Regulatory fees for veterinary medicinal products valid from 01.01.2024-31.12.2024

Application for marketing authorisation (National)	***Veterinary***
Complete dossier/ fixed combinations/ bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	476 157
Generic/ Hybrid /Informed consent Regulation (EU) 2019/6 art. 18, 19, 21	178 558
Additional formulations and strengths applied for at the same time - within the same target species	17 857
Additional formulations and strengths applied at the same time - different target specie(s)	178 558
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	476 157
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	238 078
Duplicate application (applied at the same time)	35 711
Withdrawal of application before procedure start– administrative fee	23 807

Variation applications and applications for renewal (National)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	89 281
Change of bioavailability I.II.1(a), pharmacokinetics I.II.1(b) and change or addition of a new route of administration I.II.1(e)	89 281
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	119 040
Change or addition of new food producing specie(s) I.III.1 (a)	119 040
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	89 281
Change or addition of new non-food producing target specie(s) G.I.10	89 281
Change in withdrawal period G.I.12 (S)	23 807
Change in legal status (prescription/non-prescription) G.I.9 [2 3]	89 281
Other variations with standard timetable (S) [2 3 5]	14 880
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	10 118
Renewals, MA for limited market (EU) 2019/6 art. 24 (2)	47 616
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	23 807

Parallel trade (National)	***Veterinary***
Application for parallel trade (EU) 2019/6 art. 102	19 046

MRP where Norway is the RMS

Application for marketing authorisation (MRP-RMS)	***Veterinary***
Agreement on RMS-ship [7]	59 519
Initiating MRP, regardless of legal basis [8]	119 040
Repeat use, regardless of legal basis	119 040

Variation applications and applications for renewal (MRP-RMS)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	89 281
Change of bioavailability I.II.1(a), pharmacokinetics I.II.1(b) and change or addition of a new route of administration I.II.1(e)	89 281
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	148 798
Change or addition of new food producing specie(s) I.III.1 (a)	119 040
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	89 281
Change or addition of new non-food producing target specie(s) G.I.10	95 232
Change in withdrawal period G.I.12	29 759
Other variations with standard timetable (S) [2 3 5]	14 285
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	13 093
Worksharing: change in therapeutic indication[4 9]	89 281
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling [2 3 9]	11 905
Worksharing: harmonisation of the product information	29 759
Worksharing: other variations with standard timetable (S) [9]	14 880
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	47 616
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	23 807

MRP where Norway is CMS

Application for marketing authorisation (MRP-CMS)	***Veterinary***
Complete dossier, fixed combinations, bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	119 040
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	89 281
Additional formulations and strengths applied for at the same time - within the same target species	17 857
Additional formulations and strengths applied at the same time - different target specie(s)	101 182
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	119 040
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	59 521
Withdrawal of application before procedure start– administrative fee	23 807

Variation applications and applications for renewal (MRP-CMS)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	59 519
Change of bioavailability I.II.1(a), pharmacokinetics I.II.1(b) and change or addition of a new route of administration I.II.1(e)	59 519
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	59 519
Change or addition of new food producing specie(s) I.III.1 (a)	35 711
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	41 664
Change or addition of new non-food producing target specie(s) G.I.10	29 759
Change in withdrawal period G.I.12	8 571
Other variations with standard timetable (S) [2 3 5]	11 905
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	7 738
Worksharing: change in therapeutic indication[4 9]	35 711
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling [2 3 9]	11 905
Worksharing: harmonisation of the product information	23 807
Worksharing: Other variations with standard timetable (S) [9]	11 905
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	20 237
Renewals, MA for exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	10 118

DCP where Norway is the RMS

Application for marketing authorisation (DCP-RMS)	***Veterinary***
Agreement on RMS-ship [7]	59 519
Complete dossier, fixed combinations, bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	416 638
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	178 558
Additional formulations and strengths applied for at the same time - within the same target species	17 857
Additional formulations and strengths applied at the same time - different target specie(s)	89 281
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	416 638
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	208 319

DCP where Norway is CMS

Application for marketing authorisation (DCP-CMS)	***Veterinary***
Complete dossier, fixed combinations, bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	119 040
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	89 281
Additional formulations and strengths applied for at the same time - within the same target species	17 857
Additional formulations and strengths applied at the same time - different target specie(s)	89 281
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	119 040
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	59 521
Duplicate application (applied at the same time)	35 711
Withdrawal of application before procedure start– administrative fee	23 807

Homeopathic remedies	***Veterinary***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	23 490
Variations	1 190

Clinical studies	***Veterinary***
New clinical study. Regulation (EU) 2019/6 art. 9(1)	11 624
Substantial amendments	5 812

Applications for WHO-certificates	***Veterinary***
WHO-certificate	5 812

Note

1 Medicinal products for limited markets (cf. regulation (EU) 2019/6 art. 4(29)) can apply for a reduction of fee up to 50%. The application for reduced fee must be justified, and approved by the NoMA prior to submission of the marketing authorisation application where the reduction of fee is requested.

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

3 Variations leading to other consequential variations are invoiced as one.

4 Not applicable for linguistic changes, moving of text or information on limited documentation on the use in children etc. These are invoiced as “Other variations with standard timetable (S)”.

5 Applicable for posology changes.

6 Applicable for each Marketing Authorisation

7 Applicable for each procedure/agreement. Non refundable.

8 Gjelder uansett søkergrunnlag.Applicable, independent of legal basis of the submission.

9 One fee for each invoiceable variation (independent of the number of products included in the worksharing procedure.

10 For applications in exceptional circumstances (cf. regulation (EU) 2019/6 art. 25) and renewals of these products, an application for reduction of fee can be made. The application for reduced fee must be justified, and approved by the NoMA prior to submission of the marketing authorisation application where the reduction of fee is requested.

‘

Att:

- For grouped variations, one fee will be invoiced for each invoiceable variation
- Marketing Authorisations issued without national Product Information will also be applicable for a fee
- Variations not requiring assessment (VNRA) and variations with reduced time table, where there are no changes to the SmPC, package leaflet and labelling, will not be invoiced.