

# Synchronisation of PSUR submission schemes for veterinary medicinal products authorised through national, mutual recognition and decentralised procedures

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## Information sheet for Marketing Authorisation Holders: The Core Safety Data Sheet

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**Definition:** the Core Safety Data Sheet (CSDS) is an unofficial working document prepared by Marketing Authorisation Holders. It contains core safety information, and aims to facilitate the assessment of the PSURs by the assessing competent authority. It must thus be provided in the English language.

**Content:** the CSDS should contain the following core safety information as extracted from the relevant SPC(s):

- Contra-indications
- Special precautions and warnings:
  - o User
  - o Animal
  - o Other
- Adverse reactions (frequency and seriousness)
- Use during pregnancy, lactation or lay
- Interaction with other medicinal products and other forms of interaction
- Administration route
- Overdose (symptoms, emergency procedures, antidotes), if necessary.

It is generally prepared per active but may also be done per product where several formulations and/or species are concerned, e.g. for an injectable for use in horses and chickens, a document per product would be more appropriate. It must anyhow contain all the relevant safety information of the product(s) concerned.

For immunologicals, this document should be prepared per product.

The CSDS must be easily identifiable by its date (and its revision number where applicable).

It only needs updating at each PSUR submission and not every time the SPC is amended.