18 October 2018
EMA/201498/2018

Agenda - HMA/EMA workshop on availability of authorised medicines

Multi-stakeholder meeting with the HMA/EMA Task Force on availability of authorised medicines

9 November 2018, meeting room: 3A

Co-chairs: Kristin Raudsepp (HMA) and Noël Wathion (EMA)

Background

Unavailability of medicines in the EU, either because medicines are not marketed or because of supply disruptions, has been recognised by HMA and EMA as an area of great concern[1] affecting all stakeholder groups. Problems with the availability of medicines have an impact not only on the supply chain but ultimately on healthcare systems, resulting in a significant impact on public health.

An HMA/EMA Task Force has been set up to develop and coordinate the necessary actions to help guarantee uninterrupted supply of human and veterinary medicines. The Task Force is composed of three Thematic Working Groups (TWGs) tackling the problem from three critical angles: marketing authorisation, supply chain disruptions and communication.

Availability issues are multifactorial and require actions from regulators and pharmaceutical industry alike. The Task Force would like to gather stakeholders' perspectives on how to address availability issues and to include their input into the deliverables of the Task Force. Acknowledging the important role of pharmaceutical industry in the prevention and management of medicines availability issues, on 8 November 2018 a dedicated technical meeting will be organised with pharmaceutical industry representatives covering human medicines only. This will be followed by a workshop on 9th November which will bring all stakeholders together. The workshop will mainly focus on human medicines however issues common to both human and veterinary medicines will be addressed in the context of Brexit (session 2).

[1] EU Medicines Agencies Network Strategy to 2020:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199060.pdf

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Objectives

1. Inform stakeholders about the HMA/EMA Task Force activities, expected deliverables including Brexit impact.
2. Update stakeholders on progress with deliverables and identify areas of agreement as well as areas for further discussion.
3. Share stakeholders' perspectives and (ongoing/planned) initiatives to address availability issues and discuss how these can contribute to the deliverables of the Task Force.

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07:45	Registration and reimbursement arrangements	
08:00	• Welcome, health and safety information • Workshop objectives • Feedback from technical meeting of 8th November	Noël Wathion (EMA) Kristin Raudsepp (HMA) Noël Wathion (EMA)
Session 1: Availability of authorised medicines – setting the scene *Chair: Noël Wathion*		
08:15	• Availability of medicines: Impact on public health	• Agnes Mathieu-Mendes (EC) • Francisco Blanco (WHO) • Francois Houyez (EURORDIS) • Elisabeth de Vries (ESMO)
09:15	• How regulators are working to improve prevention and management of availability problems	Kristin Raudsepp (HMA)
09:35	• Ongoing initiatives from pharmaceutical industry to improve prevention and management of availability problems	Adrian van den Hoven (Medicines for Europe)
09:55	*Discussion*	
10:30	*Coffee*	
Session 2: Impact of Brexit on medicines availability *Chair: Noël Wathion*		
10:45	• Presentations by regulatory authorities – Centrally authorised medicines – Nationally authorised medicines • Presentations by pharmaceutical industry	• Monica Dias/Ivo Claassen (EMA) • Hugo Hurts, on behalf of CMDh Chair Laura Oliveira/ Laetitia Le Letty (CMDv) • Yvonne Stewart (EBE)

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	• Panel discussion	• Rick Clayton (AnimalhealthEurope) Panellists: • Hugo Hurts (MEB/ Chair of HMA Brexit Task Force) • Priscilla Schoondermark (CMDh) • Robert Johnstone (EPF) • Joan Peppard (EAHP)
11:45	*Discussion*	
12:15	*Lunch*	
Session 3: Addressing shortages caused by supply chain disruptions *Chair: Kristin Raudsepp*		
13:00	• Improving reporting and monitoring: EU-wide shortage definition and metrics – Presentation from EMA/HMA followed by panel discussion	Brendan Cuddy (EMA) and Annette Hansen (DKMA) Panellists: • Anna Meriluoto (FIN) • Ilaria Passarani (PGEU) • Kasper Ernest (EAEPC)
13:45	• Guidance for industry to improve reporting & best practice – Presentation of proposal for guidance by EMA/HMA followed by panel discussion	Esther Martinez (EMA) and Belén Escribano (AEMPS) Panellists: • Anna Meriluoto (FIN) • Ilaria Passarani (PGEU) • Jurate Svarcaite (AESGP)
14:15	*Coffee*	
Session 4: Communication – improving access to information on availability issues *Chair: Kristin Raudsepp*		
14:30	• Current public communication practices by regulators on medicines availability and shortages – Presentation followed by panel discussion on experiences and expectations from the public on information about medicines availability	Yngvil A. Knudsen (NOMA) Panellists: • Ancel.la Santos (HAI) • Doerine Postma (KNMP) • Tiago Villanueva (UEMO)

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		• François Bouvy (EFPIA)
15:05	• Best practice guidance for EU authorities on public communication	Juan Garcia Burgos (EMA)
Session 5: Conclusions *Chair: Noël Wathion*		
15:15	• Reflections from stakeholders and identification of points for further action	All
15:35	• Concluding remarks and next steps	Noël Wathion (EMA)
15:45	*End of meeting*	