ECPC RESPONSES TO THE 'REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

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Consultation Item no. 1:

ECPC agrees that a single submission will greatly reduce the administrative burden related to the multinational clinical trial applications. In the past, too many procedures and safeguards applied without discernment to all kinds of research have contradicted in part the original purpose of the regulation, which was to protect patients and to ensure that clinical trials take place in Europe. As a result, an assessment showed that e.g. UK clinical trial units were unable or unwilling to operate clinical trials in non-UK centres due to different interpretations of the same legislation in different European countries. Key reasons stated related to lack of central guidance, lack of clarity regarding local interpretation of guidance notes, and increased burden of documentation. A single EU Portal administrated by the European Medicines Agency should be effectively connected with the national clinical assessment bodies, and supported administratively and logistically by EMA.

Consultation Item no. 2:

ECPC agrees that the separate assessment will undermine the benefits of the single submission. Separate assessment is not in line with the logic of an efficient and effective clinical trial assessment process. Separate assessment would lengthen the process and increase the risk of its refusal by one of the parties. Consequently, the cooperative and administrative effort related to the assessment of clinical trials would be even greater than under the current system. Hence, ECPC feels that the proposal of single submission with separate assessment is not suitable.

Consultation Item no. 3:

Single submission with subsequent central assessment does not bring added value at the European level. It would add more red tape and necessitate the involvement of all 27 MSs even in the cases of multinational clinical trials, for example, concerning only four Member States. This would increase the administrative and financial effort on the side of both the assessment committee and sponsors.

Consultation Item no. 4:

ECPC welcomes the proposal of a '*coordinated assessment procedure'* as a means of facilitating clinical trial applications and maintaining national competence. We support the division of the procedural assessment into three categories: risk-benefit, ethical and local aspects.

We emphasize that patients' representatives should be involved in all three elements of these appraisals. Patients have a unique experience of the disease and can bring invaluable added value to the clinical trials assessment process.

We would also like to draw the European Commission's attention to the fact that informed consent should be more precisely defined in EU regulation. Currently, there are wide discrepancies between the Member States concerning what kind of consent is accepted as 'informed' and what is not.

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Consultation Item no. 5:

ECPC maintains that "risk of the disease" should be included under the risk-benefit assessment which falls under the scope of the coordinated assessment procedure. By "risk of the disease", we mean the comparative risk - comparison between what will happen if the patient does not follow the clinical trial and is left to the normal clinical practice to what can happen as the result of participating in a clinical trial with good clinical practice. We reiterate that for many cancer patients, especially those suffering from rare cancers, not participating in clinical trials may not offer much chance of survival, so their "risk of the disease" is very high.

Consultation Item no. 6:

ECPC maintains that in cases of disagreement between the Member States taking part in the CAP, a referral mechanism to the Commission or the Agency for a decision at EU level with a time-limit for a response of 15 days should be put in place.

Consultation Item no. 7:

ECPC supports the option of making the CAP mechanism mandatory for all multinational clinical trials, as stated in Option II.

Consultation Item no. 8:

ECPC welcomes the introduction of "type-A trials" which can be identified in a pre-assessment procedure. We expect that pre-assessment will facilitate patient access to trials and fasten the assessment procedure which can safe people's lives. We think that such as pre-assessment could be done by the same Committee which is responsible for CAP. In the case of pre-assessment this Committee will assess all three aspects of the clinical trial application and will decide by unanimity if the trial can be classified as a type-A trial.

Consultation Item no. 9:

Extending the definition of "non-interventional" trials, which are currently excluded from the scope of the directive, will not lead to enhancement of patients' treatment options and quality of life. Although it might ensure better practical implementation of the clinical trials directive, from a broader perspective it will undermine past and future efforts to harmonise "non-interventional" trials at the EU level. ECPC supports the harmonisation of these types of trials at the EU level and so we oppose the change of their definition in the Clinical Trials Directive.

Consultation Item no. 10:

ECPC has often argued that the Clinical Trials Directive is responsible for the shift from academic cancer research to industry-driven research which we reiterate. Due to the difficulties involved in defining the two categories, it would be impossible to establish which trial is commercial and which non-commercial. ECPC supports the preliminary appraisal position that there should be no distinction between academic and industry-driven clinical trials as for the application of the Clinical Trials Directive.

Consultation Item no. 11:

ECPC welcomes the regulation of the content of the clinical trials application dossier and of safety reporting in the form of annexes to the legislative act. It would mean that all necessary amendments to these requirements would be made easier and allow it to be responsive to the need in the area.

Consultation Item no. 12:

ECPC is of the opinion that the key aspect which should be regulated in more closely is the definition of "informed" consent. The lack of this definition gives rise to significant differences in quality and quantity of information provided to patients across the EU27 Member States.

Consultation Item no. 13

ECPC welcomes the proposed cumulative approach proposed and stresses the importance of the introduction of the notion 'auxiliary medicinal product' since that issue is not clarified in the directive so far. We would like to stress the importance of the free-of-charge supply principle of the investigated medicine for patients, which requires that trial sponsors provide the IMP for free.

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There must also be clarification concerning the cost takeover for these new defined auxiliary medicinal products. For trials in oncology that test the best therapeutic use of innovative medicines in combination with existing therapy schemes, the free-of-charge supply implicates cost takeover of investigated medicines as well as of established co-medications. In Italy, Belgium, Sweden, and the Netherlands, specific mechanisms have been set up for non-commercial trials, which allow public cost takeover for tested drugs and co-medications (support or background treatments). There would be the need for a clarification if there is any difference between an auxiliary medicinal product and Non Investigational Medicinal Products (NIMPs) defined through the development of legislative dossier.

Consultation Item no. 14:

ECPC recognises that insurance is an important part of any clinical trial and often enhances patient and investigator safety. However, many times insurance, especially its high cost, is a factor which leads to a trial being abandoned, instead of conducted in a more balanced and effective way. ECPC is of the opinion that lifesaving treatments cannot be abandoned simply because of the high cost of the insurance. That is why we support the first option – removing insurance for low-risk trials.

Consultation Item no. 15:

ECPC disagrees with the preliminary appraisal that, choosing between a single sponsor and a “multiple sponsorship”, a single sponsor is the preferable option. ECPC backs the concept of multiple sponsorship which would enable the conduct of more complicated and costly clinical trials, which may prove necessary especially in case of rare cancers patients. ECPC recognizes, however, that the notion of liability has to be better defined and shared among the multiple sponsors. We propose a solution that one of the sponsors should be a coordinating sponsor to take responsibility for this in dealings with the national authorisation body.

Consultation Item no. 16:

ECPC fully backs the regulatory solution of emergency clinical trials which permits asking for the patient’s informed consent during or after the trial. We think that this procedure has a great deal of potential to save lives and the proposal from the Commission will put an end to a significant omission from the Clinical Trials Directive.

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About ECPC – The European Cancer Patient Coalition

The European Cancer Patient Coalition was founded in 2003 under the slogan "Nothing About Us, Without Us". It is committed to improving cancer prevention, screening, early diagnosis and best treatment, reducing disparity and inequality across the EU. ECPC seeks to ensure that policy makers, politicians, health professionals, the media and the general public recognise the serious nature of cancer and the need for concerted action to reduce unnecessary death and suffering. Further information can be found at http://www.ecpc-online.org

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