



## Informal Meeting of Health Ministers | 16 July 2020

# Summary of the Presidency

### Preliminary remarks

On 16 July 2020, the health ministers of the European Union (EU) met in a virtual format to hold their Informal Meeting within the framework of Germany's Presidency of the Council of the European Union. The EU Commission, experts from relevant EU agencies and representatives of the EFTA states and WHO EURO were also in attendance. The discussions were moderated by the German Federal Minister of Health, Jens Spahn, in the presence of Germany's trio presidency partners – Portuguese Minister of Health, Marta Temido and Slovenian Minister of Health, Tomaž Gantar – both of whom were on location in Berlin.

The Informal Meeting of Health Ministers was marked by the COVID-19 pandemic, the continuing efforts to keep the disease under control, as well as the lessons learned and insights from the pandemic control measures conducted thus far. The Presidency also wishes to explicitly thank our predecessor, the Croatian Presidency, which under quite difficult circumstances succeeded in advancing the work on important European health policy topics. This work allowed us to build on the discussion of “Supply shortages and delivery bottlenecks in medicinal products and medical devices” conducted during the Informal Meeting of Health Ministers on 12 May 2020. In May, the relocation of the manufacture of active pharmaceutical ingredients (API) to the EU had already been identified by all Member States as a core element of any future EU Pharmaceutical Strategy. In addition, it was observed that the COVID-19 pandemic had significantly exacerbated the problem of EU dependence on third countries.

Against this background, on 16 July 2020, the participants discussed the topic of enhancing EU crisis management by strengthening the European Centre for Disease Prevention and Control (ECDC) as well as that of ensuring the supply of medicinal products in the EU. Furthermore, in addition to a contribution from the EU Commission, the Presidency provided an outlook on the activities planned in the area of digital health, with a special focus on the European Health Data Space.

## Content of the Informal Meeting

In Session 1 “The COVID-19 pandemic and lessons learned – Strengthening the European Centre for Disease Prevention and Control (ECDC)”, the participants deliberated how the ECDC could contribute to better preparing for health emergencies and how it could better support Member States’ crisis management. Another topic of discussion was whether the ECDC possessed sufficient financial and human resources and whether it was necessary to expand the institution’s mandate. In the context of the latter question, participants also discussed whether additional aspects needed to be examined.

In Session 2 “Ensuring the supply of medicinal products in the EU”, the participants deliberated the possible content and priorities of a future EU Pharmaceutical Strategy, also in light of the experiences gained with the COVID-19 pandemic. The strategy is currently being drawn up by the EU Commission, for adoption in the last quarter of 2020. Specific milestones, such as increased transparency with respect to API manufacturing sites in third countries and concrete measures to guarantee the quality and availability of API effectively, were also topics of discussion. Possible financial incentives to maintain or relocate API manufacturing sites for important medicinal products were also deliberated. The goal of the milestones and the measures is a tangible improvement in the availability of medicinal products for all of Europe’s citizens.

In closing the Informal Meeting, the Presidency provided an outlook on digital health projects that are in the pipeline and pointed out the need to advance health data processing in Europe that is in compliance with data protection requirements. The EU Commission presented the results of the expert workshops conducted in the first half of 2020. The results clearly demonstrated the potential of health data exchange that is compliant with data protection requirements for purposes of research, diagnosis and treatment, while showing that more challenges still exist for cross-border use of health data in the EU. The focus of the presentations was the setting up of a joint European Health Data Space.

## Results of the discussions

The central theme of the deliberations at the Informal Meeting of Health Ministers was the aspiration of all those present to learn the right lessons from the COVID-19 pandemic and the willingness to act together as a result. The objective of acting together must be to develop a sovereign European health policy.

Against this background, the Presidency summarises the individual sessions as follows:

### **The COVID-19 pandemic and lessons learned – Strengthening the European Centre for Disease Prevention and Control (ECDC)**

1. There is broad agreement between Member States that the strengthening of the ECDC and the assignment of additional tasks to the ECDC are important lessons that can be learned from the COVID-19 pandemic. In this light, it can be concluded that when it comes to improving crisis management in the future and strengthening crisis preparedness, the focus should be placed on specific measures.

2. There is vast support for many of the following and additional measures:
  - a) The possibility for the ECDC and the Member States to jointly draw up interregional EU pandemic plans;
  - b) Setting up a Health Task Force within the ECDC;
  - c) Innovative digital solutions;
  - d) A stronger mandate for the ECDC to issue scientific recommendations;
  - e) Increased global visibility of the ECDC and networking with partner institutions worldwide.
3. The Member States agree that there is pressing need for adequate equipment for the ECDC. Only then will the ECDC be able to take on additional functions without compromising the performance of already existing tasks. That should be taken into consideration in the ongoing discussions related to the multiannual financial framework.
4. There is support that the EU Commission should start an impact assessment taking into account a review of lessons learned of the COVID-19 pandemic. This should be the basis for strengthening the ECDC in a legal proposal during Germany's EU Presidency.

## **Ensuring the supply of medicinal products in the EU**

1. All Member States emphasise that the supply shortages regarding in particular medicinal products constitute a threat to the public health systems of the Member States and that specifically the COVID-19 pandemic made this abundantly clear.
2. Based on the statements of Member States, and in the common understanding that there is a need for a joint holistic approach from availability to sustainability in the forthcoming EU pharmaceutical strategy, the Presidency concludes that the aspect of "Ensuring the supply of medicinal products in the EU" should be an integral part of it. A special focus should lie on critical medicines. For this purpose, pharmaceutical and economic policy measures should be linked also taking into account inter alia the industrial strategy.
3. There is major support amongst Member States that the EU Commission should take four cornerstones into account in drawing up the EU Pharmaceutical Strategy with the aim to ensure the supply of medicinal products in the EU: 1) increasing transparency and information exchange at EU level; 2) improving the quality of API; 3) diversifying supply chains and 4) creating financial incentives for the maintenance and relocation of API manufacturing sites to the EU. Some Member States have identified EU4Health as a potential source for such financing.
4. There is overall consensus amongst Member States that the EU Commission should take into account a number of concrete pharmaceutical and economic policy measures such as an EMA-led dialogue with the Member States at EU level, improved coordinated inspections inside and outside the EU and the creation of a data management tool for the collection of information in particular on API manufacturing sites worldwide.
5. It is unanimously clear that the EU Commission and Member States should work closely together in the development of the EU Pharmaceutical Strategy which should be tabled by autumn 2020.

6. The Presidency welcomes that the EU Commission expressed its preparedness to build a partnership with Member States and looks forward to contributing to a pharmaceutical strategy that meets the needs of Member States and that benefits the European Union at large.

## **European Health Data Space –The state of play of improvements regarding health data exchange for research and public health**

1. The Presidency emphasises that the European Health Data Space is a project of major significance for the German Presidency of the Council of the European Union and beyond. The Presidency is firmly committed to advancing this project in the interest of all of the EU's citizens.
2. In the coming six months, together with the other Member States, the Presidency will examine the measures proposed by the EU expert workshops, including taking such measures into account in possible Council conclusions.
3. The Presidency emphasises that improvements in the processing of health data, with a view to digitalisation, big data and artificial intelligence in the field of health, will be addressed at the high-level digital conference “Digital Health 2020 – EU on the Move” on 11 November 2020.
4. The Presidency emphasises that it will be collaborating closely with the EU Commission, the Member States and their national authorities involved in preparing the Joint Action for the European Health Data Space, so as to set the stage for a code of conduct process and ensure continuity in the development of a governance strategy for the secondary use of health data at European level.