Regulatory fee for human medicinal products valid from 1st of January 2024

Marketing authorisation application (national)	***Human***
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b	476 157
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c	178 558
Additional formulations and strengths applied at the same time	17 857
Annex I: applications except new formulations/strengths	107 135
Annex I (Line extension): new formulations and strenghts	119 040
Duplicate application (applied at the same time)	35 711
Application for registration of a traditional herbal medicinal product, with HMPC-monography	178 558
Application for registration of a traditional herbal medicinal product, without HMPC-monography (upon agreement)	238 079
Marketing authorisation application for natural remedies	238 079
Withdrawal of application before procedure start – administrative fee	23 807

Variation applications and applications for renewal (national)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [2]	10 118
Type II variation: change in therapeutic indication [1 2 3]	89 281
Type II variation: change in legal status [1 2]	89 281
Other type II variations[1 2 4]	14 880
Renewal [5]	47 616
Traditional herbal medicinal products: type II variation – change in traditional use indication [1 2 3]	26 783
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	10 118
Traditional herbal medicinal products; other type II variations [1 2]	14 880
Traditional herbal medicinal products; renewal [5]	23 807

Parallell import (national)	***Human***
Application for marketing authorisation	19 046
Renewal [5]	5 952

MRP where Norway is the RMS

Marketing authorisation application (MRP-RMS)	***Human***
Agreement on RMS-ship [6]	59 519
Initiating MRP, regardless of legal basis [7]	119 040
Repeat use, regardless of legal basis	119 040
Annex I: applications except new formulations and strengths	107 135
Annex I (line extension): new formulations and strengths	148 798

Variation applications and applications for renewal (MRP-RMS)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	13 093
Type II variation: change in therapeutic indication [2 3]	89 281
Other type II variations [1 2 4]	14 285
Worksharing: change in therapeutic indication [3 8]	89 281
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	11 905
Worksharing: harmonisation of SmPC	29 759
Worksharing: other type II variations [8]	14 880
Renewal[5]	47 616
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	9 523
Traditional herbal medicinal products: type II variations [1 2]	14 285
Traditional herbal medicinal products: renewal [5]	23 807

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.	119 040
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	89 281
Additional formulations and strengths applied at the same time	17 857
Annex I: applications except new formulations and strengths	59 519
Annex I (Line extension): New formulations and strengths	59 519
Application for registration of a traditional herbal medicinal products, with HMPC-monography	89 281
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	119 040
Withdrawal of application before procedure start – administrative fee	23 807

Endringssøknader og søknad om fornyelser (MRP-CMS)	***Human***
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	7 738
Type II variation: change in therapeutic indication [2 3]	41 664
Other type II variations [1 2 4]	11 905
Worksharing: change in therapeutic indication [3 8]	35 711
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	11 905
Worksharing: harmonisation of SmPC	23 807
Worksharing: other type II variations [8]	11 905
Renewal[5]	20 237
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	5 952
Traditional herbal medicinal products: type II variations [1 2]	8 331
Traditional herbal medicinal products: renewal [5]	5 952

DCP where Norway is the RMS

Application for marketing authorisation (DCP-RMS)	***Human***
Agreement on RMS-ship	59 519
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	416 638
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	178 558
Additional formulations and strengths applied at the same time	17 857
Annex I: applications except new formulations and strengths	130 943
Annex I (Line extension): new formulations and strengths	148 798
Application for registration of a traditional herbal medicinal products, with HMPC-monography	178 558
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	297 598

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.	119 040
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	89 281
Additional formulations and strengths applied at the same time	17 857
Duplicate application (applied at the same time)	35 711
Annex I: applications except new formulations/strengths	59 519
Annex I (Line extension): new formulations/strengths	59 519
Application for registration of a traditional herbal medicinal products, with HMPC-monography	89 281
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	119 040
Withdrawal of application before procedure start – administrative fee	23 807

Homeopathic medicinal products	***Human***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	23 490
Type II variation	1 190
Renewal	1 190

Clinical studies	***Human***
New application (Directive EC 2001/20)	11 624
New application – Norway as reference member state (Regulation nr. 536/2014)	73 080
New application – Norway as concerned member state (Regulation nr. 536/2014)	31 320
Variations (Directiv EC 2001/20 og Regulation nr. 536/2014)	6 264
Safety assessments – Norway as reference member state	4 176
Safety assessments – Norway as concerned member state	2 088

Applications for WHO-certificates	***Human***
WHO-certificate	5 812

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 Applicable independent of legal basis for the submission