EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality variations

Simplification opportunities and improvement of quality of submissions

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Topics to be covered

- Ongoing initiatives
- Update of processes and issues raised during validation
- Simplification of submissions
- Update of EMA guidance
- Points for discussion

Ongoing initiatives

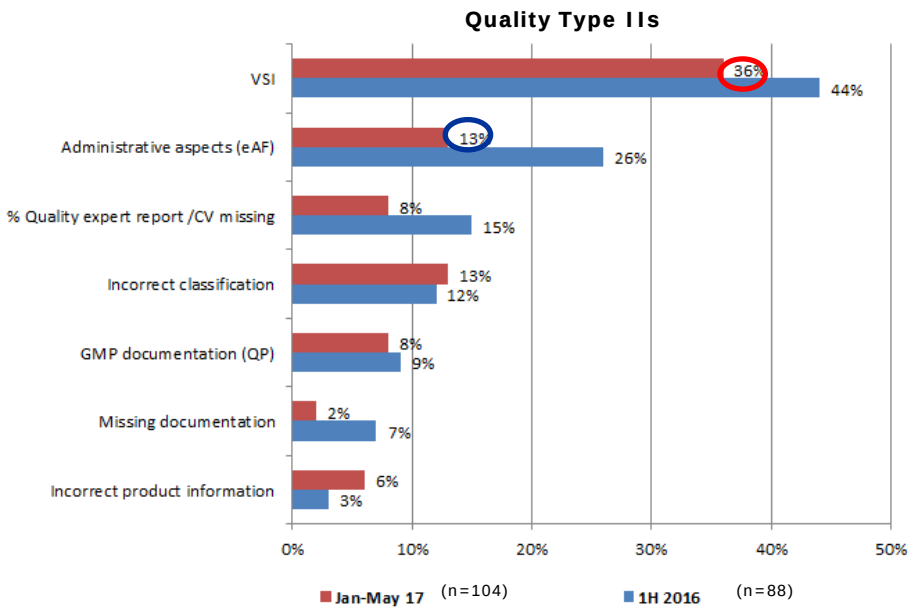
- ICH Q12 – Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

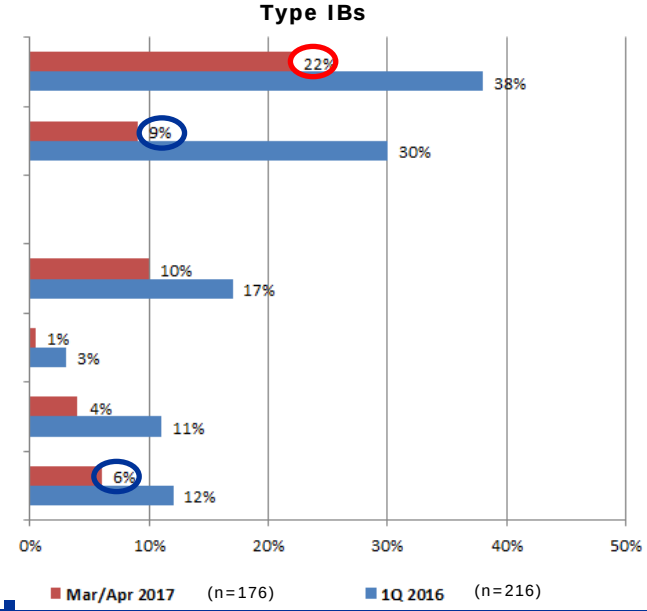
- ASMF Worksharing procedure

- Regulatory Organisation Group - Type IAs.

Update of processes and issues raised during validation

- 62% of Quality Type IIs benefited from the weekly start of procedure allowing earlier outcomes
- Reduction of issues raised during validation for IBs/ IIs, but still a significant number of Type IIs require supplementary information during validation (VSI).



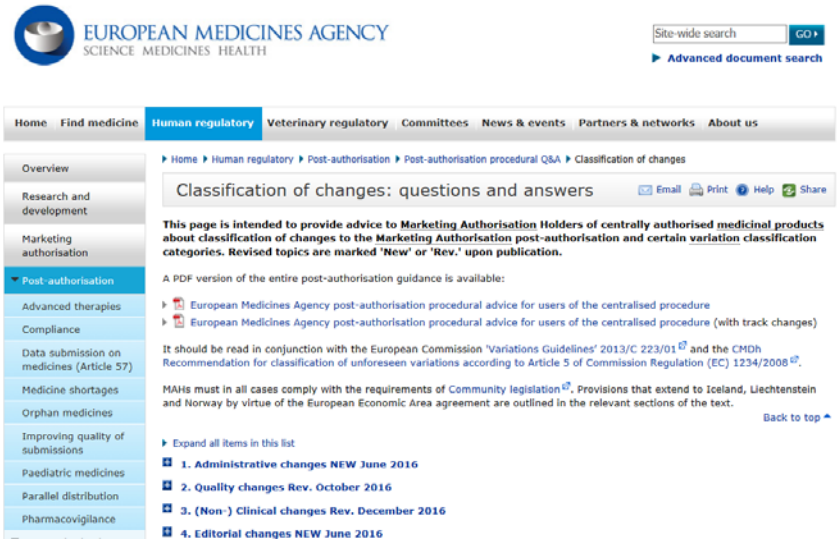


Simplification of submissions

- Simplification in the submission of multiple CEP updates (Oct 16)
- Acceptance of multiple new pack sizes outside range as grouped IAs/IB (Jun 17)
- Complex changes within a single

Type II for addition of new manufacturers

of AS (Jun 17)



Updates to post-authorisation guidance

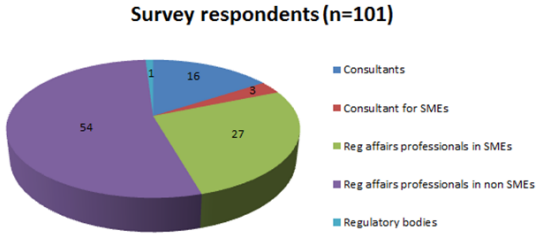
- What is a non significant in-process control or specification parameter? (Oct 16)
- New guidance for biologics medicinal products: (Jun 17)
  - how to introduce a new Working Cell Bank,
  - new reference standards,
  - how to update Section 3.2.A.1.
- Variation vs. GMP (Jun 17)
  - guidance on changes to a manufacturing site, buildings, rooms covered under GMP
  - guidance on changes in equipment

Improvement of quality of submissions (I)

First webinar on regulatory and procedural aspects of Type I variations (15/11/16)

- 6 sessions on common validation issues, eAF, dossier requirements, GMP, ASMF, CEP and update of safety information in PI for generics.
- 750 connections of participants in average
- High satisfaction on the outcome of webinar

	Agree/ Strongly agree
Information in support of improvement of quality of submissions	93%
Understanding of the relevant aspects checked at validation	94%
Awareness of relevant EMA guidance	92%
Training materials cleat and concise	81%



- Identified areas for additional sessions: grouping, worksharing, classification of variations, submission of post authorisation commitments (PAM), implementation of safety features.

Improvement of quality of submissions (II)

- Publication on guidance on wording of precise scopes (Jun 16)

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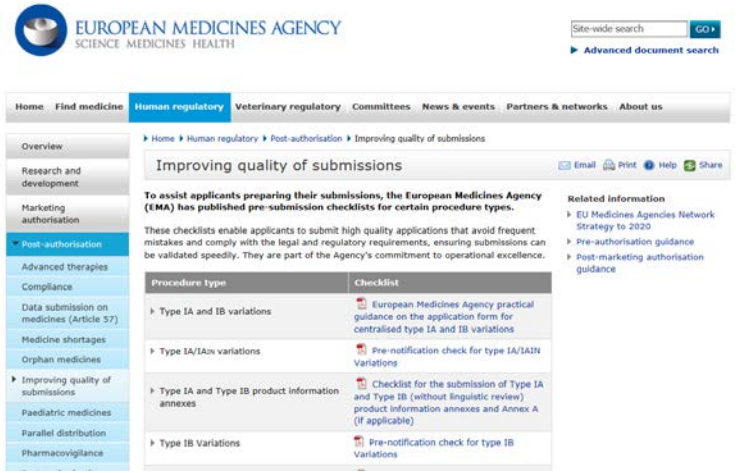
Procedure Management and Committees Support Division

Guidance for applicants for the preparation of the 'precise scope' section of the variation application form



Points for discussion

- Industry experience and challenges with submission of quality variations
- How can we work together to reduce the number of issues raised during validation
- Feedback on the published guidance and supporting documents (IA/IB checklists, document on scopes)
- Feedback on webinar and alternative ways of support to applicants
- Other proposals for the Agency’s consideration

Thank you for your attention

Further information

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