Pharmaceutical Industries Ltd.

Date: August 30, 2016

To: European Commission
Unit B4 "Medical products – Quality, Safety and Innovation"
(by email to:) SANTE-B4-GL-IMP-AMP@ec.europa.eu

From: Teva Pharmaceutical Industries Ltd

Subject: Public consultation on the revision of the "Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)"

Dear Madams, Dear Sirs,

Please find below Teva comments on the European Commission public consultation on the revision of the "Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)".

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.

1. General comments

General comment (if any)

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
87-90	Only authorised AMPs may be used in a clinical trial unless an authorised AMP is not available in the Union or where the sponsor cannot reasonably be expected to use an authorised AMP. A justification to this effect shall be included in the protocol. Comment: To address also authorised AMPs used off-label for certain indications as common practise
96	Comment: Subjects do not need to pay for AMPs: often background medication is SoC (that was stable prior to trial) which is not reimbursed by Sponsor
102	Comment: Please review this paragraph for grammar, completeness and correctness of the text.
131	Comment: It is not possible to follow AMP as SoC if not supplied by the Sponsor
138	3.3. Documentation requirements in the application dossier Comment: In view of the Clinical trial regulation, consistent requirements concerning the application dossier should be required and described. Moreover, the CTA xml file should provide the option of entering AMP details
172ff	Comment: The following sentence is grammatically incorrect: "While all SAEs and SARs should be included in the annual safety report of the relevant IMP, and non serious adverse events and non serious suspected adverse reactions should be reported in the Clinical Study Report."

Teva Pharmaceutical Industries Ltd.