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DRUGGING OF ASIA—PHARMACEUTICALS AND THE POOR

Workshop organized by IOCU, VHAI and ACHAN
Madras 6th—9th December 1985

Summary of Workshop Conclusions on National Drug Policy prepared by Dr. K. Balasubramaniam, Pharmaceutical Advisor, Caribbean Community Secretariat

The Heads of States or Governments of Non-aligned and other developing countries had at two of their summit conferences recommended unanimously that each developing country should formulate and implement an integrated national drug policy in order to ensure access of the entire population to essential drugs at reasonable cost.

At the request of the developing countries, the United Nations Action Programme for Economic Cooperation among Non-aligned and other developing countries (UN-APEC) convened a meeting of a group of experts on Pharmaceuticals in *July 1976* in *Georgetown, Guyana*. This Expert Group was mandated to prepare an Action Programme on Pharmaceuticals and present it to the *Fifth Non-Aligned Summit Conference held in August 1976* in Colombo. The Summit Conference endorsed the recommendations of the Expert Group in Resolution No. 25 on pharmaceuticals. In this Resolution, the Heads gave an outline of an integrated pharmaceutical policy and also requested the relevant UN agencies to assist developing countries by examining in depth the pharmaceutical sector in developing countries and preparing a detailed drug policy and programme suitable for these countries. Accordingly in 1978, four UN agencies—UN APEC, UNCTAD, UNIDO and WHO constituted a Joint Task Force on Pharmaceuticals and fielded an inter-agency mission to several countries in Asia, Africa and Latin America to study the pharmaceutical sector in these countries. The Mission had discussion with relevant government officials involved in the public sector pharmaceutical supply system and with the private pharmaceutical industry and reported its findings to the Joint Task Force which then prepared a comprehensive report entitled, "Pharmaceuticals for the Third World : Policy for Health, Trade and Production." The conclusions and recommendations of their report contained a detailed description of an integrated national drug policy This report was submitted to the *Sixth Non-aligned Summit Conference held in Havana in September 1979*. The Conference endorsed the conclusion and recommendations of the Task Force Redort in their Resolution No. 8 on Pharmaceuticals.

From the foregoing it is clear that the developing countries have, at the highest political level, underscored the imperative need for each developing country to formulate and implement an integrated national drug policy to ensure access of the entire population to essential drugs at reasonable cost. The policy recommended by the Heads was based on a limited list of essential drugs.

Of the countries represented at the Asian Seminar on Pharmaceuticals Bangladesh alone had in 1982 formulated and implemented a rational drug policy based on the guidelines recommended by the Non-aligned Summit Conference. Within a period of three years the pharmaceutical supply system in Bangladesh has improved tremendously. Essential drugs are increasingly available to larger sections of the population at reduced costs. On the other hand countries which had not formulated and implemented a national policy based on essential drugs are paying very high prices for their lapse. For example the Workshop was informed that in India. A child was going totally blind every 13 minutes due to the unavailability of Vitamin 'A'—a cheap and essential drug. Some participants believed that it would be amounting to criminal neglect if health authorities in other countries continued to delay the formulation and implementation of a national drug policy based on essential drugs, particularly when our Heads have on two occasions, given clear directives to this effect. The participants therefore, appeal to the Prime Minister of India, Mr. Rajiv Gandhi, as the Current Chairman of the Non-aligned Movement to use his good offices to force health authorities of the member countries of the Non-aligned Movement, particularly those in South Asia, to formulate and implement national drug policies based on essential drugs and suited to their needs without any further delay.

The workshop also took the opportunity to identify the major components of a model drug policy suitable to countries in South Asia, using as guidelines the directives given by Non-aligned Summit Conference, Countries in the region may wish to use their model drug policy as a basis to formulate their own national drug poiicies.

A MODEL NATIONAL DRUG POLICY

A national drug policy should be linked to the health needs of a country and designed to ensure access of the entire population to essential drugs at reasonable cost.

The supply of essential drugs involves the active participation of many sectors including health, industry, trade, finance etc. It is, therefore, essential that an intersectional drug committee with representatives from all relevant sectors be established prior to the formulation of a national drug policy. Failing to observe this vital point and formulating a drug policy

without participation of all the relevant sectors would result in floundering at midstream at some point in the implementation stage leading to an interruption in the drug supply system. In formulating the national drug policy care should be taken to avoid undue influence of the private drug industry, particularly the multinationals.

The following would be the major components of a model national drug policy :

Drug Needs : National lists of essential drugs selected on the basis of the health needs of a country should be established. Evidence from some developing countries and the reports of the WHO Expert Committee on Essential Drugs indicate clearly that a limited number of essential drugs of about 250-300 would be sufficient to meet the major needs of the people.

Drug Names : International Non-Proprietory names (generic names) should be used whenever possible.

Quality Assurance : Appropriate steps should be taken to assure the quality of all marketed drugs. The success of a generic drug policy is critically dependent on assuring the quality of drugs.

Objective Information on Drugs and Therapeutics : Health Authorities should provide objective information to health persons.

Drug Legislation : A country *should enact* appropriate legislation covering registration, control of drug information including therapeutic indication, mention of adverse reactions, contra-indication, drug interaction price regulation and post market survey.

Price controls or monitoring should be introduced at the import, wholesale and retail levels.

Any introduction, amendment, alteration, variation, deletion of any drug legislation or releated laws shall be made available to all organization, association and individuals.

Procurement : At present drug imports are fragmented not only between the public and private sectors but also within each of these sectors. Foreign exchange savings could be effected by pooling these purchases by means of a centralised buying agency, some of the countries in the region have a centralised buying agency for the purchase of the public sector requirements but their bargaining power is limited since they do not have the vital market intelligence.

Production : All countries in the region have already established drug manufacturing units. In the majority of the countries, local production is dominated by the private sector. The commercial practices of the private

sector with emphasis on creating a demand and generating profits are counter-productive to the large scale production of socially useful essential drugs. A national drug policy based on essential drugs cannot be implemented with the uncontrolled practices of the private sector. Countries in the region should therefore give a leading role to the public sector and to socially conscious manufacturers like GK Pharmaceuticals of Bangaladesh.

Transfer of Technology : The uncontrolled transfer of pharmaceutical technology into the countries of the region has resulted in the manufacture of a large number of non-essential expensive drugs. Production facilities brought into the country at high costs are not being used for the manufacture of essential drugs.

Priority technological needs of the country should be identified when the decision to acquire technology has been made. Explore all possible sources of technology and select the most suitable technology, if necessary with assistance from relevant international agencies. The terms and conditions of the technology transfer agreement should be carefully examined and all restrictive clauses controlled and reduced. Priority should be given to acquiring technology from another developing country.

Promotion : Drug promotion by the drug industry must be controlled by the drug regulatory authority.

Patents : All countries in South Asia except India grant patent protection to pharmaceutical products and processes. India grants protection to processes only. Product patents enable the patent holder to gaida monopoly of the market. The host country will be prevented by its own national patent legislation from buying the same drug from a cheaper source.

The Non-aligned Summit Conference has recommended that pharmaceutical products and processes should be excluded from patentability. If process patents are granted, compulsory licensing should be used for exploiting the patent locally. Other alternatives relate to shortening of the duration of patents.

Regional Cooperation : Some of the components of the drug policy would be difficult to implement at the national level by some of the smaller countries of the region. These would include quality assurance, collecting market intelligence and local production. Taking these constraints into consideration, the Non-aligned Movement recommended the formation of regional pharmaceutical centres by developing countries so that member countries belonging to a regional centre could take joint action to implement some of the components at a regional level.

Several years of multinational negotiation would be required before a South Asian Regional Pharmaceutical Centre could be established. However Health authorities in the region could initiate some joint activities.

1. Market intelligence is totally lacking in the region. Countries could exchange information on manufactures, price trends, quality of products etc. among themselves.

2. Drug regulatory authorities in the region may wish to establish drug quality norms and explore the possibilities of enacting uniform drug legislations. This would enable the smaller countries in the region with their drug registration and quality assurance.

3. Objective information on drugs and therapeutics is another component which could be provided regionally.

The crux of the matter still remains that the cheif responsibility for the formulation of Rational Drug Policies lies with the National Governments.

In the view of the availability of well defined WHO criteria for such formulation - it is possible for Asian countries to have such rational policies provided they have the political will to do so.

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