Submission of comments on "Commission Delegated Act on principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014 "

Comments from:

Dr Aurélie Mahalatchimy and Prof Alex Faulkner on behalf of the REGenableMED consortium

Please find below the answer to the 'Commission Delegated Act on principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014' by the REGenableMED consortium.

REGenableMED - REGenableMED is a United Kingdom Economic and Social Research Council (ESRC)-funded project (N°ES/L002779/1: http://www.york.ac.uk/satsu/regenablemed/). It brings together research team builds on work by social science experts based in Birmingham, Edinburgh, Sussex and York in the UK. It is coordinated by Pr Andrew Webster, Science and Technology Studies Unit at the University of York, UK. The project aims to examine the dynamics of innovation within the field of regenerative medicine. Using a mixed-methods social science approach, the project will undertake a detailed analysis of the interplay between business models, measures of clinical utility, patterns of regulatory oversight and clinical workflows within healthcare settings. The results of the research will inform strategies aimed at facilitating the responsible development of effective and useful regenerative medicine products and services.

All work packages of the project consider what we call the 'institutional readiness', i. e. the capacity and willingness of key pre-existing organisations and inter-organisational structures to adopt, respond to and utilise novel technologies, such as advanced therapy medicinal products as part of regenerative medicine. One work package led by Prof Alex Faulkner, Centre for Global Health Policy, School of Global Studies, University of Sussex, the UK is dealing with the role of a range of intermediary agencies, patient groups and health insurance companies, in determining what can be called 'healthcare readiness' for the field, that is, how the field aligns with and can be embedded in existing practice and how far changes need to be made. As part of this work a regular survey of regulatory tools (including relevant linked public consultations) that influence the pathways through which the field develops is performed. The draft response has been prepared by Dr Aurélie Mahalatchimy (academic lawyer) with Prof Alex Faulkner and Prof Andrew Webster (sociologists). A discussion between persons interested was then organised and the attached answer circulated to all project participants before submission.

The REGenableMED consortium is grateful to the European Commission to have been given the opportunity to contribute to this consultation.

COMMENTS

Page 4, line 53: To change "for human sue" by "for human use

Page 6, lines 138- 145: It should be specified that the protection of personal data should be respected in accordance with European Union law.

Page 9, line 273: The links and complementarities between this delegated act, the Commission guidelines specific to GMP for advanced therapy medicinal products and the current Annex 2 on the Manufacture of Biological active substances and Medicinal Products for Human Use should be considered and clarified.
In this Delegated Act, it should also be clarified whether the entire Delegated Act or only paragraph 2. 13 apply to advanced therapy medicinal products.

ANSWERS TO QUESTIONS
Question 1a: Would a requirement for a product specification file (a reference file containing, or referring to files containing, all the information necessary to draft the detailed written instructions on processing, packaging, quality control testing, batch release and shipping of an investigational medicinal product) be useful to be introduced?
Yes, a product specification file would be useful.

Question 2: Different options exist for the retention period of batch documentation:
a) Retention for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used, whichever is the longer period.
b) Retention for at least 25 years after the end of the clinical trial in line with the retention period of the clinical trial master file.
Please indicate the preferred option with justification.
Option b is preferred as it aligns with the retention period of the clinical trial master file.

Question 3: Would it be feasible to require that Certificates of Analysis should accompany each shipment of imported investigational medicinal products as a means to ensure that analytical control had been carried out in the third country? Please elaborate your answer to this question.
We do not know whether it would be feasible. However, both quality and safety would be better acknowledged with these certificates. Thus, it could be recommended to ask these certificates of analysis where available and as much as reasonably possible.

Question 4a: Should retention samples also be required to be retained by the manufacturer?
Yes, but this is already required lines 184- 188, unless the question relates to another manufacturer. In that case, distinction between different manufacturers should be explained.

Question 4b: If only reference samples are required, would a requirement for photos of the investigational medicinal product, the packaging and the labelling to supplement the reference sample be useful? Please justify.
Yes, it may be useful although requirements should not be overwhelming beyond what is necessary. Thus, a recommendation may be better than a requirement.