

# Yellow Fever Vaccine: Current Outlook

UNICEF Supply Division

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## Yellow Fever Vaccine - Current Outlook March 2015

**This update provides revised information on the continued constrained 2014-2017 supply availability and increased demand. Despite slight improvements in availability, a constrained market will persist through 2017.**

### 1. Summary

- Yellow Fever Vaccine (YFV) supply through UNICEF remains constrained due to persistent manufacturing difficulties. Despite the return of one manufacturer from temporary suspension during 2013 through 1Q 2014, high demand and the continued suspension of another manufacturer from WHO prequalification continues to generate a supply-demand imbalance. UNICEF anticipates constrained global production capacity through 2017.
- UNICEF's annual YFV procurement averaged 34 million doses per year from 2007 to 2014, with UNICEF procuring all WHO prequalified vaccine available to it.
- UNICEF has long-term arrangements (LTAs) with three manufacturers to cover all emergency stockpile and routine requirements. During 2014, UNICEF made additional awards to two manufacturers, increasing total awarded supply to 135.5 million doses for 2014-2017 from ~78 million. However, supply is still insufficient to meet all preventive campaign demands.
- YFV weighted average price (WAP) per dose has increased by 30% per year on average since 2000, from ~\$0.20 to ~\$0.98 in 2014. UNICEF anticipates a near-term YFV WAP per dose of ~\$1.00.

### 2. Background

Yellow Fever (YF) is an acute viral haemorrhagic disease transmitted by a mosquito vector, and causes an estimated 200,000 cases and 30,000 deaths per year globally, of which 90% are in Africa.<sup>1</sup> The virus is endemic in tropical areas of Africa and Latin America with an aggregate at-risk population of over 900 million, and with increasing incidence over the last two decades. There is no curative treatment for YF, but palliative care may address symptoms such as fever, dehydration and respiratory failure. WHO recommends the immunization of children through routine, preventive and reactive campaigns, depending upon the risk level, as the most important measures to prevent YF.

While YF incidence had previously been concentrated in West Africa, it has spread to regions in Central and East Africa.<sup>2</sup> Eleven new countries have evidence of endemic YF, and present an elevated risk of disease outbreaks.<sup>3</sup> Re-emergent YF is also evident in Latin America. WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommends that countries with YF risk introduce YFV into their expanded programme on immunization (EPI) as soon as possible. Four manufacturers offer WHO prequalified YFV, one of which is currently under suspension (Table 1).

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<sup>1</sup> WHO, [Yellow Fever: Fact Sheet](#), WHO, Geneva, March 2014.

<sup>2</sup> WHO, [Vaccines and Vaccination Against Yellow Fever, WHO Position Paper – June 2013](#), No.27, 2013, 88, WHO, Geneva, 2013, p. 271.

<sup>3</sup> WHO, [Meeting of the Strategic Advisory Group of Experts on Immunization, April 2013- Session 5: SAGE Working Group on Yellow Fever Vaccines](#), WHO, Geneva, April 2013.

**Table 1 Manufacturers with WHO Prequalified YFV**

Manufacturer	WHO PQ	Presentation	Shelf life	WHO PQ Status
Bio-Manguinhos (Brazil)	2001	5 ds	24 months	Suspended
	2007	10 ds	24 months	
	2001	50 ds	24 months	
Institut Pasteur de Dakar (Senegal)	2001	5 ds	36 months	Active
	2001	10 ds	36 months	
	2001	20 ds	36 months	
FSUE Chumakov (Russia)	2009	2 ds	24 months	Active
	2009	5 ds	24 months	
	2009	10 ds	24 months	
Sanofi Pasteur (France)	1987	10 ds	36 months	Active

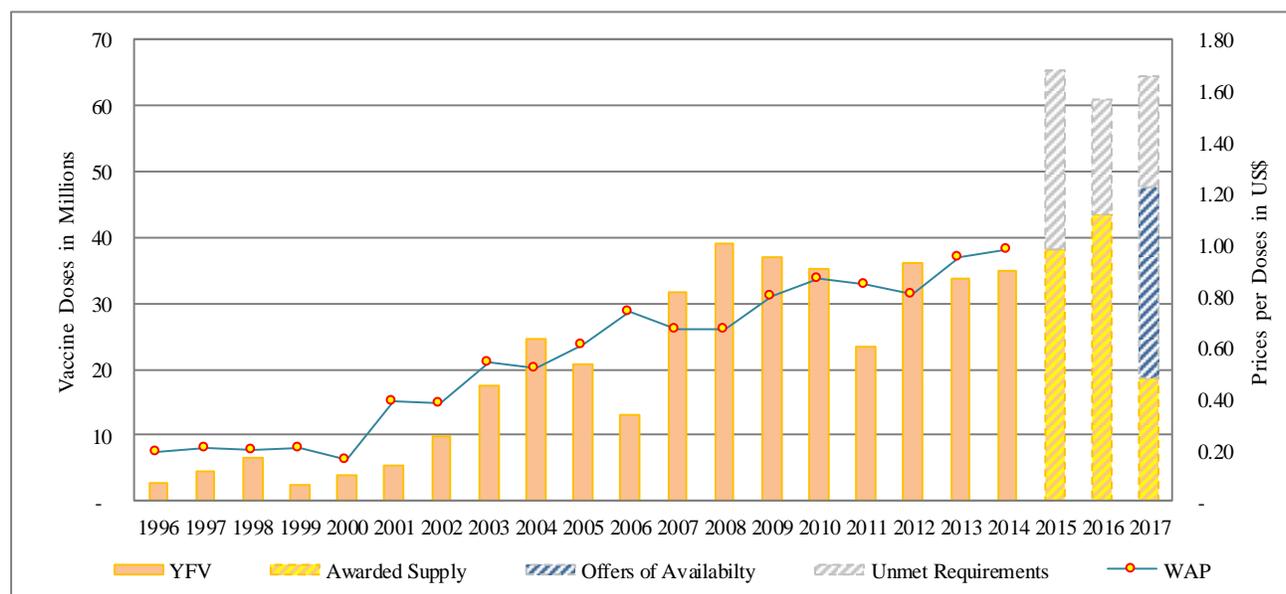
Source: WHO.

### 3. Current Market Situation

#### 3.1 Demand

Over the past decade, YFV demand has increased substantially from a pre-2002 annual average of 5 million doses. Gavi, the Vaccine Alliance (Gavi) support for preventative mass vaccination campaigns, emergency response stockpiles and increased routine immunization in a number of high-risk countries since 2001 has contributed to this trend (Figure 1).

**Figure 1 YFV Supply through UNICEF and Demand Forecast for 2015-2017**



Source: UNICEF Supply Division / GAVI SDF v.10.

The total country demand forecast through UNICEF for all vaccination activities for 2015-2017 average 64 million doses per year, and exceed current offered availability by 42%. Increased offers made to UNICEF for 2015-2017 will reduce some of this gap.<sup>4</sup>

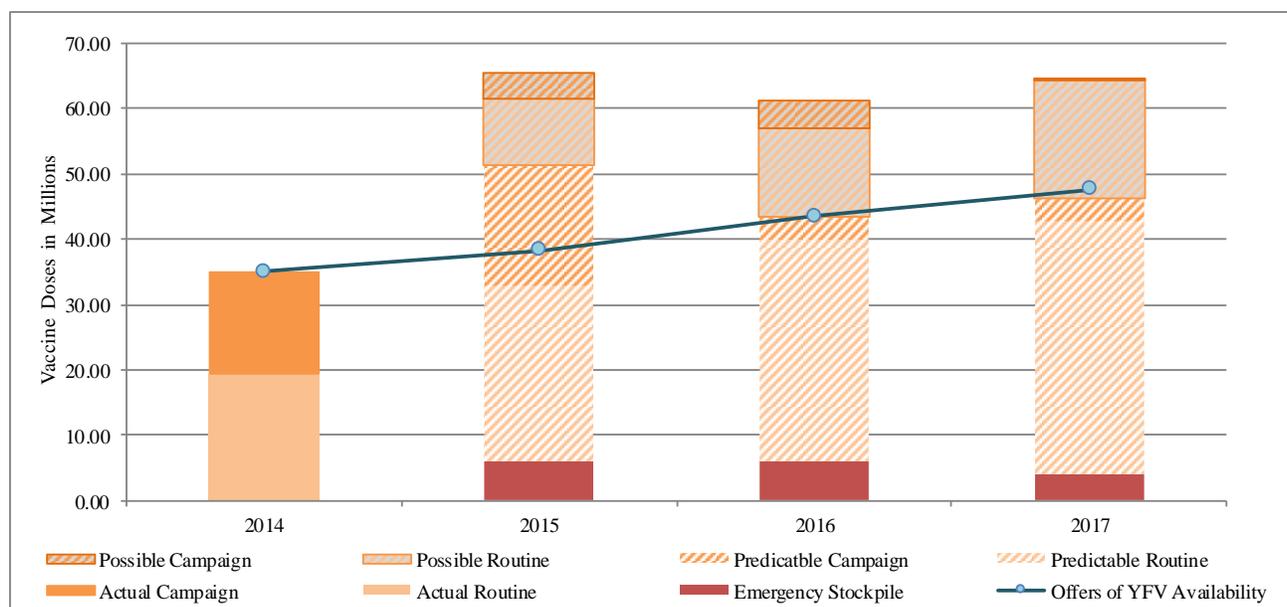
<sup>4</sup> 2017 forecast includes an additional offer of 29 million doses from one manufacturer, which has not yet been awarded under an LTA.

The Pan American Health Organization (PAHO) also forecasts requirements of approximately 20 million doses per year, which similarly place pressure on the global supply/demand balance.

### 3.2 Supply

UNICEF’s annual procurement of approximately 35 million doses per year (2012-2014) can cover routine immunization requirements, emergency stockpiles and some limited additional campaign activities. UNICEF expects offered quantities to increase during subsequent years and are anticipated to reach 47.6 million doses by 2017 (Figure 2).

Figure 2 YFV Unconstrained Demand Forecast and Supply Offers per Activity for 2014-2017



Source: UNICEF Supply Division / GAVI SDF v.10.

Offered and contracted supply through UNICEF remains fragile. YFV manufacturers have experienced a number of issues affecting their ability to produce at full capacity:

- YF bulk production depends upon sufficient specific pathogen-free (SPF) egg supply availability, from which primary chick embryo cells for vaccine production are derived. Instances of limited SPF egg availability have hindered vaccine production and earlier investment necessary to guarantee increased manufacturing capacity.
- The loss of a Good Manufacturing Practice (GMP) license by one manufacturer for one of its facilities also led to a reduction in availability and suspension of WHO prequalification.
- The increase in YFV demand for preventive mass campaigns has stretched manufacturers’ capacity to supply programme requirements.

UNICEF YFV procurement totalled 35.1 million doses for 28 countries from three manufacturers, and utilised all manufacturer capacity made available to it in 2014. Of these, 8 million doses were for preventive campaigns in Sudan. Four of the 28 countries (Cameroon, DR Congo, Nigeria and Sudan) received ~75% of the deliveries.

In 2014, the supply situation slightly improved with the return of one manufacturer from temporary WHO suspension during 2013 through 1Q 2014. UNICEF subsequently awarded the manufacturer 44 million doses to reach 52.1 million, and awarded another manufacturer incremental awards to cover

supply for the emergency stockpile. In total, these awards increased the total 2014-2017 awards from ~78 million doses to 135.5 million. The continued WHO prequalification suspension of the one manufacturer has resulted in the loss in availability of ~6 to 7.5 million doses per year in the near-term. The suspension prevents UNICEF from awarding any additional supply for the time being.

Table 2 UNICEF YFV 2014 Supply and 2015-2017 Awards

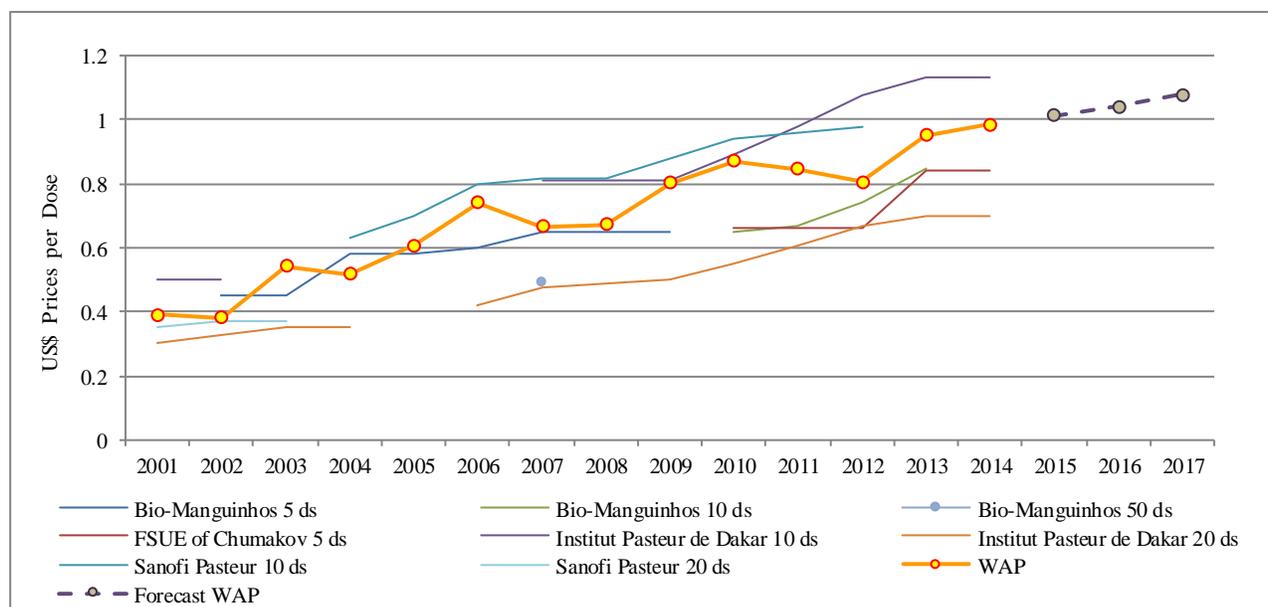
Manufacturer	2014 Actual Supply	2015	2016	2017	Total
FSUE Chumakov (Russia)	14,230,000	12,000,000	12,000,000	11,000,000	49,230,000
Institut Pasteur de Dakar (Senegal)	1,335,000	5,334,750	7,453,880	7,603,880	21,727,510
Sanofi Pasteur (France)	19,525,500	21,000,000	24,000,000	*	64,525,500
	<b>35,090,500</b>	<b>38,334,750</b>	<b>43,453,880</b>	<b>18,603,880</b>	<b>135,483,010</b>

Source: UNICEF Supply Division.

**Note** \*: Sanofi Pasteur has offered to supply 29 million doses in 2017 subject to price negotiation.

YFV WAP per dose has increased 30% per year since 2000 (Figure 1). Increased investment costs and the discontinuation of a 50-dose presentation have contributed to this trend. UNICEF anticipates a WAP of ~\$1.00 per dose for 2015-2017 (Figure 3).

Figure 3 UNICEF YFV WAP per Dose



Source: UNICEF Supply Division.

At present, UNICEF does not anticipate any new manufacturers to enter the market or seek WHO prequalification for YFV in the near future.

Protracted constrained availability delays important preventive campaigns and applies additional pressure and dependency on the remaining manufacturers. Close collaboration with countries and partners (UNICEF, Gavi, WHO and PAHO) is required to ensure vaccine availability for routine immunization programmes, outbreak response and to prioritise the allocation of available supply.

#### 4. Issues and Challenges

- Current YFV supply offers to UNICEF are not sufficient to meet the total country requirements necessary to implement YFV preventative campaigns. Total supply can only meet routine requirements and emergency response stockpiles. As a result, the implementation of some preventative mass campaign activities will need to be delayed, spread out, or carried over to subsequent years. Current offers of limited supply add pressure to the management of limited supply between vaccine activities and country requirements.
- Over the past couple of years, country demand has been concentrated at the beginning of the year, whereas supply is limited and more readily available during the second half of the year, which has reduced programme planning effectiveness and campaign implementation. UNICEF is working closely with the manufacturers to coordinate and harmonise the timing of availability and demand.
- Once preventive campaigns in African high- and medium-risk YF endemic countries are completed, the pressure on YFV demand should ease, allowing routine EPI to maintain stable vaccination coverage rates. New low-risk endemic countries are expected to apply to introduce YFV into their routine EPI.
- The Gavi Vaccine Investment Strategy (VIS) for YF (2015-2021) proposes risk assessments and preventive mass campaign vaccination to cover medium-risk endemic countries (Chad, DRC, Ethiopia, Guinea Bissau, Kenya, Mauritania, Niger, Uganda and South Sudan).

#### 5. Steps Forward

- Together with partners (Gavi, WHO and PAHO), UNICEF will continue to review YFV offers and supply availability against demand requirements to assess YFV allocation and prioritisation for preventative campaigns and routine immunization.
- UNICEF will continue to share country forecasts with manufacturers and Gavi in order to improve visibility and information on supply and demand. Countries, WHO, UNICEF and Gavi will continue to work together to finalise Risk Assessments and plan accordingly.
- UNICEF, Gavi and WHO will discuss and clarify emergency stockpile arrangements and funding sources. A WHO revolving fund was created in order to support YF outbreak response and YFV supply.
- UNICEF and partners will continue to explore and encourage the production of YFV through potential new manufacturers and/or support increased production capacity through all available markets.
- In 2017, UNICEF will issue a tender for 2018 (and beyond) supply.

For further questions or additional information, please contact:

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