Why the Safety Assessment of Marketed Medicines (SAMM) guidelines are needed

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Guidelines for company-sponsored post-marketing surveillance (PMS) of medicines introduced in 1988 [1] have recently been reviewed and major changes have ensued. The revised guidelines (known as the Guidelines for Company Sponsored Safety Assessment of Marketed Medicines or SAMM guidelines) are published in this issue of the journal. Why were the new guidelines developed? What has changed? And what has this to do with clinical pharmacology?

Need for new guidelines

The short answer to the first question is that studies performed under the 1988 guidelines [1] have provided only limited information about drug safety under ordinary conditions of use [2]. No guidelines can ensure that a study will provide useful information but the 1988 guidelines were narrow in their definition of a PMS study and, in retrospect, did not do enough to encourage good study design. A stereotyped approach developed which was the prospective cohort study conducted in general practice without comparators. Such studies are unlikely to provide either convincing reassurance that the drug is safe [2] or sufficient evidence to indicate reliably a safety hazard. There has also been a widespread perception that companies were performing these studies for marketing purposes. The case for looking again at the guidelines was therefore quite compelling [3].

The major changes

Any post-marketing study which sets out to evaluate safety is now included. This change is reflected in the new name, with the emphasis being on safety assess-

ment rather than passive surveillance. The SAMM guidelines seek to promote studies which are scientifically useful, for example by encouraging study designs which meet particular needs or problems, include comparator groups and avoid inappropriate exclusion criteria. It is now recognised that there are ethical issues involved in at least some studies which evaluate safety in ordinary use and therefore guidance on these issues is included. It can hardly be reassuring for doctors and the public to know that, previously, the drug regulatory authorities had little information about the progress of PMS studies. Detailed guidance is now provided in the SAMM guidelines about interaction with the Medicines Control Agency (MCA). The MCA has no powers to regulate these studies but, in view of its role in protecting public health through regulation of medicines, it has a major interest in ensuring that the studies are well-designed, and that it is adequately informed about them. The new guidelines are not set in stone and will need to develop along with the methodology in this field.

Relevance to clinical pharmacology

It is striking that few clinical pharmacologists have been closely involved in post-marketing safety studies. Perhaps this is because most studies have been conducted in general practice. However, many of the drugs about which we now need post-marketing safety studies are primarily used in hospitals [4]. We believe that academic clinical pharmacologists have an important role in influencing the design of such studies and in the analysis of the results. Thus the SAMM guidelines represent an opportunity for clinical pharmacologists and we hope that they will respond to this challenge.

References

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