REPÚBLICA PORTUGUESA | AGRICULTURA, FLORESTAS E DESENVOLVIMENTO RURAL

dgav Direção Geral de Alimentação e Veterinária

INSTRUCTION MANUAL
MARKETING FEES FOR VETERINARY MEDICINAL PRODUCTS

DGAMV

January 2019

Marketing fees for veterinary medicinal products

Introduction, objective and scope

Under the terms of Decree-Law no. 253/2007, of July 9, it is foreseen the payment of a commercialization fee for veterinary medicinal products.

Marketing authorization holders of each pharmacological or immunological veterinary medicinal product subject to, and not subject to, a veterinary prescription, or the entity which is responsible, on the basis of an indication of the first, for its marketing, shall be obliged to pay a commercialization fee.

The rate is 0.4% on the volume sales of each veterinary medicinal product. DGAV is responsible for the monthly collection of that fee, the value of which constitutes is own revenue. The amount charged is derived from the information contained in the monthly sales statements provided by the individuals required to pay them, according to the specific form approved by DGAV and available on the website.

Based on the monthly sales declarations provided by the subjects obliged to pay the marketing fees, it is possible to carry out a statistical analysis of the volume sales of the various types of veterinary medicines marketed in Portugal as well as to carry out the validation of the information necessary for compliance of the DGAV's duties as the competent authority for Veterinary Medicinal Products.

According to Decree-Law 253/2007 of July 9, the marketing fee is intended to cover the reinforcement of veterinary pharmacovigilance systems and the improvement of the material and human resources necessary to ensure the overall quality assurance system of the veterinary medicinal products and the guarantee of the safety, within which the services are provided.

This fee, in addition to the financial support, is also intended to support studies to evaluate the epidemiological impact of these veterinary medicinal products and to provide training and information to animal health professionals, economic agents in the agricultural sector and consumers of food of animal origin to be ensured by DGAV.

Applicable legislation

- Decree-Law no. 314/2009 of 28 October, which establishes the rules on the marketing authorization (MAH) and the its variations and renewals, the manufacture, import, export, distribution, marketing, labelling and information, advertising, pharmacovigilance, possession or possession and use of veterinary medicinal products, including pre-mixes medicinal products, immunological, homeopathic and herbal veterinary medicinal products and medical gases.

- Decree-Law no. 253/2007 of July 9th - Provides for the payment of marketing fees for veterinary medicinal products.

Siglas

DGAMV – Divisão de Gestão e Autorização de Medicamentos e Veterinários

DGAV – Direção Geral de Alimentação e Veterinária

VMP – Veterinary medicinal product

Description of procedure

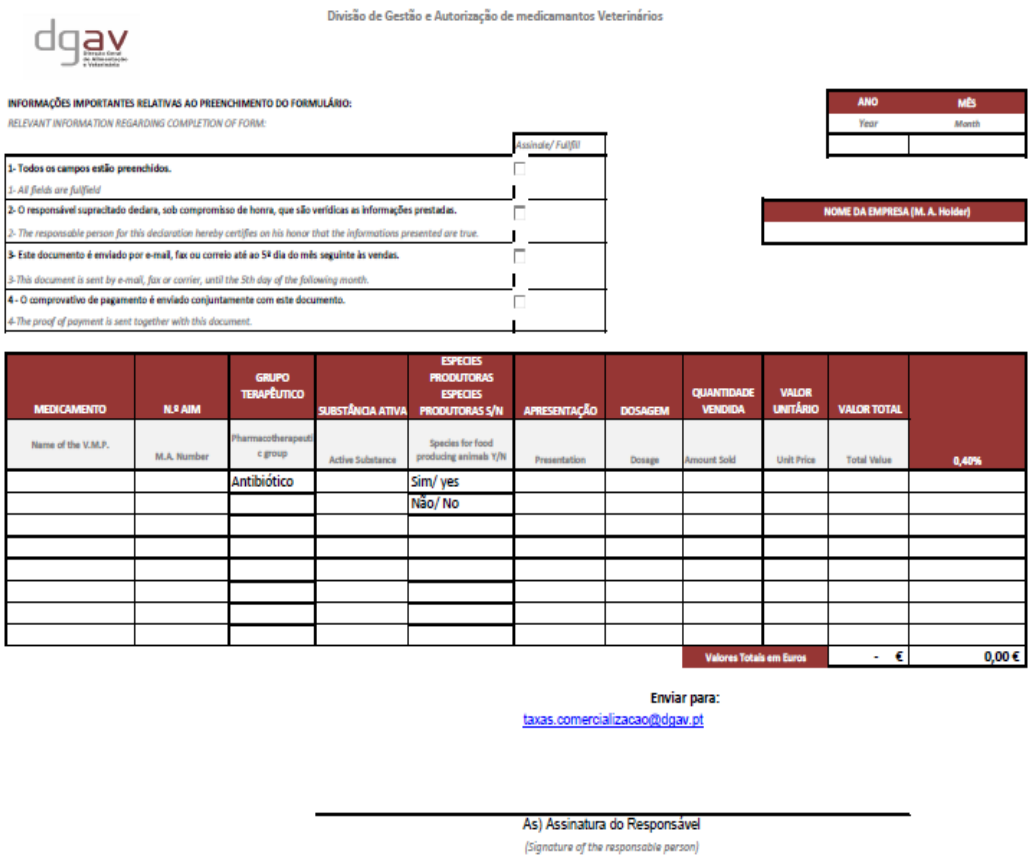
1. Completion of the Form

The correct completion of the form is a mandatory requirement and the responsibility of the holder of marketing authorization for veterinary medicinal products or of the entity legally named by the holder for this purpose.

The form to be completed is the one approved by DGAV, available for download on the DGAV Portal. The form corresponds to the information regarding the monthly sales statements.

All fields in the form are mandatory.

Information on all veterinary medicinal products should be sent, even if they have not been placed on the market.



Divisão de Gestão e Autorização de medicamantos Veterinários

dgav

INFORMAÇÕES IMPORTANTES RELATIVAS AO PREENCHIMENTO DO FORMULÁRIO:

RELEVANT INFORMATION REGARDING COMPLETION OF FORM:

	Assinale/ Fullfil
1- Todos os campos estão preenchidos. *1- All fields are fullfield*	☐
2- O responsável supracitado declara, sob compromisso de honra, que são verídicas as informações prestadas. *2- The responsable person for this declaration hereby certifies on his honor that the informations presented are true.*	☐
3- Este documento é enviado por e-mail, fax ou correio até ao 5º dia do mês seguinte às vendas. *3-This document is sent by e-mail, fax or corrier, until the 5th day of the following month.*	☐
4 - O comprovativo de pagamento é enviado conjuntamente com este documento. *4-The proof of payment is sent together with this document.*	☐

ANO	MÊS
Year	Month

NOME DA EMPRESA (M. A. Holder)

MEDICAMENTO	Nº AIM	GRUPO TERAPÊUTICO	SUBSTÂNCIA ATIVA	ESPECIES PRODUTORAS ESPECIES PRODUTORAS S/N	APRESENTAÇÃO	DOSAGEM	QUANTIDADE VENDIDA	VALOR UNITÁRIO	VALOR TOTAL	
Name of the V.M.P.	M.A. Number	Pharmacotherapeutic group	Active Substance	Species for food producing animals Y/N	Presentation	Dosage	Amount Sold	Unit Price	Total Value	0,40%
		Antibiótico		Sim/ yes						
				Não/ No						
							Valores Totais em Euros		- €	0,00 €

Enviar para:

taxas.comercializacao@dgav.pt

Ás) Assinatura do Responsável

(Signature of the responsable person)

1.1 Instructions for correct form filling

I. Year / month and Name of AIM holder

Ensure that all documentation is properly completed

ANO	MÊS
Year	*Month*

NOME DA EMPRESA (M. A. Holder)

INFORMAÇÕES IMPORTANTES RELATIVAS AO PREENCHIMENTO DO FORMULÁRIO:

RELEVANT INFORMATION REGARDING COMPLETION OF FORM:

	Assinale/ Fullfil
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II. VMP Name / MA Number / Active Substance / Therapeutic Group and Species

MEDICAMENTO	N.º AIM	GRUPO TERAPÊUTICO	SUBSTÂNCIA ATIVA	ESPECIES PRODUTORAS ESPECIES PRODUTORAS S/N
Name of the V.M.P.	M.A. Number	Pharmacotherapeutic group	Active Substance	Species for food producing animals Y/N

All these fields must be completed.

a) The column for the therapeutic group is a closed list that has the following options:

- Antibiotic
- Antiparasitic
- Anti-inflammatory
- Hormone
- Immunological
- Other

b) The species column is a closed list which has the following options:

Yes - When the veterinary medicinal product is intended for food producing species.

Note: When the product is intended for several target species even though only one of them is a food producing species, it should be placed in this column

No - When the veterinary medicinal product is not intended for food producing species

III. Presentation / Dosage / Quantity sold

APRESENTAÇÃO	DOSAGEM	QUANTIDADE VENDIDA
Presentation	Dosage	Amount Sold

a) The **presentation** of the veterinary medicinal product shall only describe the value of the volume or weight, with the respective units, for example:

APRESENTAÇÃO
Presentation
250 ml

b) The **dosage** of the veterinary medicinal product shall only describe the dosage value with the respective unit, for example:

DOSAGEM
Dosage
50 mg/ml

c) the columns relating to **quantities sold** refer to the quantity sold for a particular presentation

IV. Unit value / total value and 0.40%

VALOR UNITÁRIO	VALOR TOTAL	
Unit Price	Total Value	0,40%

NOTE: *The fields Unit value and total value and 0,4% should not be filled with formulas, since when entering the values sent in the central database of the DGAMV the transposition of the formulas gives rise to errors and impossibility of visualization and accounting values.*

Even if there were no sales, the form should be sent with VALUE 0. No cells should be left in blank.

2. Submission of information

The submission of the form and the respective proof of payment shall be the responsibility of the holder of authorizations for the placing on the market of veterinary medicinal products or of the entity legally named by the holder for this purpose.

The submission of the sales statement and the respective proof of payment shall be sent by the mentioned entities to the following electronic mail: taxas.comercializacao@dgav.pt until the 5th day of the month following the sales.

The amount of the payable fee is automatically calculated on the completed form for the Total Value of Column L.

The rate mentioned is 0.4% of the sales volume of each pharmacological or immunological veterinary medicinal product, calculated on the selling price.

3. Validation of information

DGAMV / DGAV is responsible for evaluating the information submitted. Upon receipt of the documentation, it is verified within 10 working days. In this verification the following items are analysed:

a) All fields in the form are filled out.

b) The entities declared, under a commitment, that the information provided is true.

c) The declaration is duly signed by the responsible person.

d) The documentation was sent by email until the 5th day of the month following the sales.

e) The proof of payment was sent together with the form and corresponds to the amount predicted.

(f) all veterinary medicinal products belonging to the entity submitting the form are described in the form.

g) No sales in a given month are marked with a value of 0.

a) The sales statement and the respective proof of payment are only for one month.

3.1 Valid submitted information

The DGAV / DGAMV after validation of the data shall issue the receipt of payment by mail to the holder of marketing authorizations for veterinary medicinal products or the entity legally named by the holder for this purpose, using the general billing system of the DGAV.

3.2 Information submitted is not valid

Whenever any requirement mentioned in point 3 is not fulfilled, the information shall be deemed invalid. In such cases the applicant is informed of the need to rectify the data provided by e-mail.

3.3 Non-compliance

Failure to submit a monthly sales statement, according to Article 2 (2) of Decree-Law no. 253/2007, of 9 July, constitutes a misdemeanour punishable by a fine of (euro) 250 to (euro) 3740 or euro) 44890 depending on whether the agent is a particular or legal person.

Depending on the severity of the misconduct and the fault of the agent, the following sanctions may be applied simultaneously with the fine:

a) Loss of objects belonging to the agent;

b) Interdiction of the exercise of professions or activities whose exercise depends on public title or authorization or homologation of public authority;

c) Deprivation of the right to a subsidy or benefit granted by public entities or services;

d) Deprivation of the right to participate in fairs or markets;

e) Deprivation of the right to participate in public tenders or tenders for the supply of goods and services, the concession of public services and the attribution of licenses or permits;

f) Closure of an establishment whose operation is subject to authorization or license of administrative authority;

g) Suspension of authorizations licenses and permits.

Payment Details

FEES - METHOD AND TIME OF PAYMENT

Payment must be made at the time of the application submission, by any of the following methods:

Cash – Treasurer's Office of DGV.

Portuguese cheques in €(**Euros**) made payable to "Instituto de Gestão da Tesouraria e do Crédito Público" and sent to Direcção-Geral de Veterinária, or by

Bank deposit/transfer to: "Instituto de Gestão da Tesouraria e do Crédito Público"
NIB – 0781 0112 000 0000 7784 96
IBAN – PT50 0781 0112 00000007784 96
SWIFT BIC CODE – IGCPPTPL

Bank Name and Address:
Instituto de Gestão da Tesouraria e do Crédito Público, IP
Av.ª da República, n.º 57, 6.º Piso
1050-189 Lisboa
Portugal

The amount must be the exact one (net of all bank charges).

It is advisable to initiate the bank transfer approximately 1 week in advance of the submission of the application.

Proof of payment (a copy of the deposit/transfer slip)* must accompany the application and shall also be sent to:

Tesouraria da DGAV
Campo Grande, n.º 50
1700-093 Lisboa
Tel: +351 213 239 500
Fax: +351 213 463 518

Proof of payment must quote the rering subject of payment.