Veterinary Medicines Directorate

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Post Authorisation Assessments

Avishield IB H120, Lyophilisate for Oculonasal Suspension/Use in Drinking Water, for Chickens

Vm 61812/3004

09 October 2026	Changes in the name and address and contact details of a qualified person for pharmacovigilance (QPPV).
07 October 2026	Introduction of a summary of the PSMF and changes to the summary of the PSMF not already covered elsewhere in this Annex.
19 August 2026	Deletion of the Local Representative and addition of IZO S.R.L. a socio unico as the contact to report suspected adverse reactions.
22 June 2026	Change of marketing authorisation holder from Genera d.d., Svetonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Croatia to IZO S.r.l a socio unico, Via San Zeno 99/A, 25124 Brescia, Italy.
20 May 2026	To update the SPC and QRD in line with version 9.1 of the QRD template. To add the claim for mixed use of three or two vaccines for administration to chickens via spray method.
19 November 2025	To delete the in-process control parameter 'Number of filled vials'. To delete the in-process control parameter 'Number of filled vials'. To delete the in-process control parameter 'Number of filled vials'.
30 April 2025	To replace the current stabiliser with a new stabiliser which is more stable and has a more optimised sterilisation process.
21 December 2023	Editorial changes introduced in parts 2B and 2D of the dossier.
12 June 2023	With this variation the applicant proposes to remove the warning against use in layers and breeders (during lay). The applicant provides additional safety data in order to support the claim for use in laying birds.
18 April 2023	Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance.
05 August 2022	Unlimited Renewal
06 May 2022	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Changes to a test procedure (including replacement or addition) for the active substance.
12 January 2022	Deletion of a non-significant parameter of an active substance in the manufacturing process of the active substance.

	Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Deletion of a specification parameter of the finished product.
11 June 2021	Replacement to a test procedure for the finished product. Change in the specification limits of the finished product.
05 March 2020	Addition of a supplier of packaging components or devices. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a supplier of a starting material.
11 February 2020	Change in the SPC, labelling or package leaflet due to new data.
17 May 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
02 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
26 March 2019	Addition of a supplier of packaging components.
30 October 2018	Change in RMS from UK to NL.
30 August 2018	Update to the labelling to add the local representative.
17 August 2018	Change in the local representative and distributor in Germany