The fees, currently applied in Portugal, set by Governmental Decree No. 377/2005, April 4th [Portaria n.º 377/2005, de 4 de Abril], are as follows:

Values updated 2006

1 – For each marketing authorisation application regarding a medicine:

a) According to the national procedure (complete)

i) Including one strength and one pharmaceutical form - € 2915,55;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous sub-paragraph - € 588,23;

iii) For each additional strength or pharmaceutical form, submitted after the application mentioned in subparagraph i) - € 1759,56;

b) According to the national procedure, in the cases mentioned in paragraphs a) and c), article 7, Decree-Law no.72/91, of February 8th:

i) Including one strength and one pharmaceutical form - € 1759,56;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 291,56;

iii) For each additional strength or pharmaceutical form, submitted after the application mentioned in subparagraph i) - € 588,23;

c) According to the national procedure, as a condition for the subsequent submission of a mutual recognition or decentralised application, according to the community regulations, in the cases where the ministry responsible for the health field in Portugal acts as a reference Member State:

i) Including one strength and one pharmaceutical form - € 7672,50;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 1759,66;

iii) For each additional strength or pharmaceutical form, submitted after the application mentioned in subparagraph i) - € 2046,00.

2 – For each mutual recognition procedure application:

a) Regarding a medicine already having a marketing authorisation that is valid and is in force in Portugal, acting Portugal as a reference Member State, except in the conditions mentioned in paragraph c), no. 1:

i) Including one strength and one pharmaceutical form - € 5115,00;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 1314,56;

iii) For each additional strength or pharmaceutical form, submitted after the application mentioned in subparagraph i) - € 1534,50;

b) Regarding a medicine already having a marketing authorisation granted by another Member State of the European Community or of the European Economic Area:

i) Including one strength and one pharmaceutical form - € 3069,00;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 613,80;

iii) For each additional strength or pharmaceutical form, submitted after the application mentioned in subparagraph i) - € 767,25.

3 – For each medicines parallel import authorisation application in Portugal:

a) Including one strength and one pharmaceutical form - € 1759,56

b) For each additional strength or pharmaceutical form, included in the application mentioned in previous paragraph - € 291,56.

4 – For each marketing authorisation holder transfer application, submitted under the applicable regulations:

a) Including one strength and one pharmaceutical form - € 291,56;

b) For each additional strength or pharmaceutical form, included in the application mentioned in previous paragraph - € 102,30.

5 – For each variation application in the terms of a marketing authorisation of a medicine, except in the situations mentioned in subparagraphs ii) and iii), nos.1 and 2, in paragraph b), no. 3 and paragraph d):

a) For each type I variation or minor variation:

i) Including one strength and one pharmaceutical form - € 797,94;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 271,10;

iii) When it concerns the variation of the name, company, head-office or representation of the marketing authorisation holder or of the retreat of companies involved in the manufacturing, including the batch release, of the medicine and of the active substance(s) - € 184,14;

b) For type II variations or major variations and to the extensions concerning change(s) to the active substance(s):

i) Including one strength and one pharmaceutical form - € 1585,65;

ii) For each additional strength or pharmaceutical form, submitted simultaneously with the application mentioned in previous subparagraph - € 511,50;

c) For each extension concerning changes to the strength, pharmaceutical form or administration route:

i) Including one strength and one pharmaceutical form - € 3166,19;

ii) For each additional strength or pharmaceutical form, submitted simultaneously with the application mentioned in previous subparagraph - € 368,28;

d) When variations concern marketing authorisations granted under the paragraphs a) and b), no.1 and having not been the object of the mutual recognition procedure, the price should be reduced by 40%.

6 – For each renewal application:

a) Of a medicine marketing authorisation granted under the national procedure:

i) Including one strength and one pharmaceutical form - € 1759,56;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 291,56;

b) Of a marketing authorisation granted under a national procedure and having not been the object of a mutual recognition procedure, acting Portugal as a reference Member State:

i) Including one strength and one pharmaceutical form - € 2404,05;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 291,56;

c) Of the mutual recognition of a marketing authorisation granted by the competent authority(ies) of other Member State(s) of the European Community or of the European Economic Area:

i) Including one strength and one pharmaceutical form - € 1759,56;

ii) For each additional strength or pharmaceutical form, included in the application mentioned in previous subparagraph - € 291,56.

7 - For each medicines importing authorisation, in the cases mentioned in article 59th, Decree- Law no.72/91, in the wording resulting from the Decree- Law no. 272/95, of October 23rd - € 588,23.

8 – For each medicines manufacturing application in the cases mentioned in article 54th, Decree-Law no. 72/91, in the wording resulting from the decree-Law no. 272/95, of October 23rd - € 588,23.

9 – For each type I variation or minor variation application consisting only in the variation of the name, company, address, head-office or representation of the manufacturer or of the marketing authorisation holder, in every marketing authorisation of which the applicant is holder:

a) For an initial set of up to 10 medicines, including one strength and one pharmaceutical form - € 383,63 each;

b) In case the maximum limit mentioned in the previous paragraph is surpassed, for each additional set of 1 to 5 medicines, up to the total limit of 50 - € 204,60;

c) In case the maximum limit mentioned in the previous paragraph is surpassed, for each additional set of 1 to 5 medicines, up to the total limit of 120 - € 179,03;

d) In case the maximum limit mentioned in the previous paragraph is surpassed, for each additional set of 1 to 5 medicines, without limit of number - € 153,45.

10 – For each certificate or document with an equivalent value, regarding the registration of a medicine subject to their duties, to the marketing authorisation holder, to the manufacturer or to the wholesaler:

a) Up to four pages - € 30,69;

b) For each additional set of up to four pages - € 15,35.

11 - The price to be paid for the execution of laboratory examinations should be established by the entity that performs them, added by 20%, corresponding to the technical-administrative costs to be borne by INFARMED.

12 - For the service of scientific advice to a medicine dossier, in the clinical, non-clinical, pharmaceutical and pharmacokinetics field:

a) For the simultaneous presentation of the application regarding the four fields - € 7161,00;

b) In the remaining cases, for the presentation of the application of scientific advice regarding each one of the fields concerned - € 1918,13.

13 – For the advice in regulatory affairs, for each procedure regarding a medicine - € 797,94.

14 - For each referral made by INFARMED among marketing authorisation holders, within the scope of a mutual recognition community procedure submitted to its consideration - € 1585,65.

This Governmental Decree also states:
Reimbursement
In case of no validation of any of the applications mentioned in nos. 1 to 9 of the table in the annex to the present diploma, INFARMED will return to the applicants 90% of the taxes there indicated and retain the remaining 10 % on account of administrative expenses.

Annual updating
The values mentioned in no. 1 are updated every year, proportionally to the annual increase of the inflationary rate, that is measured through the average variation of the prices index in the consumer for the Continent, and that is published by the Statistics National Institute in December of the year before the one to which the updating concerns, being the pertaining values divulged by INFARMED.

These fees can be paid by money order or bank deposit or directly in the cashier's desk at INFARMED.
The bank account numbers are as follows:

IGCP - Instituto Gestão da Tesouraria e do Crédito Público, I.P. (ex-Direcção Geral do Tesouro)
NIB: 078101120000000624751
IBAN: PT50078101120000000624751
SWIFT CODE: IGCPPTPL
Payment form: word form or pdf form