EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Melovem

## Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion / Notification[1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| R/0008 | Renewal of the marketing authorisation. | 10/04/2014 | 06/06/2014 | SPC, Annex II, Labelling and PL | The European Commission renewed the marketing authorisation for the product. |
| IB/0007 | 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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 03/01/2014 | 06/02/2014 | SPC, Labelling and PL | The Agency accepted the variation to harmonise the SPC and PL of the generic product with the reference product. |
| IA/0006 | B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer | 18/12/2013 | n/a | | The Agency accepted the variation to submit an updated Ph. Eur. certificate of suitability from an already approved manufacturer. |
| IAIN/0005/G | This was an application for a group of variations.<br><br>B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer | 18/12/2013 | n/a | | The Agency accepted a grouped variation concerning submission of a Ph. Eur. certificate of suitability from an already approved manufacturer and from a new manufacturer. |

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| | 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) | | | | |
| X/0004 | Annex I_2.(c) Change or addition of a new strength/potency | 18/07/2013 | 25/09/2013 | SPC, Annex II, Labelling and PL | The European Commission amended the decision granting the marketing authorisation to add a new strength 30 mg/ml solution for injection for cattle and pigs. |
| X/0003 | Annex I_2.(c) Change or addition of a new strength/potency | 18/07/2013 | 25/09/2013 | SPC, Annex II, Labelling and PL | The European Commission amended the decision granting the marketing authorisation to add a new strength 20 mg/ml solution for injection for cattle, pigs and a new target species horses. |
| IB/0001 | 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 product - Implementation of change(s) for which NO new additional data are submitted by the MAH | 08/04/2010 | 03/11/2010 | SPC, Labelling and PL | The Agency approved a variation to update the SPC in line with the reference product for the indication in pigs. |
| IAIN/0002/G | This was an application for a group of variations.<br><br>C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV<br>C.I.9.h - 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 pharmacovigilance system | 09/07/2010 | 09/07/2010 | | The Agency approved a grouped variation concerning a change in the back-up to the QPPV and change in DDPS. |