Regulatory fees for human medicinal products valid from 1st of January 2026

Marketing authorisation application (national)	***Human***
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b	512 044
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c	192 016
Additional formulations and strengths applied at the same time	19 202
Annex I: applications except new formulations/strengths	115 209
Annex I (Line extension): new formulations and strenghts	128 012
Duplicate application (applied at the same time)	38 402
Application for registration of a traditional herbal medicinal product, with HMPC-monography	192 016
Application for registration of a traditional herbal medicinal product, without HMPC-monography (upon agreement)	256 023
Marketing authorisation application for natural remedies	256 023
Withdrawal of application before procedure start – administrative fee	25 602

Variation applications and applications for renewal (national)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	10 881
Type II variation: change in therapeutic indication [1 2 3]	96 009
Type II variation: change in legal status [1 2]	96 009
Other type II variations[1 2 4]	16 002
Renewal [5]	51 204
Traditional herbal medicinal products: type II variation – change in traditional use indication [1 2 3]	28 802
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	10 881
Traditional herbal medicinal products; other type II variations [1 2]	16 002
Traditional herbal medicinal products; renewal [5]	25 602

Parallell import (national)	***Human***
Application for marketing authorisation	20 481
Renewal [5]	6 400

MRP where Norway is the RMS

Marketing authorisation application (MRP-RMS)	***Human***
Agreement on RMS-ship [6]	64 005
Initiating MRP, regardless of legal basis [7]	128 012
Repeat use, regardless of legal basis	128 012
Annex I: applications except new formulations and strengths	115 209
Annex I (line extension): new formulations and strengths	160 013

Variation applications and applications for renewal (MRP-RMS)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	14 079
Type II variation: change in therapeutic indication [1 2 3]	96 009
Other type II variations [1 2 4]	15 362
Worksharing: change in therapeutic indication [3 8]	96 009
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	12 802
Worksharing: harmonisation of SmPC	32 002
Worksharing: other type II variations [8]	16 002
Renewal[5]	51 204
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	10 241
Traditional herbal medicinal products: type II variations [1 2]	15 362
Traditional herbal medicinal products: renewal [5]	25 602

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.	128 012
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	96 009
Additional formulations and strengths applied at the same time	19 202
Annex I: applications except new formulations and strengths	64 005
Annex I (Line extension): New formulations and strengths	64 005
Application for registration of a traditional herbal medicinal products, with HMPC-monography	96 009
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	128 012
Withdrawal of application before procedure start – administrative fee	25 602

Variation applications and applications for renewal (MRP-CMS)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	8 321
Type II variation: change in therapeutic indication [1 2 3]	44 804
Other type II variations [1 2 4]	12 802
Worksharing: change in therapeutic indication [3 8]	38 402
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	12 802
Worksharing: harmonisation of SmPC	25 602
Worksharing: other type II variations [8]	12 802
Renewal[5]	21 762
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	6 400
Traditional herbal medicinal products: type II variations [1 2]	8 959
Traditional herbal medicinal products: renewal [5]	6 400

DCP where Norway is the RMS

Application for marketing authorisation (DCP-RMS)	***Human***
Agreement on RMS-ship	64 005
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	448 040
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	192 016
Additional formulations and strengths applied at the same time	19 202
Annex I: applications except new formulations and strengths	140 811
Annex I (Line extension): new formulations and strengths	160 013
Application for registration of a traditional herbal medicinal products, with HMPC-monography	192 016
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	320 028

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.	128 012
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	96 009
Additional formulations and strengths applied at the same time	19 202
Duplicate application (applied at the same time)	38 402
Annex I: applications except new formulations/strengths	64 005
Annex I (Line extension): new formulations/strengths	64 005
Application for registration of a traditional herbal medicinal products, with HMPC-monography	96 009
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	128 012
Withdrawal of application before procedure start – administrative fee	25 602

Homeopathic medicinal products	***Human***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	25 261
Type II variation	1 279
Renewal	1 279

Clinical studies	***Human***
New application – Norway as reference member state (Regulation nr. 536/2014)	78 588
New application – Norway as concerned member state (Regulation nr. 536/2014)	33 680
Variations (Directiv EC 2001/20 og Regulation nr. 536/2014)	6 736
Safety assessments – Norway as reference member state	4 491
Safety assessments – Norway as concerned member state	2 245

Applications for WHO-certificates	***Human***
WHO-certificate	6 250

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. Nonrefundable

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