RHINISENG

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
IB/0008	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	09/11/2018		SPC and PL	The Agency accepted the variation to update the product information with respect to adverse reactions to reflect the outcome of a PSUR. Contact details for the local representatives in the package leaflet were also updated.
II/0007	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	07/09/2017	n/a		The Agency accepted the variation to add a positive control to the potency assay of Bordetella bronchiseptica.
IG/0793	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	22/06/2017	18/06/2018	Annex II	The Agency accepted the variation to change the address of the manufacturer of the biological active substance.
IG/0623	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	11/02/2016	23/02/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.

[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

R/0003	Renewal of the marketing authorisation.	07/05/2015	30/06/2015	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for RHINISENG.
II/0004	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	10/04/2015	30/06/2015	Annex II	The Agency accepted the variation to register a site as the manufacturer of the active substance to correct the previous one.
II/0002	B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs	08/11/2012	n/a		The Agency accepted the variation to change the immediate packaging of both antigens to single use sterile polyethylene bags.
IA/0001	B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	22/07/2011	22/07/2011		The Agency accepted the variation to delete a non-significant in-process test for the PMTr antigen.