



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Best practice guide on adherence to timetables

Status update

EMA Veterinary Medicines Info Day 16-17 March 2017, London

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Why the initiative started



- Uncertainty in the timing of submission of new Marketing Authorisation Applications (MAAs) or responses to List of Questions (LoQ) or List of Outstanding Issues (LoOI)
- Influx of unplanned submissions
- Resource planning difficulties to European Medicines Agency (EMA) and National Competent Authorities (NCAs) – availability of assessors and experts
- Timely access to medicines
- Frequent and timely communication by Companies and Regulatory Agencies is key for ensuring adherence to deadlines and timely approval of medicines



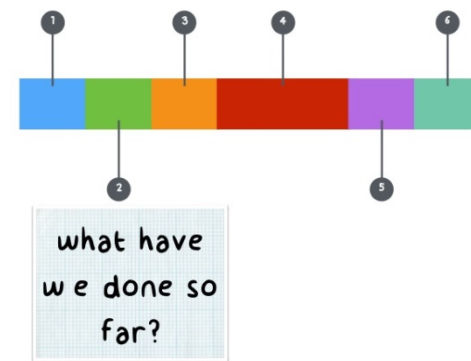
Joint EMA-HMA Task Force

- Established in September 2013 by the Heads of Medicines Agencies (HMA)
- Mandated to address issues with Timetables (TT) for applications in the centralised (CP), Mutual Recognition (MRP) and Decentralised (DCP) procedures
- Composed of representatives from EMA, Scientific Committees of the Agency (CXMP), Co-ordination Groups for MRP and DCP Procedures (CMD(x) Groups human and veterinary)
- Expected to come up with proposals improving predictability of submissions and evaluation TT



What has been done so far

- Virtual team meeting on regular basis via TCs
- March 2015: survey to better understand what lies behind the changes to submission timelines and to explore potential improvements
- April 2016: workshop to discuss key findings of the survey and potential way forward
- March 2017: Best Practice Guide released for a monthly consultation with the industry organisations (including 2 organisations for veterinary products: IFAH-Europe & EGGVP)



Best Practice Guide

- Developed for Applicants / Marketing Authorisation Holders (MAHs) and Regulatory Agencies to optimise the operation and functioning of procedures relating to medicinal products for human and veterinary use
- Expected to enable both the Regulatory Agencies and Industry to improve workload planning and resourcing of relevant procedures for the benefit of patients/animals, to ensure their timely access to new medicines
- Principles to be mutually agreed between the Regulatory Agencies and representatives of industry stakeholder associations
- Signatories expected to adhere and apply the principles across their respective organisations.

Best Practice Guide



Next steps

- 17 March 2017 – end of consultation
- Feedback received will be used for preparation of the revised version
- Revised version to be consulted with Scientific Committees of the Agency (CXMP), Co-ordination Groups for MRP and DCP Procedures (CMD(x) Groups human and vet)
- Final document to be adopted by HMA
- Publication on the EMA and HMA websites and dissemination to industry associations





Thank you for your attention

Further information

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