

# TRANSITIONING FROM DONOR SUPPORT **FOR TB & HIV** IN EUROPE



**GEORGIA:**  
ENSURING TIMELY  
ACCESS TO AFFORDABLE  
QUALITY ASSURED  
DRUGS

## CONTEXT

Georgia is located in the South Caucasus region. As shown in graphs 1 and 2, Georgia has a low HIV prevalence and decreasing incidence rates of tuberculosis (TB), indicative of strong leadership and collaboration between partners to fight the two diseases. However, there remains an increasing number of HIV cases in key populations, including people who inject drugs and men who have sex with men,<sup>1</sup> treatment outcomes remain unfavourable for people with TB and there are high rates of drug-resistant TB, for which treatment outcomes are poor.<sup>2</sup>

Global Fund to Fight AIDS, TB and Malaria (Global Fund) has provided financial assistance to Georgia's national HIV/AIDS Programme since 2003 and the National TB Programme since 2005. Global Fund plays a crucial role in ensuring access to treatment, including allowing Georgia to procure quality assured, affordable drugs through pooled procurement mechanisms, such as Global Fund's Pooled Procurement Mechanism for HIV and the Global Drug Facility (GDF) for TB. Georgia was recently re-classified as a lower-middle income country (LMIC) by the World Bank, despite

GDP per capita gradually increasing in recent years, and this could impact its co-financing requirements with Global Fund after the current 3-year funding cycle ends.<sup>3</sup>

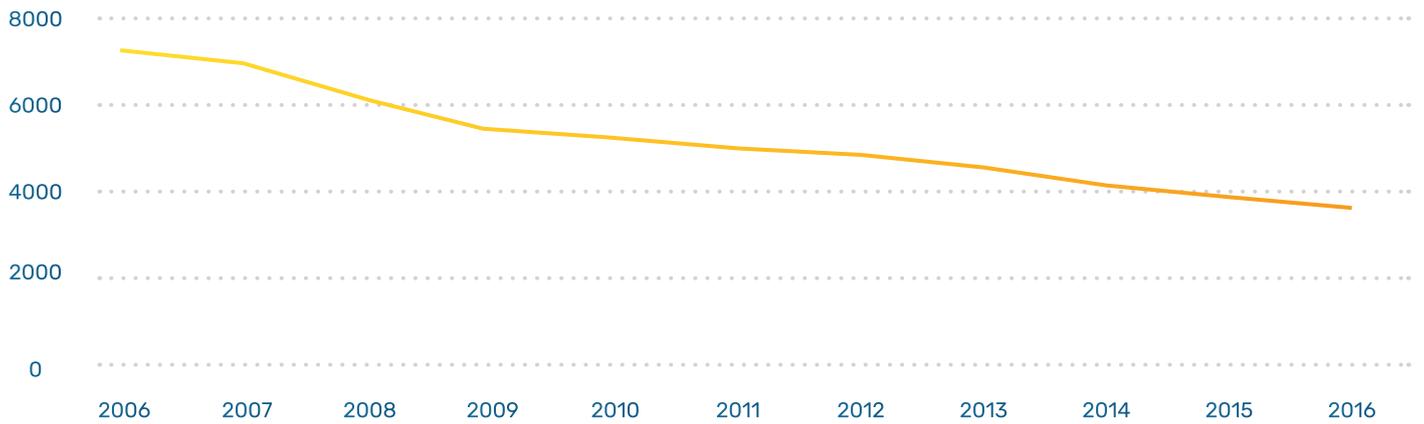
This case study explores how Georgia and the Global Fund have acted to ensure that transition from Global

Fund funding does not compromise stable procurement of TB and HIV commodities and access to medicines, in terms of both continuity and scale up. Georgia has been successful through early planning, collaboration with partners and many other reasons explored throughout this case study.

## TB AND HIV INCIDENCE RATES IN GEORGIA BETWEEN 2006 AND 2016

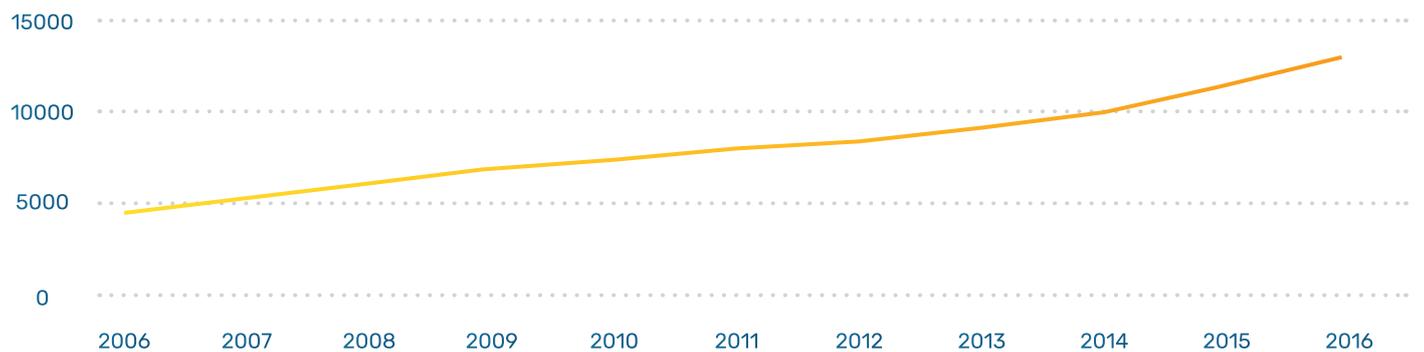
Incidence of TB

Graph 1



Incidence of HIV

Graph 2

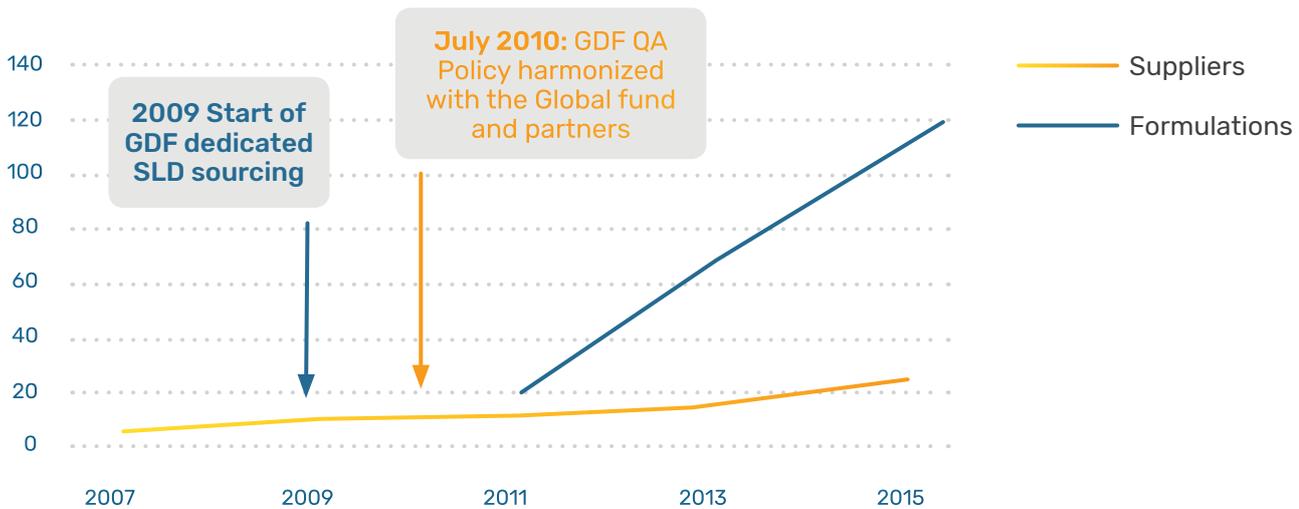


National TB programmes in Eastern Europe and Central Asia (EECA) procure many TB drugs through GDF, for example any country that receives a grant from Global Fund procures second-line drugs to treat drug-resistant TB (DR-TB) through GDF as a condition of the grant. GDF is able to use its market share to negotiate

volume-driven lower prices and procures only World Health Organisation (WHO) or stringent drug regulatory authority (SDRA) quality-assured medicines. GDF also ensures a stable supply for countries with weak procurement and supply mechanisms, and facilitates import waivers in lieu of national registration.

## THE POWER OF GDF POOLED PROCUREMENT AND MARKET INTERVENTIONS: SIGNIFICANT INCREASE IN SUPPLIERS AND FORMULATIONS OF SECOND LINE DRUGS FOR TB

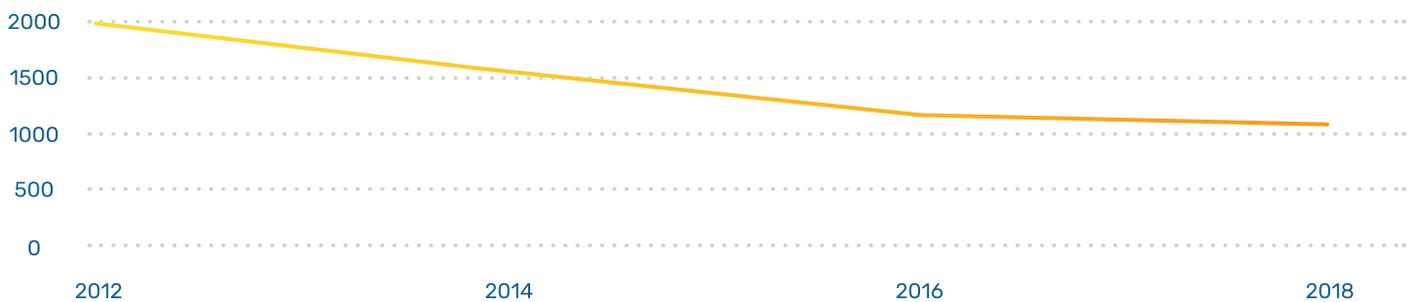
Graph 3



## THE POWER OF GDF POOLED PROCUREMENT AND MARKET INTERVENTIONS: DRAMATIC DECREASE IN GDF SECOND LINE TB DRUG PRICES FOR MULTI-DRUG RESISTANT TB REGIMENS (USD)

2012/2016 Regimen Costs

Graph 4



In line with the Global Fund's Sustainability, Transition and Co-financing,<sup>4</sup> and eligibility policies, eligible countries in EECA are shifting to national funding for procurement of first- and second-line TB drugs in greater proportions until they must rely solely on national procurement. This poses risks to timely access to quality assured, effective and affordable commodities. To mitigate these risks, Global Fund should provide technical assistance where needed and provide a roadmap for countries to navigate the transition. For example, in Georgia, Global Fund developed a roadmap along with partners such as Curatio International, using the Transition Readiness Assessment and transition planning, and integrated this into the national strategic plan. Governments must

begin preparations early to ensure that supply of, and access to, drugs is not disrupted.

It is possible for countries to continue procuring through GDF once they have shifted to state funding for medical commodities, this depends on their national regulations, requirements and laws.

Georgia is fairly unique because it has a provision in its national laws to allow procurement with state funds through GDF. In other countries, this is often prevented by patents, national legislation and other barriers. For Georgia, being a small country, access to pooled procurement is essential to ensure the continuity of quality-assured, affordable medical commodities.

## Box 1: RISKS ASSOCIATED

The impacts of moving from pooled procurement mechanisms through Global Fund grants to state funding for procurement will vary hugely between countries. A worst case scenario could see a country unable to keep the quality assured market intact, leading to increased incidence, reduced cure rates and increased mortality rates. The risks of transition on procurement of medical commodities could include:

### At the national level:

- **Failed tenders:** Individual countries may be unable to attract any bidders for tenders, due to their comparatively small markets;
- **Higher prices:** Countries that do not have the ability to negotiate volume-based discounts or access international procurement mechanisms may pay significantly higher prices;
- **Suboptimal formulations:** National legislation might place a priority on locally produced or procured medicines, despite these not being available in affordable, quality-assured or optimal formulations, such as fixed-dose combinations;
- **Poor or unknown quality:** A lack of an international quality requirement (e.g. WHO pre-qualification or SDRA approval) for drug tenders could result in suboptimal quality products entering the market at scale;

- **Supply problems:** Countries with poor forecasting, procurement and/or supply management systems may face shortages and supply problems;
- **Regulatory barriers:** Countries where key drugs have thus far been imported through Global Fund waivers could face regulatory issues that hinder access;
- **Barriers to generic competition:** Countries procuring affordable generic medicines through the Global Fund could see purchase and import options curtailed as regional initiatives, such as customs unions or regulatory harmonisation efforts, are implemented;
- **Lack of accountability:** In the absence of strong civil society monitoring and transparency, governments may procure more expensive medicines.

### Globally and regionally:

- **Sustainable prices and supply:** Splitting the market, especially for medicines with fragile market dynamics, could result in fewer suppliers, higher prices, and an unstable supply for both national procurement systems and for international systems that use higher volumes to secure prices and commitments from manufacturers.
- Countries in EECA are not attractive markets to manufacturers to register HIV and TB drugs due to low volumes.



Tbilisi, TB Dispensary #5. DOT spot, TB medications. Credit Nikoloz Mirzashvili.

# GEORGIA'S TRANSITION PLANNING

Through a transparent and participatory process involving all major stakeholders,<sup>5</sup> Georgia developed a transition plan in response to gradual allocation reductions from Global Fund over the years.

The goal is to ensure that transition to full domestic funding of the HIV and TB programmes by 2022 does not compromise services. There are two objectives of the plan:

- Create a conducive legal environment to successfully implement the national HIV and TB response and achieve greater engagement of civil society organisations.
- Enhance national structural, institutional and human resource capacities to implement and manage HIV and TB interventions without interrupting or compromising the scale, scope and quality.

## PLANNING THE TRANSITION PROJECTED CO-FINANCING REQUIREMENTS FOR HIV AND TB PROGRAMMES IN 2016-2019<sup>6</sup>

COMMODITY	YEAR	CO-FINANCING REQUIREMENT
Second and third line HIV medicines	2017	25%
Second and third line HIV medicines	2019	75%
Second and third line TB drugs	2018	50% <i>(by the end of the year)</i>
Second and third line HIV drugs	2020	85% <i>(by the end of the year)</i>

A procurement and supply chain assessment for HIV/AIDS and TB products was due to be carried out by the end of 2017, but is yet to happen (activity 2.7.1.1 in the Transition Plan for Procurement and Supply Chain

Management). In 2018, the Green Light Committee and GDF will conduct a joint visit to the country to assess drug management for TB.

## OPTIMISATION OF TREATMENT

The Georgian government has put in place measures to ensure better access to quality, affordable TB and HIV treatment.

- Takeover of funding of first-line antiretroviral (ARV) drugs for HIV was a precondition for signing Georgia's grant agreement with Global Fund (2013-2014). To ensure the best prices and supply for drug regimens for people with HIV as transition occurs, HIV drugs are procured through the Pooled Procurement

mechanism. ART guidelines are updated regularly according to WHO recommendations, and the National Centre for Disease Control (NCDC) worked with a range of partners including WHO, on treatment regimen simplification and optimisation. The last simplification happened in 2014.

- In 2018, the government introduced new guidelines for TB treatment in line with WHO recommendations.



## Procurement and supply chains

In Georgia, the procurement and supply of health products for HIV and TB is managed by the NCDC, which is the principal recipient of the Global Fund grant.

### HIV:

- Currently, all ARVs are procured through the Global Fund supported Pooled Procurement Mechanism (PPM), including the first-line ARVs that are purchased with state funds. A provision in the State Budget Law enables NCDC to procure through PPM, rather than common state procurement, due to the PPM's guarantee of quality and best available price.
- Under the Global Fund HIV grant, several initiatives will be carried out to ensure proper functioning

of existing procurement and supply chain system currently utilised by NCDC, in consultations with the Global Fund Country Coordinating Mechanism (CCM). This will be decided by the end of August 2018 for the current grant and will include integration with the transition plan.

### TB:

- The Georgian government fully funds first line anti-TB drugs, procured through GDF, and partly funds procurement of second-line TB drugs through GDF. Georgia aims to continue this collaboration with GDF for both first- and second-line TB drugs.

## Registration

Countries receiving Global Fund funding are eligible for a drug registration waiver. Currently, most ART drugs used in Georgia and second-line drugs for TB are accessed through the Ministry of Labour, Health and Social Affairs' waiver.

Once Georgia has transitioned from Global Fund support, in order to access the drugs in country, they must be registered. In Georgia, a marketing authorisation issued by the State Regulation Agency for Medical Activities (SRA) is needed to include a medicine into the register. In recent years, the procedure has been simplified and there are two mechanisms:<sup>7</sup>

- **National procedures:** used for branded and generic medicines. This takes up to three months. It costs

GEL 500 (up to US\$ 209 as of September 2015).

- **Recognition procedures:** covers medicines that are formally recognised by the European Medicines Agency, FDA and regulators of certain developed countries. The administrative procedure takes up to seven days between submitting the set of documents and adding the product to the registry. It costs GEL 2,500 (up to US\$ 1,040 as of September 2015).

The **WHO Collaborative Registration Procedure (CRP)**<sup>8</sup> accelerates approval of and access to originator and generic medicines for public health needs by expediting the registration process. Using this procedure ensures that medicines can get to the people who need them faster. Participating National Drug Regulatory

Authorities have 90 days to review the dossiers of SDRA-approved or WHO prequalified products, under confidentiality, in a globally harmonised format aligned with the same system used for WHO prequalification. Through this process, NDRAs can follow their national legislation and responsibilities, collect fees, and develop

risk-management and pharmacovigilance plans with applicants.<sup>9</sup> In Georgia, the Drug Department under the Medical Activity Regulation Agency, has been tasked to expand registration options, including those based on the WHO CRP.

## Intellectual property

The Doha Declaration Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted at the 2001 Ministerial Conference of the World Trade Organisation (WTO). It recognised the implications of intellectual property rights on both new medicine development and the price of medicines. It outlines measures, called TRIPS flexibilities, for WTO members to take to ensure access to medicines for all, such as compulsory licensing of medicine patents and the least-developed countries pharmaceutical transition measure.<sup>10</sup> Use of TRIPS flexibilities can facilitate

access to affordable, quality assured ARVs and TB medicines. For example, Georgia uses Dolutegravir which is produced by Indian companies, rather than the originator company.

In contrast, TRIPS-plus measures go beyond the minimum standards set by the TRIPS agreement and restrict access to affordable medicines, for example by extending patent terms, extending data exclusivity periods,<sup>11</sup> and introducing provisions that limit the use of compulsory licenses or that restrict generic competition.<sup>12</sup>

## Patents

The Medicines Patent Pool (MPP)<sup>13</sup> is a United Nations-backed public health organisation working to increase access to HIV, hepatitis C and TB treatments in low- and middle-income countries, through addressing the need for multiple sources of affordable, quality-assured medicines for use in developing countries. Patent holders, such as pharmaceutical companies

or academic institutions, are encouraged to share their drug patents with MPP, in turn allowing other manufacturers to produce more affordable generics and the patent holders receives a royalty in return. With multiple producers seeking licenses and competing for the market, drug prices can be driven down.<sup>14</sup>

## Quality of products

Global Fund ensures that products it funds are quality assured. Before a recipient country begins procurement, it provides a list of health products it wants to purchase to Global Fund for approval (ensuring that they meet quality standards). After the Global Fund withdraws support, countries should ensure that national guidelines reflect international guidelines on the quality of health products, rather than opt for cheaper drugs of potentially lower quality.

As principal recipient of the Global Fund grant in Georgia, the NCDC bears the responsibility for monitoring the quality of the delivered drugs. Currently, ARV and anti-TB drugs are procured in accordance

with the Global Fund Quality Assurance Policy from Pre-qualified sources (WHO PQP). Georgia uses a local laboratory “Globaltest,” accredited by the Georgian Accreditation Centre (which operates in compliance with internationally applied standards and European practices).<sup>15</sup>

The State Regulation Agency for Medical Activities is responsible for the quality control of pharmaceutical products and their safety in Georgia. In April 2018, the Ministry of Health announced that Georgia is moving to implement GMP standards and launched recruitment for the certifying body representatives.<sup>16</sup>

# LESSONS LEARNT AND RECOMMENDATIONS<sup>17</sup>

As a country with a small market size, Georgia views it as essential to keep access to pooled procurement mechanisms in order to maintain access to quality assured drugs at the best available price. Concurrent financial challenges for countries transitioning from Global Fund support include instituting laboratory capacity to conduct quality control which requires construction, purchasing equipment and investing in human resources and capacity building.

According to most stakeholders on transition planning, the involvement and clear demands from Global Fund are

necessary to push government to abide by all financial promises. Other elements for successful programme continuity include the fact that the principal recipient and key implementing partners for diagnosis and treatment services are state institutions. There is also clear commitment and political will to address the issue.

The CCM is an effective and functional structure and the government intends to retain it after transition.

## Recommendations

- Government should commit to prioritising procurement of quality-assured products and optimal formulations in line with WHO recommendations.
- Governments should commit to adopting and utilising TRIPS flexibilities to ensure generic competition and to avoiding adoption of TRIPS-plus rules.
- Governments should make available the tenders and results of the tenders, including all pricing and offers in a transparent manner.
- Governments should enrol in the WHO Collaborative Procedure (CRP) and utilise other strategies, such as import waivers, until local registrations are granted.
- Global Fund should ensure flexibility in their expectations for TB and HIV drug procurement uptake awaiting the results of a full assessment.
- Global Fund should ensure the necessary technical assistance on procurement is available to support the transfer of availability, scale-up of access to treatment and continuity of access to affordable and quality assured drugs.
- Civil society should hold their governments to account to ensure that all financial promises for TB and HIV drugs are delivered upon.

<sup>1</sup> The Global Fund. Georgia country portfolio. [Online]. Available from: <https://www.theglobalfund.org/en/portfolio/country/?k=1a011619-1610-46be-a1ac-4cbafe3e6a42&loc=GEQ>

<sup>2</sup> MSF. Alert. [Online]. 2017. Available from: <https://www.msfaccess.org/content/msf-alert-summer-2017-new-drugs-new-hope-fighting-drug-resistant-tuberculosis-georgia>

<sup>3</sup> World Bank. Country income classifications 2017-2018. [Online]. Available from: <https://blogs.worldbank.org/opendata/new-country-classifications-income-level-2017-2018>

<sup>4</sup> The Global Fund. Sustainability, Transition and Co-Financing Policy. [Online]. Available from: [https://www.theglobalfund.org/media/4221/bm35\\_04-sustainabilitytransitionandcofinancing\\_policy\\_en.pdf](https://www.theglobalfund.org/media/4221/bm35_04-sustainabilitytransitionandcofinancing_policy_en.pdf)

<sup>5</sup> Stakeholders included; CCM members, the Ministry of Labour, Health and Social Affairs of Georgia (MoLHSA), National Centre for Disease Control and Public Health (PR), TB and HIV service providers, civil society and community-based organisations, patient groups. The Policy and Advocacy Advisory Council (PAAC) composed of experts and representatives of Key Affected Communities (KAPs), advocacy groups and other civil society representatives was established to advise the TSP development process.

<sup>6</sup> Presentation by Irma Khonelidze, Deputy Director NCDC, Minsk, Belarus 2 November 2016

<sup>7</sup> Curatio Foundation. Georgia Case Study. [Online]. 2016. Available from: [http://curatiofoundation.org/wp-content/uploads/2017/01/GEORGIA-TS-CASE-STUDY\\_Final\\_Jan25-2016.pdf](http://curatiofoundation.org/wp-content/uploads/2017/01/GEORGIA-TS-CASE-STUDY_Final_Jan25-2016.pdf)

<sup>8</sup> WHO. Collaborative Registration Procedure. [online]. Available from: <https://extranet.who.int/prequal/content/collaborative-registration-faster-registration>

<sup>9</sup> MSF Access Campaign. Out of Step Report. [Online]. 2017. Available from: [https://www.msfaccess.org/sites/default/files/MSF\\_assets/TB/Docs/TB\\_Report\\_OutOfStep\\_3rdEd\\_ENG\\_2017.pdf](https://www.msfaccess.org/sites/default/files/MSF_assets/TB/Docs/TB_Report_OutOfStep_3rdEd_ENG_2017.pdf)

<sup>10</sup> WHO. Bulletin. [Online] 2018. Available from: <http://www.who.int/bulletin/volumes/96/3/17-199364.pdf>

<sup>11</sup> HAI Europe and Oxfam. Trading Away Access to Medicines Revisited. [Online]. 2014. Available from: <http://haiweb.org/wp-content/uploads/2015/09/Trading-Away-Access-to-Medicines-Revisited.pdf>

<sup>12</sup> MSF Access Campaign. TRIPS, TRIPS Plus and Doha. [Online]. Available from: <https://www.msfaccess.org/content/trips-trips-plus-and-doha>

<sup>13</sup> Medicines Patent Pool. Available from: <https://medicinespatentpool.org>

<sup>14</sup> MSF Access Campaign. Spotlight on Patent Pool. [Online]. Available from: <https://www.msfaccess.org/spotlight-on/patent-pool>

<sup>15</sup> "Globaltest" is ISO 170235 lab, accredited by Georgia ACC Georgian Accreditation Centre (GAC), which operates in full compliance with the internationally applied standard ISO/IEC 17011 and European practices. The national procurement regulation makes it possible to request the products that are WHO prequalified and/or CE certified/FDA approved.

<sup>16</sup> Ministry of Health Georgia. Announcement. [Online]. 2018. Available from: <http://moh.gov.ge/ka/news/3983>

<sup>17</sup> Curatio Foundation. Georgia Case Study. [Online]. 2016. Available from: [http://curatiofoundation.org/wp-content/uploads/2017/01/GEORGIA-TS-CASE-STUDY\\_Final\\_Jan25-2016.pdf](http://curatiofoundation.org/wp-content/uploads/2017/01/GEORGIA-TS-CASE-STUDY_Final_Jan25-2016.pdf)

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