Council of the European Union
General Secretariat

PUBLIC

Interinstitutional files:
2025/0102 (COD)

Brussels, 18 July 2025

WK 9967/2025 ADD 1

LIMITE

SAN
PHARM
MI
MAP
POLCOM
IND
COMPET
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

CONTRIBUTION

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)
N° Cion doc.:	ST 6872 2025 INIT
Subject:	Critical Medicines Act - Comments from the Finnish and Swedish delegation

Delegations will find enclosed additional comments from the Finnish and Swedish delegation on chapter IV of the Critical Medicines Act (ST 6872/25).

FI-SE draft proposal for the article 20 of the proposed CMA -regulation:

Article 20

Safeguards related to Member States' contingency stocks requirements and other security of supply measures

~~Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States~~. Member States shall, ~~in particular, avoid~~ ~~such an impact~~ **ensure that measures aimed at safeguarding the security of supply do not compromise the security of supply in other Member States** when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.

Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. **Member State shall, if such measures are deemed necessary, inform other Member States of its intentions in the Critical Medicines Coordination Group as specified in Article 26.**

Justification:

The negative impact of existing stockpiles on the internal market and other Member States is not self-evident. Potential negative impacts are mainly limited to the establishment phase of the stockpiles, when the demand of pharmaceuticals may rapidly increase. The extent of the impact is largely determined by the length of the transition period and thus, the long lead times of the pharmaceutical industry should be taken into account when transition period will be set. This enables the adjustment of production capacities to meet increased demand in order to minimize negative impacts.

The emphasis should be placed on coordinated planning and solidarity, rather than unilateral national measures. We underline that through allowing sufficient transitional periods for stock adjustments, disruptions to the single market can be avoided. The focus of possible measures should be on ensuring adequate planning with a view to adapt to the internal market requirements taking into account other Member States' needs and also informing them in advance.

The addition of the need to inform other Member States is in line with the TFEU, Article 347 and will be a bridge between Chapter X in the Pharma package to the CMA being in line with the proposed article 134 of the Regulation on Pharma package, which states that the Commission may draw up recommendations for national measures to improve security of supply of medicinal products included in the Union list of critical medicinal products.

PUBLIC