Comments received from ArisGlobal during the public consultation on the revision of the "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)").

More clarification is required on concomitant medications not even being considered AMPs (lines 76-77). Concomitant medications can form a critical part of study design in some cases – would this elevate them to the status of IMP?

"AMP" is variously used for both 'Authorized Medicinal Product' AND in this document, for 'Auxilliary Medicinal Product' – these are very different entities and same abbreviation will be a source of confusion.

Lines 102-109: This statement identifies extemporaneously manufactured items, but is not complete as It does not define their status as auxiliary medicinal product or not.

Annex 1 is referred to but doesn't have a heading. I believe it starts on line 185.