



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical type II variations

Latest process improvements to improve quality of submissions

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Topics to be covered

- Simplification of RMP variations
- Clarification of submission requirements for type II variations
- Publication of validation checklist
- Second monthly linguistic review for variations on weekly and alternative monthly timetables

Updates to post-authorisation guidance in 2016

Post-authorisation guidance updates (June 2016)

- RMP
- Type II variations (focus on submission requirements)
- Classification of changes

Period	Q1-2 2016	Q1-2 2017
Dataset	338 (non-)clinical variations started	234 (non-)clinical variations started
Validation issues	42% of submissions Mainly on scope	37% of submissions Mainly RMP, Clinical Overview, incorrect number of scopes and incorrect classification
Submission components with validation issues	App form: >50% Expert statement: 26% RMP: 20%	App form: 48% Clin trials statement: 24% Expert statement: 22% RMP: 10%
Extensions of indication	23 extensions of indication started	19 extensions of indication started
Validation issues with extensions of indication	16 (70%)	9 (47%)



Publication of type II variation **validation checklist**

- The type II variation validation checklist was published on June 26th on the webpage for quality of submissions
- Stakeholder feedback on the checklist would be highly appreciated

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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.

Procedure type	Checklist
► Type IA and IB variations	Practical guidance on the application form for centralised type IA and IB variations
► Type IA/IAIN variations	Pre-notification check for type IA/IAIN 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
► Type II variations	Pre-submission checklist for type II variation applications
► All types of variations	Guidance for applicants for the preparation of the precise scope section of the variation application form
► 5-year renewal applications	Pre-submission checklist for 5-year renewal applications
► Conditional marketing authorisation annual renewal	Pre-submission checklist for annual renewal of conditional marketing authorisation applications
► Exceptional circumstances marketing authorisation annual re-assessment	Pre-submission checklist for annual re-assessment of a marketing authorisation under exceptional circumstances application

Proposal for second monthly linguistic review

- A second linguistic review in the month could expedite implementation of variations on weekly and alternative monthly timetables
- 2 pilots run in May-June 2016 and April-June 2017
- The number of eligible procedures was ultimately small (<5/mo in 2016 and <10/mo in 2017)
- The administrative and technical complexity to implement the 2nd linguistic review at EMA and NCAs was finally considered to outweigh the benefits from having the possibility to implement PI changes slightly earlier
- The proposal was finally abandoned

Possible points for discussion

- Industry experience with the updated RMP and type II variation guidance
- Preliminary experience with updated GVP mod V and leaner RMP template
- Feedback on the published checklist would be highly appreciated at the next platform meeting
- Feedback on the introduction of the 'rolling' PRAC variations
- Other proposals for the Agency's consideration?



Thank you for your attention

Further information

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Back-up slide

Introduction of alternative monthly timetables for variations involving the PRAC

	Procedure starts	Procedure outcomes
Weekly TT	29%*	23%*
+ alternative monthly TT	61%**	39%**

*Based on 2016 data

**Based on Jan-May 2017 data

