

## Fees 2026 - Human medicinal products

### Chapter 1 - Section 1 - Part 1 : Application for MA/registration, including line extensions (national)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	46.718,21 €	709,99 €
generic/informed consent application MAD	35.441,95 €	709,99 €
application MAD or registration herbal medicine		
1) conform monograph	27.686,82 €	709,99 €
2) non-conform monograph	46.718,21 €	709,99 €

If Belgium is acting as RMS : specific contribution (see infra).  
Contribution per submitted dossier, regardless of the number of MADs.

\* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.

### Chapter 1 - Section 1 - Part 3 : Application for MA/registration, including line extensions (DCP/MRP/RUP, BE=RMS)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	67.838,83 €	709,99 €
generic/informed consent application MAD	55.382,28 €	709,99 €
application MAD or registration herbal medicine		
1) conform monograph	37.045,27 €	709,99 €
2) non-conform monograph	67.838,83 €	709,99 €

Contribution per submitted dossier, regardless of the number of MADs.

\* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.

### Chapter 1 - Section 1 - Part 2 : Application for MA/registration, including line extensions (DCP/MRP/RUP, BE=CMS)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	15.791,45 €	709,99 €
generic/informed consent application MAD	13.887,19 €	709,99 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	13.887,19 €	709,99 €

Contribution per submitted dossier, regardless of the number of MADs.

\* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.

#### + Chapter 3

a) Delayed closing of the dossier at request of the applicant 1.083,61 €

### Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s) 1.478,75 €

### **Chapter 1 - Section 2 - Part 1 : Renewal (national)**

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Renewal	8.293,44 €	709,99 €
Renewal herbal medicine	5.482,11 €	709,99 €

If Belgium is acting as RMS : **specific contribution** (see infra).

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

### **Chapter 1 - Section 2 - Part 3 : Renewal (MRP, BE = RMS)**

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Renewal	16.665,78 €	709,99 €
Renewal herbal medicine	11.167,73 €	709,99 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

### **Chapter 1 - Section 2 - Part 2 : Renewal (MRP, BE = CMS)**

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Renewal	1.290,93 €	709,99 €
Renewal herbal medicine	1.581,11 €	709,99 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

### **+ Chapter 3**

a) Delayed closing of the dossier at request of the applicant **744,66 €**

### Chapter 1 - Section 3 - Part 1 : National variations

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a) 1) Type IA variations	691,18 €	691,18 € (+ 205,42 €/additional brand)		691,18 € for vertical grouping / 709,99 € for horizontal grouping
a) 2) Type IA variations herbal medicine	1.089,06 €	1.089,06 € (+ 205,42 €/additional brand)		709,99 €
<b>Part 4</b> administrative variations	763,17 €	763,17 € (+ 213,13 €/additional brand)		709,99 €
b) 1) Type IB variations	1.281,66 €	1.281,66 € (+ 205,42 €/additional brand)		709,99 €
b) 1) Type IB variations <b>herbal medicine</b>	2.039,91 €	2.039,91 € (+ 205,42 €/additional brand)		709,99 €
c) Type II variations: analytical				
variations regarding the analytical part ****	10.261,26 €	10.261,26 € (+ 211,84 €/additional brand)		709,99 €
variations regarding the analytical part <b>herbal medicine</b> ****	9.750,64 €	9.750,64 € (+ 211,84 €/additional brand)		709,99 €
d) Type II variations: clinical				
All clinical changes	7.010,89 €	7.010,89 € (+ 744,66 €/additional brand)		709,99 €
All clinical changes <b>herbal medicine</b>	8.122,65 €	8.122,65 € (+ 744,66 €/additional brand)		709,99 €
<b>Part 5</b> e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 34.4)	1.040,42 €		not applicable	709,99 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.  
Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

\* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

\*\* For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

\*\*\* For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

\*\*\*\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

\*\*\*\*\* In case **3 or more** separate **analytical type II files** for the same product are filed at the same moment, the price is capped to 3x the contribution related to the analytical part of a type II variation.

### Chapter 1 - Section 3 - Part 2 : MRP-variations, BE = CMS

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a) 1) Type IA variations	537,50 €	537,5 € (+ 205,42 €/additional brand)		537,5 € for vertical grouping / 709,99 € for horizontal grouping
a) 2) Type IA variations <b>herbal medicine</b>	617,92 €	617,92 € (+ 205,42 €/additional brand)		1 brand 617,92 €, ≥ 2 brands 709,99 €
b) 1) Type IB variations	851,58 €	851,58 € (+ 205,42 €/additional brand)		709,99 €
b) 2) Type IB variations <b>herbal medicine</b>	541,43 €	541,43 € (+ 205,42 €/additional brand)		1 brand 541,42 €, ≥ 2 brands 709,99 €
c) 1) Type II variations: analytical	758,55 €	758,55 € (+ 211,84 €/additional brand)		709,99 €
c) 2) Type II variations: analytical <b>herbal medicine</b>	799,20 €	799,20 € (+ 211,23 €/additional brand)		709,99 €
d) 1) Type II variations: clinical	1.718,56 €	1.718,56 € (+ 744,66 €/additional brand)		709,99 €
d) 2) Type II variations: clinical <b>herbal medicine</b>	1.943,71 €	1.943,71 € (+ 744,66 €/additional brand)		709,99 €
<b>Part 5</b> e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.040,42 €		not applicable	709,99 €

If Belgium is acting as **RMS** : **specific contribution** (see infra).

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

\* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

\*\* For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

\*\*\* For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

\*\*\*\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

## Chapter 1 - Section 3 - Part 3 : MRP-variations, BE = RMS

	*	**	***	****
a) 1) Type IA variations	1.478,27 €	1.478,27 € (+ 205,42 €/additional brand)		709,99 €
a) 2) Type IA variations <b>herbal medicine</b>	865,83 €	865,83 € (+ 205,42 €/additional brand)		709,99 €
b) 1) Type IB variations	2.919,57 €		2.919,57 € (+ 205,42 €/additional brand)	709,99 €
b) 2) Type IB variations <b>herbal medicine</b>	2.788,62 €		2.788,62 € (+ 205,42 €/additional brand)	709,99 €
c) 1) Type II variations: analytical	8.391,06 €		8.391,06 € (+ 211,84 €/additional brand)	709,99 €
c) 2) Type II variations: analytical <b>herbal medicine</b>	7.832,83 €		7.832,83 € (+ 211,84 €/additional brand)	709,99 €
d) 1) Type II variations: clinical	13.305,01 €		13.305,01 € (+ 709,99 €/additional brand)	744,66 €
d) 2) Type II variations: clinical <b>herbal medicine</b>	13.894,60 €		13.894,60 € (+ 709,99 €/additional brand)	744,66 €
<b>Part 5 e)</b> change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.978,57 €		not applicable	709,99 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

\* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

\*\* For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

\*\*\* For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

\*\*\*\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

## + Chapter 3

a) Delayed closing of the dossier at request of the MAH **744,66 €**

## Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	3.094,18 €/licence
b) Renewal licence PI (RD* article 7, §1)	2.255,86 €/licence
c) Modification licence PI ( <u>except</u> RD* article 7, §§ 2 and 3)	2.255,86 €/licence

\* **Royal Decree** relating to **parallel imports** of medicines for human use and to **parallel distribution** of medicines for human and veterinary use (19/04/2001)

## Remarks:

CMS	=	Concerned Member State
DCP	=	DeCentralised Procedure
MAD	=	Marketing Authorisation Document
MAH	=	Marketing Authorisation Holder
MRP	=	Mutual Recognition Procedure
PIL	=	Patient Information Leaflet
RMS	=	Reference Member State
RUP	=	Repeat-Use Procedure
SmPC	=	Summary of Product Characteristics

"The attention is drawn to the fact that the current text is merely **informal**, and it is by no means certain that its wordings and provisions correspond to the official **text** that is 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 official text"