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Submission of comments on the Consultation Document:

"Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)"

1. General Comments

An updated guideline dealing with "auxiliary medicinal products" used during the clinical trials is welcome since this topic has evolved a lot during the last years and, in some circumstances, the trials are very complex involving several medicinal products along with the Investigational Medicinal Product(s).

It is suggested to make additional efforts to have a final version easy to understand and therefore correctly implemented during the execution of the clinical trials.

2. Specific comments

a. The title and the contents

There is a common and well established knowledge of what is an Investigational Medicinal Products and a definition is already present in the Regulation EU 536/2014. It should be evaluated if the repetition has an added value or it could pose additional problem of interpretation.
For instance, it should be better clarified that a commercial product could be an IMP as a comparator but not as a placebo (rows 54-56).

b. Requirements for AMP (paragraph 3.2)

The GMP requirements for non-authorized AMP needs further clarification. For instance, it has to be explained the meaning of the rows 115-116 where it is stated that "it (*the AMP*) shall be manufactured according to Good Manufacturing Practice (GMP) or to at least an equivalent standard". At least some examples could avoid misunderstanding or misinterpretation.

Doubts comes out from the reading of the sentence (rows 117-118) about the "full GMP equivalent to GMP for IMP may not be required". A rephrasing is welcome for a correct application so to manufacture batches of AMP having suitable quality attributes for the safety of the patients.

[redacted]31 August 2016