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CARIBBEAN COUNCIL FOR SCIENCE AND TECHNOLOGY

REPORT OF THE ECLAC/CCST WORKSHOP ON
THE PHARMACEUTICAL SECTOR IN THE CARIBBEAN

14-19 March 1986, Havana, Cuba

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In opening the meeting, the representative of ECLAC thanked the Cuban delegation for hosting the workshop and outlined the role of the Caribbean Council for Science and Technology (CCST) in the promotion of information exchange, the fostering of technical assistance among the countries of the region and the bringing together of scientists in a search for solutions to common problems.

The meeting was addressed by Dr. Ernie Brunings of Suriname, in his capacity as Chairman of CCST. Some of the aspects of the work programme of CCST were outlined and the hope was expressed that through co-operative efforts the scientific and technological base in the region could be strengthened and thus meet the region's needs and reduce dependence on the outside world. This was the key to development.

The feature address was given by Dr. Jorge Antelo, First Vice-Minister in the Ministry of Health of Cuba.

The format of this report is as follows: the major points of each theme are presented together with the pertinent questions raised in the discussion period followed by Conclusions and Recommendations agreed to for further action.

The first session of the meeting dealt with "An Overview of the Pharmaceutical Sector in the Caribbean (CARICOM) incorporating: (a) Role of Transnational Corporations; (b) International Patent Systems". This paper was presented by the CARICOM Secretariat and delivered by Dr. Kumariah Balasubramaniam and Dr. George Boyd. The main points were as follows:

Prior to the achievement of political independence within the last 20 to 30 years, the health services in the Caribbean were based on the Colonial system of high technology hospital-based curative medical care. Subsequent to Independence, Governments have emphasised primary health care but in these States economies of scale do not operate because of their small sizes and the weakness of the purchasing system in the area. In most of the lesser developed countries, a relatively large proportion of the G.D.P, 2.16 percent, is spent on the importation of pharmaceuticals, a figure much greater than the world average which is 0.73 percent. Additionally, there is a wide variation in the unit price of drugs, both within and between countries. This occurs even in those countries which have an installed capacity for producing many forms of pharmaceuticals but are unable to penetrate the market.

In developing countries the heavy dependence on pharmaceutical transnational corporations (TNCs) is maintained by three mechanisms:

- Patents
- Trademarks
- Promotion

These can all be controlled by individual countries through appropriate legislation.

Patents

The consensus of opinion of various United Nations bodies which have analysed in depth the existing industrial property systems is that the Paris Convention has a negative impact on Third World Countries, since the principle of equality protects the monopolistic interests of patent holders. Local legislation can be used to lessen the impact of patents.

Trademarks and Promotion

The impact of trademarks is even greater than patents since this lasts for the life of the product. Although Caribbean Health Ministers have advised that there should be a shift in usage from brand name to generic drugs, this has not been achieved.

In shifting to generic drugs, the efficacy of these drugs must be assured by quality-control measures.

A regional drug testing facility for all marketed drugs has recently been established. Currently, CARICOM has formulated a list of all drugs imported into the region and it is proposed to prepare a formulary which will reduce the present multiplicity of drugs to those considered essential.

Additionally, Governments need to educate doctors and public health workers in this regard and to encourage the prescribing of generic drugs. A need exists for suitable drug legislation and for countries to have drug/therapeutic committees to examine the importation of drugs. National policies need to mesh with overall regional policies. In this respect, CARICOM has proposed a Joint Caribbean Authority for the Registration of Drugs (JOCARD).

A great deal of the discussion on the presentation centred on the patent system with two diametric concerns being voiced. One was for no protection of patents for pharmaceutical products and the other was for protection by patents against international piracy of locally produced industrial property. The opinion on these was that countries with technology to sell would be protected by the use of patents, but that those which were buyers of technology would be better served without patents.

Queries were raised with respect to a lack of information and expertise on patents. In this regard, participants were informed on the Patent Information and Documentation Unit (PIDU) located within the Caribbean Documentation Centre of ECLAC, Port-of-Spain, which has been established to serve CDCC member countries on matters regarding patents.

The host country, Cuba, informed participants about the system regarding industrial property as it pertains to that country and in which the development of products is undertaken by the State. The cost of purchase of this technology outside Cuba will vary according to agreements with individual countries or regional economic blocks.

A recommendation was also made by Cuba for the establishment of a system to exchange technological information.

Policies, plans and strategies have, therefore, assumed extreme importance. Of the many problems, the lack of market information is one of the greatest; so too is the ability of local manufacturers to meet demand and to assure quality control with respect to the safety and efficacy of the drugs produced.

It was suggested that these problems could be overcome by the sharing of market information, increasing regional production through co-operation and by enacting appropriate health legislation.

Dr. Balasubramaniam incorporated the topics on "Trends relating to Commercial Development of Pharmaceutical Products in the Caribbean" and "The Prospects for Strengthening Regional Production on Pharmaceuticals in the Caribbean" into one presentation.

On the first topic, the views were expressed that any analysis must include a determination of drug requirements of both the public and private sectors and that drug formularies were successful only where drug legislation existed. There was, therefore, the need to do both for all the Caribbean region, as soon as possible. The prospects for strengthening regional production were summarised.

Discussions on these topics gave rise to a recommendation that more and better information about production in the region was needed. This took account of the situation where many of the countries represented did not know that others were also producing pharmaceuticals and had under-utilized capacity.

A second recommendation was that where existing plants were unable to meet the requirements, there was a requirement to identify areas where new regional production was needed.

Dr. Balasubramaniam informed the workshop that vaccine production was being decreased by the present producers and that perhaps this was one area that the region could develop since developing countries were in urgent need of vaccines.

In response to a question on the purchasing of raw materials and packaging, the Cuban delegation replied that purchases were made globally on the basis of tenders from producers of varying scales, and were based on a tabulation of national needs. There were still some problems to be overcome regarding packaging.

The decision to produce certain drugs as opposed to importing them are determined by strict economic analysis, so that drugs which for various reasons are too costly to produce are imported.

The view was expressed that any action for regional drug production should be aimed at medium and long-term needs with a view to supplying the expected future demand for drugs, and that debate on this topic should be centred on a strategy for fulfilling these requirements.

Another view was that unless there was a regional rationalisation of production, no reduction on a per unit basis could be achieved and that local production could be more expensive than the imported product.

The topic on "Imports and National Production in the Pharmaceutical Sector: The Case of Cuba" was delivered by Silvia Delgado Ribas of MediCuba. This paper dealt with the development by Cuba of its national pharmaceutical industry from a situation where prior to the revolution approximately 20,000 pharmaceuticals were imported, to the present where the country produces 85 percent of (approximately) 650 drugs in their various formulations used in the country.

The mechanisms through which Cuba continues to increase its self-sufficiency in the production of pharmaceuticals and plans for future development in production capacity both to meet their local needs and to take advantage of existing foreign markets were outlined.

Many questions from the other participants to the Cuban delegation were raised on this paper, especially with respect to the economic profitability of import substitution with locally produced drugs as opposed to re-direction of the supply.

In response to a question on the number of drugs in the Cuban Formulary, it was stated that there are approximately 650 basic products in approximately 860 formulations. The list is revised every six months.

The Jamaican delegate explained that her country's formulary for drugs in the public sector was divided into a list of vital, essential and necessary drugs and these were distributed according to the different types of public centres using them.

A representative of Cuba responded that Cuba was currently building a facility and a research institute for producing vaccines and other biological products which should be onstream before 1990.

A Symposium on the Exploration and Utilization of Medicinal Plants was led by the Cuban delegation. A very comprehensive account of work done on this in Cuba in which there are great prospects for TCDC was given. The Ministry of Public Health has set up a group to carry out research and development in this field which is being done on a systematic basis by the collection and analysis of all known medicinal plants. The botanical, pharmacological, agronomic and phytochemical aspects of these plants are among the areas of research studied. The three directions of development centre on the local use of popular herbal medicine; the establishment of an export industry and the commercial exploitation of specific active ingredients.

The representative of CARIRI gave a brief account of the situation in Trinidad and Tobago and spoke more specifically of the Natural Products Programme of that Institution which, at the present time, has developed two products commercially which have been patented locally. Some advice was offered to any countries establishing any natural products industry which should have a multi-purpose plant as well as assured quality control. It was indicated that possibility existed for collaboration with other smaller islands regarding raw materials supply.

The representative of the University of the West Indies in Jamaica said that further investigations needed to be carried out on the medicinal plants used in that country, though investigations into two had shown the beneficial pharmacological uses and that one of these was being further developed for international patenting and marketing.

The representative of CARICOM delivered a paper on this topic which indicated that while there is a large market for herbal medicines, there is a lack of any institutionalised structure for extracting and marketing.

Discussion on the topic revealed a consensus that there was a great amount of work being done regionally in this area, but that there was a lack of information sharing with the concomitant danger of duplication of work and resources.

To improve information sharing, several delegates offered various sources such as the action plans and working papers of the UNIDO Workshop in Beijing, China in 1982 on the pharmaceutical industry, the work of the Commonwealth Science Council, the OAS EUBITROP project (information on which could be disseminated through the CCST) and the Caribbean Documentation Centre at ECLAC, Port-of-Spain. The Government of Cuba offered to supply planting materials of medicinal plants to any interested Caribbean countries.

An important point raised was that of the lack of utilization through conventional medicines and practitioners of medicinal plants which made prescription risky. This was caused by the scepticism with which they were regarded as well as a lack of precise pharmacological information on these plants such as active ingredients, dosage levels, counter indications, etc.

A paper on the Study of Medicines Manufactured from the Flora and Fauna of the Marine Shelf was delivered by Prof. Ruth Henriques, Dean of the Pharmacy and Food Faculty of the University of Havana, the Director of the Chemistry and Experimental Institute, and President of the Cuban Society of Chemistry.

An overview of work done in this area in Cuba was given. This included the names of the extracts and an indication of worldwide production as well as the uses of these extracts from marine flora and fauna. It appeared the greatest work has been done using extracts derived from various algae, corals, sponges and cartilaginous fish notably shark. Work in this area continued to expand and international interest in this field continued as was evidenced by the increasing number of international organizations giving support to countries involved in this activity.

The delegate from CARIRI expressed interest in obtaining greater information than that contained in the summary paper and this request was acceded to by the Cuban delegation.

In respect of a request for information from the ECLAC/CCST representative for information on work done by the host country on reputed therapeutic properties of algae and on antidotes to fish poisons, the Cuban delegation replied that work continued to be done on algae but that not much information was available on antidotes.

Dr. Balasubramaniam presented a paper on The Identification of Research and Development Priorities in the Pharmaceutical Sector in which the reasons for the failure of the translation of the results of regional research and development (R+D) institutions into production as well as the lack of local investment in R + D were analysed. Several suggestions were made for overcoming these problems.

One of the major concerns arising out of discussions was the lack of information and communication among the countries of the region, the need for co-operation on research in progress particularly with respect to medicinal plants and on the lack of complementarity between research work and marketing.

In elaborating the information needed, it was emphasised that this dissemination should be speedy and at as low cost as possible.

In addition to requiring information on laboratory research, the need for market information was also stressed especially since this would greatly reduce costs with respect to drug sources, availability and latest world developments in the field. This would be especially necessary for the smaller island states which do not have the base for establishing a pharmaceutical industry.

Cuba reiterated its willingness to extend multilateral assistance and information to all CDCC member countries in all aspects of the pharmaceutical industry where this was needed especially in medicinal plants, quality control and packaging.

The discussion on Technical Co-operation among Caribbean Countries in the Pharmaceutical Sector was led by Dr. George Boyd of CARICOM. A brief history of regional co-operation in this field in the English-speaking Caribbean was given. This co-operation started with establishment of the Caribbean Regional Drug Testing Facility, the development of a system for the pooled procurement of certain drugs, the establishment of a Regional Advisory Panel on Pharmaceuticals and continued with the proposed establishment of a Caribbean Formulary of Pharmaceuticals, a regional pharmaceutical newsletter, a Caribbean Pharmaceutical Centre and the development of a Joint Caribbean Association for the Registration of Drugs (JOCARD).

The greatest area for technical co-operation was the sharing of information not only among countries through governmental channels but especially through personal contact, as it was noted that frequently information in a country did not reach the intended personnel.

Another area of concern was the danger of exchanging one form of dependence on transnational pharmaceutical corporations for another.

Mechanisms for technical co-operation among developing countries were described by the ECLAC/CCST representative who informed the meeting that the TCDC Unit in New York could provide this in addition to the ECLAC/CDCC Secretariat in Port-of-Spain, which would assist in identifying other sources of TCDC in dealing with requests for assistance.

RECOMMENDATIONS

1. The Workshop recommended that the greatest possible use be made of the available knowledge and capacities in the subregion, in order to meet rationally, economically and effectively the growing demand for medicines in the different countries of the area.
2. The Workshop proposed the establishment of a Programme for Economic Co-operation for purchasing of dosage forms, raw materials and packaging materials based on international market surveys of different areas. ECLAC/CCST Secretariat should be asked to collate all such information from countries in the region and act as a clearing house for the distribution of information twice a year.
3. The Workshop proposed the convening of a meeting of CDCC member states to seek ways for exchanges of technological and industrial information.
4. The Workshop favoured an appropriate and rational use of drugs in all fields related to prescribing, control, registration and formularies in all member countries in order to facilitate greater harmonisation of the pharmaceutical supply system in the region.
5. The Workshop asked that all CDCC member states and relevant regional organisations be invited to meetings related to health, nutrition and pharmaceutical development in the region.
6. The Workshop favoured the creation of a computerised data bank on the use of medicinal plants and marine flora and fauna resources for all CDCC member countries and an exchange of materials needed from selected species. The ECLAC/CCST Secretariat should contact the member states on the location of the Data Bank and strengthening any existing data bank in the region.

7. CDCC member states should study the possibility of establishing co-operation mechanisms for the production of finished drugs. The CDCC Secretariat should co-ordinate the relevant contacts according to the countries' interests.
8. The Workshop recommended that ECLAC/CCST Secretariat make regional development forecasts based on specialized studies of relevant disciplines to allow for a multi-disciplinary development of the Medico-Pharmaceutical Industry on a short, medium and long-term basis, for which the necessary information should be requested from CDCC member states.
9. The Workshop suggested that ECLAC/CCST provide on a continuing basis sources of information and information dissemination mechanisms relating to the pharmaceutical sector both regionally and internationally.
10. The Workshop identified as priority areas in research and development for the region: medicinal plants, dosage forms, packaging material and quality control of drugs.
11. The Workshop recommended that the Secretariat of ECLAC/CCST take the appropriate steps to obtain the financial assistance needed from the various United Nations agencies, such as WHO, UNICEF, UNIDO, UNESCO and other intergovernmental agencies, in order to implement the recommendations adopted in the Workshop designed to strengthen the co-operation that is required.

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WORK PROGRAMME OF THE TECHNICAL COMMITTEE
FOR HEALTH, NUTRITION AND PHARMACEUTICALS
OF THE CDCC FOR THE 1986-87 PERIOD

1. The Committee shall promote the implementation of the recommendations of the Workshop on Pharmaceuticals that was held in Havana, 14-18 March 1986 and those that stem from the mandates of the tenth session of the CDCC, relating to the pharmaceutical sector, which will be held in Cuba in April 1986. It should also consider the recommendations of the Workshop on the Purchasing of Drugs, which will be held in Barbados from 28 April - 2 May 1986, and the Third Symposium on Medicinal Plants, which will be held in Havana in May 1986.
2. In that respect, the Committee should promote the implementation of specific actions relating to the development of technical assistance in training, the transfer of technologies, market studies and the purchasing of inputs, raw materials and other basic elements.
3. The Committee should also supply methodological and standardization elements that will make it possible to carry out joint research in order to provide answers for the areas to which top priority has been assigned:
 - (a) research in medicinal plants
 - (b) dosage forms (posology)
 - (c) packaging, and
 - (d) quality control

4. The Committee should promote studies to determine the need for drugs and ways of meeting that demand with the help of economic and scientific-technical co-operation especially relating to:
 - (a) the rational use of drugs
 - (b) the control and registration of drugs, and
 - (c) the production of finished drugs
5. Likewise, technological and industrial information relating to health, nutrition and pharmaceuticals should be guaranteed and exchanged. In this regard, the Committee shall inform the Caribbean Documentation Centre of its willingness to contribute to the improvement of its information systems and the integral use of the information obtained from patents and other sources.
6. The Committee should consider the recommendations arising out of the Seminars on Patents that the World Intellectual Property Organization (WIPO) and the ECLAC Secretariat will hold in 1986.
7. The Committee will promote an inventory of Research in Progress and of the infrastructure of the institutions in line with the recommendations of the seminar on the subject that was held in Port-of-Spain in January 1986 sponsored by UNESCO and the ECLAC Secretariat.
8. The Committee should hold a workshop on primary health care in the Caribbean at its second meeting in February 1987 and hold a workshop on food and nutrition in the latter half of 1987.
9. The Committee should attempt to evaluate the implementation of the recommendations of the Workshop held in Cuba in March 1986 at the next meeting of the pharmaceutical sector to be held not later than 1989.

