EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ecoporc Shiga

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/1256/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	15/09/2020		Annex II and PL	The Agency accepted the group of variations to add alternative sites responsible for batch release and secondary packaging.
T/0010	Transfer of Marketing Authorisation	14/02/2020	09/03/2020	SPC, Annex II, Labelling and PL	The European Commission transferred the marketing authorisation from 'IDT Biologika GmbH', Germany, to 'Ceva Santé Animale', France.
IB/0009/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters	02/08/2019	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

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	and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
WS/1484	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.z - Change in container closure system of the Finished Product - Other variation	06/12/2018	n/a		n/a
R/0006	Renewal of the marketing authorisation.	07/12/2017	20/03/2018	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Ecoporc SHIGA.
IAIN/0005	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	30/11/2015	n/a		The Agency accepted the variation to add an additional secondary packaging site for the finished product.
IAIN/0004	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	01/10/2015	n/a		The Agency accepted the variation to add an additional secondary packaging site for the finished product.
IB/0003	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	01/04/2015	18/04/2016	SPC	The Agency accepted a variation to extend the shelf life of the finished product from 2 to 3 years.
IG/0478	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	26/09/2014	n/a		The Agency accepted the variation to update the detailed description of the pharmacovigilance system (DDPS).
IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	07/03/2014	26/02/2015	SPC	The Agency accepted the variation to extend the shelf-life from 18 to 24 months.