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Gender issue in clinical trials in Europe

Internationally, the issue of including women in clinical trials of medicines has been addressed in various guidelines issued by the International Conference on Harmonization

(ICH), which promotes regulatory standards for clinical trials. While ICH has specific guidelines on the conduct of clinical trials in paediatric and geriatric populations, there are no consolidated guidelines for the investigation of medicinal product in women. Instead, direct or indirect references to gender are scattered throughout a number of different ICH Guidelines.

In 2005, the European Medicines Agency (EMA) published the document entitled ? *ICH - Gender considerations in the conduct of clinical trial?* which summarises the different ICH guidelines that refer to women. The EMA document states that while women appear to be participating in all phases of study development, participation is lower in early Phase I and I-II studies. However, these are the studies where safety, safe dosage range and side effects are determined (EMA 2005).

In its 2005 document, EMA concluded ?that there is no need for a separate ICH guideline on women as a special population in clinical trials. Relevant ICH and regional guidelines should be consulted for guidance on demographic considerations, including gender, in the design, conduct and analysis of clinical trials?. However it holds out hope that ?this issue may be revisited if future experience suggests a change from current practice? (EMA 2005). In light of the need to implement the new Clinical Trial Legislation, it may now be an opportune time for EMA to draft new guidance.

Medicines Regulation in the European Union ? European Medicines Agency

The EMA is in fact the European Union (EU) body responsible for the scientific evaluation and approval of medicines developed by pharmaceutical companies. The EMA centrally reviews and approves innovative medicinal products, based on the clinical trial data supplied by the applicant organisation/pharmaceutical company. This approval process is strictly defined and guided by EU legislation. Once approved, the medicinal product receives a marketing

authorisation for use in the EU and European Economic Area (EEA).

Clinical Trials Regulation

The recently adopted EU Clinical Trial Regulation No 536/2014 aims to create an environment that is favourable to conducting clinical trials in the EU with the highest standards of ethical and safety protection for participants. The new CT Regulation, which repeals Directive 2001/20/EC, sets out the legal conditions under which clinical trials will have to be conducted in Europe in the future.

The law regulates the transparency of clinical trials data, including the population groups for whom the medicines are intended (also in terms of gender and age). It also contains new rules for including pregnant and breastfeeding women under strict protective measures.

Although the Regulation was adopted and entered into force in 2014, the timing of its application depends on confirmation of full functionality of the EU portal and database through an independent audit. The Regulation becomes applicable six months after the European Commission publishes notice of this confirmation.

EMA drew up a delivery timeframe, in collaboration with the Member States and the European Commission. According to this timeframe, the EU portal and database should be available for the independent audit by August 2017. If the systems pass the audit, the Regulation will come into effect by October 2018.

Transparency of Clinical Trial data

The new Regulation is a major step forward in making clinical trial date more transparent. It will improve the evidence-base on which a medicine is approved for women and older people. All clinical trials in the EU will need to be registered in a Clinical Trial Data base and a user-friendly summary of results must be published within one year after the trial has ended. Once a clinical study report has been

submitted in support of a marketing authorisation, it will also have to be made publicly available by the applicant within 30 days after the regulatory decision has been made.

Including different population groups: gender and age considerations

In terms of demographics, the new Regulation lists specific population groups to be included in clinical trials: ?Unless otherwise justified in the protocol, the subjects participating in a clinical trial should represent the popula-tion groups, for example gender and age groups, that are likely to use the medicinal product investigated in the clinical trial? and ?non-inclusion has to be justified?.

Attention to vulnerable population groups - Including pregnant and breastfeeding women

The Regulation contains new legal provisions for including and protecting pregnant and breastfeeding women in clinical trials.

Article 33, Chapter V defines the conditions under which pregnant or breastfeeding women can participate in clinical trials, provided the conditions outlined in the legislation are followed. This is a welcome step, as most medicines are counter indicated during pregnancy leaving women who have chronic conditions such as asthma, diabetes, HIV/AIDS etc. in the dark as to the safe use of medicines during pregnancy and breastfeeding.

Analysis of results according to Sex and Age

Annex IV refers to presenting sex and age differences in the clinical trial results: «population of subjects (information with actual number of subjects included in the clinical trial in the Member States concerned, in the Union and in third countries); age group breakdown, gender breakdown» and under Section C, point 1 and 2: Baseline characteristics (required) age, and gender.

Conclusion ? Moving from knowledge to practice

The scientific knowledge on sex differences is now well known, and a supportive legislative environment in Europe is coming into force. Therefore the time has come to move from the description of sex differences to a more systematic approach of implementation into regulatory and clinical practice for the benefit of patients and, ultimately, to improve health and healthcare for all.

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