EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
D(2012)

Opinion

Title **DG SANCO – Commission proposal for a Revision of the "Clinical Trials Directive" 2001/20/EC**

(Resubmitted draft version of 15 February 2012)

(A) Context

In its 2008 communication, 'Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector', the Commission announced that an assessment would be made of the working of Directive 2001/20/EC (the 'Clinical Trials Directive'). This assessment would consider, in particular, various options for improving the functioning of the Clinical Trials Directive (CTD), which harmonises legislation on the clinical research environment and sets out good clinical practice (GCP) in the EU. The Commission's comprehensive assessment report, the 'Impact on Clinical Research of European Legislation' (ICREL) was launched in 2008, funded under the 7th Framework Programme. Based upon the shortcomings identified in this and other assessments, the Commission seeks to revise the Directive on clinical trials in order to strengthen knowledge and innovation in clinical research, reduce administrative burden and delay prior to the commencement of clinical trials, avoid divergent decisions throughout the EU and enhance streamlining of reporting procedures.

(B) Overall assessment

The report has been improved along the lines of the recommendations issued by the Board in its first opinion. However, a number of aspects should be further strengthened. In particular it should better link the problems identified to the specific requirements of the Clinical Trials Directive and should better demonstrate the nature of market failures regarding insurance. The report should more fully explain the substance of and assess the insurance indemnification option, and better justify the choice of this approach. Finally monitoring and evaluation arrangements should be outlined in greater clarity.

(C) Main recommendations for improvements

(1) Provide a clearer problem definition. The report should provide a clearer description of the problems by showing the extent to which these can be related to the current Directive. In particular it should better explain how the problems relating to separate notification and submission are directly related to the Directive, since many of the issues raised can be avoided if the voluntary harmonised procedure is used. While the report provides a clearer summary of the findings of the ICREL study it should better

demonstrate how the problems identified in that study specifically relate to the current rules. Where possible, the report should strengthen the evidence of movement of trials to other regions and of stopping of trials by smaller players as a consequence of the CTD. The report should better describe the nature of market failures regarding insurance and should better explain the basis for the 800% increase in premiums. Furthermore, while stakeholders' criticisms of the Directive are included these should be more specific to the actual problems deriving from the Clinical Trials Directive. The problem definition should be expanded to better demonstrate why the inclusion of academic sponsors is a problem and why a 'national indemnification mechanism' may be necessary. Based on this expanded problem definition a more developed baseline scenario should be presented, showing how the nature of clinical trials would evolve in the absence of EU action.

(2) Strengthen the intervention logic and better explain the policy options. The report should more fully explain the substance of the option for a national indemnification mechanism in particular clarifying to whom this would apply and how it would work in practice. The report should better explain the effect of policy option 2/6 where it stated that the obligatory insurance/national indemnification would not apply for low-risk trials.

(3) Better present the impacts of the policy options. In light of the reasons given as to why the voluntary harmonised procedure approach is not considered sufficient, the report should better explain why a new procedure enshrined in legislation would be more effective. The report should better justify the choice of a national indemnification mechanism as a preferred option in light of the opposition of some Member States and national insurers associations to this approach. The terminology used in the report to indicate administrative costs, other compliance costs and total costs should still be further clarified. The report should furthermore describe in more detail how the share of "operational costs" in the total costs has been determined and how robust this estimate is.

(4) Outline clearer monitoring and evaluation arrangements. The report should clarify whether a comprehensive interim evaluation will be carried out and its timing.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation. The report is too long and should be shortened for example by making the problem definition more concise while moving some material to the Annexes.

(E) IAB scrutiny process	
Reference number	2011/SANCO/015
External expertise used	No
Date of Board Meeting	Written procedure The present opinion concerns a resubmitted draft IA report. The first opinion was issued on 20 January 2012