



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality variations

Simplification opportunities and improvement of quality of submissions

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An agency of the European Union





Topics to be covered

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



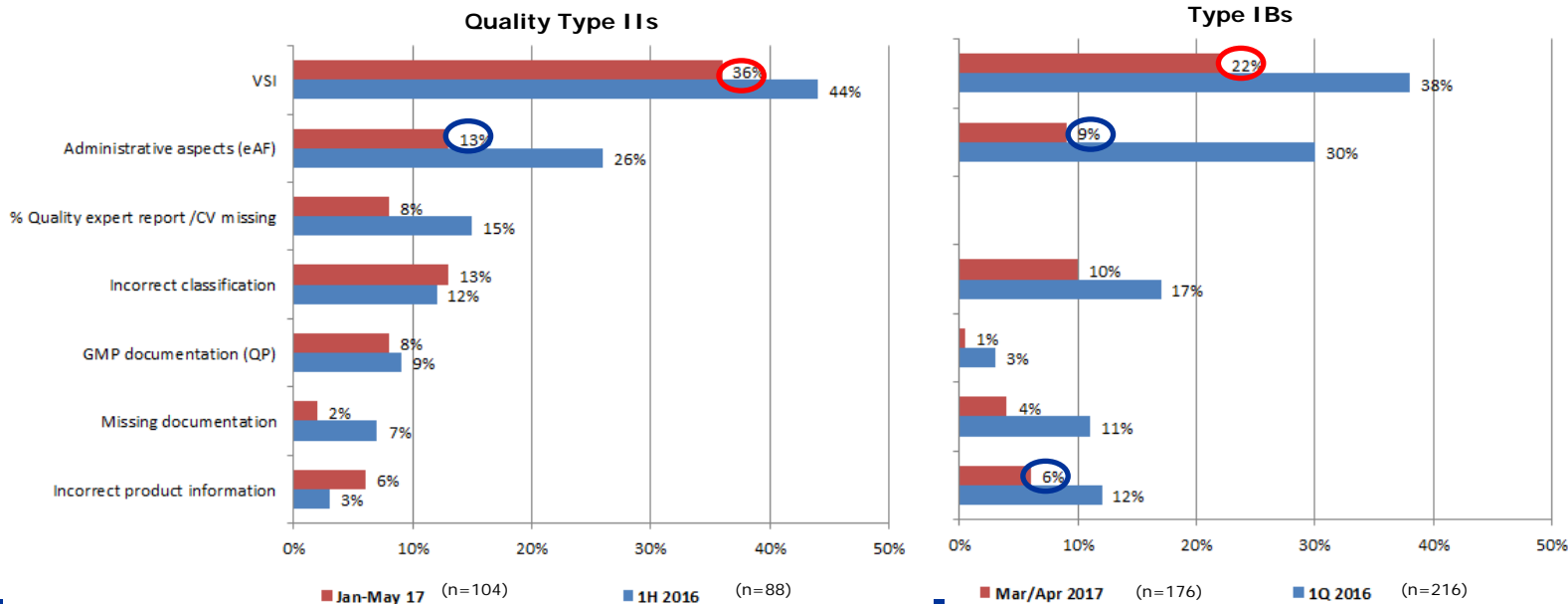
Ongoing initiatives

- 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)

The screenshot shows the EMA website's 'Human regulatory' section. The page title is 'Classification of changes: questions and answers'. The main content area contains the following text:

This page is intended to provide advice to Marketing Authorisation Holders of centrally authorised medicinal products about classification of changes to the Marketing Authorisation post-authorisation and certain variation classification categories. Revised topics are marked 'New' or 'Rev.' upon publication.

A PDF version of the entire post-authorisation guidance is available:

- ▶ European Medicines Agency post-authorisation procedural advice for users of the centralised procedure
- ▶ European Medicines Agency post-authorisation procedural advice for users of the centralised procedure (with track changes)

It should be read in conjunction with the European Commission 'Variations Guidelines' 2013/C 223/01⁴⁷ and the CMDH Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008⁴⁸.

MAHs must in all cases comply with the requirements of Community legislation⁴⁹. Provisions that extend to Iceland, Liechtenstein and Norway by virtue of the European Economic Area agreement are outlined in the relevant sections of the text.

▶ Expand all items in this list

1. Administrative changes NEW June 2016
2. Quality changes Rev. October 2016
3. (Non-) Clinical changes Rev. December 2016
4. Editorial changes NEW June 2016



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

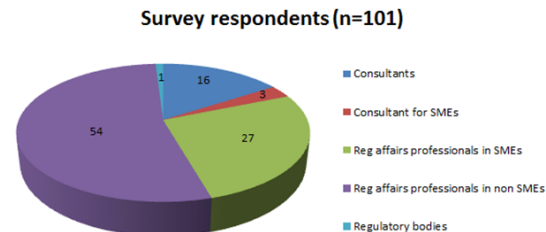


Improvement of quality of submissions (I)

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 clear 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)



16 June 2017
EMA/220707/2017
Procedure Management and Committees Support Division

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

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Improving quality of submissions

To assist applicants preparing their submissions, the European Medicines Agency (EMA) has published pre-submission checklists for certain procedure types.

These checklists enable applicants to submit high quality applications that avoid frequent mistakes and comply with the legal and regulatory requirements, ensuring submissions can be validated speedily. They are part of the Agency's commitment to operational excellence.

Related information

- EU Medicines Agencies Network Strategy to 2020
- Pre-authorisation guidance
- Post-marketing authorisation guidance

Procedure type	Checklist
Type IA and IB variations	European Medicines Agency practical guidance on the application form for centralised type IA and IB variations
Type IA/IAv variations	Pre-notification check for type IA/IAIV Variations
Type IA and Type IB product information annexes	Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable)
Type IB Variations	Pre-notification check for type IB Variations



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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