



Instructions for Submission of Periodic Safety Update Reports of Veterinary Medicines

Periodic Safety Update Reports should be elaborated according to point 6 of part I of Vol. 9B, namely points 6.3.1.1 to 6.3.1.11.

The PSURs for Centralised approved products (CAP) must be submitted preferably electronically, using the following e-mail address psur-v-submission@dgav.pt The paper version is dispensable for these products.

The PSURs for National VMP (Purely National, MRP/DCP) as PSURs under Work Share Project (PSSG) should be submitted preferably in paper. If the MAH chooses electronically submission, the paper version should be avoided.

The submission letter must comply with the following points:

- **Subject-matter: name** of the VMP (or the abbreviated name), authorization **procedure type** acronym e.g.: Nac (for National), CAP for Centralised, MRP (for Mutual Recognition) or DCP (for Decentralised) or **WS** (for PSURs under Work Share Project), the **period** and the **Chronological order of the PSUR**;

* E.g.: 1.st **6-month** PSUR; 2.nd **annual** or **48th month** PSUR.

- **Fee:** -The Periodic Safety Update Reports of national Veterinary Medicines must be submitted with the proof of payment of the fee and the calculation of the total rate paid for each PSUR. (Please consult in this site the following documents: “Fees for Periodic Safety Update Reports submission of Veterinary Medicines approved by National, Mutual Recognition and Decentralized” and “Fees for PSUR Submission of VMP Not Marketed”).

- PSURs of Centralised Medicines are not subject to payment of a fee as described in document “PSUR submission of CAP - free of fee”.

The SPC annexed should be a copy of the last version authorised by the Competent Authority (with the seal or, in most recent SPC (s), with the DGAV's or DGV's logo).