## Payments & fees FAMHP - HOMEOPATHIC MEDICINAL PRODUCTS (NATIONAL)

## Legal basis

- 1. Article 25 of the Royal Decree of 3 July 1969 as amended by the Royal Decree of 2 February 2005 and as amended by the Royal Decree of 14 December 2006 and adapted to indexation.
- 2. Article 224, 1st § of the Law of 12 August 2000 concerning social, budgetary and miscellaneous dispositions, and adapted to indexation.
- 3. Law concerning the modification of the Law of 20th July 2006 relative to the creation and functioning of the FAMHP and relative to diverse other provisions concerning the financing of the FAMHP

## Fees applicable from 1 January 2024

Application for registration / authorisation

|    |   |                                       | Non-reimbursable amount in case of invalidation or withdrawal within the legal validation period |
|----|---|---------------------------------------|--|
| a) | Homeopathic medicinal product obtained from a single stock  |                                       |  |
|    | - Article 38 or 173 (RD 14/12/2006)   | 7.746,56 €                            | 453,83 €   |
|    | - Article 41 or 176 (RD 14/12/2006)   | 7.746,56 €                            | 674,64 €   |
| b) | Homeopathic medicinal product obtained from more than one stock  - Article 38 or 173 (RD 14/12/2006)  | 16.445,56 €                           | 674,64 €   |
|    | Additional fee per stock from the sixth stock Additional fee if for a stock no previous "a)" registration or "f)" reference file has been submitted   | 200,71 €<br>4.528,37 €                | 274.046  |
|    | <ul> <li>Article 41 or 176 (RD 14/12/2006)</li> <li>Additional fee per stock from the sixth stock</li> <li>Additional fee if for a stock no previous "a)" registration or "f)" reference file has been submitted</li> </ul> | 16.445,56 €<br>200,71 €<br>4.528,37 € | 674,64 €   |
| c) | Submissions concerning a pharmaceutical form, conform art. 40 or 175 (RD 14/12/2006)  | 4.320,37 €<br>N/A                     | N/A  |
| d) | Submissions concerning a dilution type, conform art. 40 or 175 (RD 14/12/2006)  | N/A                                   | N/A  |
| e) | Submissions concerning the safety (RD 02/03/2005)   | N/A                                   | N/A  |
| f) | Reference file for stock  | 4.528,37 €                            | 453,83 €   |
| g) | Renewals and variations   | N/A                                   | N/A  |
| h) | Delayed closing of the application dossier for registration/authorisation at request of the applicant   | 1.029,65 €                            | N/A  |

## Fee on homeopathic medicinal products revenues

Homeopathic stocks and medicinal products as meant in art. 1, §1, 5) of the medicines Law of 25th March 1964 and which are legitimately on the market, including those medicinal products for which a registration or marketing authorisation was granted pursuant article 6, § 1, of the medicines Law of 25th March 1964 [I.2]

0.19323 % with minimal fee of 5.465,66 €

| Payment  |         |  |  |  |
|--|---------|--|--|--|
| These fees are payable on the Federal Agency of Medicines and Health Products account number 679-0021942-20 IBAN code: <b>BE28 6790 0219 4220</b> BIC/Swift code: PCHQBEBB |         |  |  |  |
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