

Date: November 24, 2015

To: European Commission
DG Health and Food Safety
Unit D6 “Medicinal products – Quality, Safety and Efficacy”

(by email to: SANTE-D6-GL-GMP-IMP@ec.europa.eu)

From: Teva Pharmaceutical Industries Ltd

Subject: GL on GMP for IMP – Public consultation on Detailed Commission guidelines on good manufacturing practice for investigational medicinal products, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014

Dear Madams, Dear Sirs,

See below Teva comment on the European Commission detailed Guidelines submitted for public consultation.

Teva Pharmaceutical Industries, duly represented by the private individual(s) indicated herein below, is a stakeholder company with affiliated companies incorporated and active in many Member States of the European Union (“EU”), manufacturing, marketing, distributing and selling Active Pharmaceutical Ingredients (“APIs”) and/or Finished products.

Teva does not fall within the EU definition of a small or medium- sized enterprise.

Lines 350-362

If it becomes necessary to change the expiry date, an additional label should be affixed to the investigational medicinal product. This additional label should state the new expiry date and repeat the batch number and/or clinical trial reference number. It may be superimposed on the old expiry date, but for quality control reasons, not on the original batch number.

The re-labelling operation should be performed by appropriately trained staff in accordance with GMP principles and specific and standard operating procedures and should be checked by a second person. This additional labelling should be properly documented in the batch records. To avoid mix-up, the additional labelling activity should be carried out in an area which is partitioned or separated from other activities. A line clearance at the start and end of activity should be carried out and label reconciliation performed with 100 %.

Comment:

Teva would like to have more clarity in the guidelines if re-labelling operations to change the expiry date require a manufacturing authorization. The guideline is also not clear if certification by a QP is required after re-labelling for change of the expiry date.