Eurican Herpes 205

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]
IG/1279	A.7 - Administrative change - Deletion of manufacturing sites	14/08/2020	n/a		n/a
IG/1264	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	29/07/2020		Annex II	The Agency accepted the variation to change the name of a site responsible for the manufacture of the active substance.
IG/1230	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)	08/04/2020	n/a		n/a
IG/1204/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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)	20/03/2020		Annex II and PL	The Agency accepted the group of variations to change the names of the site responsible for batch release of the finished product and the site responsible for packaging of the finished product.

[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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T/0024	Transfer of Marketing Authorisation	20/11/2019	10/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation for Eurican Herpes 205 from 'MERIAL' to 'Boehringer Ingehleim Vetmetdica GmbH.
IG/1127/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 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	10/07/2019	n/a		n/a
IB/0022/G	This was an application for a group of variations. 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) 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)	28/09/2017	n/a		n/a
WS/1151	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	07/09/2017	n/a		n/a
II/0017	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	10/09/2015	25/07/2016	Annex II	The Agency accepted the variation to add an alternative manufacturing site for the active substance.
WS/0774	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the	10/09/2015	n/a		n/a

	AS - Other variation				
IB/0018	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	31/07/2015	25/07/2016	SPC, Annex II, Labelling and PL	The Agency accepted the variation to amend sections 4.2 and 4.4 of the SPC following assessment of a PSUR and to introduce a clarification in the wording of the section 4.9 of the SPC.
IG/0581	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	15/07/2015	n/a		The Agency accepted the variation to add two new TSE certificates of suitability from EDQM for the starting material.
WS/0546	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	11/09/2014	n/a		The Agency accepted the variation relating to Foetal Bovine Serum.
IG/0430	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	06/05/2014	20/08/2015	PL	The Agency accepted the variation to add the Croatian translations of the Product Information.
II/0014	II - Other quality changes	12/03/2008	17/03/2008		The European Commission amended the decision granting the marketing authorisation on the removal of routine safety batch testing.
IB/0013	1B-25-a-2 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	08/02/2008	08/02/2008		The Agency accepted the variation on the compliance of an excipient with the European Pharmacopoeia.
II/0012	II - Other quality changes	21/06/2006	28/06/2006		The European Commission amended the decision granting the marketing authorisation on the change to the manufacturing site of the finished product.
R/0010	Renewal of the marketing authorisation.	15/02/2006	18/04/2006	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Eurican Herpes 205.
IA/0011	1A-22-a Submission of a new or updated TSE Eu. Ph. certificate of suitability for an excipient	24/02/2006	24/02/2006		The Agency accepted the variation on the updated European Pharmacopoeia Certificate of Suitability for an excipient.
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/07/2004	n/a	PL	The EMEA accepted a change in the package insert (deletion of the list of local representatives). Amendments have been made to the relevant sections of the EPAR.
I/0008	03_Change in the name and/or address of the marketing authorisation holder	12/09/2003	18/09/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the address of the marketing authorisation holder.
I/0007	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	12/09/2003	18/09/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the batch release site.

I/0006	25_Change in test procedures of the medicinal product	23/07/2003	23/07/2003		The EMEA accepted a type I variation (following a type II procedure) for a change in test procedures of the veterinary medicinal product.
I/0005	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	31/03/2003	19/05/2003	Annex II, Labelling and PL	The EMEA accepted a type I variation to change the batch release site.
I/0004	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	15/04/2003	15/04/2003		The EMEA accepted a type I variation relating to an additional bovine serum supplier.
II/0003	II - SPC update	13/11/2002	14/02/2003	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the warning relating to the mineral oil content of the product.
I/0002	30_Change in pack size for a medicinal product	14/08/2002	02/10/2002	SPC, Labelling and PL	The EMEA accepted a type I variation to add a further pack size and revised annexes to the Commission Decision were issued. The list of local representatives was also updated on this occasion.
II/0001	II - Other quality changes	13/03/2002	22/05/2002	SPC and PL	The European Commission amended the decision granting the marketing authorisation on the change to the vaccination schedule to include the option of administering the first dose of the vaccination regimen during heat as an alternative to 7-10 days after the presumed date of mating.