

WHY UNITAID MATTERS FOR PEOPLE LIVING WITH HIV/AIDS, TB AND MALARIA

MARKET IMPACT



**by the Civil Society
Delegations to UNITAID**



PROBLEM



SOLUTION



MARKET JOURNEY



GOAL

1

No appropriate product

Product adapted to needs of people in low-income countries

Product development

Acceptable and adapted

2

Poor quality, slow registration

Quality checked by WHO Pre-Qualification

Approval and registration

Quality

3

Product too expensive

No patent barrier, generic competition

Manufacture and sale

Affordable

4

Supply not secure. Stock outs

Pooled procurement

Procurement and supply

Available

5

New products introduced slowly or not at all

Health system introduction; demand by Civil Society

Uptake and use

Delivery and use

People living with and affected by HIV/AIDS, TB and malaria must have access to the right medicines, tests and products that prevent new infections. They must be:

- available in sufficient quantities
- quality assured
- affordable
- adapted to the needs of the person and delivered to the right person at the right time.

However, the markets for health products often fail to deliver what people need.

UNITAID was founded by the governments of Brazil, Chile, France, Norway and the United Kingdom in 2006, with close involvement of civil society. Its aim is to address problems in the market, and make sure people in low and middle-income countries have what they need to treat, diagnose and prevent HIV/AIDS, TB and malaria, as well as serious co-infections like viral hepatitis which occur in people living with HIV*. UNITAID is funded in large part by a tax on airline tickets, with remaining funds coming from government pledges. Civil society has played a critical role from the outset in ensuring UNITAID's work benefits affected communities.

* It should be noted the name UNITAID is not an acronym.

This leaflet will answer the following questions:

- What is a healthy market?
- What is a market journey?
- What does UNITAID do to get medicines, diagnostics and prevention products to the people who need them? What does it do to have a pro-health market impact?
- UNITAID solutions for market problems
- How can I get involved?

WHAT IS A HEALTHY MARKET?

A **healthy market** is one where well-adapted products of assured quality are sold at a reasonable and affordable price; where sufficient quantities are produced and where stock lasts; and where the market adapts as needed over time. Competitive markets (those with multiple suppliers) are almost always healthier than monopolies.

UNITAID analyses markets, identifies any problems and assesses whether they can be fixed. UNITAID then funds projects that have a lasting **market impact** so that markets stay competitive and healthy over time, benefiting people living with and affected by HIV/AIDS, TB and malaria.



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WHAT IS A MARKET JOURNEY?

A **market journey** describes the stages a product must go through from its creation to its final use.

Market journeys are especially complex for health products like the tools used to diagnose, treat and prevent HIV/AIDS, TB, hepatitis and malaria. A health product's market journey begins long before it can be bought.

For a medicine, for example, **product development** (stage 1) involves identifying a substance which has the potential to treat a condition, carrying out studies on how successful and safe it is and finding out in what form and dosage it can best be used. It also includes ensuring that the product will be well adapted for use, for example when treating poor people in challenging health settings in developing countries.

Once a medicine is **developed**, it needs to be proven to be efficacious, safe and of quality to be **approved and registered** (stage 2) by government regulators in each country. It then needs to be **manufactured** in sufficient quantities **and sold** (stage 3).

Next, a health product goes through the **procurement and supply** stage (stage 4). A finished, approved and registered health product will usually be procured (or bought) by:

- governments for distribution in government health systems
- international agencies like The Global Fund, UNITAID, UNICEF
- NGOs
- private sector actors, delivering to pharmacies, shops or private clinics.

However, getting a medicine to the place where it is needed (or ensuring its secure **supply**) is not enough to guarantee it will be used. A final step on a product's market journey is ensuring that there is **demand** for the product, in order to secure its **uptake and appropriate use** (stage 5). Demand is generated by governments recommending the health product in their treatment and diagnostic guidelines. Doctors and other health providers then need to be trained to prescribe or distribute it. In addition, people who need the health product must be informed and empowered to demand access to it, and then know how to use it as recommended.

Ensuring **demand** for a health product in this way is just as important as ensuring a product's supply.

What problems can occur in the market journey of medicines, diagnostic tools and prevention products? How do these problems affect communities?

Problems can occur at each stage of this complex market journey.

1

At stage 1, an appropriate product may never have been developed. This is often the case when companies have no interest in creating a product for which minimal profits are expected. This can be the case for products suited to the specific needs of people in low-income countries, such as medicines for children, or diagnostic tests that can be used in rural or remote settings without laboratories or electricity.

2

At stage 2, after a product has been developed, a company may not **register** the product in all the countries that need it. This means the product will not be approved for marketing and distribution especially in poor countries. As country-by-country registration can be expensive and very time-consuming, something is needed to speed up the process. In addition, some companies may make products that do not meet quality standards. However **poor quality** products can still make it to shops and clinics in countries that do not have tight control over the products bought and sold there. These products can put people's health at risk.

3

At stage 3, manufacture and sale, if there is only one company producing the product then it can run out when there is a temporary production problem. Also, a company may not want to invest in increasing its capacity to produce enough of its product. A big problem is that companies often demand too high a price. When a company discovers or develops a new product, it will often be given a patent which means it will be the only company with the rights to produce that product for 20 years. The patent leaves a company free to set any price it chooses for that product because it has no competitors. This means the **price of a new product is often very high**, and people and governments cannot afford to buy it. However, in case of need, governments can give the rights to manufacture the product to another producer (via a so-called compulsory license) or the company may give away these rights voluntarily.

4

At **stage 4**, procurement (buying) and distribution, there can be problems with purchasing enough of a particular health product at the right time and ensuring a **secure supply**. This can lead to wastage or even worse **stock outs** – where a pharmacy or health centre runs out altogether. For a producer it is very inefficient if orders are unpredictable and irregular and this means increased prices.

5

Finally, at the **demand** end of a product's journey – **stage 5** – a new product might **never be introduced** in a country unless a government (or donor) agrees to buy it and recommends its use in national health guidelines. A government may refuse to buy a product because of its high price. It may be reluctant to change the treatment guidelines or refuse to take the necessary steps to introduce it into health centres. Even if a product is bought and recommended by a government, it may still **not be used by people** if they or their doctor do not know about the product or how to use it.

All of these problems can cause people living with HIV/AIDS, TB and malaria, to miss out on treatment, diagnosis or other health products that they need.



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**WHAT DOES
UNITAID DO TO
GET MEDICINES,
DIAGNOSTICS
AND PREVENTION
PRODUCTS TO THE
PEOPLE WHO NEED
THEM? WHAT DOES
IT DO TO HAVE
A PRO-HEALTH
MARKET IMPACT?**

UNITAID analyses where a health problem is caused by a market problem along a health product's market journey, and publishes the results in what is called a 'market landscape'. It then funds projects to overcome these problems and their root causes, and to foster a healthy, sustainable, and hopefully competitive market that addresses the health needs of people. Projects are usually three to five years long, but are intended to have market and health impact long after they finish, for example when prices are reduced permanently. The market impact of a UNITAID project also helps governments and other organisations because they can purchase well-adapted products of assured quality at affordable prices over the long term. This means that each dollar UNITAID spends reaps economic and public health benefits worth far more than its original investment.

UNITAID OBJECTIVES

UNITAID has identified six strategic objectives for 2013–2016.

1. Increase access to simple, point-of-care diagnostics for HIV/AIDS, TB, and malaria.
2. Increase access to affordable, adapted paediatric medicines to treat HIV/AIDS, tuberculosis, and malaria.
3. Increase access to emerging medicines and/or regimens, as well as new formulations, dosage forms, or strengths of existing medicines that will improve treatment of HIV/AIDS and co-infections such as viral hepatitis.
4. Increase access to artemisinin-based combination therapies (ACTs) and emerging medicines, that, in combination with appropriate diagnostic testing, will improve the treatment of malaria.
5. Secure supply of second-line tuberculosis medicines, and increase access to emerging medicines and regimens that will improve treatment of both drug-sensitive and multi drug-resistant TB.
6. Increase access to products for the prevention of HIV, TB, and malaria.



PROBLEM



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UNITAID SOLUTIONS FOR MARKET PROBLEMS

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Problem 1: No appropriate product has been developed

Solution: UNITAID has supported the final stages of **product development**, to ensure products are developed to meet the needs of people in middle and low-income countries

Example UNITAID project: UNITAID is supporting the Drugs for Neglected Diseases Initiative (DNDi) to develop new HIV medicine formulations for babies and children. Existing treatment comes as a liquid which tastes terrible, has high alcohol content which can damage children's health and needs refrigeration. As a result, fewer children living with HIV can take the medicine that they need. This project will develop sprinkles or granule versions of medicines which can be mixed with food, formula or breast milk and don't need to be kept in the fridge.

2

Problem 2: Poor quality products or product not registered

Solution and example UNITAID project: UNITAID supports the WHO Pre-Qualification Programme, which checks that health products are quality assured. This involves visiting the factories where products are manufactured and examining all documents related to the production of the product. Organisations like the Global Fund to Fight AIDS, TB and malaria require the health products they buy to be certified by the WHO Pre-Qualification Programme (or through an equivalent scheme). Governments may be able to register certified products more quickly when they know that WHO has checked the quality.

At the **approval and registration** phase, UNITAID is supporting multiple companies to complete the quality and efficacy testing and registration processes for new diagnostic tests for HIV that can be used in rural/ remote settings.

Problem 3: The price of a product is too high

UNITAID has found **multiple** solutions to reduce the prices of health products and make them more affordable.

Solution 1: The price of a health product under patent is controlled by the company that originally developed it and holds the patent rights. This gives them a monopoly which results in high prices. UNITAID addresses this problem by supporting ways to overcome or bypass patents.

Example UNITAID projects: A patent may not be given to a company if its new product is very similar to an existing product. UNITAID is supporting an NGO in India to formally challenge patent applications and even granted patents. When successful, it allows other companies to produce cheaper copies of a product.

Companies can also *choose* to license a product to generic companies. Generic companies produce cheaper copies of already developed medicines. When multiple generic companies compete to produce the same product efficiently, prices reduce significantly. UNITAID founded and supports the Medicines Patent Pool, which negotiates licences on medicines to treat HIV/AIDS between the companies that develop them and the generic companies that make cheap versions. Through these licences, the Medicines Patent Pool facilitates competition and lowers medicine prices.

Solution 2: At the **procurement** stage, UNITAID projects may fund or organise large orders of health products, by finding out how much of a product will be needed across a number of countries. This mass (or pooled) procurement means UNITAID partners can negotiate much lower prices on products than if they were bought in smaller, less regular orders. Sometimes UNITAID projects will also pay an up-front amount to help negotiate lower prices.

Example UNITAID project: UNITAID has funded pooled procurement to reduce the prices of medicines to treat HIV (second-line antiretrovirals), achieving price reductions of up to 73 per cent.

UNITAID also engages in other efforts to improve manufacturing processes and market forecasting to help ensure a healthy market.

4

Problem 4: No secure supply of product, leading to stock outs

Solution: At the **procurement and supply** phase, UNITAID has supported warehouses of vital health products – or stockpiles – so that new health programmes can start up quickly, and to provide an emergency reserve of a product when a country's supply is running out.

Example UNITAID project: UNITAID supported an international stockpile of medicines to treat Multi-Drug Resistant Tuberculosis, serving more than 65 countries.

5

Problem 5: New products are introduced slowly, or not at all

Solution: UNITAID is now scaling up its work to create demand for products at the last stage of a market journey (stage 5 – securing **uptake and appropriate use**). Until now, the partners that implement UNITAID's projects, like Clinton Health Access Initiative (CHAI), have introduced new products at country level. Now, to ensure that demand for newly-introduced health products is clearly communicated, UNITAID is supporting campaigns and advocacy undertaken by civil society actors, like community organisations and NGOs. Community organisations and NGOs are well placed to make sure that governments include new products in their national health guidelines. They can also ensure that governments or donors pay for the products and that the people who need that product know about its benefits and how to use it.

Example UNITAID project: A UNITAID-supported Médecins Sans Frontières (MSF) project addressing Hepatitis C is relying on civil society organisations to create demand for testing and treatment.

Why is it important for people living with/ affected by HIV/AIDS and co-infections, TB and malaria, and for NGOs, to engage with UNITAID in their country and at the global level?

People living with or affected by HIV/AIDS and co-infections, TB and malaria, and NGOs have a critical role to play in ensuring UNITAID's success. They need to demand and ensure that:

- high **prices of health products are lowered** and that the companies who develop products do not abuse their power
- UNITAID has **enough funding** to continue its vital market impact work
- **national governments (or other donors) step in to pay for** the medicines, diagnostics and prevention products needed to fight HIV/AIDS, TB and malaria, especially at the end of a UNITAID project after UNITAID has played its market impact role
- there is **clear and visible demand in countries** for products that UNITAID funds
- there are **no stock outs** or other problems in UNITAID-supported projects, and that products are reaching the people who really need them
- UNITAID is as **responsive as it can be to people living with the diseases**, supporting the development of health products and buying the best products available, that are most suited to people's needs.

HOW CAN I GET INVOLVED?

The UNITAID Board is comprised of seats for donor governments (currently Brazil, Chile, France, Korea, Norway, Spain, and the United Kingdom, plus a seat for African countries nominated by the African Union), the Bill and Melinda Gates Foundation, the World Health Organisation and civil society.

Civil society plays a key role on the Board of UNITAID through its two Board seats. One is for communities living with or affected by HIV/AIDS, TB and malaria and one is for NGOs working on the global response to the three diseases. These two Board seats together comprise the civil society delegations to the UNITAID Board. Civil society has been involved with UNITAID since its establishment in 2006.

Anyone living with or affected by HIV/AIDS, TB or malaria, or working for an NGO on the global response to the three diseases can join the communities' or NGOs' delegations to the UNITAID Board.

Delegation members get regular opportunities to input into UNITAID Board meetings, where key decisions are made. They will also have the opportunity to help the civil society delegations lobby governments and expand civil society's work in the areas listed above, including monitoring UNITAID projects in countries and ensuring demand for vital health products.

To get involved, please email the delegations at unitaidcsdelegations@gmail.com or see www.facebook.com/CSDelegationstoUNITAIDBoard to find out more.