Annex 2

Commission procurement on behalf of or in the name of Member States and the Joint Procurement

Articles 22 and 23

	Commission Proposal	EP's mandate	Council's mandate	Comments
177	Article 22 Commission procurement on behalf of or in the name of Member States	Article 22 Commission procurement on behalf of or in the name of Member States	Article 22 Commission procurement on behalf of or in the name of Member States	
Article 22(1)				
178	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where nine or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission may initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below;	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ~~nine~~***five*** or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission ~~may~~***shall*** initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below~~;~~**:**	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ~~nine~~ ***six*** or more Member States jointly request the Commission to procure on their behalf, or in their name ***and at their costs (`the joint request`)***, the Commission may initiate a procurement procedure under the conditions ~~set out~~***laid down*** in this Article when the procurement ~~relates to~~ ***concerns*** medicinal products belonging to one of the following categories below;	
Article 22(1), point (a)				
179	(a) critical medicinal products for which a	(a) critical medicinal products for which a vulnerability	(a) critical medicinal products for which a	

	vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	
Article 22(1), point (b)				
180	(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [1], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation. _____ 1. Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: http://data.europa.eu/eli/reg/2021/2282/oj)	(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [1], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation. _____ 1. Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: http://data.europa.eu/eli/reg/2021/2282/oj)	(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation ~~*(EU) 2021/2282 of the European Parliament and the Council* [1]~~ ***2021/2282/EU*** [18], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States ~~*as per*~~***pursuant to*** Article 23(1) point (e) of that Regulation. _____ ~~*1. Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: http://data.europa.eu/eli/reg/2021/2282/oj)*~~	
Article 22(2)				
181	2. The joint request referred to in paragraph 1 shall only be made where the	2. The joint request referred to in paragraph 1 shall only be made where the medicinal product	2. The joint request referred to in paragraph 1 shall only be ~~*made*~~ ***submitted***	We strongly support the amendment proposed by the EP to include affordability as

	medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.	concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply ~~*and*~~, availability ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability ~~*and*~~, accessibility ***and affordability*** of medicinal products of common interest, as applicable.	where the medicinal product concerned fulfils one of the criteria ~~*set out*~~ ***laid down*** in that paragraph and ~~*if*~~ ***where*** the requested procurement procedure ~~*will help*~~ ***is expected*** to improve the security of supply and availability of critical medicinal products in the Union or ***to*** ensure the availability and accessibility of medicinal products of common interest, as applicable.	a criterion for requesting the the Commisison to procure on behalf of Member States. This should enable EU countries to benefit from pooling demand at the EU level and strengthening their collective negotiating position in order to secure fairer prices.
Article 22(3)				
182	3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request, through the Critical Medicines Group, and invite them to join the procedure.	3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the ***joint*** request ***referred to in paragraph 1***, through the Critical Medicines Group, and invite them to join the procedure.	3. The participation in the procurement procedure shall be open to all Member States. ***Having received the joint request,*** the Commission shall inform all ***other*** Member States of the ***joint*** request, through the ~~*Critical Medicines Group, and invite them to join*~~ ***CMCG, and set a deadline of 20 working days for Member States to declare their interest in participating in*** the procedure. ***Participation in the procurement procedure shall be voluntary for Member States.***	

Article 22(4)				
183	4. The Commission shall assess the utility, necessity and proportionality of the request and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	4. The Commission shall assess the utility, necessity and proportionality of the ***joint*** request ***referred to in paragraph 1*** and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	4. The Commission shall assess ~~*the utility, necessity and proportionality of the request and*~~ whether the ***joint*** request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could ~~*constitute*~~ ***result in*** discrimination or restriction ~~*to*~~***on*** trade or a distortion ~~*to*~~ ***of*** competition ***taking into account the utility, necessity and proportionality of the joint request***.	
Article 22(5)				
184	5. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.	5. The Commission shall ~~*inform the interested*~~***communicate to the requesting*** Member States ***its decision*** within one month of the request of its decision and state its reasons in case of a refusal. ***It shall inform the European Parliament thereof***	5. ***Within 20 working days of receiving the joint request,*** the Commission shall inform the interested Member States ~~*within one month of the request*~~ of its decision and state its reasons in case of a refusal.	
Article 22(5a)				
184a		***5a. The Commission shall ensure that any procurement procedure under this Article applies to the award criteria and requirements referred to in***		

		Article 18(1) to (4), including those on supply chain resilience, diversification and innovation.		
Article 22(5b)				
184b		***5b. The Commission shall conduct a procurement on behalf or in the name of Member States under this Article subject to the acceptance of the following conditions by the requesting Member States:***		
Article 22(5b), point (a)				
184c		***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;***		
Article 22(5b), point (b)				
184d		***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***		
Article 22(5b), point (c)				
184e		***(c) participating Member States, for the duration of the***		

		contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;		
Article 22(5b), point (d)				
184f		***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***		
Article 22(5b), point (e)				
184g		***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.***		
Article 22(5c)				
184h		***5c. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procurement procedure established herein and with which the Union has concluded a bilateral agreement providing for such a participation, without prejudice to their accession***		

		negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the requirement of a minimum of five participating Member States in accordance with paragraph 1.		
Article 22(6)				
185	6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.	6. ~~*If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.*~~	6. ~~*If in light of*~~***Where based on its assessment,*** the Commission ~~*assessment, it is*~~***may, if*** necessary~~*, in order*~~ to achieve the objectives of this Regulation, ~~*to conduct*~~***make the initiation of*** the procurement ~~*as exclusive for the*~~***procedure conditional upon the interested*** Member States ~~*or to agree to*~~***accepting binding*** minimum~~*-binding*~~ quantities, ~~*the Commission agreement to pursue the*~~***in accordance with their national need, or refraining from participating in competing subsequent procurement processes. Such a procurement*** procedure may ***only be initiated once***~~*be conditioned upon acceptance of*~~ these conditions ***have been accepted by the***~~*by*~~ interested Member States.	

Article 22(7)				
186	7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[1]. __________ 1. Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) (OJ L, 26.9.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).	7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[1]. __________ 1. Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) (OJ L, 26.9.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).	7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[1]. __________ 1. Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) (OJ L, 26.9.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).	
Article 23				
187	Article 23 Joint Procurement	Article 23 Joint Procurement	~~*Article 23*~~ ~~*Joint Procurement*~~	
Article 23(1)				
188	1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least nine Member States may engage, as	1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least ~~*nine*~~***five*** Member States may engage, as contracting parties, in a joint procurement procedure.	~~*1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least nine Member States may engage, as contracting*~~	

	contracting parties, in a joint procurement procedure.		~~*parties, in a joint procurement procedure.*~~	
Article 23,				
189	2. A joint procurement procedure may be organised following a request by the Member States or at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below:	2. A joint procurement procedure ~~*may*~~***shall*** be organised following a request by the Member States or ***may be organised*** at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below:	~~*2. A joint procurement procedure may be organised following a request by the Member States or at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below:*~~	
Article 23, ,				
190	(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	~~*(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;*~~	
Article 23, ,				
191	(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [1], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per	(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [1], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member	~~*(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [1], or which have undergone a clinical assessment carried out under the voluntary*~~	

	Article 23(1) point (e) of that Regulation. _____ 1. Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: http://data.europa.eu/eli/reg/2021/2282/oj)	States as per Article 23(1) point (e) of that Regulation. _____ 1. Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: http://data.europa.eu/eli/reg/2021/2282/oj)	~~*cooperation among Member States as per Article 23(1) point (e) of that Regulation.*~~ _____ ~~*1. Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: http://data.europa.eu/eli/reg/2021/2282/oj)*~~	
Article 23(3)				
192	3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.	3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply ~~*and*~~, availability ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability ~~*and*~~, accessibility ***and affordability*** of medicinal products of common interest, as applicable.	~~*3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.*~~	Similarly to our comment on the line 181, we support the inclusion of the affordability criterion for requesting the joint procurement.
Article 23(4)				
193	4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure.	4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure. ***It shall inform the European Parliament thereof***	~~*4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure.*~~	

Article 23(5)				
194	5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	5. The Commission shall assess the necessity of a joint action and whether the request ***referred in paragraph 2*** is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	~~*5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.*~~	
Article 23(5a)				
194a		***5a. The Commission shall ensure that any procurement procedure under this Article applies to the award criteria and requirements referred to in Article 18(1) to (4), including those on supply chain resilience, diversification and innovation.***		
Article 23(5b)				
194b		***5b. The Commission shall conduct a joint procurement under this Article subject to the acceptance of the following conditions by requesting Member States:***		
Article 23(5b), point (a)				
194c		***(a) contracting authorities from the participating Member States agree to procure minimum***		

		binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;		
Article 23(5b), point (b)				
194d		***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***		
Article 23(5b), point (c)				
194e		***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;***		
Article 23(5b), point (d)				
194f		***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***		
Article 23(5b), point (e)				

194g		***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.***		
Article 23(5c)				
194h		***5c. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procedures established herein and with which the Union has entered into a bilateral agreement governing the procurement activities referenced in this Article, without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the need for five Member States to engage in the procedure.***		
Article 23(6)				
195	6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to	6. ~~*If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding*~~	~~*6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to*~~	

	minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.	~~*quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.*~~	~~*agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.*~~	
Article 23(7)				
196	7. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.	7. The Commission shall ~~*inform the interested*~~***communicate to the requesting*** Member States ***its decision*** within one month of the request ~~*of its decision*~~, and state its reasons in case of a refusal.	~~*7. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.*~~	
Article 23(8)				
197	8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.	8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.	~~*8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.*~~	