

Revision of the clinical trials directive, 2001/20/EC

AGE Platform Europe contribution – 11 May 2011

AGE Platform Europe welcomes the recent development regarding geriatric medicines, particular the decision made by the European Medicine Agency (EMA) in February 2011 to launch a geriatric medicines strategy with two main objectives:

- “Ensuring that medicines used by geriatric patients are of high quality, and appropriately researched, evaluated, throughout the lifecycle of the product, for use in this population;
- Improving the availability of information on the use of medicines for older people, thereby helping informed prescription”¹.

This is a very satisfying development and the review of the clinical trials directive should be looked as an important opportunity to support this new strategy. That is why AGE Platform Europe would like to focus its contribution on the need to improve participation of older people in clinical trials of medicines commonly used for geriatric patients.

The **primary concern of clinical trial is patient safety**, during and after the appraisal of the medicine. 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 healthy trial subject and for the patient. As found by the European Commission funded project “Patient Partner”², patient involvement in clinical trials produces better outcomes and improves processes. 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.

AGE calls first of all for **drug treatments to be tested in clinical trials which take into account the different age groups, particularly iolder and frail elderly people** (breaking down into two age groups: 65-80 and 80+) – as seniors are the largest consumers of medicines.

As stated in the Preamble of the Charter for Older People in Clinical Trials developed through the PREDICT Project ³ “As a consequence [of the current exclusion of older people in clinical trials] both prescribers and patients are placed in unnecessarily difficult positions. Prescribers have to decide whether to prescribe a drug even though they might have only limited knowledge of its effects and side effects in older people. The patient who wants to know about the treatments’ effects in older people will be denied that opportunity.

¹For more information, please refer to EMA webpage:

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp

² For more information : <http://www.patientpartner-europe.eu/>

³ Predict is an EU funded project – under the FP7, www.predictEU.org

Decision making is even more difficult in older people with frailty who are even more rarely included in clinical trials”.

However we feel that the inclusion of older people in clinical trials may provide important information about dosage, efficacy, long-term effects, dosage regimes and safety of drugs.

For instance polypharmacy is a quite difficult issue regarding the use of medicine among older people. Many older patients use multiple drugs and this causes difficulties with respect to the addition or withdrawal of medicines based on sound diagnosis and indications. And the more drugs a patient uses, the greater the risk of interactions between these medicines and the risk of adverse reactions.

In addition, special physiological features of older organisms cannot be neglected anymore, meaning that additional rules will evidently be necessary if we really want to protect patient safety as the highest obligation. According to the different epidemiological situations and considering the current knowledge and therapeutic possibilities of chronic diseases, new drugs specially intended for older people will be necessary. It will not be possible to test them on younger, healthy volunteers anymore otherwise it will not be possible to register them properly.

Secondly, AGE would like to underline the importance **to disaggregate data between men and women**. There are biological differences between women and men that should be considered when undertaking the clinical trials. 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. In addition, women are the larger among the very elderly and this should be taken on board and reflected in the way clinical trials of geriatric medicines are organised.

Thirdly, AGE would like to insist on the **safety issue in clinical trials**. Considering specificities of older organisms and insufficient tradition of clinical trials on elderly people, all clinical trials performed on older people should be insured, including those where difficulties are not expected. Concerning “Emergency clinical trials”, AGE would like to raise some concern about them as they might be particularly dangerous in cases like high senility where greatest care is needed.

Safety issue and inclusion of older people in clinical trials implies as well that trial sponsors should recognise the need for extra support, especially for those with mobility and communication problems. As reminded in the “European Charter of the rights and responsibilities of older people in need of long-term care and assistance”⁴, the informed consent and advice should be respected. This question is even more important for specific

⁴ This Charter was developed through the EU funded project – under DAPHNE – Eustacea (a European strategy to combat elder abuse), <http://www.age-platform.eu/en/daphne>

groups like people with Alzheimer and other dementia diseases or people with severe cognitive impairments.

From a broader perspective and to better match this objective of involving all patients without undue discrimination, we will need at one stage or another to consider the training of researchers to conduct trials with specific group.

Generally, the drugs used by older people are not enough tested within their target age and gender group. AGE would like therefore to ensure a comprehensive geriatric medicines strategy that takes into account the issue of clinical trials in older- and elderly people. The leading principles for testing both older and new medicines have to be safety, efficacy, equity, evidence and efficiency. These requirements should be valid both for new medicines and medicines which have been on the market for quite some time and are up for renewal of their registration.

AGE Platform Europe is a European network of around 150 organisations of and for people aged 50+ which aims to voice and promote the interests of the 150 million senior citizens in the European Union and to raise awareness on the issues that concern them most.

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