



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



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### THE PAN AMERICAN HEALTH ORGANIZATION REVOLVING FUND FOR VACCINE PROCUREMENT

#### Introduction

1. Since its creation 32 years ago as part of the Pan American Health Organization's Expanded Program on Immunization (EPI), the PAHO Revolving Fund for Vaccine Procurement (RF) has been a critical technical cooperation mechanism for achieving the EPI objectives of reducing morbidity and mortality from vaccine-preventable diseases. The Member States of PAHO recognize the RF as a public good that has facilitated polio eradication, measles elimination, and advances in the elimination of rubella and congenital rubella syndrome (CRS) and in the control of neonatal tetanus, *Haemophilus influenzae* type b, and hepatitis B; moreover, the RF has proven instrumental in the rapid introduction of new vaccines against major causes of infant mortality, such as rotavirus and pneumococcus infection.

2. Over the past three decades, RF operations have adapted to epidemiological and operational changes, as well as to changes in the vaccine market, while faithfully upholding its foundational principles, which allow Member States to have equitable access to high-quality vaccines in a timely manner and at the lowest prices.

3. This document presents the conceptual principles and benefits that the RF, through its operating mechanisms, offers the Member States and the regional and global vaccine market.

#### Background

4. In 1977, by resolution of the Directing Council of PAHO (CD25.R27), the EPI was created and the FR as part of it, with a view to reducing mortality and morbidity from vaccine-preventable diseases. (1)

5. As an important part of the EPI and to facilitate a timely supply of quality vaccines in appropriate quantities at the lowest prices, Resolution CSP25.R27 authorizes the Director to create the Revolving Fund for Vaccine Procurement<sup>1</sup>, whose specific objectives are: (a) to enable Member States to plan their immunization activities without disruptions occurring due to a lack of supplies or funds for vaccine procurement; (b) to enable Member States to use local currency for reimbursement of the funding provided through the RF; (c) to consolidate vaccine orders so that Member States can benefit from economies of scale for the procurement of vaccines at the lowest prices; (d) to guarantee that Member States receive quality vaccines that meet PAHO/WHO standards; and (e) to establish contracts with suppliers for the procurement of vaccines and related supplies to guarantee the timely processing and delivery of both regular and emergency orders.(2,3)

6. In 1978, Resolution CSP20.R16 adopted by the 20th Pan American Sanitary Conference established the working capital for RF operations.(4) The initial capitalization of the RF was US\$ 1 million from the initial contributions of PAHO itself and several countries, among them Barbados and the Netherlands, and subsequently the United States and UNICEF.(2,3,4) This enabled the RF to formally commence operations in 1979.

### **Conceptual Vision of the Revolving Fund**

7. As a mechanism of cooperation, the RF is grounded in the principles of equitable access, the application of regional and international standards for product quality, the integration of national distribution systems, Pan-Americanism, and transparency in procurement and supply management. (5)

8. The RF employs a centralized procurement model in which the Member States participate and delegate the necessary authority to the Pan American Sanitary Bureau (PASB) to sign contracts, purchase vaccines and supplies, and make payments to suppliers.(6) The RF operates as a common fund; through which the PASB pays suppliers, giving Member States the option to defer payments for 60 days following satisfactory receipt of the vaccines and supplies and to use their national currency as necessary. (6) The PASB assumes all the operating costs; the entire recapitalization fee, which is equivalent to 3% of the net value of the vaccines and supplies, contributes to the 60-day line of credit to which the countries have access and represents resources that the countries provide in the spirit of Pan-Americanism.

9. The RF is more than a mechanism for the procurement of vaccines, syringes, and other immunization supplies; it is also a mechanism for the creation, organization, and maintenance of the market. There is no doubt whatsoever that in the past 30 years, the FR has helped to create and maintain a healthy market for vaccines and related supplies through mutual cooperation among the Member States. Centralized procurement and the negotiation of a single price for all Member States generate economies of scale to secure the lowest prices, thus promoting the financial sustainability of the Region's immunization programs. At the same time, the close ties between RF operations and the technical cooperation that the PASB provides to the Member States has led to the growth and strengthening of national immunization programs (NIPs), together with significant advances in regional public health.

10. Through these technical cooperation activities and the centralization of the market, the RF helps to create and stabilize demand, offers an efficient system for forecasting demand, and resolves quality control issues by working with the industry to improve the vaccines that are marketed and foster innovation. Thus, RF's main focus is the needs of the Member States, it has helped to accelerate the development and availability of vaccines and related supplies in the Region

### **Situation of the Revolving Fund**

11. The EPI has enabled the Region of the Americas to be the first region to be declared polio-free, the first to eliminate indigenous measles, and the region that has made the greatest strides in the elimination of rubella and congenital rubella syndrome (CRS) and in the epidemiological control of whooping cough, diphtheria, and neonatal tetanus; it has allowed the Region to achieve the most significant reductions in morbidity and mortality from vaccine-preventable diseases. The RF has been vital to maintaining high coverage by vaccination services and, consequently, to achieving equity with respect to immunological protection for the population of Latin America and the Caribbean (LAC).

12. The EPI is making a significant contribution to the attainment of the Millennium Development Goals (MDGs), especially Goal 4 for the reduction of mortality in children under 5, and Goal 5 for the improvement of maternal health.<sup>(7)</sup> Globally, it is estimated that immunizations have contributed with 50% of the reduction in mortality in children under 5. <sup>(8)</sup> In LAC, 174,000 deaths from vaccine-preventable diseases are prevented annually in children under 5, and it is estimated that universal use of the new vaccines — specifically, the rotavirus and pneumococcal conjugate vaccines— could prevent several thousand additional cases and deaths. <sup>(8)</sup>

13. These achievements are due to the commitment of the Member States which, after identifying vaccination as a public good, have boosted their operational capacity to provide these services, established budget lines that guarantee the financial sustainability

of these activities, and created the RF—a public health intervention widely recognized at the regional and international level as the ideal mechanism for procuring vaccines and other related supplies. (9)

14. For three decades, the PASB has administered the RF on behalf of the participating countries of the Americas. Requests for vaccines through the RF are aligned with the plans of action prepared by the countries for the activities of their NIPs. After consolidating the demand, the PASB selects suppliers through a public tender, basing its choice on PAHO/WHO specifications relative to quality, price, and the supplier's history of timely vaccine delivery. By ensuring a continuous supply of vaccines at the lowest possible prices, the RF has played a key role in the immunization efforts of PAHO's Member States.

15. With the creation of the RF, the accuracy of demand forecasts and budgets for vaccine procurement in the Region of the Americas has improved. This is due to the application of strict planning requirements supported by technical assistance from the PASB, and it has led to a consequent decrease in vaccine price fluctuations.

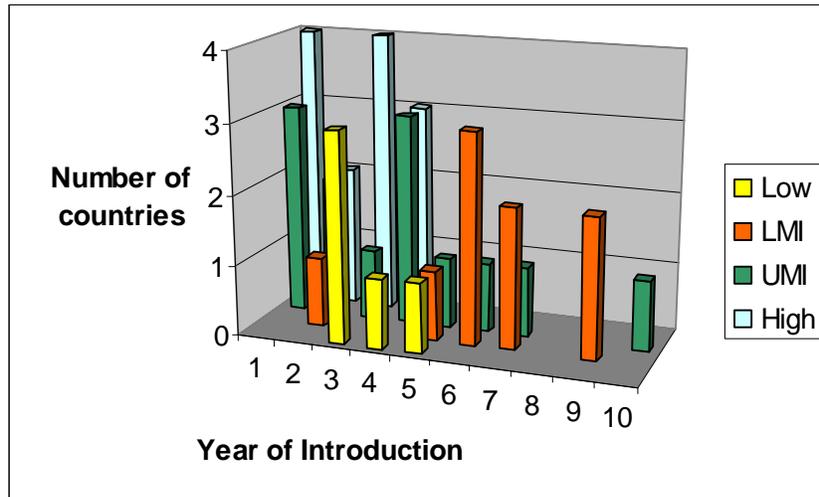
16. Thanks to better forecasting and its strict payment schedules, the RF has boosted the pharmaceutical industry's confidence in the vaccine market of the developing world, facilitating economies of scale and better prices, not only for countries of Latin America and the Caribbean, but for all developing countries. There is no doubt that the higher demand has been critical to expanding regional production capacity, which in turn has been a key factor in the success of the RF.

17. To a large extent, the RF has served as a major catalyst for the rapid, equitable, and sustainable introduction of new and underutilized vaccines, among them the measles, mumps, and rubella (MMR); yellow fever; hepatitis B (HepB); *Haemophilus influenzae* type b (Hib);<sup>1</sup> seasonal influenza; rotavirus; and pneumococcus vaccines. Some investigators have dubbed this phenomenon “the PAHO effect.” (10) Figures 1 and 2 show that the introduction of the Hib vaccine in the Americas was much faster and much more equitable than in other regions of the world. All countries of the Americas have included the Hib vaccine in their vaccination schedules, with the exception of Haiti, which plans to introduce it in 2010. This was achieved based on lessons learned through the introduction of the hepB vaccine, a process that took over 20 years due to high prices and delays in its supply through the RF. Since 2006, 16 countries have introduced the rotavirus vaccine and nine, the heptavalent pneumococcal conjugate vaccine.

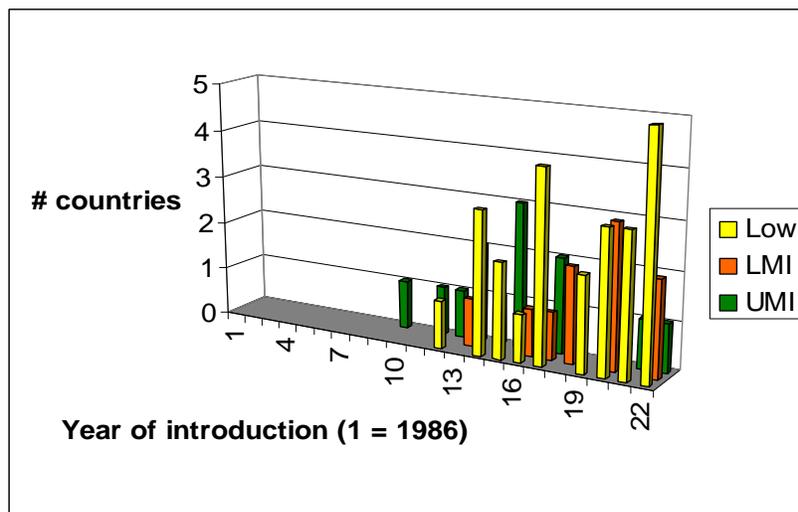
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<sup>1</sup> In the Region of the Americas, the HepB and Hib vaccines are administered in the pentavalent vaccine (Diphtheria-Tetanus-Pertussis-HepB-Hib).

**Figure 1: Introduction of the Hib vaccine\*\* in PAHO countries (through the Revolving Fund)**



**Figure 2: Introduction of the Hib vaccine\* in the rest of the world (excluding PAHO)**



Low: low income LMI: low middle income UMI: upper middle income High: high income

\* Hib: *Haemophilus influenzae* type B.

18. The RF represents a healthy, growing market that benefits the global pharmaceutical industry. Since its creation, it has forged a partnership with vaccine manufacturers, improving demand predictability, establishing transparent operation rules, and furthering competitiveness. It has also promoted the development of producers in the developing countries.

19. RF operations commenced in 1979 with eight participating countries and six antigens. By 2008, most of the Member States were participating, and 27 antigens with 39 different PAHO/WHO-prequalified presentations were offered by 13 suppliers. In 2008, 270.3 million doses of vaccine were procured through the RF, at a total cost of \$271.7 million, four times the total cost in 2000. Projected vaccine procurement for 2009 is on the order of \$369.5 million.

20. By offering access to vaccines, the RF also fosters research and the operational development of immunization programs by promoting the strengthening of epidemiological surveillance systems, the laboratory network (e.g., identification of strains), and infrastructure, as well as the training of human resources.

21. The RF also contributes to the regulation of the quality and safety of vaccines. As part of the activities of the EPI and in coordination with producers, it monitors and investigates events supposedly attributable to vaccination and immunization (ESAVI), which, combined with the measures adopted by the national regulatory authority, is an important aspect of vaccine pharmacovigilance.

22. In 2004, the World Health Organization's Office of Internal Oversight Services (OIS/WHO) performed an audit of the PASB to examine the administration of the program for the procurement of public health supplies through the RF and the Strategic Fund (SF). The audit evaluated the efficiency of the process and the effectiveness of the activities for meeting its objectives, concluding that "the RF had been extremely successful and appreciated by the countries and external partners, achieving all of its objectives while contributing to AMRO<sup>2</sup>/PAHO's [Pan American Sanitary Bureau (PASB)] leadership role in the immunization programme in the Americas. The close linkages between the RF procurement mechanism and technical support to the countries, leading to successful implementation of both aspects, was evident. While recognizing that there are many aspects of the RF unique to vaccines, lessons from the experiences with the RF will be useful for other procurement funds and mechanisms. Learning from the RF experience is very timely in view of the urgent need to assure continuous supplies of high quality drugs for the HIV/AIDS, TB, and Malaria control programs."*(11)*

23. RF operating procedures have been updated periodically throughout its 30-year existence to achieve high levels of efficiency. These procedures spell out all relevant RF

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<sup>2</sup> AMRO: WHO Regional Office of the Americas.

criteria and procedures, including: consolidation of the Member States' demand; product quality assurance; supply procurement procedures; characteristics of the public tender system; requirements for laboratories concerning the supply, sale, and delivery of products; procedures for receipt and claims by Member States; and product payment procedures. The most recent version of the Operating Procedures was issued in October 2008. (12) As part of the RF capitalization process and in preparation for the demand that the new vaccines will generate, an external evaluation was conducted in early 2009, whose recommendations are already being implemented. (13)

24. Diverse resolutions of the Directing Council urge Member States to make use of the RF for vaccine procurement. The most recent is Resolution CD47.R10 of 2006 regarding the "Regional Strategy for Sustaining National Immunization Programs in the Americas", which places special emphasis on the introduction of new and underutilized vaccines. (9)

### **Current Challenge**

25. The RF has several challenges before it: (a) new, more expensive vaccines marketed by sole suppliers; (b) new actors involved in the temporary financing of vaccines [for example, the Global Alliance for Vaccines and Immunization (GAVI)]; and (c) new mechanisms for marketing vaccines [for example, Advanced Market Commitment (AMC)].

26. Specifically, the new vaccines to fight priority diseases in the Region caused by rotavirus, pneumococcus, and human papillomavirus pose significant challenges to the Member States and the RF, since the majority of these vaccines are marketed by a sole supplier, which inevitably influences their availability and price

27. Based on past successes with the MMR, pentavalent (DPT-HepB-Hib)<sup>3</sup> and seasonal influenza vaccines, the RF has now turned its focus to accelerating sustainable and equitable access to these new-generation vaccines by all risk groups in the Region. Administered by the PASB, the RF provides a platform for NIPs and the vaccine manufacturing industry to work together towards common objectives, including the achievement of several MDGs.

28. In 2006, an estimated 95% of the total cost of vaccines administered through NIPs in the Americas was financed with the countries' own resources. (14) Thus, one of the main hurdles for the introduction of these new vaccines is their high cost, which would imply substantial increases in the budget lines of the Member States. If a Member State adds the rotavirus vaccine to its regular vaccination schedule, procurement of the

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<sup>3</sup> DTP: diphtheria, tetanus and pertussis.

biologicals alone would double its current vaccine cost if the pneumococcal vaccine were added to the package, the cost would increase more than sevenfold.

29. The RF is an essential collective cooperation mechanism that seeks to provide access to these new vaccines for vulnerable populations and promote sustainability for public health care programs.

30. Given the worrisome trends in NIPs in other regions of the world during the 1990s, and in order to increase access to immunization, the Global Alliance for Vaccines and Immunization (GAVI) was created as a public-private initiative to help save lives and contribute to the sustainability of immunization services in the poorest countries. (15) The GAVI Alliance offers time-limited support to improve immunization services, health systems and the safety of vaccination activities; and to accelerate the introduction of new and underutilized vaccines. Support is currently provided only to countries whose gross national income (GNI) in 2003 was less than \$1,000 per capita.(16) Six countries in the Americas meet the criteria for receiving GAVI assistance: Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua.

31. Since the launch of the Alliance, PAHO's experience as a leader in the field of immunization provided the framework for GAVI's development, from concepts such as the EPI's multiyear planning to foster programmatic and financial sustainability to the critical role of coordinating the partners (at the national and regional levels) through the Interagency Coordinating Committees (ICC) on Immunization, to the methodology for periodically evaluating different components of the national immunization programs, etc. Since the approval of the first proposals presented by countries of the Americas eligible for GAVI support, PAHO collaboration with the Alliance has included coverage of the indirect costs of the technical and administrative support that PAHO provides for the implementation of GAVI support to the program. PAHO's added value in the field of immunization continues to be demonstrated by the fact that the Region of the Americas has the highest approval rates for submitted proposals and the highest levels of performance in the execution of GAVI support.

32. The first four countries to receive approval of their proposals for GAVI to support introduction of the rotavirus and/or pneumococcal conjugate (PCV) vaccines were Bolivia, Guyana, Honduras, and Nicaragua. The first round of applications to support these new vaccines took place in 2007, and the proposals of these four countries were the first to be accepted. The Alliance has currently approved financing to support the introduction of the rotavirus vaccine in Bolivia, Guyana, Honduras, and Nicaragua, and of the pneumococcal conjugate vaccine in Guyana, Honduras, and Nicaragua. This support is a partial, time-limited subsidy (currently guaranteed until 2015); the countries must make progressive co-payments until they cover the entire cost of the vaccines in

question. GAVI has recognized the RF as the vaccine procurement mechanism for the countries of the Americas that are eligible for its support.

33. November 2007 marked the opening of negotiations of a Memorandum of Understanding that would permit the transfer of resources for the procurement of rotavirus and pneumococcal vaccines for countries eligible for GAVI financial assistance. This debate lasted more than a year, owing to differences in the respective approaches of GAVI and PAHO. In October 2008, an agreement was reached on the transfer of resources for procurement of the rotavirus vaccine; however, differences persist between GAVI and PAHO over resources for the pneumococcal vaccine.

34. By mid-2008, the RF entered into the first procurement agreement with the sole supplier of the heptavalent pneumococcal conjugate vaccine, after its prequalification by WHO. Accordingly, the lowest price for that year was established: \$26.35 per dose. Under these conditions and per GAVI Secretariat's advise, Guyana, Honduras and Nicaragua asked the GAVI Board to adjust the financial support approved for the purchase of the vaccine. The GAVI Board discussed this request along with an offer by the vaccine's manufacturer to donate 3.1 million doses for two countries in another region (17) and made the following decisions: (a) It did not approve additional funds for introducing the vaccine in Guyana, Honduras, and Nicaragua at the price offered to the RF; (b) It unanimously reaffirmed its commitment to tiered pricing; and (c) It requested the GAVI Secretariat to facilitate discussions among partners to find a resolution in the area of tiered pricing, including addressing PAHO's single price clause. (18) This issue was taken up again during the following session, at which time GAVI's Executive Committee issued the following decisions: (a) It approved in principle GAVI's acceptance of the donation of 3.1 million doses of heptavalent pneumococcal vaccine for Rwanda and Gambia for a period extending through 2010; and (b) It requested the GAVI Fund to accept the donation. (19) The donation offered excluded the countries of the Americas.

35. The delay in making these vaccines available to the countries of the Hemisphere eligible for GAVI support —especially, the more than a year's delay following the announced approval in the case of the pneumococcal vaccine— has had serious consequences for immunization programs of the affected countries, given the high expectations created among the population.

36. The Advanced Market Commitment (AMC), administered by the World Bank, establishes commitments with producers in advance of the purchase of the vaccines. Through this mechanism, GAVI and the World Bank are conducting a 10-year pilot project to foster the rapid introduction of the 10-valent pneumococcal conjugate vaccine (PCV-10) and future higher-valent pneumococcal conjugate vaccines in countries eligible for GAVI assistance. Given the financial and operational characteristics of the AMC, the World Bank noted a conflict with the clause guaranteeing the lowest price in RF contracts

with suppliers. The World Bank argues that the existence of this clause would keep manufacturers from offering the lowest price to the AMC and would thus keep countries eligible for GAVI support from accessing this vaccine.

37. In order to expedite procedures for eligible Member States to receive GAVI financial resources for the introduction of these vaccines, a PAHO-GAVI Working Group has been established with the collaboration of representatives from the World Health Organization (WHO), UNICEF, and the World Bank. The working group's main objective is to improve collaboration between GAVI and PAHO that will lead to the sustainable introduction of new vaccines in the poorest countries and populations of the Region of the Americas.

38. The Member States have stated their decision to continue procuring vaccines through the RF in official communications to the GAVI Secretariat and Board and in the technical session on the RF, held 23 June 2009 during the 144th Session of the Executive Committee (Report in Annex). With PAHO support, the eligible countries of the Region have also had the opportunity to state their positions to the GAVI Board representative for the developing countries of the Americas and Europe and to the Chief Executive Officer of the GAVI Alliance, in May 2009 during the World Health Assembly.

### **Future of the Revolving Fund**

39. Since in its 30 years of operation, the RF has proven an essential component of PASB technical cooperation to the Member States of the Region within the Expanded Program on Immunization, guaranteeing equitable access to quality vaccines at the lowest possible prices and helping to prevent thousands of cases and deaths due to vaccine-preventable diseases, the Member States have indicated the need to keep the RF faithful to its current criteria and principles, as declared in the Aide Memoire of the meeting of countries eligible for GAVI support, signed by the six respective ministers in October 2007 during the 27th Pan American Sanitary Conference (20) and the 2008 Nassau Declaration of the English-speaking Caribbean Countries. (21) The United Nations Regional Directors for Latin America and the Caribbean have determined that the EPI should be considered a "regional public good" and declared the use of the Revolving Fund a mechanism of regional solidarity. (22) The Regions of Africa and Eastern Mediterranean are interested in creating mechanisms similar to the RF to guarantee access to the vaccines and support the sustainability of their NIPs.

40. As it celebrates 30 years of operations, the RF continues to make progress toward a new approach that promotes family vaccination, preparations for the introduction of new vaccines (e.g., HPV, dengue, malaria, HIV, new influenza strains, among others) and the use of innovative technologies.

## Action by the Directing Council

41. The Directing Council is invited to take note of the information contained in this document.

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## **THE PAHO REVOLVING FUND FOR VACCINE PROCUREMENT IN LIGHT OF NEW CHALLENGES**

### **Summary Report of a Meeting held on 23 June 2009**

1. A meeting was held on 23 June 2009 at the Headquarters of the Pan American Health Organization (PAHO) in Washington, D.C., to discuss various technical and policy issues relating to PAHO's Revolving Fund for Vaccine Procurement and PAHO's collaboration with the GAVI Alliance, the World Bank, and the Advance Market Commitment (AMC) for pneumococcal vaccines. The meeting was convened pursuant to a request made by a representative of the United States of America during the Third Session of the PAHO Subcommittee on Program, Budget, and Administration (SPBA).<sup>1</sup>

2. Dr. Socorro Gross, Assistant Director of PAHO, opened the meeting and welcomed participants, extending a special welcome to the Ministers of Health of Haiti, Paraguay, and Suriname and the Vice-Ministers of Health of Brazil and Nicaragua. Other participants included representatives of various PAHO Member States attending the 144th Session of the PAHO Executive Committee, which took place at PAHO Headquarters from 22 to 26 June 2009, and representatives of the GAVI Alliance and the World Bank. The pharmaceutical industry was also represented. In addition, representatives of several PAHO Member States participated in the meeting via online conferencing software.

3. Introductory presentations were made by Alex Palacios of the GAVI Alliance, Susan McAdams of the World Bank, and Cuauhtémoc Ruiz of PAHO, and then the floor was opened for questions and comments. The presentations and discussion are summarized below.

#### **Presentation by Alex Palacios, Special Representative, Executive Office, GAVI Alliance**

4. Mr. Palacios began by noting that GAVI has been working with PAHO and with representatives of the World Health Organization (WHO), the World Bank, and the United Nations Children's Fund (UNICEF) to seek practical solutions to differing policies and practices concerning the procurement and delivery of vaccines that pose a challenge to the shared desire to increase access to protection against deadly diseases. While the PAHO-GAVI Working Group is relatively new, the cooperation between the GAVI Alliance and PAHO dates back to the earliest days of GAVI. The members of the Working Group, he said, have held their talks with an open mind and a desire on the part of all to find a practical solution, and other partners have also been helpful, offering ideas and precedents for consideration. He acknowledged that numerous parties are waiting to

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<sup>1</sup> See the report of the SPBA meeting for further information: Document SPBA3/FR.

hear that the problem has been solved: donors, news media, the pharmaceutical industry, and of course the countries that are waiting to receive vaccines, which have, understandably, begun to express some frustration.

5. Following the last meeting of the Working Group in late May, a subgroup made up of representatives of PAHO and GAVI was asked to consider one possible approach proposed by PAHO's leadership, and attorneys for both sides were scheduled to meet during the week of 22 June to pursue the idea. He was hopeful, he said, that the attorneys would be able to "do their important work quietly and quickly" and come back to the larger Working Group with their thoughts and considerations. He added that he looked forward to continuing his collaboration with Dr. Gross and other colleagues at PAHO, WHO, UNICEF, and the Bank over the coming months, not just to solve the current problems but also to strengthen collaboration on immunization over the coming years.

**Presentation by Susan McAdams, Director, Multilateral Trusteehip and Innovative Financing, Concessional Programs and Global Partnerships, World Bank**

6. Ms. McAdams pointed out that more than 7 million people a year die from infectious diseases, most of them in poor countries. Vaccination could prevent the vast majority of these deaths, but unfortunately vaccines are often not available where they are needed. In some cases, as with HIV/AIDS, she said, "we just haven't cracked the science." The larger problem, however, is that market conditions and uncertainties discourage vaccine manufacturers from investing heavily in vaccines for developing countries. The AMC is an initiative designed to break the vicious cycle of uncertain demand, limited supply, and higher prices.

7. While there is a strong market for vaccines, very few vaccine manufacturers are developing and introducing new vaccines at any given point in time; moreover, vaccines tend to be introduced by one company at a time, so at first there is a monopoly. It takes years for a true market to develop and for competition to bring prices down. Thus, there is a long delay in getting vaccines into the market, especially for developing countries, where manufacturers perceive that there is substantial risk and uncertainty about demand.

8. The AMC is designed to fix this market failure by subsidizing the cost of increasing manufacturers' production capacity and enabling them to scale up production in order to meet developing countries' needs. The basic idea underlying the AMC is to provide assurance to manufacturers that a market for a needed vaccine exists, but without distorting normal production incentives. The aim is to secure a financial commitment from donors to subsidize vaccine purchases at a set price for a set period; the vaccine must meet a specified target product profile (i.e., it must contain the right serotypes and meet other requirements as determined by WHO), and must be in demand from GAVI-eligible countries. The target vaccine selected for the pilot AMC is the pneumococcal vaccine. It was chosen because pneumococcal pneumonia causes more deaths globally

than AIDS, tuberculosis, or malaria, including 800,000 child deaths annually, mostly in the world's poorest countries.

9. The AMC is designed to create a market; it is not a purchase guarantee. Donors agree to provide a subsidy in order to fund a well-defined advance market commitment. The size of the subsidy is specified (US\$ 3.50 per dose in the case of the pneumococcal vaccine), as is the sale price (or the price ceiling) for the target vaccine (also US\$ 3.50 per dose for the pneumococcal vaccine), and recipient countries provide co-payment (US\$ 0.10–0.30 per dose initially, depending on country income level, with GAVI co-financing the remainder of the US\$ 3.50 sale price) in order to ensure that the demand is real and not just donor-driven.

10. The donors for the pilot AMC have agreed to pledge a total of US\$ 1.5 billion to fund the subsidy over the next 20 years, and the World Bank has guaranteed all of the donor commitments. The amount pledged will help fund the capital costs of developing needed capacity. It will be paid out for vaccine purchases at a rate of US\$ 3.50 per dose. There is also a limited purchase guarantee, equivalent to 45% of one year's committed capacity, which is offered to vaccine manufacturers in exchange for the production of a vaccine that meets the target product profile and a long-term supply commitment – 10 years in the case of the pneumococcal vaccine – at an agreed price. The goal of the pilot AMC is to guarantee 2 billion doses of the pneumococcal vaccine over the 10-year period at an overall average price of US\$ 4.25 per dose for the period (in 2009 dollars), which translates to US\$ 12.75 for a 3-dose course of immunization, compared to US\$ 200 in the United States.

11. Ms. McAdams stressed that the point of the AMC is, first and foremost, to create a market. “We all benefit when there is a market with competition,” she said. “It drives prices down, it enables us to meet demand, it enables us to vaccinate all the kids who need it.” A key part of the AMC design is to encourage at least one emerging-market manufacturer to participate in the pilot, she added, as such participation is seen as critical to the long-term success of any vaccine market. She also emphasized that the AMC is a package. It is not a one-year tender, but rather a 10–15 year commitment by the World Bank, GAVI, the donors, and the suppliers. Fundamentally, she said, it is a quid pro quo: a specific subsidy arrangement in exchange for a 10-year supply commitment at a capped low price.

**Presentation by Cuauhtémoc Ruiz, Senior Advisor, Comprehensive Family Immunization, PAHO**

12. Dr. Ruiz recalled that the Revolving Fund for Vaccine Procurement was launched by PAHO in 1979 as a mechanism for ensuring an uninterrupted supply of essential vaccines, syringes, and other inputs needed for the Expanded Program on Immunization (EPI). The Revolving Fund, he explained, is based on the principles of equity, quality, access, and Pan-Americanism; it is a cooperation mechanism that guarantees quality,

timeliness, quantity, lowest prices, and sustainability. As such, the Fund has played an important role in strengthening and ensuring the financial sustainability of immunization programs in countries, thereby also strengthening national health systems. Thanks largely to the umbrella of protection created by the Fund, the Americas was the first WHO region to eradicate polio and eliminate measles and is well on the way to achieving the elimination of rubella. The Fund has also contributed to a marked increase in the use of seasonal influenza vaccines in the Americas, especially since 2000.

13. An important aspect of the technical cooperation provided through the Fund is support for the enactment of national laws on immunization and the strengthening of national immunization budgets. The most recent data available shows that 99% of funding for national immunization programs in the Latin American and Caribbean countries comes from national sources.

14. Apart from providing technical cooperation, the Revolving Fund is a centralized mechanism for vaccine procurement and it serves as a line of credit made available to countries for vaccine purchases. The Revolving Fund has grown steadily over its 30-year history, the number of vaccines offered climbing from 6 in 1979 to 28 in 2008. The number of countries and territories purchasing through the Fund has also risen – from 8 in 1979 to 41 in 2008 – and the monetary value of the vaccines procured has grown more than a hundredfold – from US\$ 2.3 million to US\$ 271.7 million. By 2012, it is estimated that the Fund will be purchasing more than US\$ 500 million worth of vaccines.

15. The Fund offers benefits for both purchasers and suppliers. For countries it ensures a timely and continuous supply of safe, high-quality, WHO-prequalified vaccines at the lowest prices and enables accelerated and sustainable uptake of new vaccines. For suppliers, it affords long-term purchasing agreements with a single procurer, reliable forecasts, and transparent relations; and it facilitates both planning of production and deliveries and post-marketing pharmacosurveillance.

16. Dr. Ruiz sees three main challenges facing the Fund. One is that new and more expensive vaccines are being produced by single suppliers. The new vaccines include the rotavirus vaccine, the 7-valent pneumococcal conjugate vaccine, and the vaccine against human papillomavirus (HPV). The challenge lies in the fact that these new vaccines are very costly. Adding the rotavirus vaccine at current market prices, for example, would double countries' vaccine budgets, and adding the 7-valent pneumococcal vaccine would raise them sevenfold. In the face of limited funds and competing priorities, it would be difficult for most countries to afford such increases. The Revolving Fund is therefore needed to guarantee low prices. The Fund negotiates prices with vaccine suppliers through competitive public bidding, and one-year contracts are established for an approximate number of doses of a particular vaccine at an agreed price. That price is the maximum price that the Fund will pay for that vaccine for a period of one year. If the supplier subsequently offers the vaccine at a lower price, under the contract with the Fund, it agrees also to offer that price to the Fund.

17. Other challenges include the emergence of new actors in the field of immunization, including the GAVI Alliance, and the fact that vaccine markets are operating under new models, such as the Advanced Market Commitment. PAHO has been working with GAVI since its inception, contributing to its technical framework and also assisting the GAVI-eligible countries of the Americas in the preparation of proposals and the implementation of GAVI funding.

18. Dr. Ruiz expressed confidence that the Revolving Fund will adapt to the new circumstances and emerge as an even stronger support mechanism for all the countries of the Region. The high levels of poverty and inequity that prevail in the Americas, in his view, make the Revolving Fund indispensable. Although only six of the countries in the Region (Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua) meet the criterion for GAVI funding (2003 gross national income of under US\$ 1,000 per capita), 122 million people in Latin America and the Caribbean, 22% of the population of the subregion, live on less than US\$ 2 per day and 40% of the population cannot afford a basic food basket. Even in Trinidad and Tobago, the country with the highest gross national income per capita in the subregion, 40% of the population lives on less than US\$ 2 per day. In the face of new challenges, he said, the Fund will maintain its key features and remain true to the principles on which it was founded. An even stronger Revolving Fund will continue to ensure that immunization remains a public good and immunization programs remain the most cost-effective and socially acceptable public health intervention.

### **Questions and comments by meeting participants**

19. Representatives of PAHO Member States expressed resounding support for the Revolving Fund and underscored the need to protect and preserve it. “If our choice is whether to defend the Revolving Fund, I believe that we –the countries that are most directly involved- must defend it,” said Ms. Nora Orozco Chamorro, Vice-Minister of Health of Nicaragua. Participants also voiced solid support for the principles of equity, solidarity, and Pan-Americanism underlying the Fund, which was seen as a means of ensuring access to vaccines of high quality, accelerating the introduction of new vaccines, and realizing economies of scale that benefit all countries of Latin America and the Caribbean, irrespective of size or income level. Several participants suggested that other regions of the world should be encouraged to establish their own revolving funds for vaccine procurement. Dr. Ramiro Guerrero, from the Harvard Initiative for Global Health, noted that the need for increased production of existing vaccines, which is being addressed by the pilot AMC, could be addressed by revolving funds which among other benefits, help organize and consolidate demand forecast.

20. Participants also supported the Revolving Fund’s single-price approach. “At our EPI managers meeting in 2008 in the Bahamas, when we were told about the tiered price for purchasing vaccines...we unanimously voted for continuation of the Revolving Fund and we implored PAHO to lobby for this continuation,” said Dr. Yvonne Monroe of the Ministry of Health of Jamaica. Some participants expressed concern about the possibility

that the GAVI-eligible countries of the Americas might purchase vaccines outside the Revolving Fund for lower prices, which they felt could be detrimental to the Fund. It was emphasized that the Revolving Fund has a proven 30-year track record, whereas GAVI and the AMC are relatively new and, in the case of the AMC, untested.

21. Numerous participants stressed the need to bear in mind that the ultimate aim of vaccination is to save children's lives. Dr. Mirta Roses, Director of PASB, pointed out that immunization goals cannot be achieved and diseases cannot be eliminated by vaccinating only poor children. Dr. Márcia Bassit, Vice-Minister of Health of Brazil, agreed. "We mustn't lose sight of our goal, which is to provide complete coverage to all children who need it, regardless of their economic situation," she said.

22. Several participants remarked that the meeting provided an opportunity to identify the most effective elements of the three mechanisms in order to forge a strategy for ensuring access to vaccines for all children in the Americas and elsewhere in the world. Mr. John Fitzsimmons of the United States Centers for Disease Control and Prevention pointed out, for example, that the lessons learned from the Revolving Fund in the area of demand forecasting could prove useful to the AMC pilot. Dr. Esperanza Martínez, Minister of Health of Paraguay, observed that combining the Revolving Fund's successful market approach of centralized, large-scale procurement with the AMC/GAVI strategy of offering subsidies to producers to help defray the research and development costs associated with producing new vaccines could help increase vaccination coverage around the world and save the lives of many children. Dr. Yvonne Monroe, of the Ministry of Health of Jamaica, proposed that the different stakeholders and partners help support PAHO's Revolving Fund to strengthen it and allow other developing countries to have access to the lowest prices for the 10-valent pneumococcal conjugate vaccine, while GAVI-AMC subsidy is provided to eligible countries.

23. A number of questions were asked about GAVI and the AMC. Several participants asked how the two mechanisms would ensure sustainability after their support ends. Dr. Ida Berenice Molina, Head of the Expanded Program on Immunization of Honduras, voiced concern about what might happen if Honduras, a GAVI-eligible country, were to introduce the pneumococcal vaccine but then become ineligible for GAVI support because its per capita gross national income had risen slightly above US\$ 1,000. At current prices, she said, the country would not be able to continue purchasing the vaccine and its immunization program would suffer a serious loss of credibility. She and other participants urged GAVI to revise its eligibility criteria, bearing in mind that in many countries of the Americas, even if gross national income is above US\$ 1,000, a large proportion of the population continues to live below the poverty line of US\$ 2 per day. Ms. Orozco Chamorro of Nicaragua expressed concern about the lack of representation of developing countries from the Americas on the GAVI Board.

24. Several participants sought information about how the pneumococcal vaccine was selected as the target vaccine for the AMC pilot, how the AMC would manage the supply

of various types of pneumococcal vaccine (the 7-valent vaccine currently available and the 10-valent and 13-valent vaccines expected to be available soon), whether AMCs for other vaccines are envisaged, and whether the aim of the AMC is to facilitate the introduction of new vaccines or to scale up the production of existing ones. Dr. Celsius Waterberg, Minister of Health of Suriname, inquired when the vaccine against human papillomavirus (HPV) might be available through GAVI and/or the PAHO Revolving Fund.

25. Mr. Palacios of the GAVI Alliance, responding to some of the questions and comments, said that the AMC has no intention of competing with or harming the Revolving Fund. The Revolving Fund and the AMC, he explained, “are two of a number of mechanisms that are going to run simultaneously, addressing different kinds of issues and problems. There is no intention to compete, no intention to do any harm to the Revolving Fund. We agree that the Revolving Fund has achieved important things, and it can continue to do that and perhaps achieve even greater things in the years ahead.”

26. On the question of eligibility, he reported that a task force is currently reviewing the criteria in order to determine what changes, if any, might need to be made. He also noted that commitments would be maintained through a transition phase to ensure sustainability among countries that are no longer eligible.

27. With regard to sustainability, he said that since 2008 the introduction of any new vaccine with GAVI support has been accompanied by a co-financing requirement for countries. Initially the country contribution is modest, but it increases over time, the aim being that countries will eventually be able to cover their own vaccine costs.

28. The HPV vaccine, he said, is among the vaccines that the GAVI Alliance Board has approved for consideration of future support, subject to the availability of resources. However, he noted, resources are finite, and GAVI anticipates a funding gap of some US\$ 3 billion over the next six to seven years.

29. Ms. McAdams also stated that the AMC is not intended to compete with the PAHO Revolving Fund but rather is intended to work in parallel with it. “If we can hasten the delivery of pneumococcal vaccines, if we can reduce the supply constraints, if we can move more quickly to a competitive market and lower price, everybody benefits.” That is the “key complementarity” between the AMC and the Revolving Fund, she said.

30. As to how the pneumococcal vaccine was chosen for the pilot, she explained that the original idea for the AMC was to encourage and incentivize research and development for an HIV vaccine. However, an independent expert group looked at various potential candidate diseases to be targeted by the pilot, including HIV/AIDS, malaria, tuberculosis, rotavirus disease, pneumococcal disease, and HPV infection, and selected pneumococcal disease because the members of the group felt that accelerating

the introduction of the pneumococcal vaccine would have the biggest and most immediate public health impact.

31. Dr. Roses, Director of PASB, said that the PAHO Secretariat has never seen PAHO's relationship with GAVI as a competition, and it had not been aware until recently that there was any problem vis-à-vis GAVI. It had therefore been difficult to understand, she said, why the delegate of the United States had repeatedly requested that the PAHO Governing Bodies discuss the matter. She explained that she had become aware about eight months ago that a clause in the Revolving Fund procurement contract had been identified within GAVI and the AMC as a problem. Nonetheless, she was never invited to talk about the Revolving Fund or address issues with the World Bank or GAVI, and PAHO was never consulted on the design of the AMC, even though the World Bank is located only two blocks from PAHO Headquarters.

32. She reiterated that PAHO has been trying to address issues with GAVI and has tried to be as open and transparent as possible. Nevertheless, while PAHO does not view its relationship with GAVI as a competition, she pointed out that it is clearly being perceived that way by some. Citing an article entitled "Vaccine system hampers African efforts," published in the *Financial Times* on the day of the meeting,<sup>2</sup> she noted that "the countries of the Americas are being considered guilty for the lack of progress in immunization in Africa" when they have contributed in different ways, even with human resources, towards the progress of vaccination in that Region.

33. Mr. Mark Abdo, Director of Multilateral Affairs, Office of Global Health Affairs, Department of Health and Human Services of the United States, said that he was pleased to hear that PAHO does not view itself as being in competition with the other players in the global architecture for health, nor do the other players view themselves as being in competition with PAHO. That is important, he said, because "we're all working toward the same goal. Everybody wants to get vaccines into the arms of kids." All regions of the globe need to stand in solidarity, he added, to ensure that children have access to vaccines that will bring lasting improvements to their health. The Americas is fortunate to have the Revolving Fund, he said, "which has functioned outstandingly for a number of years and has helped us make the sustainable and important improvements in health that our Region has seen," although whether or not the revolving fund model should be applied in other Regions will be "a long-term discussion."

34. Mr. Palacios of the GAVI Alliance, responding to Dr. Roses' comments, said that he agreed that there had been insufficient consultation between GAVI and PAHO. "We are trying to address that in a variety of ways," he added, including through the PAHO-GAVI Working Group. Although the Working Group is currently focusing on one

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<sup>2</sup> Jack, Andrew. Vaccine system hampers African efforts. *Financial Times*, 23 June 2009. Available at: [http://www.ft.com/cms/s/0/1fef88b8-5f48-11de-93d1-00144feabdc0.html?nclick\\_check=1](http://www.ft.com/cms/s/0/1fef88b8-5f48-11de-93d1-00144feabdc0.html?nclick_check=1). (Accessed on 16 July 2009).

particular challenge, GAVI's hope, he said, is that it will become an important mechanism for ongoing communication and consultation.

35. Dr. Ciro de Quadros, Executive Vice President of the Sabin Vaccine Institute and Chair of PAHO's Technical Advisory Group on Vaccine-Preventable Diseases, said that, like the Director, he was a little puzzled about why a special meeting was being held to discuss the Revolving Fund and the AMC, since the AMC will have very little impact in the Americas and the Revolving Fund is continuing to serve the Region well.

36. Dr. Roses extended thanks to everyone who had participated in the meeting, particularly the ministers of health who had traveled to Washington expressly to attend. Summing up the discussion, she said that it appeared to her that the value of the Revolving Fund had been well established. She pointed out that the Fund had been created 30 years ago to address the same vicious cycle that the AMC is seeking to address today: an insufficient supply of vaccines caused by producers' reluctance to boost production because there was too much risk and too much uncertainty with regard to demand. The relationship between the Revolving Fund and producers, she emphasized, has been extremely positive. Thanks to the guaranteed demand generated by the Revolving Fund, vaccine manufacturers have been able to scale up production and invest in research and development. When WHO called for an expansion in the production capacity for pandemic influenza vaccines, it was the Americas that allowed producers to do so by increasing demand for seasonal influenza vaccines. The Fund has also enabled the development of producers in emerging markets, which has created greater competition and thus lowered prices, but more importantly from a public health perspective it has ensured a sustained supply of needed vaccines.

37. The issue that has arisen with regard to the AMC and the Revolving Fund relates specifically to the 10-valent pneumococcal conjugate vaccine and concerns a clause in the Fund's procurement contract which stipulates that producers will offer the Fund the lowest possible price for their vaccines. This issue, she pointed out, has arisen in a market that is highly defective from both an economic and a public health standpoint; because there is only one producer of the pneumococcal vaccine. That, not the Revolving Fund, is the problem, she stressed: there is a lack of competition because there is a single supplier.

38. She reiterated that the problem concerns only the pneumococcal vaccine; there is no problem with any of the other vaccines currently being procured through the Revolving Fund. The PAHO-GAVI Working Group is therefore focusing on finding a specific solution to that specific problem. "Unique situations such as this of course require unique solutions," she said, adding that she has made it clear to the Executive Secretary of the GAVI Alliance that she is more than willing to seek such a solution, but "without undermining the principles of the Revolving Fund and, above all, without generating tensions or differences among the countries of the Americas." To that end, she has declared a one-year moratorium on procurement of the 10-valent pneumococcal vaccine through the Revolving Fund so that the AMC pilot may go forward.

39. From her perspective, the Member States of PAHO had made it clear that they did not see any reason for further discussion on the Revolving Fund, although the discussion within the PAHO Executive Committee would, of course, take place as planned. She appealed to the Executive Committee members to give some thought prior to that discussion to how the problem of the pneumococcal vaccine might be resolved in a way that would be beneficial to all concerned.

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