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

Draft agreed by QWP	September 2017
Adopted by CVMP for release for consultation	5 October 2017
Start of public consultation	16 October 2017
End of consultation (deadline for comments)	16 November 2017
Agreed by QWP	November 2017
Adopted by CVMP	7 December 2017
Date for coming into effect	1 January 2018
Revision by QWP*	28 September 2018
Agreed by QWP	28 September 2018
Adopted by CVMP	8 November 2018
Date for coming into effect	27 November 2018

* In view of the temporary suspension of guideline work from 1 November 2018, as part of the Agency's business continuity plan, the deadline for implementation of risk assessment requirements has been extended to allow the preparation of adequate guidance.

Keywords	Elemental impurities, risk assessment, European Pharmacopoeia

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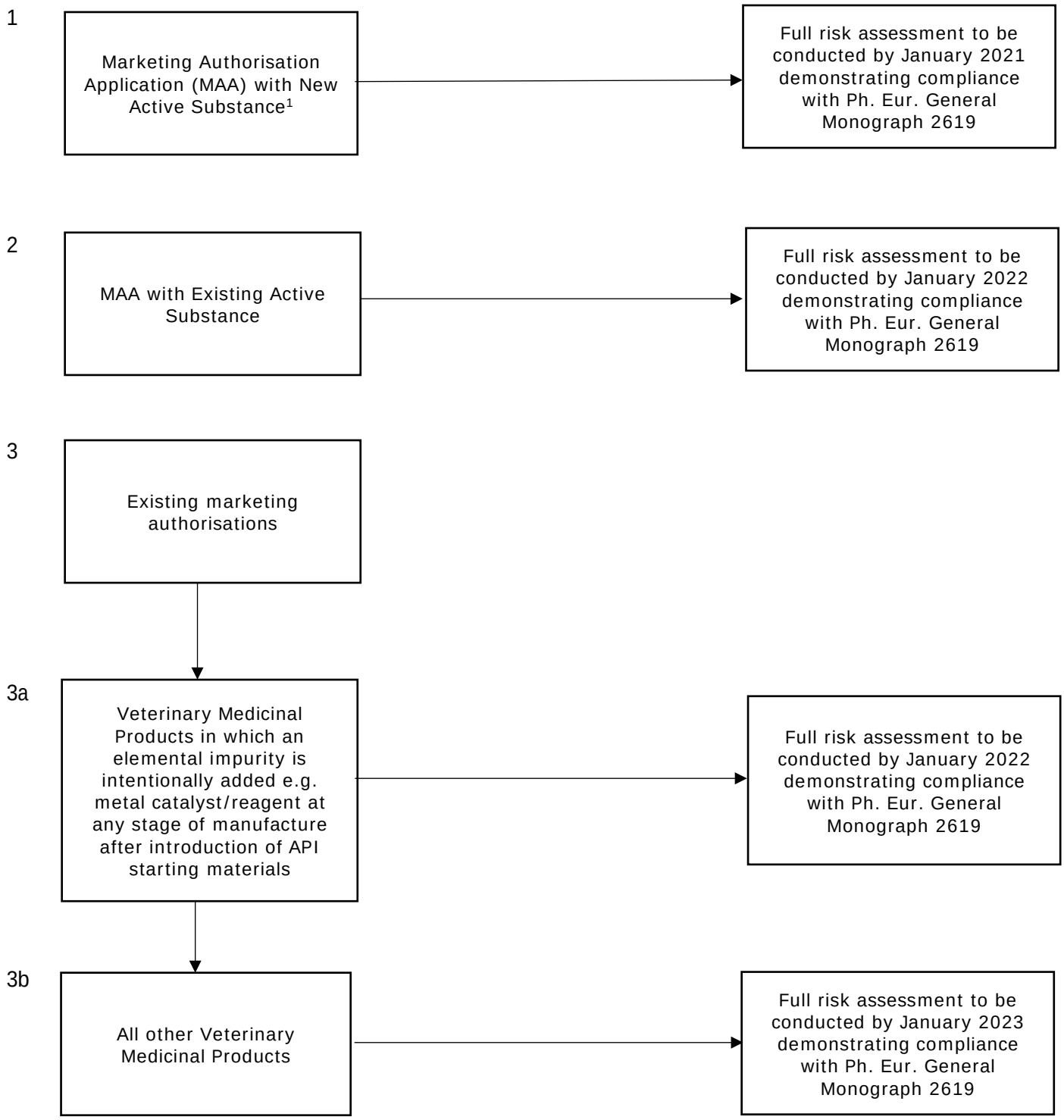
1. Introduction (background)

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. The veterinary medicinal products containing synthetic and semi-synthetic antibiotics and synthetic peptides of low molecular weight are also within the scope of this approach which does not apply to veterinary herbal products, radiopharmaceuticals and immunological products.

Regulatory action is not expected at this time i.e. routine submission of risk assessments via variations, or otherwise, is not envisaged. Current control strategies are considered acceptable until a risk assessment is required in line with the phased implementation outlined overleaf. Further guidance of expected regulatory actions will be elaborated and published in due course.



[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.