EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products

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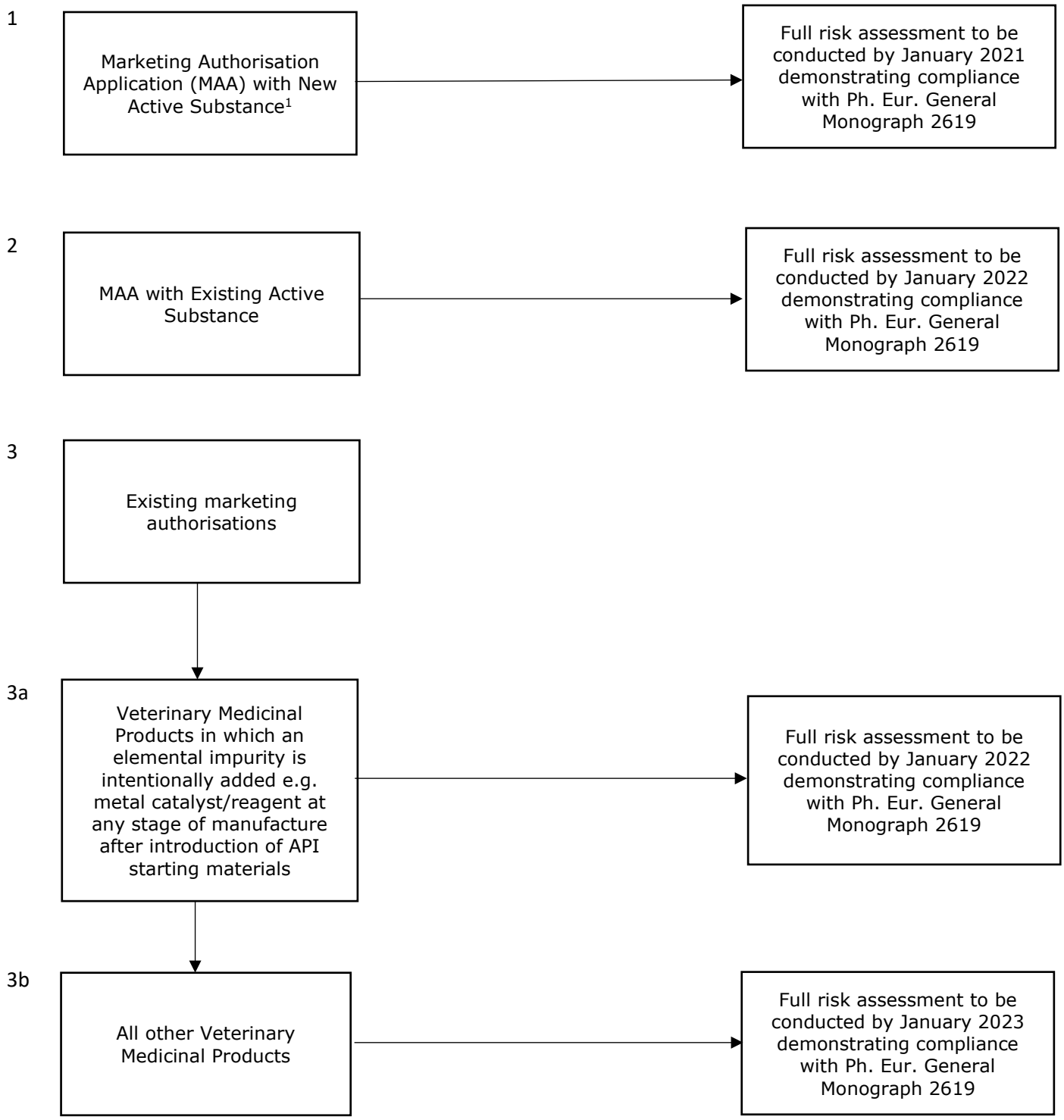
1. Introduction (background)

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. In the case of veterinary medicinal products, the scientific principles on which risk assessment/risk management should be based have not yet been elaborated as the permitted daily exposure (PDE) based approach detailed in General Chapter 5.20 and in ICH Q3D cannot be easily applied to veterinary products.

In order to allow time for regulators to elaborate guidance on the appropriate approach for a risk assessment for a veterinary medicinal product, the CVMP has adopted the following measured approach to the implementation of the monograph to existing veterinary products. The phased-in implementation of the risk assessment of elemental impurities in veterinary medicinal products is to be in accordance with the decision tree indicated in this document.

This phased implementation approach applies to veterinary medicinal products containing chemical and biological/biotechnological substances including veterinary medicinal products containing synthetic and semi-synthetic antibiotics and synthetic peptides of low molecular weight. The scope of this approach does not apply to veterinary herbal products, radiopharmaceuticals, immunological products, veterinary medicinal products designed for gene therapy, regenerative medicine, tissue engineering, blood product therapy and phage therapy or to elements that are intentionally included in a veterinary medicinal product for therapeutic benefit.

Current control strategies are considered acceptable until a risk assessment is required in line with the phased implementation outlined overleaf. For veterinary medicinal products 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 Reflection Paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) 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.



[1] The designated therapeutic moiety, which has not previously been registered in a region or Member State for use in a veterinary medicine (also referred to as a new molecular entity or new chemical entity). It may be a complex, simple ester, or salt of a previously approved drug substance.