Revision of the Clinical Trials Directive 2001/20 EC, Concept Paper for Public Consultation

An Bord Altranais Submission

May 2011

An Bord Altranais is the Irish statutory body which provides for the registration, control and education of nurses and midwives and for other matters relating to the professions and the practice of nursing and midwifery. It sees its overall responsibility to be in the interest of the public. An Bord Altranais appreciates the opportunity to offer its comments to the European Commission regarding the Revision of the Clinical Trials Directive 2001/20 EC, Concept Paper for Public Consultation. An Bord Altranais has published *Guidance to Nurses and Midwives Regarding Ethical Conduct of Nursing and Midwifery Research (2007)* to support the professions in their practices.

This response has been prepared with reference to the 18 consultation items identified in the Concept Paper. In general An Bord Altranais supports the preliminary appraisals as described in the Paper. Where relevant specific comments about an individual consultation item are included.

Consultation item no. 1: Single submission with separate assessment

An Bord Altranais agrees with the appraisal of a single submission with a designated portal acting as a distributor for the EU states. This has the benefit of reducing administrative work.

Consultation item no. 2: Separate assessment

An Bord Altranais agrees with that a separate assessment could continue to require administrative costs that are not cost effective and/or efficient for stakeholders involved in the clinical research process.

Consultation item no. 3: Single submission with subsequent central assessment

A subsequent central assessment would indeed present concerns that would not address any cultural, ethical, national or local viewpoints of member states. An Bord Altranais agrees with this appraisal.

Consultation item no. 4: Single Submission with a subsequent 'coordinated assessment procedure', completeness of the catalogue

The concept of a 'coordinated assessment procedure' (CAP) appears to be well developed. It is critical that the ethical/moral issues that may influence member states in the assessment of a submission be addressed by the individual member states. The importance of debating ethical matters relating to clinical research should be recognised as first pertaining to the scope of each member state. The risk-benefit assessment and aspects relating to medicine quality and labelling are appropriate elements to inform the CAP.

Consultation item no. 5: Agreement to include only aspects of point a for the CAP

An Bord Altranais agrees that the criteria outlined in point a is appropriate for the scope of the CAP.

Consultation item no. 6: Disagreement with the assessment report

An Bord Altranais prefers the first approach of an individual member state being allowed to opt out. This would allow for the independent decision making by each member if there were justified concerns regarding a serious risk to public health or safety of the participant. There may be singular or multiple countries which may specific considerations of public safety that are not an issue for others. Individual constitutions and legal frameworks may influence these considerations and decisions. This should be protected by the opt out method versus the other options presented.

Consultation item no. 7: Mandatory/optional use

The second option is preferable for the CAP being mandatory for all multinational clinical trials. The criteria for the CPA are robust and it would promote continuity of the process for assessment throughout the member states. Efforts could be streamlined when performing multinational trials, thus potentially reducing workload on the part of stakeholders for ensuring compliance for such trials.

Consultation item no 8: Workability of a pre-assessment in practice.

As a regulator An Bord Altranais is not directly associated with the conduct of clinical research therefore it is not in the position to make specific comment of its workability. However it would seem possible that such a pre- assessment is workable if the information provided was comprehensive and the structures and processes were understood and clearly followed by participants. The protection of the patient involved in the research is of the utmost priority thus making sure that the criteria outlined in points a and b are closely followed and monitored is critical.

Consultation item no. 9: Enlarging the definition of non-interventional trial

An Bord Altranais agrees with this appraisal to have comprehensive requirements applying to all clinical trials versus limiting the scope of the Clinical Trials Directive.

Consultation item no. 10: Excluding clinical trials by 'academic/non-commercial sponsors'

An Bord Altranais supports the appraisal not to exclude clinical trials by academic and/or non-commercial sponsors from the scope of the Clinical Trials Directive. It agrees with the rationales provided in the paper. Issues of trial subject protection (from ethical and clinical standpoints) may arise if there are exclusions permitted for these groups.

Consultation item no. 11: More precise and risk adapted rules for the content of the application dossier and for safety reporting

An Bord Altranais believes this appraisal is appropriate with detailed provisions included as part of an annex to the fundamental legislation. It is critical that a robust set of rules are in force for application records and most importantly for safety reporting. This should have the benefit of consistent reporting and comparison of safety information across member states.

Consultation item no. 12: Other key aspects on which more detailed rules are required

An Bord Altranais has not identified any other key aspects. It stresses the need for clarity and consistency in the application and monitoring of these rules in the conduct of clinical trials.

Consultation item no 13: Clarifying the definition of 'investigational medicinal product' and **establishing rules for 'auxiliary medicinal products'**

An Bord Altranais supports this appraisal. The cumulative approach suggested is comprehensive and identifies the separation of investigational medicinal products and auxiliary medicinal products.

Consultation item no. 14: Insurance /indemnification – policy options

An Bord Altranais believes optional indemnisation by member states is favourable in view of the legal and practical obstacles. There should be some requirement for indeminsation and insurance coverage regardless of the low risk(s) attached to the trial. The patient must be protected and professionals and organisations should be indemnified in participating in clinical research.

Consultation item no. 15: Single sponsor

An Bord Altranais agrees with the appraisal of maintaining the concept of a single sponsor. Clear lines of accountability and governance for communication and information sharing regarding the various aspects of clinical research (particularly safety concerns) will be optimised by the requirement of a single sponsor compared to multiple sponsorships.

Consultation item no. 16: Emergency clinical trials

An Bord Altranais supports this appraisal to ensure the patient/trial subject is protected and informed of any involvement in emergency clinical trials. The international texts referenced in this section should be used as a basis in drafting any amendments to the Clinical Trials Directive. These documents are established as best practice guidelines for ethical treatment of subjects.

Consultation item no. 17: Ensuring compliance with good clinical practices in clinical trials performed in third countries

An Bord Altranais believes that a robust regulatory framework is necessary to ensure safe ethical practice involving clinical research trials in all countries. It is aware of the increasing numbers of trials being conducted in third countries which may not have the appropriate legal and clinical governance frameworks in place. Therefore the suggested actions put forward in

Section 3 of the concept paper should be implemented in order to provide greater transparency and accountability of sponsors and their clinical research in third countries.

Consultation item no. 18: Additional comments

An Bord Altranais recognises the significant contribution of clinical trials research in the promotion of health and treatment of disease and illness for all populations. In the regulator's guidance to the nursing and midwifery professions about research it stresses the ethical principles which must be adhered to by nurses and midwives. An Bord Altranais supports the European Commission's move to revise the Clinical Trials Directive 2001/20/EC, strengthening the ethical and governance requirements for conducting clinical research.

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