EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Aftovaxpur DOE

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]
IG/1204/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	20/03/2020		Annex II and PL	The Agency accepted the group of variations to change the names of the site responsible for batch release of the finished product and the site responsible for packaging of the finished product.
T/0012	Transfer of Marketing Authorisation	26/11/2019	17/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation for Aftovaxpur DOE from 'MERIAL' to 'Boehringer Ingehleim Vetmetdica GmbH.
IG/1127/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 QPPV and/or QPPV contact details and/or back-up procedure C.I.9.b - Changes to an existing pharmacovigilance	10/07/2019	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

	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 C.I.9.c - 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 PhV system				
II/0009	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	08/11/2018	12/12/2018	SPC and PL	The European Commission amended the decision granting the marketing authorisation to change the onset of immunity to seven days post vaccination for sheep and cattle.
IA/0010/G	This was an application for a group of variations. 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 A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	31/10/2018	12/12/2018	Annex II	The Agency accepted a group of variations to change the name of the active substance and finished product manufacturer.
R/0008	Renewal of the marketing authorisation.	19/04/2018	14/06/2018	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for AFTOVAXPUR DOE.
IB/0007	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	13/01/2017	12/01/2018	SPC	The Agency accepted the variation regarding composition of the immediate packaging (stoppers).
II/0005	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	21/04/2016	n/a		The Agency accepted the variation to introduce changes to increase the antigen yield, in order to allow a possible increase in antigen content at formulation and to improve the process for all strains (except Asia1 Shamir).
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/03/2016	20/04/2016	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to change the vaccination schedule to as early as 2 weeks of age for all target species.
IG/0592	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	04/09/2015	n/a		n/a
IB/0003	B.II.c.3.a.2 - Change in source of an excipient or reagent with TSE risk - From TSE risk material to vegetable or synthetic origin - For excipients or reagents USED in the manufacture of a biol/immunol AS or in a biol/immunol medicinal product	22/08/2014	n/a		The Agency accepted the variation to change the source of an excipient from animal origin to vegetable origin.
II/0001	C.II.4 - Variations concerning the replacement or addition of a serotype, strain, antigen or combination	13/03/2014	07/04/2014	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new foot-and-mouth

	of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue				disease virus antigen strain: SAT2 Saudi Arabia to take into account recommendations of the World Reference Laboratory for FMD for antigens to be included in banks.