

Fees 2024 - 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	44.391,83 €	674,64 €
generic/informed consent application MAD	33.677,08 €	674,64 €
application MAD or registration herbal medicine		
1) conform monograph	26.308,13 €	674,64 €
2) non-conform monograph	44.391,83 €	674,64 €

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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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	64.460,73 €	674,64 €
generic/informed consent application MAD	52.624,47 €	674,64 €
application MAD or registration herbal medicine		
1) conform monograph	35.200,57 €	674,64 €
2) non-conform monograph	64.460,73 €	674,64 €

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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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	15.005,10 €	674,64 €
generic/informed consent application MAD	13.195,67 €	674,64 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	13.195,67 €	674,64 €

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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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 1.029,65 €

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s) 1.405,11 €

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

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Renewal	7.880,46 €	674,64 €
Renewal herbal medicine	5.209,12 €	674,64 €

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	15.835,89 €	674,64 €
Renewal herbal medicine	10.611,62 €	674,64 €

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	1.226,65 €	674,64 €
Renewal herbal medicine	1.502,38 €	674,64 €

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 707,58 €

Chapter 1 - Section 3 - Part 1 : National variations

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a) 1) Type IA variations	656,77 €	656,77 € (+ 195,19 €/additional brand)		656,77 €
a) 2) Type IA variations herbal medicine	1.034,83 €	1.034,83 € (+ 195,19 €/additional brand)		674,64 €
Part 4 administrative variations	725,17 €	725,17 € (+ 202,51 €/additional brand)		674,64 €
b) 1) Type IB variations	1.217,84 €	1.217,84 (+ 195,19 €/additional brand)		674,64 €
b) 1) Type IB variations herbal medicine	1.938,33 €	1.938,33 € (+ 195,19 €/additional brand)		674,64 €
c) Type II variations: analytical				
variations regarding the analytical part *****	9.750,29 €	9.750,29 € (+ 201,29 €/additional brand)		674,64 €
variations regarding the analytical part herbal medicine *****	9.265,10 €	9.265,10 € (+ 201,29 €/additional brand)		674,64 €
d) Type II variations: clinical				
All clinical changes	6.661,78 €	6.661,78 € (+ 707,58 €/additional brand)		674,64 €
All clinical changes herbal medicine	7.718,18 €	7.718,18 € (+ 707,58 €/additional brand)		674,64 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 34.4)	988,61 €		not applicable	674,64 €

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	510,74 €	510,74 € (+ 195,19 €/additional brand)		510,74 €
a) 2) Type IA variations herbal medicine	587,15 €	587,15 € (+ 195,19 €/additional brand)	1 merk 587,15 €, ≥ 2 merken	674,64 €
b) 1) Type IB variations	809,18 €	809,18 € (+ 195,19 €/additional brand)		674,64 €
b) 2) Type IB variations herbal medicine	514,47 €	514,47 € (+ 195,19 €/additional brand)	1 merk 514,47 €, ≥ 2 merken	674,64 €
c) 1) Type II variations: analytical	720,78 €	720,78 € (+ 201,29 €/additional brand)		674,64 €
c) 2) Type II variations: analytical herbal medicine	759,40 €	759,40 € (+ 201,29 €/additional brand)		674,64 €
d) 1) Type II variations: clinical	1.632,98 €	1.632,98 € (+ 707,58 €/additional brand)		674,64 €
d) 2) Type II variations: clinical herbal medicine	1.846,92 €	1.846,92 € (+ 707,58 €/additional brand)		674,64 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	988,61 €		not applicable	674,64 €

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

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a) 1) Type IA variations	1.404,66 €	1.404,66 € (+ 195,19 €/additional brand)		674,64 €
a) 2) Type IA variations herbal medicine	822,72 €	822,72 € (+ 195,19 €/additional brand)		674,64 €
b) 1) Type IB variations	2.774,19 €	2.774,19 € (+ 195,19 €/additional brand)		674,64 €
b) 2) Type IB variations herbal medicine	2.650,85 €	2.650,85 € (+ 195,19 €/additional brand)		674,64 €
c) 1) Type II variations: analytical	7.973,22 €	7.973,22 € (+ 201,29 €/additional brand)		674,64 €
c) 2) Type II variations: analytical herbal medicine	7.442,78 €	7.442,78 € (+ 201,29 €/additional brand)		674,64 €
d) 1) Type II variations: clinical	12.642,47 €	12.642,47 € (+ 707,58 €/additional brand)		674,64 €
d) 2) Type II variations: clinical herbal medicine	13.202,70 €	13.202,70 € (+ 707,58 €/additional brand)		674,64 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.880,04 €		not applicable	674,64 €

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 707,58 €

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	2.143,53 €/licence
b) Renewal licence PI (RD* article 7, §1)	2.093,55 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	1.742,19 €/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"