Council of the European Union
General Secretariat

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Interinstitutional files:
2025/0102 (COD)

Brussels, 22 April 2026

WK 5359/2026 INIT

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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 (Critical Medicines 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 28 April 2026. The draft agenda is set out in CM 2444/26.

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Presidency Flash Note
Working Party on Pharmaceutical & Medical Devices

Format 2+2

28 April 2026 10:00

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The Cyprus Presidency is pleased to invite you to the next meeting of the Working Party on Pharmaceutical and Medical Devices, that will take place on 28 April 2026. The meeting will be a full-day event.

Please find below a note outline the objectives of the meeting.

1. Adoption of the agenda

The Presidency will invite delegations to adopt the agenda set out in CM 2444/26.

2. Preparation for the 3rd political trilogue

The meeting will begin with a briefing from the Presidency, providing an update on progress in discussions with the European Parliament, based on the Interinstitutional Technical Meetings (ITMs) held on 17 and 23 March, and on 9, 10, 15, 17 and 22 April.

The discussion will then focus on the key political elements expected to be addressed at the upcoming trilogue with the European Parliament. These topics are also anticipated to form the basis of a possible overall compromise package on the Critical Medicines Act (CMA), to be prepared at Coreper I on 6 May, with a view to facilitating a successful third and final trilogue on 11 May.

While the Presidency intends to uphold the key principles set out in the Council mandate, it is clear that certain flexibility will be required. Thus, the Presidency will seek political guidance from Member States on the possibility of introducing limited and conditional flexibility on specific political issues, with a view to securing an overall agreement. These are outlined in the flash note below.

A. Articles 20, 18, 23

Article 20 — Safeguards related to Member States' contingency stocks requirements & EP Section Ia — Union coordination mechanism

The Parliament added numerous amendments by introducing a new section Ia (AMs 167l – 167bg), which includes provisions on a redistribution mechanism, and Union stockpiling. In general, PCY intends to reject any references to national stockpiling both in article 20 and the new section 1a.

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In addition, the Presidency intends to explore how to address Parliament's section Ia, by proposing narrowly framed and targeted flexibilities, in the interest of securing an overall package, in line with preserving the main elements of the Council mandate.

Specifically, the Presidency propose to be open:

1.on increasing transparency by MS reporting on aggregated data for a critical medicinal product that is subject to contingency stock requirements, only when the Voluntary Solidarity Mechanism (VSM) is activated and it is requested by the MSSG.

2. to have the MSSG issue non-binding recommendations to facilitate contributions by MAH in very narrow and exceptional circumstances (at the request of MS and when VSM has not resulted in suitable solutions). The recommendations might invite MS to consider suspending or adapting contingency stocks requirements in a voluntary and temporary basis.

Such an approach would allow for a case-by-case assessment, facilitate solidarity measures under VSM and therefore any reference to the obligatory reallocation of the contingency stock based on the decision of the Commission as the Parliament proposed, will be rejected.

Delegations are invited to indicate whether they would be opposed to the above proposals in the interest of securing a broader package.

20(1) — negative impact when imposing contingency stock requirements (row 166)

Delegations are invited to indicate whether they would be opposed to on having a stronger wording in the interest of securing an overall agreement, namely that "Measures on security of supply applied in one Member State shall to the extend possible mitigate unnecessary/adverse impact in other Member States".

20(5) — health emergency aspects and coordination of distribution with systemic wholesalers (row 167k)

Concerning the row 167k, the Presidency's preferred line remains to reject Parliament's amendment as out of scope.

Article 18 — Public Procurement Procedures

18(1) — award criteria requirements vs resilience requirements (row 157) & 18(2) — 'significant proportion of manufacture' in the EU (row 158)

Article 18 is likely to be a key landing-zone issue, as Parliament attaches particular importance to including a numerical threshold for 'significant proportion of manufacture' in the EU. In addition, the Parliament proposes to have EFTA countries included in the EU preference. In that context, and as part of a balanced package potentially preserving our mandatory resilience requirement approach in 18(1) and finding a compromise on Article 23 (see below), **delegations are invited to indicate: (a) whether a numerical threshold is acceptable in principle in the operative part; and (b) if so, whether delegations are opposed to any of the below options in the interest of securing a broader package.**

Option a

The contracting authority requires at least [50%] of manufacturing to take place in the EU. However, if this is not feasible since no bidder fulfils this condition, then the contracting authority shall use procurement requirements that favour the highest proportion of medicinal products or active pharmaceutical ingredients manufactured within the EU.

Option b

When applying procurement requirements, the contracting authority may choose the most relevant mechanism in the context of a tender. This may include different mechanisms to choose from. In this regard, PCY propose three potential mechanisms as outlined below.

a) Choose to favour the supplier that offers the most significant proportion of EU production of API or finished product, without setting a fixed quantitative threshold, and applying a scoring proportionate to the level of EU production offered.

b) Choose to favour suppliers that offer 50% or more of EU production. The minimum weight would not be quantitatively defined but would need to substantially reward EU manufacturing. with a greater weight than price.

c) When using technical specifications, the contracting authority would need to require at least [30/50%] of the total volume of all lots to be reserved for suppliers with EU production of API and finished product. In this situation applying a multi-winner approach would ensure that if no supplier reached the requested %, the continuity of supply can be ensured through other lot(s).

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Both of the above options may consider temporal aspects (in case the percentage should change over time or a product is no longer considered as a vulnerable product on the supply chain) and would be subject to a review clause.

Article 23 — Joint Procurement

The Presidency proposes to preserve the Council mandate on Article 23 and maintain its deletion. In light of an overall agreement and if further flexibility is required, **delegations are invited to indicate whether they would be opposed to retaining Article 23 while making it explicit that the Commission cannot donate, as part of the overall package and limit the joint procurement procedure only for critical medicinal products.**

B. Other expected elements of an overall package

Article 3 — Definitions (row 73)

Parliament insists on broadening the definition of medicinal products of common interest (MPCIs) to include orphan, contraceptive or abortifacient medicinal products. During the latest trilogue we couldn't reach an agreement on this. Meanwhile, the Commission confirmed at ITM that in any event MPCIs may already largely cover orphans.

The Presidency's proposed compromise would be to show some flexibility with one option being adding only orphan medicinal products to the definition of MPCIs. **Delegations are invited to indicate whether they would be opposed to such a targeted opening in the interest of securing a broader package.**

Chapter III — Expansion scope to MPCIs

Like above, we couldn't reach an agreement on the last trilogue and the Parliament insists on broadening the scope of Chapter III to MPCIs including also orphan medicines.

On Chapter III, the Presidency could consider a targeted extension in Article 3 to include orphan medicinal products which will only benefit from the provision on recognition of strategic projects and the permit-granting procedures of Chapter III but excluded from the financial incentivisation in articles 15 and 16.

Delegations are invited to indicate whether they would be opposed to such a targeted opening in the interest of securing a broader package.

Financial incentives

Art 15 — Financial support by Member States *(rows 143a, 144, 144a, 146a, 146b, 146c144) and* Article 16 — Financial support from the Union *(rows 147-149d)*

The Parliament proposed several amendments including provisions allowing Member States to require reserving manufacturing capacity, availability (including references to the next MFF 2028-2034) and affordability requirements for funded projects, establishes penalties and the possibility to fund recovery if obligations are not met and introduces the possibility of export restrictions.

The Presidency's preferred line remains to reject all these amendments and those replicated in Article 16. In order to facilitate this:

1. the Presidency intends to show flexibility on a stronger commitment by deleting "it's very best efforts" on row 144 while ensuring proportionality by imposing obligations upon the economic operators against explicit acceptance and financial compensation and by limiting those obligations towards one Member State instead of all.
2. If needed, the Presidency intends to explore how to address the MFF references requested by the Parliament, including whether a very general reference to a possible future financial contribution from the Union general budget could work.

Delegations are invited to indicate whether they would be opposed to such a targeted changes in the interest of securing a broader package.

C. Possible further flexibilities

Article 1 — Objectives and subject matter (row 63a)

The Parliament requests to include critical distribution infrastructure among the objectives of the Regulation as a way to go beyond manufacturing by also including logistics.

At first instance, the Presidency does not intend to accept the Parliament's amendment of adding critical distribution infrastructure to the objectives of the Regulation. However, if further flexibility is required, **delegations are invited to indicate whether, they would be opposed to accepting a narrowly framed refence to critical distribution infrastructure** in the interest of securing a broader package.

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Did you know that…

Cypriots had pets in antiquity ?



Shillourokampos cat is the oldest known pet cat from a burial dating to 9,500 B.C. The carefully interred remains of a human and a cat were found buried with 24 seashells, polished stones, and other decorative artifacts in a 9,500-year-old grave site on the Mediterranean island of Cyprus. This finding from the Neolithic village of Shillourokambos predates early Egyptian art depicting cats by 4,000 years or more.
According to researchers, this joint burial indicates a strong association between human and cat and that the feline is possibly the world's oldest known pet cat.



Cyprus has an exceptionally high cat population, estimated at around 2 million cats. The government has implemented sterilization programs, but these are limited, with only about 2,000 cats sterilized annually on a modest budget, though recent funding increases aim to expand these efforts.
Cats are a symbol of the island, intertwined with its heritage, tourism, and daily life.