infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Instituto Nacional de Farmácia e do Medicamento
Ministério da Saúde

2011

FEE PAYMENT FORM (ORDINANCE No. 377/2005, OF APRIL 4)

(Read the instructions carefully before filling out)

1. Applicant Identification:

COMPANY NAME:	
TAX NUMBER:	**Tax Office Code:**

2. Identification of act(s):

Number	Paragraph	Subparagraph	Cost*	Quant Qt1/Qt2	Amount
1. Marketing Authorisation Application	**a)** National procedure	i) One dosage and one pharmaceutical form	2,915.55 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	588.23 €		
		iii) Each supplementary dosage or pharmaceutical form submitted at a later date	1,759.56 €		
	b) National proc. – art. 7, a) and c) of DL 72/91, of February 8:	i) One dosage and one pharmaceutical form	1,759.56 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	291.56 €		
		iii) Each supplementary dosage or pharmaceutical form submitted at a later date	588.23 €		
	c) National proc. – subsequent submittal of an application for Mutual Recognition – where Portugal is a reference member state:	i) One dosage and one pharmaceutical form	7,672.50 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	1,759.56 €		
		iii) Each supplementary dosage or pharmaceutical form submitted at a later date	2,046.00 €		
2. Application mutual recognition:	**a)** Medicine granted a valid effective Marketing Authorisation in Portugal – where Portugal is a reference M.S., except in the conditions set forth in no. 1, c)	i) One dosage and one pharmaceutical form	5,115.00 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	1,314.56 €		
		iii) Each supplementary dosage or pharmaceutical form submitted at a later date	1,534.50 €		
	b) Medicine granted a Marketing Authorisation issued by another M.S. of the E.U.	i) One dosage and one pharmaceutical form	3,069.00 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	613.80 €		
		iii) Each supplementary dosage or pharmaceutical form submitted at a later date	767.25 €		
3. Authorisation application for the parallel import of medicines	**a)** One dosage and one pharmaceutical form		1,759.56 €		
	b) Each supplementary dosage or pharmaceutical form included in the previous application		291.56 €		
4. Marketing Authorisation holder transfer application	a) One dosage and one pharmaceutical form		291.56 €		
	b) Each supplementary dosage or pharmaceutical form included in the previous application		102.30 €		
5. Application to change the terms of a medicine Marketing Authorisation, except as provided for in nos. 1 and 2, ii) and iii), and no. 3 b) and d):	**a)** Type I variation:	i) One dosage and one pharmaceutical form	797.94 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	271.10 €		
		iii) When it refers only to changing the name, company name, head office or representation of the Marketing Authorisation holder or the removal of companies participating in the manufacturing, including the release of the batch, the medicine or the active ingredient(s).	184.14 €		
	b) Type II variation:	i) One dosage and one pharmaceutical form	1,585.65 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	511.50 €		
	c) Extensions:	i) Including one dosage and one pharmaceutical form	3,166.19 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	368.28 €		
6. Renewal application:	**a)** Marketing Authorisation of medicine granted in accordance with the national procedure:	i) One dosage and one pharmaceutical form	1,759.56 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	291.58 €		
	b) Marketing Authorisation granted via the national procedure which was subject to a mutual recognition procedure – Portugal is a reference M.S.	i) One dosage and one pharmaceutical form	2,404.05 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	291.56 €		
	c) Mutual recogn. of a Marketing Authorisation granted by the competent authority(ies) of another/other M.S. of the E.U.	i) One dosage and one pharmaceutical form	1,759.56 €		
		ii) Each supplementary dosage and/or pharmaceutical form included in the previous application	291.56 €		
7. Application to import medicines – article 59 of DL 72/91, as per the wording given by DL 272/95, of October 23			588.23 €		
8. Authorisation application to manufacture medicines - article 54 of DL 72/91, as per the wording given by DL 272/95, of October 23.			588.23 €		
9. For each type of Type I variation, or minor variation consisting only of changing the company name, address, head office or representation of the manufacturer or of the marketing authorisation holder of	**a)** Initial batch of up to 10 medicines including a dosage and a pharmaceutical form		383.63 €		
	b) More than 10 medicines – each additional batch of 1 to 5 medicines, up to 50		204.60 €		
	c) More than 50 medicines – each additional batch of 1 to 5 medicines, up to 120		179.03 €	-----	-----
	d) More than 120 medicines – each additional batch of 1 to 5 medicines		153.45 €		

10. Certificate or document of equivalent value regarding the registration of a medicine – **USE APPROPRIATE FORM**		-----		
11. The price of performing laboratory tests will be that fixed by the entities that perform them, plus 20% for the technical and administrative costs incurred by the National Authority of Medicines and Health Products (INFARMED)				
12. Scientific advice regarding a medicine procedure – clinical, non-clinical, pharmaceutical and pharmacokinetic fields.	a) Application for simultaneous scientific advice covering the four fields	7,161.00 €		
	b) Application for scientific advice covering each of said fields	1,918.13 €		
13. Regulatory device, per medicine proc.		797.94 €		
14. Arbitration carried out by INFARMED between marketing authorisation holders covering a matter submitted to its assessment.		1,585.65 €		
			Total	

*** updated annually**

No. of fields filled out in the amount column

Art. 2 – In the event of non-validation of any of the applications referred to in article 1, no. 1 to 9, Infarmed shall refund applicants 90 % of the fees laid down therein, and shall keep the remaining 10 % as payment of administrative expenses.

Applicant's signature and stamp: **_____, _____of _____ of _____**

Treasurer's Signature (INFARMED, I.P) **_____,_____of_____ of _____**

3. Identification of the medicine(s) for which the act(s) are applied:

Act	Medicine name	Pharmaceutical form	Dosage

4. Payment identification:

Cheque number	Bank	Clearing District	Amount
		Total cheques	
In writing: _____		Cash	
_____		Total deposit	

Transfer from the BIN of origin no. _____ to

BIN: 078101120000000624751 of the account held at Instituto de Gestão de Tesouraria e do Crédito Público, I.P.
IBAN: PT50078101120000000624751
SWIFT CODE: IGCPPTPL

The amount of _____, payable to AUTORIDADE NACIONAL DO MEDICAMENTO E PRODUTOS DE SAÚDE, I.P. (INFARMED, I.P), as payment for the aforementioned services.

Treasury Certification

Filling out instructions

0. General:
Fill out all fields of the "Fee Payment Form" in legible letters. The application will be deemed invalid if not fully filled out or filled out incorrectly.

1. Applicant identification:
Always clearly identify the applicant in this field.

2. Identification of act/acts:
- The acts shall be indicated in the appropriate line according to the specified description.
- The applicant shall indicate in the respective line the quantity of medicines for which the acts in question are being applied for.
- The payable amount will be determined by multiplying the list price by the quantity of applied medicines.
- In number 5, depending on whether the acts are subject to a 40% reduction or not, the field "Quant. 1" and/or "Quant. 2" shall be filled out, respectively.
- For applications referred to in no. 10, follow the available instructions using the appropriate form.

3. Identification of the medicine(s) for which the act/acts are being applied:
- The act shall be identified in the following manner: Number, Paragraph and Subparagraph, e.g.: 6. a) ii).
- For acts applied in accordance with no. 5, indicate the type, paragraph, subparagraph and type of the variation, according to the typification set forth in DL 85/2004, of April 15.
- Medicines shall always be identified by their Name, Pharmaceutical Form and Dosage, whereby this identification information shall be applicable to ONE medicine – paragraphs 7, 8, 9, 10, 12.
- Any change either to the dosage or pharmaceutical form is a new medicine.
- However, there are paragraphs where the submittal of supplementary dosages and/or pharmaceutical forms of the same medicine, is accepted a lower cost– paragraphs 1, 2, 3, 4, 5, 6.

4. Payment identification:
This field shall be filled out with the payment means / form.

5. Submitting the "Fee Payment Form" for payments made by bank transfer
The "Fee Payment Form", along with the respective proof of payment, shall be submitted in duplicate. The original shall be included in the dossier to be submitted. The duplicate shall be forwarded to Infarmed's Financial and Property Directorate.