



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 February 2026  
EMA/CVMP/366323/2025  
Committee for Medicinal Products for Veterinary Use (CVMP)

## Implementation of submission of risk assessments to control elemental impurities required by the European Pharmacopoeia in immunological veterinary medicinal products

Agreed by IWP	October 2025
Adopted by CVMP	12 February 2026
Date for coming into effect	1 September 2026

Keywords	Elemental impurities, risk assessment, European Pharmacopoeia, immunological veterinary medicinal products
----------	--

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## Introduction (background)

Revision of the European Pharmacopoeia General Monograph 2619 for Pharmaceutical Preparations which came into effect in January 2018, requires manufacturers of products outside the scope of the General Chapter 5.20 to control the levels of elemental impurities in the products using the principles of risk management.

To provide advice on these new requirements, two documents, not applicable to immunological VMPs were published initially on the EMA website: "Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products" and "Reflection paper on risk management requirements for elemental impurities in veterinary medicinal products".

In 2021, the remaining wet chemical testings for heavy metals were deleted from the monographs on substances "for veterinary use only". These revised monographs became applicable in January 2023.

In order to address these new requirements, the development of a guideline on risk management for elemental impurities in VMPs including immunological VMPs has been considered necessary.

In order to allow time for industry to implement these new requirements, the CVMP has adopted the following measured approach to the implementation of the monograph to immunological VMPs. The phased-in implementation of the risk assessment of elemental impurities in immunological VMPs is to be in accordance with the decision tree indicated in this document.

Current control strategies are considered acceptable until a risk assessment is required in line with the phased implementation outlined overleaf. For immunological VMPs authorised before the respective date of implementation detailed overleaf, regulatory action is only expected when the outcome of the risk assessment demonstrates that compliance with the Guideline on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/426245/2023) does require additional controls or changes in the dossier. Routine submission of risk assessments via variations, or otherwise, which conclude that no change is required, is not envisaged. The risk assessment should be available at the manufacturing site for inspection.

