European Association for Clinical Pharmacology and Therapeutics

Statement Regarding the EU Clinical Trials Directive 2001/20/EC

The Executive Committee of the European Association for Clinical Pharmacology and Therapeutics (EACPT) met in Sofia, Bulgaria on April 15th/16th 2011 and one of the items of business concerned the working of the EU Clinical Trials Directive (CTD)[1], which has become a matter of concern for the committee in recent years. It has become clear to EACPT that the CTD has been a major hindrance to clinical trials research for some years and this matter has been particularly highlighted for us in a report from the Academy of Medical Sciences in the United Kingdom[2]. The remit of EACPT covers all European Countries and, while the CTD has not caused major problems in every European country, it is quite clear that the UK is not the only country in Europe to be affected. The increasing length of time and resource required for clinical trials to be approved in the UK has its parallel in other European countries and is largely caused by two factors. One is the CTD, which affects all European Countries, and the other is the associated multiplication of various control bodies (such as ethics committees and other research review committees), which has developed in the UK and some other European Countries.

The CTD was introduced to improve patient care by imposing a stricter regulatory framework around research activities. While EACPT believes that patient autonomy and safety is paramount in all clinical research, there seems to be little evidence that the increased regulation has improved either. At the same time, the CTD has made it much harder for clinical researchers, especially those in the independent non-commercial sector to undertake fundamental research. This is, in fact, to the detriment of European public health and contrary to the original aims of the directive.

EACPT applauds the recommendations in the report of the Academy of Medical Sciences; in particular Recommendation 5, which states that the European Commission should act quickly to revise the EU Clinical Trial Directive. We also strongly support Recommendations 6 and 7, which state that the control organization in the UK (The Medicines and Healthcare Products Regulatory Agency) should improve its performance. It should have a more proportionate response to clinical trials regulation (Recommendation 6) should increase the quality, consistency and timeliness of advice from its Clinical Trials Unit. We call on all member states to ensure that the regulation they place on their clinical researchers is proportionate, efficient and coordinated so that it serves the interests of both the participating subjects and the needs of the public health for high quality clinical research.

1. European Commission (2001)Clinical Trials Directive 2001/20/EC http://ec.europe.eu/health/files/eudralex/vol-11/dir 2001 20/en.pdf

2. Academy of Medical Sciences. A New Pathway for the Regulation and Governance of Health Research. London, January 2011. Available at www.acmedsci.ac.uk.

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