Panacur AquaSol

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.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/01/2018	20/03/2018	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication (*Capillaria* spp. L5 and adult stages) in chickens and to modify the withdrawal period.
IG/0718/G	This was an application for a group of variations. 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 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	22/09/2016	n/a		The Agency accepted the group of variations to update the Detailed Description of the Pharmacovigilance System (DDPS).
IA/0013/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name	12/09/2016	n/a		The Agency accepted the group of variations to make changes to the quality control testing sites.

[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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	and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) 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				
R/0011	Renewal of the marketing authorisation.	16/06/2016	26/08/2016	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Panacur AquaSol.
IA/0012	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/08/2016	n/a		The Agency accepted the variation to to introduce a minor change in the manufacturing process of the active substance, fenbendazole.
II/0010	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	21/01/2016	n/a		The Agency accepted the variation for a change in the specification limits of the finished product.
IA/0009	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	25/09/2014	n/a		The Agency accepted the variation to introduce a second production batch size.
IG/0464	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	20/08/2014	n/a		The Agency accepted the variation to implement the company's updated detailed description of the pharmacovigilance system (DDPS).
X/0003	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	16/01/2014	14/03/2014	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to to add a new target species, chickens, for Panacur Aquasol.
IB/0007	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	20/09/2013	14/03/2014	SPC	The Agency accepted the variation to extend the shelf life of the finished product as packaged for sale from 2 years to 3 years.
IB/0006	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	01/08/2013	n/a		The Agency accepted the variation to change the testing frequency of one test parameter in the release specification of the finished product from batch-to-batch testing to periodic testing.
IA/0005/G	This was an application for a group of variations. B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter	19/06/2013	14/03/2014	SPC, Labelling and PL	The Agency accepted the variation to delete the 125 ml presentation (EU/2/11/135/001) as a registered pack size and to update the finished product specification with regard to this deletion.
IB/0004	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	20/02/2013	14/03/2014	SPC, Labelling and PL	The Agency accepted the variation to add a secondary packaging for the 125 ml bottle presentation and to make minor linguistic changes to the SPC and package leaflet to improve readability.

II/0002	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	13/12/2012	21/01/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new indication in pigs for treatment and control of gastrointestinal nematodes in pigs infected with Trichuris suis (adult stages).
IB/0001/G	This was an application for a group of variations. B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	22/06/2012	n/a		The Agency accepted the group of variations to change the specifications of the primary packaging and to change the shape of the containers.