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Dear Ms Patricia Benko,

EPHA Response to Consultation on the revision of the Clinical Trials Directive

I am writing on behalf of the European Public Health Alliance (EPHA) in response to the public consultation regarding the revision of the 'Clinical Trials Directive' (2001/20/EC). We recognise the European Commission's effort to improve processes surrounding Clinical Trials in the EU and are grateful for the chance to contribute to this consultation.

EPHA – Europe's leading NGO advocating for better health - is the European Platform bringing together public health organisations representing professional groups, patients, health promotion and disease specific NGOs and other health associations.

The primary concern of clinical trial is patient safety, before, during and after the approval of the clinical trial. At all times the approach taken to the modification of the directive must be a patient centered one. It should be considered at all times what the best outcome and approach is for the safety of the trial subject and the health of medicines users/future patients.

Patient involvement is essential to achieving this. As found by the European Commission funded project Patient Partner¹, patient involvement in clinical trials produces better outcomes and improves processes. It can help set the agenda for the development of medicines which address unmet patient needs and increases accountability in their production. Also, medicines for the treatment of rare diseases come to the market all too infrequently; patient involvement is one way of addressing this, for example in helping identify rare disease patients who can participate in trials. Patient involvement should be initiated from the very earliest stages of the trial as this contributes to research that is better adjusted to the real needs of patients.

It is essential that the framework of the clinical trials directive forges an environment for creating innovative medicines which combat current and future public health threats. We must remember that it is inevitable that there will be a significant amount of administration attached to clinical trials.

Participants in clinical trials should most importantly reflect the population for whom the medicine is destined. However they should not be restricted to this population as many medicines are used 'off label' and so a wider public health approach is appropriate. Biological differences between women and men should be considered when undertaking the clinical trials so that any adverse reactions may be noted in both genders and collected in disaggregated data. Women should form part of the test group for medicines which they may later consume. The existing situation whereby many medicines which are taken by women have not adequately been tested on them, is unacceptable, and should be addressed in the revision of the directive.

The exemption to this is children who are unable to give informed consent to participate in a trial. However, it is necessary for medicines destined for paediatric use should where ethically appropriate be tested on children in order to verify their safety and efficacy in a wider population of children.

¹ <http://www.patientpartner-europe.eu/en/home>

EPHA underlines the need for drug treatments to be tested in clinical trials which take into account the different age groups, particularly in older and elderly people – as the largest consumers of medicines with often a polymedication issue quite specific to this group². It is essential that this is done so that adverse reactions can be better assessed.

From a broader perspective and to better match this objective of involving all patients without undue discrimination, the need to consider the training of researchers to conduct trials with specific group should be looked at. In addition, Trial Sponsors should recognise that some participants, in particular older people, may need extra support to take part in trials and to enhance the inclusion and adherence of older people, especially those with mobility and communication problems.

Emergency trials may be acceptable only in certain exceptional circumstances. However there is a clear need for presumed consent to be taken by an **independent** investigator. It should not be the decision of the trial's principal investigator to presume consent of a trial subject, which may pose a conflict of interest. Clarification is clearly needed on what these exceptional circumstances are, when they will be evaluated and by whom.

EPHA accepts the Commission's assessment that rather than limiting the scope of the directive to 'non-interventional' clinical trials it would be better to arrive at harmonized and proportionate requirements which can be applied to all clinical trials to protect patients participating in all clinical trials. However, further detailed guidance will be needed to support such a harmonized proportionate approach.

Academics and non-commercial sponsors should not be exempt from the Clinical Trials Directive. Both commercial and non commercial sponsors of clinical trials should be subject to the same robust standards of accountability as we fear that not doing so could limit progress of clinical research. The application of the Directive should vary according to trial risk, not who the sponsor of the trial is.

Clinical trials undertaken in third countries must be held to the same clinical and ethical standards as those done within the European Community. It must be ensured that the adequate medical provision is in place following participation in the trial. Also, due to differences between the European Community and Third countries where the trials may be undertaken it must be ensured that results are comparable and can be safely applied for medicines destined for use within the Community. In the same light, all clinical trials undertaken in third countries should be recorded in a European register of CTs without exception. The current requirement that only paediatric trials done in third countries used for market authorisation are required to be registered in Europe should be expanded to trials on all patients in third countries used for market authorisation in Europe

We wish the European Commission every success in analysing the consultation responses and in drafting revising the directive. It is my hope that the concerns brought forward in this letter will be helpful in drafting these documents. We would welcome the opportunity to discuss the issues raised in this letter in more detail

Yours sincerely,



Archie Turnbull
President
European Public Health Alliance

This letter arises from the European Public Health Alliance which has received funding from the European Union, in the framework of the Health Programme. Sole responsibility for this letter lies with EPHA and the Executive Agency is not responsible for any use that may be made of the information contained therein.

² The PREDICT (Increasing PaRticipation of ELDerly people In Clinical Trials) study is an example of work being done to increase older people's participation by creating a Charter for the Rights of Older People in clinical trials (www.predictEU.org)

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