



Médecins Sans Frontières Perspectives on Wambo.org

Background

Wambo.org, launched this year by the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), is described as “a global marketplace offering a growing range of quality-assured, lifesaving medicines and health-related commodities at competitive, transparent prices.” Under development by the Global Fund since October 2014, it is already available to Global Fund grant recipients with a stated aim of being made available to public health partners.

The Global Fund is a critical actor within the public health community to improve the affordability and availability of medical tools – in particular medicines and diagnostics – for low- and middle-income countries. Today the Global Fund spends approximately USD 2 billion per year, and is one of the largest purchasers of drugs to treat HIV, tuberculosis (TB) and malaria. The Secretariat of the Global Fund intends for wambo.org to play a central role in the procurement efforts of the Global Fund and beyond.

MSF still has a range of questions and concerns regarding wambo.org that have been raised to the Secretariat. In the last year, as wambo.org has been gradually introduced, other entities and actors have also started to examine wambo.org, including potential donors and internal accountability and oversight functions in the Global Fund, such as the Technical Evaluation Reference Group (TERG) and the Office of the Inspector General (OIG).

This note summarises some of the key questions, concerns and reflections based on Médecins Sans Frontières (MSF)’s understanding of wambo.org.

Scope of Wambo.org

Since its launch in January 2016, wambo.org has already introduced bednets, antiretrovirals (ARVs) and artemisinin-based combination therapies (ACTs), with multiple orders placed by Mozambique, Bangladesh, Indonesia, Solomon Islands and Zambia. Depending on the order volumes, these three categories may eventually account for up to 76 percent of total commodity purchases enabled by the Global Fund. Over the next 18 months the Global Fund has indicated that a range of other health products will also be gradually introduced to wambo.org, including HIV diagnostic tools (viral load, early infant diagnostics and rapid diagnostic tests), TB diagnostics (GeneXpert, Hain, MGIT), malaria rapid diagnostic tests, drugs to treat opportunistic infections and condoms. The Secretariat is also anticipating adding other health products.

For TB drugs, a Memorandum of Understanding signed with the Stop TB Partnership on 17 June 2016 does not require the Global Drug Facility (GDF) to use wambo.org as a management tool for its orders. It will be up to GDF to carry on using its current tool or to have GDF Country Supply Officers manage supply through wambo.org.

By the end of 2016, 60 countries that use the Global Fund’s pooled procurement mechanism (PPM) will be trained to place orders through wambo.org. The Secretariat has also noted that it will run a parallel ordering system until the end of 2016, at which time wambo.org is expected to

become the ordering mechanism for all PPM countries. Beginning in 2017 Global Fund-eligible countries not using the PPM may also have the opportunity to use wambo.org. For products available in limited quantities that require greater oversight and coordination, such as paediatric ARVs, the Secretariat has indicated that existing coordination mechanisms (e.g. the Paediatric AIDS Product Working Group) will continue to play its role and work with the team managing wambo.org. In fact, other products that are difficult to procure or are new to the market have also been added to this working group, which has been renamed the AIDS Products Working Group (APWG).

Wambo.org is not intended to have any ‘limiting criteria’ as to which purchasers can use the website, as long as orders are linked to public health actors. As it relates to other major purchasers of global health products, the GDF is in early discussions to consider use of wambo.org (as described above), the UN Population Fund will make its tendering contracts for condoms available via wambo.org, and the Global Fund has expressed an interest to expand the use of the site to vaccines, though vaccine purchases on behalf of many countries is already managed by UNICEF.

Finally, the Secretariat has expressed a strong preference to spinning off wambo.org as a ‘global public good’. According to the Clinton Health Access Initiative (CHAI), the Global Fund and CHAI are discussing the possibility that CHAI may manage aspects of wambo.org in the future. CHAI is already lightly supporting countries with the implementation of wambo.org through its extensive networks. There is no official timeline for externalizing the website, though the Board is expected to be presented with a decision from the Secretariat as to whether or not to ‘spin off’ the website.

Potential Benefits of Wambo.org

Prior to discussing a range of risks, challenges and concerns with wambo.org, it is worth noting some of the proposed benefits and additional aspects of the website. Recently, the Secretariat has noted the following as benefits of using the site for commodities procurement:

- Generate economies of scale, and thus more leverage on prices, with increased volumes channelled through the system
- Improve tracking of volumes procured
- Offer an enhanced range of products
- Improve market visibility
- Provide an increased audit trail and increased transparency
- Improve reliability of supply
- Catalyse uptake of innovative products
- Generate improved data for analytics

The Secretariat has also noted additional benefits to MSF, including streamlined order processing – especially to avoid multiple procurement channels and multiple suppliers, promotion of local manufacturers as long as they meet quality standards set by the Global Fund, and provision of cost estimates for transport as part of a broader effort for the Global Fund to have its own contracts with freight forwarders to reduce the costs associated with ‘middle-men’ involved in moving products from sellers to buyers.

Risks, Concerns and Challenges related to Wambo.org

Despite the suggested benefits, MSF has a number of questions and concerns regarding wambo.org that have already been raised with the Global Fund Secretariat. Many of those have

been acknowledged by the Secretariat but have not been answered. Broadly speaking, it is still not clear how wambo.org fits into a wider market shaping strategy alongside the work on procurement for impact and other market shaping activities undertaken by the Secretariat. However, it is now understood that the PPM will apply wambo.org for order placement and processing, with both continuing to operate in parallel until the end of 2016.

Seven current concerns and questions regarding wambo.org are described in more detail below.

1. The Global Fund did not undertake proper risk analysis up front in establishing wambo.org and there are risks and challenges being raised through multiple channels that have not yet been addressed.

Wambo.org was not established under the auspices of any particular dialogue or engagement with the relevant committees and Board of the Global Fund. Instead, the Secretariat used ‘seed’ funding from the Gates Foundation for the development of wambo.org. Since then, risks and concerns have been raised by internal departments and oversight committees associated with the Global Fund, which to MSF’s knowledge, have not yet been addressed. In particular:

- The independent Technical Evaluation Reference Group (TERG) of the Global Fund has previously identified certain risks and challenges that should be addressed, including: (1) the risk that private companies could use wambo.org to buy and sell for profit (see below for clarification on this risk); (2) transactions purchased through wambo.org should be made public with only minimal access restrictions applied to certain parameters; and (3) the need to develop terms and conditions for selling via wambo.org that prevents ‘cream-skimming’ – namely manufacturers providing a product to only the high value or low-cost customers, while disregarding less profitable customers. The Secretariat has since shared that any purchaser willing to purchase through wambo.org needs to be registered, which would exclude private companies to buy and sell for profit.

As to these points, the Secretariat has noted that “it acknowledges there exists a number of risks necessitating further analysis related to the spin off. The Global Fund and partners have identified risks related to governance models, intellectual property and commercial analysis which could inhibit its acceptance and success as a global public good.”¹ While the Secretariat has stated it will address these risks in 2016, it does not appear that this has occurred in full, including in the most recent updates furnished by the Secretariat. According to the Secretariat, a comprehensive risk analysis will not be possible until they receive external funding for such an analysis.

- A recent report by the Global Fund’s Office of the Inspector General (OIG) reviewed the roll out of wambo.org and found a high level of non-competitive procurement of services and resources, non-compliance with procurement rules and weakness in design and execution of contracts:

“In light of the high level of non-competitive procurements and ineffective compensatory controls in place, as well as non-compliance with the procurement framework in cases

¹Global Fund 34th Board Meeting. Development of an e-marketplace for the procurement of public health commodities. 16-17 November 2015, Geneva, Switzerland. Available from: http://www.theglobalfund.org/documents/board/34/BM34_24-DevelopmentofanEmarketplaceforProcurementofPublicHealthCommodities_Report_en/

where competition happened, the OIG rates the procurement of goods and services under the wambo project as ineffective.”²

These findings, notably, are at an early stage of the roll out of wambo.org, when such risks and shortcomings should be easier to avoid. If wambo.org continues to grow, oversight and accountability – internal and external – will only become more challenging.

2. Wambo.org is not a sufficient investment for transitioning countries.

At present wambo.org is presented as the most tangible form of procurement assistance provided to countries transitioning out of Global Fund support. The challenges facing transitioning countries related to sourcing and procurement of key health products are multiple, including: (a) facing higher prices for new medicines and diagnostics due either to high prices charged by pharmaceutical companies or due to low capacity and poor procurement practices by governments; (b) inadequate quality assurance systems at the national level; (c) increased national procurement of commodities or market segmentation and inefficiency with procurement; and (d) drug shortages due to poor tendering practices or failed procurement, manufacturing shortages or unwillingness of companies to register their medicines in particular markets.

Presently, it is not clear how wambo.org will address these challenges. As further discussed below, wambo.org may not be able to address the concerns of high prices for new medicines unless manufacturers agree to extend such prices to transitioning countries through long term agreements. Inadequate quality assurance measures and poor tendering practices of governments could possibly be improved through wambo.org, yet it is far from certain that governments will adopt the platform when it switches to local procurement (see below).³ It is also not clear if wambo.org can overcome all quality assurance concerns or poor tendering practices. Wambo.org will also not be able to overcome a lack of registration by manufacturers in commercially unattractive countries that are transitioning from Global Fund support or manufacturing shortages (nor should wambo.org be expected to do so).

Ultimately, the problem lies not so much in what wambo.org is unable to do but the lack of other support, investments and forward planning by the Secretariat to support countries that will transition from the Global Fund. With the exception of wambo.org and the possible introduction of health technology assessments, it does not appear that the Global Fund has put in place any other real investments to support ‘transitioning countries’ as it relates to procurement and market shaping, despite the challenges such countries will face.

3. Wambo.org does not address any of the legal, technical or political barriers that prevent countries from getting access to more affordable prices, nor will it improve price negotiation tactics on behalf of buyers.

The Secretariat has not offered any formula for overcoming the intellectual property-driven barriers that undermine the ability of countries to secure the lowest price. Generally, the Global Fund has been unwilling to consider any major role to support countries to use

² Global Fund Office of the Inspector General. Audit Report Wambo.org. 13 June 2016. Available from : http://www.theglobalfund.org/documents/oig/reports/OIG_GF-OIG-16-016_Report_en/

³ For TB medicines, the GDF is exploring with its procurement agent – the International Dispensary Association – whether they could bid upon national public tenders on their behalf. The Global Fund Secretariat has indicated that IDA could bid through wambo.org but even here this can only function if countries agree to organise their national public tenders through wambo.org.

flexibilities and safeguards under global trade rules to overcome patent barriers, or to speak out when trade agreements or other measures threaten to undermine affordability.

In fact, wambo.org will not bring any change to the negotiating approach of the Global Fund towards manufacturers as long term agreements (LTAs) will remain. In reality, the focus of wambo.org is to better manage the flow of orders and order management that will be now be performed on one platform in lieu of relying upon different ordering channels.

In recent years, MSF has been concerned that the Global Fund is more amenable to accept tiered prices for new medicines. The Secretariat has indicated that it will not accept tiered pricing for medicines, and that one price per medicine will be offered based on its negotiations. Yet in other discussions the Global Fund has noted that the lowest price may only be a reference price, and that higher prices for specific purchasers may be necessary. The willingness or unwillingness for the Global Fund to accept tiered prices is particularly important for other large, multilateral purchasers that seek to use wambo.org since many are committed to avoiding tiered prices. The GDF, for example, recently refused to accept a tiered price for the new TB medicine delamanid, though this still led to a high price for the drug, which is now partly responsible for undermining scale-up and use.

Other concerns and questions remain. While LTAs may be able to continue obtaining one price through efforts of the Global Fund, it is not clear if that price will be available to non-Global Fund countries that may use the service, including those countries that have recently transitioned from Global Fund support. At best, such prices will only be possible on an ad hoc basis. For medicines that may eventually be introduced to wambo.org, but for which the Global Fund does not negotiate LTAs, it seems that manufacturers may be free to charge tiered, unaffordable prices and that the Global Fund or any future supervising entity will be unable to prevent such transactions from taking place.

For diagnostic technologies, a range of additional costs beyond the platform, including service and maintenance contracts, are currently included in the viral load tender. This has also included recent ‘innovations’ to reduce costs for diagnostics, including reagent rental and/or leasing for laboratory devices and equipment. Insofar as the Global Fund is able to facilitate such transactions, the output of such a tender can be made available on wambo.org. The long-term question is whether or not such a tender will be available to countries that are not within the remit of the Global Fund.

4. The Global Fund cannot assure that the platform will be taken up broadly by countries, in particular those that must switch to local procurement systems.

While in the short term it appears the Global Fund can rely upon the PPM to include a range of countries in wambo.org, there are potential difficulties for the site to be adopted by countries that must purchase drugs through their own procurement systems. The Secretariat has assured MSF that it is holding discussions at the national level to ensure that wambo.org is compatible with national public tender processing, so that it may become a possible platform for suppliers (e.g. procurement agents, manufacturers) to bid. Nevertheless, some countries will have to change their national laws to permit e-transactions. Furthermore, it is not clear how governments that use local funds with a preference to purchase locally (a growing trend) will use wambo.org without risking unfair competition between products of possibly uneven quality standards. Wambo.org will not be able to facilitate local tenders; instead governments can only upload tenders.

Before wambo.org is used beyond the Global Fund supply system, a detailed analysis of at least one year of its operations should be made public that identifies any potential corrective measures and controls that should be established before wambo.org becomes an ordering tool used at a broader scale.

5. Wambo.org will be unable to address problems related to shortages (due to multiple causes) and itself may increase the risk of shortages.

Shortages have continued to create problems across a range of key medicines. They have included manufacturing shortages (last year for lopinavir/ritonavir (LPV/r) and currently a high risk for delamanid); shortages resulting from poor planning or tendering practices by governments; and shortages induced by pharmaceutical companies that do not register a product in particular markets (and are the single or one of a few suppliers). The Global Fund has stated that wambo.org will improve supply sustainability without offering any explanation of how that will be accomplished, in particular given that many of the aforementioned concerns with supply cannot be resolved by the website. While the Global Fund should be credited with recent efforts to reduce stock-outs, measures to overcome shortages, including fostering competition to expand the number of suppliers must be prioritised and not considered ‘resolved’ by merely pointing to wambo.org.

Furthermore, there are concerns that wambo.org could *induce* shortages since there is a risk of too many orders emerging at the same time that neither a governing mechanism nor the suppliers could anticipate or respond to. While the Global Fund sourcing team takes capacity constraints into account when allocating orders, oversight may not be feasible if wambo.org is transformed into a ‘global public good.’ On the other hand, the Global Fund has indicated it will be able to accommodate small quantity orders even though there may be a minimum order quantity and some impact in terms of delivery lead time.

Finally, in part to respond to the possibility of increased demand, another challenge for wambo.org will be to ensure the platform’s flexibility to introduce new, qualified suppliers whenever needed and without limiting orders to those manufacturers that have already signed long term agreements.

6. Quality assurance may still present challenges that the Global Fund should address.

The Global Fund has offered up a plan to ensure quality assurance for all products purchased over wambo.org. All HIV, TB and malaria medicines that may eventually be purchased through the site will have to comply with the current Global Fund Quality Assurance (QA) policy. For drugs to treat opportunistic infections (OI), for which the Global Fund QA policy does not apply, the Global Fund will use the International Dispensary Association (IDA) OI catalogue, and will out-source such QA work to IDA. The Global Fund has indicated that it will expand its capacity by early 2017 to oversee QA activities for drugs to treat opportunistic infections. MSF hopes that the Global Fund can avoid ‘out-sourcing’ specific QA activities to an external party in the future.

7. Additional concerns related to wambo.org

Alongside the concerns mentioned above, MSF notes two additional ones: (a) transparency to external stakeholders of how the website will function and decisions that have been taken do not appear to have been prioritised as opposed to internal transparency and auditing, and (b) there is no clear plan or capacity in place for Global Fund or future operators to overcome monopsony.

The ‘Future’ of Wambo.org

As noted above, the Global Fund has continually supported the idea of spinning off wambo.org as a global public good, which may be hosted at a different organisation or as an independent entity. Any such ‘spin off’ of wambo.org requires careful, deliberate action. Procurement and market shaping require the active engagement of many institutions, governments and third parties. Within such a crowded landscape, wambo.org could have a positive impact but it could also create difficulties that the pharmaceutical industry could exploit and it could introduce more challenges and problems than it seeks to solve.

The Global Fund and others should consider the following when deliberating about a ‘spin-off’ of wambo.org:

- Period of incubation within the Global Fund: MSF supports a slow, deliberate multi-year incubation of wambo.org to ensure it functions properly, is de-risked and is broadly understood and accepted and key problems and risks are addressed. Additionally, to provide support to countries over the long term, the Global Fund PPM team should continue running periodic tenders for categories for qualified health products, negotiating LTAs with awarded manufacturers and managing suppliers.
- Governance and oversight of wambo.org: Given the intimate relationship of wambo.org with core functions of government, MSF would expect that there would be adequate oversight by governments and civil society. Multilateral institutions, and in particular the World Health Organization, must have a clear role to ensure that the technical functions of wambo.org can be successfully integrated, accountable and managed.
- Ultimate functions of wambo.org: There should be a clear delineation of the functions of wambo.org. If and when procurement expands on wambo.org, many challenges which governments and global health agencies already encounter through ‘off-line’ procurement, including quality assurance, avoidance of shortages, tendering strategies and legal barriers, will emerge. Users may seek wambo.org to address these challenges. Yet there are already a range of global health agencies (and government agencies) that can and do address these problems. The current and future managers of wambo.org must consider which functions to leave to institutions and agencies best suited to address such challenges, and how to ensure that wambo.org supports their efforts to ensure timely, affordable access to quality medical tools.

Conclusion

As noted above, wambo.org must fit within and enhance an over-arching strategy that seeks to improve negotiations and thus prices, while also facilitating competition. Without such an over-arching strategy, wambo.org will be able to do little more than improve price transparency and visibility on volumes. MSF hopes that wambo.org can eventually meet all of the stated ambitions of the Global Fund. More importantly, if it cannot, and if many of the risks and challenges remain, MSF strongly encourages the Global Fund and other global health agencies and donors to reconsider their approach, not only to wambo.org, but also as it relates to other measures that the Global Fund should support to improve access to medical tools. Access to medicines requires the active investment, intervention and support of governments, global health institutions and civil society. An online marketplace may reduce some of the ‘friction’ involved with procurement, but if it comes at the cost of support, engagement (technical and political) and oversight, then it will ultimately cause more problems than it seeks to solve.