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EMA Updates Guidance in Line With New Pharmacovigilance Legislation

The European Medicines Agency has revised its procedural guidance for pharmaceutical companies to include the latest information related to the new pharmacovigilance legislation. The guidance for applicants covers pre- and post-authorisation procedures. There are also specific sections for generic, hybrid and biosimilar medicines.

The update concerns all questions and answers on issues affected by the new legislation and its impact on the centralised procedures. In this context, some questions have been either completely revised or added to reflect new procedures introduced by the legislative changes, such as periodic safety update reports (PSURs), post-authorisation safety studies (PASSs) and summaries of the pharmacovigilance master file.

The guidance has been amended to reflect changes to the existing procedures, such as appointment of Pharmacovigilance Risk Assessment Committee (PRAC) rapporteurs and additional milestones as part of the PRAC assessment reflected in updated timetables.

For more information, please visit: www.ema.europa.eu

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