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DRUG LEGISLATION

by

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Legislation in any field is the formulation and registration of the accepted practice within the frame work of the community and its established machineries. In developing countries there is an understandable tendency to use legislation as a means to initiate non existing practices or enforce a radicle shift or even reversal of already entrenched ones.

In these circumstances it is usually difficult to resist the temptation to try to achieve the ideal without giving due regard to the limitations of the existing facilities and prevailing conditions.

It is a pertinent observation that under these circumstances Drug legislation in any other field under similar conditions, prove in practice to be a handicap to actual progress.

In the preregistration stage there is a special problem now that needs special attention.

With inceasingly stricter requirements of the controlling bodies in advanced countries, which in certain instances means a vast increase in research expenditure and prolonged delay of marketing, there is an increasing temptation of starting what would appear in certain cases premature clinical trials in the less advanced countries. Often in these countries there are not enough available facilities to ensure proper safeguarding the patients through meticulous planning and detailed and continuous investigations.

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Until proper international measures are taken it is the prime duty of the national authorities to safeguard against the possible dangers with W.H.O. or regional backing.

The introduction of a new drug needs registration in one form or another. In most countries the formalities would require the creation of a scientific body that can handle the responsibility of passing judgement on the merits of these new drugs. Very few developing countries can mobilize the required facilities and experience to give these formalities real substance.

It is premature to suggest that international co-operation in this field under the auspices of the W.H.O. should be established. It is however possible to handle these problems on regional basis. The pooled facilities and experience of a group of nations with similar social, climatic and economical background, may be with W.H.O. backing would seem to present the best possible solutions. It may be possible under these conditions to expect a positive and constructive contribution from the concerned exporter even if legislative enforcement is not resorted to.

The proper regulation of importation and distribution is of prime importance in developing countries. Since local manufacturing often plays only a limited role in supplying the needs of health services. Legislation is needed not only to safeguard the consumer against the hazards of unsuitable quality but it may also be needed to plan the proper use of the restricted possibilities and to ensure up to a degree supplying the real needs and not the artificial or marginal needs inflated by promotion and advanced marketing techniques.

The problem of quality control needs first the creation of the required structure that can handle it. From the legislation point of view, however, certain points need clarification.

It is to be hoped that with the availability of the up to date international pharmacopoeia the less advanced countries will resist the temptation, often dictated by requirements of prestige than real necessity or capacity, to create their own.

In my view only very few of the advanced countries have the need as well as the facilities to do that. The real requirements of most developing countries can be met by issuing supplements to the International pharmacopoeia to meet their specific needs. For these supplements to have real value and substance they should be handled piece-meal or item by item to give the limited available facilities the concentrated freedom needed to do the proper studies required. Regional or International co-operation should be encouraged.

In developing countries with the deficiency often present in health services, and the need therefore to permit a certain degree of unqualified activitivities in different fields, the stricter regulations are called for on control, labelling, distribution and storage, these regulations, however, have to be within the scope and abilities of the existing machineries.

Simple and clear labelling in the native language is of importance since unorthodox distribution is often widespread. The necessity of an authorized medical subscription cannot be strictly enforced, due to deficiencies in the available medical service. Even broad spectrum antibiotics and similar radicle therapeutic agents cannot be denied to those who cannot afford to obtain the continuous medical care and meet its expenses. The manning of other auxilliary medical services may be deficient regarding the qualifications and the experience of the available personnel, thus removing another safeguard against the misuse of drugs. Under these circumstances legislation measures are of primary importance to the safety of the population.

The manufacturer, distributor and subscriber should shoulder full responsibility for their activities each within the scope of his role. Special strict regulations are often needed to prevent unauthorized production or distribution of faulty or adulterated drugs. In this aspect the mere knowledge of the defect or the failure of the qualified personnel to ensure the safety of these drugs should be considered a sufficient proof of guilt. For the non qualified or the non authorized, the existance of the defect and the expected consequences on the health of the possible user should meet its just punishment.

The need for supervision and control or regional state control can only be partially met in many developing countries.

It is, therefore, necessary to emphasize the primary responsibility of the producer for his products even after approval of the quality control authorities.

Quality Control is not enough to enforce at the production stage, including the starting materials, but is very much required to continue on these products during distribution and storage. The prevailing climatic and storage conditions in many developing countries necessitates such emphasis.

As in all newly established industries the drug industry in developing countries often needs a co-operative but strict supervision to ensure the establishment of good manufacturing practices, the problem is more often a lack of knowledge and experience. Legislative requirements regarding the specifications of the site, the facilities, as well as manufacturing procedure may be called for but their enforcement should be more by help and advice than mere prohibition once the good faith of the manufacturer is ensured. No allowances, however, should be permitted to the local producer that is not justified enough scientifically to be also extended to the importer. In the long run this is as important to the local producer as it is to the welfare of the population.

Quality control facilities should be available on a voluntary basis to the distributors and local manufacturers in addition to legal and systematic basis enforced by the law Often the lack of non governmental facilities makes imperative for the small dealer to skip a lot of the required control measures.

The practice of fractionating the contents of the original package, common in some developing countries, should be strictly limited to qualified and authorized pharmacists and the part distributed should be supplied in a marked container with the required labelling information and the name of the distributor to allow proper control whenever required.

While these scattered observations regarding the legislative requirements of developing countries in the field of drug production, distribution and control do not cover but a fraction of the increasingly expanding field, one final observation cannot be omitted. In this legislative field, like in all others, the law enforcing officer would be certainly failing his real role if in every day of practice he does not face up to problems that require re-interpreting the letter of the specifications and legislations making new allowances and opposing old established ones.