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## NOTE

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From:	General Secretariat of the Council
To:	Council
Subject:	The European Health Union in light of the report on ‘The future of European Competitiveness’ - <i>Exchange of views</i>

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Delegations will find in Annex a note from the Presidency to steer the exchange of views on “The European Health Union in light of the report on ‘The future of European Competitiveness’” at the EPSCO Council (Health) on 3 December 2024.

## **The European Health Union in light of the report on ‘The future of European Competitiveness’**

The Spanish-Belgian-Hungarian Presidency trio committed itself to strengthen the European Health Union with a view to ensuring the resilience of health systems that are accessible to all, to build preparedness for future health emergencies and to promote health and healthy lifestyles<sup>1</sup>. In this regard, an important milestone was the approval of the Council Conclusions on the future of the European Health Union, which called on the Member States and the European Commission to make this a priority in the upcoming institutional cycle, indicating several specific health policy areas. For the Hungarian Presidency, competitiveness is a cross-cutting overarching priority and the recent publication of the report on “The future of European Competitiveness” (“Draghi report”) therefore is of particular importance, as was also recognised by the European Council in its conclusions of 17 October 2024.

The Presidency consequently deems it appropriate to initiate a discussion on the future of the European Health Union also in light of the Draghi report, including its recommendations, in particular those related to the pharmaceutical sector with a direct overall impact on the health sector, while continuing to respect the relevance of other policy areas to the pharmaceutical as well as to the health sectors.

### **The future of the European Health Union**

On 21 June 2024, the Council approved the Council Conclusions on the future of the European Health Union, which included a list of priority topics by Member States with the overall aim of keeping health and further strengthening the European Health Union high on the political agenda, throughout the term of office of the new College of Commissioners.

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<sup>1</sup> 10597/23

The envisaged priorities, as agreed by the Member States, include tackling ongoing challenges such as the health workforce crisis and the need to improve the security of supply of medicines and medical devices. The Conclusions called for work to continue in the Critical Medicines Alliance, and for consideration to be given to a Critical Medicines Act. Additional priorities are the identification and coordinated approach to unmet health-related patient and societal needs.

Regarding disease prevention, the Council Conclusions call for the main focus to be on non-communicable diseases, through the promotion of health and of healthy lifestyles, including full implementation of the regulatory actions in the Europe's Beating Cancer Plan and further strengthening the Healthier Together Initiative. The relevance of social media to the mental and physical wellbeing of children was highlighted. Actions on preparedness and communicable diseases and to tackle antimicrobial resistance (AMR) were called for. The conclusions also emphasised the importance of improving and streamlining the EU's implementation tools.

As a follow up to these conclusions, the Hungarian Presidency proposed two Council Conclusions on cardiovascular health and organ donation and transplant with a set of medium and long-term actions to tackle several chronic diseases. The adoption of the Council Recommendation on smoke- and aerosol-free environments is another important milestone towards healthier lifestyles and to the completion of Europe's Beating Cancer Plan.

### **The Draghi report: The future of European Competitiveness**

At the request of Ursula von der Leyen, President of the European Commission, Mario Draghi former Italian Prime Minister and President of the European Central Bank published a comprehensive report on the future of European competitiveness in September 2024<sup>2</sup>, presenting an overall picture of the challenges, specifically in terms of the EU's competitiveness and including close to 200 practical recommendations to address these challenges.

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<sup>2</sup> [https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead\\_en](https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead_en)

The report zooms in on the pharmaceutical sector, underlining its historically major contribution to the EU's economy and its role as a dominant employer in Europe. While acknowledging the existing strong manufacturing base, scientific know-how and academic excellence, the report also warns about an emerging competitiveness gap between the EU and its competitors, especially in the most dynamic segments (including biological and orphan medicines as well as advanced therapy medicinal products (ATMPs)).

The report identifies the main reasons underlying the EU's lagging competitiveness such as **fragmented and insufficient research and development (R&D) funding, the slow, complex and inflexible regulatory system, the fragmentation of national pricing and reimbursement processes.**

To support the expansion of the EU's R&D capacity and to close the emerging competitiveness gap for medicines, the report puts forward several short, medium and long-term recommendations, grouped into nine clusters.

These recommendations concern the impact of a European Health Data Space (EHDS), streamlining multinational clinical trial procedures, expedited market access to medicines via a coordinated regulatory approach along the life-cycle of the medicine, guidance on the use of Artificial Intelligence (AI) in medicine lifecycles, full implementation of the health technology assessments (HTA) Regulation including joint clinical assessments, increased coordination between public payers, pricing and reimbursement authorities for improved business predictability, increased public and private investments for R&D and the development of strategic international partnerships. In addition, the report highlights the importance of digitalisation in healthcare and the expansion of disease registries within the European Reference Networks for rare diseases.

Importantly, while the report identifies the “funding challenge” (with 3 to 4 times more private funding available for pharmaceuticals R&D in the US) more as a horizontal challenge for the EU cutting across sectors, it still contains a few specific recommendations, in particular regarding the coordination of public and private finance to support R&D and innovation in the EU. One example is the creation of world-class innovation hubs as a means to consolidate public support and increase the European Investment Fund’s budget to enhance EU venture capital and thus concentrate private investments. While the report is ambitious and seeks to boost the EU’s competitiveness with a wide array of reforms, a holistic assessment of the feasibility of these recommendations is still needed.

### **Synergies in Union-level actions on shared goals and priorities**

Several recommendations of the Draghi report highlight and add further support for ongoing and planned Union-level efforts that have been identified as priorities, both by the Member States in the Council Conclusions on the Future of the Health Union and by the President of the Commission in her mission letter to the Commissioner-designate for health. These priority actions and initiatives targeted at the pharmaceutical sector, which are also expected to contribute to the increased overall competitiveness of the Union, especially when contributing to better patients’ care and more sustainable health systems, could therefore be common grounds for strong EU-level cooperation between Member States supported by the Commission. These include the need to improve:

- pharmaceutical innovation and R&D,
- supply chain security and strategic autonomy for medicines,
- strategic international partnerships to solidify and bolster the EU’s international position.

**Improving pharmaceutical innovation and R&D** as a key strategic sector has been targeted by several initiatives. Improved innovation and competitiveness is one of the core objectives of the **pharmaceutical revision**, where several provisions dealing with incentives for regulatory data protection, the coordinated assessment of GMO trials with advanced medicinal products (ATMPs), the PRIME scheme, the regulatory sandbox and scientific advice are proposed to achieve this. In addition, the proposed pharmaceutical reform seeks to achieve a more streamlined, future-proof and flexible regulatory system, while maintaining high quality and safety standards for medicines in Europe. At the same time, within a broader context, the proposed pharmaceutical package also aims at striking a good balance between pharmaceutical innovation, equal access to medicinal products in all Member States and the need to improve affordability and financial sustainability.

To provide specific comparative advantage to the Union, once the **European Health Data Space Regulation is adopted**, the full potential from the secondary use of patient health data will need to be exploited. In combination with artificial intelligence this could be a robust tool to drive health-related innovation and development. To help the timely and full implementation of the EHDS Regulation, the topic was discussed at the informal health ministerial meeting in July 2024.

**The implementation of the HTA Regulation and thus the first parallel scientific advice with joint scientific consultations** between the European Medicines Agency (EMA), HTA authorities and health technology developers will start following the entry into force of the Health Technology Assessment Regulation on 12 January 2025. These are expected to clarify the evidence needs and ultimately make the market access of new and innovative medicines faster and easier. Cooperation between the authorities across their respective competences should help addressing the coordination challenge in timely access.

**Regarding supply chain security and strategic autonomy for medicines and medical devices,** the **pharmaceutical package** proposal contains a set of provisions complementary to those in the EMA mandate Regulation<sup>3</sup> to further improve supply chain security, for example by formalising the Union's list of critical medicines and the methodology to identify medicines for closer monitoring and reporting. These legislative proposals have been complemented by the **Critical Medicines Alliance** as non-legislative, multistakeholder component. A **Critical Medicines Act** as requested in the Council conclusions is expected to tackle the endemic risks presented by shortages of critical medicines in a way that complements the other mechanisms in place. In addition, the regulatory system should ensure the best **availability and competitiveness of safe medical devices and in vitro diagnostics**, even if this requires legislative changes.

At the same time, there are several shared priorities mentioned in the Council Conclusions that are not addressed by sectorial recommendations in the report, given its specific scope of competitiveness limited to the pharmaceutical sector. In the broader context of the healthcare sector, where pharmaceuticals are an important element, but patient access and sustainability play a similarly important role, in the view of the Member States, there is a need for Union-level action on:

- a comprehensive approach to preventive health and disease prevention across the life course of a disease
- tackling antimicrobial resistance (AMR)
- tackling the health workforce crisis
- the effects of climate change on health
- action in the fields of preparedness and communicable diseases.

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<sup>3</sup> OJ L 20, 31.1.2022,

Regarding **preventive health and disease prevention across the life course** of non-communicable diseases, the full implementation of the **Europe's Beating Cancer Plan**, including coming forward with a proposal for legislative acts such as the revision of the **tobacco legislation**, are of interest to all of us. Comprehensive Union actions to address non-communicable diseases will be needed. This work could build on the **Council Conclusions on mental health** approved under the Spanish Presidency and the **Council Conclusions on cardiovascular health, to be approved** during the EPSCO Council meeting of 3 December 2024. Improved health status and healthy life years in Europe would not only support more sustainable healthcare systems, but could be regarded as an important contributor to **higher productivity**.

**Regarding antimicrobial resistance (AMR)**, the implementation of the Council Recommendation<sup>4</sup> adopted under the Swedish Presidency is of common interest. In addition, the **pharmaceutical package** includes relevant provisions on both **the prudent use and**, to compensate for market failure, on **the development of priority antimicrobials**.

We would draw the attention to the importance of the **health workforce crisis** identified in the Council Conclusions as one of the biggest challenges to the sustainability of national healthcare systems. The shortages and demographic changes in the health workforce is an issue seen across Member States and affects many parts of the profession and a **comprehensive Union approach**, as outlined in the Conclusions, would therefore be necessary to reduce the negative impact without causing any Member State to suffer as a result. While shortage of the health workforce is identified as a challenge in the Council Conclusions, the Draghi report does not flag workforce-related issues in the context of pharma competitiveness although the skill need appears a cross-cutting problem.

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<sup>4</sup> OJ C 220/1 22.06.2023



**Climate change and health** is another important topic, where the Council recognised the value of an EU agenda on climate and health following the One Health approach, cooperation on detection and response, and in reducing the impacts of healthcare systems on the climate and the environment in the EU. **Health emergency prevention, preparedness and response** is indispensable to prepare for future crises. EU preparedness contributes to global health security and the EU's role in global health. There is a need for a thorough evaluation of the post-pandemic EU health emergency governance framework and, where necessary, to subsequently clarify relations between the relevant entities involved in crisis preparedness and management.

The beginning of the **new European institutional cycle** is a strategically important opportunity for a common reflection. This reflection should focus on how, through constructive cooperation between Member States and the Commission, the recommendations in the Draghi report could best contribute to implementing the priority actions identified in the Council Conclusions. It is also a good opportunity to reflect on how other priorities less directly related to competitiveness, which therefore received less visibility in the Draghi report, could be addressed, with the overall aim of further strengthening the European Health Union, making health systems more resilient and further improving the health of Europeans.

Based on the context set out above, the Council is invited to hold an exchange of views by addressing the following questions:

1. **Which of the conclusions and recommendations in the Draghi report are the most important to address the health-related challenges in your Member State?**
  2. **How can Member States and the Commission effectively coordinate to implement the recommendations?**
  3. **What other impacts can the implementation of the recommendations have on national healthcare systems and the completion of the European Health Union?**
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