Purevax FeLV

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]
IB/0028	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	14/08/2020		SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC and section 6 of the package leaflet following assessment of the 12th PSUR.
IG/1279	A.7 - Administrative change - Deletion of manufacturing sites	14/08/2020	n/a		n/a
IG/1264	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	29/07/2020		SPC and PL	The Agency accepted the variation to change the name of a site responsible for the manufacture of the active substance.
WS/1733/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished	20/05/2020		SPC, Labelling and PL	The Agency accepted the group of variations to add a 0.5 ml presentation of the liquid fraction, to register additional pack sizes for the new 0.5 ml presentation and to align the PI with the latest version of the QRD template, including proposals for improvements/rewordings and corrections to the PI.

[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

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	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.a.5 - Change in concentration of a single-dose, total use parenteral product, where the amount of AS per unit dose (i.e. the strength) remains the same				
IG/1230	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)	08/04/2020	n/a		n/a
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/0023	Transfer of Marketing Authorisation	25/11/2019	16/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation for Purevax FeLV 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 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	10/07/2019	n/a		n/a
WS/1366	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	19/04/2018	n/a		n/a
WS/1195	This was an application for a variation following a worksharing procedure according to Article 20 of	15/02/2018	n/a		n/a

	Commission Regulation (EC) No 1234/2008. 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				
WS/1095	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	15/06/2017	n/a		n/a
WS/0608	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	06/11/2014	n/a		n/a
IG/0430	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	06/05/2014	27/05/2015	PL	The Agency accepted the variation to add the Croatian translations of the Product Information.
IG/0343	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	30/08/2013	n/a		The Agency accepted the variation to tighten the limit of acceptance of the FeLV fraction of Purevax vaccines by mentioning an additional information as follows: “Clear colourless liquid with presence of cell debris in suspension”.
R/0015	Renewal of the marketing authorisation.	13/01/2010	22/03/2010	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Purevax FeLV.
II/0014	II - Other quality changes	17/09/2008	23/09/2008		The European Commission approved a type II variation concerning a tightening of release specifications for the FeLV component. This type II variation did not require any amendment to the Community marketing authorisation.
II/0013	II - Other quality changes	12/12/2007	22/01/2008	Annex II	The European Commission approved a type II variation concerning a change in manufacturer of active substance.
II/0012	II - Other quality changes	12/09/2007	15/10/2007	SPC and PL	The European Commission amended the decision granting the marketing authorisation to amend the sections "compatabilities" and "interactions" of the product literature indicating the compatability of Purevax FeLV with the vaccines of the Purevax range which do not contain the FeLV component as well as the deletion of the freeze-dried presentations.

IA/0011	1A-25-b-1 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	08/12/2005	20/01/2006		The Agency accepted the variation to show compliance of the sterilisation procedure that applies to TRIS buffer with the relevant updated European Pharmacopoeia monograph.
IB/0010	1B-02 Change in name of the medicinal product	13/05/2005	20/01/2006	SPC, Labelling and PL	The Agency accepted the variation on the change of the name of the product from "Eurifel FeLV" to "Purevax FeLV".
R/0009	Renewal of the marketing authorisation.	09/02/2005	21/04/2005	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Purevax FeLV.
X/0008	X-3-IV Change or addition of a new pharmaceutical form	08/12/2004	16/03/2005	SPC, Annex II, Labelling and PL	The European Commission approved an extension for a new pharmaceutical form.
I/0007	03_Change in the name and/or address of the marketing authorisation holder	12/09/2003	24/09/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the address of the marketing authorisation holder.
I/0006	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	12/09/2003	24/09/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the batch release site.
II/0004	II - Other quality changes	12/03/2003	12/05/2003	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to reduce the minimum titre of the vaccine from 10 7.5 to 10 7.2 CCID50 (cell culture infective dose 50%).
I/0005	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	15/04/2003	17/04/2003		The EMEA accepted a type I variation to include additional bovine serum suppliers.
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/10/2002	29/10/2002	PL	The EMEA notified the European Commission of a change in the local representatives.
II/0002	II - Other quality changes	17/04/2002	29/04/2002		The European Commission approved a type II variation relating to the use of material of ruminant origin in Eurifel FeLV and the demonstration of compliance with the CPMP/CVMP "Note for Guidance on minimising the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products".
I/0001	01a-Modification of manufacturing authorisation	12/07/2000	12/07/2000		The EMEA accepted a type I variation to change the manufacturing site for part of the manufacturing process