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LIMITE

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Biotech Act)
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency

Delegations will find attached the Presidency flash for the meeting of the Working Party on Pharmaceuticals and Medical Devices on 9-10 July 2026. The draft agenda is set out in CM 3339/26.

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The Presidency intends to hold substantial discussion on the proposed amendments to the Clinical Trials Regulation (CTR) No 536/2014 contained within Article 58 of the Biotech Act (Regulation) on 9 July and 10 July.

In order to facilitate an efficient discussion, delegations are invited to send questions or points for clarification to e[redacted] and [redacted] by 1 July.

Any questions or points for clarification received by 1 July will be shared in advance with the Commission so that they can be addressed during the Working Party meeting.

Subsequent to the meeting Member States will have the opportunity to send proposed amendments on the articles discussed (along with the associated definitions and entries in Annex I of the CTR) until 17 July, please submit concise rationale for these amendments.

Please be advised that the consolidated version of the Clinical Trials Regulation (**wk9270/2026**) may assist Member States with their review of the proposed amendments.

The planning of the meeting is as follows:

July 09 – 10

1. **Adoption of the agenda**

The Presidency will invite delegations to adopt the agenda set out in **CM 3339/26.**

2. **Presidency roadmap**

The Presidency will present a short overview of the schedule for the working party meetings in July on the Biotech Act (Regulation).

3. **Presentation from the Commission**

The Commission will provide a short overview of the experience to date with the FAST EU pilot which is piloting faster timelines and enhanced coordination of the assessment of multinational clinical trial applications.

4. **Biotech Act (Regulation) – Clinical Trials**

Under this agenda item, the WP will review the following sections in the order they appear below. The CION will provide a brief explanation of the rationale for each provision and Member States will then be invited to comment during the meeting:

A. **General principles (including minimal-intervention and low-intervention clinical trials) and authorisation procedures (including special authorisation procedures)**
   - Chapter 9**,** Article 58 - Amendments to Regulation (EU) No 536/2014

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- Point 1 (a), (b)
  - Definitions *3, 3a*
- Point 2-8
  - Articles 3-9
- Point 10-12
  - Articles 11-14a
- Point 13
  - Articles 14b – 14d
    - Delegates should note that the Commission will provide a short overview of the experience to date with the COMBINE pilot together with discussions on Article 14c.
- Point 23
  - Articles 25
- Point 31
  - Article 41(5)
- Point 27
  - Article 30(3)
- Point 32
  - Article 48(a)
- Point 34
  - Article 51(1)
- Points 36 and 40
  - Article 57 and 76(3))

The following definitions will be considered in conjunction with the relevant provisions:

- Chapter 9**,** Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 1 (c) [in part],
    - Definitions *12,*
  - Point 1 (f) [in part]
    - *36, 37, 44, 47*

The following amendments to Annex I of the CTR (as listed in Annex II of the Biotech Regulation) will also be considered in conjunction with the relevant provisions:

- Annex I CTR
  - Part I
    - Point 5 (deletion) – moved to general principle at the start of Part II of the Annex
    - Point 9 Minimal intervention category justification requirement
  - Part II
    - Section S – new section regarding translations

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B. Substantial Modifications and EU database

- Chapter 9, Article 58 - Amendments to Regulation (EU) No 536/2014
  - Points 14 - 22
    - Articles 16-23
  - Point 44(a) and (b)
    - Articles 81(2) & 81(9))

The following definitions will be considered in conjunction with the relevant provisions:

- Chapter 9, Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 1 (c) [in part],
    - *Definitions 13*
  - *Point 1 (d)*
    - *13a*

Delegations are advised that the discussion on the other amendments to the CTR in Article 58 of the Biotech Act (Regulation) will be scheduled for the WPPMD meetings on July 22 and July 23.

Did you know ...

The official logo of the Irish Presidency 2026 features the spiral structure of the nebula.

This was first identified in Ireland in the 1840s using the Great Telescope at Birr Castle.

The pattern is also inspired by Irish sculptural work reflecting a connection with ancient Irish symbols, reinterpreted through a modern lens. Each individual arm of the spiral features 27 discs which symbolise the 27 EU Member States. The resulting space at the centre forms a five-point star, a symbol from the EU flag. Blue, green and orange symbolise both the Irish state and the European Union.

The visual identity of Ireland's Presidency of the Council of the European Union emphasises the interdependence and interconnectedness of all Member States of the EU.

[redacted]

IE PRES Biotech Team