EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Technical Seminar on Brexit

Preparedness measures taken by EMA

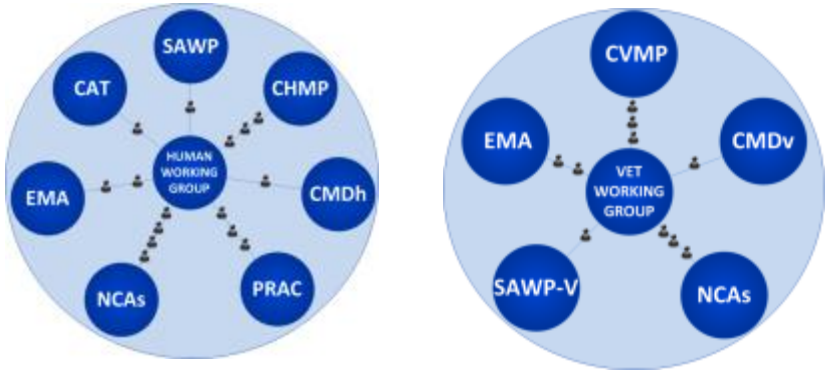
Presented by Dr Monica Dias on 8 March 2018
Policy and Crisis Coordinating Officer, Office of the Deputy Executive Director

Introduction

- EMA Task Force was set-up to ensure EMA preparedness for any possible scenario following the UK referendum and the UK exit from the EU
- Two areas of activity
  - EMA Brexit preparedness
    - **Operational preparedness: addressing the impact on EMA Scientific Committees, procedures and inspections**
    - Business continuity: ensuring continuity of EMA operations through a dedicated BCP in order to free-up resources for EMA preparedness and to address staff losses
  - After 20/11/2017 - EMA-NL collaboration for relocation to Amsterdam
- EMA Working Groups on Committees' Operational Preparedness for human and veterinary medicines were established in June 2017 to explore options for a robust allocation of the workload across the European medicines regulatory network.

EMA Working Groups on Committees' Operational Preparedness

- At the information meeting on 27 April 2017 members of the Management Board and Heads of NCAs discussed the challenges and a way forward in an EU-27 setting.
- EMA Working Groups on committees' operational preparedness for human and veterinary medicines were set up to develop general principles for the redistribution of the workload and a working methodology for the redistribution of the UK workload.



Operational Preparedness – areas addressed

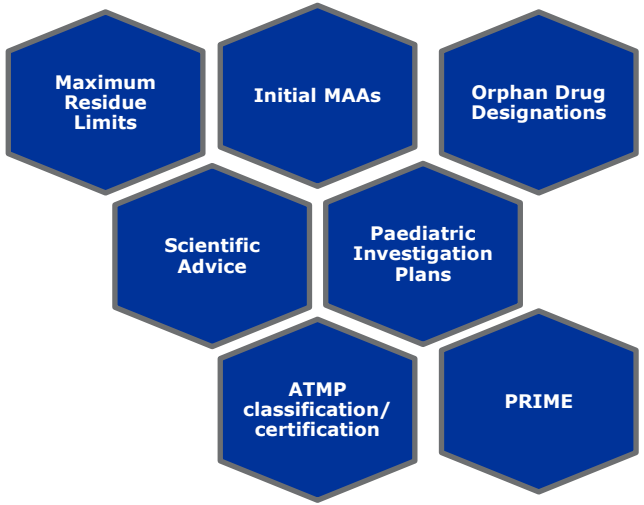
- UK's involvement in EMA activities
  - Involvement in centralised procedures
  - Leadership roles in EMA Scientific Committees and Working Parties
  - Inspections capacity (GMP, Pharmacovigilance, GCP)
- Mapping exercise on the planned increased involvement and expertise within the European medicines regulatory network
- Industry Stakeholders Preparedness Activities
- Timelines for UK involvement in EMA activities
- Redistribution of the UK centralised product portfolio
- Brexit impact on the availability and supply of medicines (CAPs)

UK involvement in EMA activities

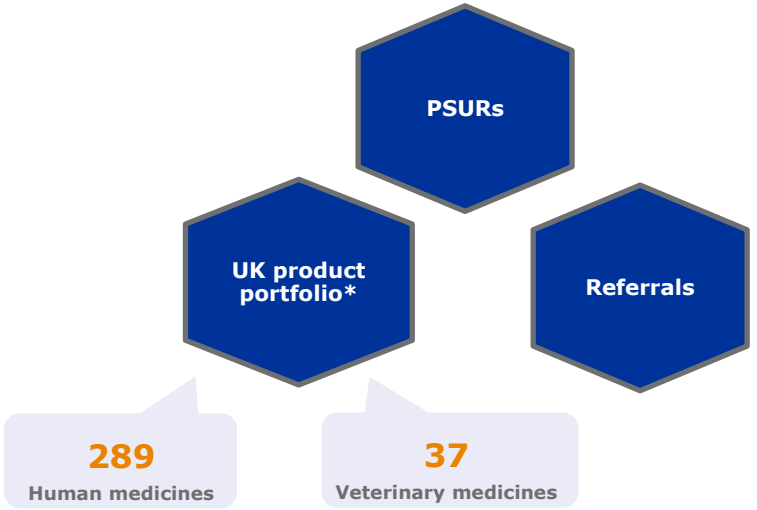
Centralised procedures, Scientific Committees and inspections

UK participation in EMA activities

- Rapporteurships in pre-authorisation

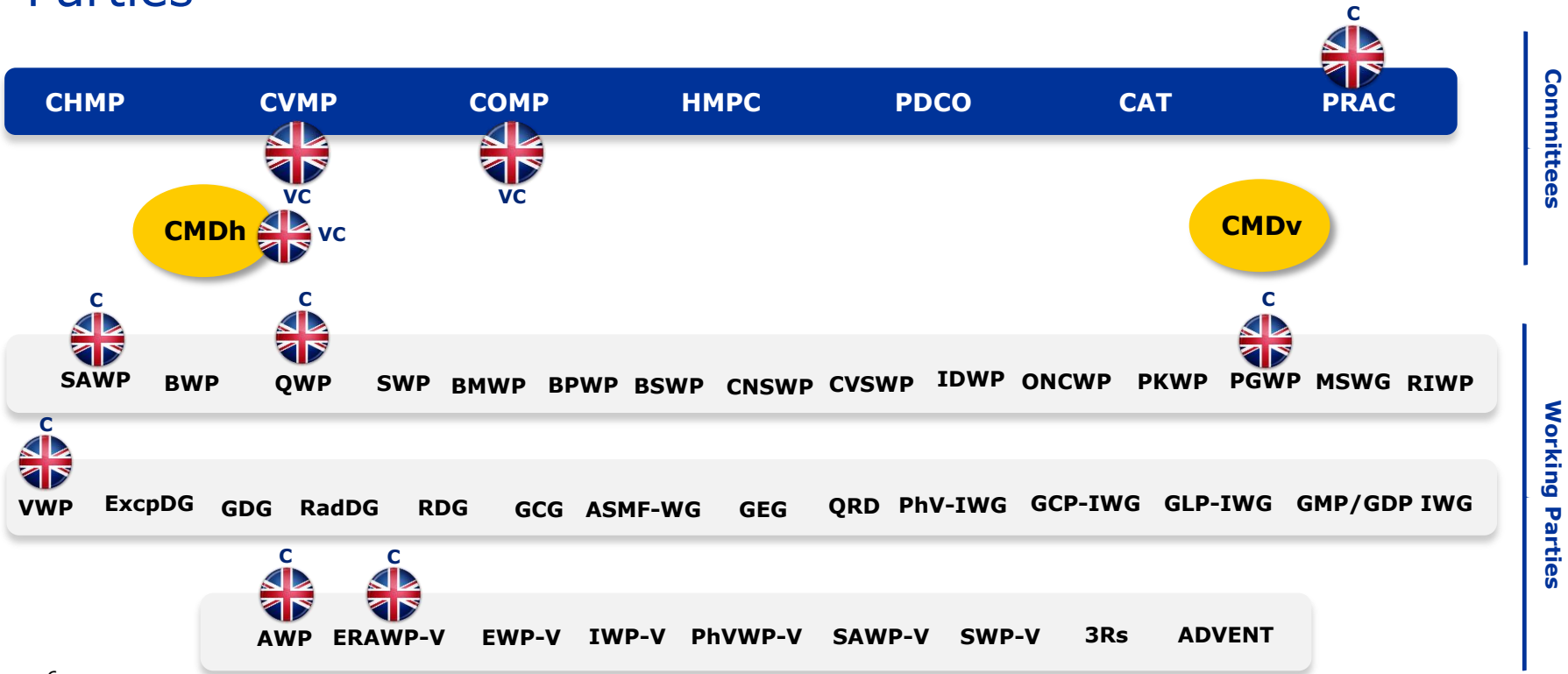


- Rapporteurships in post-authorisation



as of 6 September 2017

UK leadership roles of EMA Scientific Committees and Working Parties



Inspections capacity (GMP, PhV and GCP)

GMP Inspections

- Supervisory authority = location of batch release site

Workload redistribution will depend on the MAH decision on new location of the sites

PhV Inspections

- Supervisory authority = location of PSMF

Workload redistribution will depend on the MAH decision on new location of the PSMF

GCP Inspections

- Lead inspectorate = Rapporteur
- Supporting inspectorate = Co-Rapporteur

Workload redistribution will follow redistribution of UK portfolio

Mapping exercise on increased capacity

Survey to NCAs

Mapping exercise on the planned increased involvement and expertise within the Network

- A survey to NCAs was launched in June 2017 aiming at understanding their planned increased involvement and increased expertise, in the context of Brexit

NCAs across the Network indicated they plan to increase their capacity of assessors and inspectors in many different areas

For human medicines, NCAs plan to increase their involvement in both centralised procedures and in DCP/MRP procedures

For veterinary medicines, NCAs plan to increase their involvement in both centralised procedures and in DCP/MRP procedures

- A number of NCAs provided comments concerning uncertainties of resources due to budget constraints and pending approval from Government Ministries (i.e. Ministry of Health, Department of Health)
- A few NCAs highlighted that they had already hired new assessors

Industry Stakeholders Preparedness Activities

Industry Stakeholders Preparedness Activities

- EMA is providing guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for the UK withdrawal from the EU
- The guidance aims to ensure that companies are ready to take the necessary steps to enable undisrupted supply of their medicines for the benefit of patients

2017 Publication of guidance to Industry	
02.05.17	**Publication of EC/EMA** Notice **to marketing authorisation holders** of centrally authorised medicinal products for human and veterinary use
31.05.17	**Publication of EC/EMA** Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the centralised procedure
24.11.17	**Publication EMA** Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure
01.12.17	**Publication** of **updated EC/EMA** Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the centralised procedure

Timelines for UK's involvement in EMA procedures

(Co)-Rapporteurships

Timelines for UK participation in EMA procedures

- The scenario that is considered is the one by which the UK membership will cease to exist as of 30 March 2019. As of that date, the UK will be a "third country" and, as a consequence, will no longer be able to engage in centralised procedures as (Co)-Rapporteur which are expected to finalise after 30 March 2019.
- Therefore, timelines for UK participation in EMA procedures for human and veterinary medicines were established.
- These were extrapolated by averaging the length of each procedure from submission to outcome and by taking into consideration the deadline of 30 March 2019.

Redistribution of the UK product portfolio

Centrally Authorised Products

Redistribution of the UK centralised product portfolio Human and veterinary medicines

General principles:

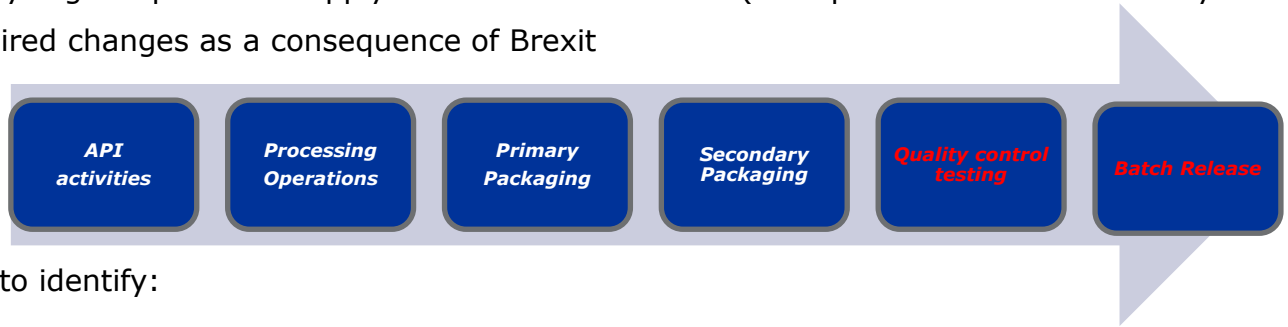
- ensure business continuity;
- ensure knowledge retention or knowledge transfer;
- comply with the legally required timelines and to maintain the quality of the output;
- be as easy as possible to implement and, in addition, should be sustainable;
- strive to allow all NCAs to participate in EMA activities, as per the capacity and capability of each NCA.

Potential Brexit impact of the supply of medicines

Centrally Authorised Products

Potential impact of Brexit on supply of medicines

- EMA is analysing the potential supply issues for critical CAPs (therapeutic use and availability of alternatives) due to the required changes as a consequence of Brexit



- The aim is to identify:
  - ✓ the manufacturing operations currently located in the UK for CAPs,
  - ✓ the type of manufacturing operations affected by Brexit, and
  - ✓ the potential risk of disruption as a number of these operations will need to be relocated to the EEA.
- The analysis is complemented by a survey to pharmaceutical companies (launched 22 January 2018) to obtain information on the timelines for submission of the necessary regulatory changes.

Conclusions (1/2)

- The involvement of the UK in centralised procedures is ~15%.
- EMA conducted a survey in June 2017 to NCAs on capacity which showed the willingness from NCAs to increase their involvement in centralised procedures. However, a number of NCAs raised concerns related to budget constraints and approval required with the Ministries of Health.
- A follow up survey on increased capacity for MRP/DCP procedures and training needs in the context of Brexit will be launched in March 2018.
- EMA together with the EU 27 Member States have developed a methodology for the redistribution of the work currently carried out by the UK.

Conclusions (2/2)

- EMA is providing guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for the UK withdrawal from the EU. The guidance is regularly updated. EMA also engages with industry associations through face to face meetings and webinars to further clarify certain aspects of the guidance.
- EMA is also undertaking an analysis, including a survey to pharmaceutical companies, to identify centrally authorised products at risk of supply. EMA will liaise directly with MAHs to address any potential medicinal product supply disruptions which could impact public and or animal health in the Union.

Any questions?

Further information

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