EC’s legal proposal for EMA’s reinforced role in crisis preparedness and how it fits with other EC strategic initiatives

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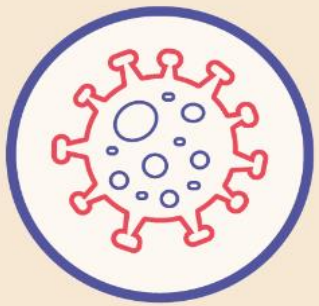
Health Union package in the context

Step 1

Step 2

European Commission

PHARMACEUTICAL STRATEGY FOR EUROPE



Learning from COVID-19, towards a crisis-resistant system

Ensuring accessibility and affordability of medicines

Supporting sustainable innovation, emerging science and digitalisation

Reducing medicines shortages and securing strategic autonomy

#EUPharmaStrategy

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Tackling Health Crises

Coronavirus impact

8.2 million
infected people in the EU since January 2020

€2.7 billion
EU emergency support for coronavirus health response, e.g. medicines, vaccines and protective equipment

66% of citizens
want more EU responsibility in health crises

Early lessons learnt from the COVID-19 pandemic show that **the EU needs**:

- more **coordination**
- more **resilient health systems**, and
- to **be better prepared** for future crises

European Commission

European Health Union package
11 November 2020

First steps towards European Health Union, as announced in SOTEU; a set of proposals to:

1. strengthen the **EU's health security framework**, and
2. **reinforce** the crisis preparedness and response **role of key EU agencies**

- Communication: Building a European Health Union - preparedness and resilience;
- Proposal for a Regulation on serious cross-border threats to health
- **Proposal to extend the mandate of the European Medicines Agency**
- Proposal to extend the mandate of the European Centre for Disease Prevention and Control

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Context

- Experiences during the COVID-19 pandemic:
  - Shortages of medicines and medical devices critical for addressing the pandemic
    - Use of ad hoc structures within Com / EMA to mitigate such shortages = the EU Executive Steering Committee / Clearing House
  - (Initially) Lack of treatment / prevention options, many ‘candidates’ →
    - Ad hoc procedures in EMA to review evidence / give (fast-track) advice on clinical trial protocols / new & repurposed medicines = Emergency Task Force
- 2-step approach: tailored approach now in view of possible further measures as part of the Pharmaceutical Strategy
- Introduction of expert panels under revised Medical Devices legislative framework

Proposal to extend the mandate of the European Medicines Agency- Preparedness

Specific objectives of the proposal are to:

a) **monitor and mitigate potential and actual shortages** of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health

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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

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 CBHT

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 Q / S /E

Shortages of medical devices and expert panels

Similar to mp 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

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

Proposal to extend the mandate of the European Medicines Agency- Response

Specific objectives of the proposal are to:

b) ensure **timely development of high quality, safe and efficacious medicinal products**, with a particular focus on addressing a given public health emergency and gaining from the experience of this public health emergency

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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*

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

Proposal to extend the mandate of the European Medicines Agency- Expert Panels on Medical devices

Specific objectives of the proposal are to:

c) ensure **smooth functioning of expert panels on medical devices** established under the Regulation on medical devices (2017) involved in the assessment of some high-risk devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.

Expert panels objective:

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

EMA to provide **secretariat** and host meetings

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

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State of play

- 7 Council Working Party meetings since March 2021
- Proposal was generally well supported by delegations who broadly agreed that it will support a stronger EHU
- Homogeneous comments brought forward by the delegations, focused on
  - **Definitions of shortages (aligned with EMA/ HMA) and major events**
  - **Inclusion of veterinary medicinal products**
  - **Sustainable funding of EMA and MS obligations**
  - **Medical devices (closer consultation of the MDCG and MDSG)**
  - **Governance of the ETF and relationship with Committees and Working Parties**
  - **Available stock at national level/ demand and supply data**
  - **Data protection and international transfer of data to third parties**
- Working towards agreed compromise text by end of PT presidency
- In Parliament, plenary votes are expected 21 June on a negotiating mandate