Roche

Pharmaceuticals

European Commission
DG SANCO
Mrs. Dr. Patricia Brunko
Mr. Stefan Führing
Unit Pharmaceuticals –
SANCO C8 (new D3)
BREY 10/114
BE-1049 Brussels

Basel, 11th May 2011

Roche Response to Public Consultation on Revision of the Clinical Trials Directive 2001/20/EC

Dear Dr. Brunko and Mr. Führing,

Thank you for providing us with an opportunity to comment on the concept paper published by DG SANCO in preparation of the legal proposal on the Clinical Trial Directive. Roche highly appreciates the sensitive selection of topics for this second consultation round and, as an innovative company in pharmaceuticals and diagnostics, we would like to provide you with our comments.

While innovation is the backbone of the EU 2020 Agenda, this high-level political objective can only be achieved if it is reflected in concrete pieces of legislation that influence the day-to-day business of innovative sectors, such as the pharmaceutical industry. In this sense, the upcoming revision of the Clinical Trials Directive can be seen as a chance to improve a piece of legislation that is central for pharmaceutical research and thus patients' access to innovative medicines.

The current regulatory framework for clinical trials, applicable since 2004, has been criticised by regulators and stakeholders alike. In addition to the strain it puts on resources, it has resulted in limited alignment between Member States regarding the scientific assessment and authorisation of clinical trial applications as well as an increase in administrative burden. Diverging practices of national authorities and ethical committees in the different Member States add to the complexity of the system. Delays in authorising clinical trials, especially in the area of multinational trials, are the rule rather than the exception. These delays may also negatively impact innovation, particularly in the early phases of development when companies require studies to be initiated in a predictably quick and efficient way. Uncertainties in obtaining a clinical trial approval may discourage companies from taking innovative approaches.

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To restore and enhance the attractiveness of conducting clinical research in Europe, key changes are necessary in relation to the assessment and authorisation of a clinical trial with the following objectives:

1. It should be possible to submit all documents required for multinational clinical trials to one single EU portal. All communication between the sponsor and national authorities and ethics committees should be coordinated via this portal. At a minimum, core documentation should only be required in English.
2. The requirements for benefit-risk documentation and assessment should be fully harmonised in the EU, preventing Member States from adding their own rules.
3. A central, up-to-date overview of requirements that fall under national competencies (e.g. insurance and ethical committees) should be established to allow for improved predictability. Better exchange and voluntary cooperation between ethical committees should be encouraged.
4. To make the process easier to predict the clinical trial application assessment should be linked with any previous scientific discussion (scientific advice, paediatric investigation plan).
5. "Centres of Excellence" for defined areas (e.g. cancer, CNS, paediatrics, ageing population) should be further promoted within the EU. The basis could be a network of experts able to take leading roles in the assessment of clinical trial applications. Efficient, timely and high-quality assessments that are accepted throughout the EU would be a required outcome.
6. Sponsors should be motivated to apply innovative standards in protocol design, trial methodology and trial management through incentives such as expedited reviews and – specifically for academic sponsors - through fee waivers.
7. For multinational clinical trials, applicants should receive only one consolidated list of questions within a defined timeframe. This should apply to the initial submission and any subsequent amendments.
8. Sequential assessments of different studies within a clinical trial program for a new medicine should be streamlined on the basis of a risk-assessment and thus lead to fast-track authorisations.
9. The maximum timeframe laid down by the legislation must be respected (currently 60 days for assessment and authorisation). As mentioned above, incentives for a faster process should be put into place.
10. Flexibility is needed to quickly expand an authorised clinical trial to centres in additional Member States in the interest of patients who may wish to participate in a given clinical trial.

While the coordinated assessment procedure proposed by the European Commission would be an improvement to the current process, we fear this will not fully address the risk of diverging administrative practices and delays.

This risk could be addressed by a centralised assessment and authorisation procedure established at the European Medicines Agency (EMA) leading to an authorisation in all Member States. Such an approach should be feasible from a legal perspective and would ensure full harmonisation. The concrete workings of a committee should be looked at in more detail so as to make it efficient and low cost. For instance, a virtual network of experts located within the national authorities could be established and video and telephone conferences could

in many cases replace expensive travelling. In addition, Member States should have the possibility to delegate their vote to others.

Another important point for industry concerns the current system of ethics committees. It is suggested that the Commission reflects on how to improve the current system whilst maintaining national competence in this field. A realistic and reasonable way forward could be enhanced cooperation mechanisms for ethics committees, leading to a better transparency, exchange on working methods and best practices. Such an approach could be driven by the Commission through the establishment of a European platform following the EUnetHTA model.

Finally, we would like to express our support for EFPIA's comments and positioning on the concept paper. In our detailed comments we specifically highlight Roche's perspectives as a purely innovative globally acting company in pharmaceuticals and diagnostics.

We agree with the publication of this letter and its attachments on the Commission's website.

Yours sincerely,

Dr. Stéphane André
Head of EU/ROW Regulatory Affairs

Sabine Atzor
Head of EU Regulatory Policies

Attachments:
1) Comments by F. Hoffmann-La Roche Ltd on the Commission' s Concept Paper
2) Legal expert assessment on specific legal question