EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cytopoint

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]
IB/0013	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	16/07/2021		SPC and PL	The Agency approved the variation to update the SPC section 4.6 and the corresponding Package Leaflet section in alignment with the text agreed with CVMP, following assessment of a PSUR. In addition, the applicant has taken this opportunity to correct minor translation discrepancies in the different languages.
IB/0012	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/07/2021	n/a		n/a
II/0011/G	This was an application for a group of variations. B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	21/01/2021	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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II/0009	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	09/09/2020	04/11/2020	SPC and PL	The Agency accepted the variation to add a new therapeutic indication for the treatment of pruritus associated with allergic dermatitis in dogs and the addition of a dog pictogram in point 7 of the package leaflet.
IB/0010	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)	05/08/2020	n/a		n/a
IB/0008	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	30/10/2019	n/a		n/a
IB/0007	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	21/06/2019	27/05/2020	SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC and section 6 of the package leaflet following assessment of a PSUR.
IB/0006/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	29/05/2019	27/05/2020	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to add a new pack size of 1 vial in a cardboard box, for each strength of the finished product.
II/0005	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	22/05/2019	27/05/2020	SPC and PL	The Agency accepted the variation to change the composition of the vial stoppers.
II/0003/G	This was an application for a group of variations. 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 B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the	21/03/2019	n/a		The Agency accepted the group of variations to make changes to the manufacturing process of the active substance, and to make consequential changes to the specifications for the active substance and for the finished product.

	approved specifications limits range for the AS B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				
IB/0004	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	07/12/2018	04/02/2019	SPC and PL	The Agency accepted the variation to update the Summary of Product Characteristics (SPC) and the package leaflet to implement an agreed wording following assessment of a PSUR. In addition, the MAH took the opportunity to delete the list of local representatives in the package leaflet.
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		n/a
IA/0001	A.7 - Administrative change - Deletion of manufacturing sites	25/01/2018	04/02/2019	Annex II	The Agency accepted the variation to delete an active substance manufacturing site. With this procedure the product information was aligned with the latest QRD template v8.1.