Purevax RCP

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				
IG/1389/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	18/06/2021	n/a		n/a
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/1732/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.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 B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) 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	20/05/2020	12/03/2021	SPC, Labelling and PL	The Agency accepted the group of variations to add a 0.5 ml presentation for the diluent and thus for the vaccine, to add a new presentation, to align the PI with the latest version of the QRD template, including proposals for improvements/rewordings and corrections to the PI and one quality-related change.

	of the currently approved pack sizes				
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	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.
T/0017	Transfer of Marketing Authorisation	28/11/2019	16/12/2019	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	19/04/2018	n/a		n/a

	biol/immunol method				
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 protocol	15/02/2018	n/a		n/a
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/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	07/05/2015	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.
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	05/05/2015	PL	The Agency accepted the variation to add the Croatian translations of the Product Information.
WS/0325/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.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	13/12/2012	24/01/2013	SPC, Labelling and PL	The Agency accepted the group of variations to add a site for the manufacturing and primary packaging of the inert diluent (water for injection) of concerned Purevax range vaccines, with a consequent change to the material used for the caps (from aluminium to plastic).
R/0007	Renewal of the marketing authorisation.	11/11/2009	25/01/2010	SPC, Annex II, Labelling and	The European Commission renewed the marketing authorisation for Purevax RCP.

				PL	
II/0006	II - Other quality changes	14/01/2009	17/02/2009	Annex II	The European Commission amended the decision granting the marketing authorisation on 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 amended the decision granting the marketing authorisation on the increase of the target formulation titre and tightening of release specifications for the R component.
II/0004	II - Update of SPC and PL	12/12/2007	25/01/2008	SPC and PL	The European Commission amended the decision granting the marketing authorisation to indicate compatibility of the vaccine with Rabisin.
II/0003	II - New Indication (same therapeutic area)	12/12/2007	25/01/2008	SPC and PL	The European Commission amended the decision granting the marketing authorisation 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	25/01/2008	Annex II	The European Commission amended the decision granting the marketing authorisation on a change in manufacturer of active substance.
II/0001	II - Other quality changes	13/07/2005	18/07/2005		The European Commission amended the decision granting the marketing authorisation to increase the batch size of the freeze-dried component of the vaccine from 80,000 vials to 170,000 vials.