EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Activyl Tick Plus

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/0016	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	06/11/2020		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 the 10th PSUR.
IG/1043	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	06/03/2019	09/03/2020	SPC, Labelling and PL	The Agency accepted this variation to introduce changes to contact details of the local representatives. In addition, minor changes to the pictograms were introduced.
IG/1026/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	17/12/2018	n/a		The Agency accepted the group of variations to change the name and address of an ASMF Holder, and to change the name of another active substance manufacturer.

[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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IG/0967/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	26/07/2018	n/a		n/a
II/0011	C.I.5.b - Change in the legal status of a medicinal product for centrally authorised products - All other legal status changes	15/03/2018	27/03/2019	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to change the legal status from prescription-only to non-prescription veterinary medicine.
IB/0012/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size 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.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.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 B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	07/12/2017	n/a		The Agency accepted the group of variations to introduce the following changes regarding the manufacture of the active substance, indoxacarb: change in the manufacturing site (deletion of site and addition of new site) and consequential changes to a test procedure, batch size and specification parameters.
II/0008	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	12/04/2017	24/05/2017	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication for sand flies (Phlebotomus perniciosus).
R/0009	Renewal of the marketing authorisation.	06/10/2016	14/12/2016	SPC, Annex II, Labelling and	The European Commission renewed the marketing authorisation for Activyl Tick Plus.

				PL	
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		n/a
IA/0007	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	27/11/2015	n/a		The Agency accepted the variation to change the name of the active substance manufacturer (for the active substance permethrin).
IB/0006	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	13/02/2015	25/02/2016	SPC, Labelling and PL	The Agency accepted the variation to introduce changes to section 4.6 the SPC following assessment of a PSUR.
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).
IB/0004	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)	18/07/2014	05/08/2014	SPC	The Agency accepted the variation to extend the shelf life of the finished product.
IG/0403	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)	05/03/2014	n/a		The Agency accepted the variation to change the current name of the manufacturing site of the finished products. The manufacturing site and all manufacturing operations remain the same.
IB/0002	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	30/08/2013	05/08/2014	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add a pictogram ("Do not use on cats") to the label for the blister (pipette label) and the sachet for Activyl Tick PLus spot-on solution for dogs.
IA/0001	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	26/10/2012	n/a		The European Medicines Agency accepted the variation to add a site for batch control/testing.