



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Best practice guide on measures improving predictability of submissions/responses and adherence to communicated submission/responses deadlines

Presentation of Revised BPG after Consultation with Industry to Committees and CMDs

June 2017





Aim of this presentation

Present the Best Practice Guide as developed by the HMA TaskForce

Inform about the outcome of the public consultation

Inform about the next steps



Background

Task Force started in 2013

Why?

- Limited resources in evaluation units
- Important to allocate staff according to timelines set
- Changing timelines is challenging
- Especially around big bank holidays and the summer break
- All procedures need the same resources

Aim of the Best Practice Guide (BPG)

Common issues → The BPG covers CP/DCP/MRP/national procedures, Human and Vet
For **Initial MAAs**

The aim is to **agree with Industry on principles** that will ensure

Predictability

Good communication

This is a start, a lot of issues remain to be solved.....



Steps in development of the Best Practice Guide

Workshop with Industry in April 2016

Consultation with Industry associations in February 2017

Comments received by March 2017

Main recommendations of the BPG

Pre-submission phase- Emphasis on Communication

Maintained

- Submission dates to be **re-confirmed 2-3 months prior to the intended submission**
- Engagement in **early dialogue** with the EMA/NCAs is encouraged
- Emphasize the importance of **mature dossiers**
- If an intended submission date is not met→ discussion with EMA/NCAs to assure the **availability of assessment teams** and **adjustment of the submission date**, if needed.
- **Early appointment** of contact points and Rapporteurs
- Transparent procedures for **booking slots**

Main recommendations of the BPG

Responses to LoQ/LoOI- Industry

Maintained

- Responses submission date→ Upon receipt of the preliminary ARs and **confirmed within 2 weeks** after receipt of the final LoQ/LoOI.
- If submission date is not met→ discussion with EMA/NCAs to assure the **availability of assessment teams** and **adjustment of the procedural TT**
- Extension of the clock-stop to be discussed as soon as possible
- **Clarification meetings** to focus on clarification of questions /discussion on the applicant's approach to respond **NOT pre-assessment**



Main recommendations of the BPG

Responses to LoQ/LoOI- Regulators

- **Timely circulation** of (preliminary/draft) ARs and Comments
- Questions in the ARs are **clear and unambiguous**
- **Late questions/ SmPC changes** after adoption of LoQs/LoOIs **to be avoided**
- **Clarifications** to questions to be provided **timely**

Very Important
for Industry



Next steps

Presentation to Committees (CHMP/CVMP) and CMDs in June 2017

Revised BPG and responses to comments to be shared with Industry in July 2017

Adoption at HMA September meeting

Publication of the BPG on HMA and HMA websites



Thank you for your attention

