

Rheumocam

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
IB/0032/G	This was an application for a group of variations. B.IV.1.z - Change of a measuring or administration device - Other variation B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	17/11/2021		SPC and PL	The Agency accepted the variation to amend the neck dimensions of the bottle used for the 10 mL and 15 mL pack size so that all the pack sizes use the same cap and to change the marking of the measuring device from mL to kg to allow dosage to be delivered in line with the dosing advice stated in section 4.9 of the SPC.
IB/0031/G	This was an application for a group of variations. 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 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)	18/03/2021	28/09/2021	SPC, Labelling and PL	The Agency accepted the group of variations to extend the shelf-life for Rheumocam 20 mg/ml Solution for Injection and Rheumocam 5 mg/ml Solution for Injection from 4 to 5 years; and to add a pack size for Rheumocam 330 mg Granules of 10 sachets per pack. In addition, the MAH took the opportunity to introduce some amendments to the local representatives in the package leaflet.
IAIN/0030	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	26/10/2020	28/09/2021	PL	The Agency accepted the variation to update the details for local product representatives in the package leaflet and in addition to correct minor typographical errors in the

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

					translated texts for Denmark and Norway.
IB/0029/G	<p>This was an application for a group of variations.</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products</p> <p>B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)</p> <p>B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p>	11/09/2020	28/09/2021	SPC, Labelling and PL	<p>The Agency accepted the group of variations including the addition of polypropylene bottles as alternative immediate packaging of the finished product, the addition of 5 ml bottles as new pack size of the finished product, the extension of the shelf-life after first opening the immediate packaging from 3 to 6 months for the 10 ml and 15ml bottles and the introduction of 14 days shelf-life after first opening the immediate packaging for the 3 ml and 5 ml bottles for Rheumocam 0.5 mg/ml oral suspension for cats. The MAH took the opportunity to update the local representatives in the product information and to align translations with the EN PI.</p>
IAIN/0028	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	28/02/2020	n/a		n/a
IB/0027/G	<p>This was an application for a group of variations.</p> <p>B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing</p> <p>B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold</p> <p>B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p>	05/02/2020	01/07/2020	Annex II and PL	<p>The Agency accepted the group of variations to:</p> <ul style="list-style-type: none"> - add a manufacturing site for part or all of the manufacturing process of the finished product; - register a manufacturing site as batch release site including batch testing/control; - make a minor change in the manufacturing process of the finished or intermediate product ; - make a change in the batch size of the finished product. <p>Additionally, the local representatives were updated from the package leaflet and editorial changes were made to the product information.</p>
WS/1618	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference</p>	20/06/2019	01/07/2020	SPC and PL	<p>The Agency accepted the variation to amend the adverse reactions section of the SPC to be in line with the reference product. The product information was also updated in accordance with the latest version of the QRD template.</p>

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0026	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	12/06/2019	n/a		The Agency accepted the variation to update the manufacturing process of the bulk used in the meloxicam finished product (granules in sachet).
X/0022	Annex I_2.(c) Change or addition of a new strength/potency	13/09/2018	19/11/2018	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new strength and pharmaceutical form for cats.
WS/1301	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/07/2018	n/a		The Agency accepted the variation to change the stability specification parameters of the finished product.
IG/0962	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	04/07/2018	n/a		The Agency accepted the variation to add a secondary packaging site.
IG/0697	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/12/2016	n/a		The Agency accepted the variation to introduce a minor change to the approved test procedure for the assay of the finished product.
WS/0933/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. 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) 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)	08/09/2016	14/09/2017	SPC	The Agency accepted the variation to extend the shelf-life of the finished product.
IG/0666	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	03/03/2016	n/a		The Agency accepted the variation to delete one of the parameter from the specifications for release and shelf life.
X/0015	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	12/03/2015	13/05/2015	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength (330 mg) and a new pharmaceutical form (granules in sachet) for horses.
IB/0018	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/12/2014	n/a		The Agency accepted the variation to to change the frequency of the particle size testing.
IG/0505	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	19/12/2014	n/a		The Agency accepted the variation to change the dimensions of the bottles for the 42 ml, 100 ml and 200 ml pack sizes.
WS/0344	This was an application for a variation following a worksharing procedure according to Article 20 of	10/01/2013	13/02/2013	SPC, Annex II, Labelling and	The Agency accepted the variation to remove the excipient due to patent issue with the reference product Metacam 20

	Commission Regulation (EC) No 1234/2008. B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product			PL	mg/ml solution for injection.
R/0012	Renewal of the marketing authorisation.	11/10/2012	18/12/2012	SPC, Annex II and PL	The European Commission renewed the marketing authorisation for Rheumocam.
X/0010	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	13/09/2012	12/11/2012	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for Rheumocam to include a new strength 5 mg/ml solution for injection for cattle and pigs.
WS/0322	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	08/11/2012	n/a		The Agency accepted the variation to change the specification for viscosity outside the approved specification limits.
IB/0011	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	03/05/2012	n/a		The Agency accepted the variation to change the range of batch sizes from 250 litres-2500 litres to 50 litres-2500 litres.
X/0008	X-3-III Extension to a new strength	10/11/2011	24/01/2012	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength 5 mg/ml solution for injection for cats and dogs.
IB/0009	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	22/07/2011	22/07/2011		The Agency accepted the variation to add a manufacturing site.
X/0007	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	09/03/2011	16/05/2011	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength 20 mg/ml solution for injection for cattle, pigs and horses.
X/0006	X-4-I Addition or change of target species	10/11/2010	24/01/2011	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength 15 mg/ml oral suspension for horses.
X/0004	X-2-1 Addition of an indication	15/07/2009	08/10/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include 1 mg and 2.5 mg chewable tablets for dogs.
IB/0003	1B-29A Change in qualitative or quantitative composition of the immediate packaging material	19/11/2008	04/06/2009	SPC, Labelling and PL	The Agency accepted the variation for a change in immediate packaging material to a container of HDPE material for a new 15 ml pack size in a 20 ml container.
IA/0005	1A-012-a Change in the specification of an active substance or starting material used in MP	09/02/2009	09/02/2009		The Agency accepted the variation to amend the particle size specification for the active substance.

IB/0002	1B-43-b Addition, replacement or deletion of a measuring or administration device	18/08/2008	18/08/2008		The Agency accepted the variation for the addition of a measuring or administration device (a second smaller dosing syringe).
IB/0001	1B-012b1 Change in the specification of an active substance or starting material used in MP	20/06/2008	20/06/2008		The Agency accepted the variation for a change in the specification of the finished product (addition of a new test parameter).