FACULTY OF PHARMACEUTICAL MEDICINE RESPONSE TO THE EUROPEAN COMMISSION CONCEPT PAPER ON THE REVISION OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC
13/05/11

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM) welcomes the opportunity to respond to the EC Concept Paper on the revision of the Clinical Trials Directive. Many of the FPM members, who are all Pharmaceutical Physicians, work in the area of clinical research so this consultation is particularly relevant.

Question 1. The FPM agrees with the proposal for a single submission possibly via an 'EU Portal'.

Question 2. The FPM agrees that a separate assessment done independently by each Member State would provide no advantage over the current scheme.

Question 3. The FPM agrees that a central assessment would not be appropriate for clinical trials approval and that a parallel national procedure would still be required for ethical, national and local issues.

Question 4. The FPM proposes a single submission procedure via a central portal but for the sponsor to be able to choose which Competent Authority should do the assessment. Such a mechanism would be similar to mutual recognition with a lead Competent Authority.

Question 5. The FPM agrees that the coordinated assessment procedure (CAP) should not include ethical review or local issues.

Question 6. A Member State must have the ability to opt out of taking part in a clinical trial.

Question 7. The FPM believes that the CAP must be optional and that sponsors should retain the ability to follow national procedures as laid down in the current Clinical Trials Directive. However, we believe that our proposal as outlined under Q4 would be advantageous to the majority of sponsors and make the clinical trial approval process in Europe much more efficient.

Question 8. The FPM strongly approves of the proposal for pre-assessment where the sponsor requests it as the sponsor believes that the trial fits the criteria as laid down in 1.3.4 (a) and (b) i.e. the trial is low risk by definition.

Question 9. There is no doubt that better harmonisation of the requirements for Clinical Trial Authorisation would be a step forward as long as the requirements did not introduce more bureaucracy into the current system. On the other hand broadening the scope of the definition of non-interventional trials could be beneficial and might lead to more harmonisation. The FPM has no strong opinion either way, but wishes to see a more efficient system than the current one.

Question 10. Under no circumstances should academic/non-commercial trials be excluded from the Clinical Trial Directive. Competent Authority decisions should be made on the basis of the trial not who the sponsor is.
Question 11. The FPM agrees with this appraisal

Question 13. The FPM supports the proposal to clarify the definition of investigational medicinal product (IMP) and particularly supports the concept that only medicines that are the subject of the study are covered by the requirements for IMP

Question 14. The FPM is of the opinion that all clinical trials covered by the Directive require indemnity but that this should be proportionate to the degree of risk. An "optional indemnisation" by Member States is an interesting concept but in our view is likely to be a pipedream within the current financial climate.

Question 15 The FPM believes that the concept of a single sponsor should be retained but the problems that have arisen around this concept could be considerably reduced by better harmonisation.

Question 17. The FPM does not agree that all third country trials should be registered with EudraCT but strongly supports the proposal that all clinical trials should be registered in an easily accessible public database. Sponsors may prefer to use other databases for third country trials e.g. Clintrials.gov. Nevertheless, the option to register these trials via EudraPharm should be made available.

Question 18. The FPM wishes to repeat its recommendation that sponsors should be able to choose its lead Competent Authority to assess its clinical trial application where two or more Member States are involved. The lead MS must have at least one centre performing the trial. We believe this will make Europe more competitive on a global basis and also lead to competition and more efficiency between Member States