Updates on type 2 OPV containing vaccines & IPV

Global Polio Partners Group
6 December 2019
UNICEF Supply Division
mOPV stockpile; purpose, governance & management

The purpose of the global stockpiles of monovalent Oral Polio Vaccine is to ensure timely supply of vaccines to respond to outbreaks of specific poliovirus types at a time when OPV is no longer used in routine immunization systems.

Establishment of the mOPV2 stockpile was a SAGE requirement for the withdrawal of type 2 containing vaccines – the Switch from tOPV to bOPV. Establishment of the mOPV1 and mOPV3 stockpiles is in progress; to be in place before withdrawal of bOPV, 4 years after last detection of WPV.

WHO governs the global stockpile of bulk and finished mOPVs. Day to day management of the stockpile is carried out jointly by UNICEF and WHO.
Today there is 21.6 million doses available
55 million doses expected to be added before end of December

Majority of supply going to Nigeria with recurrent outbreaks (65%/195Mds)
DRC with expanding outbreaks (15%/46Mds)
Responses in additional 11 countries
mOPV2 January 2019 to December 2020 including projected demand

Actions being taken to address supply gap:
Additional capacity 188 million doses available – funding is required to secure doses

Securing additional filling capacity - 203 million doses of bulk available that could be filled in 2020
Next steps to secure sufficient type 2 containing OPV to meet projected requirements

**For Sabin OPV type 2:**
- Reach out to manufacturers about the possibility of supplying tOPV
- Secure all possible filling for type 2 in 2020 from current manufacturers
  - Trade offs between bOPV and availability for endemic countries (especially Pakistan)
  - Could impact overall capacity due to down time needed for switching between antigens
- Find additional filling capacity for available bulk that can not be filled in 2020 by current manufacturers
  - Identify additional filler – this may impact bOPV availability so would need to assess impact on global supply
  - Supplier would need to have product licensed and WHO PQ

**For nOPV2:**
- Issue tender in January to secure maximum availability of nOPV for 2020 & 2021
- Ensure contract in place so that nOPV can be deployed as soon as vaccine is available and there is an approval from WHO for use under EUL
IPV Supply Update
While historically, IPV vaccine supply to UNICEF has been below the requirements, leading to a need for programmatic prioritisation – supply is finally increasing

Meeting programmatic needs as of December 2019

1. At least 1 dose of IPV for the EPI schedule in all 126 countries using OPV only in 2013, to provide individual protection against poliomyelitis after type 2 withdrawal
   ✓ Target achieved April 2019, 3 years after type 2 withdrawal

2. Catch up immunization in 35 countries to 42M children without access to IPV after the tOPV withdrawal
   ✓ 35% on track for catch up in 2019

3. 6 M ds reserved to support additional requirements in endemic countries
IPV demand for 2020-2023 through UNICEF is projected to continue to increase to secure introduction of 2nd dose in 85 countries

- Additional awards in progress for 2020-2022 supply
- 6 million doses set aside for outbreak response in 2020
- In October 2019 SAGE recommended to prioritise catch up over additional needs in endemic countries allowing sufficient IPV in 2020 for all countries to complete the catch up immunization – Projected requirement 20 million doses

Next steps:
- Access to 2 doses ahead of OPV withdrawal, assuming introductions starting in 2021 with a gradual scale up over 3 years
- Guidance from SAGE for prioritization for 2nd dose required
Procurement objectives to i) secure sufficient supply; ii) to expand the supplier base; and iii) to improve pricing (1/2)

<table>
<thead>
<tr>
<th>Nationally Licensed IPV with Supply to Domestic Markets</th>
<th>Healthy Pipeline for IPV Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beijing Institute of Biological Products (China) (S)</td>
<td>AJ Vaccines (Denmark)</td>
</tr>
<tr>
<td>Biken (Japan) (S)</td>
<td>Beijing Minhai (China) (S)</td>
</tr>
<tr>
<td>Bio Farma (Indonesia)</td>
<td>Bharat Biotech (India)</td>
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<tr>
<td>IMBCAMS (China) (S)</td>
<td>LG Chem (South Korea) (S)</td>
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<tr>
<td>Nanolek (Russian Federation)</td>
<td>Sinovac Biotech (China) (S)</td>
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</tbody>
</table>

Note (S) means Sabin polio strains

Source: Publicly available information

UNICEF’s assessment of time to market for IPV offers

<table>
<thead>
<tr>
<th>Presentation</th>
<th>2018</th>
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<th>2022</th>
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<tbody>
<tr>
<td>1-dose</td>
<td>-</td>
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<td>1</td>
<td>1</td>
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<tr>
<td>5-dose</td>
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<td>2</td>
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<tr>
<td>10-dose</td>
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<td>1</td>
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Source: UNICEF Supply Division

UNICEF expects 3 new manufacturers to have IPV vaccines prequalified in 2019/2020 based on in-house bulk production, leading to a continued increase in supply availability starting 2020
THANK YOU