Coxevac

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/0014	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	17/07/2020		SPC and PL	The Agency accepted the variation to implement changes to sections 4.6 and 4.7 of the SPC and sections 6 and 12 of the package leaflet following assessment of a PSUR.
IB/0013	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	08/12/2017	17/12/2018	SPC and PL	The Agency accepted the variation to update the SPC and package leaflet following assessment of a PSUR.
IG/0827/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.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	17/07/2017	n/a		The Agency accepted the group of variations to change the named QPPV and the detailed description of the pharmacovigilance system (DDPS).
II/0011	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a	10/11/2016	n/a		The Agency accepted the variation to change a test procedure for 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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	method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol				
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).
R/0009	Renewal of the marketing authorisation.	04/06/2015	31/07/2015	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for COXEVAC.
II/0008/G	This was an application for a group of variations. 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 B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	04/06/2015	n/a		The Agency accepted the variation to change the control tests of the active substance.
S/0007		06/11/2014	12/01/2015	SPC, Annex II, Labelling and PL	The CVMP reviewed the specific obligations and concluded that; overall, the evidence continues to support a favourable benefit-risk profile for Coxevac. Since all specific obligations have been fulfilled, there are no remaining grounds for the marketing authorisation to remain under exceptional circumstances.
II/0006	B.I.d.1.a.3 - Stability of AS - Change in the re-test period/storage period - Extension of storage period of a biological/immunological AS not in accordance with an approved stability protocol	10/07/2014	n/a		The Agency accepted the variation to extend the storage period of the active substance.
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.
S/0003		11/10/2012	06/12/2012		The CVMP reviewed the specific obligations and concluded that; overall, the evidence continues to support a favourable benefit-isk profile for COXEVAC. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion.
S/0002		15/09/2011	15/09/2011		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for Coxevac. Full approval

					will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion.
IB/0001/G	This was an application for a group of variations. B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Extension of storage period of a biological/immunological medicinal product in accordance with an approved stability protocol B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	06/05/2011	06/05/2011	SPC	The Agency accepted the variation to extend the shelf life of the finished product from 12 months to 2 years and the storage period of the active substance to 12 months.