Question Ia: A requirement to have a specification file should be included in this Delegated Act as manufacturers are expected to have such a document for inspection. It is referenced in the Detailed Commission guideline on GMP for IMP (draft). Compilation of the specification file should be the joint responsibility of sponsor and manufacturer.

Question Ib: Yes for manufacturers located in Ireland.

Question 2b: Per the Detailed Commission guideline(draft) 271-273 batch documentation is part of the Trial Master File which is to be retained for 25 years. It is recommended that this matter is also considered by legal experts with experience in clinical trial litigation.

Question3 : Imported comparators will not have certificates of analysis. If it becomes a legal requirement importation of comparators will be negatively impacted.

Question 4a: No but please see there response to 4b.

Question 4b : Yes as this would be required for effective investigations. This is an alternative to keeping a retention sample which would also be acceptable.

Question 5a: This information is not available to the . To our knowledge Article 13(3)(c) has been applied by companies specialising in this area.

Section 3.3(1): Suggest "any laboratories to which manufacturers outsource quality control testing" rather than the term "lay laboratories".