



Fees

Regulatory fees, applicable from 2010.10.01.

According to the Norwegian legislation, "Forskrift om legemidler" of 22. December 1999 § 15-3, the fees are being updated by the 2010.10. 01

Differentiated fees for products applied via the Mutual recognition Procedure (MRP), and the Decentralised procedure (DCP) are introduced.

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.

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

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).

| | RMS in DCP | |
|---|------------|------------|
| | Human | Veterinary |
| Complete dossier/well-established use/ fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b | 400000 | 200000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 200000 | 150000 |
| Generic /Informed consent, Art. 10 (1)/10c/13(1)/13c | 170000 | 100000 |
| Additional formulations and strengths applied at the same time | 120000 | 50000 |
| Annex I ¹⁾ New formulations/strengths (line extensions) | 120000 | 50000 |
| Other annex I applications ¹⁾ | 100000 | 75000 |
| Annex I for products previously approved for food producing animals | | 25000 |
| | CMS in DCP | |
| | Human | Veterinary |
| Complete dossier/well-established use/ fixed | 200000 | 50000 |

| | | |
|--|-------------------|-------------------|
| combinations, Art. 8(3)/10a/10b/12,3/13a/13b | | |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 150000 | 50000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 150000 | 50000 |
| Additional formulations and strengths applied at the same time | 100000 | 50000 |
| Annex I ¹⁾ : New formulations/strengths (line extensions) | 100000 | 50000 |
| Other annex I applications ¹⁾ | 100000 | 25000 |
| Annex I for products previously approved for food producing animals | | 25000 |
| | | |
| | RMS in MRP | |
| | Human | Veterinary |
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b | 400000 | 200000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 200000 | 150000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 170000 | 100000 |
| Additional formulations and strengths applied at the same time | 120000 | 50000 |
| Annex I ¹⁾ : New formulations/strengths (line extensions) | 120000 | 50000 |
| Other annex I applications ¹⁾ | 90000 | 65000 |
| Annex I for products previously approved for food producing animals | | 25000 |
| Variation Type IB which leads to changes in the SmPC, PL and labelling | 8000 | 8000 |
| Variation type II; change in therapeutic indication ²⁾ ³⁾ | 80000 | 80000 |
| Variation type II; change in posology ²⁾ ³⁾ | 80000 | 80000 |
| Other variation type II | 12000 | 12000 |
| Worksharing; change in therapeutic indication | 80000 | 80000 |
| Worksharing; change in posology | 80000 | 80000 |
| Worksharing Type IB | 12000 | 12000 |
| Renewals ⁴⁾ | 45000 | 20000 |
| When Norway is acting as RMS for products previously approved nationally, a fee corresponding to the difference between RMS fee and the national fee will be invoiced. | | |
| | CMS in MRP | |
| | Human | Veterinary |

| | | |
|--|--------|-------|
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b | 150000 | 50000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 120000 | 50000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 100000 | 50000 |
| Additional formulations and strengths applied at the same time | 100000 | 50000 |
| Annex I ¹⁾ : New formulations/strengths (line extensions) | 100000 | 50000 |
| Other annex I applications ¹⁾ | 100000 | 50000 |
| Annex I for products previously approved for food producing animals | | 25000 |
| Variation Type IB which leads to changes in the SmPC, PL and labelling | 8000 | 8000 |
| Variation type II; change in therapeutic indication ^{2) 3)} | 40000 | 40000 |
| Variation type II; change in posology ^{2) 3)} | 40000 | 40000 |
| Other variation type II ^{2) 3)} | 12000 | 12000 |
| Worksharing; change in therapeutic indication | 40000 | 40000 |
| Worksharing; change in posology | 40000 | 40000 |
| Worksharing Type IB | 12000 | 12000 |
| Renewals ⁴⁾ | 45000 | 20000 |

| | National | |
|--|----------|------------|
| | Human | Veterinary |
| Complete dossier/well-established use/fixed combinations, Art. 8(3)/10a/10b/12,3/13a/13b | 400000 | 200000 |
| Hybrid and biosimilar, Art. 10(3)/10(4)/13(3)/13(4) | 170000 | 100000 |
| Generic /Informed concent, Art. 10 (1)/10c/13(1)/13c | 150000 | 50000 |
| Additional formulations and strengths applied at the same time | 100000 | 50000 |
| Annex I ¹⁾ :New formulations/strengths (line extensions) | 100000 | 50000 |
| Other annex I applications ¹⁾ | 100000 | 75000 |
| Annex I for products previously approved for food producing animals | | 25000 |
| Variation Type IB which leads to changes in the SmPC, PL and labelling | 8000 | 8000 |
| Variation type II; change in therapeutic indication ^{2) 3)} | 80000 | 80000 |
| Variation type II; change in posology ^{2) 3)} | 80000 | 80000 |

| | | |
|--|-------|-------|
| Variation Type II; change in legal status (prescription/non-prescription) ^{2) 3)} | 80000 | 80000 |
| Other variation type II ^{2) 3)} | 12000 | 12000 |
| Renewals ⁴⁾ | 45000 | 20000 |
| | | |
| Radiopharmaca | 35000 | |
| Variation type II | 10000 | |
| Renewals ⁴⁾ | 35000 | |
| | | |
| Products for disinfection | | |
| For health use | 10000 | |
| For use at aquacultur sites | | 30000 |
| | | |
| Parallell import | 15000 | 15000 |
| Renewals, parallel import ⁴⁾ | 15000 | 15000 |
| | | |
| Tradisjonelle plantebaserte legemidler | | |
| - With monography | 20000 | |
| - Without monography | 30000 | |
| Reclassification from traditional herbal medicine to well established use | 30000 | |
| Renewals, all ⁴⁾ | 20000 | |
| | | |
| Clinical trials (investigators initiated trials is free) | 10000 | 10000 |
| Variations (Substantial amendments) | 5000 | 5000 |

| | |
|------------------|---|
| 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 |

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