Letter to the Editors

The impact of clinical trials legislation on clinical pharmacology: problems and solutions

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The article by Morris Brown on the impact of clinical trials legislation on clinical pharmacology [1] makes very sorry reading, as does the editorial appearing in the same issue, although less so than the Brown article. There is so much that is inaccurate in this article that it compromises the legitimate validity of his argument that bureaucracy in this country hampers clinical research.

It so happens that, in my so-called retirement, I am closely involved with the research ethics review process throughout Europe, being co-chairman of the European Forum for Good Clinical Practice (EFGCP) Ethics Working Party and the EFGCP Ethics Officer, as well as having served on UK research ethics committees (RECs) for over 12 years, now being the alternate vice-chairman of Cambridgeshire 4 REC, which used to be the former East of England MREC. I was responsible for initiating the report on the structure and function of RECs published in the *International Journal of Pharmaceutical Medicine* in February 2007 and kept up to date on an annual basis on our EFGCP website (<http://www.efgcp.be>). I am therefore in a very strong position to maintain that the UK can be proud that it has as good a grasp of research ethics as any other European state, and I would be willing to debate that vigorously in public. Sadly, Brown has not acknowledged the efficiency that now demonstrably pervades the research ethics review system in this country, allowing himself to be overwhelmed by the deficiencies of the R&D Governance process in this country, with which the National Health Service has lumbered itself. This, I freely acknowledge, is a nightmare that only recently might have shown a first sign of waking itself up. Coupled with academic regulations, with which clinical pharmacologists might well be encumbered, too, I can therefore understand the frustration that Brown demonstrates, though it is partially misdirected.

Without wishing to be personal in a letter to the Journal, I would remind Brown and his clinical pharmacology colleagues that one of the most irritating aspects of an application to a REC is the inadequacy of many patient

information sheets, whether they come from pharmaceutical companies or academic departments. By and large, clinical pharmacologists ought to be as good as any group in the production of comprehensive yet comprehensible patient information sheets that, above all, are able to be understood by the patients who are the intended subjects of research projects. Time taken to produce a really good patient information sheet must be time well spent, as the time needed to take on board the concerns of a REC may well be much greater than for the drafting of a decent document in the first place.

Referral back by a REC must be frustrating to an investigator, but the time taken to deal with the REC concerns can be minimized, and it is not right to accuse RECs of delaying tactics when the time taken for a response by an investigator may well be very protracted. Of more fundamental concern is Brown's clear lack of understanding of what research ethics are all about. No doubt Brown is a very sound medical ethicist and he tells us that medical ethics was his first academic interest. But research ethics is quite different from mainstream medical ethics. It is because RECs are established to look after the interests of patients who are the subjects of clinical research projects that they include in their membership lay persons as well as experts. The National Research Ethics Service (NRES) has ensured that all the members of RECs are properly trained in the principles of research ethics, and Brown's comments on the membership of RECs in his article are insulting in the extreme. It is the intelligent lay persons as well as the doctors, nurses, lawyers, statisticians, pharmacists, teachers and so on who are found on RECs that safeguard the interests of patients—and at Cambridgeshire 4 we operate to strict deadlines.

I hope that readers of your Journal will recognize the efficiency with which research projects are dealt with by the NRES, through its research ethics committees, and will all contribute to putting pressure on other aspects of the research approval process that are still deficient.

Competing interests

None declared.

REFERENCE

- 1 Brown MJ. The impact of clinical trials legislation on clinical pharmacology: problems and solutions. *Br J Clin Pharmacol* 2009; 67: 487–93.

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