European Parliament
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Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

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AMENDMENTS
2802 - 2985

Draft report
Vytenis Povilas Andriukaitis, Wouter Beke
(PE789.987v01-00)

Establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

Proposal for a regulation
(COM(2025)1022 – 2025/0406(COD))

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Amendment 2802
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 25 – point b a (new)
Regulation (EU) 536/2014
Article 28 – Paragraph 3a(new)

Text proposed by the Commission	*Amendment*
	(ba) Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections."

Or. en

Amendment 2803
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 25 – point b a (new)
Regulation (EU) 536/2014
Article 28 – Paragraph 3a(new)

Text proposed by the Commission	*Amendment*
	(ba) Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and

communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections.

Or. en

Amendment 2804
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 25 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the following subparagraph is added:
	4. In applying protective measures for vulnerable populations, competent authorities and ethics committees shall avoid unjustified exclusion of women of child-bearing potential. Exclusion of such women shall be justified on the basis of specific risks that cannot be adequately mitigated through measures such as contraception, pregnancy testing, pregnancy registries or enhanced monitoring.

Or. en

Amendment 2805
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 25 a (new)

Text proposed by the Commission	*Amendment*

(25a) (c) the following subparagraph is added:

4. In applying protective measures for vulnerable populations, competent authorities and ethics committees shall avoid unjustified exclusion of women of child-bearing potential. Exclusion of such women shall be justified on the basis of specific risks that cannot be adequately mitigated through measures such as contraception, pregnancy testing, pregnancy registries or enhanced monitoring.

Or. en

Amendment 2806
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 26 – introductory part

Text proposed by the Commission	*Amendment*
(26) in Article 29(1), the following ***subparagraph is*** added:	(26) in Article 29(1), the following ***subparagraphs are*** added:

Or. en

Amendment 2807
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 1

Text proposed by the Commission	*Amendment*
The communication in the context of an interview between the investigator and the subject or the investigator and the subject and its legally designated representative, as applicable, may be done remotely through use of electronic means. The record of the informed consent procedure may have an	The communication in the context of an interview between the investigator and the subject or the investigator and the subject and its legally designated representative, as applicable, may be done remotely through use of electronic means. The record of the informed consent procedure may have an

electronic form and shall be signed relying on electronic identification means complying with Regulation (EU) No 910/2014 of the European Parliament and of the Council* or the equivalent standards.	electronic form***, which shall be regulary updated, where nessessary, to reflect the continuous and evolving nature of informed consent*** and shall be signed relying on electronic identification means complying with Regulation (EU) No 910/2014 of the European Parliament and of the Council* or the equivalent standards.

Or. en

Amendment 2808
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 2 – point (a) – point (i)

Text proposed by the Commission	*Amendment*
	in Article 29(2)(a)(i) is replaced by the following: the nature, objectives, anticipated benefits, implications, risks and inconveniences of the clinical trial;

Or. en

Amendment 2809
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 2 – point (a) – point (ii)

Text proposed by the Commission	*Amendment*
	in Article 29(2)(a)(ii) is replaced by the following:
	the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to

provide any justification; Where informed consent has been given via electronic systems, it shall be ensured that subjects have the right to withdraw consent at any time through an easy-to-use and user-friendly electronic system.

Or. en

Amendment 2810
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 2 – point (a) – point (iii)

Text proposed by the Commission	*Amendment*
	in Article 29(2)(a)(iii) is replaced by the following:
	the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial and arrangements for reimbursements of expenses and compensation in regard to occurring costs for the subject;

Or. en

Amendment 2811
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 2 – point (a) – point (iv)

Text proposed by the Commission	*Amendment*
	in Article 29(2)(a)(iv) is replaced by the following:
	the possible treatment alternatives, including the follow-up measures if the

participation of the subject in the clinical trial is discontinued either by the subject itself or by the discontinuation of the trial by the clinical trials sponsor;

Or. en

Amendment 2812
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 2 – point (a) – point (iv)

Text proposed by the Commission	*Amendment*
	in Article 29(2)(a)(v) is inserted:
	The post trial provisions, including where appropriate arrangements for continued access to arrangements to an intervention as identified as beneficial and reasonably safe during the clinical trial;

Or. en

Amendment 2813
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 8a(new)

Text proposed by the Commission	*Amendment*
	in Article 29 paragraph 8a is inserted:
	The Commission in cooperation witht the European Medicines Agency and after consultation with relevant stakeholders including healthcare and patient organisations shall develop guidelines on informed consent to ensure a harmonised implementation of of this Regulation.

Or. en

Amendment 2814
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 26
Regulation (EU) 536/2014
Article 29 – Paragraph 3

Text proposed by the Commission	*Amendment*
	The information referred to in paragraph 2 shall be prepared in writing or other appropriate electronic means (e.g.visual or audiovisual means) and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.

Or. en

Amendment 2815
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 26 a (new)
Regulation (EU) 536/2014
Article 29 – Paragraph 1 – (new) second subparagraph

Text proposed by the Commission	*Amendment*
	(26a) Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. In all Member States, the process of obtaining informed consent shall be documented by means of a patient information and informed consent form. That form shall follow a harmonised structure applicable across all Member

States and shall be drawn up in accordance with guidance adopted at Union level.

Or. en

Amendment 2816
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 58 – paragraph 1 – point 26 a (new)
Regulation (EU) No 536/2014
Article 29 – paragraph 8a(new)

Text proposed by the Commission	*Amendment*
	(26a) In Article 29, the following paragraph is added:
	(8a)new. The Commission shall, in cooperation with Member States, the Agency and patient organisations, develop guidance on informed consent in clinical trials, with a view to supporting harmonised implementation across the Union and ensuring that information provided to participants is clear, concise, understandable, patient-centred and covers, where relevant, participants' rights, the possibility to withdraw consent, the use and secondary use of personal data and biological materials, reimbursement of expenses and post-trial arrangements.

Or. en

Amendment 2817
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 26 a (new)

Text proposed by the Commission	*Amendment*

	(26a) Information on any known or reasonably foreseeable sex-specific or pregnancy-related risks associated with participation in the clinical trial, and, where relevant, information on whether women are under-represented in existing evidence for the medicinal product.

Or. en

Amendment 2818
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 28

Text proposed by the Commission	*Amendment*
(28) in Article 31(1), point (e) is deleted;	***deleted***

Or. en

Amendment 2819
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 29

Text proposed by the Commission	*Amendment*
(29) in Article 32 (1), point (e) is deleted;	***deleted***

Or. en

Amendment 2820
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 30
Regulation EU No 536/2014
art 33 – Paragraph 2

Text proposed by the Commission	*Amendment*
Women who become pregnant or begin breastfeeding while participating in a clinical trial shall not be automatically excluded from participation in the clinical trial.	***The responsible inclusion of pregnant or lactating women in clinical trials shall be systematically considered.*** Women who become pregnant or begin breastfeeding while participating in a clinical trial shall not be automatically excluded from participation in the clinical trial. ***Any exclusion or discontinuation of participation shall be duly justified on scientific or safety grounds.*** ***The protection of persons in situations of particular vulnerability shall be ensured in accordance with the principles set out in the Declaration of Helsinki. In the assessment and approval of clinical trials, particular attention shall be paid to persons who may be less able to protect their own interests. Under no circumstances shall the acceleration of clinical trial approval procedures compromise the safety, dignity, rights, or well-being of such persons.***

Or. en

Amendment 2821
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 30 a (new)
Regulation (EU) 536/2014
Article 33 – (new) third subparagraph

Text proposed by the Commission	*Amendment*
	(30a) 4. Where pregnant or breastfeeding women are included in a clinical trial, the protocol shall provide for appropriate follow-up of maternal and fetal or infant outcomes, including, where feasible, the establishment or contribution to pregnancy and breastfeeding registries. The sponsor shall perform and document a specific risk–benefit assessment for pregnant and breastfeeding women,

taking into account the burden of disease in this population and the lack of alternative evidence.

Or. en

Amendment 2822
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) In Article 37, the following paragraph is inserted:
	The Union database referred to in Article 81 shall be designed so that sex-disaggregated data fields for recruitment, efficacy outcomes and adverse events can be recorded, extracted and made publicly accessible in accordance with the Annexes.

Or. en

Amendment 2823
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) Article 35, paragraph 1, point f is deleted

Or. en

Amendment 2824
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 30 b (new)

Regulation (EU) 536/2014
Article 37 – Paragraph 8a(new)

Text proposed by the Commission	*Amendment*
	(30b) 30(a) In Article 37, the following paragraph is inserted: The Union database referred to in Article 81 shall be designed so that sex- and gender-disaggregated data fields for recruitment, efficacy outcomes and adverse events can be recorded, extracted and made publicly accessible in accordance with the Annexes.

Or. en

Amendment 2825
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 31
Regulation (EU) No 536/2014
Article 41 – Paragraph 5

Text proposed by the Commission	*Amendment*
5. Reporting requirements of adverse events and serious adverse events for minimal-intervention and low-intervention clinical trials shall be simplified by applying a risk-based approach***. Any such adaptation should be clearly stated and justified in the protocol by the sponsor.:***	5. Reporting requirements of adverse events and serious adverse events for minimal-intervention and low-intervention clinical trials shall be simplified by applying a risk-based approach***, provided that reporting of serious adverse events, suspected unexpected serious adverse reactions and deaths is not weakened and remains timely and complete, and that non-confidential aggregate safety information is made publicly accessible***.

Or. en

Amendment 2826
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 31

Regulation (EU) No 536/2014
Article 41 – Paragraph 5a(new)

Text proposed by the Commission	*Amendment*
	5a. Reporting requirements for diagnostic minimal-intervention and low-intervention clinical trials shall be limited to unexpected adverse events and serious adverse events

Or. en

Amendment 2827
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 31 a (new)

Text proposed by the Commission	*Amendment*
	(31a) in Article 37, paragraph 7, second subparagraph is replaced by the following:
	‘
	In the case of early termination of the clinical trial, the sponsor shall notify each Member State concerned through the EU portal of the reasons for such action and, where subjects have received an investigational medicinal product, the follow-up measures and post-trial care to be ensured for those subjects, proportionate to the risks of the intervention.
	’

Or. en

Amendment 2828
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 58 – paragraph 1 – point 31 a (new)
Reg 536/2014

Art 38 – Paragraph 1 – new third subparagraph

Text proposed by the Commission	*Amendment*
	(31a) In Article 38, the following sub-paragraph is added:
	(1) That notification shall indicate whether sex-specific safety concerns contributed to the decision and shall, where available, provide sex- and gender-disaggregated data relevant to those concerns.

Or. en

Amendment 2829
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard, Martin Hojsík

Proposal for a regulation
Article 58 – paragraph 1 – point 31 a (new)

Text proposed by the Commission	*Amendment*
	(31a) In Article 38, the following sub-paragraph is added:
	(1) That notification shall indicate whether sex-specific safety concerns contributed to the decision and shall, where available, provide sex- and gender-disaggregated data relevant to those concerns.

Or. en

Amendment 2830
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 31 b (new)

Text proposed by the Commission	*Amendment*
	(31b) In Article 43, the following paragraph is added:
	5. Annual safety reports shall include sex-

and gender-disaggregated summaries of serious and non-serious adverse events and shall highlight any emerging differences in incidence, severity or outcome between women and men, including women of reproductive age and pregnant or breastfeeding women where applicable.

Or. en

Amendment 2831
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 31 b (new)

Text proposed by the Commission	*Amendment*
	(31b) In Article 42, the following paragraph is added:
	(2a) When reporting suspected unexpected serious adverse reactions in accordance with this Article, sponsors shall ensure that the sex of the subject is recorded and shall facilitate analysis of such reactions by sex by competent authorities and ethics committees.

Or. en

Amendment 2832
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard, Martin Hojsík

Proposal for a regulation
Article 58 – paragraph 1 – point 31 c (new)

Text proposed by the Commission	*Amendment*
	(31c) In Article 43, the following paragraph is added:
	5. Annual safety reports shall include sex- and gender-disaggregated summaries of serious and non-serious adverse events and shall highlight any emerging

differences in incidence, severity or outcome between women and men, including women of reproductive age and pregnant or breastfeeding women where applicable.

Or. en

Amendment 2833
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 58 – paragraph 1 – point 33 – introductory part

Text proposed by the Commission	*Amendment*
(33) the following Article 50a is inserted:	(33) the following Article 50a is inserted:
	When justified in the protocol, the delivery of investigational medicinal products and auxiliary medicinal products to clinical trial subjects may be ensured at a distance under the supervision of the investigator, provided that good distribution practice is fully respected and that the quality, integrity and appropriate storage conditions of the medicinal products are maintained until their supply to the subject. In the case of a minimal-intervention or low-intervention clinical trial, the distribution of investigational medicinal products may be ensured in a Member State where the clinical trial has been authorised, under the responsibility of the investigator, or by persons authorised to supply medicinal products to the subject, in accordance with national law. This paragraph shall be without prejudice to Member States' competence for the organisation and delivery of health services and medical care and to national rules governing pharmacy practice, dispensing, supply, administration and the role of healthcare professionals and persons authorised to supply medicinal products The protocol and investigator's brochure shall describe the arrangements

for direct delivery to subjects or through dispensing pharmacies or persons authorised to supply medicinal products to subjects, including the roles and responsibilities of all parties involved and procedures for secure handling, transport, appropriate storage, temperature control where relevant, traceability, delivery, supply, return and destruction. They shall also describe how the subject will receive appropriate advice and instructions from the investigator, pharmacist or another qualified healthcare professional on the use, administration, storage, adherence, reporting of adverse events and return of the medicinal products. The direct delivery to subjects shall comply with the guidelines referred to in paragraph 1 of Article 63a and in such a way as to ensure that any inefficacy, adverse event or other clinical outcome can be assessed in relation to the medicinal product under investigation and is not caused or confounded by inappropriate transport, storage, handling or delivery before supply to the subject

Or. en

Justification

Clinical trial results depend not only on the properties of the medicinal product under investigation, but also on whether the product has been properly stored, transported, delivered and used. If investigational or auxiliary medicinal products are exposed to inappropriate storage or transport conditions before delivery to the subject, this may affect their quality, efficacy or safety. In such cases, reported inefficacy, adverse events or other outcomes may be wrongly attributed to the product, when they may in fact be linked to improper delivery, storage or handling.For this reason, good distribution practice should be fully respected for all delivery models under Article 50a. The protocol should clearly describe the delivery chain, including secure handling, transport, storage conditions, temperature control where relevant, traceability, return and destruction. This is essential to protect subjects and to ensure the reliability, validity and interpretability of trial results.Pharmacies are healthcare settings with established responsibilities for the proper storage, dispensing and supply of medicines. Pharmacists can also provide subjects with advice on the appropriate use of the medicine, including administration, storage, adherence and return. This advice supports correct use by the subject and reduces the risk that trial outcomes are affected by avoidable misuse or improper handling after delivery. The amendment preserves the responsibility of the sponsor and investigator while ensuring that decentralised delivery models do not compromise medicine quality, patient safety or the scientific validity of clinical trials.

Amendment 2834
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) 536/2014
Article 50a – first subparagraph

Text proposed by the Commission	*Amendment*
When justified in the protocol, the delivery of investigational medicinal products and auxiliary medicinal products to the clinical trials subjects may be ensured at a distance under the supervision of the investigator.	When justified in the protocol, the delivery of investigational medicinal products and auxiliary medicinal products to the clinical trials subjects may be ensured at a distance under the supervision of the investigator***, provided that good distribution practice is fully respected and that the quality, integrity and appropriate storage conditions of the medicinal products are maintained until their supply to the subject***.

Or. en

Amendment 2835
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) 536/2014
Article 50a – first subparagraph

Text proposed by the Commission	*Amendment*
When justified in the protocol, the delivery of investigational medicinal products and auxiliary medicinal products to the clinical trials subjects may be ensured at a distance under the supervision of the investigator.	When justified in the protocol, the delivery of investigational medicinal products and auxiliary medicinal products to the clinical trials subjects may be ensured at a distance under the supervision of the investigator***, whilst fully respecting good distribution practice and maintaining the quality, integrity and appropriate storage conditions of the medicinal products until their supply to the subject***.

Or. en

Amendment 2836
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) No 536/2014
Article 50a – second subparagraph

Text proposed by the Commission	*Amendment*
In case of a minimal-intervention and a low-intervention clinical trial, the distribution of the investigational medicinal products can be ensured in a Member State where the clinical trial has been authorised, under the responsibility of the investigator, through the dispensing pharmacies or by persons authorised to supply medicinal products to ***thesubject***.	In case of a minimal-intervention and a low-intervention clinical trial, the distribution of the investigational medicinal products can be ensured in a Member State where the clinical trial has been authorised, under the responsibility of the investigator, through the dispensing pharmacies or by persons authorised to supply medicinal products to ***the subject, in accordance with national law***. ***This paragraph shall be without prejudice to Member States' competence for the organisation and delivery of health services and medical care and to national rules governing pharmacy practice, dispensing, supply, administration and the role of healthcare professionals and persons authorised to supply medicinal products.***

Or. en

Amendment 2837
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) No 536/2014
Article 50a – third subparagraph

Text proposed by the Commission	*Amendment*
The protocol and investigator’s brochure shall describe the arrangements for direct delivery to subjects or through dispensing pharmacies or persons authorised to supply	The protocol and investigator's brochure shall describe the arrangements for direct delivery to subjects or through dispensing pharmacies or persons authorised to supply

to the patients, including the roles and responsibilities of all parties involved and procedures for secure handling, storage.	***medicinal products to subjects***, including the roles and responsibilities of all parties involved and procedures for secure handling, ***transport, appropriate*** storage***, temperature control where relevant, traceability, delivery, supply, return and destruction***. ***They shall also describe how the subject will receive appropriate advice and instructions from the investigator, pharmacist or another qualified healthcare professional on the use, administration, storage, adherence, reporting of adverse events and return of the medicinal products.***

Or. en

Amendment 2838
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) No 536/2014
Article 50a – third subparagraph

Text proposed by the Commission	*Amendment*
The protocol and investigator's brochure shall describe the arrangements for direct delivery to subjects or through dispensing pharmacies or persons authorised to supply ***to the patients***, including the roles and responsibilities of all parties involved and procedures for secure handling, storage.	The protocol and investigator's brochure shall describe the arrangements for direct delivery to subjects or through dispensing pharmacies or persons authorised to supply ***medicinal products to subjects***, including the roles and responsibilities of all parties involved and procedures for secure handling, ***transport, appropriate*** storage***, temperature control where relevant, traceability, delivery, supply, return and destruction***. ***They shall also describe how the subject will receive appropriate advice and instructions from the investigator, pharmacist or another qualified healthcare professional on the use, administration, storage, adherence, reporting of adverse events and return of the medicinal products.***

Or. en

Amendment 2839
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) No 536/2014
Article 50a – fourth subparagraph

Text proposed by the Commission	*Amendment*
The direct delivery to subjects shall comply with the guidelines referred to in paragraph 1 of Article 63a.	The direct delivery to subjects shall comply with the guidelines referred to in paragraph 1 of Article 63a. ***The guideline shall provide guidance to ensure that any inefficacy, adverse event or other clinical outcome can be assessed in relation to the medicinal product under investigation and is not caused by inappropriate transport, storage, handling or delivery prior to supply to the subject.***

Or. en

Amendment 2840
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 33
Regulation (EU) No 536/2014
Article 50a – fourth subparagraph

Text proposed by the Commission	*Amendment*
The direct delivery to subjects shall comply with the guidelines referred to in paragraph 1 of Article 63a.	The direct delivery to subjects shall comply with the guidelines referred to in paragraph 1 of Article 63a ***and in such a way as to ensure that any inefficacy, adverse event or other clinical outcome can be assessed in relation to the medicinal product under investigation and is not caused or confounded by inappropriate transport, storage, handling or delivery before supply to the subject***.

Or. en

Amendment 2841
Oliver Schenk, Andrea Wechsler

Proposal for a regulation
Article 58 – paragraph 1 – point 37 – point a a (new)
Regulation (EU) No 536/2014 of the European Parliament and of the Council
Article 61 – paragraph 5 (b)

Present text	*Amendment*
	(a a) Article 61 – paragraph 5 (b) is replaced by the following:
(b) preparation of radiopharmaceuticals used as diagnostic investigational medicinal products where this process is carried out in hospitals, health centres or clinics, by pharmacists or other persons legally authorised in the Member State concerned to carry out such process, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres ***or*** clinics taking part in the same clinical trial in the same Member State;	"preparation of radiopharmaceuticals used as diagnostic investigational medicinal products where this process is carried out in hospitals, health centres or clinics***, or in publicly funded, non-commercial research organisations operating on a risk-based approach under a pharmaceutical quality management system***, by pharmacists or other persons legally authorised in the Member State concerned to carry out such process, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres***,*** clinics ***or such publicly funded, non-commercial research organisations,*** taking part in the same clinical trial in the same Member State;"

Or. en

Justification

Diagnostic investigational radiopharmaceuticals are frequently prepared in highly specialised academic or publicly funded non-commercial research settings which may operate in close cooperation with hospitals, health centres or clinics, but may not themselves fall within those categories. Excluding such organisations from the exemption would create unnecessary regulatory uncertainty and administrative burden for non-commercial clinical research, without providing additional benefits.

Amendment 2842
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation

Article 58 – paragraph 1 – point 44 – point a
Regulation (EU) 536/2014
Article 81 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.***;***	2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall***, where appropriate, facilitate interoperability and data exchange with other Union regulatory databases and systems managed by the Agency for the purposes of regulatory cooperation, lifecycle oversight and the efficient use of data. It shall*** also enable communication between sponsors and Member States concerned and ***the*** reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.

Or. en

Amendment 2843
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 44 – point a
Regulation 536/2014
Article 81 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.;	2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials***. It shall, where appropriate, ensure interoperability and data exchange with other Union regulatory databases and systems managed by the Agency and regulatory authorities for the purposes of regulatory cooperation, lifecycle oversight and the efficient use of data***. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.;

Or. en

Amendment 2844
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 44 – point a
Regulation (EU) 536/2014
Article 81 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU database shall be established to enable cooperation between	2. The EU database shall be established to enable cooperation between

the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.***;***	the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall***, where appropriate, facilitate interoperability and data exchange with other Union regulatory databases and systems managed by the Agency for the purposes of regulatory cooperation, lifecycle oversight and the efficient use of data. It shall*** also enable communication between sponsors and Member States concerned and ***the*** reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.

Or. en

Amendment 2845
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 58 – paragraph 1 – point 44 – point a
Regulation (EU) 536/2014
Article 81 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific	2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific

clinical trials. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be ***in an easily searchable format***, all related data shall be grouped ***together by way of*** the EU trial number***, and hyperlinks*** shall be provided to link ***together*** related data and documents ***held on the EU*** database and other databases managed by the Agency.;

clinical trials. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be ***findable, accessible, interoperable, and reusable (FAIR) in accordance with Regulation (EU) No. 2025/327. In particular***, ***they shall be accessible in suitable formats and adhere to structured input templates;*** All related data shall be grouped ***using*** the EU trial number***; Persistent identifiers*** shall be provided to link related data and documents ***recorded in the Union*** database and other databases managed by the Agency. ;

Or. en

Amendment 2846
Jessica Polfjärd

Proposal for a regulation
Article 58 – paragraph 1 – point 44 – point a
Regulation (EU) No 536/2014
Article 81 – paragraph 2

Text proposed by the Commission	*Amendment*
	2a. By [OP, please insert date: 30 months after entry into force of this Regulation] at the latest, the Agency shall, in consultation with affected stakeholders, conduct a review of the database, with particular emphasis on streamlining its core functionality and increasing ease-of-use, and based on the conclusions of that review, the Agency shall make adjustments to the database as deemed

necessary;

Or. en

Amendment 2847
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation (EU) No 536/2014
Art 83a – Paragraph 2a(new)

Text proposed by the Commission	*Amendment*
	(2a)new. Member States shall ensure that ethics committees are subject to robust safeguards preventing conflicts of interest;

Or. en

Amendment 2848
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 45
regulation EU No 536/2014
art 83 – Paragraph 2 – point (b)

Text proposed by the Commission	*Amendment*
(b) have, or have access to, a sufficient number of suitably qualified and experienced personnel, human and financial resources, operational capacity, and expertise, including technical expertise, for the effective and efficient performance of their tasks they have been made responsible for pursuant to this Regulation**.**;	(b) have, or have access to, a sufficient number of suitably qualified and experienced personnel, human and financial resources, operational capacity, and expertise, including technical expertise, for the effective and efficient performance of their tasks they have been made responsible for pursuant to this Regulation***, including the additional tasks and accelerated timelines introduced by this Regulation***;

Or. en

Amendment 2849
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation (EU) No 536/2014
‘Article 83 Paragraph 2 – point (ba)new

Text proposed by the Commission	*Amendment*
	(ba) actively engage with and implement the harmonised guidance, recommendations, and common approaches developed and endorsed by the Clinical Trials Coordination and Advisory Group (CTAG) pursuant to Article 85, particularly concerning the ethical assessment of clinical trials and the interpretation of ethical aspects covered by Part II of the application dossier, to foster greater consistency across the Union and expedite access to treatments

Or. en

Amendment 2850
Kateřina Konečná

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation (EU) No 536/2014
Article 83 – Paragraph 2 – point (ba)new

Text proposed by the Commission	*Amendment*
	(ba) are funded on a stable, multiannual basis proportionate to the volume and complexity of the applications they are required to assess, including, in particular, applications relating to advanced therapy medicinal products and to clinical trials enrolling vulnerable populations within the meaning of Regulation (EU) No 536/2014;

Or. en

Amendment 2851
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation (EU) No 536/2014
Article 83 – Paragraph 2 – point (ba)new

Text proposed by the Commission	*Amendment*
	(ba) are funded on a stable, multiannual basis proportionate to the volume and complexity of the applications they are required to assess, including, in particular, applications relating to advanced therapy medicinal products and to clinical trials enrolling vulnerable populations within the meaning of Regulation (EU) No 536/2014;

Or. en

Amendment 2852
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation (EU) 536/2014
Article 83 – Paragraph 2 – point (bb)new

Text proposed by the Commission	*Amendment*
	(bb) retain, irrespective of the procedural timelines laid down in or amended by this Regulation, full authority to apply additional ethical safeguards required by national law or warranted by the specific characteristics of the trial, in particular where the trial enrols children, persons with cognitive impairments, or persons with life-threatening or chronic conditions. By [two years after the date of application] and every [two years] thereafter, each Member State shall

report to the Commission on the resources allocated to its competent authorities and ethics committees for the performance of tasks under this Regulation, including average and median assessment times, application volumes and staffing levels. The Commission shall publish a synthesis of those reports and shall, where appropriate, formulate recommendations to address persistent capacity gaps.

Or. en

Amendment 2853
Kateřina Konečná

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation 536/2014
Article 83 – Paragraph 2 – point (bb)new

Text proposed by the Commission	*Amendment*
	(bb) retain, irrespective of the procedural timelines laid down in or amended by this Regulation, full authority to apply additional ethical safeguards required by national law or warranted by the specific characteristics of the trial, in particular where the trial enrols children, persons with cognitive impairments, or persons with life-threatening or chronic conditions.

Or. en

Amendment 2854
Kateřina Konečná

Proposal for a regulation
Article 58 – paragraph 1 – point 45
Regulation (EU) No 536/2014
Article 83 – Paragraph 2a(new)

Text proposed by the Commission	*Amendment*

2a. By [two years after the date of application] and every [two years] thereafter, each Member State shall report to the Commission on the resources allocated to its competent authorities and ethics committees for the performance of tasks under this Regulation, including average and median assessment times, application volumes and staffing levels. The Commission shall publish a synthesis of those reports and shall, where appropriate, formulate recommendations to address persistent capacity gaps.

Or. en

Amendment 2855
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 46
Regulation (EU) No 536/2014
'Article 83a – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and effectiveness of the regulatory activities or inspections performed on their territory.	1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and effectiveness of the regulatory activities or inspections performed on their territory. ***This coordination shall also actively contribute to and align with the harmonisation efforts and strategic steering provided by the Clinical Trials Coordination and Advisory Group (CTAG) under Article 85, especially regarding the ethical review process and the consistent application of ethical principles across Member States, thereby mitigating delays in patient access***

to innovative therapies.

Or. en

Amendment 2856
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 46
Regulation (EU) No 536/2014
‘Article 83a – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and effectiveness of the regulatory activities or inspections performed on their territory.	1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and effectiveness of the regulatory activities or inspections performed on their territory. ***The competent authority and etchics committee shall have equal standing in the exercise of their respective competenves.. Neither shall have the authority to influence, override, disregard or replace the decision of the other.***

Or. en

Amendment 2857
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 46
Regulation EU N0 536/2014
art 83a – Paragraph 2

Text proposed by the Commission	*Amendment*

2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other for the effective implementation of the regulatory activities and inspections provided for in this Regulation**.**;	2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other***, and with the ethics committees,*** for the effective implementation of the regulatory activities and inspections provided for in this Regulation ; ***Member States shall ensure that ethics committees operate under robust safeguards to prevent conflicts of interest and are composed in a multidisciplinary manner, and are provided with the necessary resources to perform their tasks effectively.***

Or. en

Amendment 2858
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 46
Regulation (EU) No 536/2014
Article 83a – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other for the effective implementation of the regulatory activities and inspections provided for in this Regulation.;	2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other***, including with the respective ethics committees,*** for the effective implementation of the regulatory activities and inspections provided for in this Regulation.***'***;

Or. en

Amendment 2859
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 46
Regulation (EU) No 536/2014

Article 83a – Paragraph 2a

Text proposed by the Commission	*Amendment*
	2a. 3. To preserve the integrity of the work and activities of the ethics committees, the independence and impartiality of the members of the committees, who participate in meetings it is crucial to avoid any conflict of interest to safeguarding the credibility of their decisions from being compromised by conflicts of interest.

Or. en

Amendment 2860
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.	2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials ***from the national competent authority, and in addition one member and one alternate each with expertise in the field of medical ethics representing the relevant national ethics committee***. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.

Or. en

Amendment 2861
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation EU n0 536/2014
Article 85 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.	2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. ***Member States shall ensure that the members appointed to the CTAG cover a sufficiently diverse set of skills relevant to clinical research, including, where appropriate, practical experience in patient care.*** They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.

Or. en

Amendment 2862
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and	2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and

one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.	one alternate each with expertise in the field of clinical trials ***from the national competent authority, and in addition one member and one alternate each with expertise in the field of medical ethics representing the relevant national ethics committee***. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.

Or. en

Amendment 2863
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.	2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. ***Member States shall ensure that the composition of the CTAG reflects a broad range of expertise relevant to clinical research, including where appropriate healthcare practice*** The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.

Or. en

Amendment 2864
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 2

Text proposed by the Commission	*Amendment*
2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.	2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States***, as well as cover a wide range of relevant expertise***. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.

Or. en

Amendment 2865
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate	3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate

in CTAG meetings where relevant.	in CTAG meetings where relevant. ***The representative of ethics committees of the Member States shall support CTAG in matters relating to the practical organisation, coordination and harmonisation of ethical assessment under this Regulation, including the exchange of experience and the development of guidance concerning ethical aspects of clinical trials.***

Or. en

Amendment 2866
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.	3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant. ***The representative of ethics committees of the Member States shall support CTAG in matters relating to the practical organisation, coordination and harmonisation of ethical assessment under this Regulation, including the exchange of experience and the development of guidance concerning ethical aspects of clinical trials***

Or. en

Amendment 2867
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 47

Regulation (EU) 536/2014
Article 85 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.	3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant. ***The CTAG may also draw on contributions from healthcare professionals and patients, where necessary for the examination of scientific, methodological or patient-related aspects.***

Or. en

Amendment 2868
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 47
regulation EU 536/2014
Article 85 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.	3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant. ***Where the examination of scientific, methodological or patient-related aspects so requires, the CTAG may further seek input from healthcare professionals and patients***

Or. en

Amendment 2869
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014
Article 85 – Paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.	3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant. ***The CTAG shall consult, where relevant, with helathcare professionals and patient organisations.***

Or. en

Amendment 2870
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014
Article 85 – Paragraph 3a(new)

Text proposed by the Commission	*Amendment*
	3a. For biological products addressing antimicrobial resistance, including bacteriophage therapies, clinical trial methodologies may include adaptive designs, pathogen-susceptibility guided allocation, predefined modification of product composition, platform protocols, and integration of microbiological and realworld evidence, provided that patient safety, traceability, quality control, and scientific validity are ensured

Or. en

Amendment 2871
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014
Article 85 – Paragraph 5 – point (d)

Text proposed by the Commission	*Amendment*
(d) to provide strategic steering on a common approach for the application of this Regulation and on the support of the clinical trials ecosystem in the Union;	(d) to provide strategic steering on a common approach for the application of this Regulation and on the support of the clinical trials ecosystem in the Union ***including by drawing on practical experience from Union-level initiatives facilitating and accelerating strategic clinical trials*** ;

Or. en

Amendment 2872
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014
Article 85 – Paragraph 5 – point (e)

Text proposed by the Commission	*Amendment*
(e) to contribute to the development of guidance aiming to ensure effective and harmonised implementation of this Regulation.	(e) to contribute***, in collaboration with scientific experts and healthcare professionals,*** to the development of guidance aiming to ensure effective and harmonised implementation of this Regulation.

Or. en

Amendment 2873
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 534/2014
Article 85 – Paragraph 5 – point (f)

Text proposed by the Commission	*Amendment*
(f) to contribute to the development of guidelines on the use of the artificial intelligence models and systems in clinical trials in accordance with Article [xx] Regulation (EU) …/… [European Biotech Act]*;	(f) to contribute to the development of guidelines on the use of the artificial intelligence models and systems in clinical trials in accordance with Article [xx] Regulation (EU) …/… [European Biotech Act]*; ***and in collaboration with scientific experts and healthcare professionals***

Or. en

Amendment 2874
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 5 – point (i)

Text proposed by the Commission	*Amendment*
(i) to provide a recommendation before setting up a regulatory sandbox.	***deleted***

Or. en

Amendment 2875
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014
Article 85 – Paragraph 5 – point (ia)new

Text proposed by the Commission	*Amendment*
	(ia) to facilitate coordination and exchange regarding significant divergences between Member States in the ethical assessment of clinical trials, including where national authorities consider that specific national legal or ethical considerations justify deviation from common guidance, standards or best

practices developed by the CTAG.

Or. en

Amendment 2876
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 5 – point (ia)new

Text proposed by the Commission	*Amendment*
	(ia) to support the exchange of experience between ethics committees of the Member States and to contribute to guidance and recommendations aimed at promoting consistent, efficient and proportionate ethical assessment in multinational clinical trials

Or. en

Amendment 2877
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 5 – point (ia)new

Text proposed by the Commission	*Amendment*
	(ia) to support the exchange of experience between ethics committees of the Member States and to contribute to guidance and recommendations aimed at promoting consistent, efficient and proportionate ethical assessment in multinational clinical trials.

Or. en

Amendment 2878
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 5 – point (ia)new

Text proposed by the Commission	*Amendment*
	(ia) to provide guidance on cross-border participation of subjects, where no suitable clinical trial is available in their Member State.

Or. en

Amendment 2879
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation 536/2014
Article 85 – Paragraph 5a (new)

Text proposed by the Commission	*Amendment*
	5a. For the purposes of carrying out the tasks referred to in paragraph 5(ia), the CTAG shall establish an Ethical Assessment Committee.
	a. Each Member State shall appoint five representatives and one alternate to that committee, with expertise in assessment of clinical trials. The representatives and alternates shall be selected from ethics committees of their Member State. When carrying out the ethical assessment of a clinical trial in accordance with paragraph 5(ia), the committee shall ensure the participation of at least one layperson, independent of the clinical research profession, representing the perspective of patients or trial participants.
	b. Concerned Member States may, where appropriate and having regard to the

nature, therapeutic area or specific characteristics of the clinical trial concerned, designate different representatives or alternates for participation in a specific ethical assessment.

c. The Ethical Assessment Committee shall be chaired by a representative of the Commission. The chair shall not take part in the ethical assessment.

d. When carrying out the ethical assessment of a clinical trial in accordance with paragraph 5(ia), only representatives of the Member States concerned within the ethics assessment committee shall take part in that ethical assessment.

e. For each application assessed pursuant to Article 14b(1), the representatives of the reporting Member State sitting on the Ethical Assessment Committee shall act as lead assessor and co-assessor and shall prepare a draft Part II assessment report.

f. The ethical assessment shall be conducted within the timelines applicable under Article 7 and shall result in a single ethical assessment at Union level for the clinical trial concerned.

5a(i). To support the function of the Ethical Assessment Committee, the Commission and the Agency shall:

(a) provide the necessary guidance and templates to the CTAG and Member States;

(b) facilitate coordination between participating ethics committees, including through dedicated support functions;

5a(ii). The Agency shall act as coordinator of the Ethical Assessment Committee and provide secretariat support;

5a(iii). The CTAG may, where necessary to manage increased participation or workload, establish one or more additional assessment panels within the Ethical Assessment Committee, composed

of additional representatives of concerned Member States.

Or. en

Amendment 2880
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16
Article 85 – Paragraph 5a (new)

Text proposed by the Commission	*Amendment*
	5a. develop recommendations to facilitate cross-border participation in clinical trials where an appropriate clinical trial is not available in the patient's Member State, without prejudice to Member States' competence for the organisation and financing of healthcare systems;

Or. en

Justification

Strengthens the role of the Clinical Trials Coordination and Advisory Group in promoting equitable access to multinational clinical trials through practical recommendations on cross-border participation, while fully respecting Member States' competences and existing Union legislation on cross-border healthcare.

Amendment 2881
Peter Liese

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Article 85
Paragraph 5 point (ia) (new)

Text proposed by the Commission	*Amendment*
	5a. to verify that study populations reflect the demographic diversity of the Union.

Or. en

Justification

Ensures that the requirements in the ongoing EU-CTR governance are embedded.

Amendment 2882
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) 536/2014
Article 85 – Paragraph 5b (new)

Text proposed by the Commission	*Amendment*
	5b. For the purposes of carrying out the tasks referred to in paragraph 5(ib), the CTAG shall establish a Voluntary Centralised Assessment Committee.
	a. Each Member State may appoint up to ten representatives and alternates to that Committee, of which five shall have expertise in the scientific and regulatory assessment of clinical trials, and five shall have expertise in the ethical assessment of clinical trials. Representatives and alternates may be selected from national competent authorities, ethics committees or other relevant public bodies. Member States shall ensure that the representatives appointed collectively possess expertise relevant to the assessment of Parts I and II of clinical trial applications. For the assessment of the aspects referred to in Article 6, only representatives with expertise in the scientific and regulatory assessment of clinical trials shall participate. For the assessment of the aspects referred to in Article 7, only representatives with expertise in ethical review and assessment of clinical trials shall participate.
	b. Member States may, where appropriate and having regard to the nature, therapeutic area or specific characteristics of the clinical trial concerned, designate different

representatives or alternates for participation in a specific ethical assessment.

c. The Voluntary Centralised Assessment Committee shall be chaired by a representative of the Commission. The chair shall not take part in the ethical assessment.

d. When carrying out the assessment of a clinical trial in accordance with paragraph 5(ib), only representatives of the Member States concerned within the Voluntary Centralised Assessment Committee shall take part in that assessment.

e. For each application assessed pursuant to Article 14b(2), the Voluntary Centralised Assessment Committee shall designate a lead assessor and a co-assessor from among the representatives of the concerned Member States. The lead assessor and the co-assessor shall be appointed based on expertise relevant to the clinical trial concerned.

f. The assessment shall be conducted within the timelines applicable under Article 14b(2) and shall result in a single Part I assessment report and a single Part II assessment report at Union level for the clinical trial concerned.

g. A Member State may participate in the Voluntary Centralised Assessment Committee by notifying the Commission of its decision to appoint representatives and alternates to the Committee and notification of this shall be made available on CTIS. The Commission shall maintain and publish a list of participating Member States. A Member State may withdraw its participation at any time by notifying the Commission. Such withdrawal shall not affect the assessment of clinical trials for which the Member State is already participating as a concerned Member State.

5b(i). To support Member State participation in the Voluntary Centralised

Assessment Committee and sponsor application for same, the Agency and Commission shall:

(a) provide the necessary guidance and templates to the CTAG and Member States;

(b) facilitate coordination between participating ethics committees, including through dedicated support functions;

(c) ensure adequate resourcing, expertise and training to enable consistent and high-quality assessments;

(d) monitor the performance of assessments conducted under this Article, including timelines, quality and consistency of outcomes.

5b(ii). The Agency shall act as coordinator of the Voluntary Centralised Assessment Committee and provide secretariat support

5b(iii). The Commission shall, no later than two years [from the date of application of this Regulation] submit a report to the European Parliament and to the Council assessing the functioning of the Voluntary Centralised Assessment Committee, including its impact on timelines, quality and consistency of clinical trial assessments, the level of participation by Member States and sponsors, and any further actions required to support its effective operation and uptake.

5b(iv) where the report referred to in paragraph (iii) identifies that the demand for assessments under the Voluntary Centralised Assessment Committee exceeds the operational capacity of the CTAG, the Commission shall, in cooperation with CTAG and the Agency, take appropriate measures to ensure the effective functioning of the mechanism, including by supporting the establishment of additional assessment panels operating under the Voluntary Centralised Assessment Committee.

5b(v) the CTAG may, where necessary to manage increased participation or workload, establish one or more additional assessment panels within the Voluntary Centralised Assessment Committee, composed of additional representatives of concerned Member States.

5b(vi) Where requests for assessment by the Voluntary Centralised Assessment Committee exceed the available capacity and risks preventing compliance with the applicable timelines, the CTAG may, in coordination with the Commission and the Agency, establish a transparent and objective prioritisation mechanism, for application on a temporary basis. Such a mechanism shall be based on clear and non-discriminatory criteria and shall be made publicly available.

Or. en

Amendment 2883
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 58 – paragraph 1 – point 47
Regulation (EU) No 536/2014
Article 85 – Paragraph 7

Text proposed by the Commission	*Amendment*
7. The CTAG may issue recommendations and opinions on matters related to clinical trials and shall endorse any guidance related to the application of this Regulation. The Commission shall publish the guidelines endorsed by the CTAG.	7. The CTAG may issue recommendations and opinions on matters related to clinical trials and shall endorse any guidance related to the application of this Regulation***, with a view to promoting consistent ethical review and administrative practices across Member States.*** . The Commission shall publish the guidelines endorsed by the CTAG.

Or. en

Amendment 2884
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 47 a (new)
Regulation (EU) 536/2014
Article 89

Text proposed by the Commission	*Amendment*
	(47a) Article 89 is amended as follows:
	Article 89 Exercise of the delegation
	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
	2. The power to adopt delegated acts referred to in Articles 27, 39, 45, 63(1) and 70 shall be conferred on the Commission for a period of five years from the date referred to in the second paragraph of Article 99. The Commission shall draw up a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
	2b. The power to adopt delegated acts referred to in Article 5b shall be conferred on the Commission for an indeterminate period of time from [date entry into force of EU Biotech Act]. Before adopting a delegated act, in accordance with this subparagraph the Commission shall consult the EMA and experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making
	3. The delegation of power referred to in Articles 5b, 27, 39, 45, 63(1) and 70 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that

decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 5b, 27, 39, 45, 63(1) and 70 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months from notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Or. en

Amendment 2885
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 1 – point (fa)new

Text proposed by the Commission	*Amendment*
	(fa) to perform monitoring in accordance with Article 48;

Or. en

Amendment 2886
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 1 – point (fa)new

Text proposed by the Commission	*Amendment*
	(fa) to perform monitoring in accordance with Article 48;

Or. en

Amendment 2887
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 1 – point (fb)new

Text proposed by the Commission	*Amendment*
	(fb) other activities that are ancillary to and support the sponsors' fulfilment of their obligations pursuant to this Regulation.

Or. en

Amendment 2888
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 1 – point (fb)new

Text proposed by the Commission	*Amendment*
	(fb) other activities that are ancillary to and support the sponsors' fulfilment of their obligations pursuant to this Regulation.

Or. en

Amendment 2889
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 2 – point (da)new

Text proposed by the Commission	*Amendment*
	(da) other activities that are ancillary to and support the sponsors' fulfilment of their obligations pursuant to this Regulation

Or. en

Amendment 2890
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 2 – point (da)new

Text proposed by the Commission	*Amendment*
	(da) other activities that are ancillary to and support the sponsors' fulfilment of their obligations pursuant to this Regulation

Or. en

Amendment 2891
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. For the processing assessment	4. For the processing assessment

leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679.

leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679. ***Sponsors and investigators shall act as independent controllers unless they have substantially collaborated in the development of the protocol. In such case, they shall be joint controllers with respect to the collaboratively developed aspects. Participation in advisory consultations or ethics reviews shall not constitute substantial collaboration. For the purpose of this Article, where an investigator is employed or engaged by a clinical trial site that has entered into a clinical trial agreement with the sponsor, the clinical trial site shall be considered the controller and the investigator shall process personal data under its authority.***

Or. en

Amendment 2892
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 4

Text proposed by the Commission	*Amendment*
4. For the processing assessment leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679.	4. For the processing assessment leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679. ***Sponsors and investigators shall act as independent controllers unless they have substantially collaborated in the development of the protocol. In such case, they shall be joint controllers with respect to the collaboratively developed aspects. Participation in advisory consultations or ethics reviews shall not constitute***

substantial collaboration. For the purpose of this Article, where an investigator is employed or engaged by a clinical trial site that has entered into a clinical trial agreement with the sponsor, the clinical trial site shall be considered the controller and the investigator shall process personal data under its authority.

Or. en

Amendment 2893
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 6

Text proposed by the Commission	*Amendment*
6. Personal data collected and processed in accordance with this Regulation may be further processed ***by the same controller*** for the purposes of other clinical trials conducted under this Regulation, ***or for*** scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research.	6. Personal data collected and processed in accordance with this Regulation may be further processed for the purposes of other clinical trials conducted under this Regulation, ***and in accordance with Articles 93(1) and 93(2). Subject to the safeguards required under Article 89(1) of Regulation (EU) 2016/679, personal data collected and processed in accordance with this Regulation may also be further processed for other*** scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research. ***Such processing shall be deemed necessary for the performance of a task carried out in the public interest in the area of public health within the meaning of Articles 6(1)(e) and 9(2)(i) of Regulation (EU) 2016/679. This paragraph shall not determine the qualification of the parties as controllers, joint controllers or processors under Regulation (EU) 2016/679, which shall be assessed in accordance with that***

Regulation.

Or. en

Amendment 2894
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93 – Paragraph 6

Text proposed by the Commission	*Amendment*
6. Personal data collected and processed in accordance with this Regulation may be further processed ***by the same controller*** for the purposes of other clinical trials conducted under this Regulation, ***or for*** scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research.	6. Personal data collected and processed in accordance with this Regulation may be further processed for the purposes of other clinical trials conducted under this Regulation, ***and in accordance with Articles 93(1) and 93(2). Subject to the safeguards required under Article 89(1) of Regulation (EU) 2016/679, personal data collected and processed in accordance with this Regulation may also be further processed for other*** scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research. ***Such processing shall be deemed necessary for the performance of a task carried out in the public interest in the area of public health within the meaning of Articles 6(1)(e) and 9(2)(i) of Regulation (EU) 2016/679. This paragraph shall not determine the qualification of the parties as controllers, joint controllers or processors under Regulation (EU) 2016/679, which shall be assessed in accordance with that Regulation.***

Or. en

Amendment 2895
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) No 536/2014
Article 93 – Paragraph 6

Text proposed by the Commission	*Amendment*
6. Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation***,*** or for scientific research with the ***aim of protecting public*** health, ***improving standard of care and fostering the innovation capacity of European medical research***.	6. Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation or for scientific research ***only where such further processing complies with Regulation (EU) 2016/679, is compatible*** with the ***original purpose or is based on a separate legal basis, and is subject to appropriate safeguards pursuant to Article 89 of that Regulation. Where such further processing concerns genetic data, biometric data or data concerning*** health, ***the controller shall identify the applicable condition under Article 9(2) of Regulation (EU) 2016/679 and shall ensure specific safeguards for the rights and freedoms of the data subject***.

Or. en

Amendment 2896
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 58 – paragraph 1 – point 48
536/2014
Article 93 – Paragraph 6

Text proposed by the Commission	*Amendment*
6. Personal data collected ***and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other*** clinical trials ***conducted under this Regulation, or*** for scientific research with the ***aim of protecting public health,***	6. ***6. Without prejudice to Regulation (EU) 2016/679 (GDPR),*** personal data collected ***in the context of a*** clinical trials ***may be made available for further data processing*** for scientific research ***purposes in accordance*** with the European ***Health Data Space Regulation, including the***

improving standard of care and fostering the innovation capacity of European ***medical research***.	***categories of electronic health data referred to in Article 51 thereof, provided that the conditions and safeguards laid down in the European Health Data Space Regulation and in Regulation (EU) 2016/679 (GDPR) are fulfilled***.

Or. en

Amendment 2897
Aurelijus Veryga

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation 536/2014
Article 93– paragraph 6

Text proposed by the Commission	*Amendment*
6. Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation, or for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research.	6. Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation, or for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research. ***Participants of the trial should be made aware of this in the informed consent.***

Or. en

Amendment 2898
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) No 536/2014
Article 93 – Paragraph 7

Text proposed by the Commission	*Amendment*
7. By derogation from Article 9(4) of Regulation (EU) 2016/679, Member	***deleted***

States may not maintain or introduce further conditions, including limitations, with regard to the processing of personal data, including genetic data or data concerning health in the context of clinical trials carried out in accordance with this Regulation.

Or. en

Amendment 2899
Ondřej Krutílek

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) 536/2014
Article 93

Text proposed by the Commission	*Amendment*
7. By derogation from Article 9(4) of Regulation (EU) 2016/679, Member States may not maintain or introduce further conditions, including limitations, with regard to the processing of personal data, including genetic data or data concerning health in the context of clinical trials carried out in accordance with this Regulation.	7. By derogation from Article 9(4) of Regulation (EU) 2016/679, Member States may not maintain or introduce further conditions, including limitations, with regard to the processing of personal data, including genetic data or data concerning health in the context of clinical trials carried out in accordance with this Regulation ***or other research pursuant to this article***.

Or. en

Amendment 2900
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 48
Regulation (EU) No 536/2014
Article 93 – Paragraph 8

Text proposed by the Commission	*Amendment*
8. Processing of personal data referred to in this Article shall be subject to appropriate technical and organisational	8. Processing of personal data referred to in this Article shall be subject to appropriate technical and organisational

measures to ensure the protection of the rights and freedoms of data ***subject***. In particular, the controller shall ***obtain*** informed consent of the subject in accordance with Article 29 of this Regulation. ***The controllers*** shall ***also apply confidentiality rules concerning access to records and*** personal data ***of subjects and apply further safeguards that are appropriate for a*** specific clinical trial ***as requested in point D, Part I of Annex I (ak), (al), (am)***.	measures to ensure the protection of the rights and freedoms of data ***subjects***. In particular, the controller shall ***ensure that*** informed consent of the subject ***is obtained*** in accordance with Article 29 of this Regulation. ***Such informed consent*** shall ***be clearly distinguished from consent as a legal basis for processing*** personal data ***under Regulation (EU) 2016/679. Where processing is based on consent under Regulation (EU) 2016/679, such consent shall be freely given,*** specific***, informed and unambiguous and, where special categories of personal data are concerned, explicit. Refusal or withdrawal of consent to processing for purposes not necessary for participation in the*** clinical trial ***shall not result in discrimination, exclusion from ordinary healthcare, financial penalty or any other disadvantage***.

Or. en

Amendment 2901
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 58 – paragraph 1 – point 48 a (new)

Text proposed by the Commission	*Amendment*
	(48a) Article 140 b (NEW)
	Article 140 b is inserted: Scientific opinions to support Member States early access schemes for unapproved medicines
	1. The Agency may give a scientific opinion on medicinal products approved in third countries with equally stringent scientific, safety and quality standards subject to mutual recognition agreements with the Union. For this purpose, a Member State may request such an Opinion for which a fee may apply, an application shall be submitted to the Agency in accordance with the provisions of Article 6. Such application may be

submitted and assessed together with a marketing authorisation application or any subsequent variation for the EU. The Agency may, after consulting the World Health Organization, and as appropriate other relevant organisations, draw up a scientific opinion in accordance with Articles 6, 10 and 12. The provisions of Article 13 shall not apply.

2. A subsequent application for marketing authorisation for a medicinal product subject to an opinion under this article shall undergo the normal procedures and requirements

3. The Agency shall establish specific procedural rules for the implementation of paragraph 1, as well as for the collaboration with third countries on sharing information, including on post-approval safety and efficacy information from countries where the medicinal product is approved.

Or. en

Amendment 2902
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 58 – paragraph 1 – point 49
Chapter IVb
REGULATORY SANDBOXES AND USE OF AI – Article 97 – Review

Text proposed by the Commission	*Amendment*
(49) Article 97 is replaced by the following:	***deleted***
'Article 97	
Review	
Five years after the date referred to in Article 99, second subparagpah, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact	

that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The report shall also assess progress made by monitoring as a key performance indicator the number of addition multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025;

The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation'

Or. en

Amendment 2903
Christine Anderson

Proposal for a regulation
Article 58 – paragraph 1 – point 49
Regulation (EU) No 536/2014
Art. 97 – first subparagraph

Text proposed by the Commission	*Amendment*
Five years after the date referred to in Article 99, second subparagpah, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The report shall	Five years after the date referred to in Article 99, second subparagpah, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The report shall

also assess progress made by monitoring as ***a*** key performance ***indicator*** the number of ***addition*** multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025;

also assess progress made by monitoring as key performance ***indicators*** the number of ***additional*** multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025; ***the average authorisation time; the participation of SMEs, start-ups and non-commercial sponsors; the level of private investment mobilised without public guarantees; the transparency of adverse-event reporting; the number of data-protection complaints; the extent to which trial subjects exercised rights of access, objection or withdrawal of consent; and whether the Regulation reduced administrative burdens without weakening informed consent, patient safety or ethical review.***

Or. en

Amendment 2904
Jessica Polfjärd

Proposal for a regulation
Article 58 – paragraph 1 – point 49
Regulation (EU) No 536/2014
Article 97

Text proposed by the Commission	*Amendment*
Five years after the date referred to in Article 99, second subparagpah, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The report shall also assess progress made by monitoring as	Five years after the date referred to in Article 99, second subparagpah, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, ***the impact of the changes to regulatory approval timelines as set out in Article 58 on the effectiveness of regulatory oversight,*** and the measures

a key performance indicator the number of addition multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025;	required in order to maintain the competitiveness of European clinical research. The report shall also assess progress made by monitoring as a key performance indicator the number of addition multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025;

Or. en

Amendment 2905
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 1
Regulation (EU) 2019/6
Article 3

Text proposed by the Commission	*Amendment*
(1) in Article 3, the following paragraph 3 is inserted:	***deleted***
'The Union GMO legislation shall not apply to veterinary medicinal products containing or consisting of genetically modified organisms that are authorised or manufactured in accordance with this Regulation. The administration of veterinary medicinal products shall not bring the treated animal or their products under the scope of the GMO rules.'	

Or. en

Amendment 2906
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 2
Regulation (EU) 2019/6
Article 4 – point 46

Text proposed by the Commission	*Amendment*
(46) "'veterinary medicinal products containing or consisting of genetically modified organisms' means veterinary medicinal products that contain or consist of genetically modified organisms as defined in Article 2 point (2) of Directive 2001/18/EC" excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC";	***deleted***

Or. en

Amendment 2907
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 2
Regulation (EU) 2019/6
Article 4 – point 47

Text proposed by the Commission	*Amendment*
(47) ''regulatory sandbox' means a time-limited regulatory framework that enables the development, placing on the market or use, under regulatory supervision, of innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products and which are not regulated under Union legislation;	***deleted***

Or. en

Amendment 2908
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 59 – paragraph 1 – point 2
Regulation EU No 2019/6

Article 3

Text proposed by the Commission	*Amendment*
(47) ‘‘regulatory sandbox’ means a time-limited regulatory framework that enables the development, placing on the market or use, under regulatory supervision, of innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products and which are not regulated under Union legislation;	***deleted***

Or. en

Amendment 2909
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 4 – point a
Regulation (EU) 2019/6
Article 9 – paragraph 2a

Text proposed by the Commission	*Amendment*
2a. In case of clinical trials with veterinary medicinal products containing or consisting of genetically modified organisms, the competent authorities shall assess potential adverse effects on human health and the environment, having regard to the specific characteristics of the product and in accordance with the principles for environmental risk assessment set out in Annex II. ***Where appropriate,*** the implementation of risk mitigation measures shall be required.	2a. In case of clinical trials with veterinary medicinal products containing or consisting of genetically modified organisms, the competent authorities shall assess potential adverse effects on human health and the environment, having regard to the specific characteristics of the product and in accordance with the principles for environmental risk assessment set out in Annex II. The implementation of risk mitigation measures shall be required.

Or. en

Amendment 2910
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 4 – point b
Regulation (EU) 2019/6
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
During this period, where the trial concerns a veterinary medicinal product containing or consisting of genetically modified organisms, the competent authorities ***may*** consult with the bodies set up by the Union or Member States in accordance with under Directive 2001/18/EC, in particular in case of novel questions or fist-in-class veterinary medicinal products. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.	During this period, where the trial concerns a veterinary medicinal product containing or consisting of genetically modified organisms, the competent authorities ***shall*** consult with the bodies set up by the Union or Member States in accordance with under Directive 2001/18/EC, in particular in case of novel questions or fist-in-class veterinary medicinal products. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.

Or. en

Amendment 2911
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 5
Regulation (EU) 2019/6
Article 28 – paragraph 2

Text proposed by the Commission	*Amendment*
During the process of examination of applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms, the Agency ***may*** hold consultations with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC, in particular for first-in-class products or when a novel question arises. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.	During the process of examination of applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms, the Agency ***shall*** hold consultations with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC, in particular for first-in-class products or when a novel question arises. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.

Or. en

Amendment 2912
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 59 – paragraph 1 – point 6
Regulation (EU) 2019/6
Article 40a

Text proposed by the Commission	*Amendment*
(6) The following Article 40a is inserted:	***deleted***
'Article 40a	
Extension of the supplementary protection certificate concerning biotechnology medicinal products treating zoonoses developed and authorised in the Union	
1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product developed by means of a biotechnology process referred to in paragraphs 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009[74] of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	
(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;	
(b) the veterinary medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy	

which at least euivalent to that that of any authorised veterinary medicinal product in the Union for the same zoonotic disease; and

(c) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The Agency shall assess compliance with the conditions referred to ins paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency's opinion shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under article 7 of of Regulation (EC) No 469/2009.'

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*[74] **Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1***

Or. en

Amendment 2913
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 59 – paragraph 1 – point 6
regulation EU no 2019/6
art 40a

Text proposed by the Commission	*Amendment*
(6) The following Article 40a is inserted:	***deleted***
'Article 40a	
Extension of the supplementary	

protection certificate concerning biotechnology medicinal products treating zoonoses developed and authorised in the Union

1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product developed by means of a biotechnology process referred to in paragraphs 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009[74] of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the veterinary medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which at least euivalent to that that of any authorised veterinary medicinal product in the Union for the same zoonotic disease; and

(c) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The Agency shall assess compliance with the conditions referred to ins paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency´s opinion shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under article 7 of of Regulation (EC) No 469/2009.'

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*[74] **Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1***

Or. en

Amendment 2914
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 6
Regulation (EU) 2019/6
Article 40a

Text proposed by the Commission	*Amendment*
(6) The following Article 40a is inserted:	***deleted***
'Article 40a	
Extension of the supplementary protection certificate concerning biotechnology medicinal products treating zoonoses developed and authorised in the Union	
1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product developed by means of a biotechnology process referred to in paragraphs 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009[74] of the European Parliament and of the Council , or by a patent which qualifies for the granting of such	

supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the veterinary medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which at least euivalent to that that of any authorised veterinary medicinal product in the Union for the same zoonotic disease; and

(c) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The Agency shall assess compliance with the conditions referred to ins paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency's opinion shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under article 7 of of Regulation (EC) No 469/2009.'

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[74] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1

Or. en

Amendment 2915
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a

Text proposed by the Commission	*Amendment*
Extension of the supplementary protection certificate concerning ***biotechnology*** medicinal products treating zoonoses developed and authorised in the Union	Extension of the supplementary protection certificate concerning ***best-in-class veterinary*** medicinal products treating zoonoses developed and authorised in the Union

Or. en

Amendment 2916
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product developed by means of a biotechnology process referred to in ***paragraphs*** 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009***74*** of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that	1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product***, including a veterinary medicinal product containing a chemically synthesised small molecule,*** developed by means of a biotechnology process referred to in ***paragraph*** 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009***[1]*** of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***6***-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No

all of the following conditions are met:

469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

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*[74] **Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1***

Or. en

Amendment 2917
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 1 point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;	(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union ***and does not merely constitute a new formulation, strength, route of administration, presentation or line extension of an active substance already authorised in the Union, unless the applicant demonstrates a meaningful therapeutic or One Health advantage***;

Or. en

Amendment 2918
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 1 point b

Text proposed by the Commission	*Amendment*
(b) the veterinary medicinal product has a mechanism of action ***distinctly different*** and shows a level of safety and efficacy which ***at least euivalent to that*** that of any authorised veterinary medicinal product in the Union for the same zoonotic disease; and	(b) the veterinary medicinal product has a ***novel or clearly differentiated*** mechanism of action and shows a level of safety and efficacy which ***is meaningfully superior, or otherwise demonstrates a clearly substantiated therapeutic or One Health advantage, compared with*** that of any authorised veterinary medicinal product in the Union for the same zoonotic disease***, taking into account unmet veterinary or public health need, animal health, animal welfare, zoonotic transmission risk, antimicrobial resistance, safety, effectiveness and, where scientifically appropriate, evidence generated through validated New Approach Methodologies***; and

Or. en

Amendment 2919
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 1 point c

Text proposed by the Commission	*Amendment*
(c) at least ***a*** manufacturing step, excluding packaging, quality testing and certification is performed in the Union***.***	(c) at least ***one substantial*** manufacturing step, excluding packaging, quality testing and certification is performed in the Union ***for the duration of the patent and the supplementary protection certificate, and a substantial part of the development of the veterinary medicinal product, including clinical development, field development or process development, was carried out in the Union and contributed to strengthening the Union's scientific, veterinary, One Health or regulatory knowledge base;***

Or. en

Amendment 2920
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 1 point ca (new)

Text proposed by the Commission	*Amendment*
	(ca) the marketing authorisation applicant submits an access and supply plan demonstrating how the veterinary medicinal product will contribute to the timely and equitable availability, affordability and accessibility of veterinary medicinal products relevant to the diagnosis, treatment or prevention of zoonotic diseases across the Union, including information on expected supply capacity, launch intentions in all Member States, measures to prevent and address shortages, expected implications for animal health, public health and veterinary systems, and a transparent declaration of direct public financial support received for the development of the veterinary medicinal product, without prejudice to the protection of commercially confidential information.

Or. en

Amendment 2921
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall assess compliance with the conditions referred to ***ins*** paragraph 1 as part of the marketing	2. The Agency shall assess compliance with the conditions referred to ***in*** paragraph 1 as part of the marketing

authorisation procedure concerned.	authorisation procedure concerned***, including the therapeutic or One Health advantage referred to in points (a) and (b), the representativeness of the trials, field trials or other pivotal studies referred to in point (ba), the Union-based development and manufacturing contribution referred to in point (c), the access and supply plan referred to in point (ca) and, where relevant, evidence from competent national authorities, health technology assessment bodies, veterinary experts, public health bodies, One Health networks, animal health organisations and evidence generated through validated New Approach Methodologies***.

Or. en

Amendment 2922
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 3

Text proposed by the Commission	*Amendment*
3. Where compliance is confirmed, the ***Agency´s opinion*** shall issue a statement to that effect.	3. Where compliance ***with all conditions referred to in paragraph 1*** is confirmed, the ***Agency*** shall issue a statement to that effect.

Or. en

Amendment 2923
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 6
(EU) 2019/6
Article 40a paragraph 4

Text proposed by the Commission	*Amendment*

4. A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under article 7 of ***of*** Regulation (EC) No 469/2009.	4. A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under Article 7 of Regulation (EC) No 469/2009.

Or. en

Amendment 2924
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 59 – paragraph 1 – point 8
Regulation (EU) 2019/6
Chapter IX

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 2925
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 59 – paragraph 1 – point 8
regulation 2019/6
chapter IX

Text proposed by the Commission	*Amendment*
(8) [...]	***deleted***

Or. en

Amendment 2926
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 59 – paragraph 1 – point 8
(EU) 2019/6
Article 136a paragraph 1 point a

Text proposed by the Commission	*Amendment*
(a) it can be expected that those technologies, methods or products will have a positive impact on animal health without ***unacceptable*** negative impacts on human health or the environment;	(a) it can be expected that those technologies, methods or products will have a positive impact***, based on available scientific evidence,*** on animal health without negative impacts on human health or the environment;

Or. en

Amendment 2927
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 61 – paragraph 1 – point 1
Regulation (EU) 2024/1938
Article 3

Text proposed by the Commission	*Amendment*
(1) In Article 3, the following point (60) is added:	***deleted***
'(60) 'regulatory sandbox' means a regulatory framework which allows to develop, assess and test innovative or adapted regulatory solutions within a controlled environment pursuant to a specific plan, for a limited time and under regulatory supervision and which facilitates the development, assessment, authorisation or monitoring of innovative activities or substances which are likely to fall within the scope of this Regulation.'	

Or. en

Amendment 2928
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 61 – paragraph 1 – point 1
Regulation (EU) 2024/1938
point 60

Text proposed by the Commission	*Amendment*
(60) 'regulatory sandbox' means a regulatory framework which allows to develop, assess and test innovative or adapted regulatory solutions within a controlled environment pursuant to a specific plan, for a limited time and under regulatory supervision and which facilitates the development, assessment, authorisation or monitoring of innovative activities or substances which are likely to fall within the scope of this Regulation.	***deleted***

Or. en

Amendment 2929
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 61 – paragraph 1 – point 2 a (new)
Regulation (EU) 2024/1938

Text proposed by the Commission	*Amendment*
	(2a) in Article 48, the following paragraph 5a is inserted:
	5a By way of derogation from paragraph 5, in the case of SoHO imported into the Union that are intended for use in the manufacture of products regulated by other Union legislation, where those products are exclusively for therapeutic use on the person from whom the SoHO were collected, compliance with the quality requirements, including testing for communicable diseases, of the third country in which the SoHO were procured shall be deemed equivalent to compliance with the requirements referred to in paragraph 5. The arrangements for the handling of such SoHO within the Union shall ensure appropriate protection of healthcare workers and other persons involved in their handling;

Or. en

Justification

A significant proportion of advanced therapies are developed using starting material collected outside the Union, manufactured within the Union and returned to the same patient. For autologous use of this kind, the starting material is destined for a single identified individual and does not enter the Union's clinical chains for transfusion or transplantation. Under the SoHO Regulation, imported material is governed by an equivalence principle, but the Commission retains broad empowerments to set quality and testing requirements through secondary legislation. Without an explicit carve-out for autologous-use imports, there is a real risk that EU-specific communicable disease testing standards will be imposed in parallel with the testing already performed in the country of procurement. The result would be duplicative testing, longer lead times and higher costs, for material whose public-health risk profile is fundamentally different from allogeneic SoHO. A targeted carve-out drafted by way of derogation from paragraph 5 preserves the equivalence principle in operative form while leaving the general release-verification rule in place for all other imports, including allogeneic SoHO. The closing sentence of the new paragraph 5a ensures that occupational-safety arrangements for personnel handling the imported material within the Union are preserved.

Amendment 2930
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 61 – paragraph 1 – point 4
Regulation (EU) 2024/1938
art 39a

Text proposed by the Commission	*Amendment*
(4) [...]	***deleted***

Or. en

Amendment 2931
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 61 – paragraph 1 – point 4
Regulation (EU) 2024/1938
Article 39a

Text proposed by the Commission	*Amendment*

[...]	***deleted***

Or. en

Amendment 2932
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 61 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) the following article 39b is inserted:
	1. A regulatory sandbox is established for the assessment of technological processes applied to human organs intended for transplantation, whether autologous or allogeneic, where the organ retains its function as an organ following the process ("the Organ Processing Sandbox").
	2. The Organ Processing Sandbox shall operate as a specific application, within the meaning of [Article of the general SoHO sandbox mechanism], of the general regulatory sandbox framework, adapted to the borderline between organs, SoHO and medicinal products as described in this paragrapgh and paragraphs 3 to 15.
	3. This sandbox applies to any process applied to a human organ intended for transplantation, including but not limited to: (a) ex vivo or ex-situ perfusion systems; (b) gene therapy directed at correcting a disease or dysfunction originating within the organ; (c) reconstruction, remodelling or repair of the organ by means of cells, organoids, biomaterials, or any present or future therapeutic technique; (d) any other technology intended to improve graft functionality or survival. t
	4. A process falls within this Article only where the organ, following that process,

continues to perform the physiological function of the organ concerned. Where the process results in a product that no longer performs that function, the product shall be assessed exclusively under Regulation (EU) 2024/1938 or Regulation (EC) No 1394/2007 and Directive 2001/83/EC, as applicable, and this sandbox shall not apply.

5. The sandbox shall be coordinated by the SoHO Coordination Board, acting jointly with: (a) the competent authorities for organs designated under Article 17 of Directive 2010/53/EU; (b) the European Medicines Agency; and (c) the competent pharmaceutical authorities of the Member States and of the Commission.

6. The consultation mechanism provided for in Article 12(2) of Regulation (EU) 2024/1938 shall apply, adapted so that the SCB's opinion on the applicable regulatory pathway is issued jointly with the authorities listed in paragraph 1. Decisions taken under this sandbox shall be recorded in the SoHO compendium referred to in Article 69(1), point (e), of Regulation (EU) 2024/1938, with a specific designation identifying them as organ-processing authorisations of use.

7. A process falling within the scope of paragraphs 3 and 4 shall be subject to an authorisation of use, granted by the competent authority for organs in cooperation with the SoHO national authority, following the joint opinion referred to in paragraph 6.

8. The authorisation of use is distinct in nature from a marketing authorisation for a medicinal product. It authorises the process applied to the organ and does not confer, and shall not be treated as conferring, any authorisation in respect of the organ as a product.

9. The authorisation of use shall be based on: (a) a risk classification of the process, established in accordance with paragraphs 11 to 13; (b) the scope of clinical studies or clinical trials required

to demonstrate the efficacy and safety of the process, proportionate to that risk classification; (c) outcome-monitoring and traceability conditions specific to organ transplantation, in accordance with Directive 2010/53/EU; and (d) any additional monitoring conditions specific to the technology applied, as determined jointly under paragraphs 5 and 6.

10. Applicants may rely on the clinical-trial framework established by Regulation (EU) No 536/2014 for the purpose of point (b), without prejudice to the outcome-monitoring obligations under point (c).

11. The SCB, in cooperation with the authorities referred to in paragraph 5 and with the relevant technical bodies already responsible for the European Good Tissue and Cells Practices (EuroGTP II) methodology, shall adapt that methodology to processes applied to human organs.

12. The adapted methodology shall provide, at minimum: (a) a structured framework for classifying the risk associated with a given process, taking into account its degree of manipulation of the organ, its reversibility, and its potential effect on graft function and recipient safety; (b) criteria for determining, on the basis of that classification, the scope and design of the clinical evidence required under paragraph 9, point (b); (c) criteria for determining the intensity and duration of the follow-up and outcome-monitoring obligations required underparagraph 9, point (c).

13. The Commission shall be empowered to adopt implementing acts setting out the adapted methodology referred to in paragraph 1, following consultation of the SCB, the EMA and the competent authorities for organs.

14. An authorisation of use granted under this sandbox shall not alter the legal classification of the organ as an organ

within the meaning of Directive 2010/53/EU. An organ subject to a process authorised under this sandbox shall remain subject to the donation-and-transplantation system, including allocation according to medically and socially established criteria, and shall not be removed from that system by reason of the process applied.

15. No economic or commercial consideration deriving from the process applied shall attach to, or affect the allocation of, the organ itself. This paragraph is without prejudice to the remuneration of services referred to in paragraph 16.

16. The provision of processing services falling within paragraph 3 may, following a case-by-case assessment by the authorities referred to in paragraph 5, be externalised to or licensed from a third-party entity, provided that the requirements of paragraphs 14 and 15 are complied with.

17. The Commission, assisted by the SCB, shall issue guidance on the contracting models referred to in paragraph 1, including on the allocation of liability and the traceability obligations applicable to externalised or licensed processing.

18. The Organ Processing Sandbox shall run for an initial period of 4 years from the date of the first authorisation of use granted under paragraph 7.

19. The SCB shall report annually to the Commission and the co-legislators on the authorisations granted, the outcomes monitored, and the operation of the adapted risk-based methodology referred to in paragraph 11 to 13.

20. Before the end of the initial period, the Commission shall evaluate the sandbox and shall propose, as appropriate, its extension, its conversion into a permanent regulatory pathway, or its discontinuation.

Or. en

Amendment 2933
Wouter Beke

Proposal for a regulation
Article 61 – paragraph 1 – point 4 a (new)
Regulation (EU) 2024/1938
Article 58 (10)

Text proposed by the Commission	*Amendment*
	(4a) Article 58(10) is replaced by the following:
	'10. SoHO entities that distribute reproductive SoHO from third-party donation shall comply with rules established in national legislation regarding the limits to the number of offspring from medically assisted reproduction or of human applications with reproductive SoHO from a single SoHO donor, where applicable. SoHO entities shall monitor compliance with such rules via registries for reproductive SoHO donors, in accordance with the national legislation. Without prejudice to such rules, when reproductive SoHO are distributed to another Member State, the distributing SoHO entity shall respect the limits imposed by the receiving Member State, while at the same time respecting an overarching EU-wide limit of 50 families per single donor. This Article shall not affect Member States' rules concerning limits on the cross-border distribution of reproductive SoHO.'

Or. en

Amendment 2934
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 61 – paragraph 1 – point 4 a (new)
Regulation (EU) 2024/1938

article 61, new paragraph 4a

Text proposed by the Commission	*Amendment*
	(4a) In Article 61, paragraph 4 a (new) is inserted:
	(4a) The Commission may facilitate, where appropriate and in cooperation with Member States, the exchange of best practices concerning advanced therapy medicinal products prepared in hospital settings, including on efficacy, quality, safety, pharmacovigilance, evidence generation and patient protection.
	Such cooperation shall be without prejudice to the hospital exemption regime laid down in Union pharmaceutical law, to the competences of Member States under Article 168(7) TFEU, and to the respective responsibilities of national competent authorities and Union bodies.

Or. en

Justification

Advanced therapy medicinal products prepared under the hospital exemption can provide essential access for patients with high unmet medical needs, in particular in rare and ultra-rare diseases, where centrally authorised products may not yet exist or may not be available in practice. However, divergent national implementation of the hospital exemption creates legal uncertainty, uneven quality and safety requirements and unequal access across the Union. This amendment therefore establishes a harmonised Union framework, with proportionate GMP, pharmacovigilance, inspection and registry requirements, while preserving the non-routine, patient-specific nature of the exemption and fully respecting Member States' competences under Article 168(7) TFEU. By linking the hospital exemption to ERNs, a Union registry and a dedicated transition pathway to centralised marketing authorisation, the amendment strengthens patient safety, regulatory oversight and evidence generation without undermining academic and hospital-based innovation. It ensures that real-world evidence generated in clinical practice can support future authorisation where appropriate, while preventing the hospital exemption from becoming a parallel route to avoid the normal marketing authorisation framework. The result is a balanced framework that improves patient access, supports non-commercial developers and reinforces trust in advanced therapy medicinal products across the Union.

Amendment 2935
Wouter Beke

Proposal for a regulation
Article 61 – paragraph 1 – point 4 b (new)
Regulation (EU) 2024/1938
Article 86

Text proposed by the Commission	*Amendment*
	(4b) Article 86 is replaced by the following:
	The Commission shall, by 8 August 2032, assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present its main findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. The evaluation report shall include an assessment of the implementation of Article 54 and of the impact of Article 58(10) on access to treatments with donor gametes. For the purpose of the evaluation report, the Commission shall use aggregated and anonymised data and information gathered from SoHO competent authorities and from data and information submitted to the EU SoHO Platform. Member States shall provide the Commission with additional information as necessary and proportionate for the preparation of the evaluation report, including information on the conditions for compensation of SoHO donors pursuant to Article 54. The evaluation report shall, where appropriate, be accompanied by a legislative proposal to amend this Regulation.

Or. en

Amendment 2936
Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 61 – paragraph 1 a (new)

Text proposed by the Commission	Amendment
	Amendment to Regulation (EU) …/… [reference to be added after adoption cf. COM (2023) 193 final] Regulation (EU) …/… [reference to be added after adoption cf. COM (2023) 193 final] is amended as follows: 'Article 6a Applications for critical biological medicinal products with legacy national authorisations By way of derogation from Article 6(1) of this Regulation and Article 6(2) of [revised Directive 2001/83/EC], where the application concerns a biological medicinal product the active substance of which has been authorised in at least one Member State, for the same therapeutic use and route of administration, under a national marketing authorisation granted before 20 November 2005 or before the date on which the category of medicinal products concerned became subject to mandatory Union authorisation, and where that medicinal product would, if first authorised at the time of submission of the application, fall within Annex I to this Regulation, the applicant shall not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substance of the medicinal product: (a) has been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II to [revised Directive 2001/83/EC]; (b) has been included in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation [reference to be added after adoption cf. COM (2023) 193 final] and (c) is manufactured as part of a strategic project referred to in Article 5(1)(a) of Regulation (EU) …/… [reference to be added after adoption, cf. COM(2025) 102 final] or at least one key manufacturing step relating to the

production of the active substance or the finished biological medicinal product is carried out in the Union at commercial scale, excluding packaging, quality testing and certification alone. In that event, the test and study results shall be replaced by appropriate bibliographic data, including, where relevant, real-world data generated from use in the Union, and the applicant shall establish a scientific bridge between those data and the medicinal product concerned.

Or. en

Amendment 2937
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 61 a (new)

Text proposed by the Commission	*Amendment*
	Article61a
	Amendments to Regulation (EC) No 469/2009
	Regulation (EC) No 469/2009 is amended as follows:
	1) Article 5 is amended as follows:
	(a) Paragraph (2) is replaced by the following:
	2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ('the certificate holder'), if the following conditions are met:
	(a) the acts comprise:
	(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or

(ii) any related act that is necessary for the making, in the Union, referred to in point (i), or for the actual export; or

(iii) the making of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or

(iv) any related act that is necessary for the making, in the Union, referred to in point (iii), for the actual storing, supplying or placing on the Union market after the expiry of the corresponding certificate or expiry of the basic patent, where no SPC exists .

b) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(c) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).'

(b) Paragraphs (4), (5), (6) and (7) are deleted.

Or. en

Justification

This amendment clarifies and strengthens the SPC manufacturing waiver by ensuring that manufacturers in the Union can produce for export and prepare for timely market entry immediately after SPC or patent expiry. It supports the competitiveness of Union-based generic and biosimilar manufacturers, reduces unnecessary delays in patient access to more affordable medicines, and contributes to supply security in the Union, while maintaining appropriate safeguards for certificate holders.

Amendment 2938

Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 61 a (new)
Regulation (EC) No 469/2009
Article 5

Text proposed by the Commission	*Amendment*
	Article61a
	Article 61a
	Amendment to Regulation (EC) 469/2009
	Regulation (EC) No 469/2009 is amended as follows:
	1. Article 5 is amended as follows:
	Effects of the certificate:
	1. Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.
	2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ('the certificate holder'), if all of the following conditions are met:
	a. the acts comprise any of the following:
	i. the making of a product, or a medicinal product containing that product, for the purpose of (1) export to third countries (2) storing it in the Union, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate, or (3) supplying and/or placing it on the market of a Member State where the certificate does not exist or has expired;
	ii. any related act that is necessary for the making, in the Union, referred to in point (i), or for the actual export, or for the actual storing, or for the actual supplying and placing on the market of a Member State where the certificate does not exist

or has expired.

3. Parafraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the union excludively for the purpose of repackaging, re-exporting or storing.

6. The maker shall ensure that medicinal products made pursuant to point a. (i) do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161

2. Recitals 49, 50, 52 of the Council Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products, as amended by Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019, shall be deleted.

Or. en

Amendment 2939
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 61 a (new)

Text proposed by the Commission	*Amendment*
	Article61a
	Amendment to Regulation (EU) …/… [reference to be added after adoption cf. COM (2023) 193 final]
	Amendment to Regulation (EU) …/… [reference to be added after adoption cf. COM (2023) 193 final]
	Regulation (EU) …/… [reference to be added after adoption cf. COM (2023) 193 final] is amended as follows:
	'Article 6a
	In cases where, at the time of submission

of the marketing authorisation application, no reference medicinal product is or has been authorised or if a reference medicinal product has been authorised but is not available on the market within the Union for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(1) of this Regulation and Article 6(2) [revised Directive 2001/83/EC], not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product:

a) have been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II and

b) have been included in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM (2023) 193 final]

c) are manufactured as part of a strategic project referred to in Article 5(1)(a) of Regulation (EU) …/… [reference to be added after adoption, cf. COM(2025) 102 final] or at least one key manufacturing step relating to the production of the active substance or the finished biological medicinal product is carried out in the Union at commercial scale, excluding packaging, quality testing and certification alone;

In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature, and the applicant shall establish a scientific bridge between the bibliographic data and the medicinal product concerned."

Or. en

Justification

A special centralised registration pathway for long-established, critical biological medicinal products would strengthen medicinal security across the EU. Some products on the Union list of critical medicines have proven safety and efficacy and were authorised nationally before Regulation 726/2004 created the centralised procedure. Requiring full centralised dossiers for such well-known therapies is disproportionate: it imposes major costs, causes delays and may require studies that add no real scientific or therapeutic value. At the same time, EU law offers no meaningful procedural or financial incentives for marketing authorisation holders to expand these products to all Member States. This discourages wider distribution and leaves supply fragmented. If a medicine is authorised only in a few Member States, disruption at a sole supplier may prevent rapid EU-wide redistribution. A simplified EMA pathway, based on well-established use, literature evidence and historical clinical experience, would remove barriers, align data requirements with long-documented use and improve availability of strategically important products.

Amendment 2940
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 61 a (new)

Text proposed by the Commission	*Amendment*
	Article61a
	Amendment to Regulation (EC) No 469/2009
	Article 61a Amendment to Regulation (EC) No 469/2009 Regulation (EC) No 469/2009 is amended as follows: 1) Article 5 is amended as follows: (a) Paragraph (2) is replaced by the following: '2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ('the certificate holder'), if the following conditions are met: (a) the acts comprise: (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or (ii) any related act that is necessary for the making, in the Union, referred to in point (i), or for the actual export; or (iii) the making of a product, or a medicinal product containing that

product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or (iv) any related act that is necessary for the making, in the Union, referred to in point (iii), for the actual storing, supplying or placing on the Union market after the expiry of the corresponding certificate or expiry of the basic patent, where no SPC exists. (b) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging; (c) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).' (b) Paragraphs (4), (5), (6) and (7) are deleted

Or. en

Justification

Support JURI SPC Waivber for biosimilars

Amendment 2941
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 61 a (new)

Text proposed by the Commission	*Amendment*
	Article61a
	Amendments to Regulation (EC) No 469/2009
	Regulation (EC) No 469/2009 is amended as follows: 1) (a) Article 5 is amended as follows: Paragraph (2) is replaced by the

following:

'2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ('the certificate holder'), if the following conditions are met:

(a) the acts comprise:

(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or

(ii) any related act that is necessary for the making, in the Union, referred to in point (i), or for the actual export; or

(iii) the making of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or

(iv) any related act that is necessary for the making, in the Union, referred to in point (iii), for the actual storing, supplying or placing on the Union market after the expiry of the corresponding certificate or expiry of the basic patent, where no SPC exists.

(b) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(c) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).'

b) Paragraphs (4), (5), (6) and (7) are

deleted.

Or. en

Amendment 2942
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 61 a (new)
Directive 2001/83/EC
Directive 2001/83/EC

Text proposed by the Commission	*Amendment*
	Article61a
	Amendment to [revised Directive 2001/83/EC)
	[Revised Directive 2001/83/EC] is amended as follows:
	In Article 74, the following Paragraph 4a is inserted:
	(4a) The official language obligation referred to in Articles 74.1 and 74.3 shall not apply in the following cases:
	(a) in the context of a public health emergency;
	(b) to facilitate access to medicines for which there is low demand, including medicinal products for paediatric use. In these cases, a single commonly understood language may be used in the Union, without prejudice to the patients' right to a printed copy of the package leaflet in the official language or official languages of the relevant Member State upon request and free of charge.

Or. en

Justification

The removal of the requirement for an official language (of the Member State where the product is placed) to facilitate access to certain products with expected low demand, or in public health emergencies, in addition to the electronic product information, would improve the availability of these medicines and facilitate their flexible reallocation between Member

States. These language exemptions would be consistent with the scenarios provided under art. 75 [of the revised Directive 2001/83/EC] that provides for exemptions from requirements of particulars for the labelling and package leaflet.

During the COVID-19 pandemic, this concept proved to be very efficient in addressing availability concerns, enabling specifically flexibility in (re)distribution, therefore having a positive impact on availability of medicines.

Beyond emergencies, this concept would also be useful to facilitate access to medicines for which there is notably limited demand, in particular for small populations such as medicines for paediatric use, or in small markets. This would help ensure that medicines are supplied where they are actually needed by patients. This would also avoid that products are unnecessarily kept in stock under stockpiling or contingency stock requirements in countries where there may be very limited or even no demand.

This proposed amendment shall be read in conjunction with the EU Pharma Package's objective of introducing electronic product information (ePI) so that patients would have access to ePI in their national languages.

Amendment 2943
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – title

Text proposed by the Commission	*Amendment*
Evaluation	Evaluation ***and review***

Or. en

Amendment 2944
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 63 – paragraph 1

Text proposed by the Commission	*Amendment*
1. No sooner than [insert date, five years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a	1. No sooner than [insert date, five years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a

report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective.	report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective ***and, in particular, on:***
	a) the extent to which strategic projects and high impact strategic projects recognised under this Regulation have delivered tangible added value for patients, in terms of availability, accessibility and affordability of the resulting health technologies;
	b) the environmental and biosafety impact of biotechnology products and processes supported under this Regulation across their lifecycle, including risks related to biodiversity and the management of biotechnological waste and by-products;
	c) the evolution of disparities in patient access across Member States since the application of this Regulation, compared with the situation prior to its application, including differences in the time to reimbursement, the geographical distribution of clinical trial sites, and access to innovative health biotechnology solutions;
	d) the effectiveness of the transparency and reporting obligations applicable to beneficiaries of financial support under this Regulation, including the extent to which information on public funding and associated public interest commitments has been made available to the public.
	Or. en

Amendment 2945
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 63 – paragraph 1

Text proposed by the Commission	*Amendment*
1. No sooner than [insert date, five years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective.	1. No sooner than [insert date, five years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective. ***That evaluation shall include an assessment of the Regulation's impact on competitiveness, regulatory burden, time-to-market, clinical trials conducted in the Union, investment, manufacturing capacity, SMEs, start-ups and scale-ups, patient access, intellectual property incentives, Member State competences and duplication with existing Union legislation.***

Or. en

Amendment 2946
Sirpa Pietikäinen

Proposal for a regulation
Article 63 – paragraph 1

Text proposed by the Commission	*Amendment*
1. No sooner than [insert date, five years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective.	1. No sooner than [insert date, five years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]***, and the extent to which this Regulation has supported cross-cutting enabling fields, including immunology and inflammation, that underpin the development of biological medicines, immunotherapies, vaccines, advanced therapies and immunodiagnostics,*** and present a report

	on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective.

Or. en

Justification

This remains within evaluation of the Regulation's own effects. Its purpose is to ensure that the Act's impact is assessed not only by general competitiveness indicators, but also by whether it has strengthened the scientific and translational capabilities needed for advanced health biotechnology.

Amendment 2947
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***No sooner than*** [insert date, ***five*** years after the date of entry into application of this Regulation...], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective.	1. ***By*** [insert date, ***three*** years after the date of entry into application of this Regulation...]***, and every five years thereafter***, the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective. ***That evaluation shall assess, in particular,***

Or. en

Amendment 2948
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation

Article 63 – paragraph 1 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) the impact of this Regulation on the acceleration, simplification and coordination of clinical trials in the Union;

Or. en

Amendment 2949
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) remaining regulatory and administrative fragmentation between Member States and the potential necessity for further Union-level coordination and convergence;

Or. en

Amendment 2950
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point c (new)

Text proposed by the Commission	*Amendment*
	(c) the impact of supplementary protection certificate extensions, including their impact on genuine innovation, investment in the Union, SMEs and public research actors, medicine prices, public and private healthcare expenditure, timely availability and affordability of medicines, security of supply, the entry of generics and

biosimilars;

Or. en

Amendment 2951
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point d (new)

Text proposed by the Commission	*Amendment*
	(d) the geographical balance of biotechnology capacities across the Union

Or. en

Amendment 2952
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point e (new)

Text proposed by the Commission	*Amendment*
	(e) Union and international developments in biosecurity, biosafety and bioterrorism-related risks;

Or. en

Amendment 2953
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point f (new)

Text proposed by the Commission	*Amendment*
	(f) the financial incentives and recognition of strategic projects on the

footprint of the biotechnological industry in the Union;

Or. en

Amendment 2954
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point g (new)

Text proposed by the Commission	*Amendment*
	(g) progress in the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies,

Or. en

Amendment 2955
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 1 – point h (new)

Text proposed by the Commission	*Amendment*
	(h) the uptake and effectiveness of Treaty-based coordination instruments, including the Open Method of Coordination, enhanced cooperation and mutual recognition or mutual reliance, where compatible with Union law; and

Or. en

Amendment 2956
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation

Article 63 – paragraph 1 – point i (new)

Text proposed by the Commission	*Amendment*
	(i) progress against the following key performance indicators, in particular:
	– the Union's number and share of multinational clinical trials, taking into account progress towards relevant Union-level clinical trial targets, including the 2030 targets. share of global commercial clinical trials;
	– the average authorisation timeline for multinational clinical trials;
	– the level of venture capital investment in health biotechnology in the Union;
	– the number of Union biotechnology initial public offerings on European stock exchanges;
	– the number of Member States in which advanced therapy medicinal products are accessible within twelve months of the granting of a marketing authorisation;
	– the number of patients accessing cross-border healthcare for rare disease therapies;
	– the number of operational advanced therapy medicinal product coordination units in the Union; and
	– the number of operational biotechnology development accelerators.

Or. en

Amendment 2957
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 63 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The report shall cover, as a minimum:

(a) the effects of the supplementary protection certificate extension provided for in Chapter IV on the timing of market entry of biosimilar and generic medicinal products and on prices and reimbursement of biotechnology-derived medicinal products and advanced therapy medicinal products in the Member States;

(b) the contribution of health biotechnology strategic projects and high-impact health biotechnology strategic projects to addressing unmet medical needs and to improving patient-relevant clinical benefit, in particular in chronic-disease areas where biotechnology-derived medicinal products represent a primary or essential treatment;

(c) disparities in patient access to biotechnology-derived medicinal products and advanced therapy medicinal products between Member States, including time-to-reimbursement, geographic concentration of trial sites and access to advanced therapy infrastructures;

(d) the implementation of the binding access undertakings referred to in Article 27(1), point (e), and the cases, if any, of revocation of the supplementary protection certificate extension under that provision.

Or. en

Justification

The Commission has elected not to accompany this proposal with a formal impact assessment, on the ground of urgency. The consequence is that a Regulation introducing major new industrial incentives (the supplementary protection certificate extension, strategic project status and the EU Health Biotechnology Investment Pilot) is being adopted without prior analysis of its likely effects on the access, affordability and continuity of supply of medicines on which 34 million persons living with diabetes, and many millions more living with other chronic conditions, depend daily. The five-year evaluation foreseen in Article 63 is therefore the principal instrument through which those effects will be measured, documented and, where necessary, corrected; it must be drafted accordingly.This amendment expands the existing five-year evaluation, in order to ensure that the patient-relevant effects of this Regulation are treated as a measure of whether it has achieved its stated objective and not as a subsidiary annex. Establishing a separate report would have carried the risk of those effects being deprioritised over time or treated as informational; integrating them into the principal

evaluation gives them the same legal and political weight as the rest of the assessment. The amendment is structured around four specific and measurable indicators, a procedural consultation requirement, and the standard legislative-proposal hook used elsewhere in Union law.

Amendment 2958
Kateřina Konečná

Proposal for a regulation
Article 63 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The report shall cover, as a minimum:
	(a) the effects of the supplementary protection certificate extension provided for in Chapter IV on the timing of market entry of biosimilar and generic medicinal products and on prices and reimbursement of biotechnology-derived medicinal products and advanced therapy medicinal products in the Member States;
	(b) the contribution of health biotechnology strategic projects and high-impact health biotechnology strategic projects to addressing unmet medical needs and to improving patient-relevant clinical benefit, in particular in chronic-disease areas where biotechnology-derived medicinal products represent a primary or essential treatment;
	(c) disparities in patient access to biotechnology-derived medicinal products and advanced therapy medicinal products between Member States, including time-to-reimbursement, geographic concentration of trial sites and access to advanced therapy infrastructures;
	(d) the implementation of the binding access undertakings referred to in Article 27(1), point (e), and the cases, if any, of revocation of the supplementary protection certificate extension under that provision.

Or. en

Amendment 2959
Christine Anderson

Proposal for a regulation
Article 63 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. In its evaluation, the Commission shall assess whether this Regulation has produced a general reduction of administrative burdens for biotechnology undertakings, in particular SMEs, start-ups and scale-ups, or whether its benefits have been concentrated among incumbent operators, recipients of Union funding or projects favoured by administrative discretion. The evaluation shall include recommendations for further replacing project-specific privileges with generally applicable simplification measures.

Or. en

Amendment 2960
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Member States shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.	2. The Member States***, relevant Union agencies and bodies, and, where appropriate, beneficiaries of support under this Regulation,*** shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.

Or. en

Amendment 2961
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 63 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where the evaluation or targeted review identifies major shortcomings, unjustified administrative burdens, negative impacts on affordability or access to medicines, persistent fragmentation or significant implementation gaps between Member States, the Commission shall, where appropriate, submit legislative or non-legislative measures to address those shortcomings without delay.

Or. en

Amendment 2962
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 63 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. For the purposes of the evaluation referred to in paragraph 1, the Commission shall consult relevant stakeholders, including patient organisations, healthcare professionals, civil society organisations and public health bodies.

Or. en

Amendment 2963
Kateřina Konečná

Proposal for a regulation
Article 63 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The report shall be drawn up in consultation with patient organisations and healthcare-professional associations operating at Union level and shall be published in full.

Or. en

Amendment 2964
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 63 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The report shall be drawn up in consultation with patient organisations and healthcare professional associations operating at Union level and shall be published in full

Or. en

Amendment 2965
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 63 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Where the report referred to in paragraph 1 identifies that the objectives referred to therein have not been achieved, the Commission shall, where appropriate, accompany that report with a legislative proposal to review the relevant provisions of this Regulation.

Or. en

Amendment 2966
Kateřina Konečná

Proposal for a regulation
Article 63 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Commission shall, where appropriate, accompany the report referred to in paragraph 1 with a legislative proposal.

Or. en

Amendment 2967
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 65 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall adopt implementing acts, following a consultation wit relevant stakeholders including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and industry representatives.

Or. en

Amendment 2968
Monika Beňová

Proposal for a regulation
Article 66 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. When assisting the Commission under this Regulation, the Standing

Committee on Biotechnology shall act in a manner that supports timely implementation, avoids unnecessary administrative burden, and takes due account of the needs of SMEs, start-ups and scale-ups.

Or. en

Justification

Emerging biotechnology markets that are AI enabled are highly competitive and fast moving, it is important to create conditions in the EU that promote fast pace innovation. European union has the potential to compete only if the bureaucratic process enables not stifles start up culture, while maintaining ethical and legal norms.

Amendment 2969
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 66 a (new)
Regulation 726/2004
Regulation 726/2004

Text proposed by the Commission	*Amendment*
	Article66a
	Consistency with Union medicinal products legislation
	For the purposes of the evaluation of an application for a marketing authorisation in accordance with [revised Regulation 726/2004] and [revised Directive 2001/83/EC], the competent authorities of the Member States and the Agency shall take due account of assessments performed pursuant to Regulation (EU) No 536/2014 and shall ensure consistency between such assessments and the evaluation of the application for a marketing authorisation.

Or. en

Justification

Without changing the respective roles of the Clinical Trials Regulation and the Union pharmaceutical legislation (the revised GPL), this amendment ensures consistency between the two complementary regulatory frameworks governing the entire lifecycle of a medicine. Where, during the clinical trial evaluation process, regulators have already assessed the applicability of clinical data generated outside the Union to the Union population and normal clinical practice in the Union, those findings should inform subsequent marketing authorisation assessments. This avoids duplication of regulatory work and ensures efficiency and regulatory coherence, and improves legal certainty.

Amendment 2970
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex I – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
Molecules of polymeric nucleic acids that have been synthesized de novo ***(without template)***, including single- or double-stranded RNA or DNA that is at least 50 nucleotides in length, or the corresponding amino acid sequence of at least 17 amino acids, and meets at least one of the following criteria:	Molecules of polymeric nucleic acids that have been synthesized de novo, including single- or double-stranded RNA or DNA that is at least 50 nucleotides in length, or the corresponding amino acid sequence of ***that contributes to the pathogenic or toxic hazards from of*** at least 17 amino acids, and meets at least one of the following criteria:

Or. en

Amendment 2971
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex I – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) is an exact match or best match to a sequence of an agent listed on internationally recognised control lists that is either (i) specific to any listed virus or (ii) specific to any listed bacterium that, in itself or through its transcribed or	(a) is an exact match or best match to a sequence of an agent listed on internationally recognised control lists that is either (i) specific to any listed virus or (ii) specific to any listed bacterium ***or (iii) specific to any listed toxin*** that, in itself or

translated products represents a significant hazard to human, animal or plant health. This criterion shall exclude cases where the matched sequence is a non-harmful element demonstrably present in an unregulated agent, including housekeeping genes without pathogenic function;	through its transcribed or translated products represents a significant hazard to human, animal or plant health. This criterion shall exclude cases where the matched sequence is a non-harmful element demonstrably present in an unregulated agent, including housekeeping genes without pathogenic function;

Or. en

Amendment 2972
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex I – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	For the purposes of this Section, the following nucleic acid sequences shall not be considered sequences of concern:
	(i) where the economic operator demonstrates, in accordance with guidance issued pursuant to Article 54, that the encoding or design method by which the sequence was generated is incapable of generating a sequence meeting the criteria in points (a) to (c).
	(ii) nucleic acids with sequences that meet the criteria in points (a) to (c) that are contained in end-use formulations that would significantly limit their potential to cause harm or misuse, such as positive control nucleic acids for polymerase chain reaction–based diagnostic test kits or nucleic acids components of vaccines or therapeutics.

Or. en

Amendment 2973
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
Regulation (EU) 536/2014
Annex

Text proposed by the Commission	*Amendment*
Annex I	Annex I
	The application dossier shall be submitted through the EU portal using harmonised formats and templates. Information submitted in accordance with this Annex shall not be requested again by Member States concerned in a different format or under a different heading, unless duly justified for reasons of subject safety, data protection, ethics review or national, local or site-specific requirements under Part II.

Or. en

Amendment 2974
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
(EU) 536/2014
Annex I Section B

Text proposed by the Commission	*Amendment*
	(fa) whether New Approach Methodologies have been used, and, where they have not been used, a short justification of the scientific or methodological reasons for their non-use;

Or. en

Amendment 2975
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
(EU) 536/2014
Annex I Section D

Text proposed by the Commission	*Amendment*
	(ca) a statement on the use or non-use of New Approach Methodologies to support the clinical trial design, including risk assessment, dose selection, patient stratification, endpoint selection, safety monitoring or the reduction of unnecessary animal use; where such methodologies have not been used, the sponsor shall provide a brief scientific or methodological justification for their non-use;

Or. en

Amendment 2976
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Annex II – paragraph 1 – point 1
Reg 539/2014
Annex I

Text proposed by the Commission	*Amendment*
(h) a description of the groups and subgroups of the subjects participating in the clinical trial, including, where relevant, groups of subjects with specific needs, for example***. age, gender, participation of healthy volunteers***, subjects with rare and ultra rare diseases;	(h) a description of the groups and subgroups of the subjects participating in the clinical trial, including, where relevant, groups of subjects with specific needs, for example, subjects with rare and ultra rare diseases;

Or. en

Amendment 2977
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation

Annex II – paragraph 1 – point 1
(EU) 536/2014
Annex I Section D ka new

Text proposed by the Commission	*Amendment*
	(ka) for multinational clinical trials, a concise Union-level trial delivery plan covering trial sites, recruitment strategy, patient identification pathways, use of relevant clinical networks, including European Reference Networks and other cross-border health networks where appropriate, or registries, expected recruitment timelines and measures to ensure consistent implementation across Member States;

Or. en

Amendment 2978
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
(EU) 536/2014
Annex I Section D point s

Text proposed by the Commission	*Amendment*
(s) a description of the arrangements to comply with the applicable rules for the collection, storage and future use of biological samples from clinical trial ***subjects***, where applicable, unless contained in a separate document;	(s) a description of the arrangements to comply with the applicable rules for the collection, storage and future use of biological samples from clinical trial ***participants***, where applicable, unless contained in a separate document;

Or. en

Amendment 2979
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Annex II – paragraph 1 – point 1
Reg 536/2014

ANNEX 1

Text proposed by the Commission	*Amendment*
(y) a justification for the ***gender and*** age allocation of subjects and, if a specific ***gender or*** age group is excluded from or underrepresented in the clinical trials, an explanation of the reasons and justification for these exclusion criteria;	(y) a justification for the age allocation of subjects and, if a specific age group is excluded from or underrepresented in the clinical trials, an explanation of the reasons and justification for these exclusion criteria;

Or. en

Amendment 2980
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Annex II – paragraph 1 – point 1
Reg 536/2014
Annex I

Text proposed by the Commission	*Amendment*
	(ya) a dedicated section on sex and gender considerations, including:
	(a) the planned distribution of subjects by sex and, where relevant, by gender identity, with reference to the epidemiology and expected use of the medicinal product; (b) an explanation of the reasons and justification for any exclusion or under-representation of women or men, and of women of child-bearing potential; (c) plans for sex-stratified and, where feasible, sex-by-age interaction analyses of efficacy and safety endpoints; (d) specific measures for the inclusion, protection and follow-up of pregnant and breastfeeding women where they are included in the trial.

Or. en

Amendment 2981
Stine Bosse, Katri Kulmuni, Billy Kelleher, Martin Hojsík

Proposal for a regulation
Annex II – paragraph 1 – point 1
Regulation (EU) 536/2014
ANNEX II

Text proposed by the Commission	*Amendment*
	(ya) a dedicated section on sex considerations, including:
	(a) the planned distribution of subjects by sex and, with reference to the epidemiology and expected use of the medicinal product;
	(b) an explanation of the reasons and justification for any exclusion or under-representation of women or men, and of women of child-bearing potential;
	(c) plans for sex-stratified and, where feasible, sex-by-age interaction analyses of efficacy and safety endpoints;
	(d) specific measures for the inclusion, protection and follow-up of pregnant and breastfeeding women where they are included in the trial.

Or. en

Amendment 2982
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
(EU) 536/2014
Annex I Section G

Text proposed by the Commission	*Amendment*
41. The IMPD shall also contain summaries of non-clinical pharmacology and toxicology data for any investigational medicinal product used in the clinical trial in accordance with international guidance. It shall contain a reference list of studies conducted and appropriate literature references. Wherever appropriate, it is	41. The IMPD shall also contain summaries of non-clinical pharmacology and toxicology data for any investigational medicinal product used in the clinical trial in accordance with international guidance***, including, where scientifically appropriate, data generated through validated New Approach Methodologies***.

preferable to present data in tabular form accompanied by a brief narrative highlighting the main salient points. The summaries of the studies conducted shall allow an assessment of the adequacy of the study and whether the study has been conducted according to an acceptable protocol.	It shall contain a reference list of studies conducted and appropriate literature references. Wherever appropriate, it is preferable to present data in tabular form accompanied by a brief narrative highlighting the main salient points. The summaries of the studies conducted shall allow an assessment of the adequacy of the study and whether the study has been conducted according to an acceptable protocol.

Or. en

Amendment 2983
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
(EU) 536/2014
Annex I Section G

Text proposed by the Commission	*Amendment*
43. The IMPD shall provide a critical analysis of the data, including justification for omissions of data, and an assessment of the safety of the product in the context of the proposed clinical trial rather than a mere factual summary of the studies conducted.	43. The IMPD shall provide a critical analysis of the data, including justification for omissions of data***, a statement on the use or non-use of New Approach Methodologies and, where such methodologies have not been used, a brief scientific or methodological justification for their non-use***, and an assessment of the safety of the product in the context of the proposed clinical trial rather than a mere factual summary of the studies conducted.

Or. en

Amendment 2984
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Annex II – paragraph 1 – point 1
(EU) 536/2014

Annex I Section J Part II

Text proposed by the Commission	*Amendment*
Without prejudice to Article 26 and Article 69 concerning translations of part I documents, the application dossier for an application limited to Part II of the assessment report referred to in Article 11 and the application dossier for an application referred to in Article 14 shall be limited to sections K to S of this Annex.	Without prejudice to Article 26 and Article 69 concerning translations of part I documents, the application dossier for an application limited to Part II of the assessment report referred to in Article 11 and the application dossier for an application referred to in Article 14 shall be limited to sections K to S of this Annex. ***Where documents submitted under Part II contain elements common to more than one Member State concerned, the sponsor may submit a harmonised core document accompanied, where necessary, by national, local or site-specific annexes. Member States concerned shall not require separate full documents where the same objective can be achieved through such annexes.***

Or. en

Amendment 2985
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Annex III a (new)

Text proposed by the Commission	*Amendment*
	ANNEX [IV] ***Minimum elements of the access plan referred to in Article 14(1)*** ***The access plan shall be appropriate and proportionate to the nature and stage of development of the project. It shall demonstrate the strategies of the project promoter to ensure that the products and services developed based on, or partly based on, the results of the supported activities are affordable, available and accessible to the public at fair and reasonable conditions. The access plan shall include at least the following***

elements:

(a) registration targets: the countries or regions in which the promoter intends to seek marketing authorisation or regulatory approval for the resulting products, including, where relevant, strategies to expedite registration in Member States and, where the products address significant public health needs, in low- and middle-income countries;

(b) plans to meet demand: strategies to ensure sufficient and continuous supply of the resulting products, including production capacity, supply chain resilience, and measures to avoid stockouts or shortages;

(c) approaches to pricing and affordability: a description of the broad approach to pricing that reflects ability to pay and ensures that economic barriers to access are low;

(d) intellectual property strategy: an explanation of how the promoter will ensure that intellectual property rights do not constitute a barrier to access, including, where relevant, plans to explore licensing arrangements, technology transfer, or collaboration with third parties such as non-profit product development partnerships;

(e) engagement with regulators and manufacturers: a description of plans to engage with regulatory authorities and manufacturers, in particular in low- and middle-income countries, where the products address significant public health needs in those countries;

(f) global access: where the resulting products address significant public health needs in third countries in critical need, the measures the promoter intends to adopt to facilitate access in those countries, including through development partners, voluntary licensing, or other arrangements that ensure supply at fair and reasonable conditions.

The access plan shall be submitted as part of the application for recognition as a health biotechnology strategic project or for access to financial support under this Regulation, and shall be updated upon any significant change in the product's development or market conditions. The Commission shall issue guidelines specifying the content and format of the access plan.

"Project promoters shall use their best efforts to ensure that the resulting health biotechnology products and services are broadly available and accessible, as soon as possible and at fair and reasonable conditions, for up to four years after the end of the supported activity.

In case a project promoter cannot fulfil the preceding obligation, the project promoter must, if requested by the granting authority, grant non-exclusive licences — under fair and reasonable conditions — to legal entities that commit to rapidly and broadly exploiting the resulting health biotechnology products and services and ensuring that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions.

In case of transfer of the ownership or licensing of results, project promoters must pass on the obligations set out in this Annex to the legal entities exploiting the results.

The granting authority shall be informed annually of the status of development and exploitation of the results until the expiration of the last applicable period of data protection, market exclusivity or patent protection in the Union relating to the resulting products, or for eight years after the end of the supported activity, whichever is late

Or. en