EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

STARTVAC

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/0006	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	02/03/2018		SPC and PL	The Agency accepted the variation to update the product information following the recommendation of a PSUR assessment. The applicant also took the opportunity to make changes within the list of local representatives in the package leaflet.
II/0005	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	15/02/2018		Annex II	The Agency accepted the variation to add a new manufacturer for the active substances.
II/0003/G	This was an application for a group of variations. 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 B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of	10/09/2015	25/07/2016	SPC, Labelling and PL	The Agency accepted the variation to add a new container for the vaccine (PET vials) and to add a new presentation of 125 doses (250 ml), bottled in PET vials.

[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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	sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products				
IG/0565	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	24/07/2015	25/07/2016	PL	The Agency accepted the variation for a change in the list of local representatives.
II/0002	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	11/09/2014	n/a		The Agency accepted the variation to modify the ELISA test methods used to test the level of antibodies against E. coli and against S. aureus in rabbit serum in the batch potency test.
R/0001	Renewal of the marketing authorisation.	12/12/2013	10/02/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for STARTVAC.