REQUIREMENTS FOR NATIONAL AND MUTUAL RECOGNITIONS VMP APPLICATIONS

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Applicable National Legislation and Community texts

- Decreto-lei nº 148/2008, de 29 de Julho alterado pelo DL nº 314/2009, de 28 de Outubro
- Despacho n.º 25922/2008, de 16 de Outubro
- "The Rules Governing Medicinal Products in the European Union"

The applicant shall address a letter of access, in Portuguese, to the Director Geral de Veterinária requesting the concerned authorisation.

This request must mention the name and the address of the applicant, the name of the concerned VMP and for Mutual recognition procedures (MRP) and Decentralised procedures (DCP), the European procedure number.

Content of the application

The applications shall comply with the requirements set in the national legislation (http://www.dgv.min-agricultura.pt) and, if applicable with the Community requirements namely with **"The Rules Governing Medicinal Products in the European Union"** (Vols.4, 5, 6 A e 6 B, 7, 8 and 9)
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/index_en.htm

- Submission

In order to avoid receiving great amounts of paper we would be pleased if you could send us the applications in electronic format.

E-submission

Applicants are advised that the structure of dossiers for electronic submission should be in accordance with the TIGes vet e-submission guideline (http://esubmission.ema.europa.eu/tiges/vetesub.htm)

Marketing authorisations

1 - Language:

Parts II, III, IV and answers to any list of questions, should be submitted in Portuguese or English for national procedures (NP) and only in English for MRP and DCP.

For all procedures, Portuguese is mandatory for the letter of access and for parts IA (Formulário do pedido de AIM para MV) and IB (Modelos de RCMV, rotulagem e folheto informativo para pedidos por PN, PRM e PD).

For MRP and DCP, Part IB in Portuguese should only be sent at the end of the procedures, by e-mail.

For Parts IA format and IB templates please see - http://www.dgv.min-agricultura.pt (MEDICAMENTOS VETERINÁRIOS, PRODUTOS E BIOCIDAS DE USO VETERINÁRIO >> **- Formulários**)
http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=17557&generico=17558&cboui=17558

2 - Applications/Copies and Number:

1 x 1 CD-rom **-** with a full complete application (for MR/DCP when Portugal is CMS)
3 x 1 CD-rom **-** with a full complete application (for national procedures and MR/DCP when Portugal is RMS)

In case it is not possible to send the application in electronic format, the following paper copies should be sent:

1 x full paper copies (for MR/DCP when Portugal is CMS)

3 x full paper copies (for national procedures and MR/DCP when Portugal is RMS)

In order to facilitate the distribution of the copies please send the copies divided as follows:

1 box - **A** - with:
1 complete application (including all parts)
+
part I A+ IB in Portuguese (for NP) or part I A in Portuguese (for MRP and DCP)

1 box - **B** - with:

1 complete application (including all parts)
+
part I A+ IB in Portuguese (for NP) or part I A in Portuguese (for MRP and DCP)

1 box - **C** - with:

1 complete application (including all parts)
+
part I A+ IB in Portuguese (for NP) or part I A in Portuguese (for MRP and DCP)

In case the files do not fit in just one box, they must be divided by other boxes with the following on each box:

- Correspondent letter (A, B, C, D or E)
- Sequential numbering
- Parts included

Example (referring to A):

Box A n.º 1 – Parts I and Parte IA, in Portuguese x 1
Box A n.º 2 – Parts II and III IV
Box A n.º 3 – Part IV

3 - SPC, Labels and Leaflet:

Prior to the authorisation, proposed texts of the SPC, labels and leaflet in Portuguese (and English if necessary) and proposed mock-ups in Portuguese, should be sent in electronic format. The template for NP, MRP and DCP should be used.

http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=17557&generico=17558&cboui=17558

(http://www.hma.eu/fileadmin/dateien/Veterinary_medicines/SPC/PT_CMDv_QRD_template.pdf)

4 – Responses to questions:

Please send us the responses preferably by e-mail or by other electronic means (1 copy)

Variations

1 - Applicable Legislation and Community texts:

- Decreto-lei nº 148/2008, de 29 de Julho alterado pelo DL nº 314/2009, de 28 de Outubro
- Commission Regulation (EC) No 1234/2008, of 24 November 2008
- Normas referentes às alterações aos termos das autorizações de introdução no mercado por procedimento nacional.
- Formulários para pedidos de alteração aos termos da AIM (see template)
- Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/betterreg/pharmacos/procedural_guideline_adopted.pdf

- Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/betterreg/pharmacos/classification_guideline_adopted.pdf

- Application form for variation to a marketing authorisation for medicinal products (human and veterinary) to be used in the mutual recognition and the centralised procedure

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-2/upd/variation_form_2009-12.doc

For templates please see - http://www.dgv.min-agricultura.pt (MEDICAMENTOS VETERINÁRIOS, PRODUTOS E BIOCIDAS DE USO VETERINÁRIO >> **- Formulários**) http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=17557&generico=17558&cboui=17558

2 - Language:

For all procedures, Portuguese is mandatory for the letter of access, for the variations format and for the SPC and literature, if necessary.
For MRP and DCP, literature in Portuguese should only be sent at the end of the procedures, by e-mail.

3 - Copies:

Type IA national and MRP variations when Portugal is CMS

1 CD-rom - with the complete information including the "Variations format" (Formulário para pedidos de alteração aos termos da AIM) in Portuguese.

or, the following paper copies:

Complete application (original) x 1 + Variation form, in Portuguese x 1
Part I B, if necessary, in Portuguese x 1

All other variations (Type IB national and MRP variations when Portugal is RMS and Type II)

2 CD-rom - with the complete information including the "Variations format "in Portuguese.

or, the following paper copies:

Complete application (original) x 2 + Variation form, in Portuguese x 2
Part I B, if necessary, in Portuguese x 2

RENEWALS

1 - Applicable Legislation and Community texts

A - For all procedures:

- Decreto-lei nº 148/2008, de 29 de Julho alterado pelo DL nº 314/2009, de 28 de Outubro

B - For MR/DCP:

- The "Guideline on the processing of renewals in the MRP" ("Rules governing Medicinal Products in the EC – Vol. 6C Regulatory Guidelines)
- Application form for renewal of a marketing authorisation and guidance for the completion of the application form
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-2/b/update_2007-03/renewalformrevised_final_en.doc

C - For NP:

- Formulário para pedidos de Renovação da Autorização de Introdução no mercado de um Medicamento Veterinário
http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=17557&generico=17558&cboui=17558

2 - Language:

For all procedures, Portuguese is mandatory for the letter of access, for the renewal format and for the SPC and literature.
For MRP and DCP, literature in Portuguese should only be sent at the end of the procedures, by e-mail.

3 - Content for National procedures:

1 Together with the cover letter and a comprehensive table of content the marketing authorisation holder submits a renewal application with the following annexes:

1.1 Part IA amended, if applicable

1.2 Proof of payment of fee

1.3 A list of all authorized product presentations for which renewal is sought in tabular format

1.4 Details on contact persons:

- Qualified person in EEA for Pharmacovigilance and the QP for Pharmacovigilance in Portugal
- Contact person in with overall responsibility for product defects and recalls
- The name and contact details of a contact person at the address of the marketing authorisation holder (if different from the address of the contact person during the procedure)

1.5 List of EU Member States / Norway / Iceland / Liechtenstein where the product is on the market and indicating for each country which presentations are marketed and the launch date;

1.6 Chronological list of all post authorisation submissions (variations, extensions etc.), follow-up measures and, for Community Authorisations only, any Specific Obligations submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved;

1.7 Revised list of all remaining Follow-up measures and Specific Obligations and signed letter of commitment (where applicable);

2 The currently authorised SPC and proposed texts for SPC, labelling and package leaflet to take account of issues raised by the expert. All changes must be clearly highlighted. (EN and relevant national translations);

3 Periodic Safety Update Report (PSUR) and Summary Bridging Report on safety, if applicable

4 Declaration of the current TSE status

5 Clinical expert statement / Safety expert Statement

6 Quality expert statement including Currently authorised specifications for the active substance and the finished product and Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)

7 A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority.

8 In addition for manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome.

9 In accordance with legislation manufacturing authorisation holders are required to use as starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials as adopted by the Community. The following declarations are required:

i. A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community

ii. Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community

4 - Copies:

2 CD-rom - with the complete information including the “Renewal format “in Portuguese.

or, the following paper copies:

Complete application (original) x 2 + Renewal form, in Portuguese x 2
Part I B, if necessary, in Portuguese x 2

5 – For all procedures, if necessary - SPC, Labels and Leaflet:
Prior to the authorisation, proposed texts of the SPC, labels and leaflet in Portuguese (and English if necessary) and proposed mock-ups in Portuguese, should be sent in electronic format. The template for NP, MRP and DCP should be used.
http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=17557&generico=17558&cboui=17558

(http://www.hma.eu/fileadmin/dateien/Veterinary_medicines/SPC/PT_CMDv_QRD_template.pdf)

6 – Responses to questions:

Please send us the responses preferably by e-mail or by other electronic means (1 copy)

FEES

AMOUNT DUE FOR APPLICATIONS

Please see:
http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=17622&generico=17623&cboui=17623
Página principal >> MEDICAMENTOS VETERINÁRIOS, PRODUTOS E BIOCIDAS DE USO VETERINÁRIO >> **- Taxas**

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 Publico" 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 Publico IP
Av. da República, nº 57, 6º 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 DGV
Lg. Academia Nacional de Belas Artes 2
1249-105 Lisboa
Tel: +351 21 3239500
Fax: +351 21 3239

**Proof of payment must quote the Decreto-lei nº 148/2008, de 29 de Julho alterado pelo DL nº 314/2009, de 28 de Outubro, the name of the veterinary medicinal product, the type of application (MA, Type I variation… etc) and, in case of MRP/DCP the MRP/DCP application number.*

CONTACT POINTS

1 - IMMUNOLOGICALS AND PHARMACOLOGICALS

- MRP and DCP

Marketing Authorisations
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Informations:

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