Multistakeholder workshop
on EMA's extended mandate

1 April 2022, 09:00 – 16:15 (CET)

VIRTUAL MEETING, THE EVENT WILL BE BROADCAST LIVE

Background and objectives

The regulation reinforcing EMA's role in crisis preparedness and management for medicinal products and medical devices has entered into application on 1 March 2022. It extends EMA's mandate in key areas and formalises structures that EMA has put in place already for the COVID-19 pandemic.

Under the new mandate, EMA will monitor events which might lead to a crisis situation, as well as

with the reporting of shortages of critical medicines during a public health crisis. The Agency will also coordinate, after an initial transitional period, responses of EU countries on shortages of critical Medical Devices and in vitro diagnostics occurring in crisis situations.

The new mandate gives a clear legal anchor for reinforcing the Agency's Emergency Task Force (ETF) activities in providing advice on medicines development and support to their authorisation and monitoring. It also transfers to EMA the task of coordinating the 'EU Expert Panels' for clinical evaluation of certain high-risk medical devices and in vitro diagnostics and requires EMA to invest in and leverage real world data to support crisis preparedness and response.

EMA is organising this open event to:

- Inform stakeholders of the adopted legislation and EMA's new mandate areas
- Explain plans for implementation of EMA new processes and timelines
- Listen to stakeholders' views and concerns
- Discuss processes and opportunities for engagement

During the meeting we will use www.sli.do **to collect views from stakeholders, please feel free to use #EMAExtendedMandate**

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Chaired by Fergus Sweeney (EMA)

Introduction

08:45 – 09:00	**Joining and technical checks**	**15'**
09:00 – 09:05	**Welcome and introduction** *Emer Cooke (EMA Executive Director)*	**5'**
09:05 – 09:10	**Outline of the day by the Chair** *Fergus Sweeney (EMA Head of Clinical Studies and Manufacturing Task Force)*	**5'**
09:10 – 09:25	**Presentation on the new legislation by the European Commission** *Sandra Gallina (EC Director-General SANTE)*	**15'**
09:25 – 09:55	**The European Health Emergency Preparedness context** *Emer Cooke (EMA Executive Director)* *Andrea Ammon (ECDC Executive Director)* *Wolfgang Philipp (EC Acting Director HERA)*	**30'**
09:55 – 10:25	**Opening statements from stakeholders** *Adrian van den Hoven (Medicines for Europe Director General)* *Jesus Rueda (MedTech Europe Director of Strategies, Special Projects & International Affairs)* *Marcus Guardian (EUnetHTA Chief Operating Officer)* *Ulrich Jäger (HCPWP Co-chair)* *Kaisa Immonen (PCWP Co-chair)*	**30'**
10:25 – 10:30	**Stakeholders' views (Slido)**	**5'**
10:30 – 10:40	**Coffee break**	**10'**

Session 1: Monitoring and mitigating shortages of medicines and devices

Co-chairs:

Monica Dias (EMA Head of Supply and Availability of Medicines and Devices Workstream)

Karl Broich (MSSG Co-chair)

10:40 – 10:45	**Session outline**	**5'**
10:45 – 11:05	**Introduction by topic lead** *Joao Ferreira (EMA Medicines and Medical Devices Shortages)*	**20'**

Discussion with panel experts:

11:05 – 11:15	**Panel expert *Tour de Table*** *João Ferreira (EMA Medicines and Medical Devices Shortages)* *Aleksandra Dacić-Pilčević (EMA Head of Customer Advocacy and Delivery)* *Sylvain Giraud (EC Head of Unit SANTE B4 - Medical products: quality, safety, innovation)* *Thierry Sirdey (ANSM Division for medical devices, cosmetics and in vitro diagnostic devices Director)* *Darren Scully (HPRA Medicine Shortages and Borderline Classification Manager)* *Marco Farinelli (EFPIA representative)* *Adrian Van de Hoven (Medicines for Europe Director General)* *Jesus Rueda (MedTech Europe Director of Strategies, Special Projects & International Affairs)*	**10'**
11:15 – 12:00	**Comments and questions from participants**	**45'**
12:00 – 12:05	**Stakeholders' views (Slido)**	**5'**
12:05 – 12:10	**Session wrap up**	**5'**
12:10 – 12:50	**Lunch break**	**40'**

Session 2: Addressing public health emergencies through the Emergency Task Force (ETF)

Co-chairs:

Marco Cavaleri (EMA Head of Biological Health Threats and Vaccines Strategy and ETF Co-Chair)

Bruno Sepodes (CHMP Vice-Chair and ETF Co-Chair)

12:50 – 12:55	**Session outline**	**10'**
12:55 – 13:15	**Introduction by topic lead** *Manuela Mura (EMA Biological Health Threats and Vaccines Strategy)*	**20'**

Discussion with panel experts

13:15 – 13:25	**Panel expert *Tour de Table***	**10'**
	Manuela Mura (EMA Biological Health Threats and Vaccines Strategy) *Aleksandra Dacić-Pilčević (EMA Head of Customer Advocacy and Delivery)* *Florian Schmidt (EC Deputy Head of Unit SANTE B5 - Medicines: policy, authorisation and monitoring)* *Lucia Pastore Celentano (ECDC Head of Programme, Vaccine-Preventable Diseases)* *Martin Huber (PRAC member)* *Mair Powell (VWP Chair and IDWP member)* *Ann Marie Janson Lang (CTAG and CTCG member)*	
13:25 – 14:10	**Comments and questions from participants**	**45'**
14:10 – 14:15	**Stakeholders' views (Slido)**	**5'**
14:15 – 14:20	**Session wrap up**	**5'**
14:20 – 14:30	**Coffee break**	**10'**

Session 3: Coordinating expert panels on high-risk medical devices and in vitro diagnostics

Co-chairs:

Alexis Nolte (EMA Head of Human Medicines Devices)

Anna-Eva Ampelas (EC Head of Unit SANTE B6 - Medical devices and HTA)

14:30 – 14:35	**Session outline**	**5'**
14:35 – 14:55	**Introduction by topic lead** *Silvy da Rocha Dias (EMA Committees and Quality Assurance)*	**20'**

Discussion with panel experts

14:55 – 15:05	**Panel expert *Tour de Table*** *Silvy da Rocha Dias (EMA Committees and Quality Assurance)* *Aleksandra Dacić-Pilčević (EMA Head of Customer Advocacy and Delivery)* *Claudius Griesinger (EC Project Leader, Scientific Support Medical Devices Coordinator JRC)* *Niall MacAleen (Director of Medical Devices, HPRA)* *Rob Nelissen (Orthopaedics, Traumatology, Rehabilitation, Rheumatology Expert Panel Chair)* *Olga Polydorou (Screening Expert Panel Chair)* *Matthias Niedrig (IVD Expert Panel Vice Chair)* *Oliver Bisazza (MedTech Europe Director General of Industrial Policies)*	**10'**
15:05 – 15:50	**Comments and questions from participants**	**45'**
15:50 – 15:55	**Stakeholders' views (Slido)**	**5'**
15:55 – 16:00	**Session wrap up**	**5'**
16:00 – 16:15	**Wrap up and closing remarks** *Fergus Sweeney (EMA Head of Clinical Studies and Manufacturing Task Force)*	**15'**

Abbreviations

ANSM - National Agency for the Safety of Medicine and Health Products, France

CHMP - Committee for Medicinal Products for Human Use

CTAG - Clinical Trials Coordination and Advisory Group

EC – European Commission

ECDC - European Centre for Disease Prevention and Control

EFPIA - European Federation of Pharmaceutical Industries and Associations

EMA – European Medicines Agency

ETF - Emergency Task Force

EUnetHTA - European Network for Health Technology Assessment

HCPWP - Healthcare Professionals' Working Party

HERA - European Health Emergency preparedness and Response Authority

HPRA - Health Products Regulatory Authority, Ireland

IVD - Medical devices and In Vitro Diagnostic medical devices

MSSG - Executive Steering Group on Shortages and Safety of Medicinal Products or 'Medicines Shortages Steering Group'

PCWP - Patients' and Consumers' Working Party

PRAC - Pharmacovigilance Risk Assessment Committee

SANTE - Health and food safety

VWP - Vaccines Working Party