Bluevac BTV

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]
II/0010/G	This was an application for a group of variations. C.II.4 - Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue C.II.4 - Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue C.II.4 - Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue	18/06/2020	20/08/2020	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to convert the BLUEVAC BTV8 dossier into a multi-strain dossier (BLUEVAC BTV), and to add the strains BTV1 and BTV4 into the multi-strain dossier. Additionally, the applicant takes the opportunity to slightly amend the address.
IB/0009	C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR:	16/02/2018	21/02/2019	SPC and PL	The Agency accepted the variation to update the product information with the agreed wording following assessment

[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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	implementation of wording agreed by the competent authority that does not require additional assessment				of a PSUR.
IAIN/0008	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	18/07/2016	03/08/2017	PL	The Agency accepted the variation to update the package leaflet to include the list of local representatives.
II/0007	B.III.1.b.5 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New/updated certificate from an already approved/new manufacturer using materials of human/animal origin for which a risk assessment on potential contamination with adventitious agents is required	14/07/2016	n/a		The Agency accepted the variation to add new suppliers for the starting material sterile adult bovine serum.
R/0006	Renewal of the marketing authorisation.	10/12/2015	15/03/2016	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for BLUEVAC BTV8. The CVMP reviewed the specific obligations and concluded that; overall, the evidence continues to support a favourable benefit-risk profile for BLUEVAC BTV8. Since all specific obligations have been fulfilled, there are no remaining grounds for the marketing authorisation to remain under exceptional circumstances.
II/0004/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range 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) B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition or replacement of an in-process test as a result of a safety or quality issue	15/01/2015	15/03/2016	SPC	The Agency accepted the variation to change the pH range in the finished product, to increase the shelf life of the product, and to add pH control test.
S/0003		06/11/2014	15/01/2015	SPC, Annex II, Labelling and PL	The CVMP reviewed the evidence of compliance with the specific obligations submitted by the MAH and recommended the continuation of the Community marketing authorisation for this veterinary medicinal product under exceptional circumstances.
IAIN/0005	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	22/12/2014	n/a		The Agency accepted the variation to change the marketing authorisation holder's appointed Qualified Person responsible for Pharmacovigilance (QPPV).
S/0002		07/11/2013	16/01/2014	SPC, Labelling and PL	The CVMP reviewed the evidence of compliance with the specific obligations submitted by the MAH and recommended the continuation of the Community marketing authorisation for this veterinary medicinal product under exceptional circumstances.
S/0001		08/11/2012	14/01/2013		The CVMP reviewed the evidence of compliance with the specific obligations submitted by the MAH and

					recommended the continuation of the Community marketing authorisation for this veterinary medicinal product under exceptional circumstances.