EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MS-H Vaccine

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]
IAIN/0018	A.1 - Administrative change - Change in the name and/or address of the MAH	03/05/2021		SPC and PL	The Agency accepted the variation to change the address of the marketing authorisation holder.
II/0017/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	18/03/2021	n/a		n/a
IB/0016	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	20/03/2020	n/a		n/a
IB/0015	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)	13/11/2019	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/0014/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	18/07/2019	n/a		n/a
II/0013	B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method	21/03/2019	30/03/2020	Annex II and PL	The Agency accepted the variation to change the currently approved batch release site in the UK by a new EU batch release site as a result of Brexit for MS-H Vaccine.
II/0012	C.II.7.a - Introduction of a new Pharmacovigilance system - Which has not been assessed by the relevant national competent authority/EMA for another product of the same MAH	21/02/2019	n/a		The Agency approved the variation to introduce a new pharmacovigilance system.
T/0011	Transfer of Marketing Authorisation	29/08/2018	27/09/2018	SPC and PL	The European Commission transferred the marketing authorisation from 'Pharmsure International Ltd' to 'Pharmsure Veterinary Products Europe Ltd'.
IA/0010	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	12/12/2017	n/a		The Agency has accepted the variation to change the name of the quality control testing site.
R/0009	Renewal of the marketing authorisation.	17/03/2016	17/05/2016	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for MS-H Vaccine.
T/0007	Transfer of Marketing Authorisation	21/08/2015	22/10/2015	SPC, Annex II and PL	The European Commission transferred the marketing authorisation from 'Pharmsure Ltd' to 'Pharmsure International Ltd'.
IAIN/0006/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	26/03/2014	05/05/2015	SPC, Annex II, Labelling and PL	The agency accepted the variation on the change of the name of Marketing Authorisation Holder from Pharmsure Ltd to Pharmsure International Ltd.
II/0005	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	16/01/2014	n/a		The Agency accepted the variation to increase the Maximum Release Titre of the MS-H Vaccine.
II/0004	C.I.8.a - Introduction of a new Pharmacovigilance system - which has not been assessed by the relevant NCA/EMA for another product of the same MAH	07/11/2013	n/a		The Agency accepted the variation to update the DDPS.

II/0003	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	13/06/2013	n/a		The Agency accepted a variation to add two additional swine serum suppliers
IB/0002	B.II.b.2.z - Change to batch release arrangements and quality control testing of the FP - Other variation	11/01/2013	n/a		The Agency accepted a variation to add two laboratories to perform the sterility test on the final product for batch release
II/0001/G	This was an application for a group of variations. 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 B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Change (replacement) to a biological/immunological/ immunochemical test method or a method using a biological reagent for a biological AS	09/02/2012	09/02/2012		The European Commission amended the decision granting the marketing authorisation to add an alternative supplier for butyl rubber stoppers and to make a modification to the growth test of the biological raw materials for growth media.