



Council of the
European Union

161196/EU XXVII. GP
Eingelangt am 10/11/23

Brussels, 10 November 2023
(OR. en)

15064/23

SAN 640
PHARM 142
MI 941
COMPET 1077

NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council
Subject: Open Strategic Autonomy from a health perspective
- *Exchange of views*

Delegations will find in Annex a background note from the Presidency to steer the exchange of views on “Open Strategic Autonomy from a health perspective” at the EPSCO Council (Health) on 30 November 2023.

OPEN STRATEGIC AUTONOMY IN THE AREA OF HEALTH:**MEASURES TO DEVELOP A SOLID PHARMACEUTICAL ECOSYSTEM**

The European Council recognises the European Union's open strategic autonomy (OSA) as a key objective¹. The concept of OSA refers to Europe's ability to act autonomously to safeguard its interests, values and way of life through new means of moving away from excessive dependence on third countries in strategic areas, while preserving an open economy. Therefore, the EU must retain its global leadership and strengthen its resilience^{2,3}.

Given the great importance of this objective at European level, the EU's open strategic autonomy is one of the four main areas on which Spain has focused during its presidency of the Council⁴. The Spanish Presidency's proposal to strengthen OSA and reinforce the global leadership of the EU, as set out in the Resilient EU2030 report⁵, was discussed by EU leaders at their meeting in Granada in October 2023.

Strategic autonomy in the field of health

In 2020, the COVID-19 pandemic highlighted the need to reduce our economic dependence on third-country supply chains, particularly in the area of health⁶. Although the availability of medicines has been a longstanding concern in the EU, the pandemic starkly illustrated the lack of stockpiles of medical countermeasures (MCMs)⁷ in the EU and its Member States, as well as the vulnerability of EU supply chains for strategic medicines and the related raw materials. In addition, during the winter of 2022-2023, shortages of antibiotics further increased public and political concern regarding key medicine shortages.

¹ <https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf>

² <https://www.consilium.europa.eu/en/press/press-releases/2019/06/20/a-new-strategic-agenda-2019-2024/>

³ <https://www.permanentrepresentations.nl/documents/publications/2021/03/24/non-paper-on-strategic-autonomy>

⁴ https://www.lamoncloa.gob.es/lang/en/presidente/news/Paginas/2023/20230615_eu-presidency-priorities.aspx

⁵ <https://futuros.gob.es/sites/default/files/2023-09/RESILIENTEU2030.pdf>

⁶ [https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/733589/EPRS_BRI\(2022\)733589_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/733589/EPRS_BRI(2022)733589_EN.pdf)

⁷ Medical countermeasures relevant for public health responses include pharmaceutical products and non-pharmaceutical products, such as, but not limited to, medical devices, personal protective equipment (PPE), vaccination supplies, testing material and kits and laboratory equipment.

In the context of building a stronger European Health Union⁸ – a goal set by the President of the Commission in her 2020 State of the Union address – a number of measures are foreseen to strengthen the resilience of the European Union with regard to the need for MCMs and to reduce the impact of medicine shortages:

- A reinforced role for the European Medicines Agency (EMA)⁹ in crisis preparedness and management in relation to medicinal products and medical devices. In particular, the establishment of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)¹⁰, and an equivalent group for medical devices (MDSSG), is of paramount importance, since it elevates decisions on medical devices and medicine supply issues to the highest strategic level in order to ensure their availability in the EU.
- The European Commission (EC) has also played a crucial role, proposing a new pharmaceutical strategy for Europe¹¹ and hosting the new European Health Emergency Preparedness and Response Authority (HERA), which has coordinated joint procurement agreements for medicinal products and has fostered the creation of strategic stockpiles at EU level (quickly deployed through the EU Civil Protection Mechanism), among other actions related to strategic autonomy, such as the Joint Industrial Cooperation Forum (JICF)¹².

Boosting the EU's strategic autonomy in the area of medicines

The new pharmaceutical strategy for Europe, proposed by the EC in 2020, aims to ensure the quality and safety of medicines while boosting the global competitiveness of the sector. This patient-centred strategy sets out four main objectives, including developing the EU's open strategic autonomy and ensuring diversified and secure supply chains so that Europe can provide for its needs, even in times of crisis. The main initiatives proposed in relation to open strategic autonomy are as follows:

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724>

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02022R0123-20220131>

¹⁰ <https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/executive-steering-group-shortages-medicinal-products>

¹¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761>

¹² https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/advisory-forum_en

- A structured dialogue between actors in the pharmaceutical value chain and public authorities to identify vulnerabilities in the supply chain of critical medicines, the related raw materials, intermediates and active pharmaceutical ingredients (APIs), in order to formulate policy options and inform further actions to strengthen continuity and security of supply in the EU.

Among the various vulnerabilities identified, this dialogue has highlighted the increasing complexity and specialisation of the pharmaceutical supply chain, as well as our dependencies on third countries, in particular when combined with the lack of geographical diversification of the chain¹³.

- The revision of pharmaceutical legislation, which aims to improve the security of supply and address medicine shortages by introducing new requirements for national competent authorities and the EMA in terms of monitoring medicine shortages, as well as more stringent obligations for marketing authorisation holders (MAH) regarding notifications, transparency of stocks and the prevention and management of shortages. In addition, it provides for the adoption of an EU list of critical medicines by the EC.

In June 2023, the European Council invited the EC to propose an initiative for urgent measures to ensure sufficient production and availability of the most critical medicines and components in Europe and to diversify international supply chains¹⁴.

Building on the aforementioned initiatives, the EC adopted a communication on addressing medicine shortages in the EU¹⁵ on 24 October 2023. That communication puts forward a broad set of existing and planned actions to prevent and mitigate critical shortages in the EU, with a particular focus on the most critical medicines:

¹³ https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf

¹⁴ <https://data.consilium.europa.eu/doc/document/ST-7-2023-INIT/en/pdf>

¹⁵ https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf

- Immediate and short-term actions to mitigate critical shortages and ensure supply of critical medicines:
 - Measures to improve the availability of certain key antibiotics in 2023-2024.
 - The ‘Voluntary Solidarity Mechanism for medicines’ already put in place by the MSSG¹⁶, which allows a Member State to request assistance from other Member States in obtaining stocks of a medicine in the event of critical shortages.
 - Improving demand and supply forecasting. The new European Shortages Monitoring Platform (ESMP) for reporting information on demand, supply and shortages is expected to become operational in 2025⁹.
 - Accelerating and anticipating pharmaceutical reform in cooperation with the Member States. This includes, among other measures:
 - continued management of critical shortages, through systems and processes coordinated under SPOC WP¹⁷ and MSSG;
 - recommendations by EC/EMA, such as the ‘MSSG Toolkit on recommendations on tackling shortages of medicinal products’¹⁸;
 - defining a ‘Union list of critical medicines’, currently under development by the HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use, with the first version to be available by the end of 2023. The next step will be to identify and analyse vulnerabilities in the supply chains. This analysis will be performed for EU critical medicines by April 2024 and will provide the basis for decisions on further actions.
 - A dedicated Joint Action on regulatory flexibilities will be launched in 2024.

¹⁶ https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf

¹⁷ <https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party>

¹⁸ https://www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf

- Using public procurement to enhance security of supply:
 - EU best practice guidance on procurement, integrating supply security as an award criterion: to be issued by the EC in 2024;
 - EU joint procurement: can improve the negotiating position of Member States.
- Structural measures for the mid-term and long-term:
 - The EC will launch a preparatory study by the end of 2023, paving the way for an impact assessment on a legislative initiative for an EU ‘Critical Medicines Act’.
 - The ‘Critical Medicines Alliance’ (to be operational in early 2024) will allow national authorities, industry, civil society representatives, and EC and EU agencies to promote an industrial approach, developing coordinated non-regulatory action to address supply chain vulnerabilities for critical medicines at EU level.

This work will be complementary to the work of the MSSG and could draw on a set of actions to mitigate structural risks: public procurement and capacity reservation contracts, such as EU FAB¹⁹; diversification of supply chains; boosting innovation and manufacturing capacity²⁰; discussing a possible IPCEI²¹ focusing on critical medicines; and EU stockpiling of critical medicines, based on a common strategic approach to medicine stockpiling, to be developed by HERA in cooperation with the Member States.

¹⁹ https://ec.europa.eu/commission/presscorner/detail/es/fs_22_2664

²⁰ [https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740070/IPOL_STU\(2023\)740070_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740070/IPOL_STU(2023)740070_EN.pdf)

²¹ Important Project of Common European Interest (IPCEI). https://competition-policy.ec.europa.eu/state-aid/legislation/modernisation/ipcei_en

- International partnerships for supply:
 - A network of international partners to exchange information on supply issues.
 - Strategic partnerships with third countries for the production of critical medicines and APIs.
 - Supporting production capacity at global level, through Team Europe initiatives²².

Given the importance of achieving strategic autonomy for the EU in the area of health, and the various initiatives carried out and planned in the European Union, the Presidency considers it important to table this topic for discussion by the Ministers at the EPSCO Council (Health) meeting of 30 November 2023.

Questions for discussion:

1. Do you consider that the initiatives set out in this note are likely to have a significant impact on medicine shortages in the short term?
2. Based on your experiences and initiatives at national level, would you propose any additional measure or a specific implementation plan to promote health strategic autonomy at EU level?

²² https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives_en