



Fees for Periodic Safety Update Reports submission of Veterinary Medicines approved by National, Mutual Recognition or Decentralised Procedures or PSURs under WorkSharing Project

The Portaria n.º 27/2011, from 10th January, has updated and adapted the fees for acts relating to the procedures concerning veterinary medicinal products, in order to allow, as soon as possible, real costs convergence.

According to this Portaria (point 10 of the Annex), the fee for submission of Periodic Safety Update Reports (PSURs) for Veterinary Medicinal Products (VMP) varies according the type of authorization procedure (Strictly National or Mutual Recognition/Decentralized) or the PSUR evaluation procedure (PSUR WorkSharing Project – point 11 of the Annex).

We would like to take your attention, namely, for the following changes:

- Change of the fee calculation for PSURs concerning more than one dosage of the same VMP, which is no more based on the marketing authorization number (... *para cada medicamento veterinário, independentemente do número de autorização concedido* = ... for each VMP, independently of the MA number);
- And the species number is no more relevant to the fee calculation for each PSURs.

The validation of the submission is made only on receipt of the detailed calculation on the total fee paid and the proof of payment by each PSUR.

The bank charges are borne by the applicant. If it is not credited the correct amount (rounding - up or down - are not acceptable), the submission will be invalidated.

NATIONAL PROCEDURE:

- *Fee for submission of a PSUR of a VMP (“X”) authorized by a National procedure:*

Example 1

With:

- *1 Dosage form*
- *1 Pharmaceutical form*
- *1 Diluent*

PSUR submission fee:

- ***6-month or Annual report: 160 €***
- ***Triennial report: 1 200 €***



Example 2

With:

- 2 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- **6-month or Annual report: 160 € + 25 € = 185 €**
- **Triennial report: 1200 € + 150 € = 1 350 €**

MUTUAL RECOGNITION or DECENTRALIZED:

- *Fee for submission of a PSUR of a VMP ("X") authorized by a Mutual Recognition or Decentralized procedure:*

- *when Portugal is Reference Member State (RMS):*

Example 3

With:

- 1 Dosage form
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- **6-month or Annual report: 200 €**
- **Triennial report: 1 300 €**

Example 4

With:

- 2 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- **6-month or Annual report: 200 € + 25 € = 225 €**
- **Triennial report: 1300€ + 150€ = 1 450 €**



- when Portugal is Concerned Member State (CMS):

Example 5

With:

- 1 Dosage form
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: 150 €
- Triennial report: 1 000 €

Example 6

With:

- 2 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $150 \text{ €} + 25 \text{ €} = 175 \text{ €}$
- Triennial report: $1000 \text{ €} + 150 \text{ €} = 1\ 150 \text{ €}$

Example 7

With:

- 3 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $150 \text{ €} + 25 \text{ €} + 25 \text{ €} = 200 \text{ €}$
- Triennial report: $1000 \text{ €} + 150 \text{ €} + 150 \text{ €} = 1\ 300 \text{ €}$

Example 8

With:

- 4 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $150 \text{ €} + 25 \text{ €} + 25 \text{ €} + 25 \text{ €} = 225 \text{ €}$
- Triennial report: $1000 \text{ €} + 150 \text{ €} + 150 \text{ €} + 150 \text{ €} = 1\ 450 \text{ €}$



PSURs evaluated within Work-sharing project

- Fee for submission of a PSUR of a VMP (“X”) within PSUR WorkSharing Project:

- when **Portugal is Reference Member State (RMS)**:

Example 9

With:

- 1 Dosage form
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: 200 €
- Triennial report: 1 300 €
- 5-years report: 2 000 €

Example 10

With:

- 2 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $200 \text{ €} + 25 \text{ €} = 225 \text{ €}$
- Triennial report: $1300\text{€} + 150\text{€} = 1\ 450 \text{ €}$
- 5-years report: $2\ 000 \text{ €} + 150 \text{ €} = 2\ 150 \text{ €}$

Example 11

With:

- 3 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $200 \text{ €} + 25 \text{ €} = 225 \text{ €}$
- Triennial report: $1300\text{€} + 150\text{€} = 1\ 450 \text{ €}$
- 5-years report: $2\ 000 \text{ €} + 150 \text{ €} + 150 \text{ €} = 2\ 300 \text{ €}$

Example 12

With:

- 4 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $200 \text{ €} + 25 \text{ €} = 225 \text{ €}$
- Triennial report: $1300\text{€} + 150\text{€} = 1\ 450 \text{ €}$
- 5-years report: $2\ 000 \text{ €} + 150 \text{ €} + 150 \text{ €} + 150 \text{ €} = 2\ 450 \text{ €}$



- when Portugal is Concerned Member State (CMS):

Example 13

With:

- 1 Dosage form
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: 150 €
- Triennial report: 1 000 €
- 5-years report: 1 500 €

Example 14

With:

- 2 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $150 \text{ €} + 25 \text{ €} = 175 \text{ €}$
- Triennial report: $1000 \text{ €} + 150 \text{ €} = 1 150 \text{ €}$
- 5-years report: $1 500 \text{ €} + 150 \text{ €} = 1 650 \text{ €}$

Example 15

With:

- 3 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $150 \text{ €} + 25 \text{ €} + 25 \text{ €} = 200 \text{ €}$
- Triennial report: $1000 \text{ €} + 150 \text{ €} + 150 \text{ €} = 1 300 \text{ €}$
- 5-years report: $1 500 \text{ €} + 150 \text{ €} + 150 \text{ €} = 1 800 \text{ €}$

Example 16

With:

- 4 Dosages forms
- 1 Pharmaceutical form
- 1 Diluent

PSUR submission fee:

- 6-month or Annual report: $150 \text{ €} + 25 \text{ €} + 25 \text{ €} + 25 \text{ €} = 225 \text{ €}$
- Triennial report: $1000 \text{ €} + 150 \text{ €} + 150 \text{ €} + 150 \text{ €} = 1 450 \text{ €}$
- 5-years report: $1 500 \text{ €} + 150 \text{ €} + 150 \text{ €} + 150 \text{ €} = 1 950 \text{ €}$

This document is a support to calculate the PSUR submission fee. Only the Portaria n.º 27/2011, from 10th January, is lawful.