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PAHO REVOLVING FUND FOR VACCINE PROCUREMENT: CHALLENGES AND OPPORTUNITIES

“One Pillar of the Comprehensive Regional Approach to Immunization in the Americas”

Introduction

1. For more than 35 years immunization has been fundamental in the Americas to ensuring increased life expectancy and protecting populations across national borders against vaccine preventable diseases. The success of the Region is largely due to two factors: the commitment of Member States to vaccines as a public good, as well as their commitment to a comprehensive, regional approach to delivery of immunization services.
 2. The Pan American Health Organization (PAHO) Revolving Fund for Vaccine Procurement (the Fund) is recognized as one of the essential elements of the comprehensive regional approach that has made the Americas a world leader in the elimination of vaccine-preventable diseases and in the rapid and equitable introduction of new vaccines.
 3. The Fund facilitates the timely access for national immunization programs to 46 vaccines and 29 immunization supplies, primarily funded by national budgets. It serves most of the Americas’ population. Acknowledging the relevance of the Fund within the regional approach to immunization, Member States have provided enduring support through many resolutions of the Directing Council including most recently the 2013 Resolution CD52.R5 that reaffirmed the principles of the Fund (1).
 4. This document outlines some of the contributions of the Fund to the comprehensive approach to immunization in the Region. It describes the challenges and opportunities of the global context in which the Fund will continue supporting and enhancing the success of the regional immunization program.
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Background

5. In 1977, the 25th Directing Council of PAHO established the Expanded Program on Immunization (EPI) as a comprehensive, epidemiology-based program of technical cooperation and solidarity to eliminate, and/or control vaccine-preventable diseases. At the time, Member States were facing serious difficulty managing the purchase of vaccines needed to meet EPI's goals. Unreliable access to supply resulted in frequent 'stock outs', unstable and unsustainable prices; and countries faced difficulty accessing hard currency. Together these problems undermined public confidence in immunization and threatened the ability to sustain and improve an effective EPI in the Region (2).

6. To address these issues, the Directing Council resolved to further strengthen the regional approach of enhancing immunization programs with a financial mechanism, a revolving capital fund and to pool procurement for vaccines, syringes, and cold chain equipment for those Member States requiring these products. This mechanism was viewed as the final pillar essential for success of the regional approach. It was aptly named the "PAHO Revolving Fund".

7. Outside the Region, many perceived the "Fund" as operating in isolation as a vaccine and consumables procurement mechanism for the PAHO Member States. The Fund, however, with its principles of solidarity and Pan-Americanism, has been an integral pillar of the region's comprehensive technical cooperation approach to immunization, and as such, supports the operations and functions of the multifaceted program of epidemiological, legal, financial, and logistical sustainability—and continuous improvement (3).

8. Acknowledging the importance of continued high immunization coverage across all Member States, from the smallest to the largest, equitable and effective immunization has been achieved through the strength of the regional commitment and solidarity of Member States. Inclusion of larger countries generates economies of scale for pooled procurement. And high coverage of the population in the smaller countries is achieved, in part, by the sustainable access to the pool, providing protection against cross border disease introduction.

9. Working together, Member States have met many disease elimination targets (Table 1) in the Region. In 1985, the Americas was the first region to embark on polio elimination. By 1991, it was the first region to achieve this goal, 6 years ahead of any other region (4). The Americas remains the only region to have eliminated both measles (2002) and rubella (2009) (5). In 1997, the region established a goal to eliminate measles and within 5 years the last endemic case was reported. Congenital rubella syndrome was eliminated within 6 years from when, in 2003, the region set a target for elimination.

Table 1: Vaccine preventable diseases (VPDs) goals and milestones by WHO Region

Immunization Goals and Indicators	World Health Organization Regions					
	American (AMR)	African (AFR)	Eastern Mediterranean (EMR)	European (EUR)	South East Asian (SEAR)	Western Pacific (WPR)
DTP3 Coverage (2013) (6)	90%	75%	82%	96%	77%	96%
% Member States with Hib containing vaccine	100%	98%	90%	98%	73%	96%
Certified Polio Free	Certified 1994	Not Free	Not Free	Certified 2002	Certified 2014	Certified 2000
Measles Elimination Goals and Milestones (7)	Measles Eliminated (2002)	GOAL: Measles elimination by 2020	GOAL: Measles elimination by 2015	GOAL: Measles elimination by 2015	GOAL: 95% reduction in measles mortality by 2015	GOAL: Measles elimination by 2012 (3 of 27 Member States certified 2014)
Rubella and CRS Elimination Goals and milestones (8)	Rubella eliminated (2009)	No goal established	No goal established	Elimination goal set for 2015	Accelerated rubella control by 2020	Accelerated rubella control by 2015

10. The Region remains at high risk for the introduction of measles and rubella due to continued global circulation of both viruses. Timely access to vaccine against measles, mumps, and rubella (MMR) supplies has contributed to the maintenance of the elimination goals. Currently 95% of the population served by the Revolving Fund resides in countries where this vaccine has been included in the national immunization programs.

11. Collectively, with the support of the Fund, countries in the Region were the first among developing countries to introduce new and under-utilized vaccines: Pentavalent (DPT-HepB-Hib) in 1999; since 2005 seasonal influenza, Pneumococcal (PCV) and Rotavirus (RV) vaccines; and Human Papilloma Virus (HPV) since 2010.

12. Success reaching disease elimination targets and in rapid introduction of new epidemiologically appropriate vaccines may indicate the potential for future success. Continued maintenance and improvement of all elements of the comprehensive immunization approach will provide a solid platform for the Region of the Americas to continue to lead the way against vaccine preventable diseases. The challenges of new global goals (e.g Global Polio Eradication Strategy) and introducing new vaccines (e.g Dengue vaccine) can and will be met by continued solidarity of Member States.

Situation Analysis

13. In 2013, the 52nd Directing Council adopted Resolution CD52.R5 that endorsed the principles of the Revolving Fund, including solidarity, Pan Americanism, and equal access. The Directing Council asserted that it was critical to strengthen the management of the Fund and to safeguard its principles to protect the achievements, progress, and financial sustainability of immunization programs in the region.

14. PAHO's approach to immunization faces significant challenges in the context of today's global vaccine market strategies and future vaccine supply. Thus it is important to improve regional understanding of the situation, to identify challenges and opportunities, and to ensure the sustainable success of immunization in the region.

15. There are few manufacturers of new vaccines, resulting in limited competition, plus limited supply of traditional and under-utilized vaccines; both constitute challenges. Increasing participation of international initiatives also influence the current global context. But these challenges may also offer opportunities for continued improvement and even greater success.

16. The "global vaccine market" is unique. Vaccines are unlike other pharmaceuticals as they are biological products. They are more prone to manufacturing failure, thus, require high quality manufacturing standards with resulting regulatory oversight and costs. Vaccines have a short shelf life and usually require specialized cold-chain transport, storage, and management to ensure effectiveness. Production timelines are lengthy and require considerable advance planning. Also significantly there are a limited number of manufacturers and few purchasers. Vaccines are a commodity used predominantly in publicly funded programs. The global vaccine market has quadrupled since 2000 (9) and was estimated at US\$ 24 billion in 2013.^{1,2}

¹ The combined financial value of vaccines procured through UNICEF including the GAVI-funded procurement (US\$ 1.286 billion) and PAHO (US\$ 500 million) was around 7% of the total amount spent globally on vaccines in 2013.

Source: http://www.unicef.org/supply/files/Table_of_Vaccine_Procurement_1996_2013_Value.pdf and PAHO internal information.

² "... 2011's \$26 billion market worth for human vaccines, 2012 and 2013 have seen a decline of around \$1 billion a year recently. Source: Vaccine Nation; ©2014. Available from: <http://www.vaccination.org/2014/05/30/top-5-vaccine-companies-revenue-2013/>

17. Newer vaccines purchased in the region (PCV, RV and HPV), constitute a special challenge. Supply, pricing, and procurement have a large impact on the Region because of the complexity of introducing new vaccines and the financial impact to sustain implementation. The market dynamics, future pipelines and potential competition differ.

18. Parallel monopolies for these new vaccines³ create an asymmetrical power dynamic in the procurement relationship, placing a manufacturer in a stronger position. During this period the pressure for purchasers to accept high pricing will continue as manufacturers seek to make the most of the monopolistic opportunity. Increased competition will be forthcoming in these markets where there are currently parallel monopolies, however not in the historical sense of interchangeable product presentations.⁴

19. Another aspect of these new vaccines is the increasing involvement of international initiatives, such as the GAVI Alliance, primarily in vaccine funding, designed to contribute to accelerating the introduction of new and under-utilized vaccines in eligible low income and some developing countries in the world, financed with donor resources. While PAHO and GAVI have a common goal and work together to reduce the burden of vaccine preventable disease, particularly with new vaccines, PAHO and GAVI approaches in regards to vaccine access and pricing differ.

20. With GAVI, some manufacturers have agreed to lower prices, reducing the financial impact on donors' funds for the purchase of vaccines. Non-eligible Member States (including many in the Region of the Americas) are not able to benefit from these prices when purchasing with government funds.

21. For manufacturers, the Fund continues to offer key strengths and benefits such as: secure demand and sustainable financing, and the reduced transactional costs of contracting and engaging with a single entity rather than individual Member States. However, some manufacturers and international stakeholders have been requesting that the Fund modify its principles, terms and conditions in supply agreements.

22. Specifically, manufacturers and international stakeholders would like the Fund to cease offering the same price per vaccine to all Member States and the requirement that manufacturers provide the lowest price to the Fund. Some manufacturers are choosing to refrain from entering PAHO bidding processes for supply of vaccines until the principles,

³ The currently available presentations of these vaccines are not directly competing as product choice is made on specific attributes of each in the context of the country needs, and products are not necessary interchangeable, e.g., the RV vaccines have a different schedule and timing of administration; one requires two doses while the other three; there are both quadrivalent and bivalent HPV vaccines; PCV vaccines are available in 10- and 13-valent formulations.

⁴ The future pipeline indications show potential market competition likely in the shortest timeframe for RV, followed by PCV, then at a later date for HPV. These timeframes are affected not only by production ability, but also by technology and knowledge transfer and intellectual property issues.

terms, and conditions are modified. Additionally, some manufacturers are bypassing the Fund to negotiate directly with some Member States.

23. Looking forward, it is possible that for vaccines where market competition is limited and global initiatives are involved in funding, there will be continued and possibly new challenges for the Fund to take into consideration.

24. The Pan American Sanitary Bureau (the Bureau) will continue to work with global stakeholders, to seek to establish new working relationships that achieve the best possible outcomes for all concerned parties. The support for this opportunity afforded to the Bureau through the 2013 Directing Council resolution will pave the way for a considered, practical, and equitable approach to these short-term market issues.

25. Supply challenges are not only apparent in the new vaccine markets, purchasing older traditional and under-utilized vaccines can also be complex. For traditional vaccines, dwindling or unstable demand for some has led to limited supply. These markets are no longer financially attractive to manufacturers; hence competition is unlikely to increase. Demand needs to be forecast accurately and communication between manufacturers and purchasers is essential to minimize supply interruptions.

26. Member states can contribute to improving the situation with more accurate demand forecasting, sustainable financing, and harmonization of vaccine presentations, improving economies of scale and keeping traditional vaccine markets viable.

27. Other challenges that affect the impact of the Fund may arise regionally, such as isolation of particular Member States from the Fund through individual, bilateral purchases, thus reducing the strength of the Pan-American and solidarity principles. Lessons should be learned from countries entering purchasing agreements outside the Fund. These may appear to be promising, but may ultimately weaken the economies of scale.

28. Some regional manufacturing countries are entering into agreements to develop manufacturing capacities, focusing primarily on national supply. Opportunities therefore exist to consider solidarity of the Regional approach and new regional supply options.

29. Member States should take into consideration the broader and long-term impacts of these actions and maximize opportunities for strengthening the regional approach.

Moving Forward

30. While preserving and enhancing the elements that have led to its success, the regional approach can seek opportunities to further optimize outcomes. A multi-faceted approach of engagement and commitment is required to achieve optimal results. Short term and longer term approaches are necessary.

Improving Management and Operations through Enhancing Knowledge

31. Improving Member States' knowledge of vaccine markets and dynamics will enhance understanding and recognition of the challenges in the changing environment. Information on specific vaccine markets, pipelines for new vaccines, and other aspects might be considered in decision-making regarding expansion or changes to EPI schedules. Enhanced knowledge will also highlight considerations and areas where Member States' actions can strengthen outcomes, in particular in timely demand forecasting, product harmonization, and sustainable financing. The Bureau can act as a resource for key officials in the Member States to improve their knowledge of the market.

32. To optimize the Bureau's functionality, PAHO will continue to conduct analyses of the vaccine markets, implementing proactive responses to specific vaccine issues and both short and longer-term opportunities for tailoring and improvement.

33. PAHO will continue to strengthen the Fund to administer effectively a multi-million dollar operation within the global context that is robust and responsive to the needs of the Member States.

Synergies and Partnerships

34. The Bureau will further engage with Member States, manufacturers, and partners to encourage technology transfer that promotes a sustainable regional supply. Adapting to the changing global environment in immunization and vaccine supply, the Bureau will seek opportunities to improve access to global production sources, to influence vaccine presentations to best meet the regional needs, and to seek and develop opportunities for partnerships and synergies within the region and globally.

35. The Bureau will enhance partnerships with international stakeholders such as GAVI and with other regions, in accordance with PAHO's comprehensive approach to immunization, to leverage strengths and enhance both regional and global immunization programs that impact the conditions of populations, regardless where they live.

Improve Understanding and Acknowledgement

36. The Bureau will consider with support from the Member States the opportunities to publicize the functions and achievements of the PAHO comprehensive approach in a way that will improve stakeholder relations, increase clarity, understanding and acknowledgement.

Action by the Directing Council

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

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