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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 23 March 2021 - Presentations by the Commission

Delegations will find enclosed the presentations made by the Commission at the informal videoconference of the members of the Working Party on Pharmaceuticals and Medical devices on 23 March 2021.

Mapping of EMA's different activities and linkages with other agencies (in particular the ECDC and the future HERA)

CWP meeting 23 March 2020

5.1.2e

Objectives

ECDC

Strengthening Europe's defences against infectious diseases through **surveillance, epidemic intelligence, response, scientific advice, microbiology, preparedness, public health training, international relations**.

The proposal aims to provide reinforced capacities of the Centre, to support preparedness, surveillance, risk assessment, and early warning and response to face future cross-border health threats.

EMA

Foster scientific excellence in the **evaluation** and **supervision** of medicines, for the benefit of public and animal health in the European Union (EU).

The proposal aims to:

- 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;
- ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing a given public health emergency;
- ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.

HERA

Strengthen the EU's preparedness and response in terms of **medical countermeasures for serious cross-border threats to health, both of natural and intentional origin**.

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Proposal for a Regulation on EMA

- The proposal seeks to ensure inter-Agency cooperation during emergencies, most notably with the European Centre for Disease Prevention and Control (ECDC).
- Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments
  - The Agency should cooperate and promote synergies with other Union bodies and decentralised agencies, such as the European Centre for Disease and Control (ECDC), European Food Safety Authority (EFSA) and take full advantage and ensure consistency with the EU4Health programme and other EU programmes financing actions in the domain of public health. As from 2022, the Agency would take over some tasks currently performed by the Commission under the Health programme Expert panels (JRC).

Links between the EMA proposal and ECDC proposal

- EMA and ECDC will work closely together during PHEs, sharing epidemiological data to help forecast demand for key medicines and devices and on studies to monitoring the safety and effectiveness of vaccines (already for COVID-19)

Article 8 – EMA proposal

- The Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs

Article 11 – ECDC proposal

Collection and analysis of data

- In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts […], upon request of the European Medicines Agency, in an objective, reliable and easily accessible way and on the basis of the best available information.

Links between the EMA proposal and ECDC proposal

Article 18 – EMA Proposal

Vaccines platform

- EMA and ECDC will work together to coordinate independent studies to monitor the safety and effectiveness of vaccines.
- This platform should be deployed immediately following adoption to allow for monitoring of Covid-19 vaccines.

Article 5a – ECDC Proposal

Prevention of communicable diseases

- The Centre shall coordinate independent post-marketing vaccines effectiveness and safety monitoring studies collecting new information and/or using the relevant data collected by competent bodies. That work shall be conducted jointly with the European Medicines Agency and notably though a new vaccine monitoring platform.

Proposal for a Regulation on serious cross-border threats to health

Article 20 Public health risk assessment

- The risk assessment shall be carried out in the case of a threat referred to in Article 2(1) in cooperation with the European Medicines Agency ('EMA)', where the threat is linked to medicinal products.
- *Note: EMA participates as observer in the meetings of the Health Security Committee*

Article 23 Recognition of emergency situation

- The recognition of a PHE based on the expert opinion of the Advisory Committee, formally recognise a public health emergency as trigger point for operational phase under EMA (other than major events)
- Representatives of the ECDC and of the EMA participate as observers in the Advisory Committee.

Article 25 Legal effects of *[emergency]* recognition

- The recognition of an emergency situation pursuant to Article 23 shall have the legal effect of enabling the introduction of:
  - (a) measures, which are applicable during the period of public health emergencies, related to medicinal products and medical devices provided for in *[Regulation EMA].*

Link to HERA

- HERA is a component of the European Health Union
- Impact assessment proposed for 2021
- Exact extent of HERA mandate is still being developed but will not duplicate/ replace proposed measures in EMA proposal
- Synergies will be created e.g. information gathered as evidence base for actions of HERA

HERA canalises financial and logistic support for development and deployment of potential **countermeasures**, adopting whole life cycle approach (from epidemiological and technological intelligence, threat assessment to conceptualisation, development, manufacturing and deployment of countermeasures in case of need).

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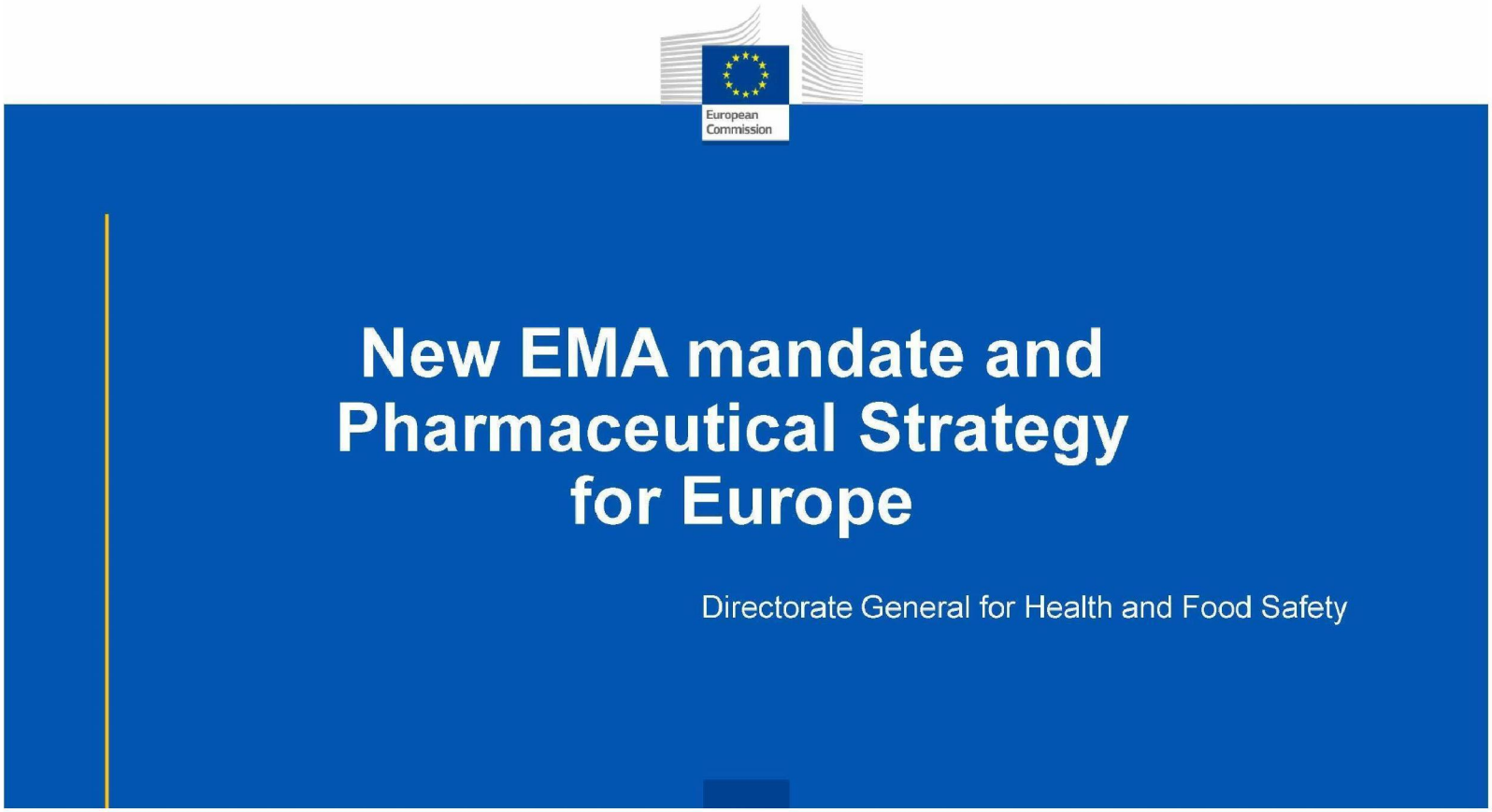
Link to HERA

- HERA would complement EMA activities as regards: horizon scanning for emerging new technologies for **medicinal countermeasures**, providing scientific and regulatory advice and logistic support in clinical trials for these countermeasures, identifying and addressing supply bottlenecks (for countermeasures that experience shortages and supply problems), data pulling, ensuring contacts with academia, ensuring training.
- More over HERA would build up market intelligence, address market failures as regards medicinal countermeasures, ensure **financial support** for last phases clinical trials, ensuring manufacturing capacities, offer public procurement capacities, ensure distribution.

Thank you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New EMA mandate and Pharmaceutical Strategy for Europe
Directorate General for Health and Food Safety

Policy context

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Proposal for a Regulation on a reinforced role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

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**:
  - 1st Revision of the EMA mandate – COVID-19
  - 2nd Possible further measures as part of the Pharmaceutical Strategy

Revision of EMA mandate: Main features

- Legal Basis: Art 114 / 168(4)(c) TFEU
- 3 main pillars
  - Shortages and safety of MPs
  - Advice on 'candidate medicines'
  - Shortages of MDs + expert panels
- Group-based structures
  - Input from MS (experts) and industry
  - Agency support (secretariat and IT tools)
  - Output in the form of recommendations / opinions

Pharmaceutical Strategy for Europe – Creating a more crisis-resilient pharmaceuticals system

Directorate General for Health and Food Safety

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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Flagships of the pharmaceutical strategy

Ensure access and affordability of medicines for patients and health systems sustainability

Unmet needs

- Boost **novel antibiotics** - 2021
- Restrict and optimise the **use** of antimicrobial medicines (2021)
- Support medicines for **children and rare diseases** (2022)
- Collaboration on unmet needs **evidence generation** , **HTA** (2021)

Accessibility

- Revise the **system of incentives and obligations** in legislation to support innovation, access and the affordability of medicines (2022)
- Improve access to **generic and biosimilar medicines** (2022)

Affordability

- Address in legislation the **market effects** impacting on affordability (2022)
- Develop **mutual learning and best-practice exchange** on pricing, payment and procurement policies (2021-2024)

Flagships of the pharmaceutical strategy

Enabling sustainable innovation

Fertile environment

- Optimise the **supplementary protection certificates system** (2022)
- Legislative proposal on **European Health Data Space** (2021)
- **Interoperable data access infrastructure** to facilitate secure cross-border analysis of health data (2021-2025)
- Support **public-private and public-public partnerships** (2021)

Innovation and digital transformation

- Adapt legislation to **cutting-edge products, scientific developments** and transformations (2022)
- **Enhance dialogue** among regulatory and other relevant authorities (2021)
- Take forward the use of **HPC and AI** (2021-2022)
- Establish the secure federated access to 10 million **genomes** (2025)

Flexible regulatory system

- **Simplification and streamlining** of approval procedures and flexibility for timely adaptation (2022)
- **Optimise the lifecycle management of medicines** more efficient and adapted to digitalisation (2021-2023)

Flagships of the pharmaceutical strategy

Ensuring availability and addressing shortages

Secure the supply

- Revise the legislation to **enhance security of supply and address shortages** (2022)
- Launch a structured dialogue to **identify vulnerabilities** in the global supply chain (2021)
- Ensure **increased transparency of the industry** on the supply chains (2021)

High quality, safe and environmentally sustainable

- Revise manufacturing and supply provisions in the legislation to **ensure environmental sustainability, quality and preparedness** (2022)
- Revise the legislation to strengthen **environmental risk assessment** requirements and conditions of use (2022)

Contribute to a crisis resistant system

- Proposal for an **EU Health Emergency Response Authority**
- Revise the general pharmaceutical legislation to complement the **reinforced role of EMA** and **excellence** of the medicines agencies network

Flagships of the pharmaceutical strategy

Succeeding on the global level

Work with the EMA and the network of national regulators, to promote **regulatory convergence** to ensure access to safe, effective high-quality and affordable medicinal products globally (ongoing)

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Thank you

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Public Health information:
http://ec.europa.eu/health/index_en.htm

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https://ec.europa.eu/health/human-use/strategy_en

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