

Recent Publications

Consistency in manufacturers' product information: the outcome of a CIOMS initiative

Manufacturers of pharmaceutical products have a responsibility to assure their safe use. Far more information is directed to clinicians, patients and consumers than has been the case in the recent past, but what is included in the prescribing information or package insert has never been precisely formalized internationally or even nationally. A working group set up under the aegis of the Council for International Organizations of Medical Scientists and consisting of representatives of research-based pharmaceutical companies and national drug regulatory authorities has explored the way in which manufacturers approach this responsibility and reviewed the relatively few relevant regulations and guidelines. The lack of criteria and conceptual guidance that now exists raised three basic questions:

- what information should be included (or not included) and how may one decide?
- on what basis and when should changes, including deletions, be made to an established sheet?
- where in the sheet should specific types of information be placed?

The group argues that lack of internationally agreed standards for the format and content of this information has given rise to discrepancies and inconsistencies. It anticipates that three advantages will stem from its proposals if such standards can be developed:

- confusion among prescribers and other health professionals generated by inconsistencies in the way that information is compiled and presented will be reduced;
- access to information required for making rational clinical decisions will be facilitated;

- the disparities resulting from different regulations and guidelines regarding national alerts and expedited reporting requirements will be eliminated.

The group conceded, however, that since the legislative framework for pharmaceuticals varies considerably from country to country, the pharmaceutical manufacturer cannot necessarily adhere to a single strategy for dealing with safety issues, although this is the objective. It also recognized that consistency over core safety data will be difficult to maintain when products containing the same drug substance are marketed by several manufacturers. When one company modifies its data, should all other companies adopt the same change? If so, how would these changes be initiated and who would be responsible?

Not surprisingly, the group offers no confident guidance on some of these issues. It is highly significant, however, that the group was convened in the first place. It seems that there is a strong undercurrent, both within regulatory authorities and large companies, that recognizes a need for consistency of information and that is determined to overcome the matters of process that would otherwise obstruct this objective.

Council for International Organizations of Medical Sciences. *Guidelines for preparing core clinical-safety information on drugs*. Report of CIOMS Working Group III. CIOMS, Geneva, 1995. ISBN 92 9036 062 3, Price Sw. fr. 15.-

The use of essential drugs

This technical report provides guidance for all countries wishing to rationalize their drug use. It includes information on every aspect involved in the establishment of a national list of essential drugs and presents WHO'S eighth model list. This list identifies core groups of substances judged capable of meeting the vast majority of health needs and thus deserving priority in purchasing decisions and procurement schemes.

The first part of the report provides updated information on several components of national drug policy necessary to assure that essential drugs, corresponding to essential health needs, are available at all times in adequate amounts and in the proper dosage form.

Topics covered include the components of quality assurance, the growing need for reserve antibiotics in areas where resistance to widely available antimicrobials has developed, the priority health needs of displaced communities, the need for relevant and reliable information on drugs, and the contribution of post-marketing drug surveillance to the rational and safe use of drugs.

The eighth WHO model list of essential drugs is then presented, together with an explanation of changes made when revising the list. Organized according to therapeutic group, the list includes information on route of administration, dosage forms, and strengths for each of 284 essential drugs.

Annexed to the report are notes on the provision and dissemination of drug information, followed by detailed guidelines for antimicrobial susceptibility testing in countries with limited resources. The report also features extensive new guidelines for good clinical practice for trials on pharmaceutical products. The guidelines, which establish globally applicable standards for the conduct of biomedical research on human subjects, specify the responsibilities of investigators, ethics review committees, pharmaceutical manufacturers and other sponsors of research, and drug regulatory authorities. Intended to help ensure the ethical and scientific integrity of clinical trials, the guidelines serve the interests of parties directly involved in the research process while also protecting the rights and safety of subjects.

Sixth report of the WHO Expert Committee on the Use of Essential Drugs. Technical Report Series, No. 850, World Health Organization, 1995. Price: Sw. fr. 21.-