17 June 2022
EMA/601355/2021

Agenda – First **I**ndustry **S**tanding **G**roup (**ISG**) meeting on EMA's extended mandate

21st June 2022, 14:00 – 17:45 (WebEx) – 3h45

Chair: Marie-Helene Pinheiro

Item	Agenda	Time
1.	**Welcome / Introductions** *Melanie Carr, EMA*	5 min
2.	**Industry Standing Group (ISG): mandate, objectives, composition** *Juan Garcia Burgos, EMA* Discussion	15 min
3.	**EMA Mandate extension implementation activities - high level status updates** a. Emergency task force – Marco Cavaleri, EMA b. Medicines shortages and Medical Devices – Monica Dias, EMA c. Medical Devices experts panels – Silvy da Rocha Dias, EMA	 5 min 5 min 5 min
4.	**Emergency task force** **4.1 Overview of ETF tasks and responsibilities** *Manuela Mura, EMA* d. Updates on implementation status including changes to IRIS for ETF Scientific Advice submission *Q&A session (All)*	 10 min 10 min
5.	**Medicine shortages and Medical Devices** *Monica Dias, EMA* **5.1 Medicines shortages activities** *Monica Dias, Joao Ferreira, Nektaria Varela, EMA* a. Industry Single points of contact (i-SPOCs) for Marketing Authorisation Holders (MAHs) for all medicinal products authorised	 35 min

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	in the Union: *for information* b. List of critical medicines for COVID-19 and draft list of "main therapeutic groups" (MTGs) of medicinal products that are necessary for emergency care, surgeries and intensive care: *for information* c. MAHs reporting obligations: *for information/discussion* d. European Shortages Monitoring Platform (ESMP) - feasibility study and development plan: *for information* *Q&A session derived from list of questions received from Industry stakeholders (All)*	40 min
	5.2 Monitoring and mitigating shortages of critical medical devices in the context of a public health emergency *Monica Dias, Klaus Kruttwig, EMA* e. Monitoring and mitigating shortages of critical medical devices in the context of a public health emergency - legal provisions: *for information* f. Executive Steering Group on Shortages of Medical Devices (MDSSG) and medical device shortages SPOC Working Party: *for information* g. Industry single point of contact (i-SPOC) for devices in the critical list: for *information/discussion* h. Obligations on economic operators and notified bodies- mandatory reporting requirements as defined in the Regulation: *for information/discussion* *Q&A session (All)*	15 min 30 min
	Coffee break	***10 min***
6.	**Medical Devices expert panels** *Silvy da Rocha Dias, EMA* a. Notified Body Conformity Assessment including EMA coordination of Clinical Evaluation Consultation Procedure (CECP) and Performance Evaluation Consultation Procedure (PECP) - presentation from EMA and Team-NB *Alexey Shiryaev, Sabina Hoekstra, Team-NB* *Miguel Antunes, EMA* b. MD Expert panels advisory role on technical, scientific and clinical matters: process development update: for information/discussion c. Medical device manufacturers' pipeline (SA requests and CECP and PECP procedures)- for discussion *Q&A session (All)*	15 min 20 min
7.	**Summary of actions and next steps** Close of meeting	5 min