Presentation from veterinary industry
EU/EEA Brexit preparedness: status and impact

HMA/EMA Task Force on Availability of Authorised Medicines stakeholder meeting

November 9, 2018

STATUS

- **EMA** Brexit-preparedness survey – Sept'18

  - ❑ **14 VMPs at risk**

- **CMDv** – Brexit impact on VMPs survey – Oct'18

  - Already authorised VMPs:
    529 (25% total) VMPs impacted - 42 MAH (11 RMSs?)
    380 VMPs (58%) already transferred
    Letter written by CMDv to all 42 MAHs - Preparedness plans and potential out of stock situations (?)

- **Companies** stepping up efforts to ensure medicine supply post Brexit

  - But 100% compliance by 29 March 2019 not possible → Vulnerability to supply disruption, potential shortages in EU markets

Brexit impact on availability (I)

- **Retesting**: Main impact and risk to supply for **UK produced products**. Disruption in supply due to transfer of UK batch release testing/certification sites to EU
  - Will impact **other Member States** and could trigger shortages
- **Multilingual packaging**: affects a large proportion of VMPs
  - **Ireland** at higher risk (70% VMPs common packaging with UK)
  - **CAP Products** → significant reorganisation of multi-language groupings; Presence of UK specific items on CAP multi-language labelling
  - **Smaller markets / smaller volumes** in larger markets more vulnerable;

Increase in internal costs, some products may no-longer be commercially viable.

Brexit impact on availability (II)

New border delays, changes to custom processes will also put availability at risk.

- Transport / logistic delays to and from UK
- UK land-bridge - re-routing of product distribution from manufacturing site to another MS i.e. not via UK.
- Increase in administrative burden: repeat testing for EU and non-EU countries

Impact for vaccines and VMPs with (very) short shelf lives

- **Economic impact**: withdrawal of commercially non-viable products (increased costs and loss of market size); loss of EU competitiveness vs e.g. US, Asian markets

- **New products**: validity of UK field trials, and reference products for generic applications – may impact availability for ongoing procedures and future applications

Continuity of supply – main challenge – retesting in EU

Article 55(2) of Directive 2001/82 veterinary medicines

In the case of medicinal products imported from a third country, where appropriate arrangements have been made by the Community with the exporting country to ensure that the manufacturer of the medicinal product applies standards of good manufacturing practice *at least equivalent* to those laid down by the Community, and to ensure that the controls referred to under point (b) of the first subparagraph of paragraph 1 have been carried out in the exporting country, the qualified person may be relieved of responsibility for carrying out those controls.

- **"appropriate arrangements" = EU issued GMP certificate for UK site**
- **For a defined period covering the critical months**

Main concerns and final considerations

- Continuity of supply
  - Multi country packaging → A pragmatic transition period is essential.
  - Replication of testing → A pragmatic transition period is essential.
- Economic impact
- Validity of UK reference products and UK field trials for ongoing procedures

Full spectrum of types of products (from vaccines to NSAIDs: from antibiotics to antiparasitics) across all animal species (farm, equine and pets) potentially at risk, with particular concerns around the supply chain for vaccines.

Also potential impact on supply within the EU-27, particularly in Ireland and smaller markets (small countries, and small products in larger countries).