VarroMed

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]
R/0005	Renewal of the marketing authorisation.	07/10/2021	04/01/2022	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for VarroMed.
IAIN/0006/G	This was an application for a group of variations. 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 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	06/10/2021	n/a		n/a
II/0004/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative	20/01/2021	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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	composition - Semi-solid and non-sterile liquid pharmaceutical forms B.II.e.4.b - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part, which may have a significant impact on the delivery, use, safety or stability of the FP B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information				
IA/0002	B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	03/05/2019	n/a		The Agency accepted the variation to update the specification limits of an excipient.
IAIN/0001/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	17/08/2018	29/08/2019	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to change the name of a manufacturer and to add a secondary packaging site.