



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



52nd DIRECTING COUNCIL

65th SESSION OF THE REGIONAL COMMITTEE

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ORIGINAL: SPANISH

PRINCIPLES OF THE PAN AMERICAN HEALTH ORGANIZATION REVOLVING FUND FOR VACCINE PROCUREMENT

Introduction

1. The commitment undertaken by the Member States by declaring vaccination to be a public good and by strengthening their operational and financial capacity to deliver vaccinations has made the Americas a world leader in the elimination of vaccine-preventable diseases and in the rapid and equitable introduction of new vaccines.
2. The Pan American Health Organization (PAHO) Revolving Fund for Vaccine Procurement (the Fund) is the regional technical cooperation mechanism that for almost 35 years has facilitated timely access to high-quality vaccines at the lowest prices for national immunization programs of Member States. It is regarded as one of the pillars of the regional immunization program's leadership position
3. This document presents the principles and benefits of the Fund, and the challenges of the current environment in which it functions and which endanger the continuity of its contributions to the progress and financial sustainability of the national immunization programs in the Region.

Background

4. In 1977, the PAHO Directing Council, through resolution CD25.R27, established the Expanded Program on Immunization (EPI), with the aim of reducing morbidity and mortality due to vaccine-preventable diseases. (1)
5. As a component of the EPI and to facilitate the timely supply of quality vaccines in appropriate quantities at the lowest prices for Member States, the Director of PAHO was authorized to create the Fund as a regional technical cooperation mechanism.

6. The objectives established for the Fund 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 Fund; 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 to guarantee timely processing and delivery of both regular and emergency orders. (2,3)

7. In 1978, Resolution CSP20.R16 adopted by the Pan American Sanitary Conference established the working capital for Fund operations. The Fund formally began operating in 1979. The initial capitalization of the Fund was US\$ 1 million from contributions made by several countries, PAHO, and other organizations. (4) The Fund is grounded in and has operated under the principles of solidarity and Pan-Americanism, equitable access, quality, and transparency, which are principles shared by PAHO.¹

8. In accordance with the principles of solidarity and Pan-Americanism, PAHO consolidates vaccine requirements of participating Member States to achieve important economies of scale in order to obtain offers from producers for appropriate quantities of vaccines at the lowest prices. Currently, through the active participation of 35 countries and six territories in the Region, the Fund annually consolidates the vaccine requirements to serve up to eight million births, equivalent to 80% of the birth cohort in Latin America and the Caribbean. In 2012, the Fund acquired 60 products, including 35 different biologicals. In total, 180 million doses were acquired at a total cost of US\$512 million. The Fund coordinated and monitored the timely arrival of approximately 1,200 shipments. (5)

9. As a form of solidarity, Member States contribute 3.5% of the net value of the purchases—3% is allocated to the working capital fund, while 0.5% covers part of the operating costs of the Fund. The working capital fund, among other things, makes it possible to offer Member States lines of credit to make purchases and defer the corresponding payments for 60 days, after satisfactory receipt of the vaccines.

10. Under with the principle of equitable access, the Fund establishes practices and procedures to offer quality vaccines to participating Member States at the same single price per vaccine. Furthermore, the Fund establishes contractual terms and conditions in its international tenders in order to guarantee that the prices of the procured products are the lowest globally.

¹ The principles of the Pan American Health Organization (PAHO) are equity, excellence, solidarity, respect, and integrity.

11. The Fund fosters transparency and competition in the procurement of vaccines through international tenders that comply with recognized procurement standards. With a view to ensuring that the procured products are high-quality, safe, and effective for the target populations, the Fund has product criteria based on the WHO prequalification system and other international references.

12. For over three decades, the Fund has been recognized by Member States as an essential mechanism for the achievement of the EPI, such as the eradication of polio; the elimination of measles, rubella, and congenital rubella syndrome; the control of preventable diseases through vaccination; and the rapid introduction of new vaccines against major causes of infant mortality, such as rotavirus and pneumococcus. (6-12)

Benefits of the Revolving Fund

13. The Fund has been vital to support the immunization initiatives of Member States by ensuring a continuous and timely supply of different biologicals in order to maintain high vaccination coverage, keeping the Region free from diseases such as poliomyelitis and measles, while also controlling other preventable diseases through vaccination. In 2012, the Region of the Americas was one of the regions with the highest vaccination coverage (93%). It is also the region with the most complete and equitable vaccination schedule in the world.

14. The line of credit offered by the working capital fund has helped to ensure timely supply of vaccines. In 2012, the majority of the countries participating in the Fund (24 countries and six territories) made all their purchases through the line of credit without having to transfer national funds in advance for the corresponding purchase. (5)

15. The Fund, as a result of its practices and procedures, yields benefits to producers. For example, the Fund offers centralized procurement, timely payment, and reliable demand, which in turn has helped increase the regional and global production capacity for certain vaccines. The Fund also represents a growing market for new vaccines with sustainable demand. (13)

16. The Fund has contributed to the sustainability of the immunization programs in the Region by establishing certain requirements that Member States have to meet in order to benefit from the Fund. One requirement is the allocation of a national budget item with a specific line item for the cost of vaccines and syringes. (14) As a result, over 95% of the cost of the vaccines acquired for Member States is covered with national funds.

17. The Fund has been an important catalyst for the rapid, equitable, and sustainable introduction of new vaccines such as the pneumococcal conjugate and rotavirus vaccines. The majority of Member States that have introduced these vaccines have acquired them through the Fund. For example, between 2006 and 2012, 13 countries in the Region

introduced the rotavirus vaccine and 17 introduced the pneumococcal conjugate vaccine through the Fund.

18. These two new vaccines have been introduced at an accelerated pace in the Region. However, the introduction of the human papillomavirus (HPV) vaccine has not kept pace. Between 2008 and 2012, four participating Member States introduced the HPV vaccine. The high price of this vaccine compared to other vaccines is one of the challenges that Member States must take into consideration if they want to include it in their immunization programs. (15)

Current Challenges

19. The global context in which the Fund functions presents various challenges. These include the cost of new vaccines compared with traditional ones, limited competition among suppliers of new vaccines, and the impact of different stakeholders primarily in the area of international financial assistance.

20. New vaccines that act against priority diseases in the Region—those caused by rotavirus, pneumococcal, and HPV—pose major challenges for Member States and the Fund, since each of these vaccines is made by only two producers and their prices are higher than traditional vaccines. Furthermore, due to a lack of evidence that these vaccines are interchangeable, parallel monopoly conditions have been created for each type of vaccine, further limiting competition.

21. Unlike other regions of the developing world, vaccines used in national immunization programs in the Americas, with few exceptions, are paid for with national funds and not international financial assistance. Thus, for Member States, one of the challenges of introducing new vaccines is their elevated cost, as substantial increases would be required in the budgets allocated to the national immunization programs. For example, in order for a Member State to include the rotavirus vaccine in its regular vaccination schedule,² its national budget for vaccines would need to double; to introduce the pneumococcal conjugate vaccine, its vaccine budget would need to increase five-fold. A country that has already introduced both vaccines would need to increase its vaccine budget by over 30% if it wants to introduce the HPV vaccine.

22. In the last decade, several international initiatives, such as the GAVI Alliance and the Bill and Melinda Gates Foundation, have made the laudable commitment to help speed up access to new and underutilized vaccines for the lowest-income developing countries, through international financing mechanisms. PAHO has fully supported these efforts by, among other things, cooperating both inside and outside the Region so that the

² The basic reference series includes the following vaccines: BCG, hepatitis B, oral polio, pentavalent (DPT-Hib-HepB), and MMR.

entire world can benefit from the technical strengths and lessons learned in the Americas. However, these initiatives, with the support of industry and other international stakeholders, have become increasingly insistent on the Pan American Sanitary Bureau (PASB) granting exceptions to the practices and terms and conditions of the Fund.

23. Member States have observed that, as a result of pressure exerted by these international initiatives and industry, PASB has conceded certain exceptions to the Fund practices and procedures, specifically related to contractual terms and conditions with suppliers in relation to the price of vaccines. Some Member States consider that outside pressure and changes to the practices and contractual terms and conditions are undermining the effectiveness of the Fund and compromising its continued, long-term success.

24. In an attempt to address some of the problems and inconsistencies that result from granting exceptions, PASB has held a series of meetings and negotiations with these financing mechanisms and initiatives, as well as with industry, in order to achieve price reductions and increase supply and competition.

25. Nonetheless, independent of PASB's attempts, several Member States have expressed their concern about the current high prices of new vaccines, specifically those vaccines for which PAHO has conceded exceptions to the Fund's practices, terms and conditions, and procedures. Similarly, Member States are concerned about the risks that the high price levels pose to the financial sustainability of national immunization programs, as well as the impact that elevated prices could have on the pace of introduction of vaccines in the Region such as the HPV vaccine, the inactivated polio vaccine, and a future vaccine against dengue.

Proposal

26. In view of the current and future challenges facing the national immunization programs, and recognizing the importance of the principles of the Fund, the Directing Council is invited to take note of the information presented herein and to consider approval of the attached proposed resolution.

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CD52/17 (Eng.)
Annex A
ORIGINAL: SPANISH

PROPOSED RESOLUTION

PRINCIPLES OF THE PAN AMERICAN HEALTH ORGANIZATION REVOLVING FUND FOR VACCINE PROCUREMENT

THE 52nd DIRECTING COUNCIL

Having reviewed the concept paper *Principles of the Pan American Health Organization Revolving Fund for Vaccine Procurement* (Document CD52/17) and considering the important contributions made by the Revolving Fund for Vaccine Procurement (the Fund) of the Pan American Health Organization (PAHO) to Member States in the field of immunization;

Taking into account that most Member States have determined immunization to be a public good that has contributed considerably to the reduction of infant mortality and that has achieved polio eradication, measles elimination, and advances in the elimination of rubella and congenital rubella syndrome, as well as epidemiological control of other vaccine-preventable diseases in the Region;

Considering that the Fund has been essential for timely and equitable access to quality vaccines for Member States, financial sustainability of immunization programs, and the introduction of new vaccines;

Recognizing the importance of maintaining the active participation of Member States pursuant to the principles of solidarity and Pan-Americanism in order to increase economies of scale and the resulting benefits;

Taking into account the impact of the current prices of the vaccines on financial sustainability and on advances in the introduction of new vaccines;

Considering the global context that poses challenges for the Fund, including different international financing mechanisms and new vaccines,

RESOLVES:

1. To urge the Member States to:
 - a) Support the Fund as the strategic technical cooperation mechanism that facilitates timely and equitable access to vaccines and related supplies for national immunization programs in the Region of the Americas;
 - b) Ratify the principles, terms and conditions, and procedures of the Fund for the benefit of public health in the Americas;
 - c) Promote solidarity and Pan-Americanism by participating in the Fund and acquiring vaccines through this technical cooperation mechanism.
2. The Director is requested to:
 - a) ensure that the Fund is administered, without exception, in a manner that respects and complies with its principles, objectives, and terms and conditions, as these have contributed to the success and progress of the national immunization programs in the Region;
 - b) maintain dialogue with the representatives of international financing mechanisms and initiatives in order to ensure a sufficient supply of vaccines that meets the global needs of the target populations, while safeguarding PAHO Member States' access to the lowest prices;
 - c) review the previously conceded exceptions to the principles, terms and conditions, and procedures of the Fund in order to determine the continued status of these exceptions, as applicable.



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
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CD52/17 (Eng.)
Annex B

**Report on the Financial and Administrative Implications
of the Proposed Resolution for PASB**

1. Agenda item:

1. 2. Linkage to Program and Budget 2014-2015*:

a) Categories: C01: Communicable diseases / 1.5 Vaccine-preventable diseases.

b) Expected result: Support the Member States with access to vaccines and related supplies that are timely, safe, effective, and at the lowest prices, in order to contribute to the goals and financial sustainability of the immunization programs.

3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities): The estimated total cost is at least US\$500,000 per biennium.

b) Estimated cost for the biennium 2014-2015 (estimated to the nearest US\$ 10,000, including staff and activities): US\$500,000.

c) Of the estimated cost noted in (b), what can be subsumed under existing programmed activities? US\$360,000.

4. Administrative implications:

- a) Indicate the levels of the Organization at which the work will be undertaken:**
Compliance with the principles, conditions, and procedures of the Revolving Fund is required at all levels (Headquarters, subregional, national), in close collaboration with the Ministries of Health of the Member States.
- b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):** At least one full-time equivalent may be required to coordinate activities related to this Resolution.
- c) Time frames (indicate broad time frames for the implementation and evaluation):**
The Resolution is for immediate implementation and the results could be evaluated on a biennial basis.

* Refers to the [Proposed PAHO Program and Budget 2014-2015](#) that was presented to the 152nd Session of the Executive Committee.



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CD52/XX (Eng.)
Annex C

**ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL
MANDATES**

1. Agenda item:

2. Responsible unit: Family, Gender, and Life Course / Comprehensive Family Immunization (FGL/IM)

3. Preparing officer: Cuauhtémoc Ruiz Matus and Daniel Rodríguez

4. List of collaborating centers and national institutions linked to this Agenda item:

Immunization programs of Member States that acquire vaccines and related supplies through the PAHO Revolving Fund.

5. Link between Agenda item and Health Agenda for the Americas 2008-2017:

This agenda item is related to the following areas of action on the Agenda:

- c) Increasing social protection and access to quality health services
- d) Reducing inequalities in health among countries and inequities within countries
- e) Reducing the risks and burden of disease

6. Link between Agenda item and the Proposed PAHO Strategic Plan 2014-2019:

Category/ Program area

11. Communicable diseases / 1.5 Vaccine-preventable diseases

7. Best practices in this area and examples from countries within the Region of the Americas:

The PAHO Revolving Fund is, in itself, a best practice of reference for other WHO regions trying to establish a similar mechanism.

8. Financial implications of this Agenda item:

The estimated cost for staff and activities is US\$500,000 per biennium.