Technical seminar on BREXIT Pharmaceuticals related issues

Brussels, 8 March 2018

Intervention DG SANTE

The EU medicines regulatory network

European Commission

Preparedness measures taken by the EU medicines regulatory Network

- *Updated information notices + procedural guidance for procedures to marketing authorisation holders*
- *Awareness meetings with industry associations*
- *Redistribution of the workload*
- *EMA survey to companies on BREXIT preparedness*
- *HMA dedicated Brexit Taskforce set up, companies survey under consideration*

EEA establishment

The EU legislation provides a number of requirements on the establishment of MAHs.

By 29 March 2019, that requires e.g.:

- **Transfer of UK-based MA and Orphan designations for CAPs**
- **Change of RMS for MRP/ DCPs**
- **Transfer of residence and tasks of QPPV**
- **Relocation of the PSMFL**
- **SME's established in EEA**

GMP/Inspections

Member States should be prepared for the following tasks:

- *Active substances imported from third countries must be accompanied by a written confirmation unless the country is listed under Article 111b of Dir 2001/83/EC. Inspections of API sites outside the EU (EEA) are conducted by MS in collaboration with EMA.*
- *Finished products imported from the UK will need to undergo batch release in the EEA. Additional sites for batch control may be required in the EU Member States.*

Clinical trials

Member States should be prepared for the following tasks:

- *MS authorities must inspect clinical trial facilities and IMP manufacturers in third countries to ensure that GMP/GCP requirements are fulfilled.*
- *Sponsors may need to update their clinical trial dossiers (for example for changes in QPs, sponsor establishments and manufacturers)*
- *For CT in VHP the Reference National Competent Authority should be located in the EU (EEA) for joint authorisations of clinical trials. The UK is currently reference NCA for many trials.*