EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Tabular overview of updated/new procedural guidance documents in line with new Pharmacovigilance legislation

Pre-submission guidance

Topic
7. What is the procedure for appointment of CHMP Rapporteur/Co-Rapporteur and their assessment teams?
17. What is the fee for a GMP/GCP inspection?
28. How and to whom shall I submit my dossier?
30. When to submit the Marketing Authorisation Application?
31. How shall my application be evaluated (timetable)?
42. How shall I submit an EU Risk Management Plan as part of my application?
43. How and when to submit a Pharmacovigilance system description?
45. Where can I find the relevant documents regarding the pharmaceutical legislation?

Generics procedural guidance (both pre-and post-authorisation)

Topic
7. When and how are Rapporteur and Co-Rapporteur appointed?
14. How shall I present my generic/hybrid medicinal product application (format)?
28. How shall my generic/hybrid application be evaluated (timetable)?
35. How and when to submit a Pharmacovigilance system description?
36. Should I submit an EU Risk Management Plan as part of my generic medicinal application?
37. Do hybrid medicinal products applications have special requirements regarding the submission of EU Risk Management Plans?

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Biosimilars procedural guidance (both pre- and post-authorisation)

Topic
10. When and how are Rapporteur and Co-Rapporteur appointed?
31. How shall my similar biological medicinal product application be evaluated (timetable)?
38. How and when to submit a Pharmacovigilance system description?
39. Should I submit an EU Risk Management Plan as part of my similar biological medicinal product application?

Post-authorisation guidance

Topic
3. Type II variations
3.2 Is the Co-Rapporteur involved in Type II Variations?
3.5 How and to whom shall I submit my Type II Variation application?
3.7 How shall my Type II application be handled (timetable)?
4. Type II variations / Extension Applications
4.3 Is the (Co-) Rapporteur involved in Extension Applications?
4.6 How, when and to whom shall I submit my Extension Application?
4.7 How shall my Extension Application be handled (timetable)?
8. Annual Re-assessment
9. Renewal
10. Conditional renewal – New Q&A
12. PSURs
13. PASS – New Q&A
15. Transfer of MA 15.12 Can I include changes to the Detailed Description of Pharmacovigilance System in my Transfer of Marketing Authorisation application?
16. Transparency/Communication
17. Pharmacovigilance system summary – New Q&A