EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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]
II/0013	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	05/11/2021		SPC and PL	The Agency accepted the variation to amend the product information to allow the use during pregnancy and lactation.
IA/0014	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	18/06/2021	n/a		n/a
WS/1887	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.II.7.b - Introduction of a new Pharmacovigilance system - Which has been assessed by the relevant national competent authority/EMA for another product of the same MAH	05/11/2020	n/a		n/a
IG/1256/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a	15/09/2020	22/06/2021	Annex II and PL	The Agency accepted the group of variations to add alternative sites responsible for batch release and secondary packaging.

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	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				
IB/0010	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	25/06/2020	22/06/2021	SPC	The Agency accepted the variation to extend the shelf-life of the finished product as packaged for sale from 18 months to 2 years.
T/0009	Transfer of Marketing Authorisation	13/03/2020	08/04/2020	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from IDT Biologika GmbH (Germany) to Ceva Sante Animale (France).
IB/0008	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	17/01/2020	08/04/2020	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 1 year to 18 months.
IG/1122	B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	17/07/2019	n/a		n/a
IB/0006	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	08/03/2019	n/a		n/a
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
II/0004	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	13/09/2018	06/09/2019	SPC, Labelling and PL	The Agency accepted the variation to apply for a widening of the limits for a finished product specification parameter (potency upper limit) and demonstrate safety in target animals. The variation introduces changes to the Summary of Product Characteristic (SPC) and other product information.
IAIN/0003	B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	23/03/2018	n/a		The Agency accepted the variation to delete a finished product test for specified extraneous agents, in accordance with the updated Ph. Eur. monograph 0963.
II/0002/G	This was an application for a group of variations.	07/12/2017	n/a		The Agency accepted the variation to add three additional

	B.III.1.b.5 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New/updated certificate from an already approved/new manufacturer using materials of human/animal origin for which a risk assessment on potential contamination with adventitious agents is required B.III.1.b.5 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New/updated certificate from an already approved/new manufacturer using materials of human/animal origin for which a risk assessment on potential contamination with adventitious agents is required B.III.1.b.5 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New/updated certificate from an already approved/new manufacturer using materials of human/animal origin for which a risk assessment on potential contamination with adventitious agents is required				bovine sera starting materials with new TSE certificates of suitability (CoS) from two already approved manufacturers: Atlas Biologicals, USA, (newborn calf serum and Equafetal serum) and Life Technologies, USA (newborn calf serum).
IB/0001	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	01/08/2017	n/a		The Agency accepted a variation to extend the shelf life of the active substance (antigen) from 5 months to 12 months.