



Post Authorisation Assessments

Avishield IBD Plus, Lyophilisate for Use in Drinking Water, for Chickens Vm 61812/5002

12 March 2026	Changing the legal entity of the MAH 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.
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'.
05 March 2025	To add updates to the data in the lyophilisation cycle table to include validation data for a 5,000-dose presentation and introduce a new specification for rubber stoppers in line with the revised Ph. Eur. monograph 3.2.9.
27 November 2024	Assessment of mock-ups.
20 June 2024	Update of SPC and QRD to version 9 of the template.
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.
21 December 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
24 November 2020	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.