

Regulatory fees for human medicinal products valid from 01.01.2024-31.12.2024

<i>Marketing authorisation application (national)</i>	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

<i>Variation applications and applications for renewal (national)</i>	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

<i>Parallell import (national)</i>	Human
Application for marketing authorisation	19 046
Renewal ⁵	5 952

MRP where Norway is the RMS

<i>Marketing authorisation application (MRP-RMS)</i>	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

<i>Variation applications and applications for renewal (MRP-RMS)</i>	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

<i>Marketing authorisation application (MRP-CMS)</i>	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

<i>Endringssøknader og søknad om fornyelser (MRP-CMS)</i>	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

<i>Application for marketing authorisation (DCP-RMS)</i>	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

<i>Application for marketing authorisation (DCP-CMS)</i>	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

<i>Homeopathic medicinal products</i>	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

<i>Clinical studies</i>	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

<i>Applications for WHO-certificates</i>	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. These 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