EDITORIAL

DISSEMINATION OF DRUG INFORMATION TO PATIENTS THROUGH DRUG PRODUCT LEAFLETS

A common problem facing clinicians and pharmacists is how to communicate drug information to patients in a clear, precise and unambiguous manner even though the patient may not have the necessary background to comprehend certain scientific concepts. It is well known that patient compliance is greatly influenced by how such information is communicated. In some way, the health professional is expected to justify in a persuasive manner the choice of specific drug, even though this is not stated. The patient may have some suspicion regarding the effectiveness and safety of a drug based on prior experience but rarely volunteers such information.

There are several ways of communicating information on drugs. An earlier editorial in this journal examined the use of posters to communicate drug-related messages to patients (East Cent. Afr. J. Pharm. Sci. Vol. 3, No. 2 (2000), 25). By far the most common one is verbal communication during dispensing. This is a very effective method since the pharmacist/clinician will choose the best method depending on each patient and take into account the level of literacy, age and complexity of dosage regimen. At times, it may be necessary to communicate in the local language or even enlist the assistance of an interpreter.

The other method of communication is by use of drug product leaflets (inserts), which is the subject of this editorial. Most national drug regulatory agencies require that each drug product must be accompanied by a product leaflet giving comprehensive details regarding reconstitution, mode of action, bioavailability, storage conditions, adverse effects, possible drug interactions, contraindications e.t.c. In some countries, such information must be directed at the patient while in others, it is directed at health professionals. The information must be in a language that the patient understands. For multinational drug companies, this poses a serious dilemma and the leaflet is often printed in several languages (English, French, Arabic, e.t.c.). Drug product leaflets are of limited use where the level of literacy is low as is the case with many African countries. Even in countries where the level of literacy is high, the majority of patients are unlikely to comprehend the significance of such details as mode of action, drug interactions and adverse effects. Many pharmacists/clinicians will recall embarrassing occasions when patients pointed at the long list of adverse effects on the leaflets and wondered aloud why they could not get an alternative drug with no or fewer adverse effects. And how does one explain to an expectant mother the significance of such statements as: "…the safety of this medicine in pregnancy has not been established…."?

The information on the leaflets is very basic and any qualified professional would be expected to be conversant with it. Even where it becomes necessary to consult the leaflet, he/she will only do it once or twice during the practice, yet all the packages for that product must carry the literature insert. The obvious question is whether the product leaflet serves the intended purpose and if so, what information needs to be included in such a leaflet. This point was brought to focus in a decision by the Committee on Drug Registration (CDR), Ministry of Health, Kenya. A leaflet was submitted by an applicant which erroneously indicated that amitriptyline, a tricyclic antidepressant, is a monoamine oxidase inhibitor (MAOI). Although the application had satisfied all the other requirements, it was referred back to the applicant to effect the necessary correction.

Dissemination of information to patients through drug product leaflets, though well intended, is based on wrong premises i.e. the patient is able to appreciate the significance and limitations which are often implied but not explicitly stated. It may be that the patient is expected to read the leaflet selectively. If so, why include scientific information that is beyond his/her comprehension? For example, it is logical to advise the patient not to take alcohol while on treatment with metronidazole

or that he/she should not drive while on medications containing antihistamines. Including such information as: "possible hallucinations in a few patients" is counterproductive. One would wish that patients could read the leaflet selectively in the same way a pastor/priest chooses which verse in the Bible to read and which one to omit. This reminds me of a rural based pastor who is fond of basing his sermons on the book of Leviticus, chapter 19. The particular verse reads: *"...Do not curse a deaf man or put something in front of a blind man …" (Leviticus 19:14).* For obvious reasons, he chooses to say nothing about the verse later in the chapter which reads, *"…Do not plant two kinds of seeds in the same field. Do not wear clothes made of two kinds of material" (Leviticus 19:19).*

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