

Comments on SI 2008/941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008

The implementation of the European Commission 'GCP Directive', 2005/28/EC has resulted in an amendment to the UK clinical trial legislation - SI 2004/1031 previously amended by SI 2006/1928 and 2006/2964.

SI 2008/941 has been introduced to implement further amendments and became effective 1st May 2008.

Summary

The amended legislation does not differ radically from the original statutory instrument (SI). However, there are some key elements to consider with respect to the Sponsor Company's operational processes.

The main points of the amended legislation are:

1. Updates to the definition of the Clinical Trials Directive (2001/20/EC, Medicinal Products Directive (2001/83/EC) and Gene Therapy Advisory Committee (GTAC) have been implemented (Regulation 2). This mainly updates cross-referenced documents offering a better understanding of the amendments for the definitions.
2. Changes to the regulations regarding ethics committees have been made which will allow greater flexibility within ethics committees to delegate to other suitable person(s) (defined as "expert members") if it is considered to be appropriate, based on their qualifications or experience (Regulation 3 and 5).

3. Updates included in this legislation include changes to the Blood Safety and Quality Regulations but impact on the aforementioned Clinical Trials Directive. Changes include that SAEs relating to the quality or safety of blood or blood components will be held for at least 15 years by the person responsible for the management of a hospital blood bank. This changes the original legislation to add a specified retention period for SAEs, where there was none previously. Additionally, this update provides a wider scope for which SAEs will be retained by the blood bank (Regulation 8).

4. Amendments have also been made to the original legislation and largely have a focus on paediatric trials. The changes made are clarifying the requirements expected for those that are acting as the legal representative of an incapacitated (mentally or physically) adult or a minor. The update is regarding informed consent (regulation 4) during times of urgent treatment or when urgent action is required and adhering to current requirements is not practicable.

Detail of the Changes

Below is a list of the main changes to the UK legislation. Please note that this is not exhaustive and additional minor text changes, clarifications and corrections to the legislation, that are considered to have negligible impact, have not been included in this review.

Part 1 - Introductory Provisions Regulation 2 (Interpretation):

- Some minor changes to definitions.

Part 3 - Authorisation for Clinical Trials and Ethics Committee Opinion

Regulation 15 (Ethics Committee opinion):

- **Paragraph 1:** removes the requirement for GTAC to give an opinion regarding a clinical trial, when a valid application is made (subject to conditions)
- **Addition of paragraph 3A:** allows ethics committees to give a favourable opinion in writing regarding a clinical trial (subject to conditions)
- **Addition of paragraph 4A:** this new section gives regulation to how GTAC may delegate to a more suitable ethics committee if required. The ethics committee may then give a favourable opinion regarding the trial instead of GTAC within the specific timelines
- **Addition of paragraph 4B:** allows GTAC to not give an opinion of the trial if notification is given to the regulatory authority by the Chairman, vice-chairman or alternative vice-chairman within the specified timelines

Schedule 1 - Conditions and Principles of Good Clinical Practice and for the Protection of Clinical Trial Subjects

- **Paragraph 1:** specifies the requirements for the legal representative for a minor regarding deferring informed consent during a clinical trial if urgent treatment or action is required, and meeting all of the prior requirements set in paragraph 1 are not practicable. It is also specified that this is only in cases that are previously agreed by an approved ethics committee

Schedule 2 - Additional Provisions Relating to Ethics Committees

- **Paragraph 1:** minor change to the definition of "expert member"
- **Paragraph 6:** updates to the regulations now insist that when a valid application is considered by an ethics committee for an opinion, the meeting must include all members of the committee where a minimum of 7 members is specified. Further clarification of the requirements of 'lay' and 'expert' members has been included. Additional regulation has also been given to clarify that responsibility of the overall final opinion can also be given by the ethics committee chairman or a specified sub-committee
- **Paragraph 7:** changes the responsibility as to who may appoint a person who can act as a deputy to the expert member. The appointing authority, instead of the ethics committee, now holds this responsibility
- **Paragraph 8:** specifies the requirements for a co-opted member who must have or must be currently a member of an ethics committee for clinical trials involving human subjects (human subjects were not specified in superseded regulations). Additionally, in the regulation updates, a co-opted member appointment and removal/release from a position must now be specified in a procedure defined by the committee

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