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Veterinary Medicines Division

Veterinary Medicines Division – handling of PSURs and their assessments

Procedural announcement

From 2017, the European Medicines Agency (the Agency) changed its process for the handling of periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products. The changes introduced aimed at reducing administrative burden related to the management of the PSUR assessment procedure to release capacity at the Agency for supporting other activities (including signal detection and management).

From 2017, the Agency discontinued circulating PSURs to CVMP members and tabling them on the CVMP agenda, in line with the practice for other dossier submissions. This means that the PSURs are no longer attached to the assessment requests to rapporteurs, or to the endorsement request to CVMP, as well as no longer added to the CVMP mailings.

Marketing authorisation holders (MAHs) are now requested to submit the PSURs to the Agency and all national competent authorities at the same time. In view of the experience gained the compliance check of the PSUR by the secretariat was not considered justified and is no longer performed, consistent with the practice on the human side. The assessment request to the rapporteurs is sent monthly, shortly after the PSUR submission deadline (end of the previous month). This gives the rapporteurs a few more days to assess the PSUR. The option for the rapporteur to request additional information or a revision of the PSUR from the MAH remains, should this be necessary to perform the assessment. Any such additional information or revisions should be requested through the procedure coordinator at the Agency.

Furthermore, the Agency applies the process for “abridged PSURs” (i. e. “no assessment necessary”) also to PSURs submitted as a full document where no sales and/or no adverse events were reported during the reporting period.

Finally, for those PSURs where no need for regulatory action was identified, and the CVMP endorsed the assessment in the written procedure prior to the CVMP plenary meeting, the assessment report is no longer reviewed, transformed into a CVMP document for adoption at plenary, and is not sent to the MAHs. The outcome letter will indicate that there is no need for regulatory action, and will include any other (minor) recommendations made in the assessment (e.g. improvements for future PSURs). The MAHs has the option to request those endorsed rapporteur’s assessments, if they wish.

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Any assessment reports that propose regulatory action or those that have received comments during the written endorsement procedure before CVMP plenary are discussed at CVMP plenary prior to adoption/endorsement. Those that propose regulatory actions are reviewed and transformed by the secretariat into CVMP assessment reports, and sent to the MAH, as before.

The secretariat is applying a risk-based approach to reviewing specific assessment reports, even if they do not propose regulatory action, and collaborates closely with rapporteurs to ensure the revised approach is efficient and effective.