

# Viral load testing

## Changing the market with a lower, all-inclusive price

Viral load testing is essential in the fight against HIV. The World Health Organization (WHO) recommends viral load testing to monitor the effectiveness of treatment for people living with HIV as countries push to achieve viral suppression targets. Without viral load testing, an appropriate treatment response cannot be achieved, which could lead to drug resistance and increased mortality rates.



### The challenge

Despite WHO's guidelines recommending the adoption of viral load testing, only 37% of people living with HIV in low- and middle-income countries had access to viral load testing by the end of 2017. There were two main reasons for this.

Firstly, the cost of viral load tests was high, fragmented and non-transparent. Price negotiations for the tests were based on test kits and some reagents only. Countries purchased control and sample collection kits, service and maintenance, training and logistics separately. These consumables often accounted for 30-50% of the total cost per test result.

Secondly, in many countries viral load testing platforms were frequently unusable due to inconsistent service and poor maintenance. As countries had to pay upfront or lease the equipment, suppliers were not incentivised to provide routine maintenance services.

This led to millions of people living with HIV missing out on viral load testing as health ministries with limited budgets could not afford the ongoing costs following the initial investment. It meant that health workers did not

have essential information to help their patients achieve viral load suppression, and patients were less empowered to make informed decisions about their health. And it prevented countries from meeting the third 90 of UNAIDS' 90-90-90 targets – for 90% of people living with HIV to be virally suppressed by 2020.

### Our response

In July 2018, MedAccess announced a volume guarantee agreement with Hologic to increase access to its Panther® viral load testing platforms in low- and middle-income countries. Since its launch, the partnership disrupted the market for viral load testing, setting a new standard for transparent pricing, and introducing a new approach to the procurement of HIV molecular diagnostics.

Under the terms of the guarantee, countries now have access to all-inclusive pricing, covering the installation of the testing platform, training of health workers, service, maintenance, test kits and consumables, freight and logistics. There are no upfront or capital costs for governments. For some countries in 2018, this new ceiling price represented a cost reduction of up to 50% per HIV viral

load test result. The adoption of the all-inclusive pricing model in 2019 by PEPFAR, the largest HIV viral load test procurer, prompted other suppliers to align their pricing accordingly, shifting the market significantly in favour of HIV patients.

The volume guarantee reduced the uncertainty Hologic faced entering a new market, enabling the company to offer a significantly lower ceiling price and, ultimately, accelerated access to an essential health product for more people in low- and middle-income countries. The agreement was implemented with support from the Clinton Health Access Initiative (CHAI) and complemented Hologic's Global Access Initiative.

### The results

As a result of the guarantee, an estimated 900,000 patients who received tests learned that they were not virally suppressed. This information can be used by their health workers to support them to improve treatment adherence or, as in the case of an estimated 430,000 patients tested thanks to the guarantee, switch to alternative HIV medication. People who achieve viral load suppression have a better chance of living longer, healthier lives and cannot pass on the virus.

## What is a volume guarantee?

A volume guarantee is an innovative finance product that provides manufacturers, procurers and health systems with the assurances they need to accelerate access to medical innovations.

Volume guarantees reduce manufacturers' risks of low sales volumes in markets where demand is uncertain. In exchange for improved demand visibility, manufacturers offer lower prices and provide stable supply commitments.

### How does it work?

MedAccess enters into legally binding volume guarantee agreements with manufacturers, where we guarantee agreed sales volumes for the duration of the agreement. In return, manufacturers commit to a ceiling price – the maximum price they will charge – and to meet projected demand for the product. Procurers and national governments enter into separate agreements with manufacturers to purchase the product at, or below, the ceiling price. If sales volumes are lower than the guaranteed levels, MedAccess will compensate the manufacturer through a shortfall payment.

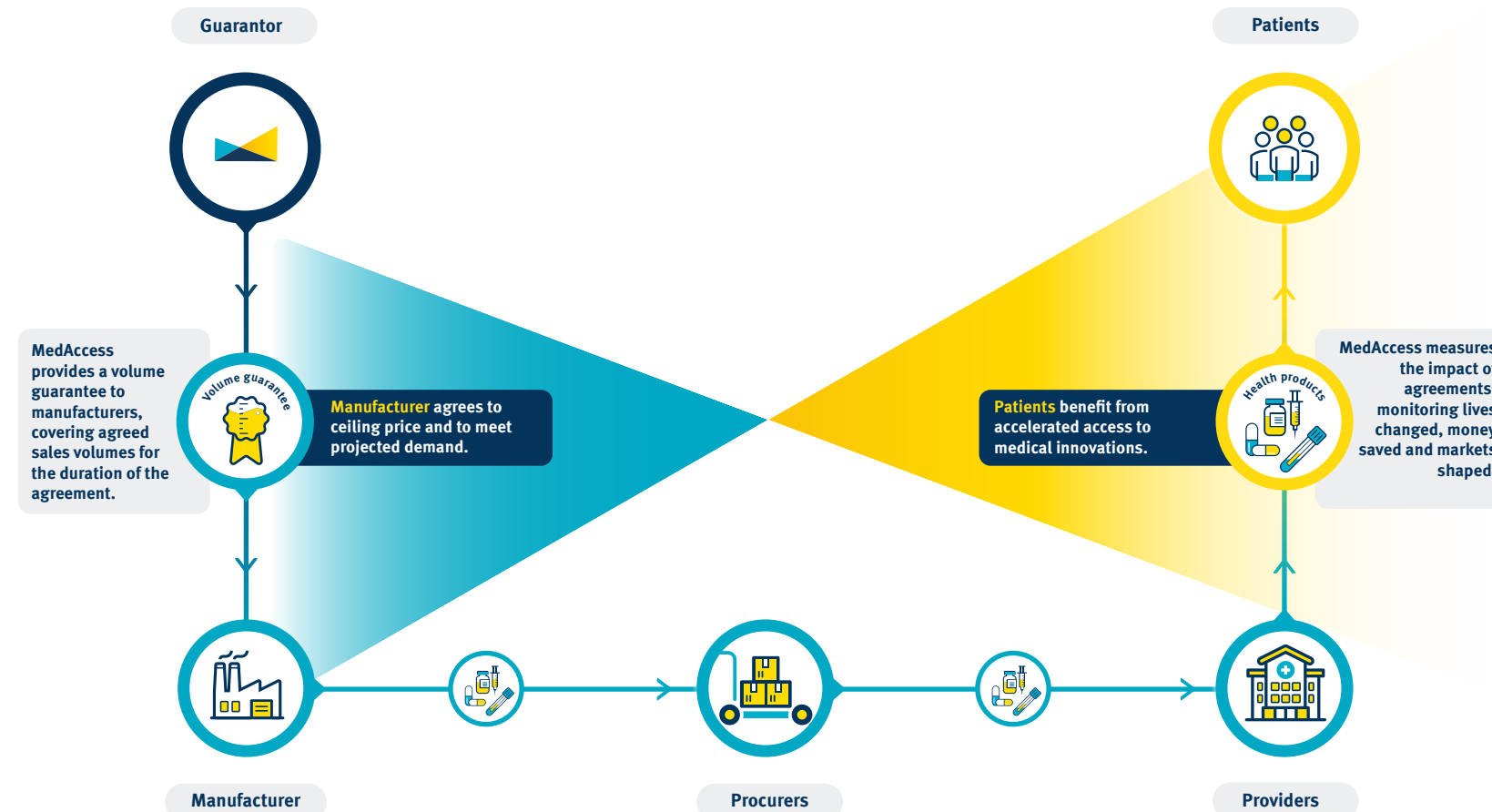
### Who benefits?

Volume guarantees build confidence among all partners. Manufacturers can enter or increase their presence in uncertain markets, as well as scale up manufacturing capacity, with the assurance that a minimum level of sales volumes is secure. Procurers have predictability on price and supply when placing orders, and benefit from more affordable prices. And countries have visibility on long-term availability when deciding which products to purchase. The ultimate beneficiaries are patients. Because all of the partners have the assurances they need to make products affordable and available, patients are able to access them more quickly than they otherwise would have.

## Hologic Panther® viral load testing platform

Hologic's Panther® testing platform provides automated sample-to-result molecular testing for HIV-1, viral hepatitis, human papillomavirus (HPV) and COVID-19. The equipment can perform tests for a range of diseases simultaneously.

The platform is small enough to fit in a standard laboratory and can run up to 320 tests in eight hours. This technology enables HIV viral load tests to be conducted quickly within the same health facility, providing rapid results to patients and enabling timely treatment decisions.



### The manufacturer's perspective

"MedAccess has been a true partner. The experience and volume guarantee they brought to the table enabled Hologic to take a much bigger risk than we would normally have. MedAccess brought a disruptive price to the market and gave us access to institutions, individuals and a number of stakeholders who are influential in the region. This was an enabler for us to supply in markets where we initially had no experience in. Over the last four years, we've had quite a significant impact. We were able to assist ministries of health in scaling up their HIV viral load by providing millions of tests and this is helping countries move closer to the 95-95-95 goal by 2030."

*Jesse Wambugu, former Director, Global Access Initiative in Africa, Hologic*

### A health provider's perspective

"Before the introduction of the Hologic platform, doctors were having difficulties switching treatment. They didn't know when a treatment was not working either. The equipment broke down frequently. We had high volumes of backlog in labs which would sometimes reach 20,000 samples per week. It was frustrating for us and the patients. The Hologic platform enables us to not only provide results faster but also to perform multi-disease tests. We no longer experience backlogs and stockouts. Every patient who needs a test can get tested anytime. The all-inclusive pricing model is a great approach. It's working, it's making our job easier and it's saving lives."

*Powell Choonga, Laboratory Advisor, Ministry of Health, Zambia*

### A procurer's perspective

"The agreement with Hologic really broke the market. We suddenly had a manufacturer who was willing to provide a product and a full service at a reasonable and transparent price. This enabled us to negotiate \$100 million to develop the laboratory network in 23 countries and we are currently envisioning to expand in more than 40 countries. The all-inclusive model is a much more sustainable way of strengthening laboratory supply chains. Today, we have functional labs that are running multi-disease tests and capable of taking on large volumes. Some countries are recording 90% and close to 100% of viral load coverage. This was unthinkable in 2015."

*Dianna Edgil, Chief of Supply Chain Division, USAID*

## How the volume guarantee worked in practice

Volume guarantees are effective at resolving high price – low demand traps, such as that faced by the HIV viral load market prior to MedAccess' intervention. In the case of the Hologic viral load volume guarantee, following negotiations with MedAccess and CHAI, Hologic agreed to offer a reduced all-inclusive price for its Panther® viral load testing platform to low- and middle-income countries.

While this addressed the price and procurement approach, African markets were still risky for Hologic. The company was new to the continent, which at the time had a deeply entrenched duopolistic HIV viral load supplier landscape. The market also lacked experience with an all-inclusive procurement approach for molecular testing. And while countries and procurers had shown interest in this new procurement approach, MedAccess recognised both Hologic and countries would need support to roll it out.

MedAccess agreed to take on part of Hologic's financial risk by guaranteeing demand to Hologic up to a specific annual level for four years. The guaranteed demand helped Hologic to focus on market entry without concerns over imminent losses.

MedAccess' partnership was not limited to the guarantee. MedAccess worked with CHAI and Hologic to understand what was needed to achieve the objectives of the partnership.

Purchasers' lack of information about Hologic's offering was seen to be a major risk to the partnership's objectives. In response, the details of the all-inclusive procurement approach were shared with key viral load stakeholders at global and local levels. In addition, Hologic worked with national HIV programmes to identify laboratories that could benefit from new or increased testing capacity. Finally, MedAccess and CHAI worked with HIV programmes and their partners to drive viral load testing demand generation.

## The impact

By lowering costs, improving procurement and increasing access to viral load testing, the MedAccess-Hologic volume guarantee had a positive impact on the lives of hundreds of thousands of people living with HIV. It enabled health workers to switch patients to more effective treatment regimens, giving them a better chance of living longer, healthier lives, and contributed to the updated global goal of 95% of people on antiretroviral therapy achieving viral load suppression by 2030. By the time the guarantee ended in December 2022, it had helped countries and global health organisations to achieve impressive results.



**932k**

people living with HIV who were not virally suppressed identified



**457k**

patients switched to second-line HIV treatment



**\$45m**

direct savings for procurers

## Hologic Panther® testing platforms

By the end of 2022, over 70 Panther® testing platforms had been installed in 12 HIV high-burden countries across sub-Saharan Africa. In Zambia, the introduction of Panther® platforms helped clear a backlog of 39,000 viral load tests within a month. Viral load testing coverage went from 38% in 2018 to more than 80% in 2021 – an increase of almost 50%.

**12 countries\***

with more than two suppliers switched to all-inclusive tender process



\* Botswana, Eswatini, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Tanzania, Uganda, Zambia and Zimbabwe



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