ProZinc

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
II/0015	C.II.1 - Variations concerning a change to or addition of a non-food producing target species	21/03/2019	26/04/2019	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new non-food producing target species (dogs).
II/0016	B.I.z - Quality change - Active substance - Other variation	21/03/2019	n/a		The Agency accepted the variation to introduce changes to the active substance manufacturing process and test procedures. Editorial and/or good manufacturing practice (GMP)-related changes were also introduced within this variation package.
IG/1031/G	This was an application for a group of variations. 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 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	14/12/2018	n/a		The Agency accepted the group of variations to register an updated version of the Detailed Description of the Pharmacovigilance System (DDPS), and to change the QPPV.

[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.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				
IB/0014/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	06/07/2018	n/a		The Agency accepted the group of variations to add two new manufacturing sites responsible for quality control testing.
R/0013	Renewal of the marketing authorisation.	15/02/2018	13/04/2018	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for ProZinc.
IB/0012	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	31/10/2017	n/a		The Agency accepted the variation for a change in the manufacturing process. In addition, the MAH took the opportunity to make editorial changes to an analytical method for testing of the finished product.
IG/0831	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	01/09/2017	28/09/2017	PL	The Agency accepted the variation to delete the list of local representatives from the package leaflet.
II/0010/G	This was an application for a group of variations. 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) 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.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes 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 A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	16/03/2017	28/09/2017	Annex II and PL	The Agency accepted the group of variations to register additional manufacturing sites of the finished product. The variation also introduces changes to the manufacturing process.

	finished product, including quality control sites (excluding manufacturer for batch release)				
IG/0722	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	27/09/2016	28/09/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IB/0008/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	05/08/2016	n/a		The Agency accepted the group of variations relating to changes in the manufacturing process.
IA/0007	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	18/07/2014	28/11/2014	SPC	The Agency accepted the variation to include the ATCvet code in the SPC

IB/0006/G	This was an application for a group of variations. B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data) B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	23/05/2014	28/11/2014	SPC, Labelling and PL	The Agency accepted the variation on a change of the storage conditions after first opening together with the extension of the shelf life after first opening.
IB/0005	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	28/03/2014	n/a		The Agency accepted the variation on minor changes in manufacturing process.
IA/0004/G	This was an application for a group of variations. B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	20/12/2013	n/a		The Agency accepted the group of variations to revise the primary packaging documentation and to update the documentation related to the flip-off seal of the product.
IB/0003	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	12/12/2013	28/11/2014	SPC, Labelling and PL	The Agency accepted the variation on the change of the storage conditions after first opening.
IB/0001/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	27/11/2013	n/a		The Agency accepted the variation to address minor changes in the manufacturing process, equipment change, administrative changes.
IB/0002	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	11/10/2013	n/a		The Agency accepted the variation on a correction to the in-process control "volume in container" of the finished product.