EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# NexGard

## Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification[1] issued on | Commission Decision Issued / amended on | Product Information affected[2] | Summary[3] |
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| IG/1203 | A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | 20/03/2020 | | Annex II and PL | To change the name of the site responsible for batch release of the finished product from Merial SAS (4 Chemin du Calquet, 31000, Toulouse, France) to Boehringer Ingelheim Animal Health France SCS. The address remains unchanged. |
| T/0028 | Transfer of Marketing Authorisation | 25/11/2019 | 17/12/2019 | SPC, Labelling and PL | The European Commission transferred the marketing authorisation for NexGard from 'MERIAL' to 'Boehringer Ingehleim Vetmetdica GmbH. |
| IB/0027/G | This was an application for a group of variations.<br><br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 04/10/2019 | 17/12/2019 | SPC, Labelling and PL | The Agency accepted the group of variations to add a new pack size of 18 chewable tablets for each strength. |

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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| WS/1559 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | 18/07/2019 | 19/08/2019 | SPC and PL | The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication: treatment of tick infestations (Ixodes hexagonus). |
| IG/1127/G | This was an application for a group of variations.<br><br>C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure<br>C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities<br>C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system | 10/07/2019 | n/a | | n/a |
| R/0023 | Renewal of the marketing authorisation. | 11/10/2018 | 19/12/2018 | | The European Commission renewed the marketing authorisation for NexGard |
| WS/1338/G | This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one<br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one<br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | 13/09/2018 | 18/10/2018 | SPC and PL | The European Commission amended the decision granting the marketing authorisation to add new therapeutic indications: for the treatment of demodicosis (caused by Demodex canis) and sarcoptic mange (caused by Sarcoptes scabiei var. canis). |
| IG/0961 | A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) | 31/07/2018 | n/a | | The Agency accepted the variation to change the name of a manufacturer and to correct an error in the address of another manufacturing site. |

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| IB/0022/G | This was an application for a group of variations.<br><br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 06/07/2018 | 18/10/2018 | SPC, Labelling and PL | The Agency accepted variations to register a new pack size of 15 chewable tablets for each strength. |
| IB/0021 | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) | 29/06/2018 | 18/10/2018 | SPC | The Agency accepted the variation to extend the shelf life of the finished product from 30 months to 3 years. |
| IB/0020/G | This was an application for a group of variations.<br><br>A.6 - Administrative change - Change in ATC Code/ATC Vet Code<br>C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR | 18/05/2018 | 18/10/2018 | SPC and PL | The Agency accepted the variation to amend section 4.6 (Adverse reactions) of SPC, following assessment of a PSUR; and to update the ATCvet code following the assignment of a separate code for isoxazolines. |
| IA/0019/G | This was an application for a group of variations.<br><br>B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms<br>B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method<br>B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier | 25/01/2018 | n/a | | The Agency accepted variations to add alternative suppliers for the primary packaging, and to register consequential changes in the composition and specification of the blister |
| IG/0876 | B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size | 05/01/2018 | n/a | | The Agency accepted the variation to register an alternative increased batch size of the intermediate substance. |
| IA/0016 | A.7 - Administrative change - Deletion of manufacturing sites | 07/04/2017 | n/a | | The Agency accepted the variation to delete a site responsible for secondary packaging. |
| IG/0610 | B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size | 25/09/2015 | n/a | | The Agency accepted the variation to register an increased batch size for the intermediate substance obtained during the manufacturing process of afoxolaner. |

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| WS/0756 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier | 10/09/2015 | n/a | | The European Commission amended the Decision granting the marketing authorisation to introduce a new manufacturing site for the active substance. |
| IG/0592 | C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure | 04/09/2015 | n/a | | n/a |
| IB/0012 | B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 03/07/2015 | n/a | | The Agency accepted the variation to extend the re-test period of the active substance. |
| IA/0011 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 18/06/2015 | n/a | | The Agency accepted the variation to register a minor change to an approved test procedure. |
| IB/0010 | C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR | 05/06/2015 | 08/10/2015 | SPC and PL | The Agency accepted the variation to update the SPC and package leaflet, further to the assessment of a PSUR. |
| IA/0009 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 13/05/2015 | n/a | | The Agency accepted a variation to register minor changes to a currently approved test method. |
| IB/0006 | B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 13/05/2015 | n/a | | The Agency accepted a variation to register an alternate test method. |
| IB/0005 | B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 13/05/2015 | n/a | | The Agency accepted a variation to register an alternate test method. |
| IA/0008 | B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size | 08/05/2015 | n/a | | The Agency approved the variation to increase the batch size of the finished product. |
| IG/0548 | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 30/04/2015 | n/a | | The Agency accepted the variation to introduce a minor change in an approved test procedure. |
| II/0001 | C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 12/02/2015 | 08/10/2015 | SPC, Annex II and PL | The Agency accepted a variation to change the summary of product characteristics and package leaflet due to new clinical data. |
| IAIN/0004 | A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | 30/10/2014 | 08/10/2015 | Annex II and PL | The Agency accepted a variation to make a minor change in the address of a manufacturer. |
| IA/0003 | B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients | 05/09/2014 | 08/10/2015 | SPC, Labelling and PL | The Agency accepted the variation to remove the preservative potassium sorbate from the composition of the product. |
| IB/0002 | B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a | 23/07/2014 | n/a | | The Agency accepted a variation to extend the re-test |

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| | re-test period/storage period supported by real time data | | | | period of the active substance from 36 to 48 months. |