



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



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FINAL REPORT

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FINAL REPORT

The 34th Session of the Subcommittee on Planning and Programming (SPP) of the Executive Committee of the Pan American Health Organization (PAHO) was held at the Organization's Headquarters in Washington, D.C., on 29 and 30 March 1999.

The meeting was attended by representatives of the following Members of the Subcommittee elected by the Executive Committee or designated by the Director: Bolivia, Canada, Costa Rica, Cuba, Dominican Republic, Ecuador, Guyana, Mexico, and United States of America. Also present were observers for Antigua and Barbuda, Honduras, Panama, and Uruguay, as well as representatives of four nongovernmental organizations.

Officers

The following Members, elected as officers by the Subcommittee at its 33rd Session in December 1999, continued to serve in their respective positions.

<i>President:</i>	Ecuador	(Dr. Bayardo García)
<i>Vice President:</i>	Cuba	(Dr. Antonio González Fernández)
<i>Rapporteur:</i>	Bolivia	(Ms. Edy Carmen Jiménez Bullaín)

Sir George Alleyne (Director, Pan American Sanitary Bureau) served as Secretary ex officio, and Dr. Karen Sealey (Chief, Office of Analysis and Strategic Planning) served as Technical Secretary.

Opening of the Session

The President opened the session and welcomed the participants, noting that the session had brought the delegates together with the common goal of enhancing the work of the Organization and contributing to the betterment of health and well-being for all the peoples of the Americas.

The Director added his welcome to the participants. He pointed out that several changes were being introduced at the Subcommittee's 34th Session in response to suggestions made during the previous session's discussion of SPP operations. For example, as a means of engaging Members more actively in the sessions, two Member Governments—Canada and United States of America—had been invited to prepare

documents and make presentations on two of the agenda items. In addition, in response to the suggestion that a broader range of actors from outside the Organization be involved in the Subcommittee's deliberations, representatives of several nongovernmental organizations had been invited to take part. He was certain that the changes would help stimulate a lively and productive debate.

Adoption of the Agenda and Program of Meetings (Documents SPP34/1, Rev. 1, and SPP34/WP/1, Rev. 1)

In accordance with Rule 2 of its Rules of Procedure, the Subcommittee adopted the provisional agenda and a program of meetings.

Presentation and Discussion of the Items

Program Budget Policy of the Pan American Health Organization (Document SPP34/3)

Dr. Sealey presented the document on this item, which reviewed the development and application of the current PAHO program budget policy, adopted by the Directing Council in 1985, and outlined the parameters and principles that were guiding the revision process. The current policy provided guidelines for the development of the program budget and the allocation of resources between regional and country programs, as well as criteria for the distribution of country and regional program funds among the countries, based on their fulfillment of collective mandates adopted by the Governing Bodies, indicators such as infant mortality and population size, and previous levels of technical cooperation.

The policy established support for country programs as a fundamental priority of the Organization, calling for not less than 35% of the total regular budget to be allocated to those programs. Funds were to be allocated to regional programs to provide direct support to country program objectives and priorities and to fulfill regional and collective mandates. The policy also contained provisions regarding mobilization and use of extrabudgetary funds, support for technical cooperation among countries (TCC), and promotion of flexible and innovative administrative mechanisms to maximize resources.

Because the policy set out few measurable objectives or specific indicators, quantitative assessment of its impact was difficult. Nevertheless, a review of the program budgets for the period 1982-2001 showed that one measurable objective—allocation of at least 35% of the total regular budget to the countries—had not only been met but had been far exceeded. As for qualitative assessment of the policy's impact, planning, programming, and budgeting had followed the guidelines of the current policy almost to

the letter. In keeping with the policy, PAHO's nature as a technical cooperation organization—as distinct from a financial cooperation institution—had been continually stressed, as had flexibility in programming and budgeting and responsiveness to the countries' needs. The amount budgeted for support of TCC had increased 122% between 1988-1999 and 1998-1999. The Organization had also had great success in mobilizing extrabudgetary funding, which currently represented around 40% of the total budget.

Various recent developments made it necessary to revise the 1985 budget policy. Most notably, in May 1998 the World Health Assembly had approved Resolution WHA51.31, which changed the methodology for distribution of funds to the WHO regions. As a result, the allocation to the Region of the Americas would be reduced by \$10 million¹ over three biennia, beginning with the current one. Other trends in the external and internal environments also had an impact on the Organization's work and therefore influenced its programming and budgeting. Among the most significant external trends were demographic and epidemiological changes, natural disasters, globalization, steady decline in Official Development Aid (ODA) and a shift toward channeling funds through nongovernmental organizations (NGOs), the United Nations reform process, and increasing demand for zero nominal growth in the budgets of all international organizations. Internally, PAHO's program budget was guided by the policy orientations approved by the Governing Bodies, especially the strategic and programmatic orientations; the Organization's core values of Pan-Americanism and equity; and a managerial philosophy that emphasized transparency, efficiency, and accountability.

The Director had established a working group—consisting of representatives of various PAHO offices and two Members of the SPP—to assist the Office of Analysis and Strategic Planning (DAP) in developing a proposal for a revised budget policy. The working group had identified some basic principles that should guide the policy development process. Those principles, which were described in greater detail in the document, included the following:

- Flexibility and responsiveness to changing needs;
- Explicit statement of any mathematical formula(s) used, recognizing that no single formula will allow sufficient flexibility;
- Development of a budget policy that will support a culture of prioritization within the Organization;
- Recognition that the Organization comprises different levels with different functions, with a distribution of funds that will allow for different weighting of

¹ Unless otherwise indicated, all monetary figures in this report are expressed in United States dollars.

- the functions that need to take place at any given time; although support for the countries should remain paramount, the importance of the work being undertaken at other levels of the Organization should be recognized and sufficient funding should be provided for that work;
- Building on PAHO's comparative advantage of having a country presence in all of the countries;
 - Rationalization of the budget structure to facilitate results-based management and reporting.

The Subcommittee was asked to comment on the adequacy and relevance of the principles, as well as the relevance and timing of the overall budget policy revision process. It was also asked to consider whether contextual factors other than those identified in the document should be taken into account in revising the policy and how frequently the Organization's budget policy should be revised.

The Subcommittee found the document a sound basis for initiating a review of the Organization's program budget policy and endorsed the principles identified by the working group. The principles of flexibility, solidarity, and equity were considered particularly important. It was emphasized, however, that any revision of the budget policy should build on the current policy, not start from scratch. Strong support was expressed for the idea of a "culture of prioritization," which recognized that PAHO could not respond to all demands for assistance and that its limited resources must be utilized where they would produce the greatest impact. Various delegates emphasized the need for flexibility in the face of changing needs, especially in the context of the health sector reform processes under way in the majority of countries. At the same time, it was pointed out that too much flexibility might tend to dilute efforts aimed at achieving common regional goals.

The Subcommittee agreed that there could be no single formula that would allow sufficient flexibility or take account of countries' differing needs and vulnerabilities. In the case of small states such as those in the Caribbean, for example, it was pointed out that, while they had relatively good health indicators, their internal capacity and resources were limited by their small size; moreover, they were frequently subject to devastating natural disasters, and so they continued to require assistance from PAHO. Several delegates cautioned against giving too much weight to health indicators in calculating country allocations. They noted that the use of indicators for that purpose would tend to penalize the countries that had made the greatest gains in health and suggested that more weight should be given to another criterion identified in the document: the commitment shown by countries in complying with mandates adopted by their collective decisions at

the regional and global levels and in their application of national resources in response to those mandates.

As for the frequency with which the budget policy should be revised, the Subcommittee felt that it would be appropriate to reexamine the policy at the time that the Organization's quadrennial strategic and programmatic orientations were discussed. However, it would probably not be necessary or advisable to completely overhaul the policy every four years; rather, the policy could be adjusted to reflect any change in the regional orientations and in global policies and priorities.

The Subcommittee considered that PAHO's program budget policy should reflect the global priorities established by WHO. However, it was also pointed out that the distinction between the policy role of WHO and PAHO's role in the delivery of technical cooperation should be recognized. Though the priorities and policies set by WHO should be taken into consideration, they should not necessarily define PAHO's policy or its actions because its role was qualitatively different in many respects. It was emphasized that the budget policy should clearly reflect PAHO's role as a catalyst and facilitator of technical cooperation, expertise, and capacity-building in the countries.

The importance of evaluation to determine the best use of resources in program budgeting was highlighted. It was emphasized that evaluation should be undertaken systematically to assess program impact and determine whether programs should continue to be funded based on their relevance and effectiveness. Several delegates stressed that the Organization's budget policy should take account of the importance of extrabudgetary funding in the Organization's total budget and should acknowledge the growing role of NGOs in health activities in the Region. It should also continue to reflect PAHO's commitment to the promotion of technical cooperation among countries. It was also pointed out that, while it was true that the budget had suffered as a result of the policy of zero nominal growth advocated by some Member States, PAHO had received an increase in assessed contributions for the current biennium, and that fact should be acknowledged.

Several delegates related experiences from their countries that might be useful in the Organization's budget policy review. The Delegate of Mexico shared the formula that her country had devised for allocating resources to each state in order to extend health care coverage, increase equity, and better meet the needs of marginalized population groups. The Delegate of Costa Rica reported that the Ministry of Health in her country had identified certain cross-cutting themes, based on national priorities, that were emphasized in the formulation of all program budgets.

Dr. Sealey said that it was clear from the Subcommittee's discussion that the principles of solidarity, flexibility, and prioritization were considered crucial. She thanked the delegates for their useful comments and suggestions, which would certainly enhance

the document and help guide the overall policy revision process. She also thanked those delegates who had shared their experiences at the national level, noting that, like PAHO, countries had to make decisions about the distribution of resources at various levels and among various programs. The idea of identifying cross-cutting themes in addition to thematic priorities was worth exploring. PAHO might apply a similar approach in order to ensure that its priorities, especially Pan-Americanism and equity, were reflected in budgetary allocations. She agreed on the importance of evaluation and pointed out that for the past six months the Secretariat had been engaged in an effort to improve the quality of program definition to enable it to better assess program impact at the end of the biennium. As for the incorporation of extrabudgetary funds into the budgeting process, when budget proposals were developed, it was standard practice to estimate not only the amount of extrabudgetary funding expected but to indicate the programs for which that funding was anticipated. However, the Secretariat was always careful to ensure that extrabudgetary resources supported the strategic orientations approved by the Governing Bodies, rather than allowing the availability of extrabudgetary funding to influence the direction of the Organization's activities.

The Director stressed that the presentation of this item to the Subcommittee represented only the first step toward developing a budget policy. The next step would be to formulate a draft policy, taking into consideration the input from Member States, the working group, and the Organization's technical staff. The draft version would undoubtedly undergo several more revisions before a final policy was approved. As the Subcommittee had pointed out, the aim of the process was to revise and enhance the current policy, building on the experience gained over the years, and not to formulate an entirely new policy.

He was pleased that the Subcommittee's discussion had focused on the program budget policy and not on the amount of the Organization's budget. The delegates had obviously recognized that that program budget was an instrument for achieving the objectives set by the Member States. He was also gratified by the Subcommittee's emphasis on flexibility and solidarity. Flexibility in budgeting was essential to enable the Organization to respond to changing needs and unexpected occurrences. The concept of solidarity was also crucial and PAHO should seek to operationalize that concept by maintaining a presence, including a budget presence, in all countries. No Member State should be excluded from the Organization's technical cooperation.

He agreed that it was important to distinguish between the roles of WHO and PAHO and also to distinguish between the functions of the regional programs and those of the country programs within PAHO. Identification of the different functions and responsibilities of various levels was a fundamental management principle for any organization, and that principle would certainly be reflected in PAHO's program budget

policy. With regard to the new methodology for allocating WHO funds to the Regions, as he had said on other occasions, that methodology—especially its use of the Human Development Index as a basis for budgeting—was conceptually flawed. The process of formulating the methodology had also been flawed because it had dealt only with allocations to the Regions, whereas it should have reexamined WHO's overall program budget, including the allocation to WHO Headquarters.

As Dr. Sealey had said, the Secretariat made every attempt to anticipate the availability of extrabudgetary funds and signal the areas in which it would seek such funding, but it was impossible to know for sure how much would be received during a biennium. Programming of extrabudgetary funds was therefore impossible. While he was extremely sensitive to the national situations that had led to the policy of zero nominal growth in some countries, he hoped that the countries would be willing to show the same flexibility in applying that policy that they asked of the Organization in its budget policy. He maintained that not all organizations should be subject to a zero-nominal-growth policy. In the case of PAHO, its application had tended to reduce the Organization's efficiency and effectiveness.

Pan-Americanism: What it Means for the Pan American Health Organization (Document SPP34/6)

The Director introduced this item, noting that Pan-Americanism and equity were the two main principles that guided the Organization's technical cooperation. He began by tracing the historical development of the concept of Pan-Americanism and then cited several examples of Pan-Americanism in action.

Simón Bolívar had first begun to promote the idea of Pan-American unity in the early 1800s, though his efforts had met with limited success. Joseph Lockey's "Essays in Pan-Americanism," published in 1939, traced the development of concept. The term "Pan-Americanism" had originated some 100 years earlier and had been a constant in political discourse since then, particularly in the context of the International Conferences of American States, which had given rise to the Organization of American States (OAS) and the entire inter-American system. Enthusiasm for the idea had been rekindled in recent years with the Summits of the Americas and the Ibero-American summits. Lockey had identified a set of principles which defined the meaning of Pan-Americanism. The principles included independence, representative government, territorial integrity, law rather than force, non-intervention, equality of all countries within the councils of the Americas, and cooperation.

Those principles continued to shape relations among the countries of the Americas, which were linked together through the organs of the inter-American system, including PAHO. Indeed, the establishment of PAHO could be regarded as an affirmation

of the spirit of Pan-Americanism. Through concerted action, the countries of the Region had made tremendous gains in health, which had benefited all of them. Moreover, it had been demonstrated that joint action on health could lead to joint action on other, more thorny issues. A notable example was the initiative “Health: A Bridge for Peace” in Central America. It had been suggested that such subregional initiatives might be inimical to Pan-Americanism, but the Secretariat felt that, on the contrary, they complemented and enhanced regionalism. Pan-Americanism did not imply that all 38 Member States would be involved in every activity. The critical issue was that the countries should “buy into” the concept of sharing and providing mutual assistance and support.

The document examined three areas of the Organization’s work in which the spirit of Pan-Americanism was especially evident: disaster relief, communicable disease surveillance and control, and immunization and vaccine procurement. The Director described some of the activities under way in the first two areas and then invited Dr. Ciro de Quadros (Director, Division of Vaccines and Immunization, PAHO) to make a presentation on the PAHO Revolving Fund for Vaccine Procurement.

In the area of disaster relief, the countries had joined forces not only in responding to disasters, but in preventing, preparing for, and reducing vulnerability to disasters. PAHO had put in place a very effective system for coordinating and channeling the generous outpouring of resources and supplies that the countries of the Americas unfailingly shared with each other in the aftermath of a disaster. A recent resolution of the Organization of American States had proposed the creation of a formal inter-American disaster response system, which would further strengthen cooperation among the countries in this area. PAHO would have a key role in coordinating the health aspects of the system.

In regard to communicable disease surveillance and control, the need for joint action was obvious, since infectious diseases did not respect national boundaries. Because success in controlling communicable diseases hinged on the availability of accurate information from the countries, the Organization had devoted considerable effort to strengthening surveillance systems and laboratory networks in the various subregions. The experience in the first two years of operation of the networks had validated that approach. The ultimate aim was to create a “network of networks” in order to achieve regionwide coverage. A striking example of the effectiveness of Pan-Americanism in this area was the joint initiative of the Southern Cone countries to control Chagas’ disease.

Several of the countries were now free of vectorial transmission of the disease, and transmission had been reduced to extremely low levels in the other countries of that subregion.

As for vaccine procurement, Dr. de Quadros pointed out that the Revolving Fund contributed to Pan-Americanism by providing a mechanism through which the countries could receive regular supplies of high-quality vaccines at affordable prices, thus strengthening national immunization programs and helping to control vaccine-preventable diseases throughout the Region. In many countries, the Fund had also facilitated the introduction of new vaccines into routine immunization programs. The Fund had been established in 1977, pursuant to a resolution of the Directing Council. It operated on an annual cycle. Countries established their yearly vaccine requirements and submitted them to PAHO, which consolidated them and then invited vaccine suppliers to bid on contracts. Once the suppliers and prices were established, PAHO placed quarterly orders for the countries. Hence, PAHO did not sell vaccines to the countries but rather established annual vaccine contracts on their behalf. The Fund's sustainability was therefore not dependent on profit. In addition to the clear economic benefits of the Fund, it had provided a means of delivering technical cooperation in relation to cold chains, calculation of vaccine needs, vaccination strategies, and other aspects of immunization programs.

The Director concluded the presentation on this item by noting that the most important way in which PAHO could strengthen Pan-Americanism was through the provision and analysis of information and the identification of issues that would lend themselves to joint action. Successful collaboration in one area would stimulate collaboration in other areas. The Subcommittee was invited to comment on future prospects for Pan-Americanism and on how the Pan-American approach might be promoted in the Region.

The Subcommittee voiced strong support for Pan-Americanism, which was seen as an expression of the concepts of solidarity and equity. It was pointed out that Pan-Americanism had formed the foundation for many of the great public health achievements in the hemisphere during the 20th century and would continue to underpin the countries' efforts to address ongoing shared problems, such as the HIV/AIDS pandemic. The recently created revolving fund for strategic public health supplies, modeled after the vaccine procurement fund, would enable more countries to afford the costly pharmaceuticals needed for the treatment of HIV infection and AIDS. The spirit of Pan-Americanism was also evident in several of the initiatives discussed by the Subcommittee, including child health and harmonization of regulations on drugs and medical devices. Health sector reform was identified as one of the areas in which Pan-American cooperation could prove most beneficial, since by sharing information and experiences, countries could help one another to avoid the pitfalls and negative consequences of reform processes. It was pointed out that one of the ways in which PAHO could best further Pan-Americanism was through the maintenance of databases and directories of professionals and specialists in order to facilitate the exchange of

information and expertise between countries. PAHO could also contribute to Pan-Americanism through translation and dissemination of health materials and publications produced in the countries.

Support was also expressed for subregional initiatives as a way of strengthening Pan-Americanism. Collaboration between neighboring countries on shared border health issues was seen as particularly valuable, and PAHO was encouraged to support such joint efforts. It was emphasized that, in order to achieve true Pan-Americanism, it was important to cultivate ties and promote cooperation not only between governments but between the peoples of the countries. At the same time, it was pointed out that there could not be joint action on every issue and that the Pan-American approach should be applied for specific purposes that would yield clear benefits for the countries involved. The need to find a balance between Pan-Americanism and the global health agenda was also highlighted. One delegate noted that the Region had a great deal to contribute to the global agenda and that the successes achieved through a Pan-American approach could serve as a model for the world.

The Subcommittee suggested several other ways in which PAHO could promote Pan-Americanism, including exchanges of visits and staff between ministries of health, promotion of internships and similar programs for young people at international agencies or in the countries, increased diversity and intensity of TCC projects, and greater use of common resources such as the WHO Collaborating Centers. In addition, PAHO was encouraged to continue its efforts to ensure that health occupied a prominent place on the agendas of regional political summits, especially the next Summit of the Americas in 2001. The Organization was also urged to take a leadership role in addressing health issues that were arising in the context of globalization and growing international trade.

At the Director's request, Dr. Daniel López Acuña (Director, Division of Health Systems and Service Development, PAHO) described how Pan-Americanism was guiding PAHO's efforts to support the countries in health sector reform through the health sector reform clearinghouse, which was a collaborative regional initiative between the Organization and the Government of the United States. The electronic clearinghouse (<http://www.americas.health-sector-reform.org>) included information on health reform activities under way in numerous countries, as well as a database with information on more than 300 people working in that area throughout the Region. A common methodology for monitoring and evaluating health sector reform had also been developed as part of the initiative.

Also at the Director's request, Dr. Mirta Roses (Assistant Director, PAHO) elaborated on the Organization's recent efforts to promote technical cooperation among countries. A specific fund to promote TCC had been established in 1998, and during 1999 a special effort had been made to support cooperation between countries. The amount

devoted to the execution of TCC projects rose to \$1.7 million, and all Member States participated in the fund. For the 2000-2001 biennium, the amount allocated to the fund was \$3.6 million. Two additional modalities existed for promoting TCC: a fund managed by the Assistant Director's Office for the support of integration initiatives in Central America, the Andean Area, and the Southern Cone, and another fund for integration activities in the Caribbean, which was managed by the Caribbean Program Coordination. Projects between neighboring countries made up approximately one third of the TCC projects currently being supported by the Organization. Another third were projects involving countries within the same subregional integration grouping. However, PAHO was receiving a growing number of proposals for horizontal cooperation between countries in different subregions—projects for the development of common statistical methodologies or projects on the regulation of health professions between countries of the Caribbean and Central America, for example. The future for Pan-Americanism through TCC thus appeared very promising.

In reply to a question from one of the delegates regarding the greatest impediments to increased TCC, Dr. Roses said that lack of knowledge about this modality of cooperation was a significant obstacle. The Organization was endeavoring to address that obstacle through dissemination of information. Another impediment was the fact that proposals for TCC in the health sector were not always fully articulated with the countries' broader foreign policy and priorities for horizontal cooperation. PAHO was seeking to stimulate discussion within the countries between the health ministries and the foreign affairs ministries with a view to promoting harmonization of interests and objectives.

The Director underscored the need to actively promote the idea of TCC and Pan-Americanism and provide information that would enable the countries to identify opportunities for cooperation between themselves. However, it must also be recognized that, for various political, social, and practical reasons, the Pan-American approach was not suitable to all areas. Collaboration between countries should be undertaken only in areas where there was mutual interest.

With regard to the fund for strategic public health supplies which had been mentioned by several delegates, as he had reported to the Governing Bodies in 1999, a trial experience was under way with Brazil. Establishing such a fund was an extremely complex undertaking. If that experience with Brazil proved successful, the fund would eventually be expanded to encompass other countries. Several delegates had also mentioned that PAHO might assist in translating materials produced at the country level, which the Organization was fully prepared to do. PAHO had a machine translation system which, while not the answer to all translation needs, could facilitate the process.

As for PAHO's role in the summit processes, the Organization would continue striving to ensure that specific health proposals were brought to the summits, and it would carry out any follow-up functions assigned to it. Finally, he stressed that Pan-Americanism was in no way inimical to a global approach to or the Region's participation in global efforts. As had rightly been pointed out, the Americas had a great deal to contribute to the global good.

Child Health (Document SPP34/8)

Ms. Carol Collado (Coordinator, Program on Family Health and Population, PAHO) presented a general description of the health situation of the Region's children and outlined some of the strategies and lines of action proposed by PAHO for achieving integral child health and development. In Latin America and the Caribbean, the child health situation was characterized by widening equity gaps, with increasing numbers of vulnerable children at risk for unhealthy development; urbanization and migration patterns that had left many children and families without traditional social support systems; changes in the State's role in health service delivery, with an expansion of the actors involved; health services that were reactive to demand (usually for curative services), with limited capacity for adequate response, referral, or the incorporation of health-promoting activities; and the emergence of new challenges, such as AIDS and certain environmental problems associated with modern life, alongside older, still unresolved issues, such as nutritional deficiencies, communicable diseases, and the risks associated with poverty and underdevelopment.

Although major challenges remained, significant progress had been achieved toward improving child health since the 1990 World Summit for Children, especially with regard to infectious disease control, immunization coverage, improvement in nutritional status, increases in prenatal coverage, and strengthening of health services. A number of valuable lessons had been learned from the experience of the past decade, notably that there were critical moments for promoting health behaviors, that early intervention yielded results though the life cycle and that investment in the health of young children was therefore amply justified, that approaches must be adapted to local realities, and that consistency and continuity were key to success.

Drawing on those lessons, PAHO proposed to move forward with a model for integral child development, with health as the centerpiece. Such a model would incorporate action to promote healthy biopsychosocial development through multiple entry points and at various levels: individual, family, community, population, and health systems and services. The strategies and lines of action for operationalizing the concept of integral child health and development were detailed in the document. The preliminary

estimate of the budget necessary to provide the personnel and activities needed for the development and first-stage implementation of the regional plan was \$1,000,000.

Dr. José Antonio Solís (Director, Division of Health Promotion and Protection, PAHO) explained that the proposal on child health, like the proposal on maternal health presented at the Subcommittee's preceding session, coincided with the end of a decade of work aimed at achieving the maternal and child health goals of the World Summit for Children. The issues surrounding maternal and child health would be further examined at the Fifth Ministerial Meeting on Children and Social Policy, which would take place in Jamaica in October 2000, and at the tenth Ibero-American Summit of Heads of State and Government, to be held in Panama in November 2000, the theme of which would be "childhood and adolescence." Topics relating to the health of adolescents would also be discussed at an upcoming meeting of the Region's First Ladies in Peru. All these events would culminate, in 2001, in a special session of the United Nations General Assembly for follow-up to the World Summit for Children, at which a proposal for revised goals for the next decade would be presented. It was therefore an opportune moment for the countries and the Organization to take stock of the progress achieved in the past decade and develop a vision and an agenda to guide work through the year 2010.

The Subcommittee supported the proposal to develop a regional plan of action on child health and endorsed the model for integral child health and development presented in the document. The holistic approach and the emphasis on prevention, behavioral change, and attention to preschool children, in particular, were applauded. It was pointed out that implementing the plan would require interprogrammatic collaboration within the Organization and intersectoral action in the countries. Joint effort with the education sector was considered particularly important. One delegate noted that in her country there were a great many government institutions and NGOs that dealt with some aspect of child health and development, but their efforts were not necessarily coordinated. She suggested that PAHO might play an important role in facilitating communication and coordination between the entities engaged in child health activities at the national level. The Subcommittee considered promotion of child health at the various international forums mentioned by Dr. Solís another key role for the Organization.

A number of suggestions were made for enhancing the document and the proposed strategies and lines of action. For example, it was suggested that the document should place greater emphasis on the human rights of children, since it was impossible for children to achieve optimum growth and development if their basic rights were not being respected. The issue of child labor also merited greater attention. The Organization was encouraged to work with other inter-American agencies on these issues, in particular the Inter-American Children's Institute, which was also concerned with children's rights. It was suggested that the document should also give more attention to two population

groups: pregnant women, in view of the long-term implications of maternal health for child health, and children aged 5-12, which was the period during which children made decisions and adopted habits that would shape the rest of their lives. It was pointed out that the health sector needed to target children in that age range with its messages of prevention and health promotion, just as advertisers targeted them with commercial messages. The role of the media should be taken into account in the development of any strategy for child health and development.

Several delegates noted that the document failed to mention the “Healthy Children” initiative launched by PAHO in December 1999 following the Directing Council’s decision to pursue the goal of reducing under-5 child mortality by 100,000 by the year 2002 (Resolution CD41.R5). The same delegates also felt that the related strategy of Integrated Management of Childhood Illness (IMCI) should figure more prominently in the document and in the proposed plan of action, especially considering that the communicable diseases targeted by the strategy continued to be significant causes of infant and child mortality in many countries. Various delegates called attention to the need to address the increasingly serious public health problems of violence among children, child abuse, and street kids. Several delegates also requested clarification regarding the proposed budget, the source of funding, the potential for extrabudgetary funding, and the distinction between the budget for child health and that allocated for IMCI. In addition, the Delegate of Mexico provided information to complement and update the information on the nutritional situation of children in her country in the document.²

Given the intersectoral and interprogrammatic nature of the issue of child health, one delegate requested that Drs. Juan Antonio Casas (Director, Division of Health and Human Development, PAHO) and Mauricio Pardón (Director, Division of Health and Environment) share with the Subcommittee how child health figured into the work of their divisions. Dr. Casas observed that the document did a good job of incorporating a human development perspective. It was increasingly being recognized that focusing resources on early child development could have a significant impact on overall human

development, poverty alleviation, and the reduction of inequity, which were the primary concerns of his division. Hence, there was a great deal of overlap between the area of child health and the activities of the Division of Health and Human Development.

² The document stated that 6% of children in Mexico were severely emaciated; however, data on the indicator “severe emaciation” are not collected in Mexico. Mexico therefore requested that that statement be removed from the text. With regard to vitamin A deficiency, the document stated that vitamin A deficiency was a problem requiring urgent attention in Mexico, which was not true. Since 1993, 4.5 million megadoses of vitamin A had been administered every two years to children living in areas considered to be at high risk.

Dr. Pardón said that the Division of Health and Environment was currently developing a project on the impact of pollution on child health. Pollution had serious implications for children's health owing to their smaller body size. The project would address specific problems, such as the effects of leaded gasoline on children and the exposure of child workers to various contaminants, as well as broader issues related to basic sanitation, without which it was impossible to achieve child health goals. The project's lines of action were fully in line with the strategy proposed in Document SPP34/9.

Dr. Collado apologized for the omission of any reference to the Healthy Children initiative and the year 2002 goal. They had been mentioned in an earlier version of the document; however, it had undergone several revisions and had been worked on by staff in various programs, which probably accounted for that omission and for the error in the information about Mexico. The Secretariat would correct those mistakes and would also incorporate the Subcommittee's suggestions for improvement in the next version of the document.

Replying to the questions on the budget, she said that the proposed budget was intended to "jump-start" the process of working with the countries to move towards a paradigm that emphasized not only prevention and treatment but the promotion of overall health and development in the child. Owing to the divisional structure of the Organization's budget, support for child health activities currently came from various areas, including the funds allocated for IMCI, immunization, environmental health, and other programs. The budget proposed in the document for the first stage of the child health plan would be additional to existing funding and would be used specifically to support the countries in developing and implementing the regional plan. With regard to possible partners, the Organization had already approached several potential donors, and it appeared that the idea was definitely "sellable." PAHO was also exploring with the Director of the Inter-American Children's Institute how the two agencies could work together.

It had been decided that the plan should target children aged 0-10 because the Governing Bodies had recently approved various child and adolescent health initiatives that focused on that age range. Particular attention was being given to preschool children because children between the ages of 1 and 5 often had very little formal contact with health services. Certainly, there had been no conscious attempt to de-emphasize the health of schoolchildren, but it had been tacitly recognized that children in that age group tended to have at least some contact with health services through schools. However, the delegates had raised some valid concerns regarding the health and development of older children, and the Secretariat would try to ensure that they were reflected in the plan.

The Director said that the Organization's prime concern in relation to the rights of children was to ensure that each child had the right to the "social and sanitary measures" to enable him or her to enjoy health, as stated in the American Declaration of the Rights and Duties of Man. That meant closing the equity gap that translated into 10 times higher infant mortality in poorer countries compared to richer countries. The Organization had recently analyzed data that indicated that the gap had changed very little over the previous 40 years. PAHO believe that it was every bit as important to take action to narrow the equity gap and ensure that all children had access to the determinants of health as it was to reduce absolute mortality rates. The plan was aimed precisely at addressing inequalities in access to those determinants. The bedrock of any such program was the availability of good data in order to identify inequities and inequalities, and the Organization was therefore engaged in a concurrent effort to improve the registration of vital statistics in the countries of the Region.

The point raised by one delegate about the role of the media was an excellent one. There was growing realization that the health sector must take a more aggressive approach to mass communication and marketing. For that reason, the Organization had gradually been incorporating additional staff to work in that area.

Prospects for Pan American Health Organization Collaboration with Nongovernmental Organizations (Document SPP34/4)

Dr. Irene Klinger (Chief, Office of External Relations, PAHO) summarized the experience of PAHO and other international organizations in collaborating with NGOs to date and examined the prospects for future collaboration. NGOs were clearly a force to be reckoned with, as had been demonstrated by the protests mounted during the recent World Trade Organization conference in Seattle. A similar campaign ("Fifty Years is Enough") had been organized by NGOs at the 1994 World Bank meetings,³ as a result of which the World Bank now sought to actively engage NGOs in many of its activities. As a group, NGOs currently delivered more aid than the entire United Nations system, and they constituted the second largest source of development assistance. Fifteen percent of all ODA and 22% of ODA for health was channeled through NGOs. As of 1998, some 1,500 NGOs had been granted "consultative status" by the United Nations Economic and

Social Council (ECOSOC). The Joint United Nations Program on AIDS (UNAIDS) was the first program of the United Nations to include NGO representatives as full participants on its governing board.

³ As this report was being prepared, NGOs were mobilizing for a new campaign to protest certain policies and practices of the World Bank and the International Monetary Fund during their April 2000 meetings.

Until 1990, PAHO had worked mainly with NGOs engaged in technical assistance, training, and research activities. Since 1991, the Organization had entered into partnerships with a broader range of NGOs, notably in areas relating to health sector reform and in the planning and delivery of health services and programs, such as those for cholera control and polio eradication. Involving NGOs in technical support and health sector reform had been accomplished mainly through trilateral relationships between governments, NGOs, and PAHO. Technical discussions on the subject at PAHO in 1996 had yielded a set of general conclusions and recommendations for strengthening the process of NGO-government collaboration for health and development. Those recommendations had called for the Organization to play a more active role in building government-NGO-PAHO alliances, increased outreach to NGOs, NGO capacity-building, improved practices in NGO-government collaboration, documentation of experiences, and increased involvement of NGOs in the Organization's internal biennial planning cycle. Currently, PAHO had official relations with 13 NGOs, but it collaborated with a number of other organizations working in health and human development in Latin America and the Caribbean.

PAHO believed that future collaboration with NGOs should be directed toward achieving objectives that could better be achieved through joint action than separately. To that end, and in keeping with the recommendations of the 1996 technical discussions, the Organization would seek to increase outreach to NGOs involved in public health activities. Once potential NGO partners had been identified, they might be engaged more actively in PAHO's agenda by establishing a consultative council of NGOs that would meet in parallel to meetings of the Governing Bodies, or ministries of health might be encouraged to include NGOs as part of their national delegations to those meetings.

In light of the need to involve more components of civil society in multilateral policy development and decision-making, the Subcommittee was asked to consider what the nature of future relations between PAHO and NGOs should be. Should PAHO continue to emphasize trilateral arrangements or should it focus mainly on PAHO-NGO interaction? What role should NGOs play in meetings of the Governing Bodies, and should multilateral organizations such as PAHO devote resources specifically to cultivating relationships with NGOs?

The Subcommittee agreed that NGOs were making many valuable contributions to the advancement of health in the Region and affirmed that PAHO should continue to work with NGOs, both bilaterally and in trilateral relationships with governments. Several delegates described how NGOs in their countries had been involved not only in health program and service delivery but also in policy dialogue and formulation at the national level. It was reported that in one Member State, the Dominican Republic, NGOs even received a portion of the official health budget, which they managed independently.

Nevertheless, several delegates pointed out that NGOs tended to be viewed with suspicion by some in official circles because at times they seemed to want to usurp the role of governments. Moreover, while some NGOs managed their finances and activities responsibly and transparently, others were less conscientious. It was suggested that one way in which PAHO could assist the countries in optimizing their relations with NGOs would be the development of a methodology for screening, accrediting, and evaluating the performance of NGOs. The Organization might also organize forums to facilitate dialogue between representatives of governments and NGOs to promote greater mutual trust and understanding. Another role for PAHO might be to serve as a broker to bring together NGOs to work toward common objectives. It was also suggested that PAHO might need to revise the criteria by which it selected the organizations with which it worked, as the number of organizations in official relations with PAHO was very small.

With regard to the role that NGOs should play in the Governing Bodies of PAHO, some support was expressed for the idea of creating a separate NGO advisory body similar to those that existed within the Organization for Economic Cooperation and Development. However, some delegates felt that it would be preferable to invite specific NGOs to participate when topics on which they had special expertise were being discussed by the Governing Bodies. It was stressed that, regardless of the mechanism through which they participated, NGOs should have consultative status, and the fact that they had resources to offer should not be allowed to influence the Organization's decisions or priorities. As for the advisability of allocating resources specifically for activities with NGOs, some delegates felt that the idea warranted consideration, given NGOs' comparative advantage and ability to leverage resources in some areas. However, it was pointed out that, before any support was provided, it would be essential to screen NGOs carefully to ensure that their interests were aligned with those of the Organization and that the collaboration would truly benefit people in the Member States. The need to periodically review the performance of NGOs was also underscored.

Dr. Klinger noted that there had been several recurring themes in the Subcommittee's discussion, in particular the ideas of transparency and accountability and the need to be selective in working with NGOs. Clearly, an important role for PAHO would be to facilitate relations between governments and NGOs. While governments tended to want to establish standards and impose certain controls on the activities of NGOs, the latter saw their greater flexibility and lack of formality as one of their main advantages and tended to resist any attempts to limit their activities. PAHO could help to find the middle ground between too much control and too little in order to ensure transparency in the management of resources and enhance NGOs' contribution to health development processes. With regard to the relatively small number of NGOs in official relations with PAHO, the Organization had traditionally established official relations only with regional NGOs that met certain legal and technical criteria and that had established a

joint plan of action with PAHO's technical programs. Undoubtedly that number would grow if the Organization engaged in greater outreach and proactively sought to work with more NGOs.

The publication *Achieving Effective Collaboration between Governments and NGOs for Health and Health Sector Reform: PAHO's Experiences and Future Strategies* provided more detailed information on PAHO's approaches to working with NGOs at the country level and its criteria for selecting the NGOs with which it would work. Those criteria included: institutional sustainability and transparency, technical excellence, territorial presence, appropriate thematic experiences, and willingness to work with government ministries. The publication, which was distributed to the Subcommittee, also provided examples of best practices in PAHO-NGO-government collaboration in the area of health sector reform.

The Director said that the Organization was well aware of the need to be selective and work only with NGOs that were legitimately trying to assist, not undermine, the activities of its Member Governments. With regard to the organizations in official relations with PAHO, they were inter-American NGOs; however, in reality, most of the Organization's activities with NGOs involved groups that worked at the national level. The regulations currently in place called for the Executive Committee to review the Organization's relations with NGOs every six years, but those reviews might be conducted more frequently—perhaps every three years as was the practice in WHO.

The issue of how to involve NGOs in the governance of international organizations was a difficult one. None of the multilateral agencies had yet found the perfect solution. The matter was problematic both for the organizations and the NGOs themselves. From the standpoint of the multilateral organizations, the problem was how to choose which NGOs would participate and how to ensure the legitimacy of those chosen. As the experience of UNAIDS had demonstrated, regardless of which NGOs were chosen, there would inevitably be dissatisfaction among other NGOs that felt that their views were not being represented. PAHO would continue to watch other organizations to see how they grappled with the issue, with a view to identifying a solution that would be in the best interests of the Member States and the Organization as a whole.

The representatives of the Emergency Care Research Institute (ECRI) and the U.S. Pharmacopoeia, two of the NGOs invited to take part in the Subcommittee session, affirmed that their relationship with PAHO had been very productive. The Organization had facilitated their access to and interaction with government officials in the countries. Both representatives felt that their organizations would not have achieved the same degree of progress without the involvement and support of PAHO. They also agreed that

NGOs must be transparent and responsible in their financial dealings in order to maintain their legitimacy and gain the trust of governments.

Medical Devices (Document SPP34/7)

Dr. Beth Pieteron (Medical Devices Bureau, Health Canada) summarized the document prepared by the Government of Canada on the subject of medical device regulation and harmonization of regulatory requirements. She began with a description of where medical device regulation fit within the “big picture” of health technology management. She then briefly reviewed PAHO’s initiatives to date in the area of medical devices and outlined the recommendations proposed in the document.

The purpose of medical device regulation was to ensure that medical devices sold in a country were safe, effective, and of high quality. Regulations helped accomplish that by setting standards for the manufacture and performance of products and by establishing the government’s legal authority to prevent the sale of products that did not meet the standards and take action against manufacturers that sold substandard products. Medical device regulation was an integral part of the overall process of medical equipment planning, procurement, and management.

Since 1993, countries had increasingly been requesting PAHO technical cooperation in the area of medical device regulation. In 1995, Canada had presented to PAHO an overview of the Canadian approach to regulation, and in 1996, PAHO had begun fostering harmonization of regulatory requirements in various Member States through the provision of technical information, advice, and expertise. The Organization had also sponsored presentations of the Canadian model in several national and international seminars. In fall 1999, PAHO held a consultative meeting on medical devices, which recommended, inter alia, that the ministries of health should assign priority to the regulation of medical devices as part of their leadership role in health sector reform and that WHO and PAHO should step up their technical cooperation in this area and promote technical cooperation between countries, including the development of specific projects. The consultation had also recommended that the Latin American and Caribbean countries should be represented at meetings of the Global Harmonization Task Force (GHTF), a voluntary international consortium that promoted harmonization of medical device regulations in developed and developing countries throughout the world. The document outlined a proposed plan of action based on those recommendations, to be

coordinated by PAHO with the support of WHO. It also contained guidelines developed jointly by PAHO and the Government of Canada for the establishment of regulatory programs in developing countries.

The recommendations of the 1999 consultation also formed the basis for the recommendations to the Subcommittee set out in the document. The three main recommendations could be summarized as follows:

- PAHO should encourage harmonization of medical device regulation among Member States.
- For that purpose, PAHO should make maximum use of the resources currently available, especially existing international standards and the documentation produced by the GHTF.
- A more formalized structure should be established within PAHO to foster the development of medical device regulations in Member States. Among other things, PAHO should establish a steering committee on medical devices, composed of representatives from regulatory authorities of Member States, representatives from WHO Collaborating Centers, industry associations, and other important actors identified by the Committee. The Committee's role would be to enable progress between workshops by coordinating, promoting, facilitating, and monitoring harmonization processes in the Americas. In addition, the Organization should host workshops every two years to promote the development of harmonized regulations.

Dr. Antonio Hernández (Regional Advisor, Health Services Engineering and Maintenance, PAHO) presented additional information on PAHO's role with respect to medical device regulation, which was a priority area related to the Organization's activities in health sector reform and strengthening of the leadership role and regulatory function of ministries of health. Regulation was essential, given the increased number of high-technology devices available, the globalization of markets for medical devices, growth in the market for used and refurbished equipment and in donations of medical equipment, a trend toward re-use of single-use devices, increased use of medical devices in the home, a more informed population, weak after-sale service support, and the need for tracking of adverse events and recalls of medical devices.

The objective of the Organization's technical cooperation in this area was to collaborate with the countries in the development and strengthening of medical device regulation in order to guarantee the safety, quality, and efficacy of the devices used. To that end, it planned to undertake the following activities, which were in keeping with the recommendations emanating from the 1999 consultative meeting:

- Preparation of a regional profile and country status report on medical devices regulation;
- Organization of five subregional workshops on medical devices;
- Promotion of participation by Latin American and Caribbean countries in GHTF meetings;
- Identification of areas for PAHO/WHO technical cooperation in coordination with the Collaborating Centers and the regulatory authorities in the countries;
- Promotion of the use of communication technologies to encourage information-sharing between countries and agencies, for example the “Med-Devices” electronic discussion group coordinated by PAHO;
- Facilitation of access to technical information, such as the two documents cited in Document SPP34/7;
- Provision of technical expertise to countries for the organization and strengthening of medical device regulation.

The estimated budget for the aforementioned activities during the period 2001-2002 would be \$300,000.

Mr. Jonathan Gaev (Representative of the Emergency Care Research Institute) said that as an NGO involved in the area of health care technology, his organization was grateful for the opportunity to contribute to the Organization’s work on regulation of medical devices. The Emergency Care Research Institute (ECRI) was a non-profit health service agency and a WHO/PAHO Collaborating Center. ECRI was in a position to support PAHO’s efforts through its information products and services, including its medical device nomenclature, problem-reporting system, databases on medical device programs, international directory of manufacturers, and directory of over 40,000 standards related to health care technology.

With over 5,000 medical devices, the first problem of any regulatory system was nomenclature. ECRI’s nomenclature system, which was available free of charge, represented the world standard.⁴ Its manufacturers’ registry included 6,500 manufacturers and was updated yearly. The Institute also had the world’s largest and oldest problem-

⁴ The nomenclature, which is available in Spanish and other languages, can be obtained from ECRI at 5200 Butler Pike, Plymouth Meeting, PA 19462, USA. Telephone: (610) 825-6000. Web site: <http://www.ecri.org>.

reporting system. Another important function of ECRI was technology assessment—i.e., evaluating medical technology to see if it was cost-effective. In summary, ECRI could assist the Member States in classification of imported medical devices, registration of the manufacturers, and monitoring of reported problems or recalls of devices. ECRI would also welcome Member States' contribution to its problem-reporting system.

The Subcommittee expressed strong support for PAHO's activities with regard to medical device regulation and endorsed the recommendations contained in the document, although some doubt was expressed as to the advisability of establishing a formal steering committee, in light of resource limitations. It was suggested that it might be preferable to create an ad hoc group to identify mechanisms within existing structures for achieving mutual objectives in the regulation of medical equipment and the harmonization of regulations.

The importance of being responsive to the differing needs of Member States was underscored. In this connection, it was pointed out that many countries had a critical need for training of human resources in the evaluation, regulation, and use of medical devices and equipment. Various delegates emphasized that personnel training should be an integral component of PAHO's technical cooperation in this area. It was suggested that such training might be incorporated into the periodic workshops proposed in the document. It was also suggested that the Organization's cooperation should be delivered in stages corresponding to the status of regulatory development in the countries. In the early stages that cooperation might be directed toward providing guidance to countries in the acquisition of equipment, while in later stages the focus would be implementation of the equipment and training of personnel.

More specific information was requested on the proposed plan of action and the funding for its implementation. One delegate inquired whether the medical devices industry might be a potential source of funding. Several questions were asked regarding the workings of the "Med-Devices" discussion group and the activities of WHO and the WHO Collaborating Centers in relation to medical device regulation. The Delegate of Cuba provided information to supplement the information in the document on the status of regulatory systems in Latin American and Caribbean countries.⁵

⁵ The Cuban Delegation requested that the paragraph on Cuba in Section 7 of the document be modified to read as follows: "In 1991, in keeping with its public health strategies, the Cuban Government identified the establishment of a medical devices registry within its Medical Equipment Regulatory Program as an indispensable requirement. In 1992, regulations for the evaluation and registration of medical equipment were implemented under Public Health Law 41, which also created a national regulatory authority within the Ministry of Public Health—the Center for Regulation of Medical Devices. Cuba's program includes risk classification; manufacturer registration; pre-marketing evaluation, with safety requirements; and demonstration of efficacy through pre-clinical, technical, and clinical trials, depending on the risks associated with the medical equipment."

Dr. Pieterse agreed on the need for incremental development of regulatory systems. Such systems certainly lent themselves to implementation in stages, and she recommended such an approach. Assessment of the needs and the technological expertise existing in a country was an essential first step in the development of any regulatory system in order to tailor the process to the country's requirements.

Dr. Hernández pointed out that the countries of Latin America and the Caribbean fell into two distinct groups: one group had fairly well-developed regulatory systems, while in the other group those systems were incipient. The Organization was working with the first group to strengthen and enhance their regulatory capacity. Those countries were also in a position to share their experience in order to assist other countries in organizing regulatory programs. With the second group of countries, which constituted the majority, PAHO was orienting its efforts toward developing regulatory systems and supporting the countries in technology management, which included planning, negotiation, acquisition, installation, use, maintenance, and renovation of medical devices and equipment, as well as evaluation of health technologies.

With regard to the Collaborating Centers, in addition to ECRI, the Organization was working with the Medical Devices Bureau of Canada and the Food and Drug Administration of the United States. It had also formed strategic alliances with the regulatory agencies of countries such as Argentina, Brazil, and Cuba, which were not formally recognized as Collaborating Centers but had provided considerable support for PAHO's activities. As for the "Med-Devices" electronic discussion group, it was one of several such groups that PAHO had established to facilitate the exchange of information, experiences, queries, and documentation on specific topics. The group was open to regulatory authorities from all the Member States, but it was intended to benefit small countries, in particular, as they did not have the means to put in place an extensive system to manage all aspects of regulation. By working in a network, they could utilize the capacity, experience, and information available from countries that already had well-developed systems.

Mr. Gaev pointed out that, while it was important to adapt information to local needs, it was equally important to utilize the large body of information that already existed. ECRI would be pleased to collaborate in the information-sharing process.

Replying to the questions regarding sources of funding for the proposed plan of action, the Director said that PAHO would certainly seek extrabudgetary funding. A great deal of support for the plan's implementation would probably take the form of in-kind contributions from organizations such as ECRI. As for internal funding, it would be necessary to reexamine the budget carefully, since any moneys the Organization allocated for this area would have to be taken from another area. Regarding the possibility of

approaching the medical devices industry for funding, PAHO generally did not solicit funds from industry. He would be particularly hesitant to do so in this case because some of the recommendations that the Organization would make to the countries might well run counter to industry recommendations.

Harmonization of Drug Regulations (Document SPP34/8)

Dr. Justina Molzon (Food and Drug Administration, United States of America) presented the document prepared by the Government of the United States on this item. She began with a brief overview of the issues involved and the current situation of drug regulatory harmonization and then described PAHO's activities in this area. She concluded her presentation with some recommendations for proposed action.

International harmonization of the technical requirements for development and registration of pharmaceuticals (drugs and biologicals) would reduce unnecessary and duplicative requirements, which would expedite the availability of pharmaceutical products and reduce the cost of their development, while also ensuring that pharmaceutical products sold in the Region met standards of safety, efficacy, and quality. Harmonization was thus in the interest of consumers and public health. Harmonization efforts were under way globally and in various regions of the world. At the global level, WHO had formed various Expert Technical Committees to carry out its constitutional mandate to develop, establish, and promote international standards for pharmaceuticals. In addition, every two years since 1980 the Organization had convened the International Conference of Drug Regulatory Authorities (ICDRA) to promote harmonization, exchange of information, and the development of collaborative approaches to problems of concern to drug regulatory authorities worldwide. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), a project launched in 1990, brought together the regulatory authorities of Europe, Japan, and the United States to seek ways of improving, through harmonization, the efficiency of the process of developing and registering medicinal products in the three regions.

At the regional level, the European Union had developed a structure and system for harmonizing the laws and regulations of its members countries. The European Agency for the Evaluation of Medicinal Products (EMA) was established to oversee, coordinate, and facilitate European harmonization of pharmaceutical requirements. In the Region of the Americas, harmonization efforts were taking place mainly in the framework of the various subregional integration groupings. The document outlined the progress that had been made in each subregion. To support drug regulatory harmonization in the Americas, PAHO had convened a series of three conferences between 1997 and 1999. The first conference had recommended that a hemispheric forum be established, with PAHO as its

Secretariat, to facilitate communication on drug regulation among the different subregional blocs. It had also recommended the creation of a Steering Committee on which each subregional group would be represented. The most recent conference, held in November 1999, had acted on those recommendations, creating the Pan American Network for Drug Regulatory Harmonization, which was to hold a conference every two years, and forming the Steering Committee to enable continued progress toward regional harmonization in the interim between conferences. The first meeting of the Network was scheduled for the first week of April 2000.

The budget for the activities of the Network and Steering Committee in the first two years was estimated at \$300,000. Financing would be sought from governments, trade and professional associations, NGOs, and other sources, as well as PAHO. Given the Organization's resource constraints, it was recommended that any financial support from PAHO be supplied through extrabudgetary sources.

The following actions were recommended to advance the process of drug regulatory harmonization in the Region:

- PAHO and the countries should make every effort to endorse and assure the success of the Network.
- The countries of the Region should officially endorse the Steering Committee.
- PAHO should provide administrative support.
- PAHO should work with the countries of the Region to strengthen the capacity of regulatory authorities involved in the harmonization process.
- Regional harmonization goals and timetables for achieving them should be established.

Ms. Rosario d'Alessio (Regional Advisor, Pharmaceutical Services, PAHO) presented additional information on the harmonization processes under way in the Americas and PAHO's work in this area. To a greater or lesser extent, each subregional grouping was dealing with the issue of harmonization. Generally speaking, the harmonization discussions taking place within each subregion were aimed at the eventual adoption of common requirements, standards, and procedures for drug registration. The most structured efforts were taking place within the Southern Common Market (Mercosur)—comprising Argentina, Brazil, Uruguay, and Paraguay—which had a special subgroup on drug regulatory harmonization. In the Andean Group, Bolivia, Colombia, Ecuador, Peru, and Venezuela had been discussing issues such as the establishment of a

common drug registry and drug policy for a number of years. A drug advisory commission created in the framework of the Hipólito Unanue Agreement—which included the five Andean countries plus Chile—had made considerable progress toward harmonization. Bilateral accords between countries had also been established.

The Central American Integration System (SICA), composed of Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua, did not have any internal structure for the discussion of harmonization issues; however, several projects related to drug regulation and strengthening of regulatory authorities had been carried out under the initiative “Health: A Bridge for Peace.” Panama and the Dominican Republic had also participated in some harmonization activities with the SICA countries. North America and the Caribbean were the subregions in which the least headway had been made with regard to drug regulatory harmonization. Among the parties to the North American Free Trade Agreement (NAFTA)—Canada, Mexico, and the United States—there had been an exchange of information on drug registration but no formal steps had been taken toward harmonization. The Secretariat of the Caribbean Community (CARICOM) had initiated activities related to harmonization in 1999 with support from PAHO.

PAHO’s mandate in the area of drug harmonization was provided by the WHO Constitution. The Organization’s efforts were directed toward supporting harmonization in the priority areas identified by the second Pan American Conference on Drug Regulatory Harmonization, namely: bioequivalence and bioavailability standards, classification of products, counterfeit drugs, good clinical practice, good manufacturing practice, good pharmacy practice, harmonization of pharmacopoeias, and development of a study to determine the feasibility of creating a regional entity for drug registration.

Mr. Miguel Angel Maito (Representative of the Asociación Latinoamericana de Industrias Farmacéuticas – ALIFAR) expressed his organization’s unequivocal support for the drug regulatory harmonization process in the Region. ALIFAR looked forward to collaborating in that process and participating in the upcoming meeting of the Pan American Network for Drug Regulatory Harmonization. The Association was also grateful for the opportunity to participate in the Subcommittee session.

Mr. José Manuel Cousiño (Representative of the Federación Latinoamericana de la Industria Farmacéutica – FIFARMA) underscored the benefits of drug regulatory harmonization for the people of the Region. Harmonization would lead to increased access to safe, effective, high-quality drugs. In FIFARMA’s view, good manufacturing practices (GMP) and studies of bioequivalence were essential aspects of drug registration and quality assurance, and they were therefore essential aspects of drug regulatory harmonization. The position of WHO had always been that drug manufacturers should guarantee the quality, safety, and efficacy of their products, and both the medical

profession and people in the countries demanded high-quality drugs. Nevertheless, in Latin America there continued to be tremendous variability in compliance with good manufacturing practices and the performance of bioequivalence studies, with little standardization or harmonization of regulations. The Organization's efforts at harmonization therefore had FIFARMA's full support. The Federation had been involved from the outset in the conferences on drug regulatory harmonization and would continue to provide financial and technical support for the Pan American Network until the objective of harmonization had been realized.

Mr. Jerome Halperin (Representative of the U.S. Pharmacopoeia – USP) agreed that the aim of harmonization was to ensure the availability of drugs of high quality, safety, and efficacy throughout the hemisphere. His organization was mainly concerned with the quality of drugs. For almost 100 years, the USP had been promoting the harmonization of quality in the hemisphere through various activities. With the collaboration of Professor José Guillermo Díaz, of the University of Havana, Cuba, it had published the first Spanish translation of the U.S. Pharmacopoeia in 1908. The U.S. Pharmacopoeia and National Formulary continued to be published in Spanish and were widely used in Latin America, as was a Spanish translation of the U.S. Pharmacopoeia Dispensing Information, a compendium of pharmaceutical information. The latter had also been translated into Portuguese. The USP had enhanced its presence in the Region through its sponsorship, with PAHO, of scientific meetings and forums on drug quality and information in Central and South America. It had also established a dialogue with the other pharmacopoeias in the Region aimed at establishing a basis for harmonization. To further that process, Dr. Enrique Fefer, former Coordinator of the PAHO Program on Essential Drugs and Technology, would be joining the USP as Director of its International Affairs Office in August 2000.

Mr. Halperin concluded his intervention by noting that on 16 April 2000 he would retire from his post as Chief Executive of the USP. His successor would be Dr. Roger Williams, who brought considerable experience in the area of drug regulatory harmonization, including having served as Chair of the International Conference on Harmonization.

Dr. Williams said that the USP was strongly committed to the success of the Pan American Network and congratulated the countries of the Region and PAHO for embarking on the harmonization initiative, which was creating a model for the world. He also commended the Organization for including other stakeholders from the drug industry, whose participation would be critical to the initiative's success. The USP would continue to support the harmonization effort in all areas related to drug quality.

The Subcommittee expressed support for the creation of the Pan American Network and endorsed the recommendations contained in the document. It was pointed out that, though PAHO could provide technical and administrative assistance, it could not take sole responsibility for maintaining the Network and moving the harmonization initiative forward. The countries must be committed and actively involved in the process. It was also pointed out that harmonization might be viewed negatively by some because of its association with globalization. The Network would have to be sensitive and responsive to the needs of individual countries and subregions to ensure that no one felt disadvantaged or excluded from the harmonization process. Ms. d'Alessio was asked to elaborate on the impediments that had hindered progress toward harmonization in some subregions. In regard to the proposed budget for the initiative, it was suggested that funding could be obtained from the pharmaceuticals industry without compromising the Organization's neutrality. However, another delegate cautioned that great care would have to be taken to see that no conditions were placed on any funding received from the industry.

Ms. d'Alessio thanked the representatives of ALIFAR, FIFARMA, and the USP for their valuable contributions to the discussion and to the harmonization effort. Responding to the question regarding impediments, she noted that reaching agreement on issues such as bioavailability/bioequivalence was not easy. Moreover, even when agreements were reached among technical experts, often there was little political support for their implementation. Frequent changes of political authorities created yet another obstacle, since agreements reached by one set of authorities might not be recognized by their successors. As a result, sometimes it was necessary to repeat the whole negotiating process. Presentation of the issues to the Governing Bodies would help to sensitize political authorities to the importance of harmonization and gain their support. As for the possibility of financing from the pharmaceutical industry, she assured the Subcommittee that any funds received from the industry or from trade associations would come with no strings attached. She also pointed out that, in the end, all stakeholders, including the industry, would benefit from harmonization.

Speaking at the Director's request, Dr. López Acuña noted that the efforts at harmonization of regulatory practices for both drugs and medical devices were clearly an expression of Pan-Americanism that required the active engagement of the countries, in addition to PAHO's efforts. The resources needed for the drug regulatory harmonization initiative would far exceed any amount that the Organization could allocate or mobilize from extrabudgetary sources in the short term. Hence, it would be crucial to have the support of countries through in-kind contributions, participation in the Network, and resource mobilization. The creation of the Network and the Steering Committee was an example of a modality of technical cooperation that allowed for multiple stakeholders

from both the private and public sectors to work together to devise realistic approaches for achieving common public health goals.

The Director said PAHO was endeavoring to provide a forum in which stakeholders could come together, exchange views, and reach positions that would be acceptable to all concerned. However, harmonization did not necessarily mean that every aspect of drug regulation had to be the same in all countries. He was pleased with the progress achieved thus far, which demonstrated that where there was commonality of interests, it was relatively easy for the public sector, the private sector, and civil society to work together. He was also gratified by the keen interest the countries had shown in the Network and the overall harmonization process. Hopefully the Network would help to stimulate the political support necessary to keep the process moving forward.

With regard to the issue of bioequivalence, one of the findings that had emerged from the Organization's work in this area was that many different mechanisms for ensuring bioequivalence existed. Some countries had the capacity to carry out studies internally, while others had to rely on external agencies or universities. In the spirit of technical cooperation among countries, the Organization proposed to facilitate exchanges so that countries that lacked capacity could learn from those that had expertise in bioequivalence testing.

Information Technology in the Pan American Health Organization (Document SPP34/5)

Ms. Diane Arnold (Chief, Department of Management and Information Support, PAHO) said that this item had been included on the Subcommittee's agenda in order to make the Subcommittee aware of certain issues relating to the Organization's ability to effectively fulfill its information functions, in particular the factors influencing information technology, the level of investment required to maintain PAHO's information technology infrastructure and possible sources of funding for that purpose, and key initiatives for 2000-2001.

PAHO, like all other organizations in the world today, was heavily dependent on information technology (IT). The Organization's IT infrastructure at Headquarters and in the field offices comprised a mainframe computer, around 2,500 desktop computers, and numerous laptops, printers, and other equipment, as well as some 100 software products. As of February 2000, the total replacement value of that infrastructure was estimated at \$25 million. Protecting the Organization's investment required policies and procedures to ensure the physical security of the equipment and safeguard the data, standards for software and hardware purchases, maintenance and periodic updating of equipment and

software applications, and prudent planning for investment to meet future needs in the face of rapid change in the IT industry.

Planning was influenced by numerous factors, including past and projected increases in the numbers of users, the demand for services, and the availability of resources for IT—both monetary and human. In the swiftly changing IT environment, it was imperative to plan for periodic hardware and software upgrades. PAHO's policy was to retain a certain level of obsolescence and replace costly equipment and software only as needed. However, the Secretariat's ability to plan was hindered by the need to fit technological decisions into the biennial budget cycles, which meant that decisions as to when to upgrade or replace hardware and software often were governed by the availability of funding and not necessarily by technological feasibility or opportuneness. As a result, PAHO sometimes incurred higher costs because products were not purchased when it was most appropriate to do so from a technological and organizational standpoint. In addition, there were periodic large "peaks" in spending on IT infrastructure.

In order to make the most cost-effective use of PAHO's limited resources and avoid "peaks and valleys" in spending, alternative methods of funding, not tied to the biennial budgeting cycle, were needed. To that end, the Secretariat proposed to use the Capital Equipment Fund, established by the Executive Committee in 1993, to cover the cost of replacing or updating electronic and computer equipment and for major software purchases. Meeting the challenges of the future would also require sound strategic planning and clearly defined organizational priorities for IT in order to ensure coordination of IT initiatives, avoid duplication of effort, and make the wisest use of resources.

The document described the major IT initiatives planned for the 2000-2001 biennium. They included replacement of the mortality and population database, as the present system, which was 15 years old, did not support the Tenth Revision of the International Classification of Diseases (ICD-10); completion of a project to update the software used in the Organization's planning, programming, and evaluation system (AMPES) and the Office Management Information System (OMIS) used in the field offices; implementation of a "data warehouse," which would merge data from many software applications into a single database to facilitate management and decision-making; and cost-benefit analysis to determine when to replace various corporate information systems, several of which were well over 10 years old. In addition, the Secretariat was studying the options available to protect the Organization's data from viruses and unauthorized access or corruption by hackers.

The Subcommittee underscored the importance of effective information management, both for the Organization itself and for the Member States, which relied on the information produced by PAHO. The Members also welcomed the move toward more user-friendly software packages, which would facilitate the countries' communication with the Organization, and they applauded the Secretariat's decision to develop a strategic plan, which would help save money and regulate spending, thus smoothing out the "peaks and valleys." Investment in IT, though expensive, was considered wise because, in the long-term, it improved efficiency and reduced costs.

Several specific questions were raised in relation to PAHO's future plans in the area of information technology. With regard to the replacement of the mortality database to accommodate the use of the ICD-10, it was pointed out that many of the countries were still using systems that did not support the ICD-10 and that it was important to plan for the introduction of new software applications not only at PAHO Headquarters and in the field offices, but also in the countries in order to ensure compatibility of systems and data. One delegate asked about the possibility of PAHO's donating used equipment or providing support to countries to enable them to strengthen their IT capabilities. Noting that there had been some problems with compatibility between the Organization's e-mail system and the systems used in some countries, another delegate inquired about future plans for e-mail communications. Several delegates asked for clarification regarding the use of the Capital Expenditure Fund and the cost and source of funding for the IT initiatives described in the document; it was pointed out that the cost of the proposed initiatives—combined with other, routine expenditures, such as software licensing fees—would probably far exceed the \$5.6 million cap on the Fund. One delegate asked whether WHO had any special fund or cost-sharing mechanism to assist the Regions in covering IT expenses, given that WHO relied on data provided by them to fulfill its statistical reporting functions. The same delegate observed that PAHO appeared to be utilizing an unusually large number of software products and asked whether there was any mechanism in place to standardize the use of software across the Organization.

Replying to the question regarding e-mail systems, Ms. Arnold said that it was difficult to ensure 100% compatibility between programs. PAHO had chosen to use Microsoft products because they were widely available around the world and were used by the largest number of individuals and organizations; however, the Organization would continue to monitor competing products that were emerging on the market and examine compatibility issues with a view to minimizing problems. As for the feasibility of donating equipment, it was Organization's practice to make equipment available to ministries of health and other partners whenever it upgraded. In regard to the large number of software products in use on PAHO's computers, it was important to note that they included not just the word- and data-processing applications typically used by staff, but also all the underlying operating systems and connection and communication

programs that enabled each personal computer to function as part of a network. PAHO did have an oversight committee that reviewed not only standardization policies for the Organization as a whole (including the field offices), but also issues relating to the advisability, timing, and funding of large IT initiatives. With respect to the questions on financing and the Capital Equipment Fund, around \$400,000 of the Fund had been used thus far. Although the strategic plan had not yet been fully developed, it was estimated that the annual cost for carrying out the initiatives described in the document, as well as anticipated future initiatives, would be approximately \$5 million.

Mr. Eric Boswell (Chief of Administration) added that, while the Fund had been established in 1993 with a ceiling of \$5.6 million, it had never been funded at anywhere near that level. Currently, there were around \$2 million in the Fund, which had been used only for relatively small projects. If, budget permitting, the Fund could be fully capitalized, the Secretariat's intention was to use it to provide a steady source of financing for IT initiatives in order to avoid the peaks and valleys to which Ms. Arnold had alluded. As for the possibility of funding from WHO, there was no provision for financial assistance to the Regions for information technology.

The Director reiterated that this item had been presented primarily in order to make the Subcommittee aware of the amount of money the Organization had had to invest and the challenges it faced in maintaining the technology needed for the production and dissemination of information, which was a constitutional responsibility. While it was true that technology enabled an organization to work more efficiently, PAHO had not found that it necessarily reduced costs because the technology itself was so expensive and because its use had not led to dramatic reductions in staff, although staff functions had changed somewhat with the introduction of the technology. The Organization was indeed willing to donate equipment, although it would never wish to donate equipment that, while still functional, was so old that it had outlived its usefulness. As for the Capital Equipment Fund, it was essential to find an alternative source of financing for IT expenditures, and the Fund was considered the best option. For the moment, the Secretariat did not believe it necessary to seek an increase in the Fund's ceiling, but it might do so in the next biennium.

Other Matters

The Delegate of the United States of America said that his delegation had found the experience of working with the Secretariat to write a paper for presentation to the Subcommittee a very enlightening experience. It now had a greater appreciation of the complexities of preparing the documents for meetings of the Governing Bodies. Initially, the personnel responsible for drafting the paper had been confused about whether the aim was to present the position of the United States or to serve as expert facilitators in the process of preparing a document that presented a more global view; ultimately, they had opted for the latter approach. In future, if the practice of asking Member Governments to prepare documents was to be continued, his delegation would recommend that the respective roles of the governments and the Secretariat should be clarified. In addition, the process should begin earlier in order to allow sufficient time for all the work involved; ideally, the Executive Committee, when it met immediately following the Directing Council each year, would decide whether there were any topics on which it wished to request a Member's collaboration in preparing a document.

The Delegate of Canada said that his delegation had also found the process a challenge and endorsed the recommendations of the United States. Recalling that it had been suggested at the previous session that the Subcommittee should meet only once a year, he inquired whether the practice of holding two sessions per year was to be discontinued. His delegation also wished to thank the Secretariat for providing information on the budget implications of the various proposed initiatives and for the increased attention given in the documents to the special needs of marginalized populations, especially women and aboriginal groups.

The Director thanked the Delegations of Canada and the United States for their efforts in preparing the documents on harmonization of regulations on medical devices and drugs. Their understanding of the approach to be taken was indeed correct: the exercise was intended to be a joint effort, in which Members States worked with PAHO staff, sharing their expertise in a particular area. He felt that the end products had been superb and hoped that the experience could be repeated with other Members at future Subcommittee sessions. He also believed that the presence and active participation of several NGOs had enhanced the session.

With regard to the number of SPP sessions to be held each year, the final decision as to any changes in the functions of the Subcommittee and/or the frequency of its sessions would have to be made by the Executive Committee in June 2000. In any case, a session would have to be held in spring 2001 to discuss the proposed budget for the

2002-2003 biennium before the proposal went to the Executive Committee in June 2001. If he felt that there was need to also hold a session of the Subcommittee in late 2000, he would so recommend to the Executive Committee.

Finally, he announced that WHO Director-General Dr. Gro Harlem Brundtland and all the WHO Regional Directors would gather at PAHO Headquarters on 11-13 April 2000 for a meeting of the Global Cabinet.

Closing of the Session

The Director expressed his gratitude to the President for the skillful and efficient manner in which he had conducted the session and thanked the participants for their insightful comments.

The President felt that the session had afforded a valuable opportunity for the delegates to exchange views under the banner of Pan-Americanism. He thanked the participants for their contributions to that exchange and then declared the 34th Session closed.

AGENDA

1. Opening of the Session
2. Adoption of the Agenda and Program of Meetings
3. Program Budget Policy of the Pan American Health Organization
4. Nongovernmental Organizations
5. Information Technology in the Pan American Health Organization
6. Pan-Americanism: What it Means for the Pan American Health Organization
7. Medical Devices
8. Harmonization of Drug Regulations
9. Child Health
10. Other Matters

LIST OF DOCUMENTS

<i>Document No.</i>	<i>Title</i>
SPP34/1, Rev. 1	Agenda
SPP34/WP/1	Program of Meetings
SPP34/2	List of Participants
SPP34/3	Program Budget Policy of the Pan American Health Organization
SPP34/4	Nongovernmental Organizations
SPP34/5	Information Technology in the Pan American Health Organization
SPP34/6	Pan-Americanism: What it Means for the Pan American Health Organization
SPP34/7	Medical Devices
SPP34/8	Harmonization of Drug Regulations
SPP34/9	Child Health

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