



Independent observer
of the Global Fund

GLOBAL FUND PUSHES BACK ON CLAIMS OF OVERDEPENDENCE ON SELECT SUPPLIERS OF ARVS

The Global Fund, one of the main purchasers of generic antiretroviral (ARV) medicines for HIV patients in low- and middle-income countries, has dismissed concerns that the limited number of manufacturers tapped to supply these drugs could result in immediate or future shortages. Fund officials said systems are in place to forecast demand, deal with any supply disruptions and increase production to meet future need.

Four manufacturers – Aurobindo, Cipla, Hetero and Mylan – supplied nearly 80% of ARVs to low- and middle-income countries in 2015, according to the [ARV Market Report](#) from the Clinton Health Access Initiative (CHAI). In a [March column](#) in the Financial Times, Brian Elliott, a former pharmaceutical industry executive and now the chief executive of Procera Consultants, cautioned that the key global purchasers are too dependent on these manufacturers.

Alongside the Global Fund, the South African government and the President's Emergency Plan for AIDS Relief (PEPFAR) – the U.S. government's bilateral HIV response – are the primary buyers of ARVs for low- and middle-income countries.

Elliott, who has consulted on drug access for international health organizations, specifically flagged two concerns: that immediate supply interruptions could result from companies having drugs delisted in the course of routine evaluations; and that the manufacturers may be unable to meet the demands created by [UNAIDS' call](#) to rapidly advance the number of people being enrolled on treatment by 2020 under its “test and treat” approach.

“Reliance on so few suppliers for continuing treatment for millions of people is dangerous because, unlike

other diseases, there are no alternatives to ARVs for the treatment of HIV,” Elliott wrote. “This dependence creates serious risks. Today, the risk of supply interruption is at a worrying level.” He called on the three main buyers to quickly diversify their procurement or risk creating situations where HIV patients on ARVs might not be able to maintain their current regimens.

High-level monitoring

Officials from the Global Fund and UNAIDS disputed Elliott’s conclusions.

Seth Faison, the Global Fund’s head of communications, told Aidspace that the Fund has processes in place to prevent any interruptions in ARV coverage in the countries it supports. This includes participating in high-level monitoring and a procurement system that weights considerations like reliability of manufacturers and sustainability of their supply.

“The Global Fund is confident that the capacity of the current supply base is sufficient to meet global demand needs, as confirmed by a number of other parties,” Faison said. “The Global Fund and its partners, including other large buyers, closely monitor any supply risks to the market.”

The high-level monitoring happens primarily at an [annual meeting](#) organized by the World Health Organization that attempts to forecast global ARV demand, based both on current use but also increases that are anticipated under new policies, like the UNAIDS’ targets. Participants at these meetings typically include representatives from the Global Fund, United Nations agencies, CHAI, the U.S. Global AIDS Coordinator, which oversees PEPFAR, the South African health ministry and pharmaceutical companies.

“In these events, both originator and generic companies engage in discussions regarding their capability to supply the ARV market,” UNAIDS said.

The forecasting meeting that took place in 2016 included [a presentation](#) comparing anticipated demand for active pharmaceutical ingredients for ARVs to global production capacity.

The meeting also dealt with developments like the U.S. Food and Drug Administration’s [decision](#) in 2016 to strip tentative approval from a first-line ARV sold by Hetero. The loss of that approval meant the Global Fund and PEPFAR were no longer allowed to procure the drug from Hetero. Officials said other manufacturers were able to fill the gap, though, and there were no service disruptions.

Faison also told Aidspace that the Global Fund’s Pooled Procurement Mechanism (PPM) “assures reliable performance and supports a sufficient supplier base for all of the needed products.” Through the PPM, the Global Fund can push prices down, but the mechanism also guarantees larger procurements to manufacturers, which helps assure the production and delivery of the ARVs. With earlier serial spot tenders, “over-promising and under-delivering was not uncommon,” Faison said.

Meanwhile, Mylan, which the CHAI ARV Market Report cited as the largest manufacturer of ARVs for lower- and middle-income countries, [publicly](#) disputed the commentary from Elliott, calling it “false and misleading.”

To meet the goal of ending the AIDS epidemic by 2030, UNAIDS has called for 30 million people to be enrolled on ARVs by 2020. The agency [announced](#) in November last year that there are currently 18.2 million people enrolled in therapy.

To meet the UNAIDS targets, Elliott wrote, buyers “must allocate their purchases to all manufacturers that meet quality standards, and allow excluded or limited suppliers the opportunity to quickly increase their volumes.” In its response, Mylan pointed to its own investments in production capacity to underscore its commitment to growing its capability to meet increasing global demands.

Other observers questioned Elliott’s premise that the main purchasers were overly dependent on four manufacturers.

Joanna Keenan, the press officer for Médecins Sans Frontières [Access Campaign](#), which advocates for increased development of and access to medicines, said that while there are four main ARV producers, “there are many others who are actively engaged and supplying in the market to meet the needs of different procurement agencies and countries.”

Officials from the Partnership for Supply Chain Management, which manages the PPM, declined an interview request, but confirmed in an email that they procure from a “long list” of WHO-approved suppliers.

The list of Global Fund ARV suppliers is available [here](#).

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