

Germany's Presidency of the Council of the EU 2020: Review by the Federal Ministry of Health

Berlin, 31 December 2020

Introduction

Between 1 July and 31 December 2020, Germany held the Presidency of the Council of the European Union (EU) for the 13th time. In the following, the Federal Ministry of Health provides an overview of results in the focus areas and events in the field of health during Germany's Presidency of the Council of the EU.

Germany's Presidency of the Council of the EU was also - and particularly in the area of health - heavily determined by the ongoing COVID-19 pandemic. This was reflected, too, in the Federal Ministry of Health's guiding principle - Acting together. Towards European Health Sovereignty - and, in connection, in the focus areas the Federal Ministry had selected in order to provide a tangible benefit to the EU. The COVID-19 pandemic not only defined the subject matter of the Presidency, but also the procedures and formats through which Council Working Party meetings, conferences and Informal Meetings of Ministers and Secretary of State-level meetings were held. The majority of those meetings and events were held in a virtual format for reasons of infection control.

The topics in detail

Improving EU crisis management: The focus of Germany's Presidency of the Council of the EU with regard to an improved EU crisis management was placed on strengthening the European Centre for Disease Prevention and Control (ECDC). Therefore, the outcomes of the Informal Meeting of EU Health Ministers on 16 July 2020 included, for instance, a call upon the EU Commission to expand the ECDC into a potent response centre for international health crises. It is therefore an achievement that the EU Commission managed to submit - at very short notice and still during Germany's Presidency of

the Council of the EU – a package of reform proposals that notably includes a legislative proposal on expanding the ECDC’s mandate, and, for instance, allows for the ECDC to deliver scientific recommendations to help contain outbreaks. Another proposal by the EU Commission concerns strengthening the mandate of the European Medicines Agency in crisis preparedness and crisis management with regard to medicinal products and medical devices. A third proposal addresses improvements to tackling cross-border health threats. Deliberations on proposals submitted by the Commission under the title ‘European Health Union’, were swiftly taken up under the German Presidency and have continued, since 1 January 2021, under the Portuguese Presidency with the aim of reaching a decision as soon as possible.

One matter frequently discussed by the EU Ministers of Health was the joint procurement of **COVID-19 vaccines** for the EU. Thanks also to a top-up of the emergency support instrument (ESI) through bilateral contributions from all Member States on the basis of a joint initiative by the EU Commission and the German Presidency, several contracts were concluded with various manufacturers to procure more than 2 billion COVID-19 vaccines for the EU. This way, the EU sends out a clear signal of unity to ensure all citizens receive equal care. Cooperation among Member States with regard to EU crisis management was increased, robust structures at EU level were built up and between existing structures, networks were established. Increased cooperation among Member States made it possible to provide cross-border healthcare to COVID-19 patients.

Ensuring the supply of medicinal products within the EU: Under Germany’s Presidency of the Council of the EU, action areas were discussed for ensuring the supply of medicinal products within the EU and particularly for reducing the EU’s strategic dependence on third countries with regard to the manufacture of active substances. The following key topics were identified during this process: improving transparency of active substance manufacturing sites and information exchange at EU level; improving international cooperation on inspections among the competent regulatory authorities to maintain active substance quality; diversifying supply chains and creating financial incentives for the maintenance and expansion of active substance manufacturing sites within the EU. The Pharmaceutical Strategy for Europe, submitted by the Commission on 25 November 2020, can be viewed as a result of the deliberations chaired by Germany. The strategy also took up as a priority field of action the topic of ensuring the supply of medicinal products. Together with our Trio partners Portugal and Slovenia, we will closely monitor the implementation of the Pharmaceutical Strategy and work towards concrete and quickly realisable measures to secure the supply of medicinal products within the EU.

Improving access to and sharing of health data: Establishing the European Health Data Space (EHDS) was of particular importance for Germany’s Presidency of the Council of the EU. Under the German Presidency, the EU Member States agreed on key requirements for the EHDS, including the access to and exchange of health data within the EU. In particular, when preparing legislative (and non-legislative) measures for establishing the EHDS, the EU Commission was called upon to duly consider the

governance options being developed in the Joint Action “Towards the European Health Data Space” to be launched in 2021. In addition, the EHDS and the questions ‘how to improve access to and exchange of health data within the EU’ were the subject of the high-level digital conference “Digital Health 2020 – EU on the Move” on 11 November 2020. During the conference, the German Presidency and the EU Commission expressed their intention to collaborate closely to ensure a safe and patient-oriented use of health data for Europe. Another important aspect was the collaboration on technical and semantic standards and on linking up national infrastructures in the eHealth Network. One more point on the European digital agenda was the joint work on common data and interoperability standards within the eHealth Network, which we advanced further together with the EU Commission. In this context, a particular achievement of the German Presidency and the EU Commission – also with a view to effectively containing the COVID-19 pandemic – was connecting coronavirus warning apps across Europe, so that since 20 October 2020 these apps have been able to exchange warnings across borders.

Strengthening the EU’s role in global health: Building on the conviction that international health crises such as the COVID-19 pandemic require a strong World Health Organization (WHO), during the German Presidency, EU Member States agreed on a leading and formative role for the EU in strengthening the WHO and in the context of the WHO reform process. This position and the corresponding action proposals were defined in Council Conclusions on the EU’s role in strengthening the World Health Organization. These Conclusions were submitted to WHO’s Executive Board in January 2021 and enable the EU to play a key role in drafting a resolution on strengthening WHO’s preparedness in health emergencies, which is to be adopted at the World Health Assembly in May 2021.

Further relevant dossiers and projects, which played an important part during Germany’s Presidency of the Council of the EU, include:

Political consensus on the new health programme **EU4Health:** The trilogue negotiations with the European Parliament and the EU Commission on the new EU funding programme “EU4Health” were concluded in record time under the German Presidency. With its budget of five billion euros, the aims of EU4Health include contributing to ensuring the supply of crisis-relevant medicinal products and medical devices, promoting the establishing of the EHDS, supporting action taken by international organisations and WHO, in particular, and improving public health within the EU as a whole.

Presentation of a comprehensive compromise proposal on **EU HTA:** The discussions on the Health Technology Assessment (HTA) regulation proposal were carried forward. The fact that after three years of difficult negotiations, a comprehensive compromise proposal could be presented, discussed and in many aspects agreed upon, within the Council Working Party on 8 December 2020, is a milestone toward concluding the negotiations. From January 2021, Portugal’s Presidency of the Council of the EU can build on this achievement.

Political consensus on a new **EU Drugs Strategy 2021 – 2025**: With the Conclusions on the new EU Drugs Strategy from 2021 to 2025, which the Council of the EU adopted on 18 December 2020, the German Presidency reached its main goal regarding drug policy. From a public health perspective, it is particularly noteworthy that alongside prevention and treatment, for the first time the strategy also contains a chapter dedicated to harm reduction. In addition, the strategy emphasizes the special support needs of vulnerable groups, such as prisoners or children from families affected by addiction. To implement the EU Drugs strategy, Portugal's Presidency of the Council of the EU submitted an EU Action Plan on Drugs 2021 – 2025, which is to be negotiated and adopted in the first half of 2021.

The high-level conference "Improving Cancer Care in Europe", which was held by the German Cancer Research Centre on 3 September 2020 under the auspices of the Federal Ministry of Health, sent out a clear sign of high-quality **cancer care** based on solidarity in Europe. A network project for paediatric oncology was also launched together with the Trio partners Portugal and Slovenia. The topic of cancer control was addressed, too, in various expert events both at interministerial level and as part of the associated programme, whereby the German EU Council Presidency organised content proposals and suggestions for the EU Commission's "Europe's beating cancer" plan. Since the EU Commission postponed the adoption of this European Cancer Plan to 2021, formal deliberations have not yet commenced.

Germany's Presidency of the Council of the EU was enriched by various European-level expert events hosted by authorities operating within the remit of the Federal Ministry of Health, such as the Federal Institute for Drugs and Medical Devices, the Robert Koch Institute and the Paul Ehrlich Institute, in the field of medicinal products, for instance.

Finally, the Federal Ministry of Health invited European policy stakeholders to get involved in the German Presidency and offered information exchange as well as closer collaboration. In the context of the associated programme, approximately 15 associations and institutions made use of the opportunity to enrich the Federal Ministry's Presidency programme with their own events and to discuss the focus areas of the German Presidency in a more multi-faceted manner.

What role did the German Presidency play during this period?

The role of a Council Presidency is that of an "honest broker" attempting to consider the interests and positions of all Member States and to find a common approach, particularly regarding the relationship with the other EU institutions. In light of the worst health crisis since the Spanish Flu, this confronted Germany's Presidency of the Council of the EU with major challenges.

Against this backdrop, adopting the **Council Conclusions on lessons learned from COVID-19**, on the EU's role in strengthening WHO and on a new EU Drugs Strategy 2021 -2025, which all required Council unanimity, represent great successes. These Council Conclusions set the course for EU health policies in the coming months and years. They will, in the medium and longer term, contribute towards a tangible improvement of healthcare both within the EU and beyond. This was largely made possible through close cooperation with European partners and very intensive and regular exchange, despite the absence of trips and physical meetings, thereby laying a solid foundation to address future tasks.

Outlook

The end of Germany's Presidency of the Council of the EU not only offers an opportunity to look back and take stock, but also to look to the future. On 1 January 2021, Portugal took over the Presidency of the Council of the EU for the fourth time. The Federal Ministry of Health strongly believes that, together with our Trio partners Portugal and Slovenia, the topics and projects in the field of European health policy, which were pursued and initiated under the German Presidency, can be advanced further and tangible results in the interest of the EU's citizens achieved. With this ambition and in light of the enormous impact of the COVID-19 pandemic, the Federal Ministry of Health has also already sought dialogue with the next Trio Presidency consisting of France, the Czech Republic and Sweden, which will hold the Presidency of the Council of the EU from 1 January 2022 to 30 June 2023.