EUROPEAN COMMISSION

Brussels, 21.02.2013
C(2013)667 final

Dear President,

The Commission would like to thank the Sejm for its Reasoned Opinion on the proposal for a Regulation of the European Parliament and the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC {COM(2012) 369 final}.

As to the Sejm's concern that the proposal would allow experimental trials without the consent of subjects participating in the clinical trial, the Commission would like to remind that the provisions on free and informed consent when clinical trials are conducted on incapacitated persons and on minors have not been substantially changed compared to the existing Directive. Rules on clinical trials conducted in emergency situations, when it is impossible to obtain a free and informed consent from the subject or from a legal representative, have been introduced in the proposal. These rules are in line with existing international guidance and specify that the explicit consent from the subject or from its legal representative has to be sought as soon as possible. Furthermore the Commission would like to stress that such trials must have been previously assessed and authorised, can only concern research related to the medical condition which has caused the incapacity to obtain the informed consent and shall not pose more than a minimal risk to the subject.

As regards the setting aside of the obligation for the sponsor to insure the clinical trial and the Member States' obligation to establish a national indemnification mechanism, the Commission would like to clarify that in the proposal the obligation for the sponsor to ensure specific compensation for any damage suffered by a subject is waived only for "low intervention" clinical trials. The rationale for this provision is that in "low intervention" clinical trials only authorised medicinal products are used and these trials should not pose more than a minimal risk to the safety of subjects; therefore, the Commission considers that for this category of trials a specific compensation mechanism is not necessary, in fact it is considered that the "standard" insurance coverage of the medical practitioner, of the institution where the trial is conducted and the product liability insurance provide a sufficient coverage for the subjects participating in these trials. For all other trials, the sponsor would either have to be insured or to make use of a national indemnification mechanism. Concerning this national indemnification mechanism, the Commission would like to refer the Sejm to the detailed analysis of the

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costs and calculated burdens of such scheme published in the Commission staff working document impact assessment report[1]*, in particular in Annex 4. Furthermore, it should be noted that Member States are given the possibility to collect fees to cover the costs of such scheme for clinical trials conducted in view of obtaining a marketing authorisation joining the scheme.*

As to the setting aside of the obligation to obtain a favourable opinion from an independent and interdisciplinary ethics committee and from the competent authority from the Member State, replacing it with a unique decision per Member State, indeed, the existing Directive provides that a clinical trial application is assessed both by a national competent authority and by an ethics committee. The responsibilities, definitions and denomination of these entities vary widely between the different Member States. The Commission has therefore suggested not to interfere with the internal organisation of the Member States concerning the bodies responsible, and on their responsibilities, for the assessment of a clinical trial application. The proposal in no way abolishes ethics committees. Quite on the contrary, Article 9 of the proposal defines the characteristics of the persons assessing the applications (in particular they have to be independent and have the necessary qualifications and experience and must include at least a "lay" person and a patient representative), in line with the definition of an ethics committee provided by paragraph 15 of the Declaration of Helsinki. The Commission would like to stress that its proposal makes it clear that all aspects of an application for a clinical trial, including ethic-related aspects, must be included in the assessment by all Member States concerned by the application.

As regards the deadlines for the assessment by Member States of clinical trials applications and the introduction of a tacit agreement procedure, the Commission considers that the timelines and the procedure for authorisation foreseen in the proposal, which are based on best-practice benchmarks in Europe and at the most advanced international level, are reasonable and do not compromise the protection of the right of the subjects participating in a clinical trial. Furthermore they would allow Europe to become a competitive place where to conduct clinical research again.

In addition, the Sejm considers that the fact of regulating non-cross border clinical trials is in breach of the principle of subsidiarity. The Commission would like to remind the Sejm that the current Directive already regulates all clinical trials conducted in Europe, not only the cross border ones. In accordance with Article 5 of Protocol (No 2) of the TFEU, the Commission has conducted extensive consultations before proposing this legislative act. From these consultations it resulted that the current Directive is severely criticised by all categories of stakeholders and the collected data confirm that since its adoption the number of clinical trials in Europe has constantly decreased. An in depth analysis of the reasons that have led the Commission to propose a revision of the Directive on clinical trials without changing its scope can be found in section 2 of the Commission document impact assessment report.

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[1] SWD(2012) 200 final
http://ec.europa.eu/health/files/clinicaltrials/2012_07/impact_assessment_part1_en.pdf

http://ec.europa.eu/health/files/clinicaltrials/2012_07/impact_assessment_part2_en.pdf

Finally, concerning the legal basis, the Commission does not consider Article 180 of the TFEU as a valid legal basis for the proposal. In fact the proposal does not tackle research activities carried out by the Union. The Commission considers that Articles 114, as the existing Directive on clinical trials, complemented by article 168 (4) are the correct legal basis of the proposal. A detailed analysis concerning the choice of the legal basis for this proposal can be found in section 3.14 of the explanatory memorandum accompanying the proposal[2].

The Commission hopes that these clarifications address the comments and concerns raised by the Sejm and looks forward to continuing our constructive political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

[2] http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf