Porcilis ColiClos

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]
IAIN/0011/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)	19/06/2020		Annex II and PL	The Agency accepted the variation to change the name of the manufacturing site for the active substance and batch release.
IAIN/0009	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	24/02/2019	26/02/2020	Annex II and PL	The Agency accepted the variation to add a manufacturer responsible for batch release.
IG/0967/G	This was an application for a group of variations. 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	26/07/2018	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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	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/0007	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	19/04/2018	n/a		The Agency accepted the variation to change the test procedure for the finished product.
R/0006	Renewal of the marketing authorisation.	19/01/2017	29/03/2017	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Porcilis ColiClos.
IG/0718/G	This was an application for a group of variations. 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	22/09/2016	n/a		n/a
IB/0004/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/07/2015	25/07/2016	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to amend the specification parameters and change in test procedures for the finished product.
IG/0465	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	20/08/2014	n/a		The Agency accepted the variation to change the qualified person for pharmacovigilance (QPPV).
IG/0420	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	04/04/2014	24/04/2015	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add the product information in the Croatian language as approved during PALCIII to the Annexes to the Commission Decision.
IB/0001	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	31/10/2012	n/a		The European Medicines Agency accepted the variation to change a specification parameter of the finished product during shelf life.