Pharmaceutical Industries Ltd.

Date: December 10, 2015

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

(by email to: sante-pharmaceuticals-D6@ec.europa.eu and ADM-GMDP@ema.europa.eu)

From: Teva Pharmaceutical Industries Ltd

Subject: Consultation on EU GMP Guidelines, revised Annex 17 on the Real Time Release Testing

Dear Madams, Dear Sirs,

See below Teva comments on the European Commission Revised Annex 17 of the GMP Guideline 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.

- Section 4.4
  Historical test for sterility results should also be taken into consideration, if available, when evaluating GMP compliance.

  Teva suggest to delete 'if available'. Even with all the detractions of the Sterility test, it is still seen as a referee test and a history of proven performance and compliance is preferable.

- Section 4.19
  Routine monitoring of the steriliser should demonstrate that the validated conditions necessary to achieve the specified process and Sterility Assurance Level are achieved in each cycle.

  The section refers to Sterility Assurance Level but there is no mention as to what the minimum should be to apply for parametric release. While sterilization processes to which parametric release can be applied is mentioned in 4.3, there is no mention as to the type of cycle validation that can be used. Teva suggests to add that parametric release should be restricted to processes that use an overkill method with appropriate sterility assurance level.