

25th July 2006

Sir David Cooksey
Chair
REVIEW OF UK HEALTH RESEARCH
Cooksey Review Secretariat
HM Treasury 4th Floor
1 Horse Guards Road
London SW1A 2HQ.

Dear Sir David,

We are pleased to have the opportunity to respond to the invitation to submit comments on the review of the best institutional arrangements for the new single fund for health research initiated by the Chancellor of the Exchequer, Gordon Brown in March 2006.

The Drug Safety Research Unit (DSRU) is a research organisation in the field of the detection and study of adverse drug reactions. For over twenty-five years, the DSRU has been monitoring the safety of newly marketed medicines, helping to identify potentially serious and sometimes fatal adverse drug reactions.

Patient safety is at the forefront of all research activities in pharmacovigilance, which is the collection, evaluation and communication of information on the safety of medicines. These activities are vital for the effective use of medicines.

In spite of the advances of modern medicines, the public health burden of adverse drug reactions in terms of morbidity and mortality remains very high. Therefore, monitoring for adverse drug effects is fundamental to the safety of patients. While many new medicines are safer than old products, drugs are becoming more complex, e.g. biotechnology products which require more complex monitoring and study. Once a new medicine is in general use, in the 'real world', outside the tightly-controlled conditions applied in clinical trials, new hazards tend to occur in groups of patients such as the elderly, children, and women of child-bearing age who were excluded in pre-marketing development programmes.

As a research organisation we have undertaken independent post-marketing activities on newly marketed medicines known as Prescription-Event Monitoring (PEM) since 1981. The DSRU has conducted over 90 studies on new medicines highlighting a number of serious drug safety concerns or class effects, while others have helped build a positive safety profile for a new product. PEM has become an important tool for evaluating the post-marketing safety of new drugs and is recognised as a valid means of post-authorisation study in the European Union. With our large-scale longitudinal database there is much more that we can do which will ultimately lead to improvements in patient care. Considering the public health burden of adverse drug reactions, more funding is needed to answer

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important research, public health and clinical questions. The pharmaceutical industry only funds projects related directly to their products, while research is needed to answer disease-related and population related questions. Public grant-giving bodies must fund this important research.

Any new grant offering entity (much stronger financially than existing organisations) needs to be dynamic (not bureaucratic). To be responsive to the needs of the biomedical research community, it should have specialist groups, functioning as near to the frontline researchers as possible, to ensure that the funding is responsive to needs in a dynamic way. The research needs in the study of the safety of medicines and pharmacovigilance, considering their impact on patient care, deserve better consideration and responsiveness than current organisations are providing.

Yours sincerely,

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Director
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