BEUC The European Consumer Organisation

The Consumer Voice in Europe

European Commission
Unit B4
"Medical products – Quality, Safety and Innovation"
B-1049

Brussels, 30 August 2016

RE: Public consultation on "Risk proportionate approaches in clinical trials"

To whom it may concern,

The European Consumer Organisation (BEUC) welcomes the opportunity to contribute on the Public consultation on "Risk proportionate approaches in clinical trials" published by the European Commission on 1 June.

Please find below our comments on the consultation document.

- **Introduction:** BEUC believes that when mentioning the "Investigational Medical Product" (IMP) a definition of this concept should be provided, since its understanding is very relevant for the comprehension of the whole text.

- **Scope:** BEUC believes that when explaining risk adaptations that apply in particular to low intervention clinical trials, a comprehensive definition of "low intervention" should be included, as well a reference to further the relevant EU legislation and documents of the European Medicines Agency.

- **Safety reporting:** BEUC believes that the document should further and better clarify which are the bases for the selection of the adverse effects that have to be recorded and reported. At the moment this section does not adequately indicates when this reporting necessarily has to occur and when not.

We thank you in advance for taking into account our comments and we remain at your disposal for any questions you may have.

Kind regards,

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Health Policy Officer

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