

**SUMMARY OF FEES in accordance with Article 25 of the Royal Decree of 3 July 1969 as amended by the Royal Decree of 17 December 2008 and in accordance with the Royal Decree of 14 December 2006 and adapted to indexation**

Version 2016 -> Applicable to submissions as from Januari 1st 2016

Applicable to all medicinal products (human + veterinary) in Belgium

**Section 2: Application for registration (national + MRP<sup>(1)</sup> + DCP<sup>(6)</sup>)**

a) complete application: known active substance(s)	6163,14 Euro/MAD <sup>(2)</sup>
b) generic application and/or bibliographic application	4926,93 Euro/MAD
c) complete application: new active substance <sup>(3)</sup>	9238,01 Euro/MAD
d) traditional herbal medicinal products ( <i>not applicable for veterinary medicinal products</i> )	3079,34 Euro/MAD
e) allergens ( <i>not applicable for veterinary medicinal products</i> )	1539,68 Euro/MAD
	(to a max of 16012,54 Euro/MAH <sup>(4)</sup> if submitted at the same time)
f) orphan medicinal product ( <i>not applicable for veterinary medicinal products</i> )	4618,99 Euro/MAD

If Belgium is acting as RMS<sup>(5)</sup>

**all fees x 2**

**Section 3: Renewal (national + MRP)**

renewal	2309,50 Euro/MAD	article 25§3 second part* 1539,68 Euro + (769,84/MAD)
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If Belgium is acting as RMS

**all fees x 2**

If orphan medicinal product (*not applicable for veterinary medicinal products*)

**all fees / 4**

If medicinal product consisting of allergens (*not applicable for veterinary medicinal products*)

**all fees / 4**

#### Section 4: National variations\*

a) Type IA variations	615,87 Euro/MAD	461,89 Euro + (153,95/MAD)	<i>article 35§1 or article 170§1**</i>
(For variation type IA no A.1, A.4, A.5a and A.5b <sup>(7)</sup> no fees are required)			
Administrative variations (transfer MAH, change in distributor, switch in language)	615,87 Euro/MAD	461,89 Euro + (153,95/MAD)	
b) Type IB variations	615,87 Euro/MAD	461,89 Euro + (153,95/MAD)	
c) Type II variations: analytical			
Variations regarding the analytical part	1385,70 Euro/MAD	1231,72 Euro + (153,95/MAD)	
(to a max of 3079,34 Euro/MAD if submitted at the same time)			
Update analytical part	3079,34 Euro/MAD		
d) Type II variations: clinical			
Changes to module 4 (part III) or module 5 (part IV) without any change in the SPC or PIL	769,84 Euro/MAD	615,87 Euro + (153,95/MAD)	<i>article 35§1 or article 170§1**</i>
Changes to the SPC or PIL without a change in the sections <i>properties, indications, posology or withdrawal period(s)</i>	769,84 Euro/MAD	615,87 Euro + (153,95/MAD)	
Changes to the SPC or PIL in the sections <i>properties, indications, posology or withdrawal period(s)</i>	3079,34 Euro/MAD	2925,38 Euro + (153,95/MAD)	
Changes to legal status (eg. medical prescription / free)	1385,70 Euro/MAD		
e) Changes concerning importer or labelling	615,87 Euro/MAD	461,89 Euro + (153,95/MAD)	

If orphan medicinal product (*not applicable for veterinary medicinal products*)

**all fees / 2**

If medicinal product consisting of allergens (*not applicable for veterinary medicinal products*)

**all fees / 2**

\* For groupings, the fee of each individual variation has to be paid. More information about the fee for groupings and worksharings can be found in the document 'National FAQ on Variations' - question 6,1

#### **Section 4 bis: MRP variations\***

a) Type IA variations	461,89 Euro/MAD	article 35§1 or article 170§1** 307,95 Euro + (153,95/MAD)
(For variation type IA no A.1, A.4, A.5a and A.5b <sup>(7)</sup> no fees are required)		
b) Type IB variations	769,84 Euro/MAD	615,87 Euro + (153,95/MAD)
c) Type II variations	same as c) and d) in section 4	

If Belgium is acting as RMS

**all fees x 2**

If orphan medicinal product (*not applicable for veterinary medicinal products*)

**all fees / 2**

If medicinal product consisting of allergens (*not applicable for veterinary medicinal products*)

**all fees / 2**

\* For groupings, the fee of each individual variation has to be paid. More information about the fee for groupings and worksharings can be found in the document 'National FAQ on Variations' - question 6,1

#### **Section 5: Re-evaluation of an authorised file**

Re-evaluation of an authorised file	3079,34 Euro/MAD
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If orphan medicinal product (*not applicable for veterinary medicinal products*)

**all fees / 2**

#### **Section 6: Unit dose packaging**

Replacing an existing packaging by a unit dose packaging  
or addition of a unit dose packaging to the existing packaging

free if the conditions, mentioned in the Royal Decree of 3 July 1969 as amended, are fulfilled.

**Remarks:** <sup>(1)</sup> MRP = Mutual recognition procedure

<sup>(2)</sup> MAD = Marketing authorisation document (for each strength, primary packaging or pharmaceutical form)

<sup>(3)</sup> New active substance = active substance not yet occurring in a medicinal product authorised in Belgium

<sup>(4)</sup> MAH = Marketing authorisation holder

<sup>(5)</sup> RMS = Reference member state

<sup>(6)</sup> DCP = Decentralised Procedure

<sup>(7)</sup> Reference is made to the "Commission guideline on the details of the various categories of variations" (following Commission Regulation (EC) No 1234/2008)

[http://ec.europa.eu/health/files/betterreg/pharmacos/classification\\_guideline\\_adopded.pdf](http://ec.europa.eu/health/files/betterreg/pharmacos/classification_guideline_adopded.pdf)

*\*Article 25§3 second part of the Royal Decree of 3 July 1969: files, submitted at the same time, covering several MAD of the same MAH on condition that the contents of the file is applicable to all these MAD.*

*\*\*Article 35§1 or article 170§1 of the Royal Decree of 14 December 2008: files covering several MAD of the same MAH on condition that the contents of the file concerns one specific type of modification and is applicable to all these MAD.*

If the application could not be accepted in accordance with Article 10 part 5 or Article 150 part 5 of the Royal Decree of 14 December 2006, or if the application has been withdrawn within the terms mentioned in these articles, fees will be refunded **less 307,95 Euro**.

### **SUMMARY OF FEES in accordance with Article 13 of the Royal Decree of 19 April 2001**

#### **Section 1 1°: Application for parallel import**

New application for parallel import in accordance with <i>Article 4</i> or modification to licence for parallel import in accordance with <i>Article 7 sections 2 and 3</i>
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1987,09 Euro/licence

#### **Section 1 2°: Renewal**

Renewal of licence for parallel import in accordance with <i>Article 7 section 1</i>
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993,56 Euro/licence

#### **Section 2: Application for modification**

Application for modification of licence for parallel import, except for modifications in accordance with <i>Article 7 sections 2 and 3</i>
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662,37 Euro /licence

All fees have to be paid in advance and the proof of payment is required (in part IA / module 1) before an application can be accepted.

Fees payable on account number: 679-0021942-20  
IBAN-CODE: BE28 6790 0219 4220  
Swift code: PCHQBEBB

"The attention is drawn to the fact that the current text is merely informal, and it is by no means certain that its current wordings and provisions correspond to the eventual final text that will be publically announced in the Belgian Law Gazette. The Federal Agency for Medicines and Health Products assumes no responsibility whatsoever as to such a lack of correspondence with the final text"