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LIMITE

SAN **VETER**
PHARM **ENV**
MI **RECH**
COMPET **CODEC**
PI

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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 German delegation

Delegations will find enclosed comments from Germany related to the Working Party on Pharmaceuticals and Medical Devices on 24 June 2025.

GERMANY

	Commission proposal	EP amendments voted on 10 April 2024	Text agreed by the Council on 4 June 2025	Draft agreement
		Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.*** ***Text in red italics ~~strikethrough~~ in this column is text that the EP proposes to delete.***	Plain text in this column is text from the Commission proposal that Council wishes to maintain. **Text in bold** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	If no comment is made, DE is neutral.

General comments by DE on EP proposals for AMR incentives:

- On the **voucher**, it is crucial to keep the blockbuster clause. Likewise, the reduction to five vouchers should be maintained. Bureaucratic complications, such as the disbursement of the amount paid for the voucher by HERA and the differentiation of the length of additional data protection afforded by the voucher, are viewed negatively and should be avoided.
- DE does not agree with the additional incentive structures proposed by the EP:
    - On **milestone payments**, DE is sceptical that the Pharma Package is the right place for this push incentive. There are already funding programmes for research that should be evaluated outside the scope of this legislation.
    - Regarding **subscription/joint procurement models**, DE is negative. The HERA pilot that attempted to decouple volume from turnover at the EU level failed due to a lack of industry interest. Due to the legal framework, DE could not participate in such procurement programmes outside of crisis situations.

General comment by DE on the EP proposal to incorporate HERA into the ECDC:

- DE rejects the proposal. HERA is a Directorate-General of the Commission and should remain an independent entity with a clear mandate relating to health security in the event of serious cross-border health threats.
- The integration of HERA into the ECDC would extend the ECDC's mandate to include chemical and radionuclear hazards. This has not been discussed or assessed in any detail.
- In addition, ECDC's autonomy and independence must be preserved, particularly in relation to the Member States' vaccination commissions. A link with the necessarily industry-oriented HERA could jeopardise this.

ANNEX B

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (Text with EEA relevance)

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Formula				
1	2023/0131 (COD)	2023/0131 (COD)	2023/0131 (COD)	
Proposal Title				
Recital 77				
87	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is	Delete: ~~***, in particular through market entry rewards and milestone reward payments. Additionally, the establishment of***~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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*** 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***	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.	~~***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.***~~ Reason: DE is sceptical of both milestone payments and subscription models. On milestone payments: Push incentives do not fit into the regulatory framework of the pharma package. There are already a number of research funding

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		programs in place that should be independently assessed. On subscription models: The HERA pilot which delinked volume from sales on EU level already failed due to lack of industry interest. Furthermore, not all MS would be able to participate outside of crisis situations due to their legal framework (among them DE). NB on bacteriophages: Their efficacy has not been demonstrated enough to merit a prominent mention in a recital. Further evidence for routine use is needed.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		rapid diagnostic tools to ensure appropriate prescriptions.		
Recital 77a				
87a		***(77a) Reluctance to invest in the development of antimicrobials exists in part because the development of antimicrobials is costly and many developers, often SMEs, cannot afford to proceed to the next stage of development. Additionally, when an antimicrobial is developed, the market is naturally limited by virtue of the need to use antimicrobials prudently. Therefore, it is necessary to consider further Union level action to support the development of antimicrobials and address existing market failures. Accordingly, a milestone payment***		~~***Additionally, when an antimicrobial is developed, the market is naturally limited by virtue of the need to use antimicrobials prudently. Therefore, it is necessary to consider further Union level action to support the development of antimicrobials and address existing market failures. Accordingly, a milestone payment reward scheme, complemented by a subscription model voluntary joint procurement scheme, should be developed to ensure that a market exists for developers that***~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		reward scheme, complemented by a subscription model voluntary joint procurement scheme, should be developed to ensure that a market exists for developers that delink volumes sold from payment received.		~~***delink volumes sold from payment received***~~ See above
Recital 77b				
87b		***(77b) Milestone payments are an early-stage financial reward granted upon achieving certain R&D objectives prior to market approval, for example successful completion of phase I. While such mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase. A subscription model consists of a series of financial***		~~***(77b) Milestone payments are an early-stage financial reward granted upon achieving certain R&D objectives prior to market approval, for example successful completion of phase I. While such mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase. A subscription model consists of a series of financial***~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		payments to an antibiotic developer for successfully obtaining regulatory approval for an antibiotic that meets specific pre-defined criteria. A subscription model scheme through voluntary joint procurement agreements should alleviate concerns for developers by ensuring there is a market for the antimicrobial when developed.		~~***payments to an antibiotic developer for successfully obtaining regulatory approval for an antibiotic that meets specific pre-defined criteria. A subscription model scheme through voluntary joint procurement agreements should alleviate concerns for developers by ensuring there is a market for the antimicrobial when developed.***~~ See above.
Recital 78				
88	(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward	(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward	(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	non-clinical and clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority.	non-clinical and clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority.	non-clinical and clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the 'WHO priority pathogens list for R&~~amp;~~D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority.	
Recital 78a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
88a		***(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 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***		~~***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.***~~ Reason: HERA has no mandate to act in other disease areas. Additionally, characteristics of cross-border health threats and rare and neglected diseases differ significantly, since the last two are not due to threats, but rather due to a lack of economic incentives for the pharmaceutical industry..

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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				
88c		***(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***		~~***(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***~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the 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]		~~***the 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).		~~***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).***~~
				Reason: The pharma package is not the right legal base to extend joint procurement beyond cross-border health threats. The discussion about an extension of joint procurement should be held under the CMA.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 79				
89	(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 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	(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 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	(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 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	~~***As an alternative, for developers who have not availed of market entry rewards and milestone payment schemes,***~~ See above The “modulation” of data protection lengths is rejected. Not only does this add a level of bureaucracy, it will reduce the expected level of investment. Any cautious investor would have to calculate with the minimal amount of data protection prolongation, leading to a smaller financial commitment. If this smaller level of investment still leads to the best outcome (reflected in a full year of data protection), the investor receives a disproportionately high

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	voucher under certain circumstances.	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 supply of the priority antimicrobial for which the voucher was created.***	voucher under certain circumstances.	outcome for the small investment. The EP's proposal therefore does not work as intended. That said, there is value in improving regulation to make sure that the innovative medicinal product is actually brought to market in sufficient quantities.
Recital 80				
90	(80) A transferable data exclusivity voucher should only be available to those antimicrobial	(80) A transferable data exclusivity voucher should only be available to those antimicrobial	(80) A transferable data exclusivity voucher should only be available to those antimicrobial	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial support given to the medicinal product.	products that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial ***and indirect*** support given to the medicinal product ***in accordance with Article 57 of [revised Directive 2001/83/EC]***.	products that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial support given to the medicinal product.	
Recital 81				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
91	(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide.	(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide ***and any indirect financial support in accordance with Article 57 of [revised Directive 2001/83/EC]***.	(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide.	
Recital 82				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
92	(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale. The value of the transaction which may be monetary or otherwise agreed between the buyer and the seller, shall be made public so as to inform regulators and the public. The identity of the holder of a voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.	(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale ***and may only be transferred once***. The value of the transaction which may be monetary or otherwise agreed between the buyer and the seller, shall be made public so as to inform regulators and the public. The identity of the holder of a voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.	(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale. The value of the transaction which may be monetary or otherwise agreed between the buyer and the seller, shall be made public so as to inform regulators and the public. The identity of the holder of a voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.	
Recital 83				
93	(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry	(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry	(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry	***Additionally, by ... [five years from the date of entry into force of this Regulation], the Commission should provide an***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure.	into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure. ***Additionally, by ... [five years from the date of entry into force of this Regulation], the Commission should provide an evaluation report on the***	into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure.	***evaluation report on the effectiveness ~~of both the milestone payment reward schemes and~~ the transferable data exclusivity vouchers in the development of priority antimicrobials*** See above

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		effectiveness of both the milestone payment reward schemes and the transferable data exclusivity vouchers in the development of priority antimicrobials.		
Recital 84				
94	(84) The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament and the Council upon proposal by the Commission on the basis of the experience acquired.	(84) The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament and the Council upon proposal by the Commission on the basis of the experience acquired.	(84) The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament and the Council upon proposal by the Commission on the basis of the experience acquired.	
Recital 135b				
145b		***(135b) More often than in the past, Member States experience***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		critical shortages of certain antimicrobials, endangering the health of patients and risking the development of antimicrobial resistance. Those critical shortages are the result of changing infection patterns, which strongly increases demand. On the supply side, the long lead times needed to boost production makes it difficult to respond quickly. This experience underlines the need for a dedicated effort from all actors to address the issue of critical shortages.		
Article 39a				
445a		***Article 39a*** ***Milestone payment reward scheme***		Deletion of whole Article (see introductory remarks)

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 39a(1), first subparagraph				
445b		***1. An antimicrobial shall be considered a 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with regard to antimicrobial resistance and it has at least one of the following characteristics:***		
Article 39a(1), first subparagraph, point (a)				
445c		***(a) it represents a new class of antimicrobials;***		
Article 39a(1), first subparagraph, point (b)				
445d		***(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 39a(1), first subparagraph, point (c)				
445e		***(c) it contains an 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.***		
Article 39a(1), second subparagraph				
445f		***In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.***		
Article 39a(2), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
445g		***2. The Commission, in consultation with the Agency, shall award milestone payments and support to potential priority antimicrobials addressing the priority pathogens referred to in paragraph 1 of this Article. The milestone payments shall be financed through resource matching by the Commission, including within the framework of Article 12(2), point (b)(i), of Regulation (EU) 2021/695 of the European Parliament and of the Council[1a] and Regulation (EU) 2021/522 of the European Parliament and of the Council[1b].*** _____ ***1a. Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1). ***1b. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).***		
Article 39a(2), second subparagraph				
445h		***The Commission shall adopt delegated acts in accordance with Article 175 to supplement this Regulation by setting the criteria for the awarding of milestone payments, including payments for the completion of pre-specified development stages and criteria, taking into account the costs of the development of that stage and***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the anticipated costs of the next stage of development.		
Article 39a(2), third subparagraph				
445i		***The awarding of milestone payments shall be contingent on legal commitments to use the payments:***		
Article 39a(2), third subparagraph, point (a)				
445j		***(a) to further develop the priority antimicrobial;***		
Article 39a(2), third subparagraph, point (b)				
445k		***(b) to apply for a marketing authorisation in accordance with this Regulation;***		
Article 39a(2), third subparagraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
445l		***(c) to conduct antimicrobial stewardship and access plans as referred to in Article 17(1), point (a), of [revised Directive 2001/83/EC]; and***		
Article 39a(2), third subparagraph, point (d)				
445m		***(d) where relevant, to apply for the joint procurement agreement referred to in Article 39b.***		
Article 39a(3)				
445n		***3. The priority antimicrobial shall also be subject to joint clinical assessment in accordance with Article 7(2), point (a), of Regulation (EU) 2021/2282.***		
Article 39a(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
445o		***4. A developer who benefits from milestone payments under this Article shall not be eligible to avail of a transferable exclusivity voucher in accordance with Article 40.***		
Article 39b				
445p		***Article 39b*** ***Subscription model for the joint procurement of antimicrobials***		~~***Article 39b***~~ Deletion of whole Article (see introduction)
Article 39b(1)				
445q		***1. The Commission and any of the Member States may engage, as contracting parties, in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		European Parliament and of the Council[1a] with a view to the advance purchase of antimicrobials. _____ ***1a. Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).***		
Article 39b(2)				
445r		***2. A joint procurement procedure as referred to in paragraph 1 shall be preceded by a joint procurement agreement***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		between the parties determining the practical arrangements governing the subscription model system and other procedures, including the length of the subscription contract and the possibility of parallel procurement.		
Article 39b(3)				
445s		***3. The joint procurement agreement shall take the form of a multi-year subscription and include the following conditions:***		
Article 39b(3), point (a)				
445t		***(a) delinkage or partial delinkage of funding from the volume of sales of the antimicrobial;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 39b(3), point (b)				
445u		***(b) commitment to continuous and sufficient supply in pre-agreed quantities;***		
Article 39b(3), point (c)				
445v		***(c) commitment to the antimicrobial stewardship and access plans as referred to in Article 17(1), point (a), of [revised Directive 2001/83/EC];***		
Article 39b(3), point (d)				
445w		***(d) commitment to the environmental risk assessment as referred to in Article 22 of [revised Directive 2001/83/EC];***		
Article 39b(3), point (e)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
445x		***(e) submission of a global access plan to supply third countries in critical need, including through development partners or voluntarily licensing.***		
Article 39b(4)				
445y		***4. Participation in the joint procurement procedure shall be open to all Member States and third countries, including the European Free Trade Association States and Union candidate countries, as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 39b(5)				
445z		***5. The Commission shall inform the European Parliament about procedures concerning the joint procurement of antimicrobials and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union. The Commission shall communicate information to the European Parliament regarding sensitive documents in accordance with Article 9(7) of Regulation (EC) No 1049/2001.***		
CHAPTER III				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
446	CHAPTER III INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'	CHAPTER III INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'	CHAPTER III INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'	
Article 40				
447	Article 40 Granting the right to a transferable data exclusivity voucher	Article 40 Granting the right to a transferable data exclusivity voucher	Article 40 Granting the right to a transferable data exclusivity voucher	
Article 40(1)				
448	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	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	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	The EP text is rejected; COM/Council text should be maintained.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	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.	paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	
Article 40(2)				
449	2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection for one authorised medicinal product.	2. The voucher referred to in paragraph 1 shall give the right to its holder to ~~*an*~~ ***a maximum of*** additional 12 months of data protection for one authorised medicinal product.	2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection **within the meaning of Article 80 paragraph 1 of [revised Directive 2001/83/EC]** for one authorised medicinal product.	The Council text is preferred, the EP text is rejected. There should be no modulation of the data protection length.
Article 40(2a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
449a		***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'.***		The EP text is rejected. There should be no modulation of the data protection length. The "modulation" of data protection lengths is rejected. Not only does this add a level of bureaucracy, it will reduce the expected level of investment. Any cautious investor would have to calculate with the minimal amount of data protection prolongation, leading to a smaller financial commitment. If this smaller level of investment still leads to the best outcome (reflected in a full year of data protection), the investor receives a disproportionately high outcome for the small investment. The EP's proposal therefore does not work as intended. That said, there is value in improving regulation to make sure

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				that the innovative medicinal product is actually brought to market in sufficient quantities
Article 40(3), first subparagraph				
450	3. An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:	*deleted*	3. An antimicrobial shall be considered 'priority antimicrobial' 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:	
Article 40(3), first subparagraph, point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
451	(a) it represents a new class of antimicrobials;	*deleted*	(a) ~~it represents a new class of antimicrobials;~~	
Article 40(3), first subparagraph, point (b)				
452	(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;	*deleted*	*(b)* its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;	
Article 40(3), first subparagraph, point (c)				
453	(c) it contains an 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.	*deleted*	(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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			combination with other active substances .	
Article 40(3), second subparagraph				
454	In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.	*deleted*	In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.	
Article 40(4), first subparagraph				
455	4. To be granted the voucher by the Commission, the applicant shall:	4. To be granted the voucher by the Commission, the applicant shall:	4. To be granted the voucher by the Commission, the applicant shall:	
Article 40(4), first subparagraph, point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
456	(a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;	(a) demonstrate capacity ~~to~~ ***and ensure the*** supply ***of*** the priority antimicrobial in sufficient quantities for the expected needs of the Union market***, as defined in a contract with the Authority***;	(a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;	
Article 40(4), first subparagraph, point (b)				
457	(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.	(b) provide information on all direct financial support ***and indirect financial support in accordance with Article 57 of [revised Directive 2001/83/EC]*** received for research related to the development of the priority antimicrobial~~.~~***:***	(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.	
Article 40(4), first subparagraph, point (c)				
457a			**(c) demonstrate that the application for granting a**	DE thinks this Council addition should be given up in the

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			marketing authorisation of the priority antimicrobial has been first submitted to the Agency or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the European Union.	negotiations. It is likely that the EU might miss out on certain antimicrobials if this requirement is put into place.
Article 40(4), first subparagraph, point (ba)				
457b		***(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];***		
Article 40(4), first subparagraph, point (bb)				
457c		***(bb) submit a global access plan to supply third countries in critical need, including through***		DE rejects this addition as adding too much bureaucratic burden.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		development partners or voluntary licensing.		
Article 40(4), second subparagraph				
458	Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.	Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.	Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.	
Article 40(5)				
458a			**5. Once the marketing authorisation is granted, the Agency shall inform without undue delay the MSSG, in accordance with Article 131**	This provision should be maintained in the negotiations.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			paragraph 2 with a view to propose a potential inclusion of the priority antimicrobial on the Union list of critical medicinal products.	
Article 40(4a)				
458b		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(EU) 2019/6 of the European Parliament and of the Council (OJ L 191, 20.7.2022, p. 58).		
Article 41				
459	Article 41 Transfer and use of the voucher	Article 41 Transfer and use of the voucher	Article 41 Transfer and use of the voucher	
Article 41(1), first subparagraph				
460	1. A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	1. A voucher may be used to extend the data protection for a period of ***6, 9 or*** 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	1. A voucher may be used to ~~extend the~~**add 12 months of** data protection ~~for a period of 12 months~~**within the meaning of Article 80 paragraph 1 of [revised Directive 2001/83/EC],** of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	The modulation of data protection length afforded by the voucher is rejected, see above.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(1), second subparagraph				
461	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 benefited from the maximum regulatory data protection period as set out in Article 81 of [revised Directive 2001/83/EC].***	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 years of regulatory data protection.~~**.**	
Article 41(1), second subparagraph a				
461a			**In case of a medicinal product other than the priority antimicrobial concerned, the use of the voucher can take place only in the fifth year of the regulatory data protection**	The maintenance of this "blockbuster clause" is crucial for DE.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			period and if the marketing authorisation holder demonstrates that the annual gross sales of that medicinal product in the Union during any of the preceding four years have not exceeded 490 million euros.	
Article 41(1a), first subparagraph				
461b			**1a. The marketing authorisation holder shall demonstrate that information about the annual gross sales referred to in para (1) is accurate and complete and that it has been audited by an independent external auditor.**	
Article 41(1), third subparagraph				
462	A voucher may only be used if the marketing authorisation of the	A voucher may only be used if the marketing authorisation of the	A voucher may only be used if the marketing authorisation of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	priority antimicrobial for which the right was initially granted has not been withdrawn.	priority antimicrobial for which the right was initially granted has not been withdrawn.	priority antimicrobial for which the right was initially granted has not been withdrawn.	
Article 41(2)				
463	2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.	2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.	2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.	
Article 41(3)				
464	3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.	3. A voucher may be transferred to another marketing authorisation holder ***once*** and shall not be transferred further.	3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.	
Article 41(3a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
464a		***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.***		Adding HERA as a "middleman" adds unnecessary bureaucratic complexity and should be rejected. That said, there is value in improving regulation to make sure that the innovative medicinal product is actually brought to market in sufficient quantities.
Article 41(4)				
465	4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency	4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency	4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available.	of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available.	of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available **on its webpage**.	
Article 42				
466	Article 42 Validity of the voucher	Article 42 Validity of the voucher	Article 42 Validity of the voucher	
Article 42(1)				
467	1. A voucher shall cease to be valid in the following cases:	1. A voucher shall cease to be valid in the following cases:	1. A voucher shall cease to be valid in the following cases:	
Article 42(1), point (a)				
468	(a) where the Commission adopts a decision in accordance with Article 47 to extend the data	(a) where the Commission adopts a decision in accordance with Article 47 to extend the data	(a) where the Commission adopts a decision in accordance with Article 47 to extend the data	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	protection of the receiving medicinal product;	protection of the receiving medicinal product;	protection of the receiving medicinal product;	
Article 42(1), point (b)				
469	(b) where it is not used within 5 years from the date it was granted.	(b) where it is not used within ~~5~~***four*** years ~~*from the date it was granted*~~***after the conditions set out in Article 41 have been fulfilled by the seller***.	(b) where it is not used within 5 years from the date it was granted.	
Article 42(2)				
470	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 resulting from a possible revocation of a voucher after the transfer, seller***	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 antimicrobial in the Union has not been fulfilled.	The EP changes are rejected. The ability to revoke the voucher after its sale would severely decrease its market value. The buyer would not be satisfied with holding the seller liable, as the firms that research AMR medicines are usually small and do not hold enough assets to meet potential liability claims.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		<u>and buyer shall make contractual liability arrangements.</u>		
Article 42(3)				
471	3. Without prejudice to patent rights, or supplementary protection certificates[1], if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II,	3. Without prejudice to patent rights, or supplementary protection certificates[1], if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II,	3. Without prejudice to patent rights, or supplementary protection certificates[1], if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Section 2 of [revised Directive 2001/83]. _____ 1. Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).	Section 2 of [revised Directive 2001/83]. _____ 1. Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).	Section 2 of [revised Directive 2001/83]. _____ 1. Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).	
Article 43				
472	Article 43 Duration of application of Chapter III	Article 43 Duration of application of Chapter III	Article 43 Duration of application of Chapter III	
Article 43, first paragraph				
473	This Chapter shall apply 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 vouchers in	This Chapter shall apply ~~*until [Note to OP: insert the date of 15 years after*~~ ***immediately from ... [***the date of entry into force of this Regulation] ***and for 15 years*** or until the date when the Commission has granted a total of	This Chapter shall apply**, taking into account the outcome of the evaluation referred to in Article 170 paragraph 6,** until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until the date	The Council position on five vouchers should be maintained.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with this Chapter, whichever date is the earliest.	10 vouchers in accordance with this Chapter, whichever date is the earliest.	when the Commission has granted a total of ~~105~~ vouchers in accordance with this Chapter, whichever date is the earliest.	
Article 43, first paragraph a				
473a		***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.***		
CHAPTER XIV				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1539	CHAPTER XIV AMENDMENTS TO OTHER LEGAL ACTS	CHAPTER XIV AMENDMENTS TO OTHER LEGAL ACTS	CHAPTER XIV AMENDMENTS TO OTHER LEGAL ACTS	
Article 175a				
1539a		***Article 175a*** ***Amendments to Regulation (EC) No 851/2004***		General comment on the proposed incorporation of HERA into ECDC: The EP proposal to place HERA into ECDC should be rejected. HERA has proven its value in the past, particularly for the new task of EU-wide crisis preparedness and readiness management.. HERA's remit requires it to exist as a separate and independent entity that cooperates with other EU actors, such as ECDC and EMA, but also with the WHO and the Member States. This applies both in times of crisis involving

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				serious cross-border health threats and under normal circumstances. Integrating HERA into ECDC would also risk undermining the independence of ECDC's recommendations on non-medical and medical protective measures. Furthermore, HERA would no longer be affiliated with the Commission. This would not do justice to the relevance of HERA's mission as currently defined. As part of the HERA review process, Germany has spoken out against dissolving DG HERA.
Article 175a, first paragraph				
1539b		***Regulation (EC) No 851/2004 is amended as follows:***		
Article 175a, first paragraph, point (1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1539c		***(1) the following articles are inserted:***		
Article 175a, first paragraph, point (1), amending provision, Article				
1539d		***Article 11aa*** ‘ ***European Health Emergency Preparedness and Response Authority***		
Article 175a, first paragraph, point (1), amending provision, Article(1)				
1539e		***1. The Health Emergency Preparedness and Response Authority (‘HERA’ or the ‘Authority’) is hereby established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control (‘ECDC’).***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 175a, first paragraph, point (1), amending provision, Article(2)				
1539f		***2. The Authority shall 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 the production, procurement, stockpiling and distribution capacity of medical countermeasures and other priority medical products in the Union.***		
Article 175a, first paragraph, point (1), amending provision, Article(3)				
1539g		***3. The Authority is represented by the Director of the ECDC.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 175a, first paragraph, point (1), amending provision, Article				
1539h		***Article 11ab*** ***Objectives and tasks of the Authority***		
Article 175a, first paragraph, point (1), amending provision, Article(1), first subparagraph				
1539i		***1. The Authority shall provide the Member States and the Union institutions, bodies, offices and agencies, with the strategic direction and the resources to develop a robust biomedical R&D capacity to address major public health issues.***		
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph				
1539j		***The Authority shall carry out the following tasks:***		DE requests the deletion of letters a-d and g-i. HERA's portfolio

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				should not be extended in this way. Letter f must be considered with a view to HERA.
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (a)				
1539k		***(a) setting out a long-term European portfolio of research and development projects in line with public health priorities set by the Commission in consultation with the World Health Organization ('WHO');***		Delete
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (b)				
1539l		***(b) setting up and supporting biomedical R&D projects addressing at least the following areas:***		Delete
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (b)(i)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1539m		***(i) the development of priority antimicrobials as defined in Article 40a of [Pharma Regulation];***		
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (b)(ii)				

See above

1539n		***(ii) the development of medical countermeasures and related technologies;***		
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (c)				
1539o		***(c) setting up and management of collaboration with third-party research centres at national and European level, not-for profit entities, academia and industry;***		Delete
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (d)				
1539p		***(d) providing strategic advice to the Commission on the allocation of relevant Union grants and other financial sources to ensure appropriate resource allocation for biomedical R&D;***		Delete

Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (e)				
1539q		***(e) detecting biological and other health threats soon after they emerge, evaluating their impacts and identifying potential countermeasures;***		
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (f)				
1539r		***(f) assessing and addressing vulnerabilities in global supply chains and strategic dependencies related to availability of medical countermeasures and medicinal products in the Union, in coordination with the Medicine Shortages Steering Group and Medical Device Shortages Steering Group, established by Regulation (EU) 2022/123;***		Must be closely evaluated with a view to the CMA.
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (g)				

1539s		***(g) addressing market challenges by identifying and ensuring the availability of production sites for priority products in the Union;***		Delete
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (h)				
1539t		***(h) facilitating joint procurement and distribution of medical products in Member States;***		Delete
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (i)				
1539u		***(i) monitoring compliance with funding and procurement agreements;***		Delete
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (j)				
1539v		***(j) establishing a mechanism of consultation and cooperation, in line with the One Health***		

		approach, internally within the ECDC and with other Union bodies and agencies, in particular the EMA, the European Food Safety Authority and the European Environment Agency;		
Article 175a, first paragraph, point (1), amending provision, Article(1), second subparagraph, point (k)				
1539w		***(k) contributing to reinforcing the global health emergency preparedness and response architecture.***		
Article 175a, first paragraph, point (1), amending provision, Article(2)				
1539x		***2. The Commission is empowered to adopt delegated acts to supplement this Regulation by expanding the priority research agenda set out in paragraph 1, second subparagraph, point (b), in order***		Delete, see above.

		to address other areas of unmet medical need. ’		
Article 175a, first paragraph, point (2)				
1539y		***(2) in Article 13, the following point is inserted:***		
Article 175a, first paragraph, point (2), amending provision, point (ba)				
1539z		‘ ***(ba) the HERA Board;*** ’		
Article 175a, first paragraph, point (3)				
1539aa		***(3) in Article 16(2), the following point is inserted:***		
Article 175a, first paragraph, point (3), amending provision, point (da)				

1539ab		‘ ***(da) ensuring that appropriate scientific, technical and administrative support are provided to the HERA Board;*** ’		
Article 175a, first paragraph, point (4)				
1539ac		***(4) the following articles are inserted:***		
Article 175a, first paragraph, point (4), amending provision, Article				
1539ad		***Article 17a*** ‘ ***HERA Board***		
Article 175a, first paragraph, point (4), amending provision, Article(1)				
1539ae		***1. The HERA Board shall be composed of one***		

		representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights. All HERA Board members shall be appointed for a two-year term, renewable once.		
Article 175a, first paragraph, point (4), amending provision, Article(2)				
1539af		***2. In addition, two public health experts shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European***		

		Parliament may submit its views for consideration to the Council, which shall then appoint those representatives to the HERA Board.		
Article 175a, first paragraph, point (4), amending provision, Article(3)				
1539ag		***3. The HERA Board shall be co-chaired by the director and an elected representative of a Member State. The members of the HERA Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise, and an absence of direct or indirect conflict of interest.***		
Article 175a, first paragraph, point (4), amending provision, Article(4)				
1539ah		***4. The term of office for members and their alternates shall be four years. That term***		

		may be extendable once consecutively.		
Article 175a, first paragraph, point (4), amending provision, Article(5)				
1539ai		***5. A representative of the Health Security Committee and a representative of the EMA shall attend the meetings of the HERA Board, as permanent observers. Other relevant Union bodies and agencies may be invited to attend as observers, where relevant.***		
Article 175a, first paragraph, point (4), amending provision, Article(6)				
1539aj		***6. The co-Chairs of the HERA Board may invite relevant stakeholders to attend the HERA Board meetings as observers. Observers shall declare their interests ahead of each meeting.***		
Article 175a, first paragraph, point (4), amending provision, Article(7)				

1539ak		*7. The HERA Board shall adopt its rules of procedure, including regarding the election of a co-Chair and voting procedures.*		
Article 175a, first paragraph, point (4), amending provision, Article(8)				
1539al		*8. The list of members and alternates, and the rules of procedure of the HERA Board, as well as the agendas and minutes of its meetings shall be made available on the Authority's website.*		
Article 175a, first paragraph, point (4), amending provision, Article				
1539am		*Article 17b* *Tasks of the HERA Board*		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph				

1539an		***The HERA Board shall:***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (a)				
1539ao		***(a) adopt the multiannual strategic planning for HERA;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (b)				
1539ap		***(b) adopt strategic decisions concerning HERA on research and innovation and industrial strategy in the area of antimicrobials and medical countermeasures;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (c)				
1539aq		***(c) adopt a long-term European portfolio of research and development projects in line with public health priorities set by***		

		the Commission in consultation with the WHO;		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (d)				
1539ar		***(d) ensure scientific and technical management of HERA;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (e)				
1539as		***(e) assess the performance of the tasks entrusted to HERA;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (f)				
1539at		***(f) contribute to the coherence of the Union's crisis preparedness and response management;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (g)				
1539au		***(g) contribute to the coordinated action by the Commission and the Member***		

		States for the implementation of Regulation (EU) 2022/2371;		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (h)				
1539a v		***(h) contribute to the implementation of the Union's Global Health Strategy, in particular in relation to addressing current and emerging health threats;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (i)				
1539a w		***(i) adopt opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health, including antimicrobial resistance;***		
Article 175a, first paragraph, point (4), amending provision, Article, first paragraph, point (j)				

1539ax		***(j) adopt proposals for the annual budget of HERA and the monitoring of its implementation.*** ,		
Article 175a, first paragraph, point (5)				
1539ay		***(5) Article 19 is replaced by the following:***		
Article 175a, first paragraph, point (5), amending provision, Article				
1539az		***Article 19*** ‘ ***Transparency and conflicts of interest***		
Article 175a, first paragraph, point (5), amending provision, Article(1)				
1539ba		***1. Members of the Management Board, members of the HERA Board, members of the***		

		scientific panels, members of the Advisory Forum, the director and the staff shall undertake to act in the public interest and in an independent manner. They shall not have any direct or indirect financial or other interests in the pharmaceutical or other medical industry which could affect their impartiality. They shall make an annual declaration of their financial interests and update them annually and whenever necessary. The declaration shall be made available upon request.		
Article 175a, first paragraph, point (5), amending provision, Article(2)				
1539bb		***2. The ECDC's and Authority's code of conduct shall provide for the implementation of this Article.***		
Article 175a, first paragraph, point (5), amending provision, Article(3)				

1539bc		***3. The ECDC and the Authority shall make available the rules of procedure, meeting agendas and minutes, and the members of the structures referred to in paragraph 1 and their declarations of interest on their website.***		
Article 175a, first paragraph, point (5), amending provision, Article(4)				
1539bd		***4. Stakeholders invited to meetings at the ECDC and the Authority shall declare their interests ahead of the meeting*** ,		