Is this a world-wide problem?

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Summary

Substitution is a worldwide problem arising from professional pride and status and pressure of economics. Substitution, legal or otherwise, is encouraged by governments, international agencies, professional and quasi-official bodies.

Some faults lie in industry and the developing use of marks but generally it is economic pressures at a time of restricted resources and increasing demand that make for economy in all sections. It is thought that the use of generic names aids economy and that is why restrictions are placed on marks in all parts of the world.

I BELIEVE that substitution is a worldwide problem and is in no way limited to the United Kingdom, and I shall explain why I hold this opinion.

Much of the trend towards increasing substitution on an international scale arises from reasons of professional pride and status and to a larger extent to the pressure of economics in a time of increasing costs and an increasing demand for medical and pharmaceutical services. Substitution, legal or otherwise, is encouraged by governments and international agencies and no less by professional and quasi-official bodies.

It must be recognized that modern trends in the practice of trade marks in the pharmaceutical sector do give rise to concern. There is a number of both new and long established products where there is a tendency to duplication which means that there may be many different trade names for similar products of different manufacturers. Worse still, this plethora of trade names leads to a blocking of the register in many countries and means that increasingly a manufacturer now has to use up to four or five trade marks for the identical product when this is marketed on a worldwide basis.

Let us look at professional pride and status. The medical profession in its teaching and work tries hard to avoid the use of trade marks and uses instead generic names. This is general in all countries and is regarded as the right thing to do, on the possible basis that the medical profession is concerned with the actual drug and its effects and not

with the brand name or commercial aspects of any one manufacturer. Doctors in hospitals overseas, as they do in the United Kingdom, authorize hospital pharmacists to indulge in legal substitution thus encouraging a continuance when the patient leaves hospital and obtains supplies from an outside pharmacist. This trend to substitution is less, however, in the non-English speaking countries where legislation often requires dispensing in manufacturers' original packs.

The pharmacist, in his dispensing today, sees his traditional skills being taken over by the manufacturer but rightly considers that he is still the expert on drugs. He cannot see why, and does not want to accept that, his dispensing freedom is bound by the trade name of one manufacturer when he knows full well, or thinks he does, that other brands of the same drug would do just as well. This professional outlook is well exemplified in the Nordic countries. The Danish and Swedish associations of pharmacists have their own manufacturing and distributing organizations making a large range of pharmaceutical specialties, many duplicating well known international brands. Such organizations are beginning to multiply and increase in power, especially having regard to their close contact with the medical profession, and thus encourage the world growth in substitution.

I have stated that governments are also encouraging the trend to substitution and I shall give a few examples. The action of governments is founded usually on economic reasons, either to cut down, as they think, the cost of drugs on social security, or to encourage indigenous industry, possibly based on licensing from research based companies. Canada, for example, in all its provinces except Quebec, now insists that substitution takes place. If a pharmacist receives a prescription for a trade marked drug and there is a cheaper alternative on a recognized list, the pharmacist must by law provide the cheapest alternative. This is mandatory, not permissive, and goes far beyond what pharmacists in some countries would like to see. The Pakistan government has banned the use of all trade marks in respect of drugs except for a small list of products. Even the

manufacturer of a patented drug product, of which he is the only supplier, must pack and market it under a free name. This means that for practically all purposes the pharmacist must dispense by generic name. Where more than one brand exists there is no restriction irrespective of what precise product the doctor has ordered. Nigeria is considering similar laws and Peru has also forbidden the use of trade marks in relation to drugs. It is feared that other South American countries will follow the example of Peru. In the United States, the American Pharmaceutical Association has adopted a policy of favouring the use of generic names and denigrating the use of trade marks. The Association is working towards having the various State legislatures repeal their fair trading and non-substitution laws so that in nearly all cases the pharmacist may supply what he considers is the generic equivalent when a trade marked product is prescribed. Only a few months ago at an international meeting of the International Pharmaceutical Federation the American Pharmaceutical Association blocked acceptance of an agreement on labelling between the representatives of the pharmaceutical industry and the retail dispensing pharmacists because some of the clauses were considered not satisfactory in respect of the use of trade marks.

International agencies are also assisting in the trend towards substitution throughout the world, although not directly nor deliberately. The United Nations Industrial Development Organization and to a lesser extent the Organization for Economic and Commercial Development are assisting in the setting up of new pharmaceutical industries in the developing and less developed countries. Because of shortage of

trained staff and the difficulty of undertaking in the early stages complex manufacture, these plants usually begin with processing operations or simple manufacture of tablets, ampoules and other formulations of items in large demand. It is hoped that companies from developed countries will assist them. The type of product produced lends itself to generic substitution. Economic pressures together with the natural desire for a distinct national identity all favour the use of generic names, rightly or wrongly, and the trade mark finds itself cast as the pharmaceutical villain in these developing industries. Regulations are sometimes made and a structure set up to favour the substitution of locally made products as against imported branded products.

All countries are under increasing pressure to provide good social services of which the health sector forms a major part. There is a belief that trade marked drugs always cost more than generics although this remains to be proved. As all social security systems suffer from lack of finance, action is taken either to persuade doctors to prescribe generically, to authorize pharmacists to substitute or as is common in overseas countries to have an approved list of drugs that may be prescribed. When such a list exists it is relatively easy for the governing body to discriminate against trade marks in favour of generic names.

It is not my task to discuss the rights or wrongs of substitution nor to point out possible dangers, which will be discussed elsewhere. My duty was to give a view as to whether substitution is a worldwide problem. I repeat that I believe it is and hope I have amply supported this view.

Discussion

In answer to a question from Professor Clarke about the position of brandy, Mr Stevens believed that if the pharmacist went far enough back in history to one of the London pharmacopoeias, he would find that only French brandy could be regarded as official.

Mrs P. C. Turnbull, a pharmacist working for Riker Laboratories, was puzzled by the inconsistency within the Department of Health and Social Security. On the one hand, doctors were encouraged to use approved names in order to save money, concentrating on the active constituent with little regard for

the importance of formulation. On the other hand, in submissions for compulsory registration of products, great emphasis is placed on the specific formulation; if more than minor qualitative or quantitative changes are made in inactive ingredients, they must be explained and supported by biological and pharmaceutical data. Mr Stevens was sympathetic to the Department of Health because of its dual capacity in relation to the pharmaceutical industry, being both a major customer and the sponsoring government department. These two view points could hardly be reconciled.