EPF Statement

EPF welcomes MEPs' move towards a more patient-centred clinical trials framework in the EU

Brussels, 11 June 2013

EPF welcomes the recent vote in the European Parliament on the legislative proposal for a Regulation on clinical trials. The ENVI Committee unanimously approved the draft report of Glenis Willmott (S&D, UK), adopting important amendments to the Commission's proposal.

EPF applauds the European Parliament for adopting a patient-centred approach. Patients voluntarily provide data for research and ultimately manage the risks involved. They therefore have the right to be involved in the way research is developed, managed and evaluated. Moreover, patient involvement has been shown to lead to trials that are ultimately more relevant to patients' needs.

EPF now calls on the Council to support the amendments of the European Parliament in order to ensure that the future EU clinical trials regulatory framework is fit for purpose, efficient, transparent, and patient-centred.

Patient involvement in the development and assessment of clinical trials

EPF welcomed the European Commission's recognition of the central importance of patients in clinical trials by introducing a mandatory provision for patient involvement; however its scope was not defined. MEPs have introduced a new definition of "ethics committee" that includes at least one patient or patient representative, and tasked the European Commission with developing guidelines on patient involvement drawing upon existing good practice. EPF strongly supports this approach as it clarifies the role of patients and ensures the patient perspective is included in ethical assessment.[1]

Furthermore, EPF is pleased that MEPs recognise the importance of involving patients in identifying research priorities. Patients often have different perceptions about what innovation would bring most value to their lives, than do clinicians or researchers. Their involvement can also ensure practical trial arrangements are supportive and thus help prevent drop-outs. Trial protocols should therefore describe whether and how the researchers took into account patients' views when identifying the research topic, questions and the overall trial design. Knowing this is a factor in the assessment can encourage sponsors and researchers to involve patients from the start in developing therapies that meet their needs and provide value for money.

[1] For more information and examples about the added value of the patient perspective in ethics review, see EPF's position papers on clinical trials, available at http://www.eu-patient.eu/Initatives-Policy/Policy/Clinical-Trials/

Improving the coordination and quality of ethics reviews

EPF welcomes the clarification that ethics review is an integral part of the assessment of clinical trial applications. The current fragmentation in ethics reviews is a major problem that causes delays for clinical trials. The fundamental principles of medical ethics are universal; it follows that ethical issues should not be considered a purely national matter. EPF supports the Parliament's call for the Commission to facilitate cooperation and sharing of best practice in ethics review. EPF suggests that a multi-stakeholder collaboration platform should be set up at EU level for this purpose, such as the network for HTA cooperation, EUNetHTA.

Information to patients and informed consent

EPF strongly welcomes MEPs' decision that core elements of information and informed consent are to be assessed jointly, while genuinely national aspects, i.e. those that are language- or culture-bound, would be addressed separately. This is a vital step towards ensuring that every person in the EU will have access to high-quality information and informed consent, regardless of in which Member State they happen to reside. European Commission guidelines, developed in consultation with relevant stakeholders including patients' organisations, are a crucial element in this process. EPF also welcomes the specific requirements that information provided to trial participants must conform to quality criteria and be relevant and understandable.

Transparency on the results of clinical trials

EPF has for several years called for the publication of the results of all clinical trials in a timely manner, regardless of the outcomes. Ensuring that after a research project finishes, the results are promptly published, can, arguably, be said to be as important as the approval of the trial in the first place. Even results of trials that "failed" or produced unexpected or inconclusive outcomes add to the totality of our evidence base and can help target future research better. Moreover, in order to implement patient-centred care and empower patients to make fully informed decisions concerning treatment options in partnership with their health professionals, it is vital that both clinicians and patients have access to all the relevant information needed to make those decisions.

Therefore EPF strongly welcomes the requirements for greater transparency, including registration of trials in the publicly accessible EU database and the publishing of results, including a lay-friendly summary whose content and structure will be developed at EU level. EPF believes that clear standards regarding what information should be included in the results posted on the EU database, and how this should be presented, should be developed with the involvement of civil society to ensure they address all groups' information needs.

EPF also strongly supports more effective data sharing from clinical trials to enable researchers to revisit and reanalyse clinical trials data. EPF believes questions around data sharing need thorough discussion, exploring all the implications and potential consequences of data sharing. EPF is committed to participating in EU-level public debates in order to find a good solution that serves science, patients, and the public interest.

For further information see EPF's position paper on clinical trials, available on our website.

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 61 member organisations, which are national coalitions of patients 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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