

Regulatory fees

Applicable from 01.01.2021

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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.	433 697	433 697
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	162 636	162 636

Additional formulations and strengths applied at the same time - Veterinary: within the same target species	16 264	16 264
Additional formulations and strengths applied at the same time - different target specie(s)		162 636
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	97 582	81 319
Annex I (Line extension): New formulations/strengths - Veterinary: within the same target specie(s) ¹	108 425	108 425
Annex I: Change or addition of new food producing specie(s) ¹		108 425
Duplicate application (applied at the same time)	32 527	32 527
Application for registration of a traditional herbal medicinal products, with HMPC-monography	162 636	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	216 849	
Marketing Authorisation application for natural remedies	216 849	
Withdrawal of application before start of procedure – administrative fee	21 685	21 685

1.2 Variation applications and application for renewal (national)

	Human	Veterinary
Type IB variation which leads to changes in the SmPC, PL and labeling ²³	9 217	9 217
Type II variation; change in therapeutic indication ²³⁴ - Veterinary: within the same target species	81 319	81 319
Type II variation - change or addition of new non-food producing specie(s)		81 319
Change in withdrawal period		21 685
Type II variation; change in legal status (prescription/non-prescription) ²³	81 319	81 319
Other type II variation ²³⁵	13 553	13 553

Renewal ⁶	43 370	43 370
Traditional herbal medicinal products; type II variation – change in traditional use indication ^{2 3 4}	24 395	
Traditional herbal medicinal products; type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	9 217	
Traditional herbal medicinal products; other type II variations ^{2 3}	13 553	
Traditional herbal medicinal products; renewal ⁶	21 685	

1.3 Parallell import (National)

	Human	Veterinary
Application for marketing authorisation	17 348	17 348
Renewal ⁶	5 421	5 421

2 MRP for which Norway is RMS

2.1 Marketing Authorisation application (MRP-RMS)

	Human	Veterinary
Agreement on RMS-ship ⁷	54 212	54 212
Initiating MRP, regardless of legal basis ⁸	108 425	108 425
Repeat use, regardless of legal basis	108 425	108 425
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	97 582	81 319
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species ¹	135 530	135 530
Annex I: change or addition of new food producing specie(s) ¹		108 425

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

	Human	Veterinary
Type IB variation which leads to changes in the SmPC, PL and labeling ²³	11 926	11 926
Type II variation; change in therapeutic indication ²³⁴ - Veterinary: within the same target species	81 319	81 319
Type II variation - change or addition of new non-food producing specie(s)		86 739
Change in withdrawal period		27 106
Other type II variation ²³⁵	13 011	13 011
Worksharing; change in therapeutic indication ⁴⁹	81 319	81 319
Worksharing; Type IB variation which leads to changes in the SmPC, PL and labeling ²³⁹	10 843	10 843
Worksharing; harmonisation of SmPC	27 106	27 106
Worksharing; other type II variation ⁹	13 553	13 553
Renewal ⁶	43 370	43 370
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling ²³	8 674	
Traditional herbal medicinal products; type II variations ²³	13 011	
Traditional herbal medicinal products; renewal ⁶	21 685	

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	108 425	108 425
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	81 319	81 319

Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	16 264	16 264
Additional formulations and strengths applied at the same time - different target specie(s)		92 160
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	54 212	54 212
Annex I: New formulations/strengths(line extension) - Veterinary: within the same target specie(s) ¹	54 212	54 212
Annex I: Change or addition of new food producing specie(s) ¹		32 527
Application for registration of a traditional herbal medicinal products, with HMPC-monography	81 319	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	108 425	
Withdrawal of application before start of procedure – administrative fee	21 685	21 685

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}	7 048	7 048
Type II variation; change in therapeutic indication ^{2,3,4} - Veterinary: within the same target specie(s)	37 949	37 949
Type II variation - change or addition of new non-food producing specie(s)		27 106
Change in withdrawal period		7 807
Other type II variation ^{2,3,5}	10 843	10 843
Worksharing; change in therapeutic indication ⁹	32 527	32 527
Worksharing; type IB variation which leads to changes in the SmPC, PL and labeling ^{2,3,9}	10 843	10 843
Worksharing; harmonisation of SmPC	21 685	21 685

Worksharing; other type II variations ⁹	10 843	10 843
Renewal ⁶	18 432	18 432
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	5 421	
Traditional herbal medicinal products; type II variations ^{2 3}	7589	
Traditional herbal medicinal products; renewal ⁶	5 421	

4 DCP for which Norway is RMS

4.1 Marketing Authorisation application (DCP-RMS)

	Human	Veterinary
Agreement on RMS-ship ⁷	54 212	54 212
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b	379 486	379 486
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	162 636	162 636
Additional formulations and strengths applied at the same time - Veterinary: within the same target species	16 264	16 264
Additional formulations and strengths applied at the same time - different target specie(s)		81 319
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	119 266	119 266
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species ¹	135 530	135 530
Annex I: Change or addition of new food producing specie(s) ¹		92 160
Application for registration of a traditional herbal medicinal products, with HMPC-monography	162 636	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	271 061	

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	108 425	108 425
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	81 319	81 319
Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	16 264	16 264
Additional formulations and strengths applied at the same time - different target specie(s)		81 319
Duplicate application (applied at the same time)	32 527	32 527
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	54 212	54 212
Annex I (line extension): New formulations/strengths - Veterinary: within the same target specie(s) ¹	54 212	54 212
Annex I: Change or addition of new food producing specie(s) ¹		48 791
Application for registration of a traditional herbal medicinal products, with HMPC-monography	81 319	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	108 425	
Withdrawal of application before start of procedure– administrative fee	21 685	21 685

6 Homeopathic medicinal products

	Human	Veterinary
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product.	1 084	1 084
Type II variation	1 084	1 084
Renewal	1 084	1 084

7 Clinical study

	Human	Veterinær
Kliniske utprøvinger - Ny studie	10 588	10 588
Kliniske utprøvinger - Endringer (Substensial amendments)	5 294	5 294

8 Application – WHO-certificates

WHO-sertifikat	5 294
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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

³Variations leading to other consequential variations is invoiced as one

⁴Not 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 ⁸Applicable independent of legal basis for submission

⁹One 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.