Council of the European Union
General Secretariat

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LIMITE

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PHARM
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COMPET
COVID-19
CODEC

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (General)
Subject:	Informal videoconference of the members of the Working Party on Pharmaceuticals and Medical devices on 5 March 2021 - Presentation by the Commission

Delegations will find enclosed the presentation made by the Commission on the proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

European Commission

Regulation on a reinforced role of the EMA in crisis preparedness and management for medicinal products and medical devices

Working Party on Pharmaceuticals and Medical devices, 5 March 2021

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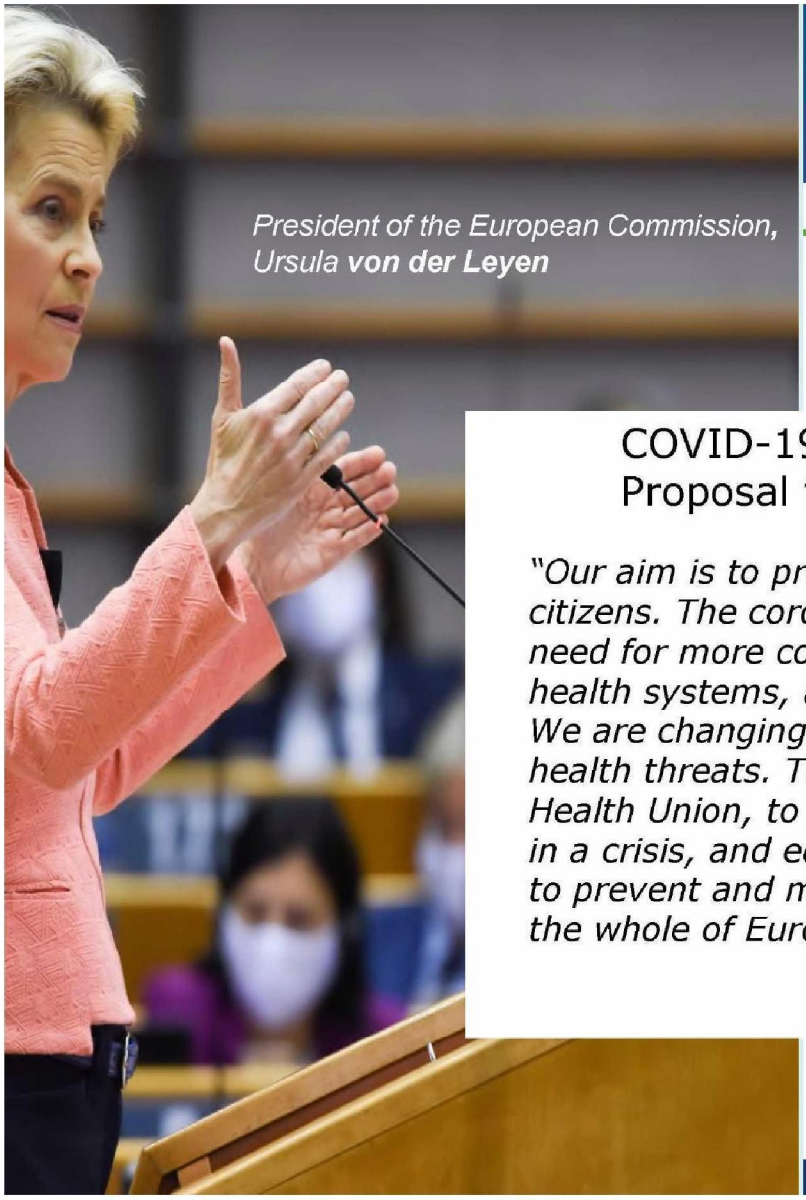
Health and Food Safety

European Commission

Stronger and more operational European Medicines Agency



COVID-19 Health Response Package: Proposal for a Reinforced EMA Role

"Our aim is to protect the health of all European citizens. The coronavirus pandemic has highlighted the need for more coordination in the EU, more resilient health systems, and better preparation for future crises. We are changing the way we address cross-border health threats. Today, we start building a European Health Union, to protect citizens with high quality care in a crisis, and equip the Union and its Member States to prevent and manage health emergencies that affect the whole of Europe."

European Commission

Shortages of medicines and crisis management

Preparatory

- Establish **Medicines Steering Group** – high-level MS representation (HMA) + COM + (Industry on an invitational basis)
- **Monitoring and reporting** procedures – MS and industry data submission; aggregation
- Develop **IT tools**
- **Escalate** when major event

Legal Basis: Art 114 / 168(4)(c) TFEU

European Commission

Shortages of medicines and crisis management

MAJOR EVENT/ PHE

Operational shortages

- Establish **list of 'critical' medicines**
- **Monitor** supply and demand - MS and industry
- **Reporting** mechanisms
- Provide **recommendation**
- Consider need for **action** for mitigation/countermeasures – link to Cross Border Health Threats

Legal Basis: Art 114 / 168(4)(c) TFEU

European Commission

Shortages of medicines and crisis management

MAJOR EVENT/ PHE

Operational – quality, safety, efficacy

- **Build on IRN structure**: IRN will continue dealing with incidents and routine measures and the steering group with major event/crises
- Assist in management of major events
- **Urgent and coordinated action** with regard to Quality / Safety /Efficacy

Legal Basis: Art 114 / 168(4)(c) TFEU

European Commission

Shortages of medical devices and expert panels

Similar to medicinal product approach, while **safeguarding** the specific characteristics of the medical device sector and its regulatory approach, with some variations possible e.g. more **sector-specific** mitigation measures

European Commission

Shortages of medical devices and expert panels

Expert panels objective:

Provide a permanent home for the **panels** and maximise how they are used, incl. during crisis

EMA to provide **secretariat** and host meetings

Additional tasks on behalf of the Commission to support work of the panels

European Commission

Emergency Task Force

Scientific response

PREPARATORY

- Establish **Emergency Task Force**
  - Membership to include various Agency committees and working groups, the Co-ordination Group for Mutual Recognition And Decentralised Procedures (CMD(h)) and the Clinical Trials Coordination and Advisory Group (CTAG))
- Specific composition and external input can be **adapted** to event
- **Develop working procedures** – submission of data, provision of Member State expertise
- **Develop IT tools** for data submission, effectiveness and safety monitoring for vaccines
- Tasks shall be performed separate from and *without prejudice to scientific committees*

European Commission

Emergency Task Force

Scientific response

OPERATIONAL (during a public health crisis)

- **Accelerated scientific advice** on draft clinical trial protocols for candidate medicines
- **Review** at the request of a developer – endorsement of the advice by CHMP
- **Involvement** of representatives of Member States where the Clinical Trial Application is or will be submitted
- Member States need to take the advice duly into account when authorising the clinical trial
- **Scientific support to facilitate clinical trials** in the EU, including advice on the possibilities to set up larger multinational trials by defining responsibilities of (co-)sponsors Rolling review' of incoming evidence
- ETF assists CHMP
- ETF may **request data** from developers and use observational data
- **Recommendations** of the use of candidate medicines in national compassionate use programmes and on 'repurposed' medicines based on request of MS or Commission
- **CHMP remains responsible for scientific opinions** – no change to current distribution of tasks – however, clarifications with regard to possibility to provide compassionate use opinions on nationally authorised products
- **Communication** activities