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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 22 and 23 July 2026. The draft agenda is set out in CM 3652/26.

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The Presidency intends to finalise 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 22 July and 23 July.

In order to facilitate an efficient discussion, delegations are invited to send questions or points for clarification to [redacted] and [redacted] by 16July. Questions received will be forwarded to the Commission.

The Presidency's objective is to go through the remaining text of Article 58 on both days to gather comments from Member States. MS will have the opportunity to send written drafting suggestions on the amendments discussed until 28 July.

Please be advised that the consolidated version of he 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 22 and 23

1. **Adoption of the agenda**

The Presidency will invite delegations to adopt the agenda set out in cm03652/26.

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

Under this agenda item, the Presidency will address the following sections in the order they appear below & Member States will be invited to provide comment on these sections during the meeting.

A. IMP core dossier

- Chapter 9**,** Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 24
    - Articles 27a-27c

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 (f) [in part]
    - Definitions 38, 39, 40, 41

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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
  - Section Ga, point 54a - Core dossier
  - Section Gb, point 54b - Possibility to refer to simplified IMPD (including an active substance master file)
  - Table I

B. Regulatory Sandboxes and Use of AI

- Chapter 9**,** Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 24 [in part]
    - Art 27(d) and 27 (e)

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 (f) [in part]
    - Definitions 45, 46

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 17 (aq) – use of AI tool

C. Vulnerable populations, protection of subjects (including data protection) and informed consent

- Chapter 9**,** Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 9
    - Article 10(6)
  - Point 25 - 26
    - Articles 28 and 29(1)
  - Points 28 - 30
    - Article 31(1), 32(1), 33
  - Point 48
    - Article 93

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 (e)
    - Definition 21

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The following amendments to Annex I and Annex II of the CTR will also be considered in conjunction with the relevant provisions:

- Annex I CTR, Part I
  - Point 17 (ap) - consent by electronic means
- Annex II CTR, Part II
  - Point 61 – informed consent – additional sentence relating to consent by electronic means
  - Point 62(f) – informed consent – new point related to electronic informed consent

D. Conduct and supervision of a trial and manufacturing and import of an IMP

- Chapter 9**,** Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 33
    - Article 50a
  - Point 35
    - Article 53(2)
  - Point 37
    - Article 61(a) and (b)
  - Points 38 – 39
    - Articles 63 and 63a
  - Point 41
    - Article 78

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 (f) [in part]
    - Definitions 42, 43

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 12a (decentralised trials)
  - Point 17 (an) to (ao) – direct delivery of medicines to patients

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E. Enforcement and governance

- Chapter 9, Article 58 - Amendments to Regulation (EU) No 536/2014
  - Point 42
    - Article 79
  - Point 43
    - Article 79a
  - Point 45
    - Article 83
  - Point 46
    - Article 83a
  - Point 47
    - Article 85

F. Final provisions

- Chapter 9, Article 58 - Amendments to Regulation (EU) No 536/2014
  - Points 49 - 50
    - Article 97 and 98
  - Point 51
    - Article 98a

DID YOU KNOW ...

The word *shamrock* comes from the Irish *seamróg*, meaning "young clover" or "little clover"?



This bright green, three-leaf plant has been linked with Ireland for centuries and is celebrated worldwide as a joyful emblem of Irish identity, heritage and good fortune. Each year on Saint Patrick's Day, 17 March, millions of people proudly wear shamrocks, transforming this tiny plant into a vibrant global symbol of celebration and pride.

Tradition tells us that Saint Patrick used the shamrock to illustrate the Christian idea of the Holy Trinity as he shared his message across Ireland many centuries ago. Whether history or legend, this story helped weave the shamrock deeply into Irish culture. Today, it can be seen everywhere - from sports jerseys and souvenirs to artwork and national symbols - a cheerful reminder of Ireland's rich traditions.

The shamrock remains one of the most instantly recognisable and warmly cherished symbols of Ireland across the world.