Eravac

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/0007	Renewal of the marketing authorisation.	17/06/2021	16/08/2021	SPC and PL	The European Commission renewed the marketing authorisation for Eravac.
II/0006	B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	20/01/2021	16/08/2021	SPC, Labelling and PL	The Agency accepted a variation to add a new presentation, 100 ml high-density polyethylene vials with 100 ml (200 doses).
II/0005/G	This was an application for a group of variations. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	05/12/2019	27/01/2020	SPC and PL	The Agency accepted a group of variations to extend the duration of immunity from 9 months to 12 months and to amend section 4.6 of the SPC.
IG/1023/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the	13/02/2019	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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	QPPV and/or QPPV contact details and/or back-up procedure C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities				
II/0003/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	15/02/2018	22/03/2018	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to amend the duration of immunity and demonstrate safety in pet (dwarf) and pregnant rabbits.
II/0002/G	This was an application for a group of variations. B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	09/11/2017	22/03/2018	SPC, Labelling and PL	The Agency accepted the variation to add a new single-dose presentation of 0.5 ml and extend the shelf life to 24 months for all presentations.
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	22/03/2018	Annex II	The Agency accepted the variation to change the address of the manufacturer of the biological active substance.