# Regulatory fees, applicable from the 15th of June 2012

Referring to the Norwegian legislation, ”Forskrift om legemidler” of 22. December 1999 § 15-3, the fees are being updated by the 2012.06.15

The Norwegian Medicines Agency will invoice the fee on the basis of received application. Please note that we invoice the company who submits the application, should no other receiver be stated in the cover letter. Reference, such as PO-number, must be stated in the cover letter. Payment is due at the latest within 30 days from date of invoice.

In specific cases the Norwegian medicines Agency may waive the required fee.

The figures are in Norwegian “kroner” (NOK).

| **National** | | |
|---|---|---|
| | **Human** | **Veterinary** |
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b | 415000 | 210000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 180000 | 110000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 160000 | 55000 |
| Additional formulations and strengths applied at the same time | 100000 | 50000 |
| Annex I-applications except new formulations/strengths Veterinary : except change or addition of, food producing animals [1)] | 90000 | 75000 |
| Annex I :New formulations/strengths (line extensions) Veterinary : Within the same target species [1)] | 110000 | 55000 |
| Annex I :Change or addition of,new food producing animal(s)[1)] | | 85000 |
| Variation Type IB which leads to changes in the SmPC, PL and labeling [2),3)] | 9000 | 9000 |
| Variation Type II; change in therapeutic indication [2),3),7)] Veterinary: Within the same target species | 85000 | 55000 |
| Variation Type II; change in posology [2),3),7)] Veterinary: Within the same target species | 85000 | 55000 |
| Change or addition of, new non- food producing animal(s)[1)] | | 70000 |
| Change in withdrawal periode | | 25000 |
| Variation Type II; change in legal status (prescription/non-prescription) [2),3)] | 85000 | 85000 |
| Other variation Type II [2),3)] | 13000 | 13000 |
| Other variation Type II – linguistic changes [9)] | 2000 | 2000 |
| Renewals [4)] | 45000 | 20000 |

| | | |
|---|---|---|
| | | |
| **Products for desinfection** | | |
| For health care use | 10000 | |
| For use at aquacultur sites | | 30000 |
| | | |
| **Parallell import** | | |
| Marketing Authorisation Application | 20000 | 20000 |
| Renewals,[4]) | 20000 | 20000 |
| | | |
| **Traditional herbal medicinal products** | | |
| Marketing Authorisation Applications -with monography | 25000 | |
| Marketing Athorisation Applications - without monography | 85000 | |
| Variation Type II, change in therapeutic indication [2),3),7)] | 25000 | |
| Variation Type II; change in posology [2),3),7)] | 25000 | |
| Variation Type IB which leads to changes in the SmPC, PL and labeling [2),3)] | 9000 | |
| Other variation Type II [2),3)] | 13000 | |
| Renewals [4]) | 25000 | |
| | | |
| **Natural remedies** | | |
| Marketing Authorisation Applications | 100000 | |
| | | |
| **Clinical trials (investigators initiated trials is free)** | | |
| Clinical trials Applications | 10000 | 10000 |
| Variations (Substantial amendments) | 5000 | 5000 |

| **MRP for which Norway is RMS** | | |
|---|---|---|
| | **Human** | **Veterinary** |
| Agreement on RMS-ship | 50000 | 50000 |
| Initiating MRP [8)] | 100000 | 80000 |
| Repeat use | 100000 | 80000 |
| Annex I-applications except new formulations/strengths Veterinary : except change or addition of, food producing animals [1)] | 110000 | 75000 |
| Annex I[1]) : New formulations/strengths (line extensions) Veterinary: Within the same target species | 125000 | 55000 |
| Annex I :Change or addition of,new food producing animal(s)[1)] | | 85000 |

| | | |
|---|---|---|
| Variation Type IB which leads to changes in the SmPC, PL and labelling [2)3)] | 12000 | 12000 |
| Variation type II; change in therapeutic indication [2), 3)]<br>Veterinary: Within the same target species | 90000 | 70000 |
| Variation type II; change in posology [2), 3),7)]<br>Veterinary: Within the same target species | 90000 | 70000 |
| Change or addition of, new non- food producing animal(s)[1)] | | 80000 |
| Change in withdrawal periode | | 25000 |
| Other variation Type II [2),3)] | 18000 | 18000 |
| Worksharing, change in therapeutic indication [6),7)] | 90000 | 90000 |
| Worksharing, change in posology [6),7)] | 90000 | 90000 |
| Worksharing Type IB which leads to changes in the SmPC, PL and labelling [2)3)6)] | 13000 | 13000 |
| Worksharing other variationsType II [6)] | 13000 | 13000 |
| Renewals [4)] | 45000 | 20000 |
| Marketing Authorisation Application -traditional herbal medicinal products, with monography | 85000 | |
| **Traditional herbal medicinal products** | | |
| Variation Type IB which leads to changes in the SmPC, PL and labeling [2),3)] | 9000 | |
| Variation Type II [2),3)] | 13000 | |
| Renewals [4]) | 25000 | |

**MRP where Norway is CMS**

| | **Human** | **Veterinary** |
|---|---|---|
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b | 155000 | 75000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 125000 | 55000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 110000 | 55000 |
| Additional formulations and strengths applied at the same time | 100000 | 50000 |
| Annex I-applications except new formulations/strengths<br>Veterinary : except change or addition of, food producing animals [1)] | 100000 | 50000 |
| Annex I[1]) : New formulations/strengths (line extensions)<br>Veterinary: Within the same target species | 110000 | 55000 |
| Annex I :Change or addition of new food producing animal(s)[1)] | | 60000 |
| Variation Type IB which leads to changes in the SmPC, PL and labelling | 9000 | 9000 |

| | | |
|---|---|---|
| Variation type II; change in therapeutic indication [2), 3)] Veterinary: Within the same target species | 45000 | 35000 |
| Variation type II; change in posology [2), 3),7)] Veterinary: Within the same target species | 45000 | 35000 |
| Change or addition of, new non- food producing animal(s)[1)] | | 40000 |
| Change in withdrawal periode | | 12000 |
| Other variation Type II [2),3)] | 13000 | 13000 |
| Worksharing, change in therapeutic indication [6)] | 45000 | 45000 |
| Worksharing, change in posology [6),7)] | 45000 | 45000 |
| Worksharing Type IB which leads to changes in the SmPC, PL and labelling [2)3)6)] | 13000 | 13000 |
| Worksharing other variationsType II [6)] | 13000 | 13000 |
| Renewals [4)] | 45000 | 20000 |
| Marketing Authorisation Application -traditional herbal medicinal products, with monography | 20000 | |
| **Traditional herbal medicinal products** | | |
| Variation Type IB which leads to changes in the SmPC, PL and labeling [2),3)] | 5000 | |
| Variation Type II [2),3)] | 7000 | |
| Renewals [4)] | 15000 | |

| **DCP for which Norway is RMS** | | |
|---|---|---|
| | **Human** | **Veterinary** |
| Agreement on RMS-ship | 5000( | 50000 |
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b | 370000 | 170000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 170000 | 120000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 140000 | 70000 |
| Additional formulations and strengths applied at the same time | 120000 | 50000 |
| Annex I-applications except new formulations/strengths Veterinary : except change or addition of, food producing animals [1)] | 110000 | 75000 |
| Annex I[1)] : New formulations/strengths (line extensions) Veterinary: Within the same target species | 125000 | 55000 |
| Annex I :Change or addition of,new food producing animal(s)[1)] | | 85000 |
| Change or addition of, new non- food producing animal(s)[1)] | | 80000 |
| Marketing Authorisation Application -traditional herbal | 85000 | |

| | | |
|---|---|---|
| medicinal products, with monography | | |

For variation of Marketing Authorisations – see the part covering MRP

| **DCP where Norway is CMS** | | |
|---|---|---|
| | **Human** | **Veterinary** |
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b | 210000 | 55000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 160000 | 55000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 160000 | 55000 |
| Additional formulations and strengths applied at the same time | 100000 | 50000 |
| Annex I-applications except new formulations/strengths Veterinary : except change or addition of, food producing animals [1)] | 100000 | 50000 |
| Annex I[1)] : New formulations/strengths (line extensions) Veterinary: Within the same target species | 100000 | 50000 |
| Annex I :Change or addition of new food producing animal(s)[1)] | | 60000 |
| Change or addition of, new non- food producing animal(s)[1)] | | 40000 |
| Marketing Authorisation Application -traditional herbal medicinal products, with monography | 20000 | |

For other variations see the parts covering MRP

**Please note:**

For grouped variations, according to Variation Regulation EC 1234/2008, the fee will be equal to the sum of each variation applicable for a fee.

Marketing Authorisations issued without national Product Information will also be applicable for a fee

Type IA and Type IB variations without changes to the SmPC, Patient Information Leaflet and labeling will not be charged

For products intended for MUMS (Minor Use/Minor Species) there is a 50% reduction in the fee MUMS-status must be clarified with the Norwegian Medicines Agency before submission.

| Footnotes | |
|---|---|

| | |
|---|---|
| **1)** | Annex I to Variation Regulation nr EC 1234/2008 |
| **2)** | For variation including several formulations and strengths of the same product one fee is invoiced. |
| **3)** | Variations leading to other consequential variations is invoiced as one. |
| **4)** | Applicable for each Marketing Authorisation number |
| **5)** | Applicable per procedure/agreement. Non- refundable |
| **6)** | One fee per chargeable variations (independent of the number of products included in the worksharing) |
| **7)** | Not applicable for linguistic changes, text being moved or information on limited documentation on the use in children etc. Those are other variations Type II |
| **8)** | Applicable independent of legal basis for submission |
| **9)** | Only applicable to minor variations not accompanied by any documentation. The fee is charged per part of the SmPC , e.g. If there is several linguistic changes in 4.1 , 4.1 and 5.1 – this is regarded as three linguistic variations. If no other variations is submitted the minimum fee is 5000,- |

Updated:2012.06.08