Regulatory fees for human medicinal products valid from 1st of January 2025

Marketing authorisation application (national)	***Human***
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b	494 251
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c	185 344
Additional formulations and strengths applied at the same time	18 535
Annex I: applications except new formulations/strengths	111 206
Annex I (Line extension): new formulations and strenghts	123 564
Duplicate application (applied at the same time)	37 068
Application for registration of a traditional herbal medicinal product, with HMPC-monography	185 344
Application for registration of a traditional herbal medicinal product, without HMPC-monography (upon agreement)	247 126
Marketing authorisation application for natural remedies	247 126
Withdrawal of application before procedure start – administrative fee	24 712

Variation applications and applications for renewal (national)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	10 503
Type II variation: change in therapeutic indication [1 2 3]	92 673
Type II variation: change in legal status [1 2]	92 673
Other type II variations[1 2 4]	15 446
Renewal [5]	49 425
Traditional herbal medicinal products: type II variation – change in traditional use indication [1 2 3]	27 801
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	10 503
Traditional herbal medicinal products; other type II variations [1 2]	15 446
Traditional herbal medicinal products; renewal [5]	24 712

Parallell import (national)	***Human***
Application for marketing authorisation	19 769
Renewal [5]	6 178

MRP where Norway is the RMS

Marketing authorisation application (MRP-RMS)	***Human***
Agreement on RMS-ship [6]	61 781
Initiating MRP, regardless of legal basis [7]	123 564
Repeat use, regardless of legal basis	123 564
Annex I: applications except new formulations and strengths	111 206
Annex I (line extension): new formulations and strengths	154 453

Variation applications and applications for renewal (MRP-RMS)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	13 590
Type II variation: change in therapeutic indication [1 2 3]	92 673
Other type II variations [1 2 4]	14 828
Worksharing: change in therapeutic indication [3 8]	92 673
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	12 357
Worksharing: harmonisation of SmPC	30 890
Worksharing: other type II variations [8]	15 446
Renewal[5]	49 425
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	9 885
Traditional herbal medicinal products: type II variations [1 2]	14 828
Traditional herbal medicinal products: renewal [5]	92 673

MRP where Norway is CMS

Markering authorisation application (MRP-CMS)	***Human***
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	123 564
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	92 673
Additional formulations and strengths applied at the same time	18 535
Annex I: applications except new formulations and strengths	61 781
Annex I (Line extension): New formulations and strengths	61 781
Application for registration of a traditional herbal medicinal products, with HMPC-monography	92 673
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	123 564
Withdrawal of application before procedure start – administrative fee	24 712

Variation applications and applications for renewal (MRP-CMS)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	8 032
Type II variation: change in therapeutic indication [1 2 3]	43 247
Other type II variations [1 2 4]	12 357
Worksharing: change in therapeutic indication [3 8]	37 068
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	12 357
Worksharing: harmonisation of SmPC	24 712
Worksharing: other type II variations [8]	12 357
Renewal[5]	21 006
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	6 178
Traditional herbal medicinal products: type II variations [1 2]	8 648
Traditional herbal medicinal products: renewal [5]	6 178

DCP where Norway is the RMS

Application for marketing authorisation (DCP-RMS)	***Human***
Agreement on RMS-ship	61 781
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	432 471
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	185 344
Additional formulations and strengths applied at the same time	18 535
Annex I: applications except new formulations and strengths	135 918
Annex I (Line extension): new formulations and strengths	154 453
Application for registration of a traditional herbal medicinal products, with HMPC-monography	185 344
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	308 907

DCP where Norway is CMS

Application for marketing authorisation (DCP-CMS)	***Human***
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	123 564
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	92 673
Additional formulations and strengths applied at the same time	18 535
Duplicate application (applied at the same time)	37 068
Annex I: applications except new formulations/strengths	61 781
Annex I (Line extension): new formulations/strengths	61 781
Application for registration of a traditional herbal medicinal products, with HMPC-monography	92 673
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	123 564
Withdrawal of application before procedure start – administrative fee	24 712

Homeopathic medicinal products	***Human***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	24 383
Type II variation	1 235
Renewal	1 235

Clinical studies	***Human***
New application – Norway as reference member state (Regulation nr. 536/2014)	75 857
New application – Norway as concerned member state (Regulation nr. 536/2014)	32 510
Variations (Directiv EC 2001/20 og Regulation nr. 536/2014)	6 502
Safety assessments – Norway as reference member state	4 335
Safety assessments – Norway as concerned member state	2 167

Applications for WHO-certificates	***Human***
WHO-certificate	6 033

Note

1 For variations including several formulations and strengths of the same product, one fee is invoiced

2 Variations leading to other consequential variations are invoiced as one.

3 Not applicable for linguistic changes, moving of text or information on limited documentation on the use in children etc. Theese are other type II variations

4 Applicable for posology changes

5 Applicable for each Marketing Authorisation

6 Applicable per procedure/agreement. Non refundable

7 Applicable independent of legal basis for the submission

8 One fee per variation applicable for a fee (independent of the number of products included in the worksharing)

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