EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
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Opinion

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

(draft version of 14 December 2011)

(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, 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 should be significantly improved in several respects. The report should present the problems identified with the current Directive in a clearer and more concise way, for example by indicating how the Directive has affected trends in the numbers of clinical trials in the EU in relation to third countries, and by better presenting the views of stakeholders. It should strengthen the intervention logic by including more operational objectives and by providing a revised policy options section, which better justifies and explains the substance of each of the options and clearly links them to the problems identified. The report should better explain the impacts of the measures and provide a clear distinction between the administrative costs and burdens, implementation costs, and total costs. Finally, the report should outline clearer measures for monitoring and evaluating the performance of the proposal in terms of the overall objectives.

Given the nature of these recommendations, the Board asks DG SANCO to submit a revised version of the report, on which it will issue a new opinion.

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(C) Main recommendations for improvements

(1) Provide a clearer problem definition. The report should briefly explain how the Directive relates to other relevant pieces of pharmaceutical legislation, such as marketing authorisation. It should then provide a clearer and more concise description of the problems, showing the extent to which these can be related to the current Directive, and/or to other factors affecting the overall environment in which clinical trials are carried out. It should try to demonstrate if there is a causal link between the impacts of the current Directive and the decline in the numbers of clinical trials in the EU, and show the extent to which this decline is reflected in a corresponding increase in clinical trials in other world regions, and what the underlying trends are. The report should also demonstrate how the current rules have had effects in terms of delays in launching clinical trials, expenditure and resources implications for pharmaceutical companies, by providing a clearer summary of the findings of the ICREL study. The report should describe the nature of market failures regarding insurance and should underpin this by available evidence. It should then identify the enterprises and research bodies primarily affected by the current situation, as well as the impact on SMEs, and clearly present the views of each stakeholder group in relation to the functioning of the Directive and the general environment for clinical trials. The report should provide more in-depth evidence of the existence of the problem of fragmentation of authorisation and assessment procedures by providing concrete examples, and indicating clearly the number and the nature (scale) of clinical trials that are conducted in more than one Member State.

(2) Strengthen the intervention logic and better explain the policy options. The report should further strengthen the intervention logic by clearly linking the problem definition to specific and more operational policy objectives and to the range of options. The report should consider explicitly including 'administrative burden reduction' and 'improved compliance' as key objectives. Options 2.3 (excluding academic sponsors) and 2.5 ('national indemnification mechanism') should be matched by a clearly identified problem. The report should more fully explain the substance of each of the options. For example it should explain under policy option 1.3 (Single submission with joint assessment) how the Member State carrying out the in-depth assessment would be chosen in practice, given the increased costs for this Member State. Also, given that under this option, separate decisions are made by the Member States following joint submission/assessment, it should be better explained how this would contribute to solving the problem of fragmented advice from National Competent Authorities, and whether all participating Member States are bound by the non-ethical elements of the decision. How the estimation of 60 days for concluding this process has been determined should be explained. The report should also further support its reasons for dismissing the baseline option, explaining why the voluntary harmonised procedure approach is not considered sufficient, and should avoid discussing in depth options that appear not to be feasible (e.g. option 2.3). Finally, the report should clearly present stakeholder views on each of the policy options. For instance, in relation to option 1.5, the report should transparently present the conflicting views of stakeholders and further discuss the merits of the use of a Regulation over a Directive in terms of the overall policy objectives.

(3) Better present the impacts of the policy options. Where a combination of options is being considered (e.g. options 2.4, 2.5, 3.2 and 3.3), the report should assess the impacts of this package of options as a whole, and compare it against the baseline scenario in its own right. The report should better explain the estimated economic benefits arising from the option for a national indemnification mechanism and should generally ensure clarity

between all estimates for administrative burdens, administrative costs, other compliance costs and total costs, ensuring their robustness, consistency and accuracy. It should clarify why the options for non-EU site inspections and regulatory systems inspections are mutually exclusive and should justify the preferred option on the grounds of subsidiarity.

(4) Outline clearer monitoring and evaluation arrangements. The report should propose more operational arrangements for monitoring of compliance and evaluation, and outline more elaborated impact indicators, which are clearly linked to operational objectives. It should also clarify the role of the Pharmaceutical Committee in monitoring the implementation process, and outline how reductions in administrative costs will be determined.

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. In order to better support decision making, the report, and the problem definition section in particular, should be presented in a more concise and focused manner. The executive summary should be fully aligned with the main report.

(E) IAB scrutiny process	
Reference number	2011/SANCO/015
External expertise used	No
Date of Board Meeting	18 January 2012