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REVIEW

SCHEDULING DRUGS AND NATIONAL LEGAL CONTROLS THE NEED FOR RESEARCH

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ABSTRACT

The system of scheduling narcotic drugs and psychotropic substances under national legislation does not always correspond to the system of scheduling under the international drug control treaties. Even though many drugs have been scheduled under the international drug control treaties, few studies have been done to identify what happens when drugs are scheduled at the national level. Preliminary studies seem to indicate that non-availability and higher prices are two problems which are associated with the scheduling process at the national level. Further research is needed to have a better understanding of the dynamics of the scheduling process and the impact of national controls.

The Concept of Scheduling

The principal international drug control treaties (Convention 1971, Convention on Psychotropic substances on narcotic) are structured on the following fundamental principles (Khan & Jayasuriya 1984).

(a) Certain substances must be permitted to be used for scientific and medicinal purposes, even though their abuse could have serious public health, social and economic ramifications.

(b) In order to minizime the possibility of certain substances being abused, effective measures are necessary to confine their use to legitimate purposes under strictly controlled conditions.

(c) For an effective international control system, it is necessary that governments comply with certain obligations to other governments as well as to concerned international organizations.

Under the Single Convention on Narcotic Drugs, 1961, as amended by the Protocol of 1972, and the 1972 Convention on Psychotropic Substances, narcotic drugs and psychotropic substances are classified, depending on their abuse potential and therapeutic usefulness, into one of eight schedules. The schedules are based on subtle distinctions (Rexed et al., 1984, Krulwich, 1984) and in translating the treaty obligations into national legislation not all countries have provided for eight schedules.

The concept of "scheduling" at the international level, therefore, is not necessarily reflected in controls at the national level. As a consequence, a drug which is subject to a certain level of control under a treaty will not necessarily be subject to the same level of control in every country which has ratified the treaty. A drug, as it moves through international commerce, will, therefore, be subject to different levels of controls. By way of example, we may consider a psychotropic substance which under the Convention on Psychotropic Substances is subject to an ordinary prescription requirement. In some countries, this substance is regulated under a law which requires that it be prescribed only by using special prescription pads available, on request, from the authorities. Due to the formalities involved in obtaining them and the far-reaching consequences which entail the loss of counter-foils of special prescription pads, a significantly large number of medical practitioners may not obtain such pads. Thus, a drug with undoubted therapeutic usefulness will not be available to a certain segment of the community of patients as a result of the classification under national legislation. Besides the prescription requirement — which may also take other forms such as special authorization of medical practitioners — the scheduling process might effectively limit the range of medical personnel who may prescribe or dispense the drug.

Problem of non-availability

The problem of non-availability of important drugs as a result of the scheduling process at the national level has been underlined for many years. For instance, as far back as 1976, a WHO consultation on Drug Treatment for Neuropsychiatric Disorders in Developing Countries highlighted that certain essential drugs for the treatment of such disorders were not available to patients on account of national prescription laws prohibiting non-medically qualified community health workers from handling them (World Health Organization 1977).

There are several other reasons for the unavailability or restricted availability of drugs:

Firstly, pharmacists in some countries do not stock certain drugs which are subject to stringent controls, especially of a tedious or cumbersome nature (Jayasuriya 1985). Record-keeping procedures and security measures, though necessary to prevent the

illegal diversion of drugs, are often not perceived favourably because of the additional administrative work involved. In a survey of 38 WHO Member States, it was found that methadone, scheduled under the Single Convention on Narcotic Drugs but which is used extensively by cancer patients for relief from pain, was not available in 23 countries (Cone & Jayasuriya 1987). In other words, methadone was available only in 40 per cent of the developed and 32 developing countries covered in the survey. To give another example, morphine is not consumed at all in certain countries and even among the countries in which morphine is used, there are significant differences in the total amount available (Angavola & Wray 1989).

Secondly, manufactures and those engaged in import-export do not wish to get entangled in complicated administrative procedures regulating the manufacture, import, export, and distribution of scheduled drugs. A good example of a dramatic decline in imports and sales, soon after controls were introduced in Thailand in the early 80's, is valium injectables (diazepam). In 1979 sales amounted to about 1,181,850 ampoules but by 1984, sales had dropped to about 400,000 ampoules (Jayasuriya 1985).

Thirdly, due to the ubiquitous problem of lack of enforcement of national legislation, regulated drugs tend to disappear from the legitimate market, a problem which has happened in some countries (Jayasuriya 1985). Some of the drugs have reappeared later in the illicit market but manufactures have claimed that these are counterfeit or spurious products illegally imported from other countries (Jayasuriya 1985).

Price increases

Some countries do not have systems of price control for drugs in place. In such countries, prices are determined by the manufacturers and/or importers. Where there is no system of price control, pharmacists tend to arbitrarily increase the prices of scheduled drugs in order to cover the expenses involved in maintaining additional administrative and security systems (Jayasuriya 1985). Some countries with price control systems do not have a mechanism in place to make adjustments for additional costs involved in maintaining administrative and security systems in respect of newly control-led drugs. Where no provision is made for such extra costs to be recovered by increasing the retail price of the drug, manufacturers or importers may decide to phase-out production, or importation, as the case may be.

The research agenda

In the past, the scheduling of drugs and the problems which arise due to the diversity in national control systems and administrative infrastructure, have not received much attention (Angarola et al., 1985, Jaffe 1985, Jayasuriya et al., 1985). The medical

community is generally not too familiar with the scheduling process either under the international treaties or under national laws. Unless there is a system in place which provides for public comment before an administrative decision is finally taken, the medical and related professions such as pharmacists may not get an opportunity to comment on the feasibility or otherwise of a drug being placed under international or national controL Scheduling decisions affect not only manufacturers and importers and exporters, but also medical practitioners, pharmacists, other health-care personnel, and patient groups and to that extent there [is] a need for more dialogue and feed-back. We need to rind out the perceptions of the relevant professional groups and patient groups with regard to drugs which have been controlled or which ought to be controlled. We need to develop channels of communication so that the relevant professional organizations could comment on proposals for drugs to be scheduled or descheduled, as the case may be. Ideally, these comments should be available to the WHO expert group which evaluates drugs prior to a recommendation with regard to scheduling is transmitted by the Director-General of WHO to the Secretary-General of the United Nations.

A large number of drugs have now been scheduled under the two treaties. Perhaps, the draftsmen of the treaties never envisaged that such a vast number of drugs will one day come under international control. Even though drugs are increasingly being placed under international control, we have hardly any information as to what happens to those drugs which have been placed under national control.

One of the considerations which should guide the scheduling process is the availability of the drug for patients with a genuine therapeutic need (Jayasuriya 1980). There is, therefore, a need for further field studies which will shed light on the problems which the scheduling process brings in its wake.

Few studies have been done on the structure, content and problems with the implementation of national legislation on drugs of abuse (Khan et al., 1984, Jayasuriya 1980). Whilst the impact of national legislation on pharmaceuticals has been measured (Dukes 1985) and there are guidelines for developing countries (Jayasuriya 1985) on the formulation of such legislation, both international organizations as well as re-searchers have so far accorded little attention to narcotics legislation.

The system of scheduling seeks to strike a delicate balance between unrestricted availability, on the one hand, and controlled availability, on the other. If a proper balance is to be maintained and if we are to reap the maximum benefits of the system, we need further research to have a better understanding of the impact of controls. Indeed, the need for further studies was accepted, in principle, at a WHO consultation on the impact of scheduling drugs on the practice of medicine and pharmacy held in 1985 (WHO report 1985), but due to budgetary constraints field studies have been scaled don. Any

international study should involve the concerned international agencies (WHO, INCB, UNDICP) and non-governmental organizations; national drug regulatory authorities; professional medical, pharmacy, and nursing associations; drug industry; and last, but not least, patient groups.

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World Health Organization, "Drug for treating mental illness and epilepsy in developing countries", WHO Chronicle, Vol.31, 1977, p.55. It should be noted that the 1971 Convention on Psychotropic Substances permits certain scheduled drugs to be supplied by "lincensed pharmacists" or other licensed retail distributors" without a prescription. In some countries drugs are distributed directly by community health workers who do not acme within the category of either licensed pharmacists or licensed retail distributors.