

# Regulatory fees

Applicable from 01.01.2022

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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.	442 805	442 805
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	166 051	166 051
Additional formulations and strengths applied at the same time - Veterinary: within the same target species	16 606	16 606
Additional formulations and strengths applied at the same time - different target specie(s)		166 051
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) <sup>1</sup>	99 631	83 027
Annex I (Line extension): New formulations/strengths - Veterinary: within the same target specie(s) <sup>1</sup>	110 702	110 702
Annex I: Change or addition of new food producing specie(s) <sup>1</sup>		110 702
Duplicate application (applied at the same time)	33 210	33 210
Application for registration of a traditional herbal medicinal products, with HMPC-monography	166 051	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	221 403	
Marketing Authorisation application for natural remedies	221 403	
Withdrawal of application before start of procedure – administrative fee	22 140	22 140

## 1.2 Variation applications and application for renewal (national)

	Human	Veterinary
Type IB variation which leads to changes in the SmPC, PL and labeling <sup>23</sup>	9 410	9 410
Type II variation; change in therapeutic indication <sup>234</sup> - Veterinary: within the same target species	83 027	83 027
Type II variation - change or addition of new non-food producing specie(s)		83 027
Change in withdrawal period		22 140
Type II variation; change in legal status (prescription/non-prescription) <sup>23</sup>	83 027	83 027
Other type II variation <sup>235</sup>	13 838	13 838
Renewal <sup>6</sup>	44 281	44 281
Traditional herbal medicinal products; type II variation – change in traditional use indication <sup>234</sup>	24 907	
Traditional herbal medicinal products; type IB variation which leads to changes in the SmPC, PL and labeling <sup>23</sup>	9 410	
Traditional herbal medicinal products; other type II variations <sup>23</sup>	13 838	
Traditional herbal medicinal products; renewal <sup>6</sup>	22 140	

## 1.3 Parallell import (National)

	Human	Veterinary
Application for marketing authorisation	17 712	17 712
Renewal <sup>6</sup>	5 535	5 535

## 2 MRP for which Norway is RMS

### 2.1 Marketing Authorisation application (MRP-RMS)

	Human	Veterinary
Agreement on RMS-ship <sup>7</sup>	55 350	55 350
Initiating MRP, regardless of legal basis <sup>8</sup>	110 702	110 702
Repeat use, regardless of legal basis	110 702	110 702
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) <sup>1</sup>	99 631	83 027
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species <sup>1</sup>	138 376	138 376
Annex I: change or addition of new food producing specie(s) <sup>1</sup>		110 702

### 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 <sup>23</sup>	12 176	12 176
Type II variation; change in therapeutic indication <sup>234</sup> - Veterinary: within the same target species	83 027	83 027
Type II variation - change or addition of new non-food producing specie(s)		88 561
Change in withdrawal period		27 675
Other type II variation <sup>235</sup>	13 284	13 284
Worksharing; change in therapeutic indication <sup>49</sup>	83 027	83 027
Worksharing; Type IB variation which leads to changes in the SmPC, PL and labeling <sup>239</sup>	11 071	11 071
Worksharing; harmonisation of SmPC	27 675	27 675
Worksharing; other type II variation <sup>9</sup>	13 838	13 838

Renewal <sup>6</sup>	44 281	44 281
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling <sup>2 3</sup>	8 856	
Traditional herbal medicinal products; type II variations <sup>2 3</sup>	13 284	
Traditional herbal medicinal products; renewal <sup>6</sup>	22 140	

### 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	110 702	110 702
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	83 027	83 027
Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	16 606	16 606
Additional formulations and strengths applied at the same time - different target specie(s)		94 095
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) <sup>1</sup>	55 350	55 350
Annex I: New formulations/strengths(line extension) - Veterinary: within the same target specie(s) <sup>1</sup>	55 350	55 350
Annex I: Change or addition of new food producing specie(s) <sup>1</sup>		33 210
Application for registration of a traditional herbal medicinal products, with HMPC-monography	83 027	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	110 702	
Withdrawal of application before start of procedure – administrative fee	22 140	22 140

### 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 <sup>23</sup>	7 196	7 196
Type II variation; change in therapeutic indication <sup>234</sup> - Veterinary: within the same target specie(s)	38 746	38 746
Type II variation - change or addition of new non-food producing specie(s)		27 675
Change in withdrawal period		7 971
Other type II variation <sup>235</sup>	11 071	11 071
Worksharing; change in therapeutic indication <sup>9</sup>	33 210	33 210
Worksharing; type IB variation which leads to changes in the SmPC, PL and labeling <sup>239</sup>	11 071	11 071
Worksharing; harmonisation of SmPC	22 140	22 140
Worksharing; other type II variations <sup>9</sup>	11 071	11 071
Renewal <sup>6</sup>	18 819	18 819
Traditional herbal medicinal products; Type IB variation which leads to changes in the SmPC, PL and labeling <sup>23</sup>	5 535	
Traditional herbal medicinal products; type II variations <sup>23</sup>	7 748	
Traditional herbal medicinal products; renewal <sup>6</sup>	5 535	

## 4 DCP for which Norway is RMS

### 4.1 Marketing Authorisation application (DCP-RMS)

	Human	Veterinary
Agreement on RMS-ship <sup>7</sup>	55 350	55 350
Complete dossier/well established use(WEU)/fixed combinations, Art. 8(3)/10a/10b/12(3)/13a/13b	387 455	387 455
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	166 051	166 051
Additional formulations and strengths applied at the same time - Veterinary: within the same target species	16 606	16 606
Additional formulations and strengths applied at the same time - different target specie(s)		83 027
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) <sup>1</sup>	121 771	121 771
Annex I (line extension): New formulations/strengths - Veterinary: within the same target species <sup>1</sup>	138 376	138 376
Annex I: Change or addition of new food producing specie(s) <sup>1</sup>		94 095
Application for registration of a traditional herbal medicinal products, with HMPC-monography	166 051	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	276 753	

## 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	110 702	110 702
Hybrid/Generic/Biosimilar/Informed consent, Art. 10(1)/10(3)/10(4)/10c/13(1)/13(3)/13(4)/13c	83 027	83 027
Additional formulations and strengths applied at the same time - Veterinary: within the same target specie(s)	16 606	16 606
Additional formulations and strengths applied at the same time - different target specie(s)		83 027
Duplicate application (applied at the same time)	33 210	33 210
Annex I: applications except new formulations/strengths - Veterinary: except change or addition of food producing specie(s) <sup>1</sup>	55 350	55 350
Annex I (line extension): New formulations/strengths - Veterinary: within the same target specie(s) <sup>1</sup>	55 350	55 350
Annex I: Change or addition of new food producing specie(s) <sup>1</sup>		49 816
Application for registration of a traditional herbal medicinal products, with HMPC-monography	83 027	
Application for registration of a traditional herbal medicinal products, without HMPC-monography	110 702	
Withdrawal of application before start of procedure– administrative fee	22 140	22 140

## 6 Homeopathic medicinal products

	Human	Veterinary
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product.	1 107	1 107
Type II variation	1 107	1 107
Renewal	1 107	1 107



## 7 Clinical study

	Human	Veterinær
Kliniske utprøvinger - Ny studie	10 810	10 810
Kliniske utprøvinger - Endringer (Substensial amendments)	5 405	5 405

## 8 Application – WHO-certificates

WHO-sertifikat	5 405
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## 9 Footnotes

<sup>1</sup>Annex I to Variation Regulation nr EC 1234/2008

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

<sup>3</sup>Variations leading to other consequential variations is invoiced as one

<sup>4</sup>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

<sup>5</sup>Applicable for change in posology

<sup>6</sup> Applicable for each Marketing Authorisation number <sup>7</sup>Applicable per procedure/agreement.

Non refundable <sup>8</sup>Applicable independent of legal basis for submission

<sup>9</sup>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.