EMA Brexit Interested Parties Meeting

Joint VMP Industry Presentation

Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human and veterinary medicinal products

AnimalhealthEurope / EGGVP / AVC

September 24, 2018

Brexit impacts on the animal medicines industry

- Main risk with UK produced products. Disruption in supply due to transfer of UK batch release testing/certification sites to EU
- Presence of UK specific items on CAP multilanguage labelling - impact on cost of goods/viability for some smaller EU markets and/or small products in larger market
- For UK marketed products: joint labelled for UK and Ireland: some products for Ireland may no-longer be commercially viable
- Transport / logistic delays to and from UK
- Re-routing of product distribution from manufacturing site to Ireland i.e. not via UK.
- Increase in administrative burden: repeat testing for EU and non-EU countries
- Economic impact: withdrawals of commercially non-viable products (the increased costs and loss of market size); loss of EU competitiveness vs e.g. US, Asian markets

Main areas of concern

- Multi country packaging
- Continuity of supply
- Replication of testing
- The absolute need for a transition period
- Economic impact
- Validity of UK reference products and UK field trials for ongoing procedures

Main areas of concern

Multi country packaging
Packaging of CAP products at and after the Brexit date:

What is the view of the agency in relation to product that mentions POM-V or other UK information and:

- is already on the market, or
- which has been released but not yet supplied to the market, or
- will be released after 29 March 2019 but using already printed packaging

Note:

- Multilanguage labelling is critical to avoid stock outs in smaller European markets and increased costs to industry.
- A pragmatic transition period approach to this particular issue is essential.

Main areas of concern

Continuity of supply

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