Council of the European Union
General Secretariat

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**Interinstitutional files:**
**2025/0102 (COD)**

**Brussels, 28 April 2026**

**WK 5995/2026 INIT**

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**MEETING DOCUMENT**

| | |
|---|---|
| From: | General Secretariat of the Council |
| To: | Working Party on Pharmaceuticals and Medical Devices (Attachés)<br>Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act) |
| Subject: | Meeting of the Working Party on Pharmaceuticals and Medical Devices<br>- Presentation by the Presidency |

Delegations will find attached the presentation given by the Cyprus Presidency on the Critical Medicines Act at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 28 April 2026.

WP PHARMACEUTICAL AND MEDICAL DEVICES

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# Cyprus Presidency of the Council of the EU

28 April 2026

#cy2026eu

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# ITM 6 – 17/3/2026

1. Follow up Trilogue 16.03.2026

– **Article 2 & Article 3(5)** (points for the next political trilogue)

- **Articles 6 and 12** Timelines (30/20 days and 70/60 +15 for ERA)

- **Article 4** (title and 1st paragraph deleted/ keep as an overall package)

2. Discussion of EP and Council amendments on:

– **Article 9 & 10** - EP wants to keep them in the text – CNS to be deal as an overall package

– **Article 15 & 16** (points for the next political trilogue)

– **Article 17** (lines in yellow – EP to provide a compromise wording in rows 151,152)

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# ITM 7 – 23/3/2026

Discussion of EP and Council amendments on:

- **Article 17** ( row 153)
- **Article 18** (157-161F) ) (points for the next political trilogue)
- **Article 19** ( row 163 yellow open issue on the timelines - reduce in 6 months than 12)

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# ITM 8 & 8bis – 9-10/4/2026

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Discussion of EP and Council amendments on:

- **Article 20** ( rows 166 – 167j)
- Row 167a deleted, rows 167c,167d,167e broadly agreed
- **New Section 1a**: Union coordination mechanism/Union stockpiling
  Initial exchange of views (Articles 20a- 20h –rows 167k-167bg)
- Rows 166 and 167k-167bg for the next political trilogue

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# ITM 9 & 9bis – 15/4/2026

Discussion of EP and Council amendments on:

1. **Article 21**(rows 168-176a) Yellow line 174 –link to article 18/ 176a COM will draft new proposal)
2. **Article 22** (yellow row 178 CNS to reflect on the may/shall provision)
3. **Article 23** (discussion point for the next political trilogue)
4. **Article 24** (yellow row 199 – EP AMs to reflect in recital/CNS to provide draft for recital)
5. **Article 25 (**green except row 204 COM to provide text that CMCG will invite where relevant, stakeholders – CNS mandate acceptable for the EP)

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# ITM 10 – 17/4/2026

Discussion on:

- **Article 18(2)** proposal
- **Article 26** ( yellow rows mainly connected with the new articles 20, row 213 connected with the discussion for the distribution infrastructure)
- **Article 26a** (EP) deleted

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# ITM 11 – 22/4/2026

Discussion of EP and Council amendments on:

- **Article 27** (rows on task for the COM are open – COM will draft a proposal)
- **Article 28** ( row 227, EP AMs linked with definitions)
- **Article 29**
- **Article 29a**(EP) - deleted
- **Article 29a** (CNS) drafting will be adjusted to incorporate EP Ams on confidential information
- **Article 30**

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# ITM 12 – 24/4/2026

Discussion of EP and Council amendments on:

- **Article 30a**
- **Article 31** (rows 249,249a to rediscuss)
- **Article 3**
- exchange views on **18(2)**

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# Article 20

**Article 20:**

- No references to national stockpiling

- New text Vs EP new section 1a (Union Coordination mechanism):
  - Increase transparency and reporting
  - Promote to a voluntary and temporary suspension or adaptation of contingency stock

- Row 166

- Row 167k

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# Article 18

Exchange views on 18(2):

**Option a** – EP might compromise as it refer to [%}

**Option b:**

- based on 3 different tools (technical specification, award criteria, contract performance clause), more flexibility for MS (can choose between the from different tools to use in each tender),
- multi-winner approach
- link to vulnerability evaluation from MSSG
- % threshold (by indicative ranges? Review clause? COM guidelines?)

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# Article 23

- Voluntary basis
- Limited to critical medicinal products only
- Clarify that Commission cannot donate in third countries

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# Article 3 – Definition of MPCIs

- Parliament broadens the scope to include the orphan medicinal products, contraceptives and abortifacients and add the term affordability.

- As a compromise, **PCY proposed to accept only the inclusion of orphan medicinal products** and delete the other additions from the EP.

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# Chapter III – Scope to MPCIs

Expansion of the scope **to include orphan medicinal products to benefit from permit-granting procedures** but not any financial support (articles 15 & 16)

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# Articles 15 & 16

- Article 15: Stronger obligation to the economic operators by deleting in row 144 “the very best effort”

- Article 16: general reference to a possible future financial contribution from the Union

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# Article 1

General objectives: to include reference to critical distribution infrastructure

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# Thank you

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