Washington, D.C., USA, 22-26 September 2003

Provisional Agenda Item 4.8

CD44/11 (Eng.) 17 July 2003 ORIGINAL: ENGLISH

SUSTAINING IMMUNIZATION PROGRAMS-ELIMINATION OF RUBELLA AND CONGENITAL RUBELLA SYNDROME (CRS)

Important breakthroughs in the fight against infectious diseases that can be prevented through vaccination have occurred in the past 25 years. The proven impact of vaccination programs in the Americas has placed immunization at the center stage in the global agenda for sustainable economic growth and poverty reduction. The Americas have also made remarkable progress in maintaining the Region without indigenous measles transmission. Advances are also reported in reaching uniform quality immunization in all municipalities. PAHO and the Member States have now established a Vaccination Week, which seeks to target immunization services to high-risk and underserved areas.

Fluctuations in the allocation of resources as a result of economic downturns and uneven management of health reform and decentralization processes are jeopardizing the even implementation of national immunization programs, potentially opening the way for higher costs in case of an outbreak of a vaccine-preventable disease. Another key challenge has been that of complacency by Member States, as a result of the absence of circulation of some vaccine-preventable diseases.

During its discussion the 132nd Session of the Executive Committee commended the sustained efforts of Member States and the support of partners to reaching the goal of measles eradication. The Committee applauded PAHO's leadership in coordinating a regionwide Vaccination Week, aimed at reaching high-risk and underserved areas, and urged for the continuation and expansion of this effort in 2004. In the context of the economic crisis affecting the Region and the impact that this is having on immunization programs, the Committee reiterated the recommendation that countries establish a specific line item for immunization within national budgets to protect the investments made by countries in immunization. Member States were also asked by the Committee to present to finance ministers the consequences resulting from pockets of low immunization coverage, or from a country not sustaining the introduction of new vaccines of public health importance. At the regional level, the Committee requested the Director of PAHO to foster joint action by the international financial institutions to establish provisions within public budgets that ensure uninterrupted allocation of funds to national immunization programs. In an effort to keep the Region free from measles virus circulation, the Committee requested that Member States maintain high vaccination coverage and timely surveillance. The Executive Committee also requested that Member States elaborate within a year national plans of action for rubella and congenital rubella syndrome elimination fro 2010.

The Directing Council is requested to review this document and consider the Resolution CE132.R7 in the Annex.

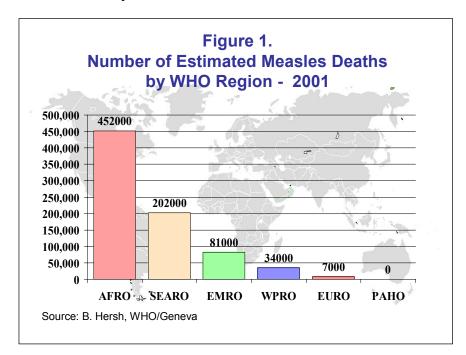
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Sustainable Immunization Programs in Times of Crisis

Introduction

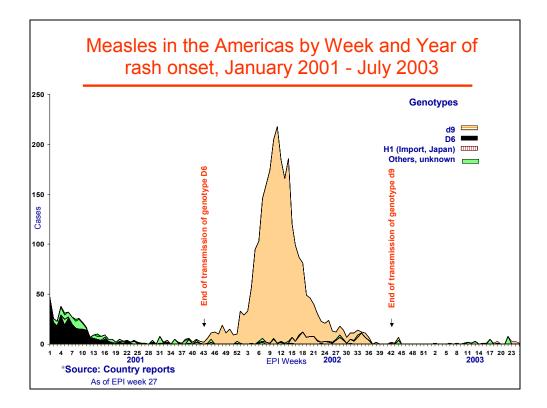
- 1. The Expanded Program on Immunization (EPI) of the Americas celebrated its 25th anniversary in 2002 as one of the most successful health interventions in the field of public health. This success is primarily attributed to the Member States' commitment to establishing national immunization programs and to providing the necessary support to ensure their effective performance. Improved knowledge of diseases and new vaccine development have further allowed the Region of the Americas to introduce new vaccines of public health importance and to expand vaccination to other age groups.
- 2. The Pan American Health Organization (PAHO) and the Members States have sustained one of the most successful public health partnerships. The legacy of this partnership is a Region with the lowest morbidity and mortality record of vaccine-preventable diseases in the world (Figure 1). PAHO and the Member States have collectively built comprehensive networks for immunization delivery and vaccine-preventable disease surveillance at the regional and country levels, with key support from the international community.



- 3. The cross-border externalities of immunization interventions have made immunization a distinct public good, which has been a principal responsibility of the State. The countries in the Region with the technical cooperation of PAHO have built a Regional Program on Immunization, providing an enabling technical and political environment for immunization activities at the national and regional levels.
- 4. Establishing cooperation networks in the area of vaccine-preventable diseases remains one of PAHO's principal strategies to potentiate country initiatives and make appropriate use of available information and technology in the Region. Surveillance networks developed initially for polio and measles have been adapted for use with bacterial meningitis, pneumonia, congenital rubella syndrome, and rotavirus. These networks have aided countries in generating useful data on disease burden for decision-makers in order to prioritize new or underused vaccine introduction, to determine the cost of alternative treatments, and to measure vaccination impact.
- 5. The proven impact of vaccination programs in the Americas and their potential future contributions toward the reduction of ill health due to vaccine-preventable diseases have placed immunization goals prominently on the global agenda for sustainable development and poverty reduction. Immunization objectives are part of the Millennium Development Goals endorsed by all States of the United Nations, the international financial institutions' Poverty Reduction Strategies, and one of three indicators being used by the United States Government (Treasury Department) to assess aid effectiveness.

National Immunization Programs: Progress to Date

6. The hemispheric interruption of indigenous measles transmission is within reach as a result of intensified vaccination efforts guided by surveillance activities and the active search of cases in health centers, schools, and high-risk communities. The full implementation of PAHO's recommended strategy for measles eradication, endorsed by all ministries of health in all countries of the Americas, has remained the cornerstone of the efforts in interrupting indigenous measles virus transmission. As of epidemiological week 27 (5 July 2003), the Western Hemisphere has been free of d9 measles virus transmission for 34 consecutive weeks (Figure 2). The d9 measles genotype was introduced in Venezuela by a traveler from Europe in 2001. In November 2002, the Region achieved the successful interruption of the D6 measles virus genotype. This genotype had circulated widely in the Americas since 1995, causing outbreaks in Argentina, Bolivia, Brazil, Dominican Republic, and Haiti during 1997-2001.



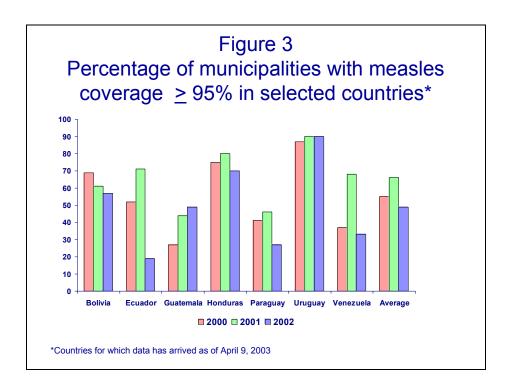
- 7. The eradication of wild polio has been maintained by countries since 1991. Most countries have responded to the need for strengthening acute flaccid paralysis (AFP) surveillance as a result of the Sabin 1 vaccine-derived polio outbreak in Hispaniola during 2000 and 2001. The two countries affected in Hispaniola are now at the stage of rebuilding their surveillance and vaccine delivery infrastructure with the support of the international community.
- 8. The incidence of neonatal tetanus (NNT) continued its downward trend in the Region, and the disease is now confined to less that 1% of all districts in the Americas. Epidemiological data continue to show that cases occur predominantly among rural infants of multiparous women who at times lack prenatal care, are unvaccinated, and, for the most part, have delivered at home.
- 9. Cases of selvatic yellow fever continue to occur in countries located within the enzootic area of the Americas. Between 1999 and 2000, there was a decrease in the number of reported cases due to intensive vaccination efforts carried out in the Region, mainly by Bolivia and Brazil. The number of cases reported in 2001 and 2002 has been 82 and 88 respectively. The natural occurrence of this zoonosis, coupled with the identification of virus circulation outside the enzootic areas observed in recent years and the known widespread distribution of *Aedes aegypti*, remain major concerns due to the

risk of the reurbanization of the disease. PAHO has therefore recommended that the policy of strengthened surveillance and sustained mass vaccination of under-risk populations be maintained.

- 10. The network of sentinel hospitals that are linked to public health laboratories and epidemiological units at the ministries of health continues to expand as part of regional initiatives to develop critical epidemiological data on the disease burden of vaccine-preventable diseases. These hospitals are monitoring bacterial pneumonia and meningitis, particularly those due to *S. pneumoniae*, *H influenzae*, and *N. meningitidis*. A similar network will be used for monitoring rotavirus diseases. A bridge has been established with ongoing clinical trials of pneumococcal vaccines that uses chest X-ray interpretation as the confirmatory criteria for bacterial pneumonia. Brazil, Chile, and Uruguay have also carried out cost-effectiveness studies on pneumococcal vaccine, in an effort to generate comparative costing for various interventions.
- 11. The record of vaccine introduction in the Americas in recent years has been remarkable, particularly for the newer products, such as the pentavalent vaccine, which adds two important vaccines (hepatitis B and *Haemophilus influenzae* type b) to the schedule without adding new injections. The incorporation of underused vaccines, such as measles, mumps, rubella vaccine (MMR), and hepatitis B vaccine, is finally widespread; and efforts are also being made to consistently use yellow fever vaccine. Work is also underway in finding the means of introducing other new vaccines against *S. pneumoniae* and *N. meningitidis* in the Region.
- 12. National immunization programs have embarked on the equity goal of reaching uniform immunization coverage levels in all municipalities. Parallel efforts have been aimed at improving the accountability of immunization services delivery at the district/municipal level, with particular attention to enhanced supervision, immunization safety, financial and human resource management, and the reliability of vaccination data collected, analyzed, and reported to the central level. Established in 1983, the principal instrument used by PAHO to leverage these changes aimed at poor-performing districts remains the use of national and local plans of action.
- 13. In regards to the Region's efforts in reducing coverage disparities, PAHO and the Member States have established a Vaccination Week in the Americas, to be held every year, to promote vaccination of high-risk population groups and underserved areas.

Immunization Programs in Critical Situations

14. The challenge undertaken by the Member States in reducing vaccination disparities seeks to curb the differences in access to vaccines and immunization services that continue to undermine the principle of equity on which immunization programs are based (Figure 3). These efforts are being challenged by severe economic crises in the Americas which have affected countries' social programs, including immunization programs. These crises situations are occurring while countries seek to introduce new vaccines of public health importance in routine vaccination schedules. New vaccines have increased the cost per immunized child for the six basic EPI vaccines from US\$ 1 for the biologicals plus \$14 for administering the vaccine to approximately \$12 for the biologicals only. Additional costs associated with the incorporation of new vaccines include surveillance and cold chain, as well as the expertise to handle these new technologies.



- 15. The sustainability of new or underused vaccine introduction is a matter of serious concern and has pressured some Member States to reconsider scheduled plans to add new vaccines due to a lack of sustained resources. Others have introduced new vaccines with the support from the international community, only to pull them back once donor monies have ceased to flow. Furthermore, today there are still countries that find themselves unable at all to incorporate additional vaccines that have been on the market for over 15-20 years.
- 16. The economic hardships affecting Member States are also having substantial impact on the delivery of routine vaccination programs, even with the basic EPI vaccines. Several Member States have incurred large debts with the PAHO Revolving Fund for Vaccine Procurement, leaving them without the ability of placing new vaccine orders. These countries are now facing the dangerous situation of having no vaccines for regular operations. One such country has reported a lack of available vaccines for a period of eight months. Others, forced to interrupt immunization activities due to insufficient vaccines, have found it difficult and more costly to track people for vaccination schedule completion once vaccines were back in stock. Missed opportunities for vaccination are occurring daily among the poor that lack affiliation with social security systems when they visit health services in search for free vaccination services. Immunization programs are suffering from lack of staff at all levels of the health system and those who are in the system have lost key access to decision-makers. The armed conflict in Colombia has resulted in the closing of rural health services in over 300 municipalities that are directly affected by the conflict.
- 17. Almost parallel to the consequences of the economic crises on immunization programs occurring in the Region has been the impact of changes in the steering and delivery of national health programs resulting from health reform and decentralization. These processes are being approached by immunization as an opportunity to ensure that vaccination programs are delivered in an equitable way in all areas of a country and to broaden the support for immunization at all levels of society. In practice, however, these systemic changes have represented a challenge for the effective and uniform implementation of national immunization programs. Particular areas where weaknesses are evident include local management of immunization delivery and surveillance areas, as well as aspects related to financial flows to local levels and human resource management. Moreover, local capabilities are not in place to secure an ongoing flow of quality and standardized information on vaccine preventable diseases throughout the health system.
- 18. PAHO has advocated at the national level for a clear role in the regulation and steering of decentralized immunization services; while on the other hand, it has supported national immunization authorities in assuring that the technical and managerial

capabilities to deliver immunization services, as well for the collection and use epidemiological information and diagnostic capabilities are in place at the local level.

Fluctuations in the Allocation of Resources

- 19. Fluctuations in the allocation of resources resulting from economic downturns and uneven management of health reform and decentralization processes are jeopardizing the implementation of national immunization programs, potentially opening the way for higher costs in the case of an outbreak of a vaccine-preventable disease. As introduced in last year's meeting of the 26th Pan American Sanitary Conference, the consequences resulting from pockets of low immunization coverage or from a country not sustaining the introduction of a new vaccine are sufficiently important to be addressed in a regional framework. Concurrently, the impact of decentralization, particularly in the allocation of resources to local health programs that include immunization, also warrants regional discussion.
- 20. It was deemed that in order to safeguard the public health achievements and proven impact of national immunization programs, as well as enable their continued growth, Member States and the international community needed to initiate a dialogue to identify and assess sustainable options to protect the investments made in immunization and ensure a steady flow of affordable vaccines to Member States.

Recommendations

Advocacy with the Ministries of Finance

- 21. The financial sectors of Member States need to be informed of the consequences of a breakdown in immunization activities, which depend on reaching high levels of vaccination coverage generation after generation. Given that ministries of finance are key decision-makers regarding country health budgets, efforts should be made to gain the support of the financial sectors of government in identifying sustainable options to protect the investments made in immunizations, including, but not limited to, laws that establish specific budget lines for the purchase of vaccines, syringes, and operational costs. The availability of secure financing mechanisms for immunization programs at the country level needs to be principally driven by equity criteria.
- 22. PAHO already has experience in advocating for the development of legislation which establishes specific budget lines in the national budget that commit resources for recurrent costs associated with the purchase of vaccines, syringes, as well as operational costs of national immunization programs.

23. Health authorities should become familiar with the main sources of financing in their own countries that include domestic public funds, such as tax revenues and social health insurance, as well as private funds, which are resources from households and employers. Careful review of a country's level and composition of external domestic funding, comprised principally by official development assistance (bilateral and multilateral), either in the form of concessionary or regular lending, as well as by external private resources should also be undertaken. The Member States also need to define the criteria that will differentiate the allocation of secured funding for immunization for budget support and funding to support immunization programs in unique circumstances or emergency situations.

Strengthening of Managerial Capabilities at the Local Level

- 24. Member States, with the support of PAHO, should contribute toward strengthening managerial capacity, knowledge, and commitment to immunization goals at the municipal and local levels, to ensure adequate allocation of resources by local immunization managers. The road towards sustainable immunization programs will also by in large depend on Member States' accountability and management of the policy and service delivery environments governing immunization. To improve accountability and quality of work, regular educational supervision should be implemented and budgeted in all countries.
- 25. The link between improved accountability of immunization service delivery at the district/municipal level and the sustainability of immunization programs has led PAHO to emphasize key programmatic areas. These have included, besides enhanced supervision, the management of vaccine supply to improve forecasting and planning of long-term vaccine needs; the optimization of vaccine use to reduce missed opportunities for vaccination and wastage; immunization safety; financial and human resource management; and the reliability of vaccination data collected, analyzed, and reported at all levels of the health system.

Strengthening the Demand for Vaccination Services and Improving Social Participation

26. Member States should provide sustained funding for the implementation of information, education, and communication strategies to improve the community's knowledge of the benefits of vaccination and motivate the demand for such services, especially for high-risk population groups. One such example is the recently launched initiative, Vaccination Week in the Americas, to be held every year to promote vaccination in high-risk and underserved areas.

Partnerships and Strategic Alliances

- 27. A key issue strongly being advocated by PAHO is the reinforcement of the universal consensus that immunization programs are a public good. Given that public goods require inputs and actions outside the national boundaries and jurisdictions, these have generally called for collective action, for both their production and financing. The driving idea has been that of shared responsibility in paying for public goods with externalities that accrue across international borders. As a regional/international public good with important cross-border externalities, the dialogue of Member States with the international community on immunization financing should include the development of new financial mechanisms that support initiatives that are international in reach.
- 28. There have already been discussions during recent ministerial meetings held at the World Bank that public goods programs produce benefits which flow substantially beyond developing countries and that additional resources should be provided to ensure that scarce development assistance is not diverted to finance these desirable externalities. Discussions are underway to explore the expansion of concessional loans issued by the World Bank's International Development Association (IDA) for public goods with especially strong impact on poverty reduction. The Bank is also moving towards restructuring its grant-making capacity through the Development Grant Facility (DGF) in lieu of the growing recognition of the need for international action and financing of international public goods. During the 2002 Annual Meeting of the Inter-American Development Bank's (IDB) Board of Governors, the President of that institution talked about the regional Bank's indispensable participation in the production of public goods to remain relevant in its assistance to the Region.
- 29. An interagency collaborative group, comprised by the World Bank, IDB, and PAHO has been formed to address the issue of sustainable financial sources for national immunization programs, and to provide support to country efforts in seeking to protect their investments in immunization. This effort also has the participation of the United States Agency for International Development (USAID).
- 30. Jointly with these interagency efforts, PAHO has initiated the development of alliances at the national and international levels to bring about consensus on the best way forward to protect the investments made by the Member States in immunization. For example, there is already ample evidence that some sources of financing, such as user fees for immunization, are counterproductive for equity reasons. In this regard, PAHO has been a strong promoter of the need to maintain immunization services free of charge in the Americas.

31. The partnership of countries and the international community have played a decisive role in countries' attainment of immunization goals. Emphasis has so far been given to strengthening the State's ability to guide the delivery of effective immunization services. Partners have aided in the introduction of vaccines and program support, and Member States have had an incremental role in the funding of recurrent costs of immunization programs. This precedent in the relationship between countries and the international community has been standing policy for 25 years. The precedent is being challenged with the economic crises affecting a large portion of Member States, and the restructuring of the way health systems are organized and financed at country level. The continuation of the strong financial commitment by countries will require careful dialogue, coordination, and action with the Member States, as well as with partners in the international community, public and private alike. Only through the continuation of these collective efforts will the Region be able to protect the investments made in national immunization programs, and allow its population to benefit from a wider number of vaccines of public health importance.

Hemispheric Goal of Rubella and CRS Elimination by 2010

- 32. At the 1999 Meeting of PAHO's Technical Advisory Group on Vaccine Preventable Diseases, an accelerated rubella control and CRS prevention strategy was developed for the Americas, which followed the experience in adult mass vaccination campaigns against rubella of the English-speaking Caribbean and Cuba. The strategy rested on a combined vaccination schedule of adult men and women, coupled with rubella vaccine introduction into national childhood immunization programs. This combined vaccination strategy sought to achieve rapid reduction of rubella virus circulation, while preventing the shift of disease burden to susceptible young adults, particularly women of childbearing age, thus, avoiding the incidence of CRS.
- 33. The principal rationale of an accelerated vaccination strategy is to reduce the time it takes to interrupt rubella virus circulation and prevent CRS occurrence. Most countries in the Region have already implemented routine childhood rubella vaccination, and this strategy is protecting children as they reach their first year of life. Nevertheless, this vaccination strategy is likely to take over 20 years to control CRS, as several cohorts of childbearing women will remain susceptible to rubella virus.
- 34. Several countries have embarked on the accelerated control of rubella and congenital rubella syndrome (CRS) prevention. Important lessons and knowledge are being generated from the continuous development of successful and sustainable vaccination strategies of adults that reach coverage levels of at least 90%. Experience is being gained in the mass vaccination of heterogeneous population groups that have included men, women, and adolescents in Costa Rica, Honduras, and the English-speaking Caribbean countries. The mass vaccination against rubella of 28 million women

in Brazil has provided important lessons on the vaccination of large population groups. The experience of the English-speaking Caribbean countries has also provided useful insights on the cost-benefits of immunizing against rubella infection. Studies from these experiences show that the benefits of an accelerated vaccination strategy far outweigh the costs associated with treatment and rehabilitation of CRS. The cost-benefit ratio was estimated at 13.3:1 for the interruption of rubella and CRS prevention in the entire English-speaking Caribbean. The cost-effectiveness of the mass campaigns has been estimated to average US\$ 2,900 per case of CRS prevented. The countries of Barbados and Guyana estimated their own costs for interruption of transmission, with a cost benefit ratio of 4.7:1 for Barbados, and of 38.8:1, for Guyana, and a cost-effectiveness of \$1,633 per CRS case prevented.

- 35. The impact of the accelerated rubella vaccination strategies on the rapid reduction of CRS morbidity in Cuba, the English-speaking Caribbean and Chile is being reported, as well as the rapid interruption of rubella virus transmission in Costa Rica. CRS is now recognized as a serious public health problem, but limited surveillance data remains a source of concern, providing only a partial view of real disease burden and success of initiatives. In response, additional tools that can enhance the identification of suspected CRS cases are being implemented.
- 36. Benefits have already accrued as a result of the heightened attention given to rubella and CRS in the Americas. A rapid increase in the number of countries and territories reporting rubella morbidity is evident, thus allowing for improved analysis of rubella disease burden. This increased attention has further resulted in advances in the integration of rubella and measles surveillance systems in the Region and improved sensitivity and specificity of rubella diagnosis.
- 37. The rapid reduction in disease burden which has resulted from the implementation of an accelerated rubella control strategy, combined with the availability of a safe, affordable and efficacious vaccine, the evidence on the cost-benefit of immunizing against rubella, and the ample support provided by the public and health authorities from Member States, have paved the way for the decision to establish the goal of rubella and CRS elimination in the Americas by the year 2010.

Action by the Directing Council

38. The Directing Council is invited to consider the annexed Resolution CE132.R7 recommended by the Executive Committee.

Annex

132nd SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 23-27 June 2003

CD44/11 (Eng.) Annex

RESOLUTION

CE132.R7

SUSTAINING IMMUNIZATION PROGRAMS

THE 132nd SESSION OF THE EXECUTIVE COMMITTEE,

Having analyzed the progress report of the Director on sustaining immunization programs (Document CE132/17),

RESOLVES:

To recommend that the 44th Directing Council adopt a resolution along the following lines:

THE 44th DIRECTING COUNCIL,

Having seen the progress report of the Director on sustaining immunization programs (Document CD44/11);

Recognizing the important breakthroughs in the fight against vaccine-preventable diseases to protect the children of the Region made possible through the close partnership of the Member States and the international development community;

Noting with great pride the sustained collective efforts by the Members States in fulfilling the goal of interruption of indigenous measles transmission in the Western Hemisphere;

Considering the remarkable progress and experience gained by the Member States in the accelerated control of rubella and the prevention of congenital rubella syndrome

(CRS) initiatives, which seek to achieve a more rapid decrease of rubella cases and infants born with CRS;

Taking note of the spirit of solidarity and Pan Americanism in the implementation of the first *Vaccination Week* in the Americas that targeted immunization services to high-risk and underserved areas;

Concerned with the fluctuations in the allocation of resources in public budgets to these activities at the national level, mainly due to economic downturns; and

Cognizant of the potential negative impacts of certain health sector reform and decentralization processes on the implementation of national immunization programs, including disease surveillance activities,

RESOLVES:

- 1. To urge Member States to:
- (a) Encourage the establishment of a specific line item for immunization in their national budgets and the timely allocation of financial resources towards vaccines, supplies, and operational costs;
- (b) Inform the finance ministers and senior budgetary decision-makers about the benefits of sustaining immunization programs and the risk resulting from pockets of low immunization coverage;
- (c) Implement health sector reform and decentralization policies and programs in a manner that safeguards the achievements made in immunization;
- (d) Support the implementation of an annual hemispheric Vaccination Week, to be held in April, targeting high-risk population groups and underserved areas;
- (e) Maintain the Region free of indigenous measles through high, routine (>95%) measles vaccination coverage by municipality or district, and follow-up measles vaccination campaigns at least every four years, timely surveillance, and outbreak investigation and control;
- (f) Maintain high (≥95%) and homogenous vaccination coverage by municipality or district for all antigens;

- (g) Eliminate rubella and congenital rubella syndrome (CRS) from their countries by the year 2010; to accomplish this, they are requested to draft the respective national plans of action within one year.
- 2. To request the Director to:
- (a) Elaborate a regional plan of action and mobilize resources in support of a rubella/CRS elimination goal for 2010;
- (b) Continue advocating for an active mobilization of national and international resources to sustain and expand the investments made in immunization programs by the Member States;
- (c) Foster joint action by the International Monetary Fund, the World Bank, and the Inter-American Development Bank and Member States, ministries of health and finance, to establish provision within the public budgets that ensure the uninterrupted allocation of funds to national immunizations programs;
- (d) Promote the annual hemispheric Vaccination Week to improve equity in immunization.

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