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# Non-information for patients: selling drugs in developing countries

S. van der Geest

The majority of medicines are commonly divided into two types: prescription-only and non-prescription medicines. The former are restricted by law to sale or supply on a doctor's prescription and should be taken only in accordance with a doctor's instruction. The latter are on open or pharmacy-supervised sale to the public and are available for self-treatment without a doctor's prescription. Other terms used for the latter category are 'over-the-counter (OTC) medicines' and 'proprietary medicines', although these are not exact synonyms.

There is one major problem with this conventional classification: it applies only to the industrialized countries of the West. In almost all developing countries the category 'prescription-only medicines' does not exist. The medicines which are labeled as 'prescription-only' are available, but there are virtually no medicines which can be obtained only on a doctor's prescription. Nearly every medicine, including the so-called 'prescription-only' ones, are available for sale, in informal drug-stores as well as in official pharmacies. Under these circumstances there is only one class of medicines: the non-prescription type.

To avoid a misunderstanding, it should be emphasized that the situation just described is seldom in accordance with the official local legislation. The laws concerning the sale and use of drugs in developing countries are often as strict as those in the industrialized west, but the actual practice widely diverges from the rule.

There are several explanations of this divergence. The most obvious one is that the norms for drug-distribution postulated in the legislation are simply replicas of those used in Western countries and are hardly realistic for the circumstances in developing countries. Industrialized countries have a highly developed infra-structure of medical facilities, including doctors and pharmacists, therefore the norm that certain medicines should only be obtained through a doctor is realistic. However, in most developing countries doctors are often not available or their accessibility is greatly hampered by geographical and social distance, lack of transport, etc. To insist on the norm of a doctor's prescription in such countries would be absurd and could be extremely harmful to people's health. Therefore it is understandable that the official laws are often not observed. Other factors promoting the open sale of all medicines are closely linked to the poor medical infra-structure. They include the strong emphasis on self-treatment which has a long tradition in most non-industrialized societies[1,2]; the presence of drug pedlars and non-authorized drug-stores[3–6]; the practices of unqualified 'injection doctors'[7,8]; and the frequent incidence of induced abortion[9,10]. These factors are discussed more elaborately elsewhere[11,12]. The only medicines which are probably 'prescription-only' in most developing countries are narcotics.

The fact that so-called 'prescription-only' medicines are on open sale in developing countries is largely ignored by the companies selling pharmaceuticals to these countries. Drug companies seem conveniently to assume that the strict rules concerning drug distribution which prevail at home also exist abroad. When it is pointed out to them that conditions in developing countries may be very different, they seem to regard this merely as the responsibility of the local government. Leaving for the moment the question of responsibility, it is clear that the situation is grave enough to require attention. The exportation of dangerous medicines to countries where they are likely to be wrongly used due to the lack of adequate patient information and the by-passing of doctor's prescriptions should no longer be tolerated.

Drug companies have recently been continuously accused of reprehensible sales policies in developing countries. The main criticism levelled against them is that they do not exercise the same strictness and care in developing countries as they do at home. Several instances have occurred of companies selling pharmaceuticals to developing countries which are forbidden, or in any case not registered, in the exporting country itself. Perhaps the best illustrated example is the selling of over 10 million capsules of chloramphenicol by Parke-Davis to clinics of former South Vietnam shortly after it had been virtually banned for use in the U.S.A.[13]. Other examples of drugs with a similar history are 'Depo-Provera', an injectible contraceptive[14], 'Albamycin-T', an antibiotic, and quinoform[15].

Another criticism is that companies change the descriptions of their products to promote sales in developing countries. Silverman[16] and others[17] have shown that the manner in which certain drugs are described to doctors in the U.S.A. differed considerably from the description given to doctors in Latin America and other developing countries. In the latter countries the listed indications were far more numerous while the hazards and contra-indications were fewer.

The publicity around these improper marketing practices has led to various reactions demanding that pharmaceutical companies treat developing countries in the same way as they do industrialized countries and that they observe the same marketing standards. The International Federation of Pharmaceutical Manu-

*Sjaak van der Geest is at the Anthropological-Sociological Centre, University of Amsterdam, Sarphatistraat 106 A, 1018 GV Amsterdam, The Netherlands.*

facturers' Associations (IFPMA) has responded to these demands by drawing up a 'Code of Pharmaceutical Practice'[18] in which the obligation to observe the same standards in developing countries is recognized. According to this proposed code the obligations of the industry are:

To ensure that all products it makes available for prescription purposes are backed by the fullest technological service and have full regard to the needs of public health.

To produce pharmaceutical products under adequate procedures and strict quality assurance.

To base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions for use.

To provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contra-indications, tolerance and toxicity.

To use complete candour in dealings with public health officials, health care professionals and the public[18].

Viewed in the light of the malpractices mentioned above such a code would seem a great improvement. However, in a recent document[19] the organization Health Action International (HAI) describes the proposed code as a 'sham' which does not curb the malpractices, but is meant 'to prevent any serious attempt to do this by independent authorities'. HAI's main criticism is that the code is not enforceable. But even if the code was made enforceable and the high standards were actually put into practice in developing countries, many problems would remain.

Ironically, equal standards would perpetuate the existing inequality between developing and industrialized countries. 'Strict quality assurance' and 'objective scientific information' have little effect if the drugs end up in a sales circuit where most of the information is lost and where incorrect use is more likely to occur than correct use. Obviously, even the highest quality drugs become harmful when they are used wrongly. The 'objective scientific information' with respect to the drug's indications, contra-indications, tolerance and toxicity often does not reach the public because in the informal market-sector drugs are retailed in very small quantities and the original packing with the information is not usually seen by the client.

In its critique of the proposed code HAI rightly states, 'the phrase "full regard to the needs of public health" has little meaning unless it takes fully into account the conditions typical of many developing countries, where prescription drugs are freely available over-the-counter and widely used for self-medication'.

Some examples may clarify this point. Recently a Dutch firm was severely criticized for promoting an anabolic steroid preparation called 'Orabolin' for children with retarded growth in Bangladesh. This was a clear example of misinformation, because obviously the real cause of retarded growth in Bangladesh children is under-nutrition. Moreover, in the U.K. Orabolin is explicitly 'not recommended for children'. But even if the information in Bangladesh had been correct, there would still have been ample chance that Orabolin would become a popular medicine for better growth of children on the informal medicine market. The fact that Orabolin is a prescription-only medicine did not prevent it from being sold without prescription all over Bangladesh, in pharmacies as well as in drug stores.

'Lomotil' is an antidiarrhoeal drug marketed by a U.S.A.-based pharmaceutical company. Its story, which sounds very similar to that of Orabolin, has recently been spelled out by Medawar and Freese[20]. They write, 'In a developed country, Lomotil is available only on prescription. It can be obtained only on the advice of a licensed physician, and dispensed only by a properly qualified pharmacist. The circumstances under which Lomotil should and should not be prescribed are notified to physicians and spelled out in detail, as the law requires. The information that is given to physicians reflects the existence of a significant literature on the drug; as well as information from formal systems used to collect and evaluate data on untoward side effects and adverse reactions. In a developing country, Lomotil is freely available over the counter and probably widely used for self-medication. Users get no instructions; and many have no real understanding of what Lomotil is or does'.

Many more examples could be added. The two examples just mentioned caught the public's attention because the companies' marketing methods were patently misleading. Ironically, even more damage may be caused by drugs which are marketed in a rather 'correct' way, but are used wrongly on a very large scale. Countless antibiotics which cause wide-spread resistence without curing anything provide probably the most dramatic example.

In conclusion, attempts to force pharmaceutical companies to observe the same marketing standards in developing countries as they do in industrialized countries are not sufficient to improve the distribution and use of drugs in the Third World. Paradoxically, equal marketing procedures by the pharmaceutical industry will perpetuate the existing problems of drug misuse. The reason being that products which are labeled 'prescription-only' drugs are sold openly to the public in most developing countries. The patient information which is provided through the doctor's prescription in the western world is often lacking in the Third World. As a result, precription drugs which are bought for self-medication are often wrongly used, due to a lack of adequate information, and cause great harm.

It is in the interest of the pharmaceutical industry to ignore these problems and simply to continue their sale of prescription drugs to developing countries. It is, however, in the interest of the people in these countries that measures be taken to prevent potentially useful drugs from causing harm instead of curing disease. The aim of this brief report has been to call attention to the present situation.

Recommendations as to how the situation could be changed are more difficult to give. Recent developments in some developing countries suggest that measures against the proliferation of uninformed medicine use are only effective when the country itself decides to pursue a policy of restricting the import of non-essential drugs, following WHO guidelines[21].

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# Books

## Information mines

**British National Formulary, No. 4**
*edited by G. R. Brown, published jointly by the British Medical Association and The Pharmaceutical Society of Great Britain, 1982. £4.50 (xiv + 440 pages) ISBN 0 85369 143 6*

**USP DI, 1983. Vol. 1: Drug Information for the Health Care Provider.**
**Vol. 2: Advice for the Patient**
*published by the United States Pharmacopeial Convention, Inc., Washington, U.S.A., 1983, $37.95 for both volumes; $17.95 for Vol. 2 only; $9.00 for Updates to December 1983. (Vol. 1: xxv + 982 pages. Vol. 2: xxi + 793 pages)*

**Consumer Drug Digest**
*edited by the American Society of Hospital Pharmacists, Facts on File, Inc., 1982. $9.95 (xvi + 477 pages) ISBN 0 87196 686 7*

**Compendium of Pharmaceuticals and Specialities, 17th edn**
*published by the Canadian Pharmaceutical Association, 1982 (distributed outside Canada by Marcel Dekker, Inc., New York, U.S.A.) Sfr 185 (x + 650 pages).*

These four publications, all produced by official bodies, represent consensus view-points and between them provide a veritable mine of information on three major aspects of drug information. Being produced in three different countries, they obviously cover information on drugs and preparations available in the country of origin (Therefore, beware of terminology).

'Full disclosure' information which is required by law to be available to the prescriber in order to assist him as regards approved indications, dosage, side-effects, contra-indications etc. is provided for Canadian products by the *Compendium of Pharmaceuticals and Specialities*. This collection of information can be considered the Canadian equivalent of the British *Data Sheet Compendium* and the American *Physicians Disk Reference* (PDR). However, in contrast to these, it includes entries on not only the branded products, but also on the approved preparation e.g. acetaminophen or paracetamol with a cross-reference to the branded product and vice versa. Entries are listed alphabetically (unlike the aforementioned British and American equivalents) and these two modifications improve the usefulness of such a compendium. Like the PDR, it is well referenced with brand/approved name, manufacturers and therapeutic index, together with a coloured, product-recognition guide. As a guide to full disclosure information on Canadian products it is an excellent publication.

'Practical prescribing advice' relating to British products is included in the *British National Formulary (BNF) No. 4*. Unlike the above books it does not contain 'full disclosure' information, but sufficient is provided to allow this pocket-size book to be used in deciding on what therapy should be given. The BNF is arranged in pharmacological order with separate subsections covering the drugs and preparations used within that general area. It is well-indexed and each section provides, prior to the individual drug entries, general advice on the choice and problems associated with such therapy. A guide to the approximate cost of the drug(s) chosen is also provided, although this has to be limited to broad ranges and is based at present on an arbitrary number of tablets rather than a dosage regime. The BNF also draws the attention of prescribers to products which it is felt should not be prescribed i.e. are not recommended, for example compound analgesics. Included in this very useful guide are sections on prescribing in certain problem areas e.g. pediatrics, liver disease, renal impairment and pregnancy. General advice is also offered on prescription writing, legal requirements and the treatment of poisoning. The BNF, which is now updated every 6 months, offers the prescribing doctor a very useful guide