Regulatory fee for human medicinal products valid from 1st of January 2023

National

Marketing authorisation application (national)

	Human
Complete dossier/well established use (WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b	456 089
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c	171 033
Additional formulations and strengths applied at the same time	17 104
Annex I: applications except new formulations/strengths	102 620
Annex I (Line extension): new formulations and strengths	114 023
Duplicate application (applied at the same time)	34 206
Application for registration of a traditional herbal medicinal product, with HMPC-monography	171 033
Application for registration of a traditional herbal medicinal product, without HMPC-monography (upon agreement)	228 045
Marketing authorisation application for natural remedies	228 045
Withdrawal of application before procedure start – administrative fee	22 804

Variation applications and applications for renewal (national)

	Human
Type IB variation which leads to changes in the SmPC, PL and labeling [2]	9 692
Type II variation: change in therapeutic indication [1 2 3]	85 518
Type II variation: change in legal status [1 2]	85 518
Other type II variations[1 2 4]	14 253
Renewal [5]	45 609
Traditional herbal medicinal products: type II variation – change in traditional use indication [1 2 3]	25 654
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	9 692
Traditional herbal medicinal products: other type II variations [1 2]	14 253
Traditional herbal medicinal products: renewal [5]	22 804

Parallell import (national)

	Human
Application for marketing authorisation	18 243
Renewal [5]	5 701

MRP - Norway as the RMS

Marketing authorisation application (MRP-RMS)

	Human
Agreement on RMS-ship [6]	57 011
Initiating MRP, regardless of legal basis [7]	114 023
Repeat use, regardless of legal basis	114 023
Annex I: applications except new formulations and strengths	102 620
Annex I (line extension): new formulations and strengths	142 527

Variation applications and applications for renewal (MRP-RMS)

	Human
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	12 541
Type II variation: change in therapeutic indication [2 3]	85 518
Other type II variations [1 2 4]	13 683
Worksharing: change in therapeutic indication [3 8]	85 518
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	11 403
Worksharing: harmonisation of SmPC	28 505
Worksharing: other type II variations [8]	14 253
Renewal[5]	45 609
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	9 122
Traditional herbal medicinal products: type II variations [1 2]	13 683
Traditional herbal medicinal products: renewal [5]	22 804

MRP - Norway as CMS

Markering authorisation application (MRP-CMS)

	Human
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	114 023
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	85 518
Additional formulations and strengths applied at the same time	17 104
Annex I: applications except new formulations and strengths	57 011
Annex I (Line extension): New formulations and strengths	57 011
Application for registration of a traditional herbal medicinal products, with HMPC-monography	85 518
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	114 023
Withdrawal of application before procedure start – administrative fee	22 804

Variation applications and applications for renewal (MRP-CMS)

	Human
Type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	7 412
Type II variation: change in therapeutic indication [2 3]	39 908
Other type II variations [1 2 4]	11 403
Worksharing: change in therapeutic indication [3 8]	34 206
Worksharing: type IB variation which leads to changes in the SmPC, PL and labeling [1 2 8]	11 403
Worksharing: harmonisation of SmPC	22 804
Worksharing: other type II variations [8]	11 403
Renewal[5]	19 384
Traditional herbal medicinal products: type IB variation which leads to changes in the SmPC, PL and labeling [1 2]	5 701
Traditional herbal medicinal products: type II variations [1 2]	7 980
Traditional herbal medicinal products: renewal [5]	5 701

DCP - Norway as the RMS

Application for marketing authorisation (DCP-RMS)

	Human
Agreement on RMS-ship	57 011
Complete dossier/well established use(WEU)/fixed combinations, Directive 2001/83/EF art. 8(3), 10a, 10b.	399 079
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	171 033
Additional formulations and strengths applied at the same time	17 104
Annex I: applications except new formulations and strengths	125 424
Annex I (Line extension): new formulations and strengths	142 527
Application for registration of a traditional herbal medicinal products, with HMPC-monography	171 033
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	285 056

DCP - Norway as 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.	114 023
Hybrid/Generic/Biosimilar/Informed consent, Directive 2001/83/EF art. 10(1), 10(3), 10(4), 10c.	85 518
Additional formulations and strengths applied at the same time	17 104
Duplicate application (applied at the same time)	34 206
Annex I: applications except new formulations/strengths	57 011
Annex I (Line extension): new formulations/strengths	57 011
Application for registration of a traditional herbal medicinal products, with HMPC-monography	85 518
Application for registration of a traditional herbal medicinal products, without HMPC-monography (upon agreement)	114 023
Withdrawal of application before procedure start – administrative fee	22 804

Homeopathic medicinal products

	Human
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	22 500
Type II variation	1 140
Renewal	1 140

Clinical studies

	Human
New application (Directive EC 2001/20)	11 134
New application – Norway as reference member state (Regulation nr. 536/2014)	70 000
New application – Norway as concerned member state (Regulation nr. 536/2014)	30 000
Variations (Directiv EC 2001/20 and Regulation nr. 536/2014)	6 000
Safety assessments – Norway as reference member state	4 000
Safety assessments – Norway as concerned member state	2 000

Applications for WHO-certificates

	Human
WHO-certificate	5 567

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 for each invoiceable variation (independent of the number of products included in the worksharing procedure)