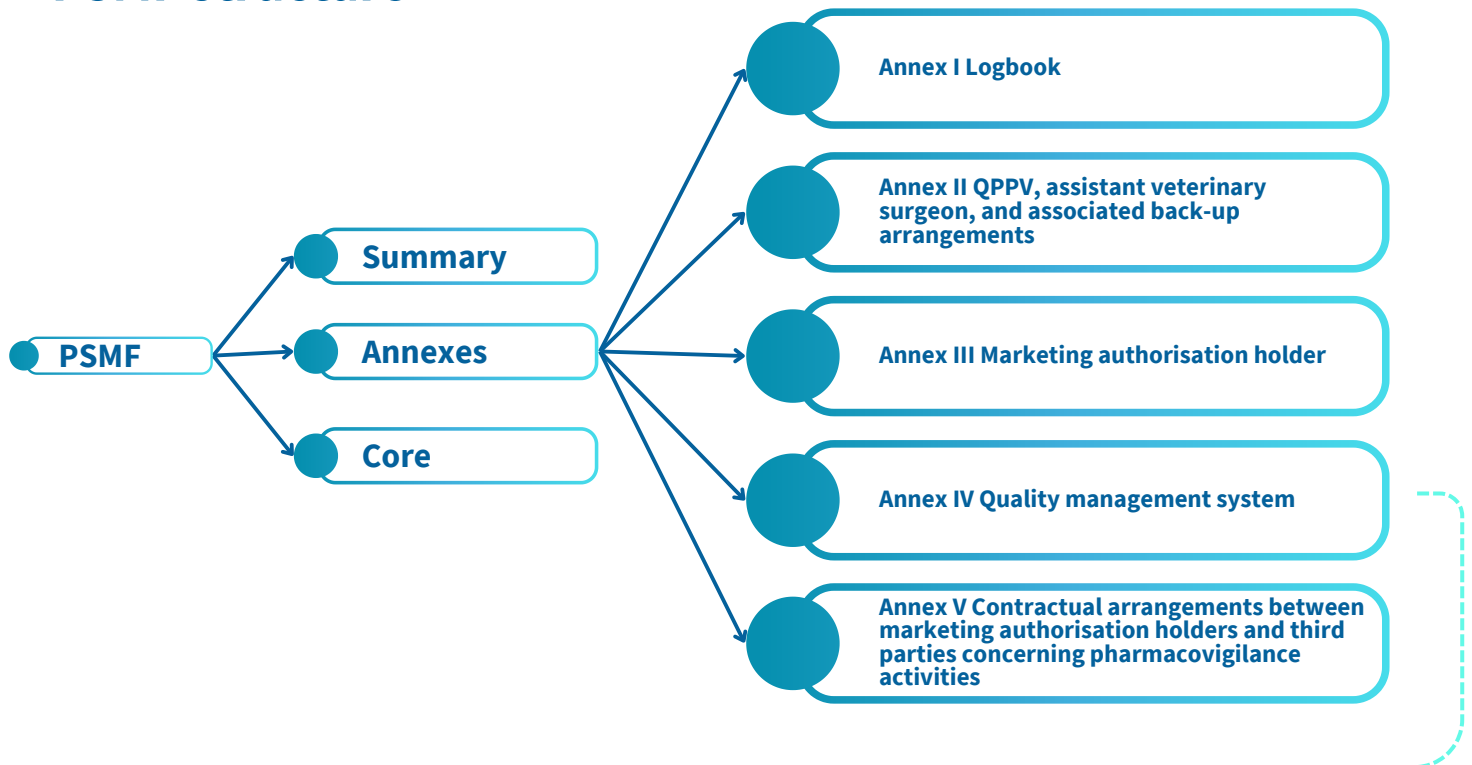


PSMF Veterinary



PSMF structure



Annex IV Quality management system - Dose factor

Determine the average number of animals of a particular target species which can be treated by a single pack of a specific size of a product, regardless of the formulation

✓ Provided for all volume of sales data and target species per package identified and per country

✓ Positive numerical value



1 13 October 2023
2 EMA/CVMP/PRVWPV/399363/2023
3 Committee for Veterinary Medicinal Products (CVMP)

4 Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD)

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-calculation-dose-factor-be-submitted-union-product-database-upd_en.pdf