Versican Plus Pi/L4R

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IB/0014	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/04/2019		SPC, Annex II, Labelling and PL	The Agency accepted the variation to correct translation errors in the product information in several language versions (except English) following a quality defect.
WS/1414	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.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	13/09/2018	n/a		The Agency accepted the variation for a minor change in the manufacturing process of the active substance.
WS/1413	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.z - Change in the manufacturing process of the finished or intermediate product - Other variation	13/09/2018	n/a		The Agency accepted the variation for a change to the manufacturing process for the lyophilisate.
WS/1398	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	13/09/2018		SPC and PL	The Agency accepted the variation to update the SPC and package leaflet following PSUR assessment and to align the

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR				text to the latest QRD template.
WS/1337	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	13/09/2018		SPC, Labelling and PL	The Agency accepted the worksharing procedure to use the products Versican Plus range during the second and third stages of pregnancy. However, safety of the products during the early stage of pregnancy and during lactation have not been investigated and this has been stated in the product information. The product information has been simultaneously aligned with the latest QRD template. Annexes A of all products of the range have been updated.
IG/0951	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	05/07/2018	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
IG/0747	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	23/03/2017	05/05/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
IB/0006	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	12/08/2016	05/05/2017	SPC and PL	The Agency accepted the variation to update the SPC and the PL to include a clarifying wording related to 'type of expected hypersensitivity reactions'.
WS/0785	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	21/04/2016	05/05/2017	SPC and PL	The European Commission amended the decision granting the marketing authorisation to extend the duration of immunity for the rabies component to 3 years following the primary vaccination course.
WS/0754/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.1.d - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New manufacturer of material for which an assessment is required of viral safety and/or TSE risk 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	10/12/2015	n/a		The Agency accepted the variation to change the suppliers for starting materials of biological origin, serum and trypsin, to add an additional supplier option and to add a new irradiation vendor.
WS/0753/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.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a	10/09/2015	n/a		The European Commission amended the decision granting the marketing authorisation to increase the batch size for the freeze-dried fractions.

	biological/immunological medicinal product and the change requires an assessment of comparability 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)				
IG/0538	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	01/04/2015	n/a		The Agency accepted the variation to change the QPPV.
IB/0001	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	23/12/2014	n/a		The Agency accepted the variation to add an in-process test.