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 2013 -> Applicable to submissions as from Januari 1st 2013

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

Section 2: Application for registration (national + MRP[1] + DCP[6])

a) complete application: known active substance(s)	6051,80 Euro/MAD[2]	
b) generic application and/or bibliographic application	4837,93 Euro/MAD	
c) complete application: new active substance[3]	9071,12 Euro/MAD	
d) traditional herbal medicinal products *(not applicable for veterinary medicinal products)*	3023,71 Euro/MAD	
e) allergens *(not applicable for veterinary medicinal products)*	1511,86 Euro/MAD (to a max of 15723,28 Euro/MAH[4] if submitted at the same time)	
f) orphan medicinal product *(not applicable for veterinary medicinal products)*	4535,56 Euro/MAD	

If Belgium is acting as RMS[5] **all fees x 2**

Section 3: Renewal (national + MRP)

		*article 25§3 second part**
renewal	2267,78 Euro/MAD	1511,86 Euro + (755,93/MAD)

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

		*article 35§1 or article 170§1***
a) Type IA variations	604,75 Euro/MAD	453,55 Euro + (151,18/MAD)
	(For variation type IA no A.1, A.4, A.5a and A.5b [7] no fees are required)	

Administrative variations (transfer MAH, change in distributor, switch in language)		604,75 Euro/MAD	453,55 Euro + (151,18/MAD)
b) Type IB variations		604,75 Euro/MAD	453,55 Euro + (151,18/MAD)
c) Type II variations: analytical			
	Variations regarding the analytical part	1360,67 Euro/MAD (to a max of 3023,71 Euro/MAD if submitted at the same time)	1209,47 Euro + (151,18/MAD)
	Update analytical part	3023,71 Euro/MAD	
d) Type II variations: clinical			*article 35§1 or article 170§1***
	Changes to module 4 (part III) or module 5 (part IV) without any change in the SPC or PIL	755,93 Euro/MAD	604,75 Euro + (151,18/MAD)
	Changes to the SPC or PIL without a change in the sections *properties, indications, posology* or *withdrawal period(s)*	755,93 Euro/MAD	604,75 Euro + (151,18/MAD)
	Changes to the SPC or PIL in the sections *properties, indications, posology* or *withdrawal period(s)*	3023,71 Euro/MAD	2872,53 Euro + (151,18/MAD)
	Changes to legal status (eg. medical prescription / free)	1360,67 Euro/MAD	
e) Changes concerning importer or labelling		604,75 Euro/MAD	453,55 Euro + (151,18/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**

Section 4 bis: MRP variations

			*article 35§1 or article 170§1***
a) Type IA variations		453,55 Euro/MAD (For variation type IA no A.1, A.4, A.5a and A.5b [7] no fees are required)	302,38 Euro + (151,18/MAD)
b) Type IB variations		755,93 Euro/MAD	604,75 Euro + (151,18/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**

Section 5: Re-evaluation of an authorised file

Re-evaluation of an authorised file	3023,71 Euro

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: (1) MRP = Mutual recognition procedure
(2) MAD = Marketing autorisation document (for each strength, primary packaging or pharmaceutical form)
(3) New active substance = active substance not yet occuring in a medicinal product authorised in Belgium
(4) MAH = Marketing autorisation holder
(5) RMS = Reference member state
(6) DCP = Decentralised Procedure
(7) 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_adopted.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 302,38 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 *Article 4* or modification to licence for parallel import in accordance with *Article 7 sections 2 and 3*	1951,20 Euro/licence

Section 1 2°: Renewal

Renewal of licence for parallel import in accordance with *Article 7 section 1*	975,61 Euro/licence

Section 2: Application for modification

Application for modification of licence for parallel import, except for modifications in accordance with Article 7 sections 2 and 3	650,40 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"