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#### **UPDATE ON THE SITUATION AND CHALLENGES OF INACTIVATED POLIOVIRUS VACCINE SUPPLY TO MAINTAIN POLIO ERADICATION IN THE REGION OF THE AMERICAS**

##### **Introduction**

1. In September 2017, the 29th Pan American Sanitary Conference adopted Resolution CSP29.R16, Situation Update on the Challenges of Supplying Inactivated Polio Vaccine to Maintain Eradication of the Disease in the Region of the Americas (1). This resolution requested the Director of the Pan American Sanitary Bureau (PASB) to negotiate the best possible price for procurement of inactivated polio vaccine (IPV) for the Region of the Americas and, if necessary, adjust the terms and conditions of the Pan American Health Organization (PAHO) Revolving Fund for Vaccine Procurement (Revolving Fund) for this occasion only in order to address the special circumstances currently existing and provide the supply of IPV for the Region. In addition, it requested the Director to maintain coordination with the Global Polio Eradication Initiative and to maintain dialogue with partners and global producers of IPV in order to accelerate and ensure capacity to produce the necessary doses of IPV for the Region of the Americas, and to continue to support the Member States of PAHO in preparation for the use of fractional dose inactivated polio vaccine (fIPV), equivalent to one fifth of a dose of IPV.

##### **Background**

2. The Region of the Americas was the first in the world to eradicate polio, an achievement that has been maintained for 26 years, as a result of the leadership and commitment of Member States, as well as the efforts of thousands of health workers in the Region.

3. In 2012, the Member States reaffirmed their commitment to the global eradication of polio and supported the 65th World Health Assembly Resolution WHA65.5, which “declares the completion of poliovirus eradication a programmatic emergency for global public health” (2). The intensification of the global eradication initiative requires that all countries introduce at least one dose of IPV in their national immunization programs

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(Document A66/18) (3). This was successfully implemented by all PAHO Member States during 2015 and 2016. However, due to the global shortage of IPV, several countries in other regions have been unable to introduce this vaccine, while others are facing stock-outs. This shortage will remain acute for at least the next two years and is not expected to improve until 2020.

4. Accordingly, the World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) on immunization and PAHO's Technical Advisory Group (TAG) on Vaccine-Preventable Diseases considered the evidence available and recommended the use of fractional doses of this vaccine. Efficacy of fIPV has been researched since the 1950s. In recent years, the evidence has grown to conclusively demonstrate that a two-dose fIPV schedule administered via the intradermal route offers higher immunogenicity than one full intramuscular dose of IPV. However, the use of fractional doses requires specific training due to the administration technique.

### **Situation Analysis**

5. In light of this situation, PASB has monitored the limited IPV supply capacities and maintained constant communication with global partners and vaccine suppliers to successfully ensure a minimum supply of this vaccine for Member States.

6. By the end of 2017, approximately 5.8 million IPV doses were supplied through the PAHO Revolving Fund, which falls short of the 8.0 million doses required overall. Specific mitigation strategies were implemented, including preparation for fIPV introduction in various countries and procurement of pre-filled IPV syringes for an interim period until IPV supply in vials improves.

7. During the fourth quarter of 2017, PASB, with financial resources from WHO/Global Polio Eradication Initiative, supported nine countries in preparation for the introduction of fIPV. Five of these countries could start introducing fractional doses without delay if the supply of affordable IPV is not secured by PAHO. PASB recommends that once a national program has implemented fIPV, it is not advisable to reintroduce full-dose schedules.

8. Manufacturers' capacity to increase production, global epidemiologic priorities, and market factors continue to have an impact on the regular supply of IPV. This situation could continue to limit the supply of this vaccine globally, including to PAHO Member States, with an overall negative impact on the sustainability of polio eradication in the Region. Likewise, PASB is monitoring the global supply of syringes suitable for fractional IPV dosing, as the availability of this product could be constrained through 2018.

### **Action Necessary to Improve the Situation**

9. Throughout the first quarter of 2018, supply planning continued with the allocation to countries of limited numbers of IPV 5 dose vials and pre-filled syringe presentations.

PASB has continued to monitor the situation. Member States received an update during the 12th Session of the Subcommittee on Program, Budget, and Administration in March 2018.

10. In March 2018, PAHO reconvened its TAG and provided an update on the IPV supply situation. The TAG commended PASB for its efforts to improve the IPV supply for the Region. However, recognizing that the ongoing global IPV supply constraints could still affect countries of the Region, the TAG recommended that all countries of the Region—without exception—be prepared in case of a shortage. The TAG also commended countries that had begun preparation to switch to a fIPV dose schedule, and encouraged them to proceed with the implementation of the fIPV schedule.

11. PASB has continued negotiations with the supplier of IPV 10 resulting in a supply agreement for 2018 and 2019. PASB country offices were informed of the results and relayed the details to national counterparts. This supply agreement adds the 10 dose vial presentation for Member States and is expected to increase the available supply against the PASB's consolidated demand forecast for participating countries from nearly 47% to 88% for 2018.

12. PASB is also continuing to meet with other suppliers, including the supplier of IPV 5 dose vials, to find ways to sustain fulfillment of the total regional demand.

13. PASB will disseminate the TAG recommendations to countries and will follow up on programmatic implementation. PASB will continue to closely monitor the IPV supply plans with both manufacturers, as well as the timely fulfillment of IPV needs with countries.

#### **Action by the Directing Council**

14. The Directing Council is invited to take note of this report and provide any comments it deems pertinent.

#### **References**

1. Pan American Health Organization. Situation update on the challenges of supplying inactivated polio vaccine to maintain eradication of the disease in the Region of the Americas [Internet]. 29th Pan American Sanitary Conference, 69th Session of the WHO Regional Committee for the Americas; 2017 Sep 25-29; Washington, DC. Washington, DC: PAHO; 2017 (Resolution CSP29.R16) [cited 2017 December 13]. Available from: [http://www.paho.org/hq/index.php?option=com\\_docman&task=doc\\_download&gid=42332&Itemid=270&lang=en](http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=42332&Itemid=270&lang=en)

2. World Health Organization. Poliomyelitis: intensification of the global eradication initiative [Internet]. 65th World Health Assembly; 2012 May 21-26; Geneva. Geneva: WHO; 2012 (Resolution WHA65.5) [cited 2017 December 13]. Available from: [http://apps.who.int/gb/ebwha/pdf\\_files/wha65/a65\\_r5-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/wha65/a65_r5-en.pdf)
3. World Health Organization. Poliomyelitis: intensification of the global eradication initiative [Internet]. 66th World Health Assembly; 2013 May 20-28; Geneva. Geneva: WHO; 2013 (Document A66/18) [cited 2017 December 13]. Available from: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA66/A66\\_18-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_18-en.pdf)

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