Essential Drugs Monitor

N°17 (1994)

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The Essential Drugs Monitor is produced and distributed by the WHO Action Programme on Essential Drugs. It is published in English, French and Spanish, and has a global readership of some 200,000 to whom it is free of charge. The Monitor carries news of developments in national drug policies, therapeutic guidelines, current pharmaceutical issues, educational strategies and operational research.

WHO's Action Programme on Essential Drugs was established in 1981 to provide operational support to countries in the development of national drug policies and to work towards the rational use of drugs. The Programme seeks to ensure that all people, wherever they may be, are able to obtain the drugs they need at the lowest possible price; that these drugs are safe and effective; and that they are prescribed and used rationally.

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In this issue:

EDITORIAL

QUALITY control of drugs is of vital importance. It is often viewed as applying primarily to the "hardware", or the chemical substance of a product. Yet if a drug is to be used safely and effectively, the "software", or the information that accompanies it, is of equal importance. If inaccurate information on indications, risks and the side effects is conveyed to prescribers and consumers then a drug's potential for benefit is converted into potential for harm.

During the last two decades much concern has been expressed nationally and internationally about standards of drug information, particularly within the context of drug promotion. Within industrialised countries, strengthened regulatory control and greater commercial responsibility have led to improved marketing practices. When unethical marketing does occur, one highly effective recourse used in the USA has been to require the offending company to publish retractory statements in all media which contained the original misleading promotion (see EDM 16).

However, despite improvements in drug marketing, problems remain and these are particularly acute in the developing world. This issue of the *Monitor* describes some recent studies that highlight areas of concern. In particular, they indicate frequent double standards in how products are marketed in countries with strong pharmaceutical regulation (most industrialised countries) compared with countries with much weaker legislative infrastructure and capacity for regulatory enforcement (most developing countries). Such ethical discrepancies continue to be documented in many parts of the world.

Industry spends a large proportion of its promotional budget on representatives who regularly visit prescribers to promote company products. Clearly such face to face interaction is effective or companies would not invest so heavily in it. But such encounters are difficult to monitor. The two studies of drug representatives in action in France and the Philippines, included in this issue, are therefore particularly interesting. An innovative training programme to teach medical students how to interact most effectively with medical representatives and how to evaluate different sources of drug information is also described.

This issue also traces the development of WHO's Ethical Criteria for Medicinal Drug Promotion. As far back as 1968 concern about improper pharmaceutical advertising led to the adoption by the 1968 World Health Assembly of Ethical and Scientific Criteria for Pharmaceutical Advertising. Twenty years later, following the Nairobi Conference on Rational Drug Use, these Criteria were expanded to include all pharmaceutical promotion, and again adopted by the World Health Assembly. The Criteria place drug promotion firmly within a public health context. They state unambiguously that drug promotion should be in keeping with national health policies; should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste; and that it should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks.

Noting that "little information was available on any progresss in controlling medicinal drug promotion through the use of the concepts embodied in the WHO Ethical Criteria", the World Health Assembly in 1992 called for a joint CIOMS/WHO meeting to discuss how the Criteria could be furthered. The recommendations of this meeting, summarised in this issue, were endorsed by the World Health Assembly in May this year. In particular, the Assembly called on WHO to disseminate the Ethical Criteria widely and to monitor their implementation: to develop and disseminate related educational materials; and to support member states in strengthening their regulatory capacity.

As a first response to the Assembly's call, this issue of the *Monitor* reprints the WHO Ethical Criteria in their entirety, and examines some of the current problems faced by developing countries. But WHO's role, although important, is just one among many. Industry, legislators, educators, medical professionals, the media and consumers all have critical roles to play if drug promotion is to consistently and globally meet the ethical standards outlined in the Criteria and endorsed by all Member States.

However, greater awareness is needed that even when commercial promotional material meets ethical standards, its contribution to the rational use of drugs is limited. Such material promotes a certain product, and does not provide the comparative, comprehensive and independent information needed by prescribers and consumers to make a fully informed choice. Sole reliance by prescribers on such sources of information can lead to drug use that may be unnecessarily expensive, therapeutically inappropriate, or even harmful. Reliance by consumers only on commercial drug information may lead to the purchase of drugs that are heavily promoted but irrelevant to real health care needs - such as expensive vitamins, tonics, appetite stimulants and cough mixtures. When family incomes are small - the case in most developing countries - there is the risk that inessential purchases, induced by marketing, may replace necessities, such as adequate food or a truly needed medicine.

Ethical drug promotion is vital if drugs are to contribute to health care and not detract from it. However, educating prescribers and consumers, and promoting access to independent, non-commercial information, is of equal importance if drugs are to be used appropriately and cost-effectively. ❑