# Rabigen SAG2

## 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 |
|---|---|---|---|---|---|
| IG/0984 | 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 | 26/10/2018 | | PL | The Agency accepted the variation to update the local representatives in the package leaflet. |
| IG/0724 | 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 | 21/12/2016 | 06/03/2017 | PL | The Agency accepted the variation to update the list of local representatives in the package leaflet. |
| IB/0005 | C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR | 19/02/2016 | 06/03/2017 | SPC, Labelling and PL | The Agency accepted the variation to amend the section on adverse reactions in the SPC and package leaflet, in accordance with the recommendations made by the CVMP following a PSUR assessment. |
| R/0004 | Renewal of the marketing authorisation. | 09/12/2009 | 16/03/2010 | SPC, Annex II, Labelling and PL | The European Commission renewed the marketing authorisation for Rabigen SAG2. |
| II/0003 | II - New Indication (same therapeutic area) | 12/03/2008 | 16/04/2008 | SPC, Labelling and PL | The European Commission amended the decision granting the marketing authorisation to add a new target species, raccoon dogs. Amendments have been incorporated into the relevant sections of the EPAR. |

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
**Send a question via our website** www.ema.europa.eu/contact

| | | | | | |
|---|---|---|---|---|---|
| II/0002 | II - Other quality changes | 21/06/2006 | 20/07/2006 | SPC, Labelling and PL | The European Commission amended the decision granting the marketing authorisation to replace the excipient beef tallow by white soft paraffin. |
| R/0001 | Renewal of the marketing authorisation. | 09/02/2005 | 11/04/2005 | SPC, Annex II, Labelling and PL | The European Commission renewed the marketing authorisation for Rabigen SAG2. |