30 August 2016

Public consultation on the revision of "Definition of IMPs and use of AMPs"

Comments from:

Name of organisation or individual
[redacted]

1. General comments

PSI CRO AG welcomes the **revision of "Definition of IMPs and use of AMPs"** document. It provides clear guidance in accordance with the CT regulation, but there are several aspects that would need further clarification, as follows.

Specific comments on text

Line number(s) of the relevant text	Comment and rationale; proposed changes
54-56	It should be clarified what types of not registered IMP used as reference medicinal products are acceptable for use in CTs: products not registered in the respective country but registered in another European MS or in an ICH country? Or products registered in another region/country?
87-90	It should be clarified what type of unregistered AMP are acceptable for use in CTs: products not registered in the respective country but registered in another European MS or in an ICH country? Or products registered in another region/country? Or products not registered in any country.
95-98	Can the cost of AMPs be covered by Health insurance companies or National Insurance Schemes?
99-100	Additional clarifications should be provided regarding the paragraph "Member States shall ensure that unauthorised AMPs may enter their territories for the purpose of their use in a clinical trial".
102-109	This paragraph has no predicate (verb is missing).
113-121	Will a simplified dossier be required for modified AMPs? The requirements for this dossier should be specified (see previous version of this guideline, Annex 2).
163	What is the justification for not reporting SARs for unauthorized AMPs?
173	First "and" should be deleted.