

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 2016 -> Applicable to submissions as from Januari 1st 2016

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) | 6163,14 Euro/MAD ⁽²⁾ |
| b) generic application and/or bibliographic application | 4926,93 Euro/MAD |
| c) complete application: new active substance ⁽³⁾ | 9238,01 Euro/MAD |
| d) traditional herbal medicinal products (<i>not applicable for veterinary medicinal products</i>) | 3079,34 Euro/MAD |
| e) allergens (<i>not applicable for veterinary medicinal products</i>) | 1539,68 Euro/MAD |
| | (to a max of 16012,54 Euro/MAH ⁽⁴⁾ if submitted at the same time) |
| f) orphan medicinal product (<i>not applicable for veterinary medicinal products</i>) | 4618,99 Euro/MAD |

If Belgium is acting as RMS⁽⁵⁾

all fees x 2

Section 3: Renewal (national + MRP)

| | | |
|---------|------------------|--|
| renewal | 2309,50 Euro/MAD | article 25§3 second part* 1539,68 Euro + (769,84/MAD) |
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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