NexGard Combo

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]
IG/1468	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	10/12/2021	n/a		n/a
II/0002/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	07/10/2021	29/11/2021	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add new therapeutic indications: for the treatment of notoedric mange (caused by *Notoedres cati*); and the treatment of infections with *Aelurostrongylus abstrusus* (L3, L4 larvae and adults) and prevention of aelurostrongylosis (by reduction of the level of infection with L3, L4 larvae of *Aelurostrongylus abstrusus*); and to support the safe use of the product in breeding, pregnant and lactating queens. The MAH took the opportunity to implement minor changes in the product information.
IA/0004	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	03/09/2021	n/a		n/a
IB/0003	B.I.d.1.a.4 - Stability of AS - Change in the re-test	03/06/2021	n/a		n/a

[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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	period/storage period - Extension or introduction of a re-test period/storage period supported by real time data				
IG/1337	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	10/02/2021	n/a		n/a