10 October 2017
EMA/CVMP/QWP/631010/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

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

Draft

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	<Month YYYY>
Adopted by CVMP	<DD Month YYYY>
Date for coming into effect	<DD Month YYYY>

Comments should be provided using this template. The completed comments form should be sent to Vet-Guidelines@ema.europa.eu

Keywords	

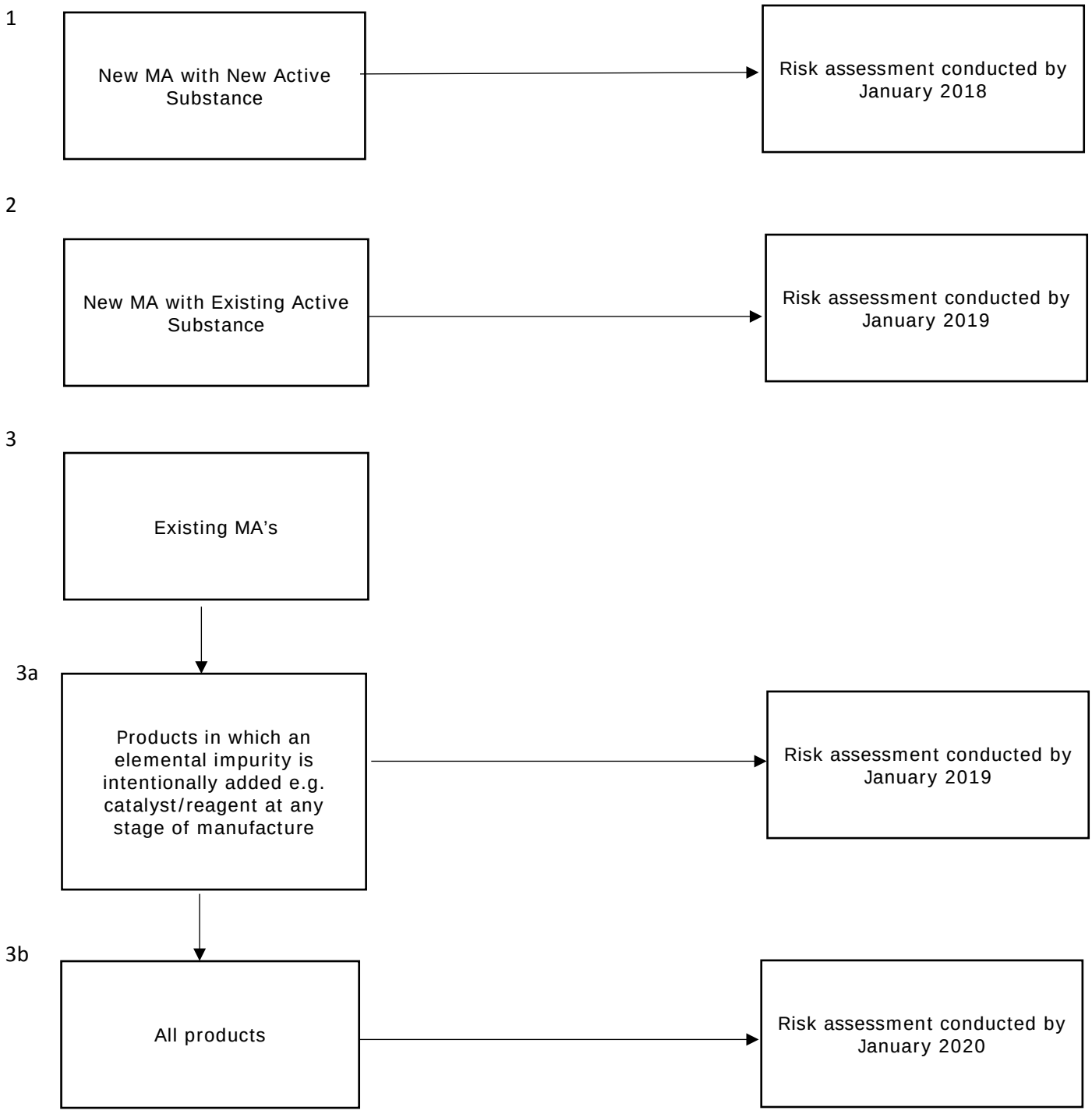
30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. Introduction (background)

Revision of the European Pharmacopoeia General Monograph 2619 for Pharmaceutical Products which comes 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.

Regulatory action is not expected at this time and routine submission of risk assessments via variations, or otherwise, is not envisaged. Further guidance of expected regulatory actions will be elaborated and published in due course.


1
New MA with New Active Substance
Risk assessment conducted by January 2018
2
New MA with Existing Active Substance
Risk assessment conducted by January 2019
3
Existing MA's
3a
Products in which an elemental impurity is intentionally added e.g. catalyst/reagent at any stage of manufacture
Risk assessment conducted by January 2019
3b
All products
Risk assessment conducted by January 2020