

01 March 2018 EMA/132201/2018 Corporate Stakeholders Department

## Agenda – Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products

23 March 2018, 14:00 -16:00

Chair: Marie-Helene Pinheiro

Item	Preliminary draft agenda	Time
1.	Welcome and introductions	5′
2.	Operational preparedness for Brexit and re-allocation of UK product portfolio in the centralised procedure	15′
3.	Update on EMA-EC Q&As and practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure	15′
4.	Update on EMA Survey to Centrally Authorised Marketing Authorisation Holders to assess procedural workload resulting from "Brexit"	15′
5.	Industry update on Brexit preparedness activities	15′
6.	Questions & Answers session	50′
7.	Close of meeting: next steps	5′

