EPF Statement

EPF welcomes transparency provisions but regrets lack of patient involvement as a backwards step

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As a representative umbrella organisation of patients across the EU, many of whom are potential participants in clinical trials, the European Patients' Forum welcomes the fact that Member States have reached a common position on the this important legislative proposal.

Although the timelines for assessment have been significantly lengthened, the compromise nevertheless stresses the need for a well-coordinated process at Member State level and retains tacit authorisation as an incentive. The adoption of single submission through an electronic portal, coupled with coordinated assessment, should lead to a more streamlined and efficient assessment of trial applications.

There are other important positive aspects in the compromise, particularly as regards greater transparency around clinical trials. Nevertheless, we are disappointed that key provisions of the Parliament for patients' involvement and empowerment were sidelined by Member States. Removal of these provisions is a retrograde step out of touch with developments since the last Directive was adopted.

Below we address these key issues. This statement is not a comprehensive position of EPF on all aspects of the Regulation, on which we will publish a detailed paper following a further consultation with our membership.

Transparency of clinical trial results

EPF strongly supported the European Parliament's position on transparency, including publication of the Clinical Study Report. We called for summary results of clinical trials to be communicated in a way that is unbiased, comprehensive, relevant, and understandable to patients. We welcome the improved provisions for ensuring transparency of all clinical trial results, whether positive or negative. We also welcome the fact that all clinical trials results must include a "lay summary", which will be available on a publicly accessible, user-friendly EU clinical trials database.

However, the definition of the lay summary introduced in Annex IIIb is not sufficient. It is far from clear how this list of items would meet patients' information needs, since to our knowledge no patient groups were asked to comment on it. Moreover, the information will only be understandable if it is presented in a patient-friendly language and format. For this reason, the content of the lay summary needs to be checked by patients to ensure it is comprehensive, and the principles for its communication need to be defined through a consultation process involving patients and their representative organisations.

Informed consent and information to patients

EPF welcomes the more detailed guidance aimed at improving the quality of information given to patients and the process of informed consent under Articles 28 and 29.

However, we regret the Council's deletion of the European Parliament's provision for a process to develop EU-level guidelines addressing the core elements and main principles of information and informed consent. This was critical given the current unacceptable divergence in the quality and quantity of information provided to patients. Good information is a fundamental patients' right, regardless of where in the EU a clinical trial takes place.

The patient community insists that European guidelines should be defined, drawing on existing best practices and taking into account the views of patients. We believe they are necessary even for the purpose of checking compliance with the provisions of the current Article 29. Such guidelines could be developed in a consultative process or through an expert platform facilitated by the European Commission.

Furthermore EPF has some concerns over the application of Article 29a (the "simplified" informed consent). We will further consult our membership on this.

Patient participation in ethics committees

The European Parliament mandated the participation of patients in ethics committees, along with lay persons. Regrettably, Council has deleted this. The provisions that merely encourage Member States to involve lay persons and patients are in our view too weak.

Patient involvement is seen increasingly as a priority in all aspects of healthcare, including research. The perspective of patients is not equivalent to the perspective of lay persons: the latter, being often ethics experts or lawyers, do not possess the experiential knowledge of patients so the role they play in ethics committees is different and complementary. The unique value of the patient perspective lies in the direct experience of a person living with a condition or disease. Patients and their organisations also have a unique insight into the feasibility of certain practical aspects of trials, and a better perception of the appropriateness of the information given to participants. Patient involvement is also critical to improve the lagging participation rates and public perceptions about clinical research.

From the patients' perspective, patient participation in any review of a clinical trial application should not be an optional matter. For this reason EPF calls for careful monitoring of implementation to ensure that ethics committees really do ensure the participation of patients, alongside lay persons. The patient community is committed to working with researchers, ethics experts, health professionals and policy-makers to develop solutions for making this a reality across the EU.

We are disappointed that the Member States failed to grasp the opportunity for better co-operation to harmonise operational aspects of ethics reviews, ensure their efficiency and help build best practice across the EU. Similar cooperation networks already exist in other areas, e.g. those based on Directive 2011/24/EU. The current diversity of ethics committees and their working methods is not in the interests of patients, nor does it in our view contribute to optimal ethical assessment of clinical trials.

We are, however, very supportive of the provision in Annex I that trial protocols should include a description about how patients were involved in the design of the trial. We believe that this will encourage sponsors and researchers to involve patients from the start in developing therapies that meet their needs, and it should be given the appropriate weight in the trial assessment process.

Conclusion

The patient community does not accept information to patients and ethics as "purely national issues". On the contrary, in our view better European cooperation is essential as it will benefit patients and improve the quality of clinical trials and therefore the future competitiveness of research in Europe. The medical landscape is changing fast: innovation has potential to transform the lives of patients with serious lifelong conditions, while resources are limited and need to be focused on innovation that provides real value. There is a pressing need for forming new kinds of partnerships – between researchers, regulators, academia, industry and patients – and to move from research "on patients" to research with patients.

While we welcome the positive aspects of the current compromise, we regret that Member States have failed to use this opportunity to ensure the EU is at the forefront of innovation when it comes to patient involvement in clinical trials. EPF and our members are committed to working with all stakeholders to address the current gaps and drive a genuine partnership approach in research.

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The **European Patients' Forum (EPF)** was founded in 2003 to ensure that the patients' community drives policies and programmes that affect patients' lives to bring changes empowering them to be equal citizens in the EU. EPF currently represents 62 member organisations, which are national coalitions of patient organisations and disease-specific patient organisations working at European level. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases throughout Europe.

EPF's vision for the future is that all patients with chronic and/or lifelong conditions in the EU have access to high quality, patient-centred and equitable health and social care.

The EPF strategic goals focus on areas such as health literacy, healthcare, patients' involvement, patients' empowerment, sustainable patients' organisations and non-discrimination.

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