19 October 2018
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Draft agenda - HMA/EMA technical meeting on availability of authorised human medicines

Technical meeting between industry and the HMA/EMA Task Force on availability

8 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 end users.

An HMA/EMA Task Force has been set up to develop and coordinate the necessary actions to help guarantee uninterrupted supply of 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 8th 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 about the HMA/EMA Task Force activities, expected deliverables including Brexit impact;
2. Update industry on progress of Task Force deliverables to date.
3. Gather feedback from industry on the Task Force deliverables to date.
4. Invite industry to provide an update on progress made and solutions going forward.

8 November 2018		
10:30	Registration, tea and coffee	
10:45	Welcome, health and safety information and introductions	Noël Wathion (EMA)
11:00	Workshop objectives	Kristin Raudsepp (HMA)
Session 1: Availability of authorised medicines – current regulatory landscape *Chair: Noël Wathion*		
11:15	Availability of medicines: overview of EMA/HMA taskforce activities	Kristin Raudsepp (HMA)
	• What constitutes a medicine shortage – proposed definition	Belen Escribano (HMA)
	• Notification of potential medicine shortages from the supply chain – who, when, how and what	Darren Scully (HMA)
	• Proposed metrics for shortages	Maria Filancia (EMA)
	• Facilitating and promoting the planning and use of multi-lingual packages to avoid availability problems	Alexios Skarlatos (EMA)
Session 2: Impact of Brexit on availability of human medicines - further developments *Chair: Noël Wathion*		
12:45	• Status report for CAPs • Q&As	Monica Dias (EMA) All
13:15	**Lunch break**	
Session 3: Implementing best practices already developed for shortage prevention *Chair: Kristin Raudsepp*		
14:15	• Industry feedback on task force deliverables • Industry measures to ensure supply chain continuity • E.g. Example of a company who has implemented the developed guidance	Pharmaceutical industry (TBD)
	• Q&As	All

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16:45	**Tea/Coffee break**	
Session 4: Building on best practices and next steps *Chair: Kristin Raudsepp*		
17:15	• Consolidation of ideas: reflections from stakeholders and identification of points for further action	Maria Filancia and Esther Martinez (EMA)
Session 5: Conclusions *Chair: Kristin Raudsepp*		
18:00	• Concluding remarks	Noël Wathion (EMA) / Kristin Raudsepp (HMA)
18:15	**End of meeting**	