Purevax RCP 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]
WS/2201	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment	16/02/2022		SPC and PL	The Agency accepted the variation to implement changes in section 4.6 of the SPC following PSUR assessment.
WS/2166/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.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a	19/01/2022	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

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	biological AS				
WS/2004	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.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	15/04/2021	n/a		n/a
IG/1337	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	10/02/2021	n/a		n/a
IG/1296	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	14/10/2020	12/03/2021	Annex II	The Agency accepted the variation to change the name of a site responsible for the manufacture of the active substance.
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	12/03/2021	Annex II	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 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	20/05/2020	12/03/2021	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.
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	20/03/2020	12/03/2021	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.

	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)				
T/0018	Transfer of Marketing Authorisation	27/11/2019	17/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Merial SAS' to 'Boehringer Ingelheim Vetmedica 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/1517	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	24/01/2019	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 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	15/02/2018	n/a		n/a

	protocol				
WS/1151	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	07/09/2017	n/a		n/a
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/1013	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	10/11/2016	n/a		n/a
WS/0606	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/01/2015	15/03/2016	SPC, Labelling and PL	The Agency accepted the variation to extend to 3 years the duration of immunity (DOI) after revaccination for feline rhinotracheitis and feline calicivirus components.
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/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/0007	Renewal of the marketing authorisation.	11/11/2009	15/01/2010	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Purevax RCP FeLV.
II/0006	II - Other quality changes	14/01/2009	13/02/2009	Annex II	The European Commission approved a type II variation concerning the addition of an alternative manufacturing site for the production of inactivated feline calicivirus antigens

					(G1 and 431 strains).
II/0005	II - Other quality changes	17/09/2008	22/09/2008		The European Commission approved a type II variation for an increase of the target formulation titre for the R component and tightening of release specifications for the R and Ch components. This type II variation did not require any amendment to the Community marketing authorisation.
II/0004	II - Update of SPC and PL	12/12/2007	22/01/2008	SPC and PL	The European Commission approved a type II variation concerning an update of the product literature to indicate compatibility of the vaccine with Rabisin.
II/0003	II - New Indication (same therapeutic area)	12/12/2007	22/01/2008	SPC and PL	The European Commission approved a type II variation concerning a change in the product literature to shorten the onset of immunity of the R, C and P components of the vaccine.
II/0002	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/0001	II - Other quality changes	13/07/2005	18/07/2005		The European Commission approved a type II variation to increase the batch size of the freeze-dried component of the vaccine from 80,000 vials to 170,000 vials. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.