Council of the European Union
General Secretariat

Brussels, 11 April 2025

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

WK 4847/2025 INIT

LIMITE

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

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

CONTRIBUTION

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

Delegations will enclosed comments on subject matter and scope (ST 7201/25).

Subject matter_scope_ST 7201_25 Deadline: ***10 April 2025***

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**' or formatting (for example **bold-underline** for additions and ~~strike-through~~ for deletions, **where necessary, in a different colour**).

To make it feasible to consolidate all contributions, the structure of the table must not be changed, so **no rows can be added or deleted.**

New provisions may only be added in any of the **'existing cells'.**

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Thank you for your cooperation!

Presidency compromise	Suggested adaptations to the text and Comments
General comments	
CHAPTER I	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
SUBJECT MATTER, SCOPE AND DEFINITIONS	
RECITALS	
REVISED DIRECTIVE	
(1) The Union general pharmaceutical legislation was established in 1965 with the dual objective of safeguarding public health and harmonising the internal market for medicines. It has developed considerably since then, but these overarching objectives have guided all revisions. The legislation governs the granting of marketing authorisations for all medicines for human use by defining conditions and procedures to enter and remain on the market. A fundamental principle is that a marketing authorisation is granted only to medicines with a positive benefit-risk balance after assessment of their quality, safety and efficacy.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(5) The essential aim of any rules governing the authorisation, manufacturing, supervision, distribution and use of medicinal products must be to safeguard public health. Such rules should also ensure the free movement of medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union.	SI (Comments): SI supports the addition proposed by Latvia in Recital 5 that underlines that the purpose of the marketing authorisation must be to actually place the medicinal product on the market and to ensure its availability to patients. LV (Suggested adaptations to the text): (5) The essential aim of any rules governing the authorisation, manufacturing, supervision, distribution and use of medicinal products must be to safeguard public health. Such rules should also ensure the free movement of medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union. ***Obtaining a marketing authorisation should bear the objective of an actual market launch and availability of the medicinal product to patients in the Member State where it is authorised and required.*** LV (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	We propose to add a recital to clarify that activities related to obtaining a marketing authorisation of medicinal products should be aimed at and result in the actual availability of the authorised medicinal product in the Member State(-s) where it is authorised if required.
(6) The regulatory framework for medicinal products use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.	
(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope, due to scientific and technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(14) The determination of whether a product falls within the definition of a medicinal product must be made on a case-by-case basis taking into account the factors set out in this Directive, such as the product's presentation or pharmacological, immunological or metabolic properties.	
(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the rules for medicinal products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(16) The new definition for a substance of human origin (SOHO) by the ~~[~~SoHO Regulation~~]~~ **(EU) 2024/1938 of the European Parliament and the Council**[1] covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to humans in the future. Such substances of human origin, other than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns concentrating, separating or isolating elements in the	

[1] **Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L 1938, 17.07.2024, p. 1)**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
preparation of blood components, this should not be considered as changing their inherent properties.	
(17) For avoidance of doubt, the safety and quality of human organs intended for transplantation are regulated only by Directive 2010/53/EU of the European Parliament and of the Council, and the safety and quality of substances of human origin intended for medically assisted reproduction are regulated only by [SoHO Regulation or if not in force, Directive 2004/23/EC]**, in accordance with the principle of voluntary and unpaid donation, as set out in Article 54 of Regulation (EU) 2024/1938 of the European Parliament and the Council**.	
(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and **then** used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an	IE (Suggested adaptations to the text): 18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and then used within

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less complex ATMPs that have been developed and used under the hospital exemption. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States.	the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should ~~be excluded from the scope of this Directive subject to~~ **subject to a general exemption,** **while applying the rules specific to the 'hospital exemption'.** ~~which whilst at the same time~~ ensuring ~~ing~~ that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of **the** hospital exemption among Member States. To improve the application of **the** hospital exemption**,** this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of **the** hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less complex ATMPs that have been developed and used under the hospital exemption. When an authorisation for the manufacturing and use of an ATMP under **the** hospital exemption is revoked because of safety

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	concerns, the relevant competent authorities shall inform the competent authorities of other Member States. LV (Comments): In our view, these may be two legal entities, e.g. the manufacturer and the hospital where the patient will receive the exempted advanced therapy medicinal product. The guidance on Good Manufacturing Practice (GMP) Part IV (GMP for ATMPs) provides GMP requirements for the manufacture of authorised ATMPs, investigational ATMPs and also hospital exemption, recognizing/emphasizing that ATMPs may be developed in hospitals, academic institutions or industrial companies. Thus, the manufacturer and the user of a hospital exemption product may be two different legal entities (as the patient use will only be in a hospital), which is not addressed in the proposed Directive (Art. 2 foresees that the same operator obtains the authorization for both manufacturing and use). We would support a more flexible approach where the manufacturer and the user can be different legal entities.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(18a) In accordance with scientific knowledge, haptens, when combined with an endogenous carrier substance, are allergens and should be construed as such for the purpose of pharmaceutical legislation.	SE (Suggested adaptations to the text): **(18a) In accordance with scientific knowledge, haptens, when combined with a~~n endogenous~~ carrier substance, are allergens and should be construed as such for the purpose of pharmaceutical legislation.** SE (Comments): What is the purpose of this recital and which products are intended? We think the use of "endogenous" is unclear as it could refer both to endogenous human, or endogenous for the bacteria.
REVISED REGULATION	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(6) For the sake of clarity, it is necessary to replace Regulation (EC) No 726/2004 of the European Parliament and of the Council[2] with a new Regulation.	
(7) Veterinary medicinal products are governed by Regulation (EU) No 2019/6 of the European Parliament and of the Council[3]. These medicinal products are outside the scope of this Regulation, even if certain provisions regarding the governance and general tasks of the Agency set out in this Regulation apply to these medicinal products. The specific tasks of the Agency in respect to veterinary medicinal products are laid down in Regulation 2019/6 and Regulation 470/2009 of the European Parliament and of the Council[4].	

[2] **Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).**

[3] **Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).**

[4] **Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 1).**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(8) The scope of centrally authorised medicinal products has been adapted to the realities of the market and technological development as well as the need to ensure a centralised assessment for certain categories of medicinal products. In the light of the Commission's report[5] on the experience gained, it has proved necessary to improve the operation of the marketing authorisation procedures for the placing of medicinal products on the Union market and to amend certain administrative aspects of the European Medicines Agency. In addition, the regulatory framework should be adapted to the current market conditions and economic reality, while continuing to safeguard a high level of protection of public health and the environment. The conclusions of that report call for corrections to some of the operating procedures and require adaptations to take account of scientific and technological development.	

[5] **Report from the Commission to the European Parliament and the Council on the experience acquired with the procedures for authorising and supervising medicinal products for human use, in accordance with the requirements set out in the EU legislation on medicinal products for human use, COM(2021)497 final.**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
It also emerges from the report that the general principles previously established which govern the centralised marketing authorisation procedure ('centralised procedure') should be maintained.	
(8a) Without affecting the rules laid down in this Directive, Member States remain the sole responsible for their own national security and defence. They are responsible in defending their essential State functions, including ensuring their territorial integrity and safeguarding national security and defence. In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security.	AT (Suggested adaptations to the text): AT: Without affecting the rules laid down in this ~~Directive~~ **Regulation** AT (Comments): AT: The recital refers to the Regulation. General comment: Corresponding exemptions should be laid down in the binding text where relevant. SE (Comments): Sweden support 8a, we wonder if the same should not be added to the regulation, as it concerns article 115a in chapter X. LV

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): We suggest checking whether the reference is to a Regulation or to a Directive, as it is currently in the Regulations section (if it is a Directive, it should be moved elsewhere).
(9) As to the scope of this Regulation, the authorisation of antimicrobials is, in principle, in the interest of patients' health at Union level and therefore it should be made possible to authorise them at Union level.	
(10) With a view to maintain a high-level of scientific evaluation for new medicinal products and medicinal products that will serve the entire Union population, the centralised procedure should be mandatory for high-technological medicinal products, particularly those resulting from biotechnological processes, priority antimicrobials, orphan medicinal products, paediatric use medicinal products and any medicinal product	IE (Suggested adaptations to the text): (10) With a view to maintain a high-level of scientific evaluation for new medicinal products and medicinal products that will serve the entire Union population, the centralised procedure should be mandatory for high-technological medicinal products, particularly those resulting from

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
that includes an active substances not authorised before the last important change to the scope of the centralised procedure in 2004.	biotechnological processes, priority antimicrobials, orphan medicinal products, paediatric use medicinal products and any medicinal product that includes an active substances not **previously authorised in the Union.** ~~authorised before the last important change to the scope of the centralised procedure in 2004.~~
(11) As regards medicinal products for human use, optional access to the centralised procedure should also be foreseen in cases where use of a single procedure produces added value for the patient. The centralised procedure should remain optional for medicinal products which, although not belonging to the categories of products to be authorised by the Union, are nevertheless therapeutically innovative. It is also appropriate to allow access to this procedure for medicinal products which, although not innovative, may be of benefit to society or to patients, including paediatric patients, if they are authorised from the outset at Union level, such as certain medicinal products which can be supplied without a medical prescription. This option may be extended to generic and biosimilar medicinal products authorised by the Union, provided that this in no way undermines either the harmonisation achieved when the	IE (Suggested adaptations to the text): 11) As regards medicinal products for human use, optional access to the centralised procedure should also be foreseen in cases where use of a single procedure produces added value for the patient. The centralised procedure should remain optional for medicinal products which, although not belonging to the categories of products to be authorised by the Union, are nevertheless therapeutically innovative. It is also appropriate to allow access to this procedure for medicinal products which, although not innovative, may be of benefit to society or to patients, including paediatric patients, if they are authorised from the outset at Union level, such as certain medicinal products which can be supplied without a medical prescription. This option may be extended to generic, **hybrid**,

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
reference medicinal product was evaluated or the results of that evaluation. At the same time, to ensure wide availability of generic medicinal products, those medicinal products may be authorised in any case by the competent authorities of the Member States, even if they are based on a centrally authorised reference medicinal product.	~~and~~ biosimilar **and bio-hybrid** medicinal products authorised by the Union, provided that this in no way undermines either the harmonisation achieved when the reference medicinal product was evaluated or the results of that evaluation. At the same time, to ensure wide availability of generic medicinal products, those medicinal products may be authorised in any case by the competent authorities of the Member States, even if they are based on a centrally authorised reference medicinal product.
(154) This Regulation is based on the double legal basis of Article 114 and Article 168(4), point (c), TFEU. It aims at achieving an internal market as regards medicinal products for human use, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously. These two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation establishes a European Medicines Agency and provides	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
specific provision with regard to the central authorisation of medicinal products, therefore ensuring the functioning of the internal market and the free movement of medicinal products. Regarding Article 168(4), point (c), TFEU, this Regulation sets high standards of quality and safety for medicinal products.	
(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science.	
(156) The objective of this Regulation is to ensure the authorisation of high quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union. Where this objective cannot be sufficiently achieved by the Member States but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	
REVISED DIRECTIVE	
Article 1	
Subject matter and scope	
1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, **advertising, supervision,** control and use of medicinal products for human use.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
2. This Directive shall apply to medicinal products for human use intended to be placed on the market.	
3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products.	LV (Comments): LV: We have concerns about scope and burden, as more flexible solutions already exist today, e.g. in Plasma Derived Medicinal Products, the collection and storage of plasma until transfer to a fractionation facility can be carried out under a SoHO authorisation (Blood Directive) without the need for a manufacturing authorisation. Also, we encourage the deletion of "starting materials".
4. In cases where~~, taking into account all its characteristics,~~ a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail.	IE (Comments): The equivalent provision in Article 2(2) of the current Directive acknowledges the potential for doubt to exist as to whether a product falls within the definition of a 'medicinal product' or the definition of another product covered by other community legislation. Such doubt can exist

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	particularly with respect to the second part of the definition of a medicinal product as there may be uncertainty in relation to: a) how an individual substance achieves its medicinal effect and whether this is based on a pharmacological, metabolic or immunological action (such uncertainty still exists for some active substances that have been authorised for many years) and b) in the case of a product where multiple substances contribute to the medicinal effect of a product, which substance is primarily responsible for that medicinal effect and consequently which is the primary mechanism of action. Consequently, there should be an onus on any entity placing a product on the EU market to justify the chosen legal framework and demonstrate compliance with the relevant definitions and provisions. Most importantly in cases where there is scientific uncertainty and/or limited available data, the burden of proof in this regard should lie with that entity rather than the competent authority.
5. The Directive shall not apply to:	IE (Suggested adaptations to the text): 5. The Directive shall not apply to:

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula');	FI (Suggested adaptations to the text): (a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula'), **if the specific needs of an individual patient cannot be met by an authorised medicinal product.** FI (Comments): The priority of using authorised medicinal products should be included in 5 (a). The preparation should be justified only under very strict provisions. The preparation should be justified only in cases where there is a medical necessity for preparation for individual patient. In these cases there shouldn't be available any medicinal product that has a marketing authorisation. The relevant judgments of the Court should be also taken into consideration (Judgment of the Court of 16 July 2015 Abcur AB v

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Apoteket Farmaci AB and Apoteket AB joint Cases C-544/13 and C-545/13 and Judgement of the Court of 26 October 2016 Hecht-Pharma GmbH v Hohenzollern Apotheke Case C-276/15). In case Abcur the referring court asked, whether medicinal products such as those at issue in the main proceedings are capable of being covered by any of the exceptions in Article 3, points 1 or 2, of Directive 2001/83, in particular where there are **other authorised medicinal products with the same active substance, same dosage and same pharmaceutical form which have obtained an MA**. The court ruled that, "as a preliminary point, it must be noted that the fact raised by the referring court, which refers to Article 5(1) of Directive 2001/83, **pursuant to which there are other medicinal products with the same active substance, same dosage and same pharmaceutical form which have obtained an MA, is irrelevant for the purpose of the application of the exceptions set out in Article 3, points 1 and 2, of Directive 2001/83**, which requires only that the conditions expressly provided for in that article be met."

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	According to above mentioned case law, the exceptions in the current directive's Article 3, paragraphs 1 and 2, which would be regulated in paragraphs 1 and 5 (a) and (b), could be applied even if an equivalent authorised medicinal product is available in the Member State concerned for patient treatment. Therefore there needs to be stricter rule, that these exceptions concerning pharmacy preparation can be applied only if there are no authorised medicinal product available. IE (Suggested adaptations to the text): (a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient (‘magistral formula’); IE (Comments): The concept paper prepared to assist in the development of the COM’s proposal noted the need to move away from the concept of ‘industrial process’ to future-proof the legislation and take into account scientific

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	and technical progress and we would like to avoid re-introducing this concept here. We see a need to maintain a clear distinction between the role of a pharmacy and an authorised manufacturing site. Therefore we are not in favour of introducing a possibility for a pharmacy to supply other pharmacies with medicines they have prepared using this provision. We could agree to allow pharmacies to supply such medicines to hospitals they serve and have proposed to amend the wording accordingly LV (Comments): We would suggest to define the terms more clearly, so that there is less room for interpretation. It would be beneficial to define "non-industrial scale" to ensure clarity. At the same time, we suggest deleting "by a method not involving an industrial process," as it is not possible to define which process is exclusively industrial.
(b) medicinal product**s** prepared in a pharmacy **(‘serving pharmacy’) on a non-industrial scale and by a method not involving an industrial process** in accordance with ~~a~~ **European** pharmacopoeia **or with the**	CZ (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
pharmacopoeia of a Member State and intended to be supplied directly to **any of the following** ~~the patients served by the pharmacy in question or to the hospitalserved by the pharmacy or another pharmacy which intends to supply the medicinal prodeucts directly to the patients~~ (‘officinal formula’)~~:~~;	medicinal product**s** prepared in a pharmacy ~~(‘serving pharmacy’) on a non-industrial scale and by a method not involving an industrial process~~ in accordance with ~~a~~ **European** pharmacopoeia ~~or with the pharmacopoeia of a Member State~~ and intended to be supplied directly to ~~any of the following~~ **the patients served by the** ~~pharmacy in question or to the hospitalserved by the pharmacy or another pharmacy which intends to supply the medicinal prodeucts directly to the patients~~ (~~officinal formula’)~~:~~;~~ **i) the patients served by the serving pharmacy in question;** **ii) a hospital for dispensing directly to its patients;** **iii) another pharmacy for dispencing directly to its patients.** CZ (Comments): CZ does not support the proposed changes by PL PRES. We prefer to maintain the initial EC proposal which is in accordance with the current legislation. Changes proposed by PL PRES do not contribute to clarity of the text. CZ is of the opinion that the text proposed by EC is sufficient and we propose to delete these changes. Moreover, provision of letter ii) does not correspond to the current EU legislation and the current practice in this matter as hospitals do not dispense medicines to patients. Hospitals

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	administer medicines or provide them to patients. Using of the term "dispensing" could have impacts on other parts of Directive Proposal. Please see the changes proposed. EE (Suggested adaptations to the text): (b) medicinal product**s** prepared in a pharmacy ~~**('serving pharmacy')**~~ ~~**on a non-industrial scale and by a method not involving an industrial process**~~ in accordance with ~~a~~ **European** pharmacopoeia **or with the pharmacopoeia of a Member State** and intended to be supplied directly to ~~**any of the following**~~ the patients served by the pharmacy in question **or to the hospital served by the pharmacy or another pharmacy which intends to supply the medicinal prodeucts directly to the patients** ('officinal formula')~~:~~; EE (Comments): *We propose to revert to the previous compromise text, which provides sufficient clarity. The new wording is going too much into detail and adds unnecessary complexity, e.g non-industrial scale and close proximity are not clear concepts. To ensure the quality and safety of medicinal*

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	products, pharmacy-to-pharmacy supply should also be permitted, as the level of specialisation can vary between pharmacies. FI (Suggested adaptations to the text): (b) medicinal product**s** prepared in a pharmacy **('serving pharmacy')** ~~**on a non-industrial scale and by a method not involving an industrial process**~~ in accordance with ~~a~~ **European** pharmacopoeia **or with the pharmacopoeia of a Member State** and intended to be supplied directly to **any of the following** ~~the patients served by the pharmacy in question~~ ~~**or to the hospitalserved by the pharmacy or another pharmacy which intends to supply the medicinal prodeucts directly to the patients**~~ ('officinal formula'), **if medicinal products are supplied in response to the needs of patients, which cannot be met by an authorised medicinal product**~~:~~; FI (Comments): See our comment above concerning 1. (5)(a).

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	In this Article 1. (5)(b) the priority of using authorised medicinal products should also be mentioned. This is essential in order to prevent pharmacy preparations in situation where there is a equivalent authorized medicinal product available. The requirement of "a non-industrial scale and by method not involving an industrial process" can be deleted only if there will be added a provision concerning the priority of using authorised medicinal products. See our detailed comment on the case law above in the comments of Article 1(5)(a). **According to above mentioned case law, the exceptions in the current directive's Article 3, paragraphs 1 and 2, which would be regulated in paragraphs 1 and 5 (a) and (b), could be applied even if an equivalent authorised medicinal product is available in the Member State concerned for patient treatment.** Therefore there needs to be stricter rule, that these exceptions concerning pharmacy preparation can be applied only if there are no authorised

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	medicinal product available. In that case, pharmacy preparation would be the last option and would occur out of genuine need. The use of authorised medicinal products should always be the priority. If the exception concerning pharmacy manufacturing in section b) does not mention the requirement for prioritizing authorised medicines or the extent of manufacturing, it practically allows continued extensive pharmacy manufacturing for medicines, even when an authorised product is available. Such pharmacy manufacturing can be done for cost reasons because using authorised medicines is more expensive. However, this should not be the basis; instead, authorised medicines, whose efficacy, safety, and quality are ensured, should always be prioritized. Pharmacy manufacturing should only be restricted to situations where no other medicine is available for patient treatment. The requirement for manufacturing according to the pharmacopoeia does not sufficiently limit this production. In Finland, for example, hospital pharmacies manufacture the radiopharmaceutical Fluorodeoxyglucose (18F), which is used for patient imaging. A similar authorised product is

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	available, but production is done for cost reasons in hospital pharmacies. Some monographs recognize this preparation, which is why it is unclear whether such cost-based manufacturing can continue in the future based on Article 1(5)(b). **This cannot be the purpose of the medicinal directive.** This is just one example of situations where pharmacy preparation is carried out, but it highlights the need for stricter regulation. The risk is that pharmacy preparation is done extensively outside the marketing authorisation system, creating two different markets that do not require the same standards. Considering the purpose and objectives of the medicinal directive, it should be clearly regulated that the use of authorised products is a priority, and pharmacy preparation is a very exceptional situation where no other options are available for patient treatment.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	NL (Suggested adaptations to the text): (b) medicinal products prepared in a pharmacy **('serving pharmacy') on a non-industrial scale and by a method not involving an industrial process** in accordance with a ~~**European**~~ pharmacopoeia ~~**or with the pharmacopoeia of a Member State**~~ and intended to be supplied directly to **any of the following** ~~the patients served by the pharmacy in question~~ **or to the hospitalserved by the pharmacy or another pharmacy which intends to supply the medicinal prodcucts directly to the patients** ('officinal formula')**:**~~;~~ NL (Comments): We prefer to keep the previous wording: 'in accordance with a pharmacopoeia'. This will give room for using pharmacopeia in broad sense, both national as pharmacopeia in other jurisdictions. SE (Suggested adaptations to the text): (b) medicinal products prepared in a pharmacy **('serving pharmacy')** ~~**on a non-industrial scale and by a method not involving an industrial**~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	~~**process**~~ in accordance with ~~**a**~~ **European** pharmacopoeia **or with the pharmacopoeia of a Member State** and intended to be supplied directly to **any of the following** ~~the patients served by the pharmacy in question or to the hospitalserved by the pharmacy or another pharmacy which intends to supply the medicinal prodeucts directly to the patients~~ (‘officinal formula’)**:** SE (Comments): The concepts “prepared industrially or manufactured by a method involving an industrial process” are used in the current directive but are relatively unclear and difficult to interpret and it was an advantage that they were not included in the Commission's proposal. To now propose the introduction of the concepts would represent a major step backwards and constitute an obstacle to, among other things, technological development (e.g. 3D printing) and the quality that comes with larger-scale manufacturing than from artisanal processes. IE (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(b) medicinal products prepared in a pharmacy ~~('serving pharmacy') on a non-industrial scale and by a method not involving an industrial process~~ in accordance with **the** European pharmacopoeia or with the pharmacopoeia of a Member State and intended to be supplied directly to **the patients served by the pharmacy in question or dispensed to a hospital adjacent to the pharmacy and within the same Member State.** ~~llowing~~ ('officinal formula');; SK (Comments): Slovakia welcomes the proposed wording, as it may help ensure medicine availability in situations where an industrially manufactured product is not available on the market.
i) the patients served by the serving pharmacy in question;	EE (Suggested adaptations to the text): ~~**i) the patients served by the serving pharmacy in question;**~~ SE (Suggested adaptations to the text): **i) the patients served by the serving pharmacy in question**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	IE (Suggested adaptations to the text): ~~i) the patients served by the serving pharmacy in question;~~
ii) a hospital for dispensing directly to its patients;	EE (Suggested adaptations to the text): ~~**ii) a hospital for dispensing directly to its patients;**~~ SE (Suggested adaptations to the text): **ii) a hospital for dispensing directly to its patients;** IE (Suggested adaptations to the text): ~~ii) a hospital for dispensing directly to its patients;~~
iii) another pharmacy for dispencing directly to its patients.	EE (Suggested adaptations to the text): ~~**iii) another pharmacy for dispencing directly to its patients.**~~ SE (Suggested adaptations to the text): **iii) another pharmacy for dispencing directly to its patients.**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	SE (Comments): Important to keep in legislation. IE (Suggested adaptations to the text): ~~iii) another pharmacy for dispencing directly to its patients.~~
The hospital and pharmacy listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;	AT (Suggested adaptations to the text): **AT:** **The hospital ~~and pharmacy~~ listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;** AT (Comments): AT: We definitely do not recommend basing this paragraph on a certain distance (‘close proximity’) to other pharmacies. Firstly, there is no precise definition of the word ‘proximity’, secondly, there are cases

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	where specific pharmacies are able to prepare specific magistral/officinal formulas, whereas others are not. These pharmacies should be able to supply other pharmacies (for individual patients) regardless of their distance within a member state. CZ (Suggested adaptations to the text): ~~The hospital and pharmacy listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;~~ CZ (Comments): Please see the CZ comment above on this Article. EE (Suggested adaptations to the text): ~~The hospital and pharmacy listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;~~ SE (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	~~**The hospital and pharmacy listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;**~~ SE (Comments): The proposal does not take into account that different countries have different geographical conditions and have therefore organized their pharmaceutical supply in different ways. Such a requirement is also not possible in SE based on Swedish conditions, i.e. a sparsely populated country. It is a limitation that there is no need for, it reduces flexibility and does not benefit patients. The proposal would also make it more difficult to organize hospital pharmacies. A hospital pharmacy is not always located in a hospital or even in the region that the pharmacy supplies with pharmaceuticals. IE (Suggested adaptations to the text): ~~The hospital and pharmacy listed above shall be in close proximity to the serving pharmacy within the same Member State which intends to supply the medicinal products directly to the patients;~~ LV

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): We share the view that serving another pharmacy should be allowed without referring to "close proximity" in the legislative act, as this lacks precise definition. Some pharmacies may have the capability to prepare specific formulas, while others do not. These pharmacies should be allowed to supply other pharmacies for individual patients, regardless of their location within a member state.
Point (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/2204].	CZ (Suggested adaptations to the text): ~~**Point (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/2204].**~~ CZ (Comments): Please see the CZ comment above on this Article. EE (Suggested adaptations to the text): ~~**Point (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/2204].**~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	IE (Suggested adaptations to the text): ~~Point (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/2204].~~
(c) investigational medicinal product**s** as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014	
~~**(d) SoHO preparations as defined in Article 3 (37) of Regulation (EU) No 2024/1938, unless the requirements of a SoHO derived medicinal product are met**~~ **substances of human origin, unless they fall within the definition of an advanced therapy medicinal product or a SoHO-derived medicinal product other than ATMPs.**	SE (Suggested adaptations to the text): substances of human origin, unless they fall within the definition of an advanced therapy medicinal product**,** ~~or a~~ SoHO-derived medicinal product other than ATMPs~~.~~**, starting materials, active substances, excipients or intermediate products.** SE (Comments): SoHo used in the manufacturing of medicinal products must not be excluded from the legislation. Otherwise, Article 1.3 would not apply if

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	starting materials, active substances, excipients or intermediate products are SoHo.
6. Medicinal products referred to in paragraph 5, point (a), may be prepared ~~in duly justified cases~~ in advance by a pharmacy ~~serving a hospital~~, on the basis of the estimated medical prescriptions ~~within that hospital~~ for the following **period of up to** ~~seven days~~ **four weeks, taking into account the properties of the medicinal product**.	CZ (Comments): The changes proposed by PL PRES reflect comments of Member States, including CZ, therefore, we can support this addition. FI (Comments): This section is acceptable and necessary**, provided that an addition is made to Article 1(5)(a) stating that the exception can be applied if an authorized medicinal product is not available.** If this restriction is not added to section (a), it allows for even broader ex tempore medicine manufacturing in pharmacies. Current legal practice based to the Court cases regarding pharmacy manufacturing requires that production can only begin once a prescription has been issued for an individual patient, and thus the manufacturing truly happens for a single patient. The preliminary stock production based on the proposed section 6 is necessary

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	so that pharmacies can manufacture ex tempore preparations in series and thus ensure the quality of the preparations and their immediate availability if, for example, a pediatric patient requires such an ex tempore preparation urgently. **However, if a restriction on the prioritization of authorised medicinal products is not simultaneously stipulated in section 1(5)(a), pharmacies can extensively manufacture any prescription medicines, which would no longer be about meeting the needs of an individual patient. This cannot be the purpose of the medicinal directive. See also our detailed comments on 5(1) (a) and (b).** NL (Comments): We prefer that pharmacies are able to decide on the desired size of the stock by themselves, based on the demand and characteristics of a product. However, in order to compromise, we could support the period of up to four weeks. IE

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Suggested adaptations to the text): 6. Medicinal products referred to in paragraph 5, point (a) **and point (b)** , may be prepared ~~in duly justified cases~~ in advance by a pharmacy ~~serving a hospital~~, on the basis of the estimated ~~medical prescriptions~~ **usage** ~~within that hospital~~ for the following ~~-~~**period of up to** ~~seven days~~ **four weeks, taking into account the properties of the medicinal product.** LV (Comments): 4 weeks could be considered too long, especially for non-preserved and non-sterilized medicinal products.
7. ~~Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations~~ **in accordance with Article 54 of Regulation (EU) No 2024/1938**~~.~~	
8.~~—~~**Without affecting the rules set out in Regulation (EU) 2024/1938, including as regards the principle of voluntary and**	LV (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
unpaid donations, ~~T~~this Directive and all Regulations referred to therein shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission.	Wording should be revised as neither SoHO regulation 2024/1938 nor the principle of voluntary, unpaid donation applies to material of animal origin. Only animal welfare requirements would apply.
9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.	
10. This Directive shall not affect the application of national legislation prohibiting or restricting the following:	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(a) the sale, supply or use of medicinal products as contraceptives or abortifacients;	
~~(b) the use of any specific type of substance of human origin or animal cells, on grounds not dealt with in the aforementioned Union law;~~	
(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in Union law.	LV (Suggested adaptations to the text): the sale, supply or use of medicinal products containing, consisting of or derived from ~~these~~ animal cells or substances of human origin, on grounds not dealt with in Union law LV (Comments): We believe that the word "these" should be deleted as it is not relevant now that point (b) has been deleted.
	SE (Suggested adaptations to the text): **11. (new) Nothing in this Directive shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate regarding narcotic and psychotropic substance**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	SE (Comments): It is important that it remains possible for MSs to continue to impose national requirements regarding the regulation of narcotics. The draft directive states that such national rules are possible regarding wholesale trade and marketing. Such possibilities should also apply, for example, to the manufacture of narcotic drugs. Sweden has previously put this forward and has also submitted a proposal for wording. Corresponding wording is found in the Veterinary Medicinal Products Regulation (EU) 2019/6 Article 2.9
The Member States shall communicate the national legislation concerned to the Commission.	
Article 2	
Advanced therapy medicinal products prepared under hospital exemption	CZ (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	CZ supports the current text as we believe that it is necessary to maintain the hospital exemption in the proposed form, so that the possibility of using it in the field of personalized treatment is preserved.
1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared **within the same Member State** on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient ('advanced therapy medicinal products prepared under hospital exemption').	EE (Suggested adaptations to the text): 1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared ~~**within the same Member State**~~ on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient ('advanced therapy medicinal products prepared under hospital exemption'). EE (Comments): *Suggest the deletion to keep the flexibility for possible necessary testing activities that may not take place in the same Member State.* SE

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Suggested adaptations to the text): By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared ~~**within the same Member State**~~ on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient ('advanced therapy medicinal products prepared under hospital exemption'). SE (Comments): We are concerned that the addition will make it difficult for cross border cooperation, f.ex between hospitals in different side of a border. IE (Comments): Comment: We consider that if an ATMP manufactured in a hospital does not meet the terms of the hospital exemption, it becomes an unauthorised medicine. While we note the Commission's view that you cannot use a different exemption, it is not clear to us in the legal text that a doctor in

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	another MS cannot prescribe the product for a patient under their care. We think this needs to be clarified in the text if this is the intention. LV (Suggested adaptations to the text): By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared **within the ~~same~~ Member State** on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient ('advanced therapy medicinal products prepared under hospital exemption'). LV (Comments): We would suggest deleting "same", as the product is first produced, then used, and 'the same' is already mentioned there and fits the context. We would also like to seek for clarification, whether the use of decentralised manufacture is not possible (i.e. whether it is prohibited) in case of ATMP hospital exemption.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
2. The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency.	SE (Suggested adaptations to the text): The manufacturing **and use** of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency. SE (Comments): For the sake of clarity. LV (Suggested adaptations to the text): The **use** ~~manufacturing~~ of an advanced therapy medicinal product prepared under hospital exemption shall require an approval **of use of particular product** by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency. LV

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): We propose replacing the term **"manufacturing"** with **"use"** to clearly differentiate between these two distinct activities, which can be conducted by different legal entities. In all sections regulating ATMP Hospital Exemption (ATMP HE), the legislation should, besided manufacturing authorisation, explicitly provide for an **approval for use** that covers: • Conditions of use, including indication and administration, • The obligation to provide the competent authority with safety and efficacy data. This **approval for use** must be **separate from the manufacturing authorisation** to ensure patient safety. **Rationale for Separate Approval for Use** The manufacture of ATMP HEs follows the same authorisation process as other medicinal products under the **Community Manufacturing Licence format**, which allows for specific restrictions—such as limiting

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	production to HEx medicines. In addition to that, an **authorisation for use** is required in our opinion at the institutional (hospital) level where patients will receive treatment. A **manufacturing authorisation alone does not ensure safe use** because patient safety depends on various non-manufacturing factors, including: • The patient group receiving treatment, • Conditions of use (indications, administration routes), • Monitoring of safety and efficacy (pharmacovigilance, patient follow-up). These elements must be assessed by the **national competent authority (NCA)** before granting an authorisation for use. This is particularly crucial as NCAs are responsible for collecting and providing safety and efficacy data to the European Medicines Agency (EMA). **Safety Considerations in Cross-Hospital Use** Since HEx medicines may **only be used in the Member State (MS) where they are manufactured**, they could potentially be used in

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	multiple hospitals under different healthcare professionals for various indications. In such cases, **each use scenario must be separately assessed** for safety and efficacy risks. **GMP inspectors assessing manufacturing processes lack the expertise** to evaluate: • The adequacy of the product's specifications, • Its quality for specific clinical use, • Its safety and efficacy in real-world applications.
The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located.	
3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
requirements equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007[6] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004].	
4. Member States shall ensure that data on the use, **such as the number of patients and administrations,** safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported **in an aggregated manner** by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.	EE (Suggested adaptations to the text): 4. Member States shall ensure that data on the use, ~~**such as the number of patients and administrations,**~~ safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported **in an aggregated manner** by the hospital exemption approval holder to the competent authority of the Member State at least annually. EE (Comments):

[6] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1).

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	We would propose not to include examples of data on use. All the data sets should be specified in a consistent manner in the implementing act as foreseen in p. 7. It would not be advisable to single out some data in the Directive. LV (Suggested adaptations to the text): Member States shall ensure that data on the use, **such as the number of patients and *product* administrations,** safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported **in an aggregated manner** by the hospital exemption approval *for use* holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the *pharmacovigilance* requirements referred to in paragraph 3. LV (Comments): This provision concerns “use” in the context of safety and efficacy, which further justifies the need to separate manufacture from approval for use.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	The competent authority should receive this information from the hospitals where patients are treated, not from the manufacturing site, which is primarily responsible for quality assurance. We also suggest to change to "use" as the manufacturer can be another legal entity (manufacturer, academic institution, another hospital) licensed to produce Hex, but the use can only take place in a medical institution (including another hospital in the same MS).
5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency**.** **The Agency shall inform** ~~and~~ the competent authorities of the other Member States.	LV (Suggested adaptations to the text): If a hospital exemption approval ***for use*** is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency**.** **The Agency shall inform** ~~and~~ the competent authorities of the other Member States. LV (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Our suggestion is to add 'for use", because in the case of safety and efficacy concerns, the focus is on stopping further use in patients, not manufacturing.
6. The competent authority of the Member State shall transmit the **available** data related to the use, **including the name and class of the medicinal product, the indication and the location of the use, as well as** ~~,~~ safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data**, including the mechanism for electronic submission**.	EE (Suggested adaptations to the text): 6. The competent authority of the Member State shall transmit the **available** data related to the use, ~~**including the name and class of the medicinal product, the indication and the location of the use, as well as**~~ ~~,~~ safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. EE (Comments): *There should be a coherent approach and all the data should be specified in the implementing act, we prefer not to include these examples in the Directive.* SE (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	The competent authority of the Member State shall transmit the **available** data related to the use, **including the name and ~~class~~ active subsance ~~of~~ ~~the~~ medicinal product, the indication and the location of the use, as well as** ~~,~~ safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data**, including the mechanism for electronic submission.** SE (Comments): Active substance provides more information than class. LV (Suggested adaptations to the text): The competent authority of the Member State shall transmit the **available** data related to the use, **including the name and class of the medicinal product, the indication and the location of the use *and the route of administratiojn*, as well as** ~~,~~ safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	authorities of Member States and the Commission, set up and maintain a repository of that data**, including the mechanism for electronic submission**. LV (Comments): We would like clarification on whether the words "class of the medicinal product" mean only the type of ATMP (gene, somatic cell and tissue engineered) or something else? At the same time, we suggest adding the words “and route of administration” after “location”, as both are important in relation to safety and efficacy.
7. The Commission shall adopt implementing acts to specify the following:	
(a) details of the application for the approval of hospital exemption referred to in paragraph ~~1~~2, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
prepared under hospital exemption for the approval and the subsequent changes;	
(b) the **content and** format for collection and reporting of data referred to in paragraph 4 **together with a description of such data**;	
(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States;	LV (Suggested adaptations to the text): the modalities for the exchange of knowledge between hospital exemption approval ***for use*** holders within the same Member State or different Member States; LV (Comments): We propose adaptation to the text. : (c) the modalities for the exchange of knowledge between hospital exemption approval **for use** holders within the same Member State or different Member States
(d) the modalities for preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	
8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. The first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.	AT (Comments): AT: For transparency reasons these reports should be made publicly available and factored into any legislative decision-making.
Article 3	NL (Comments): We stress that authorised medicinal products should always be the standard. However, we note that we have the responsibility to address patients' need when no authorised medicinal product is available in a MS. We propose to have this flexibility as an exception and with the right safeguards for public health. This is the current proposal that the NL has.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	However, we are working on another proposal, to better suit the needs and concerns MS has expressed during the CWP.
Exceptions under certain circumstances	
1. A Member State may, in order to fulfil special needs, exclude from the scope of this Directive**:**	IE (Suggested adaptations to the text): 1. A Member State may, in order to fulfil special needs, exclude from the scope of this Directive:
(a) medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility**. This point shall only apply if a medicinal product authorised in the Union law is not available in that Member State**;	AT (Suggested adaptations to the text): AT: (a) medicinal products supplied in response to a bona fide unsolicited order, ~~prepared~~ in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. This point shall only apply if a medicinal product or **a comparable** authorised in the Union law is not available in that Member State; AT

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): AT: It should be clear that the "prepared requirement" is not based on individual preparation, but that import of medicinal products authorised in other states is also possible. Generics should also be considered, because authorised medicinal products should be prioritised. EE (Suggested adaptations to the text): **(a)** medicinal products ~~supplied~~ **used** in response to a bona fide unsolicited order, ~~prepared~~ **formulated** in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility**.** ~~**This point shall only apply if a medicinal product authorised in the Union law is not available in that Member State:**~~ EE (Comments): *We propose to revert to the existing wording in the current Directive and replace 'prepared' with 'formulated'. There is a well-established practice and changing the wording could create different interpretations.*

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Replacing 'supplied' with 'used' helps to further clarify and overcome the burden related to importing such medicines in the Member States in order to speed up access to treatment (for example, it should be possible to bring the necessary medicine to the country but it can be dispensed to the individual patient only based on the order by the treating physician.) *We request the deletion of the added sentence. Such a condition would exclude the use of necessary medicines in situations where existing authorised medicines have not provided the desired treatment result, but the patient could receive help from a medicine that has a marketing authorisation and is available from third countries. Also, it would not be possible to use the exception in situations where a medicine with a marketing authorisation in the EU has a European-wide supply problem and it can only be obtained from a third country.* FI (Suggested adaptations to the text): medicinal products supplied in response to a bona fide unsolicited order, **formulated** in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	direct personal responsibility**. <u>This point shall only apply if a medicinal product authorised in the Union law is not available in that Member State</u>**: FI (Comments): It must be ensured that current special permit procedures can be maintained. The term "formulated" should remain, because the term "prepared" could narrow the actual producing options of the medicine without justification. This provision is needed for the treatment of individual patients. NL (Suggested adaptations to the text): **<u>(a)</u>** medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility**<u>. ~~This point shall only apply if a medicinal product authorised in the Union law is not available in that Member State;~~</u>**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	NL (Comments): we thank the presidency for considering our proposal and note that the new addition might be based on our proposal. However, without the other additions, this will lead to unnecessary restrictions of the current practice. We propose to delete the last sentence. SE (Suggested adaptations to the text): **(a)** medicinal products supplied in response to a bona fide unsolicited order **or anticipated bona fide unsolicited order**, prepared in accordance with the specifications of an authorised healthcare professional ~~and for use by an individual patient under their~~ **who bears** direct personal responsibility **for their patient.** SE (Comments): SE supports the proposal made by NL in this regard. SI (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(a) medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility~~. This point shall only apply if a medicinal product authorised in the Union law is not available in that Member State;~~ SI (Comments): SI would propose to revert to the previous text, as we consider that the amendment included unnecessarily restricts the activities of MS. IE (Suggested adaptations to the text): (a) medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. ~~This point shall only apply if a suitable the medicinal product authorised in the accordance with Union law is not available in that Member State;~~ IE

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): Comment: 1(a) We consider that the original text was better as it is not clear what the intention of the additional text is and it risks unnecessarily limiting this exemption. LV (Suggested adaptations to the text): medicinal products supplied in response to a bona fide unsolicited order, ~~**prepared**~~ in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility**. This point shall only apply if a medicinal product authorised in the Union law is not available in that Member State** LV (Comments): We strongly recommend deleting the word "prepared," as this paragraph should also apply to the import of this specific product, which aligns with the public interest.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(b) medicinal products supplied in response to unavailability of the medicinal product due to a critical shortage in the Member State due to withdrawal, suspension, cessation of marketing or shortages, prepared under the direct supervision of a pharmacist in accordance with a European pharmacopeia or with the pharmacopeia of a Member State or national monographs, if the unavailability or the shortage in the Member State cannot be prevented or resolved through Union coordination in accordance with ~~e~~Chapter X of [revised~~ees~~ ~~d~~Directive 2001/83] ~~of authorised medicinal products~~ and for as long as the critical shortage in the Member State is not resolved.	CZ (Suggested adaptations to the text): **medicinal products supplied in response to unavailability of the medicinal product due to ~~a critical shortage in the Member State due to~~ withdrawal, suspension, cessation of marketing or shortages, ~~prepared under the direct supervision of a pharmacist in accordance with a European pharmacopeia or with the pharmacopeia of a Member State or national monographs,~~ if the unavailability or the shortage in the Member State cannot be prevented or resolved through Union coordination in accordance with ~~e~~Chapter X of [revised~~ees~~ Directive 2001/83] ~~of authorised medicinal products and for as long as the critical shortage in the Member State is not resolved.~~** CZ (Comments): CZ supports the option to temporarily supply a non-authorised medicine in the case of shortages or market failure. However, the changes proposed by

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	PL PRES narrow this option. Moreover, new subpara 3 limits preparation of medicines in a pharmacy as it stipulates an obligation to fulfil requirements equivalent to good manufacturing practice. Additionally, we would like to point out that exclusion of such medicine from the full scope of the Directive, as opposed to excluding it from rules on authorisation to place such medicine on the EU market, could have consequences on distribution and use of such medicine. **We consider it important that in case of shortages of an authorised medicine, the option to place on the market, distribute and use a non-authorised medicine in a particular Member State is maintained, as it is in accordance with the current EU legislation**. For these reasons, we are not in favour of the changes proposed by PL PRES in letter b) of this subpara 3. Please see the changes proposed. EE (Comments): *The added text seems to extend the scope of pharmacy preparations as foreseen in Art 1 (5), which we do not consider appropriate to remedy unavailability of specific products.* *In case of unavailability (either there is no authorised product in the EU, the authorised product has not been placed on the market in the*

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	particular MS or is not available in sufficient quantities), the Member States should have the possibility to allow the use of unauthorised products in exceptional circumstances where no authorised alternatives with equivalent therapeutic effect are available in the Member State. These exceptions should be justified by public health needs and ensure that equivalent quality and safety standards are met. These are products that for example are important for the national immunisation programmes or for the treatment of communicable diseases such as TB and HIV. The first choice in such exceptional circumstances should be to seek medicinal products authorised in another EU Member State or a third country. *We would propose to foresee the possibility to allow the use of unauthorised products in case of unavailability as a targeted exception in a separate paragraph and not as a broad exclusion from the scope of the Directive.* FI (Suggested adaptations to the text): **medicinal products supplied in response to unavailability of the medicinal product due to a critical shortage in the Member State due**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	to withdrawal, suspension, cessation of marketing or shortages, or if the medicinal product has not been placed on the market in that Member State, prepared under the direct supervision of a pharmacist in accordance with a European pharmacopeia or with the pharmacopeia of a Member State or national monographs, or manufactured or imported by a manufacturing authorisation holder in the EU, if the unavailability or the shortage in the Member State cannot be prevented or resolved through Union coordination in accordance with eChapter X of [revisedees dDirective 2001/83] ~~of authorised medicinal products~~ and for as long as the critical shortage in the Member State is not resolved. FI (Comments): The use of medicinal products that possess marketing authorisation in the Member State is consistently the primary option in pharmacotherapy. In circumstances where an authorised medicine is unavailable to ensure public health due to the authorised medicine not being marketed in Member State or experiencing a supply disruption, it becomes necessary

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	to use a medicinal product that is authorised in another Member State or third country. Currently, based on its own assessment, the Finnish Medicines Agency may grant a special permit for a medicinal product for the treatment of patient group or population or for the prevention of the disease on its own initiative, without an application (a fixed-term special permit). In that case, medicinal products may be released for consumption without a patient or institution-specific special permit granted by the Finnish Medicines Agency if they are prescribed and supplied in accordance with the terms of the fixed-term permit. In other cases, the release for consumption requires a patient or institution-specific special permit from the Finnish Medicines Agency. A medicinal product subject to a special permit or a fixed-term permit does not have a marketing authorisation in Finland. The Finnish Medicines Agency inquires whether the proposed Article 205 applies to above mentioned fixed-term special permits despite the fact that the article concerns the granting of a certain type of marketing authorisation. If the Article 205 does not apply, Article 3 should enable fixed-term special permits instead.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	In addition to the special permits and the fixed-term special permits, the Finnish Medicines Agency may grant a batch-specific exemption from the conditions of a marketing authorisation or registration, if a medicinal product is critical for the Finnish pharmaceutical services and its availability would otherwise be jeopardised. The exemption can only be granted for a preparation that has a valid marketing authorisation or registration. The exemption from the conditions of marketing authorisation may apply situations other than language requirements (as proposed in article 75). The decision regarding an exemption from the conditions of a marketing authorisation or registration is always based on the comparison of the possible risk caused by the deviation and the risk caused by the stock-out situation. An exemption is generally granted for a specific batch or for a short period of time. The marketing authorisation holder must usually supply to the Finnish Medicines Agency at least the following information: • A description of the problem and the requested exemption for the marketing authorisation.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	• Justifications for the criticality of the preparation. • An estimate of the duration of non-availability and the sales data of the preparation. • Information about the lot that the exemption applies to (lot number, expiry date, number of packages) • If necessary, mock-ups of packages that are in a foreign language An exemption application can either be approved or rejected. It is worth of mention that the MSSG/EMA is recommend that regulatory flexibilities will be applied in certain cases. MSSG Toolkit on recommendations on tackling shortages of medicinal products: "Release by the Qualified Person (QP) of a product with deviations from the requirements set in the EU marketing authorisation that do not have any substantial impact on safety or efficacy of the product (e.g. due to a minor quality defect or for a product that originally has been produced for other markets with differences in the authorisation dossier), subject to agreement by the Rapporteurs/ Lead MS, Supervisory Authority (SA) for the EU batch release site and respective local NCAs for the impacted

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	MSs." https://www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf In order to safeguard public health and availability of essential medicines, Article 3 (1) b) should also apply to situations where the product has not initially been placed on the market in the Member State. In addition, when there is a critical shortage, Member States should have the option to also allow the use of, for example, products authorised in another Member State or in third countries. The proposed point b) only concerns products manufactured in shortage situations, but the point should also enable an exception procedure for medicinal products imported from elsewhere. This would be important especially for small market areas. NL (Suggested adaptations to the text): **(b) medicinal products supplied in response to unavailability or shortage of the medicinal product ~~due to a critical shortage~~ in the Member State ~~due to withdrawal, suspension, cessation of marketing or shortages, prepared under the direct supervision of a~~**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	~~**pharmacist in accordance with a European pharmacopeia or with the pharmacopeia of a Member State or national monographs, if the unavailability or the shortage in the Member State cannot be prevented or resolved through Union coordination in accordance with cChapter X of [revisedees dDirective Regulation 2001/83] of authorised medicinal products and for as long as the critical shortage in the Member State is not resolved**~~. NL (Comments): In our opinion the scope is now too narrow. - the current wording only creates more space for pharmacy preparations. However, we see the need for a basis to import products which are registered in another country and are similar to a registered products which at the time are unavailable. We propose to change the text to "unavailability and shortage" and broaden the scope. SE

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Suggested adaptations to the text): **medicinal products supplied in response to unavailability of the medicinal product due to a critical shortage in the Member State due to withdrawal, suspension, cessation of marketing or shortages, prepared under the direct supervision of a pharmacist in accordance with ~~a~~ the European pharmacopeia or with the pharmacopeia of a Member State or national monographs, if the unavailability or the shortage in the Member State cannot be prevented or resolved through Union coordination in accordance with eChapter X of [revisedees ~~d~~Directive 2001/83] ~~of authorised medicinal products~~ and for as long as the critical shortage in the Member State is not resolved.** IE (Comments): Comment 1(b): We find this exemption confusing as it uses the officinal exemption already outlined in point Article 1(5)(b) to address shortages. In relation to shortages, we are not opposed to an exemption but we consider that in the first instance, an exemption should not be used when there is suitable alternative medicine on the market where the shortage

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	occurs. As this is a shortage of an authorised medicine on your market, the same authorised medicine from another MSs should be used in the first instance.. Secondly, if that is not available, an equivalent generic from another MS should be used. Thirdly if a suitable alternate is available from a MS it should be used. Only when those options have been failed should the option of pharmacy preparation should occur. We also consider that, other than in a PHE, the volumes should be limited. LV (Comments): We have serious concerns regarding the establishment of a routine parallel system for unauthorised pharmacy mass preparations alongside the standard manufacturing and authorisation pathways. In our view, this poses significant public health risks by compromising quality, efficacy and safety of medicinal products. We consider that pharmacy preparations are already sufficiently regulated under Article 1, Paragraph 5, and the exemption outlined in subparagraph (b) is not needed. SK (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Slovakia welcomes the proposed wording, as it may help ensure medicine availability in situations where an industrially manufactured product is not available on the market.
However, in such cases Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.	
Member States shall ensure that medicinal products referred to in point (b) are prepared in a facility that complies with the requirements equivalent to the good manufacturing practices referred to in Article 160.	AT (Comments): AT: this requirement is not in line with the idea of pharmacy preparation under point (b). CZ (Suggested adaptations to the text): ~~**Member States shall ensure that medicinal products referred to in point (b) are prepared in a facility that complies with the**~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	~~**requirements equivalent to the good manufacturing practices referred to in Article 160.**~~ CZ (Comments): Please see the CZ comment above on this Article and see the changes in wording proposed. LV (Comments): We would like to express our support to adding this provision.
	NL (Suggested adaptations to the text): - **ensure that medicinal products referred to in this article are only for use by patients within the same Member State**
The exception of point (b), first subparagraph shall not apply to medicinal products listed in points 1 and 2 of Annex I of [revised Regulation (EC) No 726/2004] that have been included, either directly or as part of a category of medicinal products, on a list published by the Agency, of medicinal products or categories of	CZ (Suggested adaptations to the text): ~~**The exception of point (b), first subparagraph shall not apply to medicinal products listed in points 1 and 2 of Annex I of [revised Regulation (EC) No 726/2004] that have been included, either directly**~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
medicinal products that, when prepared under the conditions of point (b), first subparagraph, are reasonably likely to lead to a negative impact on the safety or efficacy of the medicinal product or category of medicinal products, taking into account their specific characteristics and the benefits and risks to patients.	~~**or as part of a category of medicinal products, on a list published by the Agency, of medicinal products or categories of medicinal products that, when prepared under the conditions of point (b), first subparagraph, are reasonably likely to lead to a negative impact on the safety or efficacy of the medicinal product or category of medicinal products, taking into account their specific characteristics and the benefits and risks to patients.**~~ CZ (Comments): Please see the CZ comment above on this Article and see the changes in wording proposed. NL (Suggested adaptations to the text): **The exception of point (b), first subparagraph shall not apply to medicinal products listed in points 1 and 2 of Annex I of [revised Regulation (EC) No 726/2004] that have been included, either directly or as part of a category of medicinal products, on a list published by the Agency, of medicinal products or categories of medicinal products that, when prepared or**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	manufactured under the conditions of point (b), first subparagraph, are reasonably likely to lead to a negative impact on the safety or efficacy of the medicinal product or category of medicinal products, taking into account their specific characteristics, ~~and~~ the benefits and risks to patients and whether there is a well-established use of the product. SE (Comments): Needs clarification, this text is unclear and difficult to interpret.
For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	
3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.	SE (Comments): SE is of the opinion that, in cases where there are no authorized products in a MS or in the EU it must be possible for that MS to fulfil patients' needs. These needs are sometimes urgent and of exceptional importance. Like NL, SE is of the opinion that it must therefore be possible for a MS to take actions before a specific patient is identified. There should always be an identified need even if an individual patient not yet is identified. Therefore, SE proposes that also medicinal products supplied to an anticipated bona fide unsolicited order shall be excluded from the scope of this Directive.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[7] – OP please replace reference by new instrument COM(2022) 495 when adopted], shall not be affected by paragraph 3.	
REVISED REGULATION	
CHAPTER I	
SUBJECT MATTER, SCOPE AND DEFINITIONS	
Article 1	
Subject matter and scope	

[7] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	
This Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions. Member States may choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
Article 3	NL (Comments): Articles 3 and 4 and Annex I together determine the scope of the centralised procedure. Our vision for the scope is explained in detail in the annex to our written comments.
Centrally authorised medicinal products	
1. A medicinal product listed in Annex I shall only be placed on the Union market if a marketing authorisation for that medicinal product has been granted by the Union in accordance with this Regulation ('centralised marketing authorisation').	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
2. Any medicinal product not listed in Annex I, may be granted a centralised marketing authorisation in accordance with this Regulation, if the product meets at least one of the following requirements:	
(a) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of marketing authorisation in accordance with this Regulation is in the interest of patients' health at Union level, including as regards antimicrobial resistance and medicinal products for public health emergencies;	
(b) it is a medicinal product intended solely for paediatric use.	
	NL (Suggested adaptations to the text): **(c) the medicinal product concerns an abridged application for which the reference medicinal product has been authorised by the Union.**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(d) the medicinal product concerns a consent application for which the medicinal product with regard to which consent is given has been authorised by the Union. **(e) the application for marketing authorisation is submitted in accordance with Article 6 of [revised Directive] for a medicinal product containing an active substance which is or has been authorised by the Union** NL (Comments): For a detailed explanation, see the annex to our written proposals.
3. Homeopathic medicinal products shall not be granted a marketing authorisation in accordance with this Regulation.	NL (Suggested adaptations to the text): 3. Homeopathic **and herbal** medicinal products shall not be granted a marketing authorisation in accordance with this Regulation. NL (Comments): For a detailed explanation, see the annex to our written proposals. SE

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Suggested adaptations to the text): **Allergen medicinal products, traditional herbal medicinal products and ~~H~~h**omeopathic medicinal products shall not be granted a marketing authorisation in accordance with this Regulation SE (Comments): We support that allergen medicinal products, traditional herbal medicinal products and homeopathic medicinal products should be excluded from the centralised procedure. We propose that this is clarified here in article 3 point 3 instead of Annex I point 3. We propose that Annex I point 3 is updated accordingly, please see below. For herbal medicinal products with new active substance, the possibility for the centralised procedure should remain.
4. The Commission shall grant and supervise centralised marketing authorisations for medicinal products for human use in accordance with Chapter II.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
~~5. The Commission is empowered to adopt delegated acts in accordance with Article 175 to amend Annex I to adapt it to technical and scientific progress.~~	
	SE (Suggested adaptations to the text): **5. (new) Nothing in this Regulation shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate regarding narcotic and psychotropic substances.** SE (Comments): It is important that it remains possible for MSs to continue to impose national requirements regarding the regulation of narcotics. The draft directive states that such national rules are possible regarding wholesale trade and marketing. Such possibilities should also apply, for example, to the manufacture of narcotic drugs. Sweden has previously put this forward and has also submitted a proposal for wording. Corresponding wording is found in the Veterinary Medicinal Products Regulation (EU) 2019/6 Article 2.9

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
Article 180	
Transitional provisions	
(X) Marketing authorisations of human medicinal products authorised in accordance with Directive 2001/83/EC shall be deemed to have been issued in accordance with this [revised] Directive, irrespective of whether those products are covered by Annex I to [Revised Regulation (EC) No 726/2004.	SE (Comments): Where is this proposal intended to be included? It is currently placed in the regulation, but written as if it is placed in the directive.
Article 4	SI (Comments): SI supports the proposal from Germany to include Member State authorisation also for “hybrid” and “biohybrid” medicinal products. IE (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Article 4
*Member State authorisation of generics**, and biosimilars,** of centrally authorised medicinal products*	AT (Comments): AT: We would propose to include "hybrid" in the heading (and the paragraph) of Article 4 Draft Regulation. NL (Suggested adaptations to the text): *Member State authorisation of **abridged and consent consent based applications** ~~generics~~**, and biosimilars,** of centrally authorised medicinal products* NL (Comments): For a detailed explanation, see the annex to our written proposals. IE (Suggested adaptations to the text): Member State authorisation of generics, **hybrids**, ~~and~~ biosimilars **and bio-hybrids** of centrally authorised medicinal products IE

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): To reflect the proposed increase of the scope of decentralised procedures
~~A~~ ~~g~~**G**eneric ~~**and a biosmilar**~~ medicinal product**s**~~**, and biosimilars**~~ of a reference medicinal product**s** authorised by the Union may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:	AT (Suggested adaptations to the text): AT: ~~A~~ ~~g~~**G**eneric ~~**and a biosmilar**~~ medicinal product**s**~~**, hybrid medicinal products and biosimilars**~~ of a reference medicinal product**s** authorised by the Union may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions: AT (Comments): AT: **Very high priority** (requested by DE as well). **Applicants of generics and hybrids referencing to centrally authorised medicinal products should be able to choose freely between centralised or national procedures as is already possible under the current legislation for generics and hybrids.**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Even small changes like a pre-filled syringe vs a vial requires the applicant to submit a hybrid application. This should not force the applicant to submit the application to the Agency. NL (Suggested adaptations to the text): ~~A~~ ~~g~~**G**eneric, ~~**and a biosmilar**~~ **hybrid, biohybrid and biosimilar** medicinal products~~, and biosimilars~~ of ~~a~~ reference medicinal product**s** authorised by the Union **and consent applications for which the medicinal product with regard to which consent is given has been authorised the Union** may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions: NL (Comments): For a detailed explanation, see the annex to our written proposals. IE (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	Generic medicinal products, **hybrids**, ~~and~~ biosimilars **and bio-hybrids** of a reference medicinal products authorised by the Union may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions: IE (Comments): We support other MSs who have proposed the addition of Art 10(hybrid) and Art 12 (bio-hybrid) applications to the scope of this article. We see many circumstances in which it would be appropriate to allow applicants the flexibility to apply either for centralised or national MAs for such products. We do not support point (c) as drafted it as it would have the effect of excluding all Monoclonal antibodies (MABs), many of which are well established and understood, are not ATMPs and in our view, are suitable for national biosimilar applications.
(a) the application for marketing authorisation is submitted in accordance with Article 9 **or 11** of [revised Directive 2001/83/EC];	AT (Suggested adaptations to the text): AT:

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(a) the application for marketing authorisation is submitted in accordance with Article 9, **10 or 11** of [revised Directive 2001/83/EC]; AT (Comments): AT: high priority It should be possible for applicants of both generics and hybrids to CAP RefMPs to choose procedure freely. Not every company might have the infrastructure and the financial resources to file an application for a centralised authorisation. In fact less products will be authorised. This could cause more shortages. CZ (Suggested adaptations to the text): **the application for marketing authorisation is submitted in accordance with Article 9 – ~~11~~ 12 of [revised Directive 2001/83/EC];** CZ (Comments): CZ fully supports the proposed extension of the scope of Article 4 to biosimilar medicines and we support inclusion of hybrids and biohybrids

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	as well. We propose to add into letter a) of this Article the reference to Articles 9-12. In our opinion, DCP or MRP procedures can be used to authorise biohybrids and hybrid medicines, and we would like to point out that selection of the appropriate procedure depends on MAH as well. This comment corresponds to the expected huge administrative burden on CHMP which could be alleviated if the above-mentioned medicines were not authorised exclusively by the centralised procedure. Please see the changes in wording proposed. NL (Suggested adaptations to the text): (a) the application for marketing authorisation is submitted in accordance with Article**s 9, 10, ~~or~~ 11, 12 or 14** of [revised Directive 2001/83/EC]; NL (Comments): For a detailed explanation, see the annex to our written proposals. SE (Suggested adaptations to the text):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(a) the application for marketing authorisation is submitted in accordance with Article 9**, 10 or 11** of [revised Directive 2001/83/EC]; SE (Comments): In line with Concept Paper 7, it should remain possible also for hybrids to apply via the national procedures. IE (Suggested adaptations to the text): (a) the application for marketing authorisation is submitted in accordance with Article 9 ~~or 11~~ – **12** of [revised Directive 2001/83/EC];
(b) the summary of product characteristics and the package leaflet are in all relevant respects consistent with that of the medicinal product authorised by the Union~~.~~**;**	IE (Suggested adaptations to the text): (b) the summary of product characteristics and the package leaflet are in all relevant respects consistent with that of the medicinal product authorised by the Union.; …… Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the generic, **hybrid, biosimilar or bio-hybrid** medicinal product was marketed and where the applicant for the generic, **hybrid**, ~~or~~ biosimilar **or bio-hybrid** medicinal product has requested not to include this information in their marketing authorisation.
(c) the reference medicinal product is not an advanced therapy medicinal product in accordance with Annex I, points 1 or 2.	FI (Suggested adaptations to the text): **the reference medicinal product is not ~~an advanced therapy~~ medicinal product in accordance with Annex I, points 1 or 2.** FI (Comments): This makes it clear that Annex 1 points 1 and 2 are excluded (not only point 2/ advanced therapy medicinal product) NL (Suggested adaptations to the text): **(c) the ~~reference~~ medicinal product is not ~~an advanced therapy~~ a medicinal product in accordance with Annex I~~, points 1 or 2~~.**

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	NL (Comments): For a detailed explanation, see the annex to our written proposals. IE (Suggested adaptations to the text): **c) the reference medicinal product is not an advanc~~ed~~ed therapy medicinal product in accordance with Annex I, points ~~1 or~~ 2.**
Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the generic~~,~~ **or biosimilar** medicinal product has requested not to include this information in their marketing authorisation.	AT (Suggested adaptations to the text): AT: Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the generic, **hybrid or biosimilar** medicinal product was marketed and where the applicant for the generic,

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	hybrid **or biosimilar** medicinal product has requested not to include this information in their marketing authorisation. AT (Comments): AT: **Very high priority** (requested by DE as well). See comment above. NL (Suggested adaptations to the text): Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the ~~generic~~ medicinal product **authorised in accordance with Article 9, 10, 11, 12 or 14 of [revised Directive 2001/83/EC]** was marketed and where the applicant for ~~the generic~~**~~, or biosimilar~~ that** medicinal product has requested not to include this information in their marketing authorisation. NL

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	(Comments): For a detailed explanation, see the annex to our written proposals.
CHAPTER V	
PRE-AUTORISATION REGULATORY SUPPORT	
Article 61	
Scientific recommendation on regulatory status	
1. For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer ~~or,~~ a competent authority of the Member States **or the Commission on its own initiative** may submit a duly substantiated	SE (Suggested adaptations to the text): 1. For products under development ~~which may fall within the categories of medicinal products to be authorised by the Union listed in~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product'~~, including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council~~[8].	~~Annex I~~, a developer ~~or~~, a competent authority of the Member States **or the Commission on its own initiative** may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product'. SE (Comments): To encourage innovation, but also simplify the regulatory work for NCAs, there is a need for common recommendations on regulatory status. These recommendations should be open for all kinds of innovative medicinal products, not only for medicinal products aimed for the central procedure. The mandate should be open enough for no unnecessary discussions of what would be included (cf. VMP, Art 144(d) of Reg (EU) 2019/6). IE (Suggested adaptations to the text):

[8] ~~Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	1. For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, **or products submitted nationally where its classification, or otherwise as a medicinal product is a matter of Union public health,** a developer ~~or~~**,** a competent authority of the Member States **or the Commission on its own initiative** may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product', ~~including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council8~~ IE (Comments): While we welcome this new provision, we believe that its scope needs to be extended beyond products potentially falling within the mandatory scope of the centralised procedure, to also support Member States in addressing borderline issues giving rise to significant public health concerns at Union level.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
The Agency shall deliver its recommendation within 60 days of receiving such a request, which shall be extended by an additional 30 days where a consultation in accordance with paragraph 2 is required.	
2. When forming the recommendation referred to in paragraph 1, the Agency shall consult, ~~where~~ **as** appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. In **particular, in** the case of products which are based on substances of human origin, the Agency shall consult the Substances of Human Origin (SoHO) Coordination Board as established in Regulation (EU) No [*reference to be added after adoption cf. COM(2022)338 final*].	
The advisory or regulatory bodies consulted shall reply to the consultation within 30 days of receipt of the request.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
~~**Where as a result of such consultation it is identified that the product is not considered to be a medicinal product but may fall within the scope of another Union legislation, the Agency recommendation may advise the developer or the competent authority to engage with the relevant advisory or regulatory bodies.**~~	
The Agency shall **annex to its scientific recommendation the opinions received from the relevant advisory or regulatory bodies referred to in the first subparagraph and shall** publish summaries of the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.	
Article 62	
Decision on regulatory status	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
1. In the case of duly substantiated disagreement with the Agency's recommendation, in accordance with Article 61(2), a Member State may request the Commission to decide whether the product is a product referred to in Article 61(1).	
The Commission may initiate the procedure referred to in the first subparagraph on its own initiative.	
2. The Commission may ask the Agency for clarifications or refer the recommendation back to the Agency for further consideration where a Member State's substantiated request raises new questions of a scientific or technical nature or on its own initiative.	
3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure referred to in Article 173(2), taking into account the scientific recommendation of the Agency.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
ANNEX I	
MEDICINAL PRODUCTS TO BE AUTHORISED BY THE UNION	
1. Medicinal products developed by means of one of the following biotechnological processes:	
– recombinant nucleic acid technology;	
– controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells.	
2. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
3. Medicinal products for human use containing a~~n~~ **new** active substance which on 20 May 2004 was not authorised in the Union, excluding allergen **medicinal** products or herbal medicinal products, which shall in any case not be authorised by the Union.	AT (Suggested adaptations to the text): AT: 3. Medicinal products for human use containing a~~n~~ **new** active substance which **on** ~~20 May 2004~~ **the date of entry into force of this Regulation** was not authorised in the Union, excluding allergen **medicinal** products or herbal medicinal products, which shall in any case not be authorised by the Union. AT (Comments): AT: **The addition of "new" is fully supported by AT**. Without the addition of "new" nearly all abridged applications have to be authorised via the Agency (except those refering to really old reference products) this could worsen the shortage situation. Moreover, it is necessary to replace "20 May 2004" by "the date of entry into force of the Regulation" to clarify the meaning of the paragraph and to avoid confusion. Otherwise "new" can also be interpreted as to not

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	being authorised on 20 May of 2004. In this regard, we support the ES proposal. FI (Comments): It remains unclear why herbal medicinal products are completely excluded from the Union authorisation procedure. According to the current Regulation, herbal medicinal products follow the same rules as other medicinal products for human use if containing a new active substance or a certain indication. More precise instructions will be needed if proceeding this way. Chapter X does not cover new active substances of herbal medicinal products. NL (Suggested adaptations to the text): Medicinal products for human use containing a~~n~~ **~~new~~** **an** active substance ~~which on 20 May 2004 was~~ not **authorised or not previously** authorised in the Union **on the date of application of [revised Regulation]**~~, excluding allergen~~ **~~medicinal~~** ~~products or herbal medicinal products, which shall in any case not be authorised by the Union.~~

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	This provision does not apply to medicinal products for which an application is made in accordance with article 9, 10, 11, 12, 13, or 14 of [revised Directive]. NL (Comments): For a detailed explanation, see the annex to our written proposals. SE (Suggested adaptations to the text): 3. Medicinal products for human use containing a~~n~~ **new** active substance ~~which on 20 May 2004 was~~ not authorised in the Union~~,~~ ~~excluding allergen medicinal products or herbal medicinal products, which shall in any case not be authorised by the Union~~. SE (Comments): We support that only **new** active substances not authorised in the Union are listed here. We support that allergen medicinal products and traditional herbal medicinal products should be excluded from the centralised procedure but propose that this is clarified in article 3 point 3,

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	please see above. For herbal medicinal products with new active substances, the possibility for the centralised procedure should remain. IE (Suggested adaptations to the text): 3. Medicinal products for human use containing a new active substance which ~~on 20 May 2004~~ was not authorised in the Union **prior to the date of entry into application of this Regulation**, excluding allergen medicinal products or herbal medicinal products, which shall in any case not be authorised by the Union. IE (Comments): As per the previous comment on the newly proposed transitional provision in Art 180, a simpler solution could be to amend this date to be in line with the entry into application of this new Regulation
4. Medicinal products that are designated as orphan medicinal products pursuant to this Regulation.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
5. Medicinal products authorised in accordance with a paediatric use marketing authorisation.	NL (Suggested adaptations to the text): 5. Medicinal products **to be** authorised in accordance with a paediatric use marketing authorisation. NL (Comments): Editorial change
6. Priority antimicrobials as referred to in Article 40.	
REVISED DIRECTIVE	
Article 4	
Definitions	LV (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	At present, in Article 4 there are definitions for gene therapy medicinal products and somatic cell therapy medicinal products. We suggest including here also a definition of tissue engineered medicinal products. We strongly believe that it would be beneficial to have definitions for all three categories of ATMP together in one legislative act.
(1) 'medicinal product' means ~~any substance or combination of substances that fulfils at least one of the following conditions~~:	
(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; or	AT (Suggested adaptations to the text): AT: any substance or combination of substances that is presented as having properties for treating or preventing disease **or other pathological conditions** in human beings; or AT (Comments): AT: Not every pathological symptom has an underlying disease, therefore it is recommended to insert "or other pathological conditions".

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(b) any substance or combination of substances that may be used in or administered to human beings with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	
(2) 'substance' means any matter irrespective of origin, which may be:	LV (Comments): We suggest adding "plasma derived products" as this is more in line with the definition/concept of an 'active substance' of a medicinal product and there should be some change to what is SoHO or simply animal derived material (without significant modification or API isolation):
(a) human, e.g. tissues and cells, human blood, human secretions and human blood products;	CZ (Suggested adaptations to the text): human, e.g. tissues and cells, human blood, human secretions and human blood products; **breast milk and faecal microbiota** CZ (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	In the context of SoHO Regulation, CZ proposes to wide definition by breast milk and faecal microbiota. Please see the changes proposed. LV (Suggested adaptations to the text): human, e.g. tissues and cells, human blood, human secretions and human blood **plasma derived** products;
(b) animal, e.g. whole animals, animal organs and parts thereof, animal tissues and cells, animal secretions, toxins, extracts, animal blood and animal blood products;	LV (Suggested adaptations to the text): animal, e.g. whole animals, animal organs and parts thereof, animal tissues and cells, animal secretions, toxins, extracts, animal blood and animal blood **derived** products;
(c) vegetal, e.g. plants, including algae, parts of plants, plant secretions and exudates, extracts;	
(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;	SI (Suggested adaptations to the text): (d) chemical, e.g. elements, naturally occurring chemical materials**, sustainable-by-design chemicals, including sustainable bio-based chemicals,** and chemical products obtained by chemical change or synthesis;

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	SI (Comments): SI would like to propose to specify the wording definition of chemical substance.
(e) micro-organisms, e.g. bacteria, viruses and protozoa;	
(f) fungi, including micro-fungi (yeast);	
(3) 'active substance' means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;	
(4) 'starting material' means any material from which an active substance is manufactured or extracted;	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(4a) 'intermediate product': means any product that has been prepared by the manufacturer with the intention of further processing to obtain the active substance ~~and~~/or finished product.	FI (Comments): supported
(5) 'excipient' means any ingredient of a medicinal product other than the active substance;	
(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action ancillary to that of the active substance but does not have a therapeutic contribution on its own;	NL (Comments): The Netherlands is of the opinion that a definition is not needed, since the current practice already allows requesting extra data on these excipients when needed. Including a definition in legislation poses a risk that all functional excipients should oblige to stringent GMP-rules. In our opinion, addressing these aspects at guidance level rather than in the legislation would make the legislation future-proof and allow for a wider consultation with all relevant stakeholders.

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(7) 'advanced therapy medicinal product' means advanced therapy medicinal product as defined in Article 2(1), point (a), of Regulation (EC) No 1394/2007;	
(8) 'allergen **medicinal** product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the immunological response to an allergen;	
(27) 'immunological medicinal product' means:	
(a) any vaccine**, toxin,** ~~or~~ allergen **medicinal** product, or **any other medicinal product eliciting an active and specific immune response;**	AT (Suggested adaptations to the text): AT: a) any vaccine, toxin **based**~~,~~ or allergen medicinal product, or any other medicinal product eliciting an active and specific immune response; AT (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	AT: Human breast milk and microbiota may also have a specific immune response. We think that this should not be an immunological medicinal product in any case. A clear borderline is needed. AT: We consider the definition in point (a) too broad with regard to toxins. According to the wording, any toxin eliciting an active immune response would be classified as an "immunological medicinal product", even if it does not have any therapeutic purpose (and may not even fulfil the general criteria of medicinal product). SE (Suggested adaptations to the text): (a) any vaccine, ~~toxin,~~ ~~or~~ allergen **medicinal** product, or **any other medicinal product eliciting an active and specific immune response;** SE (Comments): Not all toxins are immunological medicinal products (e.g. botulinum toxin). It is not necessary to list "toxins" specifically as all relevant toxins either are vaccines or are "other medicinal product eliciting an active and specific immune response".

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	SK (Comments): SK welcomes the proposed wording, as the definitions are clearer and better reflect actual practice.
(b) any medicinal product consisting of ~~toxins or~~ serums**, polyclonal or monoclonal antibodies or other immunoglobulins** used to produce passive immunity or to diagnose the state of immunity;	SE (Suggested adaptations to the text): (b) any medicinal product consisting of toxins, ~~or~~ serums**, polyclonal or monoclonal antibodies or other immunoglobulins and that is** used to produce passive immunity or to diagnose the state of immunity; SE (Comments): Some toxins mediate their effect by producing passive immunity and therefore need to be included here. We therefore not support the removal of toxins. To avoid problems to interpret the last part of the sentence, a conjunction is needed to specify that "used to produce passive immunity …" doesn't refer to "other immunoglobulins" but to all listed substances. SK (Comments):

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
	SK welcomes the proposed wording, as the definitions are clearer and better reflect actual practice.
(28) 'vaccine' means any medicinal product that is intended to elicit an **active and specific** immune response for prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;	SK (Comments): SK welcomes the proposed wording, as the definitions are clearer and better reflect actual practice.
(29) 'gene therapy medicinal product' means a medicinal product, except vaccines against infectious diseases, that contains or consists of:	
(a) a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that contain or consists of cells **or tissues** subjected to such modification; or	
(b) a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells **or tissues** subjected to these modifications;	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(30) 'somatic cell therapy medicinal product' means a biological medicinal product that has the following characteristics:	
(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	
(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	
For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	

From: AT, CZ, EE, FI, NL, SE, SI, IE, LV, SK

Presidency compromise	Suggested adaptations to the text and Comments
(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing, consisting of or deriving from a substance of human origin (SoHO), as defined in Regulation [SoHO Regulation], other than tissues and cells, that is of standardised consistency and is prepared by:	
(a) a method involving an industrial process which includes pooling of donations; or	LV (Comments): In our view, clear criteria should be established to determine how many donations fall under the definition of an "industrial process." These criteria could be specified either in the preamble or the main text, but they are needed to ensure clarity and consistency.
(b) a process that extracts an active ingredient from the substance of human origin or transforms the substance of human origin by changing its inherent properties;	