



Brussels, 1 December 2020

Informal video conference of the ministers of Health 2 December 2020

Chair: Jens Spahn, German Federal Minister of Health

The meeting will begin at 10.00. In a session dedicated to the current pandemic situation and the responses to it, Andrea Ammon, the Director of the European Center for Disease Prevention and Control (ECDC) will inform ministers about the **epidemiological situation** in the EU. The presidency will then provide information about the work on the Conclusions on **COVID-19 lessons learned in health**. This will be followed by a public policy debate on building a **European Health Union**, which will also focus on current legislative proposals. The morning session will end around 12.30.

In the afternoon, the meeting will resume at 14.00 with an exchange of views on the **pharmaceutical strategy for Europe**. Then, the presidency will, among others, inform ministers about the state of play in relation to the Regulation on **health technology assessment** (public session) and the Regulation on **EU4Health Programme** (public session). The Commission will provide information about the **Europe's beating cancer plan** and the implementation of the **Regulation on medical devices** and the **Regulation on in vitro diagnostic medical devices**.

Online press conference with Minister Spahn and Commissioner Kyriakides at +/-13.15.

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Meeting page

Press conferences and public events by video streaming

Video coverage in broadcast quality (MPEG4) and photo gallery

This note has been drawn up under the responsibility of the Press Office.

"Building a European Health Union": three legislative proposals - exchange of views

The discussion will focus on the Commission communication from 11 November "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats", as well as on three legislative proposals: for a Regulation on serious cross-border threats to health, for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, and for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. The aim of the proposals is to strengthen the EU's health security framework and reinforce the crisis preparedness and response role of the European Centre for disease prevention and control (ECDC) and the European Medicines Agency (EMA).

The aim of the discussion is to provide guidance for the future examinations of the proposals by the Council working groups. Ministers will be given the opportunity to share their initial views on whether the legislative package is fit for purpose and can ensure stronger preparedness and strengthened response capacity during health crises.

To structure the debate, the presidency will invite ministers to provide answers to the following questions:

- Do you think that the three Commission proposals of 11 November 2020 on "Building a European Health Union" respond to the need for improved pandemic preparedness and response at EU level?
- How do you assess the proposals with respect to the governance structure, with respect to
 the interaction of the different crisis management bodies and mechanisms (e.g. the Health
 Security Committee, the Advisory Committee on Public Health Emergencies, the
 Committee on Serious Cross Border Threats to Health, ECDC, the EU Integrated Political
 Crisis Response Arrangements (IPCR) and with respect to the future role of the ECDC?

<u>Communication from the Commission - Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, 11 November 2020</u>

Proposal for a regulation on serious cross-border threats to health, 11 November 2020

<u>Proposal for a regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, 11 November 2020</u>

Proposal for a regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, 11 November 2020

A pharmaceutical strategy for Europe - exchange of views

Health ministers will share their first assessments of the recently presented strategy with a focus on the much needed cooperation between member states and the Commission. They will also discuss concrete measures to tackle shortages of medicinal products in the EU.

The Pharmaceutical Strategy for Europe was presented by the European Commission on 25 November 2020. The main aims of the initiative are to help ensure Europe's supply of safe and affordable medicines to meet patients' needs and to facilitate for the European pharmaceutical industry to remain an innovator and world leader. Further to this, the strategy is intended to make European pharmaceutical systems better prepared and more resilient in the face of present and future challenges.

Ensuring the supply of medicinal products in the EU is one of the priorities of Germany's presidency in the area of health. In relation to this, ministers will be invited to share their views on the following questions:

- What is your initial assessment of the Strategy, in particular considering its elements of cooperation between Member States and the Commission?
- Which should be the priority items to effectively tackle shortages of medicinal products in the EU with concrete measures to be implemented already in 2021?

Communication from the Commission - Pharmaceutical strategy for Europe, 25 November 2020

Other business:

1. The presidency will inform ministers about the state of play in relation to the proposal for a regulation on **health technology assessment** (public session).

Proposal for a regulation on health technology assessment, 31 January 2018

2. The presidency will brief about the state of play in relation to the proposal for a regulation on the **EU4Health Programme** for 2021-2027 (public session).

<u>Proposal for a regulation on the establishment of a Programme for the Union's action in the field of health – for the period 2021-2027, 28 May 2020</u>

Council's mandate for negotiations, 21 October 2020

- 3. The Commission will provide an updated information on the Europe's beating cancer plan
- 4. The Commission will brief ministers about the Implementation of the Regulation on **medical devices** and Regulation on **in vitro diagnostic medical devices**

Regulation (EU) 2017/745 on medical devices, 5 April 2017

Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, 23 April 2020

Regulation (EU) 2017/746 on in vitro diagnostic medical devices, 5 April 2017

- 5. The Netherlands delegation will provide information on measures taken to address **COVID-19 outbreaks in mink farms**
- 6. The German delegation will provide a summary of **Council activities in the Health area** during the German Presidency
- 7. The Portuguese delegation will present the **work programme of the incoming presidency** in the area of Health

EU health policy (background information)

COVID-19 coronavirus pandemic and the EU's response (background information)