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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Improvac Solution for Injection for Pigs

Vm 42058/5028

•	26 April 2023	Changes 4.5: to add: 'The safety and efficacy of the veterinary medicinal product in non-target species such as horses has not been evaluated. Adverse events have been observed in horses including serious anaphylactic type reactions which have led to fatalities.'
•	21 February 2023	To extend the inter-dose interval from 4 to 8 weeks, and to reduce the minimum age of vaccination in female pigs. One-off alignment of the product information with version 9.0 of the QRD templates i.e., major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 and alignment with version 1 of the GB template.
•	22 December 2022	Change in the specification parameters of starting material used in the manufacturing of the active substance.
•	04 November 2022	To change the test procedure for epitope density for the active substance.
•	25 October 2022	Re-introduction of the option to use casamino-acids that are not treated for salt removal for the manufacturing of diphtheria toxoid.
•	25 February 2022	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place.
•	23 February 2022	Addition of a new therapeutic indication.
•	February 2022	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place.
•	20 December 2021	Changes to a test procedure for a starting material.