Council of the European Union

Brussels, 8 July 2026
(OR. en)

11244/26

Interinstitutional File: 2025/0404 (COD)

LIMITE

SAN 554
PHARM 122
MI 719
COMPET 890
CODEC 1334

PUBLIC

WORKING DOCUMENT

From:	Presidency
To:	Delegations
No. prev. doc.:	7254/26; 7253/26
No. Cion doc.:	16919/25 + ADD 1
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- Exchange of views*

Delegations will find in Annex the first Presidency compromise text on Clusters 3 and 4 – block 2 (Clinical evidence, clinical evaluation, clinical investigations, non-clinical data, clinical data, SS(C)P, PMCF, combined studies and technical documentation) to be discussed at the meetings of Working Party on Pharmaceuticals and Medical Devices on 15-16 July 2026.

Changes compared to the Commission proposal are indicated in ~~strikethrough~~ for deletions and **bold** for new text. Text from the MDR or IVDR not included in the Commission proposal and added to this compromise text is indicated in *italics*. Changes to that text are indicated in ~~*strikethrough*~~ for deletions and ***bold*** for new text.

ANNEX

PUBLIC

Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(…)

(2) Article 2 is amended as follows:

(…)

‘(48) ‘clinical data’ means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following:

- clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other studies published in **peer-reviewed** scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;’

(e) the following points (72), (73), (74), (75) and (76) are added:

(…)

‘(73) ‘combined study’ means a clinical trial, as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, ~~of~~**concerning** one or more medicinal products, combined with a performance study of one or more in vitro diagnostic medical devices as defined in Article 2, point (42), of Regulation (EU) 2017/746,

and/or with a clinical investigation of one or more devices **as defined in Article 2, point (45) of this Regulation**;'

(24) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For class IIb implantable devices and for class III devices, other than custom-made or investigational devices and well-established technology devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52. The manufacturer shall ensure that the summary of safety and clinical performance is available in Eudamed as part of the information on the device to be provided pursuant to Article 29(1) and mention on the label or instructions for use where that summary is available.';

(b) in paragraph 2, point (h) is replaced by the following:

'(h) information on any residual risks or undesirable effects, and any warnings and precautions.';

(52) Article 61 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

'1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to**, at least,** confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and ~~shall~~ evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

PUBLIC

The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose~~, taking into consideration paragraph 10~~.

The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.';

(b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following:

'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:';

(c) paragraph 5 is replaced by the following:

'5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation**, the manufacturer has sufficient access to relevant information on the design, materials and the clinical evaluation of the equivalent device,** and the manufacturer provides clear evidence thereof to the notified body.';

(d) paragraph 6 is amended as follows:

(i) the introductory wording is replaced by the following:

'The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable class IIb devices and class III devices:';

(ii) point (b) is replaced by the following:

'(b) that are well-established technology devices for which the clinical evaluation is based on sufficient clinical evidence and is in compliance with the relevant product-specific CS **or harmonised standards**, where ~~such CS are~~ available**, provided that the manufacturer sets in place appropriate specific PMCF activities to ensure early systematic monitoring of the clinical safety and performance of the devices under real world conditions**;'

(e) paragraph 8 is deleted;

(f) paragraphs 10 and 11 are replaced by the following:

'10. Without prejudice to paragraph 4, where the confirmation of safety and performance based on clinical data is not deemed appropriate, adequate justification **for any such exception** shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer and the data available for the generic device group. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, in vitro, ex vivo, in silico testing, computational mode**l**ling or simulation and pre-clinical evaluation, to be adequate.

11. The clinical evaluation, its documentation and, where applicable and needed, the summary of safety and **clinical** performance referred to in Article 32 shall be updated throughout the life cycle of the device concerned with data and findings obtained from the implementation of the manufacturer's PMCF plan in

accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84, whenever those data and findings ~~obtained from PMCF~~ provide information relevant for the confirmation of safety and performance of the device. **For Class IIb implantable and Class III devices, these shall be updated at least every two years.';**

(g) paragraph 12 is deleted;

(h) the following paragraph 14 is added:

'14. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annex XIV in order to adapt it to technical and scientific progress and developments at international level, having due regard to the protection of the health and safety of patients, users or other persons and other aspects of public health.';

PUBLIC

(53) ~~in~~ Article 62~~, the introductory wording is replaced by the following~~ **is amended as follows**:[1]

(a) The title is replaced by the following:

'*General requirements regarding* ***certain*** *clinical investigations* ***of devices that have not been placed on the market or put into service'*****;**

(b) In paragraph 1, the introductory wording is replaced by the following:

'Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of this Article, of Articles 63 to 73 and of Articles 75 to 80, the acts adopted pursuant to Article 81, and Annex XV, where they are carried out to assess an investigational device that has not been placed on the market or put into service in accordance with this Regulation and where carried out for one or more of the following purposes:';

(c) In paragraph 1, points (a), (b) and (c) are replaced by the following:

'(a) to ***assess,*** *establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2, and achieves the performance intended as specified by its manufacturer;*

(b) to ***assess,*** *establish and verify the clinical benefits of a device as specified by its manufacturer;*

(c) to ***assess,*** *establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and*

---

[1] The Presidency suggests adding the following recital: 'To ensure that clinical investigations accurately represent the target population in all its diversity, and to enhance the medical devices available for vulnerable populations, medical devices which are likely to offer significant clinical benefit should be fully and appropriately studied in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical investigations. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.'

PUBLIC

assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.'

(54) in Article 64(1), point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved

(ii) ~~a~~**some** benefit for the population represented by the incapacitated subject ~~provided that~~**concerned when** the clinical investigation ~~poses~~**relates directly to the life-threatening or debilitating medical condition from which the subject suffers and such clinical investigation will pose** only minimal risk to, and ~~imposes~~**will impose** minimal burden on, the incapacitated subject **concerned** in comparison with the standard treatment of the subject's condition.';

(55) in Article 65, point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the minor subject outweighing the risks and burdens involved;

(ii) ~~a~~**some** benefit for the population represented by the minor subject ~~provided that the~~**concerned and such a** clinical investigation will pose only minimal risk to, and will impose minimal burden on, the minor subject in comparison with the standard treatment of the subject's condition.';

(56) in Article 66, point (a) is replaced by the following:

'(a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved, or if the clinical investigation has not the potential to produce such direct, the following conditions are met:

(i) a clinical investigation of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the clinical investigation contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction, or other embryos, foetuses or children;

(iii) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth.';

(57) ~~in Article 68(1), point (b) is replaced by the following:~~

'(b) ~~there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce either of the following:~~

(i) ~~a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;~~

(ii) ~~a benefit for the population represented by the subject provided that the clinical investigation will pose only minimal risk to, and will impose minimal burden on, the subject in comparison with the standard treatment of the subject's condition;';~~

(58) in Article 72, the following paragraph 7 is added:

'7. The processing of personal data in the context of a clinical investigation, including the secondary use of personal data initially collected for other investigations, shall be deemed to be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679**, without prejudice to the obligations and requirements set out in that Regulation**.';

(58a) In Article 73, paragraph 3, point (a) is replaced by the following:

'(a) protection of personal data in accordance with Regulation ***(EU) 2018/1725*** *~~(EC) No 45/2001~~;'*;

(59) in Article 74, paragraph 1 is replaced by the following:

‘1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose and in accordance with its PMCF plan, a device which already bears the CE marking in accordance with Article 20(1), (‘PMCF investigation’), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II, Sections 1, 3 and 4, of Annex XV as part of the notification. Article 62(4), points (b) to (k) and (m), Article 75(1), Articles 76 and 77, Article 80(5) and (6), and the relevant provisions of Annex XV shall apply to PMCF investigations involving additional invasive or burdensome procedures.’;

(60) Article 75 is amended as follows:

(a) in paragraph 1, the first sentence is replaced by the following:

‘If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, it shall notify, by means of the electronic system referred to in Article 73, the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications.’;

(b) paragraph 2 is replaced by the following:

‘2. Where the clinical investigation has been the subject of an authorisation in accordance with Article 62(4), point (a), the Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.

The Member State shall notify the sponsor of the outcome of its assessment within 38 days of receipt of the sponsor’s notification under paragraph 1.

During its assessment, the Member State may request additional information from the sponsor. The period of 38 days shall be suspended from the date of the first request until such time as the additional information has been received.';

(c) in paragraph 3, the introductory wording is replaced by the following:

'The sponsor may implement the modifications referred to in paragraph 1 as soon as the Member State concerned has notified the sponsor of its authorisation or~~, where there is no authorisation, at the earliest 38 days after the notification from the sponsor referred to in that~~ **following expiry of the period defined in** paragraph **2, whichever is sooner**, unless:';

(61) Article 78 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following:

'The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11.';

(b) paragraph 5 is replaced by the following:

'5. Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request. The expiry of the last deadline pursuant to paragraph 4, point (d), shall be suspended from the date of the request until such time as the additional information has been received.';

(c) in paragraph 6, the reference to '50 days' is replaced by '~~20~~**30** days';

(d) the following paragraph 15 is added:

'15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of clinical investigations subject to a coordinated assessment.';

PUBLIC

(62) Article 79 is deleted;

(63) the following Article 79a is inserted:

'Article 79a

Clinical investigations in combined studies

Clinical investigations that are part of combined studies, and which are subject to authorisation in accordance with Article 62, ~~may~~**shall** be carried out in accordance with Article 14c of Regulation (EU) No 536/2014.

~~If the sponsor chooses to apply~~**Where** Article 14c of Regulation (EU) No 536/2014 **applies**, the requirements laid down therein and in any implementing or delegated acts adopted in accordance with that Article shall apply instead of the corresponding requirements laid down in this Regulation.

Member States shall ensure that the assessment of the clinical investigation part of the combined study is done in accordance with the requirements specified in article 71.';

(64) Article 82 is ~~deleted~~**replaced by the following**;

'1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1) ***or Article 74****, shall comply with the provisions of Article 62 (2) and (3), points (b)~~, (c), (d), (f), (h), and~~* ***to*** *(l) of Article 62(4)****, Article 62(5)*** *and Article 62(6).*

2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1) ***or Article 74****, each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.*

3. Article 80 shall apply for clinical investigations of devices conducted in accordance with this Article. Where the device already bears the CE marking in accordance with Article 20(1), the provisions on vigilance laid down in Articles 87 to 90 and in the acts adopted pursuant to Article 91 shall apply instead of Article 80.'

(2) Annex II is amended as follows:

(a) Section 6.1. is amended as follows:

(i) the heading of Section 6.1. is replaced by the following:

‘6.1. Non-clinical, pre-clinical and clinical data;’

(ii) point (a) is replaced by the following:

‘(a) results of tests, such as engineering, laboratory, in vitro, ex vivo, in silico testing, computational mode**l**ling, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;’:

(iii) point (c) is replaced by the following:

‘(c) the clinical evaluation plan, the clinical evaluation report and its updates referred to in Article 61(1) and Part A of Annex XIV.’;

(iv) point (d) is deleted;

(b) Section 6.2. is amended as follows:

(i) in point (b), the first sentence is replaced by the following:

‘(b) Where a device is manufactured utilising substances of human origin or tissues or cells of animal origin, or their derivatives, and is covered by this Regulation in accordance with Article 1(6), points (f) and (g), and where a device incorporates, as an integral part, substances of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with Article 1(10), first subparagraph, a statement indicating this fact.’;

(ii) the following point (h) is added:

‘(h) Where the device incorporates as an integral part an in vitro diagnostic medical device that has an action ancillary to that of the device, as

PUBLIC

referred to in Article 1(7) of this Regulation, the documentation shall include the results of the assessment of the conformity of the in vitro diagnostic medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746 contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the in vitro diagnostic medical device. Where those results of the conformity assessment are not available and where for the conformity assessment of the in vitro diagnostic medical device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/746, an opinion on the conformity of the in vitro diagnostic medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation 2017/746 issued by a notified body designated in accordance with that Regulation for the type of device in question shall be included in the documentation.';

(12) Annex XIV is amended as follows:

(a) Section 1 is amended as follows:

(i) point (a) is amended as follows:

(1) the first indent is replaced by the following:

'- an identification of the general safety and performance requirements that require support from relevant clinical data, or adequate justification that confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10);';

(2) the seventh and eighth indents are replaced by the following:

'- an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable substances of human origin or non-viable animal tissues, are to be addressed;

— where applicable, a clinical development strategy indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B with an indication of milestones and a description of potential acceptance criteria**. Where a clinical development strategy is deemed not applicable, the manufacturer shall provide a justification in the clinical evaluation plan**;';

(2a) Points (b) to (e) are amended as follows:

'(b) identify available clinical data relevant to the device and its intended purpose ~~and any gaps in clinical evidence through a systematic scientific literature review~~;

(c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

(d) ~~generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues;~~ ***analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits and identify any gaps in clinical evidence; and***

(e) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues.'

(ii) the following paragraph is added:

'Points (b) to (e) shall not apply to devices for which confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10).';

(b) in Section 3, the second and third indents are replaced by the following:

‘- Biological: the device uses the same ~~or similar~~ materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

– Clinical: the device is used for the same ~~or similar~~ clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.’;

(c) in Section 5, the following sentence is inserted after the first sentence:

‘Where PMCF is deemed not applicable, the manufacturer shall provide a justification in the post-market surveillance plan as referred to in Section 1 of Annex III.’;

(d) Section 7 is replaced by the following:

‘7. The manufacturer shall analyse the findings of the PMCF and document the results in the clinical evaluation report and the technical documentation.’;

(e) Section 8 is replaced by the following:

‘8. The conclusions of the PMCF shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.’;

(13) Annex XV is amended as follows:

(a) in Chapter I, Section 2.6., the following sentence is added:

‘For combined studies, endpoints reporting on the device and medicinal product together may be used.’;

(b) Chapter II is amended as follows:

(i) Section 1.4. is replaced by the following:

‘1.4. status of the clinical investigation application (i.e. first submission, resubmission, substantial modification);’;

(ii) Section 1.6. is replaced by the following:

‘1.6. If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or, in the case of substantial modification, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews.’;

PUBLIC

Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(…)

(2) Article 2 is amended as follows:

(…)

(d) the following points (72), (73), (74), (75) and (76) are added:

(…)

‘(75) ‘combined study’ means a clinical trial as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, **concerning one or more medicinal products,** combined with a performance study **of one or more in vitro diagnostic medical devices as defined in Article 2, point (42) of this Regulation, or with**~~, and/or~~ a clinical investigation **of one or more devices** as defined in Article 2, point (45), of Regulation (EU) 2017/745;’

PUBLIC