

Regulatory fees

Applicable from 01.01.2020

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1. National

1.1 Marketing Authorisation application (national)

	Human	Veterinary
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b.	422 707	422 707
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	158 515	158 515

Additional formulations and strengths applied at the same time - Veterinary: within the same target species	15 852	15 852
Additional formulations and strengths applied at the same time - different target specie(s)		158515
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	95 109	79 258
Annex I (Line extension): New formulations/strengths - Veterinary: within the same target specie(s) ¹	105 677	105 677
Annex I: Change or addition of new food producing specie(s) ¹		105 677
Duplicate application (applied at the same time)	31 703	31 703
Application for registration of a traditional herbal medicinal products, with HMPC-monography	158 515	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	211 354	
Marketing Authorisation application for natural remedies	211 354	
Withdrawal of application before start of procedure – administrative fee	21 135	21 135

1.2 Variation applications and application for renewal (national)

	Human	Veterinary
Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	8 983	8 983
Type II variation; change in therapeutic indication ^{2 3 4} - Veterinary: within the same target species	79 258	79 258
Type II variation - change or addition of new non-food producing specie(s)		79 258
Change in withdrawal period		21 135
Type II variation; change in legal status (prescription/non-prescription) ^{2 3}	79 258	79 258
Other type II variation ^{2 3 5}	13 210	13 210

Renewal ⁶	42 271	42 271
Traditional herbal medicinal products; type II variation – change in traditional use indication ²³⁴	23 777	
Traditional herbal medicinal products; type IB variation which leads to changes in the SmPC, PL and labeling ²³	8 983	
Traditional herbal medicinal products; other type II variations ²³	13 210	
Traditional herbal medicinal products; renewal ⁶	21 135	

1.3 Parallell import (National)

	Human	Veterinary
Application for marketing authorisation	16 908	16 908
Renewal ⁶	5 284	5 284

2 MRP for which Norway is RMS

2.1 Marketing Authorisation application (MRP-RMS)

	Human	Veterinary
Agreement on RMS-ship ⁷	52 838	52 838
Initiating MRP, regardless of legal basis ⁸	105 677	105 677
Repeat use, regardless of legal basis	105 677	105 677
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	95 109	79 258
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species ¹	132 096	132 096
Annex I: change or addition of new food producing specie(s) ¹		105 677

2.2 Variation applications and application for renewal (MRP-RMS)

	Human	Veterinary
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Type IB variation which leads to changes in the SmPC, PL and labeling ²³	11 624	11 624
Type II variation; change in therapeutic indication ²³⁴ - Veterinary: within the same target species	79 258	79 258
Type II variation - change or addition of new non-food producing specie(s)		84 541
Change in withdrawal period		26 419
Other type II variation ²³⁵	12 681	12 681
Worksharing; change in therapeutic indication ^{4 9}	79 258	79 258
Worksharing; Type IB variation which leads to changes in the SmPC, PL and labeling ²³⁹	10 568	10 568
Worksharing; harmonisation of SmPC	26 419	26 419
Worksharing; other type II variation ⁹	13 210	13 210
Renewal ⁶	42 271	42 271
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling ²³	8 454	
Traditional herbal medicinal products; type II variations ²³	12 681	
Traditional herbal medicinal products; renewal ⁶	21 135	

3 MRP for which Norway is CMS

3.1 Marketing Authorisation application (MRP-CMS)

	Human	Veterinary
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b	105 677	105 677
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	79 258	79 258

Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	15 852	15 852
Additional formulations and strengths applied at the same time - different target specie(s)		89 825
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(ls) ¹	52 838	52 838
Annex I: New formulations/strengths(line extension) - Veterinary: within the same target specie(s) ¹	52 838	52 838
Annex I: Change or addition of new food producing specie(s) ¹		31 703
Application for registration of a traditional herbal medicinal products, with HMPC-monography	79 258	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	105 677	
Withdrawal of application before start of procedure – administrative fee	21 135	21 135

3.2 Variation applications and application for renewal (MRP-CMS)

	Human	Veterinary
Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	6 869	6 869
Type II variation; change in therapeutic indication ^{2 3 4} - Veterinary: within the same target specie(s)	36 987	36 987
Type II variation - change or addition of new non-food producing specie(s)		26 419
Change in withdrawal period		7 609
Other type II variation ^{2 3 5}	10 568	10 568
Worksharing; change in therapeutic indication ⁹	31 703	31 703
Worksharing; type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3 9}	10 568	10 568
Worksharing; harmonisation of SmPC	21 135	21 135

Worksharing; other type II variations ⁹	10 568	10 568
Renewal ⁶	17 965	17 965
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	5 284	
Traditional herbal medicinal products; type II variations ^{2 3}	7 397	
Traditional herbal medicinal products; renewal ⁶	5 284	

4 DCP for which Norway is RMS

4.1 Marketing Authorisation application (DCP-RMS)

	Human	Veterinary
Agreement on RMS-ship ⁷	52 838	52 838
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b	369 869	369 869
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	158 515	158 515
Additional formulations and strengths applied at the same time - Veterinary: within the same target species	15 852	15 852
Additional formulations and strengths applied at the same time - different target specie(s)		79 258
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	116 244	116 244
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species ¹	132 096	132 096
Annex I: Change or addition of new food producing specie(s) ¹		89 825
Application for registration of a traditional herbal medicinal products, with HMPC-monography	158 515	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	264 192	

5 DCP for which Norway is CMS

5.1 Marketing Authorisation application (DCP-CMS)

	Human	Veterinary
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b	105 677	105 677
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	79 258	79 258
Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	15 852	15 852
Additional formulations and strengths applied at the same time - different target specie(s)		79 258
Duplicate application (applied at the same time)	31 703	31 703
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	52 838	52 838
Annex I (line extension): New formulations/strengths - Veterinary: within the same target specie(s) ¹	52 838	52 838
Annex I: Change or addition of new food producing specie(s) ¹		47 555
Application for registration of a traditional herbal medicinal products, with HMPC-monography	79 258	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	105 677	
Withdrawal of application before start of procedure– administrative fee	21 135	21 135

6 Homeopathic medicinal products

	Human	Veterinary
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product.	1 057	1 057
Type II variation	1 057	1 057
Renewal	1 057	1 057

7 Clinical study

	Human	Veterinær
Kliniske utprøvinger - Ny studie	10 320	10 320
Kliniske utprøvinger - Endringer (Substensial amendments)	5 160	5 160

8 Application – WHO-certificates

WHO-sertifikat	5 160
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9 Footnotes

¹Annex I to Variation Regulation nr EC 1234/2008

²For variations including several formulations and strengths of the same product one fee is invoiced

³ Variations leading to other consequential variations is invoiced as one

⁴ Not applicable for linguistic changes, moving of text or information on limited documentation on the use in children etc. Those are other type II variations

⁵Applicable for change in posology

⁶ Applicable for each Marketing Authorisation number

⁷Applicable per procedure/agreement. Non refundable

⁸ Applicable independent of legal basis for submission

⁹ 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
- For products intended for MUMS (Minor Use/Minor Species) there is a 50% reduction in the fee
MUMS-status must be clarified with the Norwegian Medicines Agency before submission.