

## Fees 2019 - Human medicinal products

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

|  |          | *     |
|--|----------|-------|
| full/hybrid/bibliographic/biosimilar/fixed combination application MAD | 31.855 € | 566 € |
| generic/informed consent application MAD                               | 27.725 € | 566 € |
| application MAD or registration herbal medicine                        |          |       |
| 1) conform monograph   | 24.816 € | 566 € |
| 2) non-conform monograph   | 31.855 € | 566 € |

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\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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

|  |          | *     |
|--|----------|-------|
| full/hybrid/bibliographic/biosimilar/fixed combination application MAD | 51.153 € | 566 € |
| generic/informed consent application MAD                               | 42.960 € | 566 € |
| application MAD or registration herbal medicine                        |          |       |
| 1) conform monograph   | 31.671 € | 566 € |
| 2) non-conform monograph   | 51.153 € | 566 € |

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\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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

|  |          | *     |
|--|----------|-------|
| full/hybrid/bibliographic/biosimilar/fixed combination application MAD                       | 10.838 € | 566 € |
| generic/informed consent application MAD   | 9.324 €  | 566 € |
| application MAD or registration herbal medicine<br>(regardless of conformity to a monograph) | 9.324 €  | 566 € |

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\* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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 **863 €**

### Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s) **1.027 €**

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

|                         |                | *            |
|-------------------------|----------------|--------------|
| Renewal                 | <b>5.905 €</b> | <b>566 €</b> |
| Renewal herbal medicine | <b>7.343 €</b> | <b>566 €</b> |

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)

|                         |                 | *            |
|-------------------------|-----------------|--------------|
| Renewal                 | <b>12.035 €</b> | <b>566 €</b> |
| Renewal herbal medicine | <b>12.084 €</b> | <b>566 €</b> |

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)

|                         |                | *            |
|-------------------------|----------------|--------------|
| Renewal                 | <b>1.070 €</b> | <b>566 €</b> |
| Renewal herbal medicine | <b>1.242 €</b> | <b>566 €</b> |

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

593 €

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

|  | *       | **                               | ***                                | ****                           |
|--|---------|----------------------------------|------------------------------------|--------------------------------|
| a) 1) Type IA variations   | 551 €   | 551 € (+ 163 €/additional brand) |                                    | 1 brand 551 €, ≥2 brands 566 € |
| a) 2) Type IA variations herbal medicine   | 458 €   | 458 € (+ 163 €/additional brand) |                                    | 1 brand 458 €, ≥2 brands 566 € |
| For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 551 €, respectively 458 €, is also due. |         |                                  |                                    |                                |
| <b>Part 4</b> administrative variations  | 439 €   | 439 € (+ 169 €/additional brand) |                                    | 1 brand 439 €, ≥2 brands 535 € |
| b) 1) Type IB variations   | 1.202 € |                                  | 1.202 € (+ 163 €/additional brand) | 566 €                          |
| b) 1) Type IB variations herbal medicine   | 1.128 € |                                  | 1.128 € (+ 163 €/additional brand) | 566 €                          |
| c) Type II variations: analytical  |         |                                  |                                    |                                |
| variations regarding the analytical part *****   | 7.257 € |                                  | 7.257 € (+ 168 €/additional brand) | 566 €                          |
| variations regarding the analytical part <b>herbal medicine</b> *****  | 9.201 € |                                  | 9.201 € (+ 168 €/additional brand) | 566 €                          |
| d) Type II variations: clinical  |         |                                  |                                    |                                |
| All clinical changes   | 6.896 € |                                  | 6.896 € (+ 593 €/additional brand) | 566 €                          |
| All clinical changes herbal medicine   | 7.345 € |                                  | 7.345 € (+ 593 €/additional brand) | 566 €                          |
| <b>Part 5</b> e) change(s) to the PIL and/or labelling without impact on SmPC                                    | 766 €   |                                  | not applicable                     | 566 €                          |

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

|  | *       | **                               | ***                                | ****                                    |
|--|---------|----------------------------------|------------------------------------|---|
| a) 1) Type IA variations   | 357 €   | 357 € (+ 163 €/additional brand) |                                    | 1 brand 357 €, 2 brands 520 €, ≥3 566 € |
| a) 2) Type IA variations herbal medicine   | 383 €   | 383 € (+ 163 €/additional brand) |                                    | 1 brand 383 €, 2 brands 547 €, ≥3 566 € |
| For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 357 €, respectively 388 €, is also due. |         |                                  |                                    |   |
| b) 1) Type IB variations   | 355 €   |                                  | 355 € (+ 163 €/additional brand)   | 1 brand 355 €, 2 brands 518 €, ≥3 566 € |
| b) 2) Type IB variations herbal medicine   | 313 €   |                                  | 313 € (+ 163 €/additional brand)   | 1 brand 313 €, 2 brands 476 €, ≥3 566 € |
| c) 1) Type II variations: analytical   | 528 €   |                                  | 528 € (+ 168 €/additional brand)   | 1 brand 528 €, ≥2 brands 566 €          |
| c) 2) Type II variations: analytical herbal medicine   | 954 €   |                                  | 954 € (+ 168 €/additional brand)   | 566 €                                   |
| d) 1) Type II variations: clinical   | 1.343 € |                                  | 1.343 € (+ 593 €/additional brand) | 566 €                                   |
| d) 2) Type II variations: clinical herbal medicine   | 1.649 € |                                  | 1.649 € (+ 593 €/additional brand) | 566 €                                   |
| <b>Part 5</b> e) change(s) to the PIL and/or labelling without impact on SmPC                                    | 766 €   |                                  | not applicable                     | 566 €                                   |

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  | 587 €    | 587 € (+ 163 €/additional brand) |                                     | 566 € |
| a) 2) Type IA variations herbal medicine  | 587 €    | 587 € (+ 163 €/additional brand) |                                     | 566 € |
| For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 587 € is also due. |          |                                  |                                     |       |
| b) 1) Type IB variations  | 1.830 €  |                                  | 1.830 € (+ 163 €/additional brand)  | 566 € |
| b) 2) Type IB variations herbal medicine  | 1.930 €  |                                  | 1.930 € (+ 163 €/additional brand)  | 566 € |
| c) 1) Type II variations: analytical  | 6.022 €  |                                  | 6.022 € (+ 168 €/additional brand)  | 566 € |
| c) 2) Type II variations: analytical herbal medicine  | 6.022 €  |                                  | 6.022 € (+ 168 €/additional brand)  | 566 € |
| d) 1) Type II variations: clinical  | 10.140 € |                                  | 10.140 € (+ 593 €/additional brand) | 566 € |
| d) 2) Type II variations: clinical herbal medicine  | 10.140 € |                                  | 10.140 € (+ 593 €/additional brand) | 566 € |
| <b>Part 5</b> e) change(s) to the PIL and/or labelling without impact on SmPC               | 766 €    |                                  | not applicable                      | 566 € |

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 **593 €**

### **Chapter 6 : Parallel import**

|  |                        |
|--|------------------------|
| a) New application licence PI (RD* article 4) <u>or</u><br>modification licence PI (RD* article 7, §§ 2 and 3) | <b>1.061 €/licence</b> |
| b) Renewal licence PI (RD* article 7, §1)  | <b>1.061 €/licence</b> |
| c) Modification licence PI ( <u>except</u> RD* article 7, §§ 2 and 3)  | <b>911 €/licence</b>   |

\* **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

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"