Regulatory fees for veterinary medicinal products valid from 1st of January 2025

Application for marketing authorisation (National)	***Veterinary***
Complete dossier/ fixed combinations/ bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	494 251
Generic/ Hybrid /Informed consent Regulation (EU) 2019/6 art. 18, 19, 21	185 344
Additional formulations and strengths applied for at the same time - within the same target species	18 535
Additional formulations and strengths applied at the same time - different target specie(s)	185 344
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	494 251
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	247 125
Duplicate application (applied at the same time)	37 068
Withdrawal of application before procedure start– administrative fee	24 712

Variation applications and applications for renewal (National)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	92 673
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)	92 673
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	123 564
Change or addition of new food producing specie(s) I.III.1 (a)	123 564
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	92 673
Change or addition of new non-food producing target specie(s) G.I.10	92 673
Change in withdrawal period G.I.12 (S)	24 712
Change in legal status (prescription/non-prescription) G.I.9 [2 3]	92 673
Other variations with standard timetable (S) [2 3 5]	15 446
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	10 503
Renewals, MA for limited market (EU) 2019/6 art. 24 (2)	49 425
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	24 712

Parallel trade (National)	***Veterinary***
Application for parallel trade (EU) 2019/6 art. 102	19 769

MRP where Norway is the RMS

Application for marketing authorisation (MRP-RMS)	***Veterinary***
Agreement on RMS-ship [7]	61 781
Initiating MRP, regardless of legal basis [8]	123 564
Repeat use, regardless of legal basis	123 564

Variation applications and applications for renewal (MRP-RMS)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	92 673
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)	92 673
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	154 453
Change or addition of new food producing specie(s) I.III.1 (a)	123 564
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	92 673
Change or addition of new non-food producing target specie(s) G.I.10	98 850
Change in withdrawal period G.I.12	30 890
Other variations with standard timetable (S) [2 3 5]	14 828
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	13 590
Worksharing: change in therapeutic indication[4 9]	92 673
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling [2 3 9]	12 357
Worksharing: harmonisation of the product information	30 890
Worksharing: other variations with standard timetable (S) [9]	15 446
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	49 425
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	24 712

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.	123 564
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	92 673
Additional formulations and strengths applied for at the same time - within the same target species	18 535
Additional formulations and strengths applied at the same time - different target specie(s)	105 027
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	123 564
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	61 782
Withdrawal of application before procedure start– administrative fee	24 712

Variation applications and applications for renewal (MRP-CMS)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	61 781
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)	61 781
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	61 781
Change or addition of new food producing specie(s) I.III.1 (a)	37 068
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	43 247
Change or addition of new non-food producing target specie(s) G.I.10	30 890
Change in withdrawal period G.I.12	8 897
Other variations with standard timetable (S) [2 3 5]	12 357
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	8 032
Worksharing: change in therapeutic indication[4 9]	37 068
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling [2 3 9]	12 357
Worksharing: harmonisation of the product information	24 712
Worksharing: Other variations with standard timetable (S) [9]	12 357
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	21 006
Renewals, MA for exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	10 503

DCP where Norway is the RMS

Application for marketing authorisation (DCP-RMS)	***Veterinary***
Agreement on RMS-ship [7]	61 781
Complete dossier, fixed combinations, bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	432 471
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	185 344
Additional formulations and strengths applied for at the same time - within the same target species	18 535
Additional formulations and strengths applied at the same time - different target specie(s)	92 673
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	432 471
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	216 235

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.	123 564
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	92 673
Additional formulations and strengths applied for at the same time - within the same target species	18 535
Additional formulations and strengths applied at the same time - different target specie(s)	92 673
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	123 564
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	61 782
Duplicate application (applied at the same time)	37 068
Withdrawal of application before procedure start– administrative fee	24 712

Homeopathic remedies	***Veterinary***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	24 383
Variations	1 235

Clinical studies	***Veterinary***
New clinical study. Regulation (EU) 2019/6 art. 9(1)	12 066
Substantial amendments	6 033

Applications for WHO-certificates	***Veterinary***
WHO-certificate	6 033

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.