Regulatory fees for veterinary medicinal products valid from 1st of January 2026

Application for marketing authorisation (National)	***Veterinary***
Complete dossier/ fixed combinations/ bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	512 044
Generic/ Hybrid /Informed consent Regulation (EU) 2019/6 art. 18, 19, 21	192 016
Additional formulations and strengths applied for at the same time - within the same target species	19 202
Additional formulations and strengths applied at the same time - different target specie(s)	192 016
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	512 004
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	256 022
Duplicate application (applied at the same time)	38 402
Withdrawal of application before procedure start– administrative fee	25 602

Variation applications and applications for renewal (National)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	96 009
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)	96 009
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	128 012
Change or addition of new food producing specie(s) I.III.1 (a)	128 012
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	96 009
Change or addition of new non-food producing target specie(s) G.I.10	96 009
Change in withdrawal period G.I.12 (S)	25 602
Change in legal status (prescription/non-prescription) G.I.9 [2 3]	96 009
Other variations with standard timetable (S) [2 3 5]	16 002
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	10 881
Renewals, MA for limited market (EU) 2019/6 art. 24 (2)	51 204
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	25 602

Parallel trade (National)	***Veterinary***
Application for parallel trade (EU) 2019/6 art. 102	20 481

MRP where Norway is the RMS

Application for marketing authorisation (MRP-RMS)	***Veterinary***
Agreement on RMS-ship [7]	64 005
Initiating MRP, regardless of legal basis [8]	128 012
Repeat use, regardless of legal basis	128 012

Variation applications and applications for renewal (MRP-RMS)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	96 009
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)	96 009
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	160 013
Change or addition of new food producing specie(s) I.III.1 (a)	128 012
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	96 009
Change or addition of new non-food producing target specie(s) G.I.10	102 409
Change in withdrawal period G.I.12	32 002
Other variations with standard timetable (S) [2 3 5]	15 362
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	14 079
Worksharing: change in therapeutic indication[4 9]	96 009
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling [2 3 9]	12 802
Worksharing: harmonisation of the product information	32 002
Worksharing: other variations with standard timetable (S) [9]	16 002
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	51 204
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	25 602

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.	128 012
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	96 009
Additional formulations and strengths applied for at the same time - within the same target species	19 202
Additional formulations and strengths applied at the same time - different target specie(s)	108 808
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	128 012
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	64 006
Withdrawal of application before procedure start– administrative fee	25 602

Variation applications and applications for renewal (MRP-CMS)	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	64 005
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)	64 005
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	64 005
Change or addition of new food producing specie(s) I.III.1 (a)	38 402
Change in therapeutic indication – within the same target species (er) G.I.7.a[2 3 4]	44 804
Change or addition of new non-food producing target specie(s) G.I.10	32 002
Change in withdrawal period G.I.12	9 217
Other variations with standard timetable (S) [2 3 5]	12 802
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling[2 3]	8 321
Worksharing: change in therapeutic indication[4 9]	38 402
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labeling [2 3 9]	12 802
Worksharing: harmonisation of the product information	25 602
Worksharing: Other variations with standard timetable (S) [9]	12 802
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	21 762
Renewals, MA for exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	10 881

DCP where Norway is the RMS

Application for marketing authorisation (DCP-RMS)	***Veterinary***
Agreement on RMS-ship [7]	64 005
Complete dossier, fixed combinations, bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	448 040
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	192 016
Additional formulations and strengths applied for at the same time - within the same target species	19 202
Additional formulations and strengths applied at the same time - different target specie(s)	96 009
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	448 040
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	224 019

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.	128 012
Generic, hybrid, informed consent Regulation (EU) 2019/6 art. 18, 19, 21	96 009
Additional formulations and strengths applied for at the same time - within the same target species	19 202
Additional formulations and strengths applied at the same time - different target specie(s)	96 009
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	128 012
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	64 006
Duplicate application (applied at the same time)	38 402
Withdrawal of application before procedure start– administrative fee	25 602

Homeopathic remedies	***Veterinary***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	25 261
Variations	1 279

Clinical studies	***Veterinary***
New clinical study. Regulation (EU) 2019/6 art. 9(1)	12 500
Substantial amendments	6 250

Applications for WHO-certificates	***Veterinary***
WHO-certificate	6 250

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 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.

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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.