586

PAEDIATRIC RESEARCH BEFORE AND AFTER THE EU REGULATION 1901/2006: SURVEYS CONDUCTED BY THE EUROPAN FEDERATION OF CROS (EUCROF)

C.A. Rizzi[1], A. Alemany[2], A. Cournot[3], P. Galletti[4], A. Jurczynska[5], M. Dehlinger-Kremer[6], J. Schaefer[7], P. Smit-Marshall[8], N. Thevenet[9], EUCROF Paediatric Working Group

[1]Medineos S.R.L., Milan, Italy, [2]Trial Form Support, Madrid, Spain, [3]Research Pharmaceutical Services, Boulogne Billancourt, France, [4]Pierrel, Sesto S. Giovanni, Italy, [5]Quantum Experimental, Madrid, Spain, [6]Omnicare Clinical Research, Bad Soden am Taunus, [7]Conreso, Munich, Germany, [8]PharmaNet, Amersfoort, The Netherlands, [9]Euraxi Pharma, Joué-lès-Tours, France

The European Community Regulation governing clinical research in paediatrics, which came into force in January 2007, is aimed at ensuring a better care for children and setting quality and scientific standards for evidence-based use of medicines in Paediatrics. The related obligation system, affecting the medical community and even more the pharmaceutical industry, is expected to increase the number of controlled trials, in order to have more drugs approved in Paediatrics and less off label use.

Two surveys in 16 countries on the pre-Regulation period (2005-2007) were conducted to better understand the status of paediatric research at the start of the new era. The experience of paediatrc trials is mostly in Phase III, and the major hardles were found in preparing an appropriate protocol and in practical issues (to be intended as submission document preparation and logistic issues). Thus, it is assumed that many trials before the Regulation are investigator's initiated and that the support by industrial sponsors has been poor when compared to other developmental projects. The ranking by therapeutic area (respiratory>endocrinology>infectious diseases>oncology) does not fit with the needs for controlled trials identified by EMA in a survey on the off label use of non-authorised medicines for children.

All together these data on years 2005-2007 support the need expressed by the Regulation for a higher qualitative and quantitative commitment in Clinical Research in Paediatrics. A third questionnaire (results expected October 2011) is aimed at monitoring the first years of the Regulation (2007-2010), in order to understand its initial impact.