LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

2016-08-31 Dnr: 3.4-2016-064618

European Commission
SANTE-B4-GL-IMP-AMP
F101 08/058
B-1049 Brussels
Belgium

Comments from the Medical Products Agency to the public consultation on "Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)" (previously called "Guidance on Investigational Medicinal Products (IMPS) and Non-Investigational Medicinal Products (NIMPs))"

1. General comments

1. Non-authorized AMPs should only be used when relevant justification has been presented. It is recommended that the sponsor seek national or central advice (SAWP) early to receive acceptance for the use of non-authorized AMPs before finalization of the study protocol in clinical trials.

2. Specific comments

Line number in original document	***Proposed change*** and *rational*
102-109	Very long sentence – however it is not complete. *Clarification needed*
121-122	Long sentence – recommended to delete "among other things" Appropriate GMP requirements foreseen for the safety of the patients should still be applied and the sponsor should ensure that AMPs are of appropriate quality for the purposes of the trial, taking into account, ~~***among other things,***~~ the source of the raw materials and any repackaging. *Deletion proposed*
177	Reference unclear. "..and Answers ~~***Paper***~~ Version XX"

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

	Unclear why reference restricted to Paper Version is given.
182-183	The heading has been separated from the Annex text. **Annex 1 – Types of AMPs with Examples – this heading should be moved to next page.** *Typographical error*
283	Replace "doctor's" with "physicians's" … according to the ***~~doctor's~~ physician's*** judgement. *Proposed rewording.*