

The Consumer Voice in Europe

Brussels, 30 August 2016

RE: Public consultation on "Summary of Clinical Trial Results for Laypersons"

To whom it may concern,

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

Please find our specific comments on the consultation document.

On the whole we consider that the document greatly illustrates the way a clear summary should be presented, taking into account many important aspects of its readability. The template is an excellent example and we wish that this will be followed by sponsors when writing their summaries. Few specifications:

- BEUC believes that the document should have a very direct and simple language since its very beginning and therefore we suggest that in the title the word "layperson" is replaced by "citizens" or "general public".
- **Readability and use of plain language:** BEUC believes that in order to define the readability score, each test should involve members of the public in addition to patients with a particular disease. The latter group is likely to have a higher literacy on the topic and therefore its opinion might be slightly biased than that of a common individual.
- **10 elements:** BEUC suggests that the wording of 10 elements to be included in the summary will be mandatory so as to have the same wording and expressions in the all summaries. Also the order on which of these elements will be listed should be the same, so as to facilitate their reading and comparison.

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,

Francesca Cattarin
Health Policy Officer