Regulatory fees

– veterinary medicinal products valid from 1st of January 2023

Application for marketing authorisation (National)

Application type	***Veterinary***
Complete dossier/fixed combinations/bibliographic application [1] Regulation (EU) 2019/6 art. 8, 20, 22.	456 089
Generic/hybrid/informed consent Regulation (EU) 2019/6 art. 18, 19, 21	171 033
Additional formulations and strengths applied at the same time - within the same target species	17 104
Additional formulations and strengths applied at the same time - different target specie(s)	171 033
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	456 089
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	228 044
Duplicate application (applied at the same time)	34 206
Withdrawal of application before procedure start - administrative fee	22 804

Variation applications and applications for renewal (National)

Application type	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	85 518
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)	85 518
New formulations I.II.1(d) or strengths I.II.1(c) - within the same target specie(s)	114 023
Change or addition of new food producing specie(s) I.III.1 (a)	114 023
Change in therapeutic indication - within the same target species(s) G.I.7.a[2 3 4]	85 518
Change or addition of new non-food producing target specie(s) G.I.10	85 518
Change in withdrawal period G.I.12 (S)	22 804
Change in legal status (prescription/non-prescription) G.I.9 [2 3]	85 518
Other variations with standard timetable (S) [2 3 5]	14 253
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labelling[2 3]	9 692
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	45 609
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	22 804

Parallel trade (National)

Application type	***Veterinary***
Application for parallel trade Regulation (EU) 2019/6 art. 102	18 243

Application for marketing authorisation (MRP-RMS)

Application type	***Veterinary***
Agreement on RMS-ship [7]	57 011
Initiating MRP assignments, regardless of legal basis [8]	114 023
Repeat use, regardless of legal basis	114 023

Variation applications and applications for renewal (MRP-RMS)

Application type	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	85 518
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)	85 518
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	142 527
Change or addition of new food producing specie(s) I.III.1 (a)	114 023
Change in therapeutic indication – within the same target specie(s) G.I.7.a[2 3 4]	85 518
Change or addition of new non-food producing target specie(s) G.I.10	91 218
Change in withdrawal period G.I.12	28 505
Other variations with standard timetable (S) [2 3 5]	13 683
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labelling[2 3]	12 541
Worksharing: change in therapeutic indication[4 9]	85 518
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labelling [2 3 9]	11 403
Worksharing: harmonisation of the product information	28 505
Worksharing: other variations with standard timetable (S) [9]	14 253
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	45 609
Renewals, MA in exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	22 804

Application for marketing authorisation (MRP-CMS)

Application type	***Veterinary***
Complete dossier/fixed combinations/bibliographic application Regulation (EU) 2019/6 art. 8, 20, 22.	114 023
Generic/hybrid/informed consent Regulation (EU) 2019/6 art. 18, 19, 21	85 518
Additional formulations and strengths applied for at the same time, within the same target species	17 104
Additional formulations and strengths applied at the same time, different target specie(s)	96 918
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	114 023
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	57 012
Withdrawal of application before procedure start - administrative fee	22 804

Variation applications and applications for renewal (MRP-CMS)

Application type	***Veterinary***
Changes to the active substance(s) I.I.1(a–f)	57 011
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)	57 011
New formulations I.II.1(d) or strengths I.II.1(c) within the same target specie(s)	57 011
Change or addition of new food producing specie(s) I.III.1 (a)	34 206
Change in therapeutic indication - within the same target specie(s) G.I.7.a[2 3 4]	39 908
Change or addition of new non-food producing target specie(s) G.I.10	28 505
Change in withdrawal period G.I.12	8 210
Other variations with standard timetable (S) [2 3 5]	11 403
Variations with reduced timetable (R) which leads to changes in the SmPC, PL and labelling[2 3]	7 412
Worksharing: change in therapeutic indication[4 9]	34 206
Worksharing: variations with reduced timetable (R) which leads to changes in the SmPC, PL and labelling [2 3 9]	11 403
Worksharing: harmonisation of the product information	22 804
Worksharing: Other variations with standard timetable (S) [9]	11 403
Renewals, MA for limited market (EU) 2019/6 art. 24 (2) [6]	19 384
Renewals, MA for exceptional circumstances (EU) 2019/6 art. 27 (2) [6 10]	9 692

Application for marketing authorisation (DCP-RMS)

Application type	***Veterinary***
Agreement on RMS-ship	57 011
Complete dossier/fixed combinations/bibliographic application Regulation (EU) 2019/6 art. 8, 20, 22	399 079
Generic/hybrid/informed consent Regulation (EU) 2019/6 art. 18, 19, 21	171 033
Additional formulations and strengths applied for at the same time - within the same target species	17 104
Additional formulations and strengths applied at the same time - different target specie(s)	85 518
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	399 079
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	199 539

Application for marketing authorisation (DCP-CMS)

Application type	***Veterinary***
Complete dossier/fixed combinations/bibliographic application Regulation (EU) 2019/6 art. 8, 20, 22.	114 023
Generic/hybrid/ informed consent Regulation (EU) 2019/6 art. 18, 19, 21	85 518
Additional formulations and strengths applied for simultaneously - within the same target species	17 104
Additional formulations and strengths applied simultaneously - different target specie(s)	85 518
Applications for limited markets[1] Regulation (EU) 2019/6 art. 23	114 023
Applications in exceptional circumstances [10] (EU) 2019/6 art. 25	57 012
Duplicate application (applied simultaneously)	34 206
Withdrawal of application before procedure start– administrative fee	22 804

Homeopathic remedies

Application type	***Veterinary***
Application for registration. The fee covers all dilutions of one pharmaceutical form of a product	22 500
Variations	1 140

Clinical studies

Application type	***Veterinary***
Clinical trial - new clinical study Regulation (EU) 2019/6 art. 9(1)	11 134
Clinical trial - Substantial amendments	5 567

Applications for WHO-certificates

Application type	***Veterinary***
WHO-certificate	5 567

Notes

1 For medicinal products for limited markets (cf. regulation (EU) 2019/6 art. 4(29)) up to a 50% reduction in fees can be applied for. 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 or moving of text. 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, a further reduction in fee can be applied for. The application for reduced fee must be justified and approved by the NoMA prior to submission of the marketing authorisation or renewal 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 timetable where there are no changes to the SmPC, package leaflet and labelling, will not be invoiced.