

Regulatory fees

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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.	409 600	409 600
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	153 600	153 600
Additional formulations and strengths applied at the same time - Veterinary: within the same target species	15 360	15 360
Additional formulations and strengths applied at the same time - different target specie(s)		153 600

Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	92 160	76 800
Annex I (Line extension): New formulations/strengths - Veterinary: within the same target specie(s) ¹	102 400	102 400
Annex I: Change or addition of new food producing specie(s) ¹		102 400
Duplicate application (applied at the same time)	30 720	30 720
Application for registration of a traditional herbal medicinal products, with HMPC-monography	153 600	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	204 800	
Marketing Authorisation application for natural remedies	204 800	
Withdrawal of application before start of procedure – administrative fee	20 480	20 480

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}	8 704	8 704
Type II variation; change in therapeutic indication ^{2 3 4} - Veterinary: within the same target species	76 800	76 800
Type II variation - change or addition of new non-food producing specie(s)		76 800
Change in withdrawal period		20 480
Type II variation; change in legal status (prescription/non-prescription) ^{2 3}	76 800	76 800
Other type II variation ^{2 3 5}	12 800	12 800
Renewal ⁶	40 960	40 960
Traditional herbal medicinal products; type II variation – change in traditional use indication ^{2 3 4}	23 040	

Traditional herbal medicinal products; type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	8 704	
Traditional herbal medicinal products; other type II variations ^{2 3}	12 800	
Traditional herbal medicinal products; renewal ⁶	20 480	

1.3 Parallell import (National)

	Human	Veterinary
Application for marketing authorisation	16 384	16 384
Renewal ⁶	5 120	5 120

2 MRP for which Norway is RMS

2.1 Marketing Authorisation application (MRP-RMS)

	Human	Veterinary
Agreement on RMS-ship ⁷	51 200	51 200
Initiating MRP, regardless of legal basis ⁸	102 400	102 400
Repeat use, regardless of legal basis	102 400	102 400
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	92 160	76 800
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species ¹	128 000	128 000
Annex I: change or addition of new food producing specie(s) ¹		102 400

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 ^{2 3}	11 264	11 264
Type II variation; change in therapeutic indication ^{2 3 4} - Veterinary: within the same target species	76 800	76 800

Type II variation - change or addition of new non-food producing specie(s)		81 920
Change in withdrawal period		25 600
Other type II variation ^{2 3 5}	12 288	12 288
Worksharing; change in therapeutic indication ^{4 9}	76 800	76 800
Worksharing; Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3 9}	10 240	10 240
Worksharing; harmonisation of SmPC	25 600	25 600
Worksharing; other type II variation ⁹	12 800	12 800
Renewal ⁶	40 960	40 960
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	8 192	
Traditional herbal medicinal products; type II variations ^{2 3}	12 288	
Traditional herbal medicinal products; renewal ⁶	20 480	

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	102 400	102 400
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	76 800	76 800
Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	15 360	15 360
Additional formulations and strengths applied at the same time - different target specie(s)		87 040

Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	51 200	51 200
Annex I: New formulations/strengths(line extension) - Veterinary: within the same target specie(s) ¹	51 200	51 200
Annex I: Change or addition of new food producing specie(s) ¹		30 720
Application for registration of a traditional herbal medicinal products, with HMPC-monography	76 800	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	102 400	
Withdrawal of application before start of procedure – administrative fee	20 480	20 480

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}	6 656	6 656
Type II variation; change in therapeutic indication ^{2 3 4} - Veterinary: within the same target specie(s)	35 840	35 840
Type II variation - change or addition of new non-food producing specie(s)		25 600
Change in withdrawal period		7 373
Other type II variation ^{2 3 5}	10 240	10 240
Worksharing; change in therapeutic indication ⁹	30 720	30 720
Worksharing; type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3 9}	10 240	10 240
Worksharing; harmonisation of SmPC	20 480	20 480
Worksharing; other type II variations ⁹	10 240	10 240
Renewal ⁶	17 408	17 408

Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling ^{2 3}	5 120	
Traditional herbal medicinal products; type II variations ^{2 3}	7 168	
Traditional herbal medicinal products; renewal ⁶	5 120	

4 DCP for which Norway is RMS

4.1 Marketing Authorisation application (DCP-RMS)

	Human	Veterinary
Agreement on RMS-ship ⁷	51 200	51 200
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b	358 400	358 400
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	153 360	153 360
Additional formulations and strengths applied at the same time - Veterinary: within the same target species	15 360	15 360
Additional formulations and strengths applied at the same time - different target specie(s)		76 800
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	112 640	112 640
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species ¹	128 000	128 000
Annex I: Change or addition of new food producing specie(s) ¹		87 040
Application for registration of a traditional herbal medicinal products, with HMPC-monography	153 600	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	256 000	

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	102 400	102 400
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	76 800	76 800
Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	15 360	15 360
Additional formulations and strengths applied at the same time - different target specie(s)		76 800
Duplicate application (applied at the same time)	30 720	30 720
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) ¹	51 200	51 200
Annex I (line extension): New formulations/strengths - Veterinary: within the same target specie(s) ¹	51 200	51 200
Annex I: Change or addition of new food producing specie(s) ¹		46 080
Application for registration of a traditional herbal medicinal products, with HMPC-monography	76 800	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	102 400	
Withdrawal of application before start of procedure– administrative fee	20 480	20 480

6 Homeopathic medicinal products

	Human	Veterinary
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product.	1024	1024
Type II variation	1024	1024
Renewal	1024	1024

7 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.