PAN AMERICAN HEALTH ORGANIZATION

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PAHO/WHO TECHNICAL COOPERATION IN THE FIELD OF BIOTECHNOLOGY

I. Introduction

At the XXVI Meeting of the ACHR, held in Rio de Janeiro in August 1987, the conceptual bases and general strategies of action were established for PAHO/WHO technical cooperation in the field of biotechnology. At that gathering, it was recognized that an explicit policy needed to be defined for the Organization in that field, given its importance to the solution of health problems and the scientific and technical development of the Member Countries, as well as in light of the increasing number of activities in PAHO/WHO and the countries of the Region that involve biotechnology.

The ACHR recommended that a subcommittee be established composed of specialists with recognized expertise in that field to advise the Director of PAHO/WHO on the formulatio nand follow-up of PAHO's policy on technical cooperation in Biotechnology.

Those recommendations were ratified at the XXXII Meeting of the PAHO/WHO Directing Council. In September 1987, the ACHR's Advisory Subcommittee on Biotechnology* and the Internal Advisory Committee on Biotechnology were formed, the latter made up of staff members from the different technical programs active in Biotechnology. The latter had the purpose of advising the Director on policy implementation and coordination of the Organization's activities in that field.

At the first meeting of the ACHR's Advisory Subcommittee on Biotechnology, which was held in San José, Costa Rica in October 1987, the principal lines of work on which the Organization's efforts should be focused were defined, and guidelines were prepared for their realization. These directions or lines of work are:

a) Implementation of a "Regional Program for the development of Biotechnology Applied to Health in Latin America and the Caribbean," which is directed toward strengthening the scientific and technical infrastructure in that field;

b) Financial support for research projects to develop diagnostic methods with biotechnological techniques;

c) The organization of events and debates on topics that provide orientation for the definition of national policies on biotechnology development;

d) Coordination of the specific activities related to the different technical areas of the Organization.

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* The members of the Committee are: Dr. Rodrigo Zeledón, President (Costa Rica), Dr. José Azocar Silva (Venezuela); Dr. Manuel Limonta (Cuba); Dr. Alberto Marcipar (Argentina); Dr. Jaime Martuscelli (Mexico); Dr. Carlos Morel (Brazil); and Dr. Ruth Nussenzweig (United States)

The following is a report of the activities carried out in each of these lines of work, including an assessment of achievements and of the difficulties encountered, designed to give the ACHR the information it needs to formulate recommendations that may be carried out as effectively as possible.

II. Regional Program for the Development of Biotechnology Applied to Health in Latin America and the Caribbean

Through a series of working activities carried out prior to, during, and after the October 1987 meeting, by March 1988 preparation of a Regional Program devoted to strengthening scientific and technological infrastructure in Biotechnology had reached completion, initially in six countries of the Region (see publication ACHR 27/89.10.1).

In preparing the Program the members of the Subcommittee, in consultation with the national agencies for scientific and technical development, identified institutions active in the area of Biotechnology in their respective countries. The principal criterion for selection was the leadership role that these institutions played at the national level due to their recognized technical excellence and the flow of resources and information achieved throughout their history.

Each institution selected prepared an assessment of its human, material, and physical resources, the activities it had carried out in the areas of research and production, etc., and its plans for expansion over the next three to five years. Based on the differences between their present situation and the one being sought, needs for support were identified in terms of equipment, installations, manpower training, etc.

The Regional Program seeks to articulate these different institutional projects, from the standpoint of gaining cooperation and complementarity among them. Integrating projects and mechanisms that maximize efforts were established to form a collaborating network among the participating institutions. These integrating projects involve access to and domination of basic technologies for research and production in biotechnology, the strengthening of scientific and technical information systems, and joint procurement of goods.

The total resources envisaged for the Program during five years of execution, including both institutional projects and integrating projects, total US$25 million. PAHO/WHO's contribution would be in the form of activities for coordination, follow-up, and evaluation, as well as the development of some of the components of the integrating projects. The remaining resources would need to come from different financing and cooperation agencies.

April 1988 marked the beginning of a series of activities aimed at gathering the resources needed to implement the Regional Program. At three meetings, during the months of May, June, and August, contact was made with staff members from different sections of the European Economic Community (EEC). The general conclusion at these encounters was that, at the technical level, the project was of great interest and very well formulated, but as far as financial support went, it would be necessary to have clear evidence of the countries' interest in its implementation. In other words, it was necessary to have an explicit declaration of political support made through the embassies and presented before the EEC.

Copies of the project and letters requesting support were sent to twelve international and national agencies of cooperation. In July 1987 letters went out to the Ministers of Health of the countries participating in the Program, asking them to serve as intermediaries in requesting the formal support of their respective governments. To date, several responses have been received from the agencies, offering congratulations on the initiative, but regretting the impossibility of committing funds to it. From the Ministers of Health came only one formal reply expressing agreement and support for the Program.

At its III Meeting, held in Havana, Cuba, 24-26 April 1989, the Subcommittee assessed the progress of the PAHO/WHO Regional Program on Biotechnology, expressing concern over the difficulties encountered both in seeking political support in the participating countries, and in mobilizing financial resources. It was considered that a clear demonstration of political commitment on the part of the countries was a fundamental requirement for orienting national investment in support of the Program and for attracting external resources.

The subcommittee recommended on that occasion that the Ministers of Health be urged to give their governments' opinions of the Program and that the Program document be sent for revision to the national committees created under the UNDP/UNESCO/UNIDO Regional Program on Biotechnology, with the goal of expanding political and technical support and increasing coordination with the UNDP Program. Both recommendations were carried out.

Finally, the Subcommittee recommended that the next meeting of the ACHR (XXVII) focus on the discussion of mechanisms and actions with a more aggressive approach to the mobilization of political and financial support for the Program.

III. Research Projects on the Development of Diagnostic Methods

Based on the recommendation of the I Meeting of the Subcommittee that PAHO/WHO should support research projects devoted to the development of methods for diagnosing diseases transmitted through the blood, this area was made one of the priorities in the PAHO/WHO Research Grants Program. Based on a reference document entitled "Development Plan" which defined the lines of research, topics, and corresponding approaches, promotion and support was provided to eleven (11) research proposals for a total amount of US$220,000. The great majority of these projects began execution during the first quarter of 1988 (see publication ACHR 27/89.10.3).

At the II Meeting of the Subcommittee, held in Caracas, Venezuela from 17-21 October 1988, the projects in progress were reviewed and the Subcommittee expressed its satisfaction with the success of the initiative, saying that it should be viewed as a model for the promotion and coordination of research projects. Emphasis was placed on the organization and interrelationships of the projects that are articulated under a common reference category, as well as on the coherence of the chain of activities, from the formulation of priorities, up through project implementation. At the same meeting the Subcommittee mentioned the need for PAHO/WHO to specify ways of disseminating the resulting information to the productive sector, particularly with regard to the mechanisms for transfer of the technological innovations that would be developed. The Subcommittee felt, in addition, that the eleven projects had fulfilled the objectives defined in the first

Development Plan, and it recommended that, for the III Meeting, discussions be programmed on laboratory needs at the level of local health systems so that, through a second Development Plan, research could be promoted that would seek to meet those needs.

At the III Meeting in April 1989, the projects in progress were reviewed once again, it was confirmed that some of them are already in their final stages, and it was suggested that there is a need to establish new support mechanisms that will allow them to continue on another scale. Highlighted as the first candidate for a new stage was the project to develop diagnostic kits for AIDS utilizing recombinant antigen, a project which is being carried out by the Center for Genetic Engineering and Biotechnology (CIGB) of Cuba. This kit has been tested in Cuba, Czechoslovakia, and Sweden and should be validated for the sera of patients in the Region in the panels prepared with the support of the Grants Program in Argentina and Brazil. The Subcommittee recommended that, if the merit of the recombinant antigen is verified, PAHO should become involved in supporting subsequent development of the project for scaling production. The Subcommittee also felt that this would be an excellent opportunity to demonstrate that, by providing support during the entire product development cycle, it would be possible to create conditions conducive to local development and production of diagnostic kits that could meet a good proportion of regional needs under competitive conditions in terms of quality and price. CIGB should direct a request to PAHO/WHO for support to help achieve that objective.

In relation to the new Development Plan to promote a new set of projects in answer to the recommendation made at the previous meeting, at the III Meeting specialists in the topic were invited to make presentations on laboratory needs and organization, methods, and appropriate diagnostic techniques at the level of local health systems.

In those presentations and during subsequent discussions on the topic, what was stressed was the extreme heterogeneity of situations, resources, and problems found at the level of local health systems. This makes it practically impossible to prepare a list of common needs in the area of diagnostic methods. There was a consensus that the main thrust of the effort should be focused on the development of techniques which, while sophisticated in terms of their development, are easy to use and do not require any specialized human or material resources.

In view of the above factors, the Subcommittee did not recommend promoting the development of diagnostic methods for specific diseases. Given the heterogeneity of needs, the new Development Plan should promote projects whose objective is to master technologies which, due to their strategic nature, could serve as a basis for the development of diagnostic methods for different diseases, and which are simple, rapid, sensitive, specific, and inexpensive. This would make their use possible at the local level.

It was pointed out that the principal technologies having the above characteristics which were candidates for diagnostic tests would rely on new approaches to the use of biomolecular markers that were based on methods employing enzymes, fluorogenes, colloidal gold, etc., as well as new approaches to the development and/or improved use of supports made of latex, gelatin, cellulose, etc.

The proposals that encompass the development of techniques utilizing these technologies should give priority to the diseases selected in the first Development Plan, particularly AIDS and Hepatitis.

The Secretariat was assigned the task of preparing brief technical and scientific guidelines that would make it possible to promote development projects having these characteristics among the research community in the Region.

IV. Promotion of Meetings and Debates to Establish National Policies for Biotechnology Development

With respect to this line of work, seminars and meetings were promoted on topics of interest in the field of biotechnology which might provide bases and directives for policy definition.

In answer to one recommendation of the I meeting of the Regional Directing Council of the UNDP/UNESCO/UNIDO Regional Program on Biotechnology, PAHO/WHO, together with the IICA, the OAS, and the OIE organized a meeting in San José, Costa Rica in January 1988, on "Standards and Models of Biosafety for the Management and Use of DNA Recombinant Techniques." Prior to the meeting, the existing standards in various countries of the world were compiled and analyzed. Based on that preliminary study, the scientists present at the meeting reviewed the proposed guidelines for biosafety adapted to the conditions of the laboratories in the Region. The resulting publication (see ACHR 27/89.10.4)) is a contribution to the countries for use by researchers and for the definition of legislative standards in this area. A similar initiative is planned for January 1990 which would be devoted to biosafety standards governing the release into the environment of microorganisms modified by means of recombinant DNA techniques.

Also in relation to this line of work, immediately before the II Meeting of the Subcommittee in Caracas, Venezuela on the 17 and 18 of October 1988, there was a forum of debates on "Research, Development, and Marketing of Biotechnology Applied to Health." This forum was attended by researchers, technicians, and interested professionals, in addition to the members of the Subcommittee; the topics discussed included the training of human resources in Biotechnology, patent and industrial production, private and official financing of the Biotechnological industry, regional integration in biotechnology, etc. The central topic was "Technology Transfer in Biotechnology," with a focus on the technical and scientific, legal, and economic and financial aspects of the relationships between research and production in the field of biotechnology (see publication ACHR 27/89.10.2).

V. Activities on Biotechnology of PAHO/WHO's Technical Programs

Several of the Technical Programs of the Organization have been active for some years in technical cooperation in Biotechnology, particularly in the areas of development of inmunobiologicals and diagnostic methods for communicable diseases. The Internal Advisory Committee on Biotechnology is presented as a mechanism for exchange and discussion concerning those activities, and the Advisory Subcommittee of the ACHR analyzes them from the perspective of their articulation with the Organization's overall policy on Biotechnology development. In addition to specific activities, the II and III Meetings of the Subcommittee reviewed the ongoing negotiations for the creation of two Regional Vaccine Research Centers.

The members of the subcommittee felt that PAHO should continue to act as a catalyst with regard to the creation of the Regional Vaccine Research Centers, seeking to maintain critical support for all facets of project development. With regard to the activities of the various Technical Programs, it was reiterated that there is a need to coordinate activities by using a common frame of reference, along with the existing coordination mechanisms, so that the activities concentrate on strategic areas and thus avoid disjointed efforts.