THE PUBLIC'S RIGHT TO DRUG INFORMATION

LE DROIT DU PUBLIC A L'INFORMATION PHARMACEUTIQUE

Mr. W. Maszczak
Drugs Directorate
Health Protection Branch
Health and Welfare Canada
Ottawa, Ontario K1A 0L2

ABSTRACT

The paper deals with future trends in patient disclosure. Beside recognizing the patient's right to know what he is taking, other reasons for provision of information include improved patient compliance, prevention of some drugs-drug and drug-food interaction, and self-recognition of the early sign of drug toxicity. One of the ways of providing information to patients is by means of an accompanying leaflet called a SIM (Supplementary Information on Medication). Development, content, style and distribution of SIM's is examined.

RESUME

L'auteur traite des tendances futures dans la divulgation de l'information aux patients. En plus de reconnaître le droit du patient à savoir ce qu'il prend, il existe d'autres raisons motivant cette divulgation de l'information dont l'amélioration de l'attitude générale du patient, la prévention de certaines intéractions nocives entre les médicaments et de ceux-ci avec la nourriture, et enfin l'auto-dépistage des premiers symptômes de l'intoxication aux médicaments. L'une des méthodes pour fournir l'information aux patients est une brochure intitulée ISM (Information Supplémentaire sur les Medicaments). L'auteur discute de l'élaboration, du contenu, du style et de la diffusion du ISM.

THE PUBLIC'S RIGHT TO DRUG INFORMATION

I am with the Drugs Directorate of the Health Protection Branch. For those of you who may not be familiar with us, we are the government agency that regulates the importation, manufacture and the sale of drugs in Canada.

Perhaps regulate is not a good word to use because regulations are not always the best way to achieve our objectives.

Besides the availability of safe and effective drugs, one of our objectives is the judicious and proper use of these drugs. A way of achieving this is through the provision of information about drugs.

This issue of patient disclosure is one that has been subject to much debate in North America lately. It is also an area where we have seen considerable changes in attitude.

There used to be an old medieval maxim to the effect that "in the presence of the patient, Latin is the language". For centuries, the ethics of the medical profession discouraged the disclosure of drug information to patients. The 1647 version of the code of ethics of the Royal College of Physicians states "Let no physician teach the people about medicines, or even tell them the names of the medicines, particularly the more potent ones, such as purgatives, opiates, narcotics, abortifacients, emetics or any other which are particularly dangerous, for the people may be harmed by their improper use. This under penalty of forty shillings." Medical practitioners have demonstrated, throughout history, a certain proficiency or talent for secrecy. Medicine itself has always been surrounded with mystery and secrecy.

It was merely a few decades ago that prescriptions were written in Latin, a reflection of physicians' beliefs regarding the concealment of information from patients. Indeed, parts of prescriptions are still written using Latin terminology, oftentimes in indecipherable handwriting. While most health professionals are now willing to disclose drug information and generally endorse practices which lead to better informed patients, there is significant concern about total disclosure, perhaps in the same spirit as the 1647 Code of the Royal College of Physicians "... for the same people may be harmed ...". There are those who still say that providing too much information to consumers encourages them to practice medicine without a licence.

Nevertheless, the mystery and pharmacological secrecy are slowly and gradually being replaced with information and knowledge through increased communication between health professionals and patients. Perhaps one of the most important changes in this area is the appearance of the product name on the label of prescription drugs. This requirement is the key which

enables consumers to seek detailed information in the health sciences literature in the absence of widely distributed written information at the time of purchase of prescription drugs.

There has been an increased interest in drug information. This is a phenomenon which is consistent with current changes in the health care process, that is, motivation of patients for their own self-care, the recognition by patients of their rights as individuals, and an increased awareness of the limitation of drugs.

It has been recognized that consumers/patients have a right to more information about drugs than is now made available to them.

The pharmaceutical industry, health care professionals and governments have always been preoccupied with the provision of high quality, optimally effective and safe therapeutic agents to patients who then often failed to comply with their prescribed therapy. It is widely recognized that in spite of all the research, testing, control, distribution and diagnostic efforts by all these well-intentioned groups, prescription drugs may be ineffective or even dangerous if the patient fails to comply with his/her medication regimen.

This particular problem is beginning to receive considerable attention. It has been known for some time that for some forms of treatment, the rate of adherence by the patient to instructions may be as low as 30% especially if measured over longer pericds of time. This is a common factor with anti-hypertensive drugs. Hypertension can be largely an asymptomatic disease, meaning that there are no symptoms. Because of this, patients often complain that they feel better without their medication than they do when taking it. Nonetheless, it is of the utmost importance that anti-hypertensive medication be used in a regular conscientious manner. Indeed, for some anti-hypertensive agents, rebound hypertension can occur if only a few doses are omitted.

A similar situation occurs with antibiotics, which are sometimes taken until the patient feels better and then he stops. The danger here is that the infection is often not yet completely cleared up and will recur.

Thus, provision of information can influence a patient's behaviour so that he or she will be motivated and reinforced in some manner for compliant drug-taking behaviour. A prime example of this would be informing a patient that the risks involved in taking a specific prescribed drug outweigh the risks of not taking it and, in general terms, apprising the patient of the reasons why.

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During the past decade, several studies of drug reactions have suggested that many are preventable by simple adherence to instructions with regard to storage, expiry dates, concomitant use of foods and drugs and, of course, alcohol. Adverse reactions which are allergic in nature sometimes are occasioned by unrecognized similarities in structure of what appears to be unrelated drugs, and also because of the many different trade names employed for the same pharmaceutically active ingredient.

It would appear that some simple instructions to patients about their drug therapy might bring about a number of benefits including increased compliance and decreased numbers of therapeutic failures. They might also increase self-recognition of the early symptoms of drug toxicity. Indeed, the majority of papers published in the last few years on this matter suggest in one way or another that supplementary information on medication for the user can, and does, have a significant positive impact on therapy and compliance rates.

Frequently the explanations given verbally by a physician to a patient at the time of prescribing are simply not heard and certainly not remembered some hours later. This is particularly true if several prescriptions are received at the same time. Moreover, there is an obvious limit to the amount of time which a physician can devote to informing his/her patient verbally in a language he/she can understand.

I think, from these arguments, you will see that if a patient is to use a drug wisely and minimize risks from adverse reactions, there is a need for more information.

Through resolutions passed by consumer groups, there is also evidence of a desire for more information abouts drugs they are taking.

Just to sum up, I think we see that there is a recognition of the right to know, a recognition of the need to know, and indeed there is evidence of a desire to know and to be given more information about drugs. It is reasonable to conclude that more information should be made available.

The question then arises about how the information should be provided.

The obvious simple solution would be for the Health Protection Branch to pass a regulation that all prescriptions must be accompanied by additional information. But is this really the best way? Let me outline some of the difficulties and drawbacks.

One is that two levels of government are involved. The Federal Government is responsible for the labelling and sale of

drugs. The Provincial Government is responsible for the professions of pharmacy and medicine. Obviously, there will be some overlapping of jurisdiction. Any unilateral move by the Federal Government could be seen as an intrusion into provincial jurisdiction.

Also, the two professions of pharmacy and medicine are involved and each has their own sphere of responsibility. Some members of these professions, just as some of the public, resent what they feel is an unnecessary government intrusion into their daily lives.

The manufacturing sector with literally thousands of drugs on the market also has an interest in how additional information is distributed. Over the last several years there has been a lot of discussion on the economic effects of regulation.

It is incumbent on government to examine alternate ways of achieving a desirable goal.

In many European countries persons who need and want information about drugs will ask the pharmacist for it at the time of dispensing. In North America, few persona have been raised in this tradition. In general, the Canadian pharmacist does not ask about the nature and extent of the information that has been provided by the prescribing physician to the patient. Indeed, the North American pharmacist has not, until very recently, been trained to act as a drug ccunsellor. Because of this, pharmacy premises are not usually suitable for this task. Nevertheless, there is an expressed desire on the part of Canadian pharmacists to be involved in the provision of drug information, and it is uncommon to attend any pharmaceutical association meeting today where this topic is not raised and discussed.

One mechanism of providing more information would be as part of the product label. A prime example of this is with oral contraceptives. The decision here was made somewhat easier by the fact that these drugs are almost always dispensed in the manufacturer's original packaging. This is not the case with the large majority of other prescription drugs.

Despite the problems I have told you about, a consensus has developed that perhaps the most effective way of conveying drug information to patients is by means of an accompanying leaflet in support of and reinforcing information given verbally by the health professionals. This would be distributed by the pharmacist at the same time the prescription is dispensed. This leaves the patient with a permanent document which he/she can review at home and seek further assistance from the physician or the pharmacist as required.

We next come to the question of who should develop these drug information leaflets.

The Health Protection Branch has taken the view that drug information leaflets, with a few exceptions, should be developed under the leadership of those who will be responsible for their distribution. At the same time, we feel there is a need for a co-operative approach to the development of these leaflets. Industry, health professionals, consumers and governments all have an interest in the provision of information to patients and should work together in setting a policy for this purpose.

In 1977, the Canadian Pharmaceutical Association initiated consultation with other interested parties for the development of a policy approach on the matter. This phase of the project has now been concluded and supplementary information on medication, known as SIM's in Canada, has been developed on a priority basis and distributed to pharmacists on a voluntary basis. The Branch supports the C.Ph.A. in its efforts and we hope that this co-operative endeavour will preclude the need for mandatory requirements to disclose drug information in written form.

One of the concerns raised with this approach is the possibility of patients experiencing various side effects and anxieties based on the power of suggestion provided in a drug information leaflet. In some cases, the concern about the consequences of developing adverse reactions -- which do not occur very frequently -- may result in a refusal to comply with the physicians' instructions to use the particular medication. However, it is generally felt that the benefits to be obtained in terms of increased patient compliance and possible early detection of drug toxicity will outweigh this consideration.

Another important consideration is what information should be contained in these SIM's.

There is a need for the pharmacological classification and major use of the drug. Also included are effects of the drug on normal daily activities - especially activities that are affected when the drug modifies the level of consciousness of the patient. There will be information on how to take the drug. For instance, whether it should be taken before or after meals or with food, what to do when a dose is missed. There is also information on symptoms of some of the more common side effects and how they can be handled. The SIM will also describe the symptoms of the more serious side effects, which would act as warnings on when to stop taking the medication and call a physician or visit the emergency ward. Again there is a need for information on what foods or other drugs should be avoided while taking this medication and how the drug should be stored.

I think it goes without saying that the SIM's should be written in laymen's language, so they are easily understood.

With several thousand different drug products on the market today, I think you realize that it is impractical to have a SIM for each different product. For that very practical reason, the majority of SIM's will describe a drug class or subclass.

In summary, we in the Health Protection Branch feel that additional information to patients on drugs is important. At this point in time, we favour the voluntary approach for prescription drugs as proposed by the Canadian Pharmaceutical Association, with the participation and consultation of all interested parties. We are confident that these voluntary efforts will preclude the need for mandatory requirements to provide additional information on prescription drugs to the consuming public.

As I said in the beginning, regulation is not the only or the best way of achieving a desired objective.

Our sister organization in the United States, the Food and Drug Administration or FDA, attempted to proceed with compulsory requirements for what they called PPI's or patient package inserts. The original proposal was eventually scaled down to a pilot program for ten drug entities. Regulations were due to come into force earlier this year. This has now been cancelled by the new administration under pressures from several interest groups. The whole program is back at square one. I don't mean this is a criticism of the FDA; their situation is in many ways different from ours and they have their own realities to face and they will require their own solutions.

However, in Canada, we have a program that is now functioning and which we have every reason to believe will be successful.