HMA/EMA multi-stakeholder workshop on shortages

1-2 March 2023, EMA, Amsterdam

Hybrid meeting - WebEx/Room 1D

Background and objectives

Improving the availability of human and veterinary medicines authorised in the EU is a key priority of the EU Network.

An HMA/EMA Task Force was established by EU regulators in 2016 to develop and coordinate actions for better prevention, identification, management of and communication on issues that can affect the availability of medicines, in order to improve continuity of supply of human and veterinary medicines across Europe.

Shortages and availability problems are complex with no quick solutions. Medicine regulatory authorities are only one of the many actors involved in availability issues, however they play an important role in their prevention and management. By bringing together experts from various EU member states, the work of the task force lays the foundations for an improved and harmonised EU approach in addressing the problems of medicines' availability issues.

It is designed to function as a 'supply and availability hub', tracking progress on the medicine availability and shortage-related activities that the European medicines regulatory network is undertaking under the following EU projects:

- the European medicines agencies network strategy to 2025
- the European Commission's Pharmaceutical Strategy for Europe
- the 'Joint Action on Shortages', a three-year plan starting at the end of 2022 to enhance national systems in tackling medicines shortages in a harmonised way

This aims to streamline processes, ensure synergies and avoid duplication of work within the network.

In the meantime, the regulation reinforcing EMA's role in crisis preparedness and management for medicinal products and medical devices entered into application on 1 March 2022. Complementary to the HMA/EMA Task Force, the regulation has prompted EMA to set up structures and processes for dealing with medicine shortages focusing on crisis situations. 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 aims of the workshop are to:

- Inform stakeholders about the HMA/EMA Task Force activities on medicines shortages and availability and interfaces with other initiatives.
- Update stakeholders on progress with the Task Force deliverables and identify areas of agreement as well as areas for further discussion.
- Share stakeholders' perspectives and (ongoing/planned) initiatives to address availability issues and discuss how these can contribute to the future deliverables of the Task Force.

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Chaired by Monica Dias (EMA) and Hugues Malonne (HMA)

Day 1 - 1 March 2023, 13h00-17h45 (CET)

13:00 Joining and technical checks

13:15 Welcome and opening speech

Welcome and introduction **10'**
Emer Cooke (EMA)

Outline of the day and objectives **10'**
Hugues Malonne (HMA)

13:35 Session 1: Setting the scene

Moderator: Karl Broich (HMA)

EU initiatives on shortages and availability of medicines **15'**
Sylvain Giraud (DG SANTE, EC)

European Medicines Agencies Network initiatives **15'**
Lorraine Nolan (HMA)

Monitoring of events and preparedness for public health emergencies **25'**
Agnes Marta Molnar (DG HERA, EC)
Anthony Humphreys (EMA)

What happened with the HMA/EMA Task Force on availability of authorised medicines (TF AAM) since 2018 **15'**
Hugues Malonne (HMA)
Monica Dias (EMA)

Q&A **20'**

15:10 *Coffee break*

15:25 Session 2: Parallel breakout sessions

Room 1A	Room 1D	Room 1G
Immunoglobulins	**Biosimilars**	**Medicines for veterinary use**

Room 1A

Breakout session 2A: Immunoglobulins
Facilitators: María Jesús Lamas (HMA)
Rapporteur: Emilija Matelytė (EMA)

Overview of immunoglobulins supply situation in the EU *Klaus Kruttwig (EMA)*	**15'**
EU legislation and policy on blood and blood components *Stefaan van der Spiegel (DG SANTE, EC)*	**15'**
SUPPLY project *Fabio Candura (ISS)* *Daphne Thijssen-Timmer (European Blood Alliance)*	**15'**
Discussion on immunoglobulins shortages in the EU Tour de table	**60'**
Wrap up and key messages to report to plenary	**25'**

Room 1D

Breakout session 2B: Biosimilars
Facilitators: Steffen Thirstrup (EMA)
Rapporteur: Rosa Gonzalez-Quevedo (EMA)

Work plan of the HMA Biosimilar Working Group (BSWG) *Esa Heinonen (HMA)*	**15'**
Scientific rationale for interchangeability of biosimilars in the EU *Elena Wolff-Holz (PEI)*	**10'**
HMA/EMA statement on interchangeability of biosimilars *Steffen Thirstrup (EMA)*	**10'**
Discussion Tour de table	**70'**
Wrap up and key messages to report to plenary	**25'**

Room 1G	**Breakout session 2C: Medicines for veterinary use** *Facilitators: Ivo Claassen (EMA) and Constance McDaniel (HMA)* *Rapporteur: Janos Kovacs (EMA)*	
	Selected presentations: *Nancy de Briyne (FVE)* *Elsa Vecino (Accessvetmed)* *Rick Clayton (AnimalHealthEurope)* *Paule Carnat-Gautier (ANSES)* *Inke Reimer (BVL)*	**60'**
	Discussion Tour de table	**60'**
	Wrap up and key messages to report to plenary	**15'**
17:45	**End of day 1**	

Day 2 - 2 March 2023, 09h00-16h45 (CET)

08:30 Joining and technical checks

09:00 Welcome and summary of day 1

Welcome and introduction **15'**
Monica Dias (EMA) and Hugues Malonne (HMA)

Reporting from breakout sessions **45'**
Rapporteur session 2a: Emilija Matelytė (EMA)
Rapporteur session 2b: Rosa Gonzalez-Quevedo (EMA)
Rapporteur session 2c: Janos Kovacs (EMA)

10:00 Session 3: Prevention of shortages

Moderator: Darren Scully (HMA)

Short presentations by stakeholders **40'**
Ancel.la Santos (BEUC)
Stephan Roenninger (Industry)
Jorge Batista (PGEU)
Nancy de Briyne (FVE)

Network priorities to 2025: TF AAM workplan **15'**
Maria-Jesus Alcaraz Tomas (EMA)

Discussion **40'**

11:40 *Coffee break*

11:55 Session 4: Permanent withdrawals from the market

Moderator: Momir Radulovic (HMA)

Flash statements by stakeholders **35'**
Charlotte Roffiaen (EPHA)
Mary McCarthy (UEMO)
Adrian van den Hoven (Industry)
Michael Ermisch (GKV-Spitzenverband)
Matjaz Marc (JAZMP, SPOC WP)

Network priorities to 2025: TF AAM workplan **15'**
Joao Ferreira (EMA)
Michael Berntgen (EMA)

Discussion **30'**

13:20	***Lunch***	
14:00	**Session 5: Communication and transparency**	
	Moderator: Yngvil Knudsen (HMA)	
	Short presentations by stakeholders *Marko Korenjak (PCWP)* *Jean-François Duliere (Industry)* *Rosa Giuliani (HCPWP)* *Diego Pernas (AEMSP)*	**30'**
	Network priorities to 2025: TF AAM workplan *Juan Garcia Burgos (EMA)* *Inga Abed (EMA)*	**15'**
	Discussion	**30'**
15:20	***Coffee break***	
15:30	**Session 6: Work ahead to 2025**	
	Panel discussion on: What have we learnt so far? What is missing? What needs to improve?	**45'**
16:20	**Closing remarks**	
	Wrap up: take-home messages and next steps *Monica Dias (EMA) and Hugues Malonne (HMA)*	**10'**
16:30	**End of meeting**	

List of speakers

Inga Abed	Medical writer, Public and Stakeholders Engagement Department, EMA and member of the TF AAM Thematic Working Group on
Jorge Batista	Professional Affairs Advisor, Pharmaceutical Group of the European Union (PGEU) and member of EMA's Healthcare Professionals' Working Party (HCPWP)
Michael Berntgen	Head of Scientific Evidence Generation Department, EMA
Karl Broich	President, Federal Institute for Drugs and Medical Devices, Germany (BfArM), Chairperson of the Heads of Medicines Agencies (HMA) Management Group and Co-chair of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)
Fabio Candura	Director, Plasma and Plasma-derived Medicinal Products Area, National Blood Centre (ISS), National Institute of Health, Italy
Paule Carnat-Gautier	Deputy Director, French Agency for Veterinary Medicinal Products (ANSES)
Ivo Claassen	Deputy Executive Director and Head of Veterinary Medicines Division, EMA, member of the TF AAM
Rick Clayton	Technical Director, AnimalhealthEurope
Emer Cooke	Executive Director, EMA
Nancy de Briyne	Executive Director, Federation of Veterinarians of Europe (FVE)
Monica Dias	Head of Supply and Availability of medicines and Devices, EMA and Co-chair of the TF AAM
Jean-François Duliere	Representative of industry associations
Michael Ermisch	Specialist for medicinal products at GKV-Spitzenverband, the National Association of Statutory Health Insurance Funds, Germany
Joao Ferreira	Supply and Availability of medicines and Devices' specialist, EMA and secretariat of the TF AAM
Juan Garcia Burgos	Head of Public and Stakeholders Engagement Department, EMA and Co-Chair of the TF AAM Thematic Working Group on Communication
Sylvain Giraud	Head of Unit Medical Products: Quality, Safety, Innovation, European Commission (DG SANTE, EC)
Rosa Giuliani	European Society for Medical Oncology (ESMO) and Co-Chair of EMA's Healthcare Professional Working Party (HCPWP)
Rosa Gonzalez-Quevedo	Scientific Research Officer, Public and Stakeholders Engagement Department, EMA

Esa Heinonen	Senior adviser, Finnish Medicines Agency (Fimea) and Chair of the HMA Working Group of Biosimilars (BSWG)
Anthony Humphreys	Head of Regulatory Science and Innovation Task Force, EMA
Maria Jesus Alcaraz	Medicines and Medical Devices Shortages Specialist, EMA and Co-Chair of the TF AAM Thematic Working Group on availability and supply disruptions
María Jesús Lamas	Director, Spanish Agency for Medicines and Medical Devices (AEMPS), member of the TF AAM Steering Commitee
Yngvil Knudsen	Unit for Communication, The Norwegian Medicines Agency, and Co-Chair of the TF AAM Thematic Working Group on communication
Marko Korenjak	President of the European Liver Patient Association (ELPA) and Co-Chair of EMA's Patient and Consumer Working Party (PCWP)
Janos Kovacs	Scientific Administrator, Veterinary Medicines Division, EMA
Klaus Kruttwig	Medicines and Medical Devices Shortages Specialist, EMA
Hugues Malonne	Federal Agency for Medicines and Health Products, Belgium (AFMPS), and Co-chair of the TF AAM
Matjaz Marc	Head of Division for pharmacoeconomics, market monitoring and HTA, Agency for medicinal products and medical devices, Slovenia (JAZMP) and member of the EMA Medicines Shortages Single Point of Contact (SPOC) Working Party
Agnes Marta Molnar	Deputy Head of Unit, Intelligence Gathering, Analysis and Innovation, European Commission (DG HERA, EC)
Emilija Matelytė	Medicines and Medical Devices Shortages Officer, EMA
Mary McCarthy	European Union of General Practitioners (UEMO) and alternate member of EMA's Healthcare Professionals' Working Party (HCPWP)
Constance McDaniel	Head of Unit, Federal Office for Consumer Protection and Food Safety, Germany (BVL) and member of the TF AAM Steering Committee
Lorraine Nolan	Chief Executive, Health Products Regulatory Authority, Ireland (HPRA), EMA's Management Board Chair and member of the TF AAM Steering Committee
Diego Pernas	Head of communications and PR, Spanish Agency of Medicines and Medical Products (AEMPS) and member of the TF AAM Thematic Working Group on Communication
Momir Radulović	Executive Director, Agency for Medicinal Products and Medical Devices, Slovenia (JAZMP), EMA Management Board member, Heads of Medicines Management Group member (HMA), and member of the TF AAM Steering Committee
Inke Reimer	Federal Office for Consumer Protection and Food Safety, Germany (BVL)
Stephan Roenninger	Representative of industry associations

Charlotte Roffiaen	European Policy Advisor at France Assos Santé (EPHA member) and Representative of EMA's Patients' and Consumers' Working Party (PCWP) at the MSSG
Ancel·la Santos	Senior Health Policy Officer, European Consumer Organisation (BEUC), Member of EMA's Patients' and Consumers' Working Party (PCWP)
Darren Scully	Medicine Shortages and Borderline Classification Manager, Health Products Regulatory Authority, Ireland (HPRA) and Co-Chair of the TF AAM Thematic Working Group on availability and supply disruptions
Daphne Thijssen-Timmer	Director Sanquin Bloodbank, Netherlands and vice president of the executive board of the European Blood Alliance
Steffen Thirstrup	Chief Medical Officer, EMA
Adrian van den Hoven	Representative of industry associations
Stefaan van der Spiegel	Team Leader - substances of human origin, Unit Medical Products: Quality, Safety, Innovation, European Commission (DG SANTE, EC)
Elsa Vecino	Technical Director, Access VetMed
Elena Wolff-Holz	Medical Assessor, PEI, up to recently Chair of EMA's Biosimilar Medicinal Products Working Party (BMWP)