Our Ref: 1/2018 15 January 2018

Consultation Document on the Transposition of Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use

Objectives and Scope

Commission Directive 2003/94/EC applies to both medicinal products for human use and investigational medicinal products for human use.

In accordance with Article 63(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council, the Commission is empowered to adopt a delegated act laying down principles of good manufacturing practice for investigational medicinal products for human use.

Main Changes

Deletion of references to investigational medicinal products for human use. Changes to be transposed to Subsidiary legislation 458.42 in line with Directive (EU) 2017/1572.

Publication of these regulations shall repeal Legal Notice 477 of 2012 titled 'Good Manufacturing Practice in Respect of Medicinal Products, Active Substances and Investigational Medicinal Products for Human Use Regulations'.

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Comments

Your comments on the proposed Legal Notice are invited.

Comments are to reach the Medicines Authority in writing or via email consultations.medicinesauthority@gov.mt by the 25th February.

Should any further information be required kindly contact the Medicines Authority using the following contact details:

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