**Summary of Supply Situation as of end Q1 2013**

## General Overview

Since January, UNICEF has supplied more than 286 million doses of OPV, which included an additional campaign in Nigeria in January, additional campaigns in high risk West African countries, outbreak response campaigns in Niger, Yemen, Egypt and other countries, and SIA activities in multiple West Africa countries advanced from later in the year to April with March 2013 supply deliveries. Nigeria and Pakistan alone represented more than 60% of the overall supply requirements for Q1 2013, and by June 2013 will have increased their overall requirements by more than 150 million doses of bOPV supply beyond what had been originally planned based on the FRR by end of 2012. At the same time, UNICEF experienced several supply-related delays of licensed product putting additional strain on already limited availability of licensed supply for priority countries. However, almost all campaign requirements were met, which was due primarily to the addition of a new WHO pre-qualified supplier, WHO's approval to postpone the production stop for one manufacturer, as well as the increased buffer allowance. As the programme continues to intensify activities in the endemic and priority countries, the second half of the year will now face gaps in supply, unless mitigation measures are taken.

## Situation early 2013

The first quarter of 2013 has proved to be challenging for polio supply. Following the UNICEF tender for OPV supply covering the years 2013-2017, offers from manufacturers were insufficient to meet the expected demand for the first half of 2013, resulting in an imminent gap of 300 million doses. UNICEF and other GPEI partners succeeded at filling this imminent gap through various mitigation measures: postponing a production stop for Haffkine until Q4 2013 to ensure continued supply; fast-tracking the WHO pre-qualification of SII's bOPV and making conditional awards on an exceptional basis for a non-WHO pre-qualified product; and shifting some non-priority activities to Q3. In addition, to ensure sufficient supply of OPV in case of outbreaks and/or programmatic changes, UNICEF and GPEI partners had agreed to increase buffer requirements from 20 million doses per OPV type to 30 million doses of tOPV and 40 million doses of bOPV, above and beyond the SIA and routine demand requirements.

Despite these efforts, UNICEF and the Programme still entered into 2013 with a tight supply situation, with limited flexibility for changes in campaign dates or increased requirements, except for emergency outbreak or priority country needs on a case by case basis. At the same time, manufacturers with licensed product were experiencing supply release delays which had started already in Q4 2012 and carried over to early 2013. This led to delayed deliveries to Pakistan for their January campaign, and although successful, made it difficult to meet Nigeria's additional January campaign, requiring last minute changes in suppliers and emergency transportation. The tight supply situation created significant pressure and strain on manufacturers and all parties involved to secure timely deliveries. In addition, one manufacturer also licensed in Nigeria and Pakistan, postponed 35 million doses of tOPV until August 2013. This vaccine, originally allocated to meet Nigeria's February SIA round, put further strain on the other licensed manufacturers and reducing availability for later campaigns. Finally, UNICEF Supply Division was informed only late February that one of the two manufacturers producing tOPV in 10 dose vials for routine immunisation would no longer be able to supply their awarded 36 million doses

of tOPV in this presentation in 2013, in order to maximize 20 dose vial filling. This has further constrained tOPV 20 dose supply, as large countries such as Bangladesh and Ethiopia normally receiving 10 dose vials will have to substitute with tOPV20 dose vials. UNICEF has already awarded an additional 20 million doses of tOPV-20 to one manufacturer and has also been able to secure a limited quantity (6.4 million doses) of additional tOPV in 10 dose vials to meet a portion of the demand for Bangladesh and Ethiopia.

UNICEF bases its supply allocation on the global SIA calendar planned in line with the current epidemiology and reflected in the annual Financial Resource Requirements (FRR), as well as based on routine immunisation requirements per country forecasts and historical trends. Although there have been challenges with supply early in Q1 2013 due to supplier release delays as well as shifts in supply availability to Q3 and Q4, UNICEF has been able to meet most of the additional requirements for campaigns and outbreak response to date.

Due to the need to ensure sufficient supply to meet the planned campaigns for endemic and priority countries, particularly with licensed product, UNICEF coordinated closely with the Programme on supply allocations, including for requests for additional vaccine or changes in campaign dates or type. This coordinated approach contributed to meeting Programmatic SIA requirements.

**Current situation as of April 30, 2013**

UNICEF is now facing a potential gap in supply beginning in June or July for the second half of the year, in both bOPV and tOPV 20 dose vials, and which could affect Nigeria June and July and Pakistan July campaigns. This constraint continues to be compounded by the limited number of licensed products available for both Pakistan (3, with one exiting after 2013) and Nigeria (3, but one with limited supply), which places significant pressure on the licensed manufacturers and limits UNICEF's flexibility in managing the global supply and to appropriately address the urgent and changing needs of these two countries.

WHO and UNICEF SD and PD recently held their quarterly supply and demand review meeting in mid-April, during which maximum efforts were made to secure priority endemic country campaigns and maximize availability of bOPV for the 2nd half of the year. Outcomes of the review meeting included shifts in some non-risk countries to later in the year as well as change in vaccine type to tOPV for countries with cVDPV. For Nigeria and Pakistan campaigns, both countries would be able to have their full bOPV NIDs, but only on the condition that they license or provide temporary import waivers for SII, which is the only supply available; and that the countries are flexible on dates for campaigns, with potential shifts of 1-2 weeks as necessary, due to timing of supply availability. If Pakistan and Nigeria do not allow the importation of SII, then Nigeria's June campaign will be mixed with tOPV and their July campaign will be 50% of the requirements; Pakistan would have the option to conduct a bOPV SNID in July and a NID in August once licensed supply becomes available. Pakistan's June campaign is currently covered.

In addition to the supply-related issues, all three endemic countries have been plagued by delays in the signing of their World Bank Buy Down Agreements. For these countries, alternative financing solutions have been required through the support of various partners including BMGF and CDC. For Nigeria, UNICEF has procured vaccine for 2 rounds without actual funds to do so, while the Nigerian Government has also blocked some limited funds for routine immunisation as

a guarantee until the World Bank funds are disbursed.

Finally, severe logistics challenges and flight constraints into Afghanistan due to bans of most major airlines has recently become an issue and has resulted in some delays. This affected recent and currently planned campaigns. Information has been received that the flight ban is due to be lifted by May 14 but this needs close follow-up.

**Short term outlook and mitigation measures**

Given the push to stop transmission and the need to maintain the momentum with eradication efforts, it is expected that activities will continue to remain at the scale they are throughout the remainder of 2013 into 2014. With additional activities already included in the SIA calendar for Q4, UNICEF will face even more gaps in supply. UNICEF is also working with partners to ensure the appropriate balance of bOPV and tOPV to meet programmatic requirements.

- During the quarterly planning meeting, UNICEF and WHO further mapped out all additional requirements by type in order to plan for additional supply that could or should be awarded to manufacturers.
- Additional awards of up to 210 million doses will be made in the coming 2-3 weeks in both tOPV and bOPV to ensure sufficient supply and buffer are available to meet currently planned as well as any unplanned activities.
- GPEI partners are strongly encouraging Nigeria and Pakistan to license additional products to increase flexibility with supply. SII already has received a blanket waiver for importation into Nigeria for multiple products, except for OPV. A follow up was made with the Country to explore extending this waiver to OPV. In addition, during the last ERC in Nigeria, there was a specific recommendation to license SII and further communications have provided positive feedback on the likelihood of being able to import SII product. Pakistan has also been approached and one manufacturer is still pending registration; however, no further information on the likelihood for registration of an Indian product has been received.

**Medium-term outlook for supply**

- A reliable supply of OPV is an essential component for achieving the goals of eradication and End Game. It will be critical to ensure adequate demand and supply planning to ensure the appropriate balance of OPV type in line with epidemiological requirements.
- Following the Value for Money report, the management of both funding and supply resources has gained increasing attention and importance. In particular, during this year of constrained supply, it will be critical to address vaccine management and immunisation supply chain challenges in countries to ensure the most efficient use of available resources (vaccines and funds). UNICEF HQ (PD and SD) are working closely with countries and partners to develop and implement polio vaccine management SOPs and guidelines for use during SIA and ensure appropriate capacity in priority countries. There is still need to incorporate indicators reflective of vaccine management into GPEI monitoring tools and reports at various levels to advocate for visibility to this important area of work and monitor progress.
- The next years will be critical as GPEI crosses the threshold of eradication, including the planning for the withdrawal of OPV type 2, the switch from tOPV to bOPV in routine

and SIAs, and the unprecedented global introduction and scale up of IPV in routine immunization programmes. Close coordination with Industry and all GPEI and Global Immunisation partners will be key. The work of the Immunization Management Group and the various work streams to be developed will be critical the success of this process.