

Informal Meeting of Health Ministers | 2 December 2020

Summary of the Presidency

Preliminary remarks

On 2 December 2020, the German Presidency of the Council of the European Union (EU) held an informal videoconference of the EU ministers of health. This meeting replaced a formal meeting of the Council of the European Union in the configuration Employment, Social Policy Health and Consumer Affairs (EPSCO) in the framework of Germany's Presidency of the Council of the EU. The Commission, the European Centre for Disease Prevention and Control (ECDC) and the European Medical Agency (EMA) also participated in the meeting.

The ministers discussed the following topics:

1. Current pandemic situation and response to it
 - a) Information from the ECDC and EMA and state of play
 - b) Conclusions on COVID-19 lessons learned in health
 - c) Building a European Health Union: three legislative proposals
2. A Pharmaceutical Strategy for Europe
3. Any other business: Regulation on HTA, Regulation on the EU4Health Programme, Europe's beating cancer plan, Implementation of the MDR and the IVDR, Mink and COVID-19, Summary of the Council activities in the health area during the German Presidency, Work Programme of the incoming Portuguese Presidency

Content and results of the meeting

1. Current pandemic situation and response to it

In its introductory remarks, the Presidency highlighted the need to rapidly place authorised COVID-19 vaccines on the market. These vaccines must undergo the regular authorisation procedure to ensure safe and efficacious vaccines of a high quality for EU citizens.

At the beginning of the meeting, the Director of the ECDC, Dr. Andrea Ammon, informed the ministers about the epidemiological situation in the EU, also with a view to the forthcoming festive season. She

stated that she was cautiously optimistic about the current trend in relation to the number of infections and positivity rates, but that it would be too early to proceed with easing the current restrictions. Next, the Director of the EMA, Emer Cooke, informed delegations the evaluation process of applications to approve COVID-19 vaccines, stressing that the decision on whether or not to approve the first vaccine would be held at the end of the year.

In this context, the Presidency referred to the draft of the Council conclusions on “COVID-19 lessons learned in health” and asked Member States for their political approval and for a signal that EU health ministers would work closely together and make the decisions needed for European health policy. The Council conclusions cover four key areas of the German Presidency 1) Improving EU crisis management, 2) Ensuring the supply of medicinal products, 3) Improving access to and sharing of health data, 4) Strengthening the EU’s role in Global Health.

The Commission mentioned the “Staying safe from COVID-19 during winter strategy” adopted the same day, stressed the need for public health measures to be maintained until the situation improved with the large-scale deployment of vaccines and call for a timely preparation of the roll-out of the vaccine(s). The Commission stressed that the Health Union package would improve the EU’s collective health security and provide a solid framework for EU preparedness, surveillance, risk assessment, early warning and response.

In their interventions, ministers paid particular attention to the set of legislative proposals put forward by the Commission on 11 November 2020 aimed at strengthening the EU’s health security framework and reinforcing the crisis preparedness and response role of key agencies. Given the recent publication of these proposals, ministers exchanged their initial views and stressed the need to closely analyse these proposals.

Overall, ministers welcomed the legislative proposals by the Commission as a decisive step towards building a strong and autonomous EU better prepared to counter serious cross-border health threats. A great majority of ministers emphasised that ECDC and EMA need to be strengthened and provided with more human and financial resources to assist Member States in preventing and countering cross-border health crises. At the same time, many delegations identified a number of areas that should be addressed during the forthcoming discussions on the legislative proposals, such as avoiding duplication of tasks and additional administrative burden, responsibilities of the different crisis management bodies and mechanisms, and a clear distinction between expert and political decision-making levels. In relation to this, ministers agreed that national competencies needed to be respected. They also stressed the importance of enhanced transparency, closer cooperation and intensive dialogue, also with organisations such as the World Health Organization (WHO).

2. A Pharmaceutical Strategy for Europe

The ministers shared their first assessments of the Pharmaceutical Strategy for Europe presented by the Commission on 25 November 2020. They also discussed priority actions in the Strategy’s implementation phase to ensure the supply of medicinal products, one of the priorities of Germany’s Presidency in the area of health within the EU.

Health ministers expressed general support for the Strategy and its ambitious objectives to help ensure Europe’s supply of medicinal products, access to affordable medicinal products and to assist the European pharmaceutical industry remain an innovator and world leader. They also agreed that the Strat-

egy and its implementation should aim to better prepare the EU to face future health-related challenges. On cooperation, ministers expressed their wish to see Member States fully involved in all future discussions and actions in the context of implementing the Strategy, and called for strengthening the dialogue with all stakeholders. In relation to ensuring the supply of medicinal products, many delegations referred to the need to ensure European strategic autonomy. Diversifying production and supply chains, ensuring strategic stockpiling, and encouraging production and investment in Europe for critical medicinal products were among the measures identified by ministers to reduce the vulnerabilities, including dependencies, of the global supply chains. Many Member States welcomed the Commission's study on the root causes of shortages of medicinal products. Some delegations suggested the need to increase transparency in supply chains, improve collaboration and information exchange at EU level, monitor shortages and to concentrate measures on critical medicinal products. Many Member States underlined the importance of antibiotics and the issue of AMR. Member States agreed that prioritisation of objectives and a rapid implementation are crucial. The time for concrete measures had come.

The Commission presented the strategy and stressed it had a patient-centered approach and aimed to address long-term structural changes, notably in terms of access and affordability, supporting competitiveness, innovation and sustainability and noted the importance of addressing security of supply.

3. AOB: Regulation on HTA, Regulation on the EU4Health Programme, Europe's beating cancer plan, Implementation of the MDR and the IVDR, Mink and COVID-19, Summary of the Council activities in the health area during the German Presidency, Work Programme of the incoming Portuguese Presidency

The Presidency informed ministers about the state of play in relation to the proposal for a regulation on health technology assessment (HTA) and briefed the ministers on the state of play in relation to the proposal for a regulation on the EU4Health Programme for 2021-2027. The Commission provided an update on "Europe's beating cancer plan" to be adopted at the beginning of next year. This was followed by interventions of the Dutch, Belgian and French delegations who stressed the importance of a more EU coordinated approach for the future supply of medical radioisotopes for diagnostics and treatment of cancer. Moreover, the Commission briefed ministers on the implementation of the Regulations on medical devices and on in vitro diagnostic medical devices. Regarding measures taken to address COVID-19 outbreaks in mink farms, the Dutch, the Danish and the Italian delegations shared their views and expressed their concern and the ECDC gave its assessment of the situation.

Towards the end, the Presidency summarised the Council activities in the area of health during the German Presidency. The Presidency stressed that health ministers had set the course for an improved EU crisis management with key roles played by ECDC and EMA and an improved supply of medicinal products and medical countermeasures. The Presidency emphasised that health ministers had collectively contributed to placing safe and secure COVID-19 vaccines on the market and highlighted that health ministers had set the course for a European Health Data Space to improve healthcare in general and in times of crisis. The Presidency reported that health ministers had worked on how best to strengthen the WHO and had concluded that the EU should play a leading role in this process.

The head of the Portuguese delegation presented an outlook on the work programme of the upcoming Portuguese Presidency of the Council of the EU, highlighting that Portugal would continue to work on European recovery while also taking up the fight against global warming and disinformation. The Portuguese delegation stressed that the COVID-19 pandemic, the EU Health Union, health data, access

to medicinal products and global health policy would be priorities of the Portuguese Presidency in the area of health.