

TRANSITIONING FROM THE GLOBAL FUND: WORK IN PROGRESS

I. Transition definition, rationale and need

Definition and rationale: The Global Fund (hereafter the Global Fund) defines transition as “the mechanism by which a country, or a country-component, moves towards fully funding and implementing its health programs independent of Global Fund support while continuing to sustain the gains and scaling up as appropriate.”¹

The rationale for transitioning is based on the core belief that planning for sustainability is inherent to programme design and should be considered by recipient countries as early as possible in the development continuum. Transition planning and investment should thus be envisaged in all stages from advocacy project design and implementation to training and evaluation.

In its 35th Board meeting², the Global Fund decided to adopt a new transition policy, as part of a wider “Sustainability, Transition and Co-financing policy” (hereafter STC policy), that it defined as follows:

“Long-term sustainability is a fundamental aspect of development and global health financing. It is essential that countries are able to scale up and sustain programs to achieve lasting impact in the fight against the three diseases and to move towards eventual achievement of Universal Health Coverage. Countries that have experienced economic growth over the last decade are able to move progressively from external-donor financing for health toward domestically funded systems that deliver results but must be supported to do so... The Sustainability, Transition and Co-Financing Policy... outlines the high-level principles for

engaging with countries on long term sustainability of Global Fund supported programs, as well as a framework for ensuring successful transitions from Global Fund financing. Experience shows that supporting countries to sustainably transition from Global Fund support requires significant time. As such the Global Fund’s approach to supporting sustainability and transition is based on the central premise that planning for sustainability is something that should be taken into account by all countries regardless of where they sit on the development continuum.”

Based on four main principles, differentiation³, alignment⁴, predictability⁵ and flexibility⁶, the STC policy has been applied since 2016.

Need for transition: Upper Middle-Income Countries (UMICs)⁷ with low / moderate disease burden, or High-Income Countries (HICs) have always been ineligible to the Global Fund intervention.⁸ However, the requirement to consider alternative criteria for external financial support for health than pure income emerged in parallel of the SDGs’ adoption, as part of the Financing for Development conference that took place in Addis Ababa in July 2015. Indeed, if GNI per capita is a relevant indicator to measure wealth and to determine whether a country is eligible for international financial assistance, it

was deemed insufficient to capture the reality of the 109 MICs that are home to 73% of the global poor with immense unmet health needs, to 70% of people living with HIV (by 2020⁹), and to the vast majority of TB and malaria cases¹⁰ despite being engines of the global growth that made many of



TB prevention in Sri Lanka. The TB component in Sri Lanka is projected to transition between 2020 and 2022. © Global Fund

them progressively ineligible to the Global Fund support (as well as to other international institutions).

The Equitable Access Initiative (EAI) was thus launched by 9 international agencies¹¹ “to consider alternatives to GNI as a framework to assess countries ‘need for external financial support for health¹²’.

Findings of the EAI reflected that “policy making should not rely on a single variable to inform complex health financing policies on the eligibility for and the prioritization of investments.”¹³ It was recommended that a multi-criteria framework taking into account income levels and health needs would be best fitted to assess eligibility, while also considering complementary policies allowing for a ‘planned gradual transition’, and domestic fiscal capacity and policy that should contribute to increase the level of domestic funding available for health.

II. Eligibility criteria and transition tools

Eligibility criteria: The STC policy document of the Global Fund thus highlighted eligibility criteria for transition funding, depending on the income status of recipient countries as well as on the disease burden, and defined co-funding requirements^{14 15}. Once a country reaches UMI status, it becomes ineligible for funding if it has less than a “high” disease burden (“extreme” for G20 countries) for a particular component (HIV, TB, or malaria). It can however apply for transition funding (except G20 countries and members of OECD-DAC that are not eligible to transition money).

In May 2017¹⁶, the Global Fund notified its Governing Board on the implementation of the STC policy, highlighting the need to ensure successful transitions and to strengthen sustainability of the Global Fund investment in recipient countries. In its document to the Board of May 2018 in Skopje, the Global Fund recalled eligibility criteria for funding requests, retaining GNI per capita as a valid indicator for country income, and using an average of the last 3-year GNI per capita to define income thresholds. As such, all Low-Income Countries (LICs) and Lower-Middle Income Countries (LMICs) remain eligible regardless of the disease burden and

all UMICs that meet a specific disease burden threshold are also eligible, with special provisions applying¹⁷.

In the same document, the Global Fund requested the Board to approve of a revised Eligibility Policy that will update “the disease burden metrics, in particular the change to incidence for the TB burden metric¹⁸, and the inclusion of provisions meant to address significant malaria resurgences in non-eligible LICs and MICs. The revised policy will also helpfully prevent an unintended and precipitous transition for a large high burden country and will

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therefore enable continued impact and sustainability planning,” it says, while highlighting that “the revised Eligibility Policy does not narrow eligibility, which could jeopardize sustainability and transition planning for currently eligible countries¹⁹”.

While the Global Fund has placed much effort into transition preparedness in the last years, several transition processes ended up with a series of unintended consequences at country level, e.g. in terms of access to quality and affordable medicines, or as regards prevention and harm-reduction policies, raising questions as to the actual adequacy of the STC policy vis-à-vis local transition constraints.

It remains that transitions are needed to accompany recipient countries in taking ownership of health policies regarding the three diseases, among others. It also allows the Global Fund to focus its efforts on countries that have the highest disease burden: “the Eligibility Policy is intended to ensure that available resources are allocated and invested in countries and regions with the highest burden of disease, the least economic capacity, and where key and vulnerable populations are disproportionately affected by the three diseases²⁰”.

Transition tools: Further to developing “quality, evidenced-based National Health Strategies, Disease Specific Strategic Plans and Health Financing Strategies²¹,” the Global Fund supports countries in applying “transition readiness assessments” (TRAs) “to serve as a tool to stimulate dialogue at country level around transition related needs, from both a programmatic and financial perspective, identify key gaps in programming that can be planned for, and highlight areas where

The cost of current Global Fund transition components is extremely reasonable, standing at US\$ 38.4 million between 2017 and 2019, or 0.37 % of all country allocations for the period.

technical assistance may be required²²”. TRAs are based on 4 thematic areas of transition, each of them having 3 indicators of progress to help measure a country’s readiness to transition²³. Readiness is then assessed against indicators in 3 possible stages:

- *Stage 1:* a country has made some progress towards preparing for a sustainable transition, but significant barriers remain;
- *Stage 2:* a country is actively in the process of making positive changes, but some time is still needed before systems will be prepared for a sustainable transition to domestic financing;
- *Stage 3:* identifies a country that is imminently ready to transition, with all core mechanisms in place to sustain programming after external donor funding ceases.

Based on TRAs, transition workplans are then prepared “addressing key bottlenecks and leverage opportunities towards successful transition²⁴”. According to the Global Fund, workplans should be “SMART” (Specific, Measurable, Achievable, Time-bound) to allow measuring progress.

In their report on “PEPFAR transitions to country ownership²⁵”, A. Vogus & K. Graff pointed at 9 key areas that should be evaluated to determine a country’s readiness for transition:

- Leadership and management capacity;
- Political and economic factors;

- Policy environment;
- Alternative funding sources;
- Integration of HIV programmes;
- Institutionalized processes;
- Procurement and supply chain management;
- Staffing and training needs;
- Private sector and civil society engagement.

While prepared for transitions of HIV programmes in the Caribbean, most of above key features could apply to transitions of other components in other geographical contexts. And most have actually been integrated into TRAs’ key thematic areas and indicators, as developed by the Global Fund.

But the question remains why, if countries reach low marks in their TRAs, the Global Fund adamantly pursues transitions in so short timeframes.

III – Key determinants for successful transitions

Several studies have identified good practice for successful transitions of HIV response plans and proposed a series of key steps that contribute to their sustainable facilitation. A. Vogus & K. Graff²⁶ detail 6 conditions towards planning an effective transition:

- Develop a roadmap;
- Invest in stakeholder participation;
- Communicate the plan through high-level diplomacy;
- Support mid-term evaluations;
- Provide technical assistance throughout the process;
- Provide long-term M&E support.

Some of the determinants have later been taken into consideration by the Global Fund, as we will see. Of note however, A. Vogus and K. Graff emphasize the need for continuous support throughout the transition process, and for continuous M&E during and *after* transition processes.

In another study²⁷, P. Piot et al. have analysed 21 transitions plans in 13 countries, and have concluded that conditions for success are:

- A medium-term duration of about 5 years;

- Key financing or high-level political signees;
- Clear and monitorable financial targets for all parties, including donors and government;
- Inputs from economic and epidemiological data;
- Costed HIV strategies and trusting dialogue;
- Reliable M&E systems, including transparent process for tracking fin. commitments;
- A series of binding incentives, including penalties and rewards, to meet financial commitments or for failing to attain them.

While P. Piot et al. recommended transition plans of a 5-year duration, the Global Fund has maintained transitions of 3 years, aligned with allocation periods²⁸. Preparedness start well before, but transitions *per se* do not exceed a triennium, regardless of whether transitions are successful or not²⁹. It is then up to countries to manage, or not, transitioned components.

The cost of current Global Fund transitions is extremely reasonable though, standing at US\$ 38,409,916 for the 12 components transitioning between 2017 and 2019³⁰, i.e. 0.3729% of all country allocations for the period³¹. In spite of the counterproductive message it would send to transitioning countries, extending failed transition components at the end of the 3-year period would certainly be cost-effective, when considering the long-term benefits of successful transitions.

Undeniably, the commitment of national / regional or local authorities to prepare for and finance the response to the 3 diseases is fundamental to a smooth implementation of transition plans. In particular, countries' economic situations and their fiscal capacity to increase public financing for prevention, treatment and care should be assessed carefully before transitions start.

The policy and legal frameworks that underpin recipient states' ability and willingness to contract NGOs also have to be analysed and reviewed if need be.

Human rights and gender related barriers should also be assessed and overcome to avoid prevention

restrictions or treatment gaps for key populations and vulnerable groups.

How public health systems are structured, what is their capacity to plan, implement and monitor services beyond the Global Fund funding, how

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public procurement is designed and managed, whether key services of national health strategies for the 3 diseases are included in national health insurance schemes are also key enabling factors to be assessed and adapted.

Downstream, the epidemiological context and particulars of service delivery for key and vulnerable populations should be considered for optimal planning and costing, and to ensure programme continuity, a key factor to avoid developing resistance to treatments.

Failure to consider so inevitably leads to unsuccessful or incomplete transitions, to the detriment of patients in general, and of key and vulnerable populations in specific.

Example: The FYR of Macedonia lost eligibility to the Global Fund financing in 2014 when the new funding model was introduced. The last grant was due to be fully spent by June 2017. In the meantime, a political crisis erupted that lead to major instability in 2015 - 2017 and to the absence of a government for several months the latter year. In spite of early and fairly comprehensive transition planning, the political crisis triggered a disruption of services as transition processes were stalled.

IV – Issues arising from past and ongoing Global Fund transition processes

There are 12 components in 11 countries at a transitioning stage in the 2017-2019 allocation period of the Global Fund portfolio. Six more components in 6 countries are also using the "transition tailored funding request"³². As noted above, the cost of current transitions remains low, standing at 0.3729% of total country allocations³³.

The Global Fund has also prepared a list of components / countries that are projected to transition by 2025³⁴: Six components in 3 countries would move to UMI status during the current triennium and would be eligible for transition funding in 2020 – 2022, with an additional 7 components in 5 countries going through the same process in the triennium 2023 – 2025. Four recipient countries with 5 more components would become totally ineligible for Global Fund funding as they would be upgraded to high-income status between 2017 and 2025. Altogether, 21 countries (out of 124 that are currently eligible for Global Fund funding) would become ineligible by 2025, i.e. 17% of recipients.

Countries that have faced or that are currently going through transitions start providing feedback on some issues that are important to consider, identifying weaknesses or achievements of transitions so as to improve practices. On its side, the Global Fund has also recognized that a number of key questions should be carefully considered during transition planning:

- *Programmes for key and vulnerable populations*

Key populations are the first victims of transitions. Because of legal restrictions, social marginalization or prejudice they face increasing difficulties accessing information, harm reduction services for people using drugs, or HIV prevention for sex workers or men who have sex with men (MSM), that NGOs who have lost funding cannot provide anymore.

Example: In at least 2 cases (Serbia and Montenegro), unplanned transition has led to countries becoming re-eligible to the Global Fund support, after HIV rates among MSM increased again.

In Bulgaria, a new 3-year TB and HIV national programme was adopted in 2017, with less

funding available for prevention from the domestic budget.

- *Capacity and role of non-state actors in service provision*

NGO activities and services in favour of key populations are paramount in achieving progress in the response to the 3 diseases, in the fight against HIV / AIDS in particular.

In some countries facing transition though, social contracting has not been put in place in due course, leaving NGOs without access to state funding for service provision. In addition, the use of domestic government funding for advocacy purposes could result in conflict of interest. And alternative sources of funding, e.g. bridge funding from other international organisations, are seldom available.

The development of social contracting mechanisms that allow government financing of civil society-led interventions is deemed essential for smooth transition processes.

Example: in spite of a planned transition and access to EU funding, Bulgaria has not managed to pass legislation on social contracting of NGOs, thus increasing the risk of a discontinuity of services for key populations.

- *Ownership of key interventions and integration into national systems*



Testing of malaria in the Philippines. This component may receive transition funding in 2023 – 2025. © Global Fund

Integration of HIV, TB or malaria services into national health systems is key to manage transitions, both from an epidemiological perspective to achieve combined treatment delivery, and to ensure people-centred prevention and care. The transition period should be used to integrate services as much as possible in an effort to optimise the use of resources and identify gaps and potential overlaps.

Example: Estonia partially managed to integrate TB and HIV services into its health system, though fragmentation remains at financial and management levels.

- *Fiscal capacity and domestic financing*

Switching to progressive government financing of key interventions is a significant factor of success for transitions. As recipient countries are progressively upgrading to higher income status, they should increase their fiscal capacity in parallel, as well as their ability to finance disease programmes and their health systems at large. The STC policy includes a co-financing element aimed at encouraging increased domestic financing for health: a minimum 15% co-financing incentive has been put in place, that countries can access if and when they commit additional domestic investments in health.

On the paper, Global Fund co-financing requirement and incentive work: domestic financing of health programmes by partner countries has increased by 41% between the triennium 2012-2014 and the following 3-year period³⁵. In its investment case for the period 2017-2019³⁶, the Global Fund has projected that domestic investment in programmes related to the 3 diseases would reach US\$ 41 billion globally, i.e. over 3 times direct Global Fund investment (that would gradually decrease from 18% down to 15% of total investment over the triennium).

If it is good news for donors, and indeed a positive sign of progressive ownership of domestic health policies by implementing countries, one should nevertheless question whether such dynamic projection of domestic financing for health is realistic in first place, and if it does not take place at the cost of growing out-of-pocket payments by the patients themselves, rather than through improved fiscal policies or health insurance schemes.

- *Integrating salaries and operational costs into national health budgets*

Gradual integration of prevention, treatment and care costs into national budgets during the

transition phase should be considered carefully by stakeholders. Failure to do so results in inadequate budgeting, and in a possible

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disruption of service provision to vulnerable and key populations, and possible subsequent resurgence of epidemics.

Example: in the FYR of Macedonia, in spite of a fairly well managed transition, political instability in 2016 and 2017 led to difficulties for a smooth transition, and the departure of trained NGO staff (who were not paid) threatened to disrupt services to key populations.

- *Strong monitoring and evaluation (M&E) systems*

Capturing and analysing data for action is at the core of efficient health interventions. Gathering such data, particularly around key and vulnerable populations who fall through the cracks of official statistics, often relies on non-governmental organisations, who stop collecting information when unfunded, thus rendering epidemics transmissions unchecked for months or years!

- *Reliable and efficient health products procurement and supply chain systems*

This is a key element of successful transitions. The procurement of affordable and quality medicines for prevention, treatment and care of patients is at the core of national HIV / AIDS, malaria and TB programmes. In times of Global Fund funding, access to drugs is ensured through 2 main mechanisms: The Pooled Procurement Mechanism (PPM) for HIV and malaria drugs, laboratory or diagnostic products, and the Global Drug Facility (GDF) for TB treatment.

Established in 2009 to guarantee a cost effective and efficient procurement process by compensating for countries' procurement bottlenecks and supply chain management

weaknesses, and facilitating timely access to pharmaceuticals and health products, the PPM is a “Global Fund strategic initiative that aggregates order volumes on behalf of participating grant recipients to negotiate prices and delivery conditions with manufacturers. In 2017, the Pooled Procurement Mechanism managed US\$1 billion in orders, serving grant recipients in 63 countries³⁷”.

As to the GDF, it was established in 2001 by Stop TB Partnership. It provides “a package of services, including technical assistance in TB drug management and monitoring of TB drug use, as well as procurement of high-quality TB drugs at low cost. The mission of the GDF is to facilitate worldwide, equitable access to tuberculosis medicines and diagnostics”, with an aim to “shape the market (working with suppliers, donors and other stakeholders to ensure the availability of quality-assured and sustainably priced products that respond to market needs), to facilitate access to innovative medicines and diagnostics and to provide best-in-class procurement services for tuberculosis medicines and diagnostics³⁸”.

When countries lose Global Fund funding, they also lose access to the PPM mechanism³⁹, leaving them alone to manage procurement, quality control and pricing of drugs and other supplies directly with providers. In other words, through which mechanism and at what price medicines will be purchased becomes a central issue in the development of national HIV and malaria programmes.

In its audit report on transition management processes⁴⁰, the Office of the Inspector General (OIG) of the Global Fund noted that “the Global Fund has an existing arrangement with the Pan American Health Organization and other countries to leverage the PPM to buy medicines with their own resources. This could enable countries with transitioning components to have continuous access to affordable and quality medicines.”

In the same vein, the piloting of WAMBO⁴¹ for domestic funded procurement should hopefully improve access of transitioned countries to

quality and affordable medicines, provided that those are granted access to the mechanism. In the meantime, transitioning countries are confronted with 3 major challenges, that can result in important disruptions of procurement and supply:

- *Quality drugs:* In 1969, the twenty-second World Health Assembly endorsed requirements for Good Practices in the Manufacture and Quality Control of Drugs (“GMP as recommended by WHO”). These comprise internationally recognized and respected standards that all Member States were urged to adopt and to apply. These standards also provided the basis for the “WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. The Scheme is an administrative instrument that requires each participating Member State, upon application by a commercially interested party, to attest to the competent authority of another participating Member State that a specific product is authorized to be placed on the market within its jurisdiction;... that the plant in which it is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to GMP as recommended by WHO...⁴²”

According to WHO, more than 100 countries have incorporated the WHO GMP provisions into their national medicines’ laws, and more have adopted its provisions in defining their own national GMP rules. But some countries that transitioned had not adhered to the WHO Scheme, as procurement through the PPM provided all guarantees in terms of quality, delivery lead-time and pricing. Managing their own procurement for HIV and malaria drugs, these countries often had to resort to one-time waivers instead of upgrading their protocols to WHO standards, creating uncertainties as to quality over time.

Transitioning countries however have the possibility to use the “WHO Collaborative Procedure for Accelerated Registration” that “enables National Medicines Regulatory Authorities to make use of work already carried out by WHO and to strengthen their

own regulatory oversight processes⁴³. Such procedure shortens the timeframe needed to register WHO prequalified pharmaceutical products to just a few weeks or months⁴⁴.

Simultaneous and uncoordinated transition of global health financing mechanisms might have a worrying impact in terms of the recipient countries' ability to sustain efforts through domestic health expenditure.

- *Procurement:* national laws in countries facing transition do not always allow direct public procurement of HIV and malaria medicines via tenders, as the PPM mechanism was often the sole procurement channel, guaranteeing quality and good pricing. Therefore, national laws must be adapted and include new provisions allowing public procurement of HIV and malaria products through competitive tenders.

Also of concern is the fact that a single “low disease burden” country launching separate tenders is not always attractive to manufacturers. Quantities tendered for are too small to raise commercial interest by pharma companies, who try and set high price tags to maximize profit, or who simply do not respond to public tenders. Several failed tendering procedures were reported in transitioning countries (e.g. in Armenia), leaving them with short or no supplies, and creating potential barriers to the access of HIV treatment by patients.

An additional problem lies in commitments imposed by the EU in Association Agreements with neighbouring European countries, under the World Trade Organisation (WTO) so-called TRIPS agreement⁴⁵. TRIPS imposed increased monopoly patent protection periods for pharmaceutical products in many countries, leading to increased pricing of HIV treatment, and in many LMICs with limited health insurance coverage, to out-of-pocket payments, and when prices soar, to medicines becoming unaffordable to the poorest.

In its negotiations with many LMICs, the EU even attempted to limit countries’ possibility to use TRIPS flexibilities, or to denounce measures legal under TRIPS, such as compulsory licensing⁴⁶, not to mention the inclusion of TRIPS-plus provisions⁴⁷ in bilateral or regional trade negotiations.

Example: Georgia had to commit to the TRIPS agreement as part of the Association Agreement (AA) with the EU signed in 2014, though parties to the AA agreed to “recognise the importance of the Declaration of the Ministerial Conference of the WTO on the TRIPS Agreement and Public Health adopted on 14 November 2001⁴⁸” and commit to “respect the Decision of the WTO General Council of 30 August 2003⁴⁹”.

If successful among piloting countries managing their own procurement on domestic funding, Wambo should become a viable solution to resolve this problem, as well as that of pricing. In the meantime, national legislations on state procurement, regulation of intellectual property and patent rights in transitioning countries have to be adapted to increase flexibility and ensure public procurement of quality medicines at affordable prices, what requires significant work.

- *Pricing:* the PPM lies on framework agreements with pharma companies, whereby negotiated prices allow recipient countries to avoid paying patent rights. As soon as countries have to procure medicines on their own, they lose access to negotiated prices and have to deal with pharma companies on the basis of the TRIPS agreement.

Example: A recent quick comparative study⁵⁰ highlights discrepancies of ARVs’ cost in Georgia (using PPM), Poland and Latvia (state procurement): the unit cost of Abacavir in Georgia (US\$ 0.1832) is 19 times cheaper than in Latvia (US\$ 3.4702) and 20 times cheaper than in Poland (US\$ 3.8125).

Atazanavir is 25 times cheaper in Georgia than in Poland and Latvia (US\$ 0.6 / unit in the former vs. US\$ 15.4167 and US\$ 14.8337 respectively in the latter two).

Monopolies of pharma companies in Poland and Latvia are clear hindrances to the availability of generic medicines on national markets, thereby restricting competition and potential reduction in prices of ARVs. While both countries provide treatment to patients for free through their national health systems, it is not the case of many transitioning LMICs confronted with the same obligation to purchase ARVs or malaria drugs on the international market outside PPM's support.

- *Governance during and after transition*

In countries where the Global Fund operates, Country Coordinating Mechanisms (hereafter CCMs) were put in place. CCMs are "national committees... that submit funding applications to the Global Fund on behalf of the entire country. They include representatives from government, the private sector, technical partners, civil society and communities living with the diseases⁵¹". Their role is to "coordinate the development of the national request for funding, nominate the Principal Recipient, oversee the implementation of approved grants, approve any reprogramming requests, ensure linkages and consistency between Global Fund grants and other national health and development programs⁵²".

While CCMs are generally inclusive and operational as long as the Global Fund provides grants to recipient countries, those have no obligation to maintain CCMs in place as such once the Global Fund pulls out, raising questions as to continued inclusiveness of various stakeholders, transparency and ownership of the response in terms of prevention, treatment, or coordination and information-sharing on the long run. Governments should thus put mechanisms in place to ensure that these issues are duly taken care of during and after transitions.

The new "CCM policy⁵³" approved by the Global Fund Board in May 2018 should help in this venture

by defining core principles of inclusion of affected communities and partnership with external stakeholders with an aim to eliminate stigmatization of and discrimination against those affected by the 3 diseases. It also highlights that "CCMs should work with countries to strengthen the sustainability of the Global Fund financed programs and prepare for transition towards domestic financing."

It however implies strong, well-established, trustful relationships between civil society and government or public stakeholders, whereby local representatives of affected communities and key populations are considered as allies rather than as threats.

Example: in 2016 in Albania, the Government had no plan as to the evolution and possible institutionalization of the CCM, e.g. as an inter-ministerial committee. Also, for the CCM to become sustainable, the CCM Secretariat should have been funded by the Government. Finally, no decision-making or accountability mechanism were thought of to monitor and evaluate achievements of the national HIV strategy and programmes.

V – Possible consequences of simultaneous and uncoordinated transitions

A significant number of countries are going to transition out of international health financing schemes by 2025. Those include funding from the Global Fund of course, but also from GAVI, from the Global Polio Eradication Initiative (GPEI), from IDA⁵⁴ (World Bank) or from PEPFAR, though the latter does not have a transition policy *per se*.

Of all health-financing multilateral initiatives, the Global Fund has 124 countries eligible to its grants, while IDA has 75, and GAVI 74. GPEI counts 73 eligible nations but works mainly in 16 priority countries and PEPFAR has recently designated a group of 13 countries eligible for "accelerated" progress towards epidemic control⁵⁵ among the 31 that receive funding.

A recent study⁵⁶ shows that the simultaneous and uncoordinated transition of these global health financing mechanisms might have a worrying impact in terms of the recipient countries' ability to sustain efforts through domestic health

expenditure. As a matter of fact, GPEI, GAVI, the Global Fund and IDA are all preparing transitions in a number of their beneficiary countries:

- *GPEI*: among all institutions, it is the most worrying foreseen winding down of activities, as the Initiative “directly pays for 145 laboratories and more than 30,000 public health workers around the world, of whom 25-50% also support non-polio functions such as routine immunization, general disease surveillance and supply chain / logistics strengthening⁵⁷”. In January 2017, WHO also emphasized “the need to accelerate opportunities to shift or reprofile the 43% of staff funded by the GPEI who work in polio-free countries⁵⁸”.

In Afghanistan for instance, the GPEI accounted for over 85% of domestic general government health expenditure in 2015⁵⁹. While GPEI prepares for transition in the 16 countries where it currently concentrates its operations⁶⁰, many of which are also recipients of the Global Fund funding, it lets the governments of these 16 priority countries “lead the timely development of national plans that determine what polio functions will be integrated into other existing initiatives, and what may be prioritized or gradually phased out⁶¹”. Of these 16 countries, 8 are considered by the study at high fiscal risk from global health transitions between 2015 and 2040⁶².

- *GAVI*’s transitions happen “relatively early in a country’s economic development⁶³”, though preparatory and accelerated transition phases can last up to 15 years for LICs or LMICs. On the 44 countries that will have to transition from GAVI funding between 2015 and 2040, 30 will already be excluded from GAVI support by 2025⁶⁴, and 20 will have fully transitioned by 2020. But one only has already started to transition from the Global Fund financing (Sri Lanka), and none other will transition from the Global Fund before 2025.

- *IDA*: very few countries are projected to transition from IDA by 2040⁶⁵, though 43 would actually exceed the income threshold⁶⁶ above which IDA financing may not be available, but for which the eligibility to IDA support is unknown. Only Sri Lanka would actually have transitioned by 2025 among countries receiving funding from the Global Fund.

However, a recent working paper suggests that “the countries that graduated from IDA in the previous 2010-15 period had stronger capacity to manage the donor transition than that of upcoming graduates. The upcoming cohort seems to have, on average, lower per capita income, greater indebtedness, weaker capacity to efficiently use public resources, more limited and less effective health systems, weaker governance and public institutions, and greater inequality⁶⁷”.

Afghanistan, Cameroon, DRC, Ethiopia, Nigeria, Pakistan and South Sudan would face high fiscal risk from global health transitions⁶⁸ between 2017 and 2022 according to R. Silverman⁶⁹. But none will transition from the Global Fund before 2025.

It remains that the cumulative effect of multiple transitions might be difficult to handle for countries like Nigeria or South Sudan and could undermine their capacity to manage HIV / AIDS or malaria responses in an attempt to compensate for GAVI’s⁷⁰ or GPEI withdrawal, as well as their ability to co-finance part of the prevention, treatment and care for the 3 diseases.

Minimum coordination among agencies and with countries that will face simultaneous transitions is necessary to avoid fiscal cliffs, immunization or treatment gaps that would inevitably increase dependence vis-à-vis external health financing again and could jeopardize results achieved thus far.



TB patients in Colombo, Sri Lanka. © Global Fund

VI – Conclusion

Since 2016, the Global Fund has given due policy and political consideration to transitions, in an ambition to sustain results achieved in the fight against the 3 diseases over time. However, the emphasis placed on the development of a specific policy field and renewed practice has not translated into additional financial commitment vis-à-vis transitioning countries.

Contrary to other multilateral players, the Global Fund has managed to include disease burden as valid eligibility criteria for funding, above and beyond income thresholds of concerned recipient countries, to mitigate the impact of classifications upgrading. As a result of very flexible transition criteria, the number of countries transitioning from the Global Fund remains minimal (in absolute terms, and also compared with other multilateral funding instruments), and the budget involved is even less substantial.

Indeed, if preparedness to transitions is given adequate attention, transitions processes *per se* are limited in time. If they fail even partially, ongoing transitions would hamper progress towards sustainability as the resurgence of epidemics would impose the Global Fund to intervene again, as it happened in Kazakhstan, Serbia and Montenegro⁷¹.

The timeframe dedicated to transitioning does not allow all countries to adapt national laws and fiscal policies to new requirements in terms of public procurement or quality control of drugs, leaving some with medicine shortages and inadequate public and / or private financing to cover new expenditure.

The question of governance, social contracting, human rights should also be given due care to avoid losing access to key populations if CCMs are dissolved or change membership rules, and civil society demands are put on the back burner.

Finally, synchronisation among international health initiatives is needed to avoid damaging consequences of uncoordinated parallel transition processes.

Transitioning is much of a work in progress, where recipient countries are confronted with multiple

parallel challenges and demands. Support from the Global Fund to manage transitions is now better designed and adapted to individual country needs. But challenges remain, as outlined by the Office of the Inspector General (OIG) of the Global Fund in its recent Audit Report⁷². And all necessary tools that would allow transitions to succeed are not yet in place. Continuous monitoring of transition processes and final evaluations of completed transitions should also be part of the Global Fund and allies set of measures to support transitions and promote sharing of lessons learned and best practices.

VII – Advocacy messages / recommendations for action

Based on this study, Friends of the Global Fund Europe recommends 5 major axes of advocacy, that could support the Global Fund STC policy, and encourage the organization to reinforce its policy in terms of:

- **Procurement and pricing of medicines:** according to the Global Fund, “Wambo.org is available to Global Fund recipients using Global Fund grant funds to procure through the Pooled Procurement Mechanism. Global Fund implementers not registered with Pooled Procurement Mechanism may access a basic wambo.org membership that offers visibility into products and prices but does not allow the organizations to place orders⁷³”.

Making Wambo available as an online procurement platform for transitioning and transitioned countries should be given due consideration, to allow smooth transitions and avoid drugs shortages and sudden increase in prices of LLINS, ACTs, ARVs or viral load diagnostics, among other products, in those countries.

- **Domestic financing and fiscal space:** the capacity of supported countries to expand fiscal space and increase domestic funding on core health services is an essential component of the STC policy. But the analysis of transitioning countries’ fiscal space and projections of

domestic financial contributions to HIV, TB and malaria responses should segregate the structure of additional domestic funding between new fiscal resources, health insurance and innovative financing schemes, and the possible impact of the Global Fund withdrawal on additional out-of-pocket payments that could lead to catastrophic health expenditure for the poorer segments of population, in particular for key and vulnerable people.

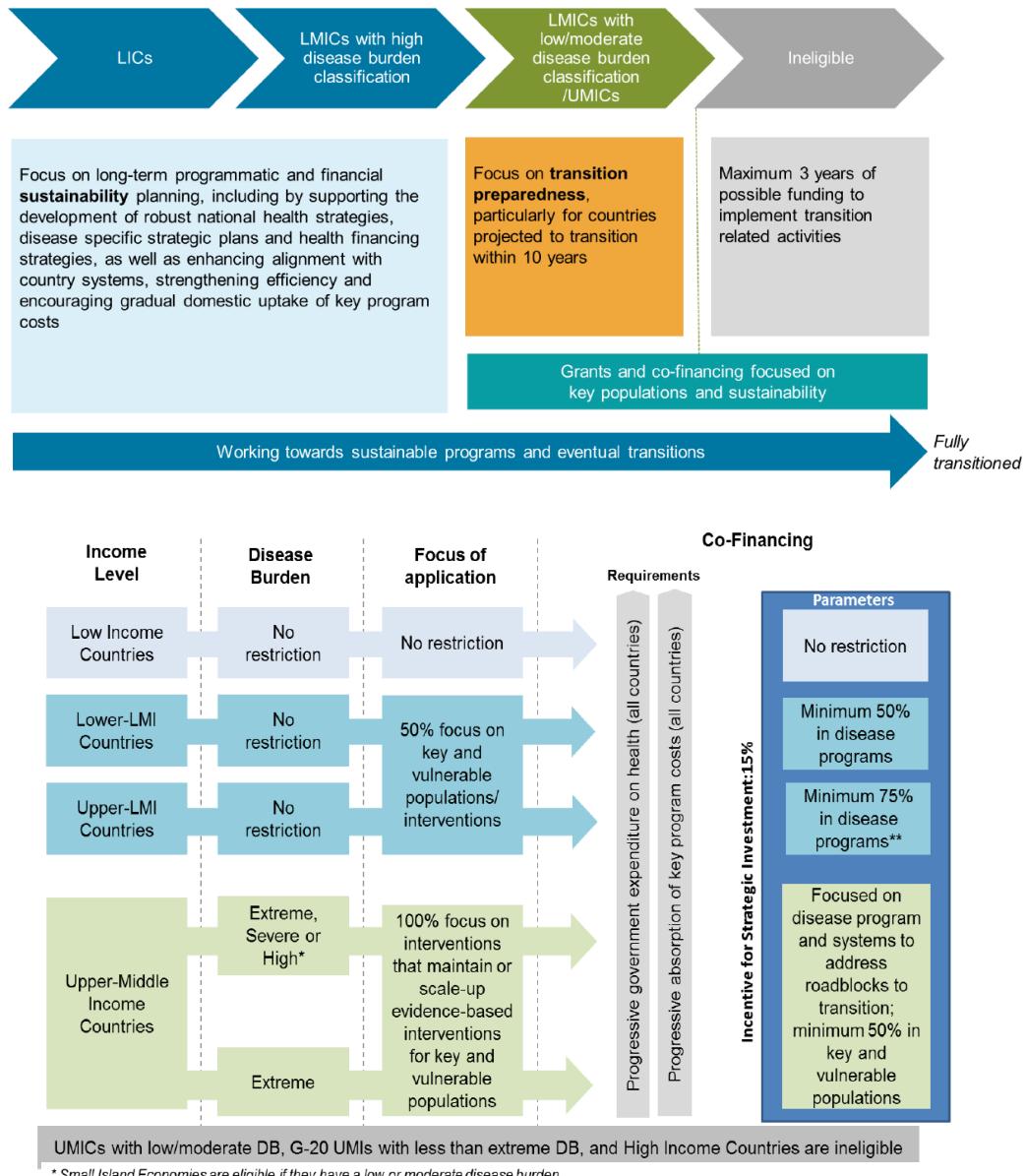
- **Simultaneous transitions:** coordination among health institutions, and with transitioning countries, is paramount to avoid a cumulative negative impact in recipient states. Though few Global Fund recipient countries will experience simultaneous transitions, sequenced and organized transitions with approved planning, budgeting and programming priorities are necessary preconditions for successful combined efforts towards self-reliance and sustainability.
- **Governance and inclusiveness:** while both issues have been duly incorporated into TRAs, as indicators for successful transitions, due consideration should be given to the establishment of an inclusive governance structure based on CCMs' experience as a key factor of success for transitions from the Global Fund financing towards domestic funding. NGOs should remain critical partners in the delivery of services to key and vulnerable populations once transitions are completed and should be closely associated to the management of prevention, treatment and care for marginalised groups. Close monitoring of such process should be incorporated in transition evaluations, and due consideration should be given to maintaining a Global Fund presence (or minimal funding) in those countries where access to treatments of marginalized groups is not safeguarded by national authorities as the transition process comes to an end.

- **Transition Completeness Assessments (TCAs):** based on the findings of Transition Readiness Assessments (the technical components of which should be made available to Board members in first place), the Global Fund and allies should prepare Transition Completeness Assessments that would evaluate achievements of transitions processes based on continuous monitoring, highlight successes and remaining weaknesses, provide recommendations for the future and draw best practices that could easily be shared with new transitioning countries.

Possibly, a peer learning network could be put in place, based on the GAVI's Learning Network for Countries in Transition (LNCT)⁷⁴.

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Annex 1 – Eligibility criteria set by the Global Fund for transition funding



Group of 20 (G-20) Rule: Requires that UMIC G-20 countries must have an 'extreme'⁸ disease burden in order to be eligible, unless they meet the requirements for the exception to the OECD-DAC ODA requirement (described further below).

OECD DAC ODA Requirement for HIV/AIDS: In order for UMICs to be eligible for funding for HIV/AIDS they must first meet the disease burden threshold and secondly be on the Organisation for Economic Co-operation and Development (OECD) Development Assistance Committee (DAC) List of Recipients for Official Development Assistance (ODA).⁹

Exception to OECD-DAC ODA Requirement for funding civil society for HIV/AIDS (formerly referred to as the "NGO Rule"): Allows for UMICs that meet the disease burden threshold who are not on the OECD DAC List of ODA Recipients to potentially be eligible for funding for civil society and non-governmental organizations, if there are demonstrated political barriers to providing services for key populations in that country, as supported by a country's epidemiology.

Small Island Economy (SIE) Exception: allows for UMICs classified by the International Development Association (IDA) as "Small Island Economy Exceptions"¹⁰ to be eligible regardless of disease burden.

Annex 2 – Components and countries in transition from the Global Fund in 2017 - 2019

12 disease components receiving transition funding	Albania (HIV, TB) Algeria (HIV) Belize (TB) Botswana (malaria) Cuba (HIV) Dominican Republic (TB)	Paraguay (TB) Panama (TB) Sri Lanka (malaria) Suriname (TB) Turkmenistan (TB)
6 additional components requested to use or have opted to use tailored transition funding request	Malaysia (HIV) Panama (HIV) Belize (HIV)	Romania (TB) Suriname (HIV) Kosovo (HIV)
Ineligible since 2014-16 allocation and receiving transition funding in 2017-2019	Projected to become ineligible in 2017-2019 based on country move to UMI status and may receive transition funding in 2020-2022	Projected to become ineligible based on country move to UMI status in 2020-2022 and may receive transition funding in 2023-2025
Countries projected to move to High Income status and become ineligible (High Income countries are not eligible for transition funding)		
Projected to become ineligible over 2017-2019	Projected to become ineligible over 2020-2022	Projected to become ineligible over 2023-2025
Panama (HIV)	Malaysia (HIV)	Costa Rica (HIV) Kazakhstan (HIV, TB)

HIV/AIDS	Tuberculosis	Malaria⁸
HIV national prevalence greater than or equal to (\geq) 1% OR Prevalence in a key population greater than or equal to (\geq) 5% ⁹	TB incidence rate per 100,000 greater than or equal (\geq) to 50 OR Proportion of new TB cases who are drug-resistant (resistance to rifampicin) greater than or equal (\geq) to 5 percent.	Mortality rate greater than or equal to (\geq) 0.12 OR Contribution to global deaths greater than or equal to (\geq) 0.25% OR Mortality rate less than ($<$) 0.12 AND Morbidity rate greater than ($>$) 65 OR Country with documented artemisinin resistance

Annex 4 – Thematic assessment areas for Global Fund transitions and related indicators

Thematic Area	Indicators		
POLICY	Indicator 1. Transition Plan: A fully-resourced Transition Plan including harm reduction is proactively guiding transition.	Indicator 2. Legal and Policy Environment: There are no legal or policy barriers to the implementation of harm reduction programs.	Indicator 3. NGO Contracting Mechanisms: Policy or legislation is in place for state and/or municipal governments to contract or grant NGOs for the delivery of harm reduction and other HIV prevention services.
GOVERNANCE	Indicator 4. Sustainable Governance Body: A multi-stakeholder national governance body, including at least government, civil society, and technical partners, is institutionalized to steer the transition process and to continue program planning and oversight after the end of donor funding.	Indicator 5. Program Oversight: The multi-stakeholder national governance body has an oversight function to monitor implementation of the National HIV Program and harm reduction/PWID outcomes are measured as a distinct program area.	Indicator 6. Financial Oversight: The new governance body has an oversight function to monitor expenditure against the planned budget and harm reduction/PWID expenditure is measured as a distinct track of expenditure
FINANCE	Indicator 7. Optimised Budget: Funds for harm reduction are allocated according to an optimized budget scenario.	Indicator 8. Financing for NGOs: Core harm reduction services are funded by the government and delivered by NGOs via grants or contracting mechanisms.	Indicator 9. Procurement Systems: Donor procurement systems are integrated into national systems and assuring reasonable price controls.
PROGRAM	Indicator 10. Standardised Monitoring: Provision of core harm reduction services is monitored according to defined standards.	Indicator 11. Services Coverage: Core harm reduction services are available at levels of coverage recommended by the World Health Organization.	Indicator 12. Partnership with NGOs: NGOs are critical partners in the delivery of harm reduction and other HIV prevention services financed by domestic resources.

Annex 5 – Summary of key success and risk areas for transitions
(as proposed by previous studies and based on the Global Fund experience)

Preparedness and timing

- Develop a roadmap;
- Prefer medium-term duration of about 5 years.

Participation and inclusiveness

- Invest in stakeholder participation;
- Build on the capacity and role of non-state actors in service provision;
- Programme for key and vulnerable populations;
- Discuss governance during and after transition;
- Communicate the plan through high-level diplomacy;
- Involve key financing or high-level political signees.

Implementation and evaluation

- Provide technical assistance throughout the process;
- Ensure ownership of key interventions and integration into national systems;
- Have reliable, strong M&E systems, including transparent process for tracking financial commitments;
- Build reliable and efficient health products procurement and supply chain systems;
- Support mid-term evaluations and provide long-term M&E support.

Finance

- Get inputs from economic data;
- Define clear and monitorable financial targets for all, including donors and government;
- Include salaries, operational costs and trainings in transition plans and beyond;
- Ensure that HIV strategies are costed through inclusive dialogue;
- Define a series of binding incentives, including penalties and rewards, to meet financial commitments or for failing to attain them.

Notes

¹ 35th Board Meeting - The Global Fund Sustainability, Transition and Co-financing Policy - Global Fund/B35/04 – Revision 1 Board Decision

² April 2016, in Abidjan, Ivory Coast

³ “The policy and associated processes are differentiated based on a country’s place within the development continuum according to income level, epidemiological context, disease burden, human rights and gender contexts, and other regional, country, and context specific factors.”

⁴ “Wherever possible, Global Fund requirements related to sustainability and transition should build off already existing systems or processes in country.”

⁵ “Wherever possible, countries should have sufficient notice, time and associated resources to plan for transition.”

⁶ “Country level implementers and the Global Fund should have the flexibility to adapt certain aspects of this policy to particular country and regional contexts for impact and to maintain services.”

⁷ “The world’s Middle-Income Countries (MICs) are a diverse group by size, population, and income level. They are defined as lower middle-income economies - those with a GNI per capita between \$1,006 and \$3,955; and upper middle-income economies - those with a GNI per capita between \$3,956 and \$12,235 (2018). Middle income countries ... represent about one third of global GDP” (source: World Bank).

⁸ Until 2006, upper middle-income countries were only eligible to apply for Global Fund financing if they faced “very high disease burden”, focused on poor and vulnerable populations, and also met additional requirements for co-financing and reliance on domestic resources. At the 13th Board Meeting in April 2006, it was decided to expand eligibility to UMICs if the applicant fell under the “small island economy” exception as classified by the World Bank/IDA regardless of national disease burden, or if there was an HIV sero-prevalence rate of more than five percent in a vulnerable population, regardless of national disease burden.

⁹ Estimate by MSF – Press release at the IAS conference on 22.07.2015.

¹⁰ 97% of TB cases are concentrated in Low and Middle-Income Countries (One campaign) and Africa accounts for 90% of malaria cases.

¹¹ GAVI, the Global Fund, UNAIDS, UNDP, UNFPA, UNICEF, UNITAID, the World Bank and WHO.

¹² The Equitable Access Initiative - 2016

¹³ As above

¹⁴ Contrary to GAVI that uses income status as the sole indicator for transition, irrespective of vaccination coverage.

¹⁵ See annex 1

¹⁶ 37th Board Meeting - Update on Sustainability, Transition, and Co-Financing for Board Information - Global Fund/B37/ 17 Kigali, Rwanda 03-04 May 2017

¹⁷ See annex 1

¹⁸ See annex 3

¹⁹ As above

²⁰ Document for decision of the 39th Board meeting, May 2018

²¹ The Global Fund STC policy, p. 9

²² As above

²³ See annex 4

²⁴ The Global Fund STC policy, p. 11

²⁵ PEPFAR Transitions to Country Ownership: Review of Past Donor Transitions and Application of Lessons Learned to the Eastern Caribbean - Abigail Vogus & Kylie Graff – Global health: Science and practice, 2015

²⁶ As above

²⁷ The Lancet - A UNAIDS–Lancet Commission on Defeating AIDS—Advancing Global Health, 25.06.2015

²⁸ 2014-2016, 2017-2019, 2020-2022, etc.

²⁹ At the 39th Board Meeting of the Global Fund in Skopje in May 2018, the Strategic Committee “discussed the potential for allowing a second allocation of transition funding where one has been deemed insufficient. The SC agreed to maintain the current policy which allows for one allocation of Transition Funding and that any request for a second allocation would remain an exception requiring Board approval.”

³⁰ List in annex 2

³¹ Additional US\$ 4.4 million are also made available under catalytic investments to support transition planning and preparedness.

³² List in annex 2

³³ US\$ 38,409,916 of US\$ 10,300,000,000 country allocations in the 2017 – 2019 allocation period.

³⁴ List in annex 2

³⁵ Global Fund “Focus on Domestic Financing for Health” – December 2017

³⁶ Investment Case for the Global Fund’s 2017-2019 Replenishment, “The Right Side of the Tipping Point For AIDS, Tuberculosis and Malaria” presented on 17 December 2015 at the Global Fund’s Fifth Replenishment Preparatory Meeting in Tokyo, Japan

³⁷ <https://www.theglobalfund.org/en/sourcing-management/health-products/>

³⁸ <http://www.stoptb.org/gdf/whatis/>

³⁹ Access to the GDF direct procurement service is available to countries implementing the DOTS strategy, countries and NGOs approved by the GDF for grants of free TB drugs, countries and NGOs approved by the Global Fund for grants to fight TB, and donors supporting the former categories of countries. Therefore, countries losing Global Fund funding do not necessarily lose access to the GDF direct procurement service.

⁴⁰ The Global Fund – Office of the Inspector General – Audit Report: Global Fund Transition Management Processes – 03.09.2018

⁴¹ <http://wambo.org/home> : “Wambo.org’s mission is to make available at competitive prices all the quality-assured health products – and many of the non-health products – needed to run successful programs to combat HIV, TB and malaria in order to serve the people and communities most in need.”

⁴² http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/

⁴³ Finished pharma products that are WHO-prequalified have been evaluated and inspected according to international standards. But they must still be approved for use by the national authorities of the countries for which market entry is sought. Repeated assessment and inspection of these products take resources and extend the time needed to make them available to patients. WHO has designed this collaborative procedure that allows shorter time for registration, avoid duplication of work and save resources.

⁴⁴ If the medicines regulatory authority of the country in which registration is sought agrees to apply the procedure, it commits to reaching its decision within 90 days of receiving access to the assessment and inspection information, as to whether it will register the pharmaceutical products, and to communicate its decision to WHO and the applicant within a further 30 days (<https://extranet.who.int/prequal/content/collaborative-registration-faster-registration>).

⁴⁵ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member states of the WTO. It sets down minimum standards for the regulation by national governments of intellectual property (IP) as applied to nationals of other WTO member nations. TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994 and is administered by the WTO. It entered into force on 1 January 1995.

⁴⁶ Government-authorised licence to produce and market a cheaper generic version of a patented medicine, at times with payment of a small licence fee to the patent holder.

⁴⁷ TRIPS-plus rules exceed requirements of the TRIPS agreement, limit TRIPS flexibilities and impose stricter intellectual property obligations to states;

⁴⁸ Article 185 of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part

⁴⁹ On 6 December 2005, WTO members approved changes to the intellectual property agreement making permanent the decision on patents and public health originally adopted in 2003. The decision directly transforms the 30 August 2003 “waiver” into a permanent amendment of the WTO Agreement on TRIPS. That waiver made it easier for poorer countries to obtain cheaper generic versions of patented medicines by setting aside a provision of the TRIPS Agreement that could hinder exports of pharmaceuticals manufactured under compulsory licences to countries that are unable to produce them.

⁵⁰ Big Pharma Greed and Artificial Prices – Knocking on Door to Limit Access to HIV Medicines in Georgia - 18.07.2018, Curatio International Foundation

⁵¹ <https://www.theglobalfund.org/en/country-coordinating-mechanism/>

⁵² As above

⁵³ https://www.theglobalfund.org/media/7421/ccm_countrycoordinatingmechanism_policy_en.pdf?u=63667930654000000

⁵⁴ The International Development Association does not support health directly, but investments, be it in terms of grants or loans, in social services, gender, infrastructure or public services contribute to improving access to health.

⁵⁵ Haiti, Uganda, Zambia, Rwanda, Malawi, Kenya, Tanzania, Zimbabwe, Lesotho, Ivory Coast, Swaziland, Botswana and Namibia.

⁵⁶ Projected health financing transitions: timeline and magnitude – Rachel Silverman – Centre for Global Development – working paper 488, July 2018

⁵⁷ As above

⁵⁸ WHO Executive Board 140th session of 27.01.2017

⁵⁹ As a percentage of GDP

⁶⁰ Afghanistan, Angola, Bangladesh, Cameroon, Chad, Democratic Republic of Congo, Ethiopia, India, Indonesia, Myanmar, Nepal, Nigeria, Pakistan, Somalia, Sudan, and South Sudan.

⁶¹ GPEI Polio transition: information note, February 2018

⁶² Afghanistan, Cameroon, Chad, DRC, Ethiopia, Nigeria, Pakistan and South Sudan

⁶³ Projected health financing transitions: timeline and magnitude – Rachel Silverman – Centre for Global Development – working paper 488, July 2018

⁶⁴ Sao Tome, Ivory Coast, Bangladesh, Timor-Leste, Nigeria, Lao P.D.R., Kenya, Djibouti, Ghana, RDC, Sudan, Solomon Islands, India, Angola, Papua New Guinea, Indonesia, Armenia, Guyana, Bolivia, Nicaragua, Moldova, Sri Lanka, Azerbaijan, Georgia, Bhutan, Vietnam, Uzbekistan, Honduras, Mongolia and Kiribati.

⁶⁵ Bolivia, Dominican Rep., Grenada, Maldives, Sri Lanka and Vietnam.

⁶⁶ GNI per capita of US\$ 1,165 in 2018

⁶⁷ Transitioning from foreign aid: is the next cohort of graduating countries ready? Gavin Yamey, Diana Gonzalez, Ipchita Bharali, Kelly Flanagan, Robert Hecht Working Paper, 03.2018 – Centre for Policy Impact in Global Health & Pharos Global Health Advisors

⁶⁸ High risk is defined as: facing one or more transitions during the same period, and with total annual funding from global health institutions exceeding 10% of government health expenditure as a percentage of GDP.

⁶⁹ Projected health financing transitions: timeline and magnitude – Rachel Silverman – Centre for Global Development – working paper 488, July 2018

⁷⁰ Among Gavi’s implementing countries, co-financing has increased more than six-fold from US\$ 21 million per year in 2008 to US\$ 133 million in 2016 with over 90% using domestic resources to pay for co-financing, but without prior coordination with other multilateral health institutions on the potential impact that the use of these domestic resources may have on the funding of other health programmes.

⁷¹ Only the HIV component became eligible again in the 3 countries.

⁷² The Global Fund – Office of the Inspector General – Audit Report: Global Fund Transition Management Processes – 03.09.2018

⁷³ <https://www.theglobalfund.org/en/sourcing-management/wambo/>

⁷⁴ <https://lnct.global/>