Impact of Brexit on veterinary medicines availability

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Presentation objectives

- Communication
- Regulatory Impact on existing veterinary medicinal products (VMPs)
- Impact on availability
- Preparedness of National Competent Authorities (NCAs)

Communication – CMDv website

Regulatory Impact on existing VMPs

- Transfer of Reference Member State (RMS)
- Transfer of Marketing Authorisation Holder (MAH)
- Qualified Person for Pharmacovigilance (QQPV) located in EU
- Change of Batch Control/Batch Release site or addition of site responsible for Import in EU

After 29 March 2019 UK will not be able to act as a RMS.
The MAH will not be able to make any regulatory submission until a new RMS other than the UK is appointed.

Regulatory Impact on existing VMPs

Monitor change of RMS:

- Total number of VMPs concerned = 657
- RMS changes realised: 417

63 %

To: IE, FR, DE-BVL and DE-PEI, NL, ES, AT, HU, BE, PT, IT, CZ, NO, BG.

Impact on VMPs – Availability

- Already authorised VMPs: 2146 VMPs registered via RM/DC –

  21 RMS

  - 529 VMPs concerned by Brexit (MAH/QPPV/BC/BR sites)
  - 42 MAH concerned
- Letters sent to these 42 MAH to know their preparedness plans, to remind them their duties, to remind them timelines.

  Availability issues?
  Alternatives available?

- Few answers received….

  Difficult to monitor availability issues and therefore to look for available alternatives

Impact on availability

"For new marketing authorisation applications, if the procedure is not completed before 30 March 2019 (i.e. agreement of the concerned Member States in accordance with Article 32(4) or Article 33(3) or decision of the Commission in accordance with Article 38(1) of Directive 2001/82/EC) the procedure is stopped and the applicant needs to submit a new application to a new Reference Member State. Applicants are advised to take this into account already at the time of submission of the application."

- Re-submission with a new RMS = Delay in granting new marketing authorisations
- CMDv works on the list of ongoing procedures wich closing dates near or after Brexit: MA, renewals, type II, WS

Preparedness of NCA

1. CMDv survey in September 2017
   - First figures for NCAs to get prepared
2. HMA survey on NCAs capacities
   - Shows that NCAs are ready to take over existing procedures and RMSship for new procedures
3. To be compared: capacities offered and reality of transfer of RMS

Any questions?

Further information

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See websites for contact details

European Medicines Agency www.ema.europa.eu

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