EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Spironolactone Ceva

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
IAIN/0014	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	23/11/2016		SPC, Labelling and PL	The Agency accepted the variation to change the name of the medicinal product from PRILACTONE to Spironolactone Ceva.
IG/0620	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	06/11/2015	n/a		The Agency accepted the variation to update the detailed description of pharmacovigilance system (DDPS).
IA/0012	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	22/06/2014	n/a		The Agency accepted the variation for a minor change in the manufacturing process of the finished product, concerning the tablets presented in bottles.
WS/0408	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.9.z - Changes to an existing pharmacovigilance system as described in the DDPS - Other variation	10/10/2013	n/a		The Agency accepted the variation on the modification of the pharmacovigilance system to be in accordance with the revised Guideline EMEA/531641/2010. The main change concerns the change of electronic database including the change of the Qualified person.

[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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IAIN/0010/G	This was an application for a group of variations. B.II.b.2.b.2 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	07/09/2012	31/10/2012	Annex II and PL	The Agency accepted the group of variations to add an alternative batch release site and to update certificates for active substance manufacturers
II/0008	B.II.a.3.b.5 - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study	13/09/2012	31/10/2012	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new flavoured tablet formulation packed in a new presentation, a bottle containing 30 tablets for each strength
IB/0009	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	11/09/2012	n/a		The Agency accepted the variation to add a manufacturer of the finished product
R/0007	Renewal of the marketing authorisation.	08/03/2012	22/05/2012	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for PRILACTONE.
IB/0006	B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue	26/11/2010	26/11/2010		The Agency accepted the variation for the replacement of a specification parameter as a result of a quality issue.
IA/0005	1A-15-b-2 Submission new or updated Eu. Ph. cert suitability active substance	02/12/2009	02/12/2009		The Agency accepted the variation for the submission of a European Pharmacopoeia certificate from a new manufacturer.
II/0002	II - Update of SPC and PL	17/06/2009	20/07/2009	SPC and PL	The European Commission approved a type II variation for additional information to be included in section 5.1 of the SPC and section 14 of the package leaflet regarding the reduction in the relative risk of mortality in treated dogs.
IA/0003	1A-15-a Submission of new or updated Eu. Ph. certificate of suitability active substance	13/07/2009	13/07/2009		The Agency accepted the variation for a new European Pharmacopoeia certificate of suitability for the active substance from a currently approved manufacturer.
IA/0001	1B-33 Minor change in the manufacture of the finished product	07/03/2008	07/03/2008		The Agency accepted the variation concerning minor changes in the manufacturing process of the finished product.