Comments for EC Public Consultation on recommendations for Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)

Name of Organisation: Gilead Sciences International Ltd.
Category of Organisation: Company/Business

Line no.	Comments
55	By definition a medicinal product with an MA can not be a "placebo" (which is the way this statement reads), consider fragmenting the statement. Suggestion: "test product or reference product (active comparator or placebo)"
87-90	In the draft guidance, the expectation is to include a justification for the use of an AMP not authorized in the Union in the protocol. For multinational studies which involve countries outside the EU, where the definitions of IMP/AMP are different and where the approval status of products is different, this would cause confusion. The guidance currently in effect suggests that such a justification be included in the cover letter, rather than the protocol. It is suggested that the sentence be amended and the justification included in the cover letter, as per the current guidance.
118-122	In situations where the AMP is supplied by the investigator site, it is not feasible for the sponsor to ensure that appropriate GMP requirements are met. It seems that would be the institution's responsibility.
157-184	Clarity is requested on what would be expected with regard to the use and management of reference safety information for AMPs. It is acknowledged that the RSI for IMPs are required to be submitted as part of the CTA and if revised a substantial amendment is required, and that the current approved RSI is required for expectedness assessments. It is requested that the same level of control would not be required for AMPs, i.e. the SmPC would not be required to be submitted as part of CTA application nor submitted as a substantial amendment if there is a change in the RSI.
170-172	If AMP is not authorised in EU, would EudraVigilance accept reports ie. necessary E2B fields?
211-212	Considering line 121, which advises the sponsor to take into account the purpose of the trial, if the pre-medications given routinely as prophylaxis for infusion reactions are not central to the purpose of the trial, should such drugs

	be considered AMPs? For example, acetaminophen and diphenhydramine HCL are routinely given prior to infusion with rituximab per an institutional standard as opposed to a protocol requirement.
275	In this example, as the study subject is already on the background therapy, the sponsor would be unable to confirm the level of compliance described in Section 3.2.
285-287	How shall the sponsor determine the Member States' consensus on standard of care?
302-303	This example seems to describe drug that was prescribed to patients as part of standard of care outside of the clinical trial. It would not be feasible for the sponsor to follow all of the guidance for AMPs in this situation, for example, to ensure appropriate GMP requirements are met, or capture traceability information, such as lot numbers for vials of drug dispensed outside of the clinical trial.