



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



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### **REGIONAL STRATEGY FOR SUSTAINING NATIONAL IMMUNIZATION PROGRAMS IN THE AMERICAS**

Remarkable progress has been made over the past decade towards an umbrella of protection against vaccine-preventable disease (VPD), including the eradication of polio, elimination of measles and neonatal tetanus, control of yellow fever, and introduction of rubella and pentavalent vaccines. Political commitment has been expressed by the successful introduction of pentavalent and influenza vaccines. Despite excellent progress, national immunization programs (NIPs) continue to face significant challenges, which include completing the unfinished agenda of achieving 95% coverage in low-performing districts; reaching the target of the elimination of rubella and congenital rubella syndrome (CRS) by 2010; and introducing new-generation vaccines against priority diseases of children, adolescents, and adults.

The availability and rising cost of vaccines has confronted countries with the need to strengthen their capacities for: (1) enhancing surveillance and adverse event reporting systems for new priority diseases and vaccines; (2) making evidenced-based decisions including economic analyses on the sustainable introduction of new vaccines according to national health priorities; and (3) securing sustainable financing for new vaccines.

PAHO has undertaken steps to improve the efficiency of the vaccine supply chain and strengthen participation in the Revolving Fund to ensure safe and affordable vaccines. Guided by country initiatives to integrate vaccine-preventable disease control with other health programs, and consistent with the strategies and new disease control targets within WHO Global Immunization Vision and Strategies (GIVS) guidelines, PAHO is supporting countries in their strategic vision to transition from childhood to family immunization. This vision, initially driven by the need to more effectively deliver influenza and rubella vaccines to those who need them most, will result in an effective platform for providing human papillomavirus vaccine (HPV) against cervical cancer and HIV vaccine against AIDS when these vaccines become available.

The Secretariat requests that the Executive Committee reaffirm the initiative to eliminate rubella and CRS (CD44.R1) and achieve 95% immunization coverage in all districts (CD42.R8). In addition, PAHO seeks the endorsement of the Executive Committee regarding a strategic vision to transition from child to family immunization, achieve global disease reduction targets (GIVS guidelines and Millennium Development Goals), and maximize country participation in the revolving fund for the procurement of new and underutilized vaccines.

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## **Introduction**

1. Remarkable progress has been made over the past decade towards providing an umbrella of protection against vaccine-preventable disease (VPD). Progress includes eradication of polio, elimination of measles and neonatal tetanus, control of yellow fever, and the sustained introduction of rubella and pentavalent vaccines. Political commitment has been outstanding and sustained, exemplified by the successful introductions of pentavalent and influenza vaccines. Mortality has been reduced by more than 90% for most VPD. The use of the PAHO Revolving Fund for Vaccine Procurement (RF) by countries is at the highest level to date. Using the experience gained, new and under-utilized vaccines may empower programs to control other killer diseases, such as pneumococcal and rotavirus infections.

2. WHO/PAHO estimates of preventable mortality from rotavirus disease in Latin America and the Caribbean ranges from 11,000 to 17,000 deaths per year, and for pneumococcal disease more than 20,000 deaths per year. The Global Alliance for Vaccines and Immunization (GAVI) is positioning itself to offer assistance to GAVI-eligible countries for vaccines against rotavirus and pneumococcal infections in Phase 2 of its strategy for 2006-2015. Additionally, in line with the Millennium Development Goals (MDGs), WHO's Global Immunization Vision and Strategy (GIVS) calls for a two-thirds reduction in mortality of these diseases by 2010. However, these vaccines represent new paradigms for all countries; they are much more expensive than traditional vaccines. New programmatic challenges face policy-makers if they are going to utilize these new technologies against diseases that kill children.

3. It is against this backdrop that some Member States are at risk for falling into a state of complacency. Such risk threatens the possibility of leaving no child beyond the benefits of the routine immunization program and also of achieving rubella elimination.

4. The guidance and support of the Executive Committee, in addition to consideration of a draft resolution on sustainable immunization program development—reaching all of the unreached, introducing new vaccines of public health importance, and transitioning to family immunization—will be critical to maintaining the achievements of the past decade, while meeting the challenges of the future.

## **Achievements of Immunization in the Americas**

### ***Umbrella of Protection***

5. PAHO Member States have sustained the successes of polio, measles, and neonatal tetanus by implementing high-quality surveillance, attaining and maintaining high levels of immunization coverage in the regular program, and conducting mass

vaccination campaigns to achieve rapid reduction of disease-susceptible populations (Figure 1). For 2004, reported average regional coverage of all childhood vaccines exceeded 90%. All international reviews of national immunization programs coordinated by PAHO have documented that programs are generally strong, supported by a high degree of political commitment.

6. Strategies for polio eradication and measles elimination were first developed and implemented in the Americas. These strategies include high-quality surveillance and rapid reduction of disease-susceptible populations by achieving high levels of immunization coverage in the regular program and conducting mass vaccination campaigns. The Taylor Commission Report<sup>1</sup> demonstrated important by-products of these efforts, including more effective intersectoral coordination, strengthened public health infrastructure, and improved awareness in the community about the importance of prevention.

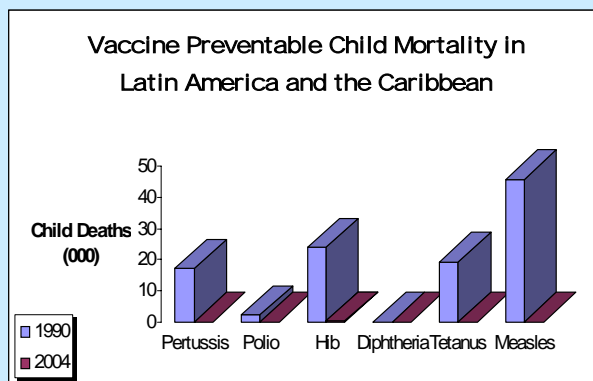
7. All countries, except Haiti, have introduced rubella vaccine. Where epidemiologically indicated, countries have accelerated the use of yellow fever vaccine. Countries have also accelerated the introduction of seasonal influenza vaccine into routine schedules in recent years. An important by-product of seasonal influenza vaccination has been strengthening access to adult populations in readiness for a possible influenza pandemic.

8. In September 2003, PAHO's 44th Directing Council adopted a resolution to eliminate rubella and congenital rubella syndrome (CRS) by 2010. Extraordinary levels of political commitment by countries conducting mass rubella vaccination campaigns have been instrumental in ensuring that countries are currently on track for the 2010 target. The elimination strategies spearheading this initiative include: (a) achieving high coverage in the routine immunization program; (b) implementing a mass vaccination campaign against rubella, targeting men and women in all countries with endemic transmission; (c) integrating and achieving high-quality measles and rubella surveillance; (d) implementing CRS surveillance; and (e) strengthening the laboratory diagnosis of rubella and CRS. In 1998, 135,000 rubella cases and an estimated 20,000 CRS cases were reported compared to 4,158 rubella cases and 7 CRS cases reported in 2005 (preliminary data as of 26 May 2006).

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<sup>1</sup> Pan American Health Organization, Special Program for Vaccines and Immunization. Final Report of the Taylor Commission: The Impact of the Expanded Program on Immunization and the Polio Eradication Initiative on Health Systems in the Americas. Washington, DC: PAHO; March 1995.

## Figure 1: Reducing Child Mortality and Morbidity, The Americas, 1990-2004



Sources: WHO Global Burden of Disease Report, 1990; PAHO Health Data - Registered Under 5 Deaths, 2004 (except Hib, which is an estimate based on modeling)

- **Substantial progress toward MDG 4**
- **Rubella and CRS not yet eliminated**
- **New vaccines against priority diseases now available**

### *Cost-effective Interventions*

9. Recent Harvard University research<sup>2</sup> has indicated that the true dimensions of morbidity and sequelae prevention achieved through childhood immunization have been understated in traditional ‘best public health buy’ concepts of immunization. In other words, the cost-effectiveness of immunization using traditional techniques of measurement has been greatly underestimated, indicating that PAHO Member State investment in immunization continues to represent outstanding value for the money spent.

### *Vaccination Week in the Americas*

10. Vaccination Week in the Americas (VWA), originally proposed by the ministers of health of the Andean Region, continues to focus on strengthening the routine vaccination program in each country, and on identifying populations with low access to health services that are at the most risk of contracting vaccine-preventable diseases. These populations are the most vulnerable. VWA has been a valuable country-level tool

<sup>2</sup> Bloom D, Canning D, Weston M. The Value of Vaccination. *World Economics* 2005;6( 3):15-39.

for preventing morbidity and mortality through enhanced border coordination between countries, while gathering political support for disease elimination, promoting Pan Americanism, and maintaining immunization on the political agenda. Countries face exciting new challenges while sustaining VWA, including the formation of local- level partnerships with Healthy Schools and Healthy Municipalities programs. Sustained political commitment for VWA will enable countries to reach vulnerable populations and protect the Region against measles importations causing large outbreaks extremely expensive to control.

## **Framework for Country Support**

### ***Partnership***

11. Partnership is at the core of sustainability. PAHO continues the promotion and development of partnerships at family, community, national, subregional, regional, and global levels. The 2005 rubella elimination vaccination campaign conducted in Paraguay highlights one of the better examples of family, community, and other local partnership. The community mobilized almost a third of the necessary resources to conduct the national rubella vaccination campaign, which vaccinated more than 95% of the nation's population aged 5 to 39 years. Venezuela's response to the 2006 measles virus importation demonstrates the critical national coordination needed to control measles outbreaks in countries previously measles-free. This required a national intersectoral partnership that extended to the local level.

12. Vaccination Week in the Americas exemplifies cross-border coordination and partnership at the highest level. In 2005 the European Region emulated the Region of the Americas by conducting its first Vaccination Week in Europe using many of the lessons learned in the Americas.

### ***Guiding Principles***

13. The Regional Strategy for Sustaining National Immunization Programs in the Americas is based on the guiding principles presented at the 2004 PAHO Technical Advisory Group on Vaccine-Preventable Diseases (TAG) and on the principles used for the renewal of primary health care (PHC). These principles focus on reducing inequities, strengthening public health infrastructure, cultivating a culture of prevention, galvanizing political commitment, and striving for excellence in technical cooperation. The specific elements for regional support elaborated in the Public Health Plans for the Americas Concept Paper (Document SPP40/8) are also addressed.

### *Strategies*

14. PAHO will continue to strive to maintain well-functioning technical oversight and partner coordination groups (such as the TAG and the Regional and Country Interagency Coordination Committees). These groups will continue to help ensure that the technical strategies stay on track and sufficient resources are available to do the job. PAHO's mobilization of resources to maintain the network of PAHO's country-based international immunization consultants and various grants to conduct immunization activities, such as the elimination of measles and rubella and the introduction of new vaccines has been well received, particularly by the resource-poor countries. PAHO plays a critical role in sharing national experiences and the lessons learned from all the countries.

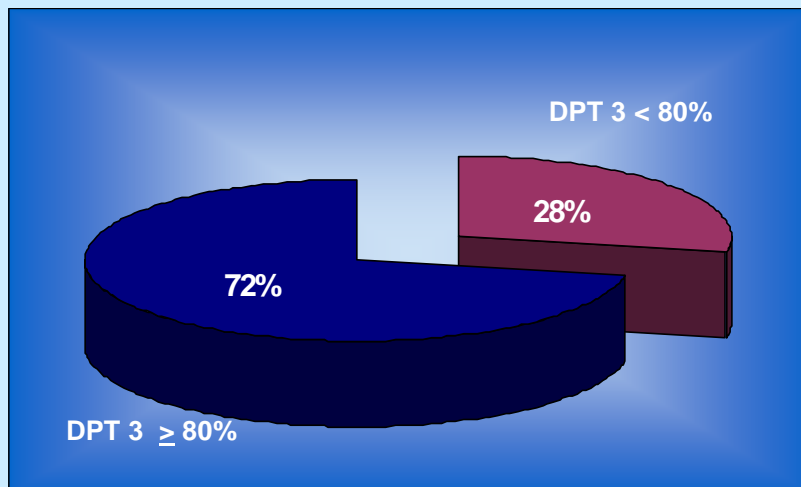
15. Lessons learned from the sustained introductions of measles-mumps-rubella vaccine (MMR) and pentavalent vaccines and the development of accurate forecasting of national vaccine requirement and cold chain assessments will be applied to the accelerated uptake of seasonal influenza vaccine and introduction of new-generation rotavirus, conjugate pneumococcal, and HPV vaccines. Effective management of PAHO's Revolving Fund will continue to provide a safe and affordable vaccine supply in the face of new, more expensive vaccines.

### **Future Technical and Programmatic Challenges**

#### *The Unfinished Agenda*

16. The immunization umbrella of protection does not yet extend to all of the Region's children and vulnerable women. Approximately one child in three in Latin America and the Caribbean lives in an underserved district (Figure 2). Completing the unfinished agenda for immunization requires that these unreached children and women have equitable access to the benefits of immunization. Sustaining measles elimination will require improving immunization coverage to the regional target of 95% in each municipality and service quality in the low-performing districts. Key strategies for achieving and sustaining target coverage levels of all routine vaccines can include as appropriate: reestablishment of regular outreach services where necessary; supportive supervision and on-site training; strengthening community links with service delivery; monitoring and use of data for action; and better planning and management of human and financial resources.

**Figure 2: Children living in municipalities reporting DPT3 coverage < 80%**



17. Maintaining the scale of past successes with immunization is a major challenge for national decision-makers and program managers. Disturbing evidence from industrialized countries has indicated the vulnerability of successful public health programs including immunization to defunding as the memory of childhood killer diseases fades. Lapses in public vigilance in Australia, the United States of America, and the United Kingdom and other European countries resulted in dramatic drops in immunization coverage in the early 1990s. High-level policy changes and extensive and very costly programmatic efforts were required in each of these countries to restore immunization coverage to the 1980s levels.

18. While enormous progress has been made towards rubella elimination, resource mobilization and sustained political commitment need added attention by Member States and PAHO to finish the job. This should be a top priority. Developing high-quality surveillance to monitor progress and to verify that CRS has been eliminated also needs urgent attention. Special focus must be directed to particular technical situations, such as monitoring postvaccine events during rubella vaccination campaigns, planning for safe injections, and disposal of waste. Equally important, supervision of health workers at different levels of the health care system must be strengthened. PAHO is supporting



Member States in the creation of an enabling environment to address the unfinished immunization agenda.

### ***Introducing New-Generation Vaccines***

19. The introduction of new vaccines and immunization technologies into routine schedules poses significant technical challenges to countries. Vaccines either at or near the point of market readiness include those against diseases caused by rotavirus, pneumococcus, and human papillomavirus. However, in many countries: surveillance systems for these diseases are not yet fully functioning; burden-of-disease and related epidemiological studies have not been completed; cold chain capacity has not been adequately assessed; and adverse-events monitoring capacity remains suboptimal. Laboratory networks to support postmarketing surveillance will also need to be strengthened. Infrastructure development, such as strengthening surveillance, will need attention.

20. At the time vaccines containing *Haemophilus influenzae* (Hib) were introduced into routine childhood immunization schedules in the Americas, burden-of-disease data was not available for Hib infections in all countries. However, good data from Chile, the United States of America, and Uruguay demonstrated the remarkable impact Hib vaccines had on disease incidence. Other countries used these experiences to justify vaccine introduction.

21. With the new-generation vaccines, there is a necessity to establish burden-of-disease estimates caused by these agents that are subregion-specific. There is also a need to set mortality reduction targets for these diseases addressing the MDGs in accordance with the WHO Global Immunization Vision and Strategies guidelines. Country-specific introduction decision-making processes should be based more on the local situation. This will allow better monitoring of the impact of immunization against these disease agents on the achievement of the Millennium Development Goals.

22. PAHO is promoting renewed emphasis on strengthening national capacity to make evidence-based decisions for vaccine introductions in the context of all health priorities. A regional training plan has been developed to help equip national policy-makers with all the evidence needed to make sound policy decisions for vaccine introduction.

23. New generation vaccines are order-of-magnitude more costly than the basic vaccines of the Expanded Program on Immunization. These increasing costs present enormous challenges for immunization program managers seeking to introduce new products based on sound epidemiological evidence alone. The doubling of program budgets needed to introduce, for example, rotavirus vaccine, has required that countries

begin to assess the potential for creating fiscal space—the room in a national budget that allows provision of resources without jeopardizing overall financial sustainability or economic stability—for the new vaccine introductions under consideration.

24. In this context, PAHO has commenced a process of systematic review of the quality and effectiveness of existing vaccine legislation and regulations in Member States. The purpose of this review is to define best practice to sustain national immunization programs financially and to use improved laws to reduce country transaction costs for immunization programs. A draft model law, including the best elements of those national laws reviewed, has been prepared.

25. Once decisions for vaccine introduction have been taken, operational plans need to be developed in full coordination and integration with other areas of work. The plan for rotavirus introduction should be carried out in full collaboration with child health programs such as diarrhea control and the integrated management of childhood illness (IMCI). The plan to accelerate seasonal vaccination with influenza vaccine should be carried out in full collaboration with programs being conducted to prevent and prepare for pandemics and disasters. The plan for HPV introduction should be carried out in full collaboration with women's health and reproductive health programs.

### ***Transition from Child to Family Immunization***

26. Family immunization will eventually target all members of the family in all stages of their life cycle with vaccines. The family immunization approach should be grounded in the comprehensive primary health care strategies. The benefits of such efforts should be the reduction of preventable morbidity and mortality in older individuals who have been immunized with appropriate vaccines, and the strengthening of systems that can be used in the event of emerging epidemics affecting children and adults alike. Specifically, this transition means that immunization programs will be better positioned to prevent influenza, pneumococcal, HPV, and HIV infections when appropriate. The transition to family immunization should begin with achieving high coverage of influenza, tetanus, and rubella vaccines in target adult populations. The lessons learned from influenza control and neonatal tetanus and rubella elimination will be applied to prevent influenza, cervical cancer, and AIDS deaths in the Region.

27. The achievement of the child and maternal mortality targets within the Millennium Development Goals presents cross-cutting challenges to maternal and child health programs. National immunization programs in almost all countries of the Region have developed strong service delivery systems. Based on these systems, and supported by internal PAHO partnerships to explore innovative approaches to more effective service delivery integration, the transition to family immunization can contribute to a more integrated approach to maternal and child health programs. Effective integrated

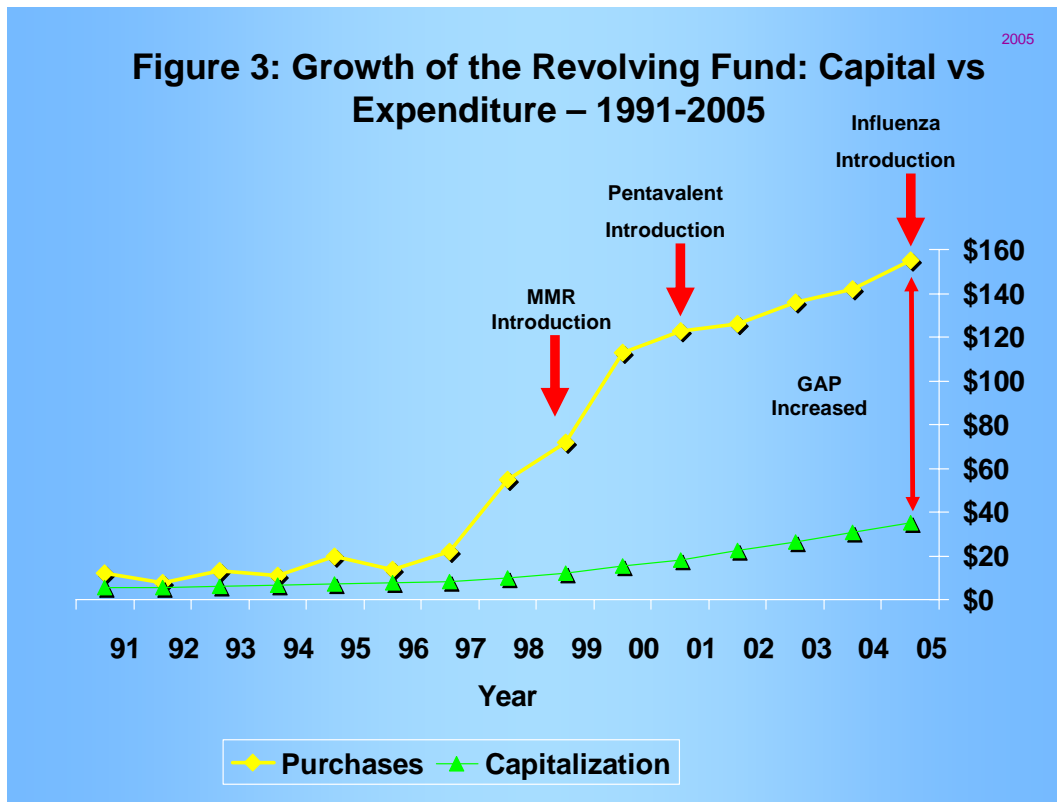
family immunization can also contribute to the achievement of the Millennium Development Goals in the Americas.

***The Revolving Fund***

28. Over the past 10 years, the PAHO Revolving Fund for Vaccine Procurement has grown significantly through the increased volume of vaccine purchases and the compounding effect of the 3% service fee applied to each order. At the close of 2005, the RF was capitalized at just over \$34 million and had total expenditures of over \$154 million that year (Figure 3).

29. By ensuring an uninterrupted supply of affordable vaccines, the RF has been instrumental in supporting PAHO/WHO Member States efforts to provide an umbrella of protection for their children. The RF has increased supplier confidence through prompt payment terms and better forecasting accuracy, which reduces demand uncertainty and enables planning for investment in production. The RF has provided significant benefits to participating countries including: cost savings, due to lower, uniform vaccine prices resulting from bulk purchasing contracts; increased consistency and adequacy of vaccine supply; flexibility in the use of local currency; and greater cooperation between immunization programs of Member States when emergencies occur.

30. There are currently 37 countries participating in the RF for the purchase of some or all of their vaccine requirements.



31. The RF mission is to provide high-quality vaccines to countries of the Region at a single price affordable to all. Essential to addressing the challenge of more costly new-generation vaccines will be unprecedented levels of country participation in the Fund, as this will provide the volume of demand needed to both stabilize supply and negotiate best prices. New supply chain partnerships, drawing on the operational and programmatic experiences of PAHO Member States not routinely using the RF, will be key to achieving maximum participation.

32. There are multiple entry points for participation in the RF. Countries can purchase vaccines through the fund and use either prepayment or line-of-credit financing mechanisms. Under the principle of Pan Americanism, countries can make or receive loans or donations of vaccines to cover unforeseen supply shortages. Countries can also participate as suppliers of WHO prequalified vaccines to the RF. The RF management principle of bulk purchasing with uniform prices is the most sustainable and equitable approach in Latin America and the Caribbean since it uses classic market forces to achieve the one best price for all. Greater coordination between bulk purchasing agencies through periodic supply chain meetings, and expanded country participation in the RF will enable the scale of benefits to be substantially increased.

33. There is a risk to the Region if countries using the RF for vaccine purchases engage in bilateral supplier contracts for new-generation vaccines that have not been prequalified by WHO. The prequalification process remains a key element in the assurance of the safety of these products, given the limited capacity of many national regulatory authorities in Latin America and the Caribbean to assess vaccine quality. In addition, there will be no easy mechanism for shifting stock among countries in response to unexpected supply variation, experienced recently for example with the MMR and pentavalent vaccines. With bulk procurement through the RF, risks associated with supply failures can be better managed and impact minimized.

### **Strategic Vision and Key Issues for Executive Committee Consideration**

#### ***The Unfinished Agenda***

34. There are two important issues regarding the unfinished agenda for the Executive Committee to consider. First, the unfinished agenda for immunization contributes to continuing, preventable child mortality in the Americas. Coverage of greater than 95% for all scheduled childhood vaccines in every administrative unit of every country is an essential target, but much remains to be done. The Executive Committee is requested to reiterate its endorsement of achieving greater than 95% target coverage in all municipalities as an on-going expression of regional commitment to further reducing preventable child mortality in line with the MDGs. This inequity needs to be corrected.

35. Second, to date more than three-quarters of the countries in the Americas have large cohorts of adults protected against rubella, with coverage greater than 95%. However, outbreaks of rubella and consequent cases of CRS in 2005 in countries that have implemented the rubella and CRS elimination strategies, together with the continuing endemic disease patterns in the eight countries planning campaigns in 2006-2007, indicate much more work remains. The Executive Committee is requested to reiterate its endorsement of the elimination of rubella and CRS in the Americas by 2010 and to request an update on progress in 2007, including the identification of resource gaps necessary to finish the job.

#### ***Introducing New-Generation Vaccines***

36. New targets in mortality reduction, consistent with the WHO Global Immunization Vision and Strategies will provide incentives for countries to invest in new generation vaccines and immunization technologies, including those supporting the achievement of the Millennium Development Goals. Currently, GAVI is positioning itself to provide eligible countries with complementary support for the introduction of rotavirus and pneumococcal vaccines. PAHO will need to continue to assist all countries in their efforts to mobilize necessary resources. The Executive Committee is requested to

endorse the principle of mortality reduction targets for diseases caused by infections with rotavirus, pneumococcus, and human papillomavirus and to support work being conducted on the establishment of disease-specific targets and dates, and mobilization of resources.

***Transition to Family Immunization***

37. The transition from childhood to family immunization is consistent with regional priorities for the integration of primary health care activities and with the WHO Global Immunization Vision and Strategies guidelines. The Executive Committee is requested to endorse the principle of programmatic transition from childhood to family immunization. This will include promoting rubella and influenza immunization.

***The Revolving Fund***

38. The PAHO Revolving Fund for Vaccine Procurement remains critical to regional progress in reducing mortality due to vaccine-preventable diseases. A high level of country participation will be needed to maximize the RF advantage in price negotiations for new-generation vaccines and immunization technologies, consistent with the principles of equity and Pan Americanism. The Executive Committee is requested to once again mandate its highest level of commitment to the RF and its principles of management during this new era of vaccine introduction.

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