards and milestone reward payments and joint procurement scheme.
3. row 87b– new recital 77b.	Support to subscription model and milestone reward payments.
4. row 88a– new recital 78a.	The French authorities do not support the proposal about HERA.
5. row 88b– new recital 78b	Scrutiny reservations, this recital is linked with data protection modulation.
6. row 88c – new recital 78c.	
7. row 89 – to recital 79.	Support Concerning the use of an authority for monetary transfer: scrutiny reservations.
8. row 90 – to recital 80.	
9. row 91 – to recital 81.	Same comment as recital 80.
10. row 92 – to recital 82.	Support to the following PE's amendment *(may only be transferred once)*
11. row 93 – to recital 83.	The French authorities support the principle of an assessment of the scheme.

Article 39a (EP) – Milestone Payment Reward Scheme

Row	*Position*
	445b to 445f: We support the Council's version regarding identifying priority antimicrobials.

12. rows 445a to 445o – new Article 39a.	445g: We support the definition of the funding arrangements by the Commission through a delegated act or an implementing act.
	445h to 445m: We support the amendments.
	445n: It will be necessary to activate the mechanism provided for in Article 7(3) of the HTAR to avoid blocking the market entry of priority antimicrobials that have benefited from milestone payments. In 2030, all centrally authorised products will be subject to JCA.
	445o: We support the provision that a beneficiary of milestone payments cannot also benefit from the sale of a voucher.

Article 39b – Subscription Model for the Joint Procurement of Antimicrobials

Row	*Position*
13. rows 445p to 445z– new Article 39b.	445q to 445v: We support this alternative solution.
	445w: (PE) The draft directive requires an environmental risk assessment for all marketing authorisation applications. This requirement may not be essential.
	445x: (PE) We have doubts about the feasibility of supplying these antimicrobials to third countries, even though we fully understand the need. This obligation could discourage some developers.
	445y: (PE) Along the same lines, it is necessary to verify the legal feasibility of extending joint procurement procedures to third countries.

Article 40 – Granting the Right to a Transferable Data Exclusivity Voucher

Row	*Position:* **We have strong reservations about the TEV mechanism.**
14. row 448– to Article 40.1.	
15. row 449– to Article 40.2.	449: We are in favour of allowing a data protection period shorter than 12 months, and we welcome the clarifications on the modulation provided in 449a.

16. row 449a– new par. 2a in Article 40.	
17. rows 450 to 454– deletion of paragraph 3 in Article 40.	450 to 454: We support the Council's provisions concerning the criteria to identify priority antimicrobials (article 40.3).
18. rows 455 to 458 – to Article 40.4.	457a : this amendment could inadvertently exclude relevant candidates, discourage global development strategies, and introduce unnecessary procedural rigidity. Moreover, given that these products are intended to be used as a last resort and preserved for future need, the issue of early market access in the EU should not take precedence over ensuring long-term availability. 457c : this amendment raises feasibility issues
19. row 458b – new paragraph 4a in Article 40.	

Article 41Transfer and use of the voucher

Row	*Position*
20. rows 460 to 462 – to Article 41.1.	460 : (PE) we support the modulation of extension of data protection (article 40.1). 461 : (PE) we support the restriction of use.
21. row 464 – to Article 41.3.	
22. row 464a – new paragraph 3a.	464a: scrutiny reservations concerning TEV.

Article 42 Validity of the voucher / Article 43 Duration of application of Chapter III

Row	*Position*
23. row 469 – to Article 42.1.b.	469 : (PE) to be examined according to the chosen conditions.
24. row 470 – to Article 42.2.	470 : (PE) it seems not necessary to specify the condition of a contract
25. rows 472 to 473a – to Article 43	473: We support the Council's version, subject to the limit of five vouchers and the consideration of the evaluation. **Article 43 Duration of application of Chapter III** 473a : (PE) We support the principle of evaluating the provision, as already foreseen in Article 170(5) of the Council's version.

Article 175 (new)

Row	*Position*
26. rows 1539a to 1539bd – new Article 175a	The French authorities do not support the proposal about HERA.

LITHUANIA

Lithuanian position on proposals by the EP regarding Articles 39a, 39b, 40, 41, 43, 175a of Regulation

Article 39a. ***Milestone payment reward scheme***

In principle, Lithuania could support the introduction of alternative incentive mechanisms for priority antimicrobials. However, the proposed milestone payment reward scheme raises several concerns, namely:

- the conditions for applying the incentive remain unclear, as the criteria for awarding milestone payments will be determined through delegated acts;
- it is not specified which development stages will be defined, nor how compliance with these stages will be assessed.

The source of funding for these payments is ambiguous, particularly given that the referenced financial framework appears to have expired in 2007.

Article 39b. Subscription model for the joint procurement of antimicrobials

We are flexible regarding the proposed model. However, it should be moved to the Critical Medicines Act where joint procurement procedures are regulated.

Article 40. Granting the right to a transferable data exclusivity voucher

Paragraph 2a provides for the Commission to adopt delegated acts determining pathogen eligibility for graduated protection periods 12, 9 or 6 months based on their classification as *critical, high*, or *medium* priority.

While we acknowledge the intention to incentivise antimicrobial development, **we are concerned that proposed approach may lack sufficient appeal** to developers and manufacturers. In particular:

- the lack of clarity regarding the classification criteria and implementations timelines may undermine predictability;
- developers may perceive it as **insufficient motivation** to invest in costly research and production.

Regarding **paragraph 4**, LT could support proposed amendments that require applicants to submit stewardship and access plans. However, we have doubts about the proposal to make global access plan aimed at supplying third countries in critical need – a mandatory component of the joint procurement contract.

We fully recognise the importance of global health solidarity and antimicrobial access in third countries. Nevertheless, we believe that **this requirement should remain voluntary**, to avoid unintended pressure on manufacturers.

Article 41. Transfer and use of the voucher

We do not support the amendments to Article 41, incl. graduation periods provided for in Article 40. We support the compromised text agreed in the WG of the Council.

Article 43. Duration of application of Chapter III

We support proposed amendments to Chapter III, in particular obligation of the Commission after five years from the date of entry into force of the Regulation to submit an evaluation report containing scientific assessment measuring the progress with regard to antimicrobial research and development and the effectiveness of the incentives and rewards.

Article 175a. Amendments to Regulation (EC) No 851/2004.

Changing the legal status of the Health Emergency Preparedness and Response Authority (‘HERA) is rather political question, furthermore it should not be discussed within the pharma legislation framework.

MALTA

At this point Malta would prefer to stick to the Council position on the vouchers. Malta may consider the inclusion of milestone payments and the subscription model.

Malta is also open to move towards the EP on line 87a, 87b, 88b, and 88c.

It is premature to consider that HERA becomes an independent agency

THE NETHERLANDS

Recital 77			
(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure ***whereby antimicrobial research and development (R&D) is hampered by the low commercial value of the antimicrobial medicinal product market.*** It is therefore necessary to ***maintain the efficacy of existing antimicrobials for as long as possible and to*** consider ***a number of*** new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, ***and not-for-profit entities***	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.	NL: Acceptance of this recital depends on the outcome of the disucssions of the proposed measures. Same for row 87a and row 87b

	which choose to invest in this area. ***It is equally necessary to support research and development of novel antimicrobials through the different phases of antimicrobial development, in particular through market entry rewards and milestone reward payments. Additionally, the establishment of subscription models which delink the volume of antimicrobial sales from the reward received, in particular through voluntary joint procurement, can help overcome such market failures. Such measures should facilitate the development of alternative treatments, such as bacteriophages, which are effective against multi-drug resistant bacteria and can be used as an alternative treatment or together with antibiotics. However, addressing anti-microbial***		

	resistance will not be possible by relying on R&D alone. To ensure prudent use of existing antibiotics, the Authority should also support the development and procurement of rapid diagnostic tools to ensure appropriate prescriptions.		
Recital 78a			
	(78a) To effectively address major ongoing and upcoming public health challenges, in particular antimicrobial resistance, while also building on existing resources, the Health Emergency Preparedness and Response Authority ('HERA' or the 'Authority') should be established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control (ECDC), which was established by Regulation (EC) No 851/2004 of		Acceptance of this proposed recital depends on the outcome of the discussions

	the European Parliament and of the Council[1a]. The Authority should be responsible for creating, coordinating and implementing the long-term European portfolio of biomedical research and development agenda for medical countermeasures against current and emerging public health threats, as well as providing tools to ensure Union-wide access to those products, including tools to support the production, procurement, stockpiling and distribution capacity for medical countermeasures and other priority medical products in the Union. The Authority will play a crucial role in addressing health threats globally. The Authority should primarily focus on the fight against the most urgent health threats, including antimicrobial resistance and shortages of		

	medicinal products. However, in the future as its capacity increases, the Authority should expand the scope of its mission, specifically to tackle other areas of unmet medical need such as rare and neglected diseases. The Authority should have adequate resources to fulfil its mandate. _____ ***1a. Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).***		
Recital 78c			
	(78c) Joint procurement, whether within a country or involving more than one country, can improve access to, affordability, and security of supply of medicinal products. Member States interested in joint procurement of medicinal products should be able to request the		Acceptance of this proposed recital depends on the outcome of the discussions

	Commission to facilitate joint procurement of centrally authorised medicinal products at Union level conducted pursuant to Directive 2014/24/EU of the European Parliament and of the Council[1a] _____ ***1a. Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).***		
Recital 79			
(79) The creation of a voucher rewarding the development of priority antimicrobials through an additional year of regulatory data protection has the capacity to provide the needed financial support to developers of priority antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the	(79) ***As an alternative, for developers who have not availed of market entry rewards and milestone payment schemes,*** the creation of a voucher rewarding the development of priority antimicrobials through an additional ~~year~~***period*** of regulatory data protection has the capacity to provide the needed financial support to developers of priority	(79) The creation of a voucher rewarding the development of priority antimicrobials through an additional year of regulatory data protection has the capacity to provide the needed financial support to developers of priority antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the	Acceptance of this proposed recital depends on the outcome of the discussions

developer of the priority antimicrobial and not the buyer of the voucher, the number of available vouchers on the market should be kept to a minimum. It is therefore necessary to establish strict conditions of granting, transfer and use of the voucher and to further give the possibility to the Commission to revoke the voucher under certain circumstances.	antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the developer of the priority antimicrobial and not the buyer of the voucher, the number of available vouchers on the market should be kept to a minimum. It is therefore necessary to establish strict conditions of granting, transfer and use of the voucher and to further give the possibility to the Commission to revoke the voucher under certain circumstances. ***Additionally, the monetary value paid for the transfer of the voucher should be transferred to the Authority, which should distribute the corresponding amount, in yearly instalments, to the marketing authorisation holder, in order to ensure manufacturing capacity and***	developer of the priority antimicrobial and not the buyer of the voucher, the number of available vouchers on the market should be kept to a minimum. It is therefore necessary to establish strict conditions of granting, transfer and use of the voucher and to further give the possibility to the Commission to revoke the voucher under certain circumstances.	

	supply of the priority antimicrobial for which the voucher was created.		
Article 39a			
	Article 39a ***Milestone payment reward scheme***		As stated during the CWP, NL underlines the urgency of Antimicrobial Resistance and the need for effective countermeasures to address this growing issue. Furthermore as a general remark, we urge to stick as close as possible to the knowledge and experience of HERA on the topic of AMR. EP has proposed the milestone payment reward scheme and joint procurement subscription model **additionally** to the voucher. For the Milestone payment reward scheme, we wonder why EP has chosen to add the milestone payment reward scheme in addition to the voucher and its proposal for joint procurement subscription model. During the CWP the NL has expressed its positive position

			towards Joint Procurement Subscription model. The NL needs to assess additionally which combination of instruments will be most effective. For this, the reasoning of EP on its proposal is helpful.
Article 39b			
	Article 39b ***Subscription model for the joint procurement of antimicrobials***		As stated during the CWP, the NL is positive towards a joint subscription model proposal of the EP. The NL urges to keep this model in line with the experience gained by the HERA. Therefore, we would like to ask the EP whether and how it took into account HERAs work in its proposal? What is the reasoning of the EP to include the Joint procurement subscription model in addition to the voucher?
Article 40(1)			
1. Following a request by the applicant when applying for a	1. Following a request by the applicant ~~*when applying*~~ for a	1. Following a request by the applicant when applying for a	As a general remark on the voucher: The NL is of the opinion that the EP

marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	marketing authorisation***, made before the marketing authorisation is granted***, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in ~~*paragraph 3*~~***Article 39a(1)***, under the conditions referred to in paragraph 4 ***of this Article*** based on a scientific assessment by the Agency.	marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	amendments on the voucher are too complex and unfeasible which makes the instrument less attractive for companies. Furthermore, it will put more administrative burden on Member States and will increase the risk of objections of companies. We urge to stick to the Council's mandate on the voucher articles.
Article 40(4a)			
	4a. The priority antimicrobial shall be added to the list of antimicrobials which are to be reserved for treatment of certain infections in humans and added to the Union list as established by Commission Implementing Regulation (EU) 2022/1255[1a]. _____ ***1a. Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of***		EP proposes here that priority antimicrobials shall be added to the list of antimicrobials to be reserved for certain infections in humans as drawn up via Implementing Regulation (EU) 2022/1255. This list is based on the criteria included Delegated Regulation (EU) 2021/1760. EP's proposal in fact means that additional criteria would be added

	antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191, 20.7.2022, p. 58).		to those already provided for in this delegated act. EP's proposal implicates that, for instance, certain new classes of antimicrobials cannot be used in animals. This is not only unethical in situations where no other treatment is effective, but it also poses a serious risk to human health. After all, untreated infectious diseases in animals significantly increase the risk of zoonoses. The delegated act is the outcome of long, careful deliberations in the EU in order to strike the right balance between animal and human health, taking into consideration not just the risk of AMR in humans but also ethical principles and the risk of zoonotic diseases. Any revisions to the EU

			pharmaceutical legislation should not affect this balance. It is therefore proposed that the EP proposal is replaced by wording indicating that any new priority antimicrobial that fulfils the criteria provided for in Delegated Regulation 2021/1760 is to be added to the list of antimicrobials reserved for certain infections in humans as drawn up via Implementing Regulation (EU) 2022/1255.
Article 41			
Article 41 Transfer and use of the voucher	Article 41 Transfer and use of the voucher	Article 41 Transfer and use of the voucher	The NL is of the opinion that working with modulation within the voucher makes the instrument less effective and too complex.
Article 41(3a)			
	3a. The monetary value paid for the transfer of the voucher shall be directed to the Authority,		EP proposes in Article 41 REG that the MAH shall transfer the money received for the transfer of the TEV

	which shall in yearly instalments transfer the amount to the marketing authorisation holder, in order to ensure the manufacturing capacity and supply of the priority antimicrobial. The Commission shall adopt delegated acts in accordance with Article 175 to supplement this Regulation by setting up the framework for the conditions and functioning of annual instalments.		to 'the Authority' and that the Authority shall then transfer the amount to the MAH in yearly instalments. It is unclear which authority is referred to, we assume this is HERA. It is however very inappropriate for medicine regulatory authority to operate as a banking authority for MAHs. The NL thinks that this proposal is therefore not feasible and too complex.
Article 175a			
	Article 175a ***Amendments to Regulation (EC) No 851/2004***		First of all, according to the HERA-evaluation, it works effectively as Commission DG. Secondly, the tasks and roles of HERA and ECDC are not completely aligned. ECDC's mission is to identify, assess and communicate current and emerging threats to human health

			posed by infectious diseases, it conducts monitoring, surveillance and early warning functions, and provides scientific advice, guidance and expertise to inform prevention, preparedness and response to serious cross-border threats to health, informing Member States, the European Commission and, among others, the Health Security Committee (HSC) which is managed by DG SANTE. DG HERA was established in the aftermath of the COVID-19 pandemic to anticipate threats and potential health crises, through intelligence-gathering and building the necessary response capacities. In the event of an emergency, HERA will oversee the

			development, production and distribution of medicines, vaccines and other medical countermeasures (MCMs) – such as gloves, vaccines and masks. Furthermore it focuses on risk prioritization for and ensures the availability of supply of medical countermeasures to respond to such threats. As such, DG HERA functions – when an EU public health crises is announced – as the operational structure supporting the Health Crisis Board once established under the Emergency Framework Regulation. Nevertheless, NL is interested to learn more about the perceived synergies behind the EP's proposal.

ROMANIA

Article 39a - Milestone payment reward scheme

RO is in favour of further discussing the proposed milestone payment reward scheme, as this may be seen as an alternative to TEV. However, more evidence is needed about the potential of this mechanism to be more effective in incentivizing the development of novel antimicrobials than the current version agreed by the Council.

A vital element of this proposed mechanism is funding and considering that no clear picture at this time of what may be available for the proposed mechanisms, we have a scrutiny reservation on the funding sources.

Article 39b - Subscription model for the joint procurement of antimicrobials

RO is in favour of further discussing the EP proposal but more elements needs to be provided to support this proposal. For example, the added value compared with the agreed Council`s version.

Article 40 - Granting the right to a transferable data exclusivity voucher

Regarding the definition of the 'priority antimicrobial', we support the definition as agreed in the Council text version at paragraph 3.

*Regarding **Articles 41, 42,** RO supports the text agreed by the Council.*

***Art. 43** – RO can support the amendment of the EP for an evaluation of the progress performed by the COM with regard to antimicrobial research and development and the effectiveness of the incentives and rewards provided in this chapter. We could even support a shorter period than proposed by the EP, for example three years. Such evaluation may prove beneficial to assess the effectiveness of the proposed mechanisms, impact on innovation and the overall strengths and weaknesses.*

SLOVAKIA

Article 40(1)			
1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	1. Following a request by the applicant ~~*when applying*~~ for a marketing authorisation***, made before the marketing authorisation is granted***, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in ~~*paragraph 3*~~***Article 39a(1)***, under the conditions referred to in paragraph 4 ***of this Article*** based on a scientific assessment by the Agency.	1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	The preservation of this provision **in the form as agreed in the Council** ensures a high degree of predictability, particularly from an economic perspective, in the use of the voucher for priority antimicrobial medicines when applied only in the fifth year of data protection and under the condition that the annual gross revenues of the concerned medicine do not exceed €490 million in any of the preceding four years. This mechanism guarantees the targeted nature of the incentive, prevents abuse of the system to extend blockbusters' monopolies, and protects the availability of generics, which is crucial for the Slovak public healthcare system. From the standpoint of potential alignment in seeking a compromise with the European Parliament's proposal, the only practically applicable condition appears to be the

			requirement that the gross annual turnover of the medicine does not exceed €490 million in any of the preceding years.
Article 40(2a)			
	2a. The Commission shall adopt delegated acts in in accordance with Article 175 to supplement this Regulation by setting up the eligibility of pathogens for the protection periods referred to in paragraph 2 of this Article in accordance with the WHO priority pathogens list or an equivalent established at Union level, with 12 months of data protection for an authorised product ranked 'critical', 9 months of data protection for those ranked 'high' and 6 months of data protection for those ranked 'medium'.		SK considers it appropriate to establish a model whereby the length of data protection corresponds to the pathogen's severity category as defined by the WHO/EU list. Such a provision could enhance proportionality, optimize the efficiency of allocated incentives, and reinforce the targeted nature of the system.
Article 40(3), first subparagraph			
3. An antimicrobial shall be considered 'priority antimicrobial' if	*deleted*	3. An antimicrobial shall be considered 'priority antimicrobial'	The preservation of the substantively defined concept of a "priority

preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:		if **it addresses a multi-drug resistant organisms causing a severe or a life-threatening infection, and for which the** preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:	antimicrobial medicinal product," which is linked to significant clinical added value in addressing AMR and meets at least one of the explicitly specified innovation criteria (such as a new class, new mechanism of action, or new active substance targeting MDR infections), ensures legal predictability and consistent interpretation and application. However, within the context of the revised European Parliament wording in Article 40(2a), this definition may be somewhat redundant; nonetheless, if retained, it is viewed positively. It is also noted that the definition of "priority antimicrobial medicinal product," together with the reference to the WHO list of priority pathogens, has been relocated in the EP proposal to Article 39a(1).
Article 40(4), first subparagraph, point (ba)			
	(ba) submit the stewardship and access plan as referred to Article 17(1), point (a), of and Annex I to [revised Directive 2001/83/EC];		SK considers the obligation to submit a responsible use (stewardship) plan and a global access plan, including for low- and middle-income countries, to be an

			important integrative element within national AMR strategies. Even at present, the vast majority of inpatient healthcare providers have developed and implemented stewardship programs, in which hospital pharmacists play a key role in managing rational antimicrobial pharmacotherapy.
Article 40(4), first subparagraph, point (bb)			
	(bb) submit a global access plan to supply third countries in critical need, including through development partners or voluntary licensing.		SK considers the obligation to submit a responsible use (stewardship) plan and a global access plan, including for low- and middle-income countries, to be an important integrative element within national AMR strategies. Even at present, the vast majority of inpatient healthcare providers have developed and implemented stewardship programs, in which hospital pharmacists play a key role in managing rational antimicrobial pharmacotherapy.
Article 40(4a)			

	4a. The priority antimicrobial shall be added to the list of antimicrobials which are to be reserved for treatment of certain infections in humans and added to the Union list as established by Commission Implementing Regulation (EU) 2022/1255[1a]. _____ ***1a. Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191, 20.7.2022, p. 58).***		SK perceives this provision as potentially beneficial: the inclusion on the reserved list pursuant to Commission Implementing Regulation (EU) 2022/1255, which, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council, designates certain antimicrobials or groups thereof exclusively for the treatment of specific infections in humans. The adoption of this provision would ensure controlled use of the most critical antimicrobial agents, thereby preventing their overprescription and inappropriate use in veterinary medicines and medicated feed.
Article 41(1), second subparagraph			
A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection.	A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection. ***The voucher shall not be used for a product which already***	A voucher ~~shall only~~**can be transferred at any time before its use. A voucher may** be used once **only** and in relation to a single centrally authorised medicinal product ~~and only if that product is within its first four~~	The preservation of this provision, as agreed in the Council, ensures a high degree of predictability—particularly from an economic standpoint—in the application of the voucher for priority antimicrobial medicines. This applies exclusively in the fifth year of data protection and only if the

	benefited from the maximum regulatory data protection period as set out in Article 81 of [revised Directive 2001/83/EC].	~~years of regulatory data protection.~~**.**	annual gross revenues of the relevant medicine do not exceed €490 million in any of the preceding four years. This mechanism ensures the incentive remains targeted, prevents system abuse aimed at extending monopolies on blockbuster drugs, and safeguards the availability of generics, which is vital for the Slovak public healthcare system. From the perspective of achieving alignment in negotiations with the European Parliament's proposal, the only practically feasible condition appears to be the cap on the gross annual turnover of the medicine not exceeding €490 million in any of the preceding years. SR is concerned that a functional limitation on the use of the voucher in case the medicinal product concerned has already reached the maximum level of data protection under Article 81 of the draft revised Directive 2001/83/EC may significantly reduce its practical applicability. and reduce the overall incentive effect of vouchers.

Article 41(3a)			
	3a. The monetary value paid for the transfer of the voucher shall be directed to the Authority, which shall in yearly instalments transfer the amount to the marketing authorisation holder, in order to ensure the manufacturing capacity and supply of the priority antimicrobial. The Commission shall adopt delegated acts in accordance with Article 175 to supplement this Regulation by setting up the framework for the conditions and functioning of annual instalments.		Slovakia regards this amendment proposed by the European Parliament as potentially advantageous. The revenue generated from the voucher is administered by a public authority, which disburses it to the marketing authorization holder in annual installments. This distribution mechanism provides a safeguard that the funds will be dedicated to securing the production and supply of the respective medicine, thereby aligning with the public interest.
Article 42(2)			
2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.	2. The Commission may revoke the voucher ~~*prior to its transfer*~~ as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled. ***To protect the buyer from damage***	2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply **by any Member State or the Commission**, procurement or purchase of the priority	Slovakia perceives the compromised text of the Council as beneficial. The provision allowing the Commission to revoke the voucher in the event of a failure to meet a Member State's supply demand preserves an essential enforcement mechanism. SK considers this measure particularly

	resulting from a possible revocation of a voucher after the transfer, seller and buyer shall make contractual liability arrangements.	antimicrobial in the Union has not been fulfilled.	important for ensuring adequate supply in response to demand from Slovakia or other Member States, thereby safeguarding smaller markets.
Article 43, first paragraph a			
	By … [five years from the date of entry into force of this Regulation], the Commission shall submit an evaluation report to the European Parliament and to the Council containing a scientific assessment measuring the progress with regard to antimicrobial research and development and the effectiveness of the incentives and rewards in this Chapter.		Slovakia regards this provision drafted by the EP as potentially advantageous. A comprehensive evaluation report by the Commission after five years is imperative to assess the measure's effectiveness, practical viability, and overall benefits. Such an assessment should rigorously examine the system's efficiency and its impact on pharmaceutical innovation, patient access, and public spending.

SPAIN

Spain's preference is to advance the trilogue negotiations in an agile and efficient manner, with the aim of reaching an agreement as soon as possible. In this regard**, we are open to combining different types of incentives**, bearing in mind that each type supports different stages in the development of an antimicrobial medicinal product.

More specifically, **we would prefer the milestones payment reward scheme (Article 39a) not to exclude the possibility of receiving a transferable exclusivity voucher (TEV) (Article 40)**, since the TEV is Spain's preferred incentive. We acknowledge that granting both milestones and TEVs could result in double incentivisation, which should be mitigated. One option would be to notify Member States so that they can factor this into their pricing and reimbursement decisions.

To provide flexibility and streamline the process, **we could consider priority review vouchers** (Article 39 bis, PRV), and allow the laboratory to choose its preferred mechanisms. The European Commission and the Member States could then ensure that funding and incentives are not provided in multiple ways, without impacting future funding. We are aware that they have not been included in the mandates of either the Council or Parliament. Nevertheless, they are an interesting option for complementing the early payment mechanism by reducing costs.

With regard to **the subscription model for the joint procurement of antimicrobials (Article 39b), we believe that the details of its implementation should be defined within the framework of the Critical Medicines Act**, rather than within EU general pharmaceutical legislation.

SWEDEN

First, a comment regarding the concerns expressed by the Commission in the WP on June 24, 2025, on the definition of a Priority Antimicrobials as proposed by the Council in its adopted text:

The intention behind the Council's definition, from our perspective, is to support novelty, and from both a clinical and innovation perspective, advanced substances that are clinically relevant to tackle resistance where there are unmet medical needs.

The criteria are not meant to strive towards rewarding novel combinations of two or more approved products on the market.

The types of combinations that could be eligible by the Council's definition are:

- 1. Two novel substances, where the combination is clinically relevant and of importance to overcome antimicrobial resistance of a pathogen, and where the substances each have a merit on their own in a therapeutic arsenal.

  An example could be the combination of two novel active antibiotics substances in life threatening septicaemia, where antibiotic resistance is a known clinical problem not likely to be resolved by monotherapy.

  Safeguard: If any of the substances in a proposed combination already has received/been granted a voucher, that substance cannot be eligible for the development program for a combination. The combination of two novel substances in 1. may enable collaborations between innovator companies/SME:s/not-for-profit organisations.

- 2. A new substance combination, where one of the substances must be novel, where the combination will enhance or restore the antimicrobial effect towards a pathogen/s, it should be of great clinical value to meet an unmet medical need (e.g. the combination of an antibiotic and a modulator of its mechanism of action with regard to overcome antimicrobial resistance).

- In 2. this could be for example an old betalactam combined with a novel betalactamase-inhibitor, in analogy of amoxicillin whose effect is enhanced and resistance reversed to some pathogens by the addition of clavulanic acid, the latter having a weak antimicrobial effect. Other examples of combinations in this category: the combination of sulbactam + durobactam or the inhibitor zidebactam, to be combined with different antibiotics to enhance their effects to antimicrobial resistant pathogens.

The definition should, if possible, also be applied for milestone payments dedicated to the development steps of priority antimicrobial products. We suggest that EMA establishes guidelines to Industry on the topic, see red text below.

3. An antimicrobial shall be considered 'priority antimicrobial' if **it addresses a multi-drug resistant organism causing a severe or a life-threatening infection, and for which the** preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics

~~(a) it represents a new class of antimicrobials;~~

(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

(c) it contains ~~an~~**a new** active substance ~~not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection~~ **used either alone or in combination with other active substances**.

In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall establish guidelines and take into account the '~~WHO priority pathogens list for R&D of new antibiotics', or an equivalent~~ list of pathogens established at Union level.

Article (s) in EP's proposal, and recitals	SE comments
Article 39a *Milestone payment reward scheme* Recitals	We are in general positive to the combination of different incentivizing tools, since their combination supports different steps of the development and the life cycle of an antimicrobial medicinal product. We are flexible as to keep the Article or to support milestone payments within other relevant frameworks. As for para 1. And the definition of a priority antimicrobial: We suggest the definition is the same as for the voucher in the Council's proposal. See our comment on the rationale behind the Council's definition above the table. A prerequisite for milestone payments, however, is funding. For such a mechanism to work, EU funding is needed and must be allocated within the MFF. We have a scrutiny reservation on the sources for funding*:* If there are already milestone payment projects within Horizon Europe, including for AMR (1 billion EUR, mentioned by COM) or Europe4Health (we encourage the Presidency or COM to present how and where in the EU-funds incentives for development of antimicrobials are funded- it seems scattered) , we suggest to allocate and secure AMR-specific funding, by reprioritization in the Multiannual Financial Framework (MFF). We cannot accept financing by redistributing already allocated funding in existing AMR-funds e.g. from the framework of the Partnership in One Health.

	In the event that milestone payments are introduced in the legislation, a suitable criterium for the next instalment would be that the next phase has already been initiated, to better ensure progress of the project. AMR is a concern to all parties (Industry, MS, health care, patients). We would like to ask the Commission, through the DK Presidency, if a mutual AMR fund has ever been discussed as a means to finance different push and pull incentives together? To our knowledge Industry has created their own AMR-fund and the possibility to contribute with EU-funding could possibly be an option.
Article 39b *Subscription model for the joint procurement of antimicrobials*	We are flexible to the EP proposal, but perhaps this Article could be anchored in the Critical Medicines Act, where similar tools on joint procurement are to be negotiated shortly and where a possible subscription model could be amended into the proposal. Also here, the funding of such a mechanism must be presented, whether parts to be paid by the EU and parts by the Member States who choose to participate.
Article 40 *Granting the right to a transferable data exclusivity voucher*	The TEV is important for Sweden. We prefer the Council's text version. The blockbuster clause should be retained. **The only item we do support in the EP version is the absence of modulation criteria in 40 4.c in the Council's version.** Why: These criteria also appear in Article 81 in the Directive. As a consequence, priority antimicrobials eligible for a voucher will need to fulfil both the criterium of UMN and those in 40 4 c. We believe the modulations in 40 4 c will be hard for SMEs with products of therapeutic interest that want to enter the EU market after approval and clinical trials outside the EU. This does not serve to tackle AMR in the EU. We specifically **do not support:** The EP definition of priority antimicrobial

	2a – the WHO list (we will go with the EU list, as proposed by COM) 4 a, b, ba, bb The mutual exclusivity of milestone payments and the voucher – they should be able to co-exist as they address different parts of the development chain. The modulation of market exclusivity suggested by the EP
Article 41 *(Transfer and use of the voucher)*	We prefer the Council's text. We do not support modulation of the voucher, it augments complexity. We do not support the role of HERA in 3a as it makes the process too complicated. We do not support the requirement of an access plan mentioned in several Articles, first in Article 12(4) ma. Why: these antimicrobial products will have to abide to all other new Articles to ensure access in the Council's version of the two legal Acts. In addition, some of these products may be regarded as critical medicines, where the CMA will apply.
Article 42 *(Validity of the voucher)*	SE prefers the Council's text.
Article 43 *(Duration of application of Chapter III)*	SE acknowledges the Council's text has a limit of 5 vouchers. In Article 180, however, all parties (EP, the Council and the Commission), mention 10 vouchers in total. SE would like to see a change in Article 180, so as to have 5 + 5 vouchers, the extension of 5 only after evaluation, and in accordance with recital 84, where the EP can approve an extension upon the initiative of the Commission. See suggestion below.

Article 180 *(Transitional provisions)*	13. By way of derogation from Article [Duration of application of Chapter III] vouchers granted until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until the date when the Commission has granted a total of 10 (5+5) vouchers, where the extension should be allowed based on the evaluation by the Commission, in accordance with Chapter III, whichever date is the earliest, shall continue to be valid according to the conditions set out in Chapter III.
Article 175a Recital 78a	SE is preliminarily positive to the EP proposal of HERA's role and placement under ECDC. However, this is a considerable political question and primarily concerns the Commission. As the evaluation of HERA is ongoing, these discussions should mainly take place in processes outside the Working Party.