Pharmaceutical Industries Ltd.

Date: August 30, 2016

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

From: Teva Pharmaceutical Industries Ltd

Subject: Public consultation on Risk proportionate approaches in clinical trials

Dear Madams, Dear Sirs,

See below Teva comments on the European public consultation on **Risk proportionate approaches in clinical trials**.

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.

General comments
We would like to have clarified if this process will become a mandatory process that sponsor will need to undergo even if there is no wish to get the low intervention waiver
The consultation paper refers to the need to reevaluate the status of the study periodically to see that the conditions didn't change and if yes, it might result in withdrawing the waiver. We like to have clarified if we will be required to start from that point on to "treat" the study as a "regular" risk, or if we need to go back to the study start and gather the required information as if it is a "regular risk study".

Teva Pharmaceutical Industries Ltd.