

OPERATIONAL FRAMEWORK

ARV Procurement Working Group

June 2016

1. Background

The Global Fund Board Decision in May 2011 (Twenty-Third Board Meeting) on Market Shaping Strategies identified the need to “secure the paediatric ARV market” among other strategic interventions on ARVs¹. The UNITAID/CHAI Paediatric Project, which entailed a single procurement mechanism for paediatric ARVs in 40 countries has phased out, with countries transitioned to various financing and procurement mechanisms. This had therefore raised concerns on the risk of an already fragile market reverting to a more fragmented state.

As part of its Market Shaping Strategy, the Global Fund Board mandated the Secretariat to adopt a more coordinated approach to the procurement of paediatric ARVs. This resulted in the establishment of the Paediatric ARV Procurement Working Group (PAPWG) in September 2011, comprising of various partners and stakeholders.

At its meeting in January 2016, the group recognised that many supply challenges had been improved for paediatric ARVs as there had been significant consolidation around a limited number of “optimal” products. However supply challenges remained for some new products and a few “limited-use” paediatric ARVs. The group approved the expansion of the scope of the Working Group to additional products that face similar market conditions - in the first instance, low volume but WHO recommended adult ARV formulations, and soon-to-launch new adult ARV products during their early launch period. This is aligned with key strategies of most of the member organisations² to support the introduction of new optimal products including recent investments to support new product introduction from UNITAID³ and USAID⁴. This Operational Framework is to define the mechanism by which the various partners and stakeholders will work in a collaborative manner to achieve the objectives of securing and sustaining the ARV market place. The Operational Framework is a working document, whereby the various partners and stakeholders will contribute, collaborate and align where feasible, market dynamics-related and procurement activities to improve the accessibility and sustainability of the ARV market.

2. Goal

The goal of the ARV Procurement Working Group is to secure the market to ensure timely and consistent access to ARVs in order to sustain and scale-up HIV treatment. The group has been tracking previously agreed upon key performance indicators. These may be updated as necessary with the expanded scope.

3. Set up

Two distinct but inter-linked groups were identified within this mechanism, with market coordination and support, being the cross-cutting sub-group.

3.1. The ARV Procurement Working Group (APWG) is the umbrella group which includes all stakeholders and partners of various interests and mandates in supporting the collective efforts towards securing the market.

The **Working Group** which includes all stakeholders is a collaborative network that provides the platform for:

1. Creating awareness with partners and stakeholders
2. Aligning procurement
3. Securing financing
4. Engaging manufacturers / suppliers
5. Providing in-country support

¹ <http://www.theglobalfund.org/Knowledge/Decisions/GF/B23/DP21/>

² <http://www.theglobalfund.org/Knowledge/Decisions/GF/B34/DP08/>

³ http://unitaid.org/images/Resolutions/eb23/RESOLUTION_3-2015-e.pdf

⁴ <http://www.grants.gov/web/grants/view-opportunity.html?oppId=276936>

6. Promoting product optimization
7. Coordinating / collaborating with similar working groups

Working Group Members (as of April 2016)⁵

- Clinton Health Access Initiative (CHAI)
- Enfants et VIH en Afrique (EVA)
- Ethiopia Pharmaceuticals Fund and Supply Agency (PFSA)
- Global Fund to Fight AIDS, TB and Malaria (The Global Fund)
- Global Health Supply Chain (GHSC) Procurement and Supply Management (PSM) Program
- Kenya Medical Supply Authority (KEMSA)
- Organization of Eastern Caribbean States (OECS)
- Pan American Health Organization (PAHO)
- Partnership for Supply Chain Management (PFSCM)
- President's Emergency Plan for Aids Relief (PEPFAR)
- UNTAID
- United Nations Children's Fund (UNICEF)

Working Group Observers (as of April 2016)

- Early Infant Diagnostics Working Group (EIDWG)
- Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
- Drugs for Neglected Diseases initiative (DNDi)
- International AIDS Society (IAS)
- Medicines Patent Pool (MPP)
- Médecins Sans Frontières (MSF)
- United Nations Development Programme (UNDP)
- World Health Organization (WHO)

Approach

Five key areas of collaboration are defined:

1. Promotion of product optimization by emphasizing the use of the WHO HIV treatment guidelines and the IATT list - and taking newly developed prequalified products into account
2. Country support to strengthen forecasting and procurement planning
3. Alignment of procurement activities
4. Consultations with manufacturers
5. Information sharing

3.2. The Procurement Consortium: Within the Working Group, a sub-set of the members will form the Procurement Consortium. The Consortium as a sub-group will focus on the alignment and coordination of procurement operational activities in-order to achieve the coordinated procurement approach defined and agreed upon by the APWG.

⁵ As new members join the list will be updated.

The following organizations participate in the Procurement Consortium:

- Clinton Health Access Initiative (CHAI)
- Ethiopia Pharmaceuticals Fund and Supply Agency (PFSA)
- Global Fund to Fight AIDS, TB and Malaria (The Global Fund)
- Global Health Supply Chain (GHSC) Procurement and Supply Management (PSM) Program
- Kenya Medical Supply Authority (KEMSA)
- Organization of Eastern Caribbean States (OECS)
- Pan American Health Organization (PAHO)
- Partnership for Supply Chain Management (PFSCM)
- President's Emergency Plan for Aids Relief (PEPFAR)
- UNITAID
- United Nations Children's Fund (UNICEF)

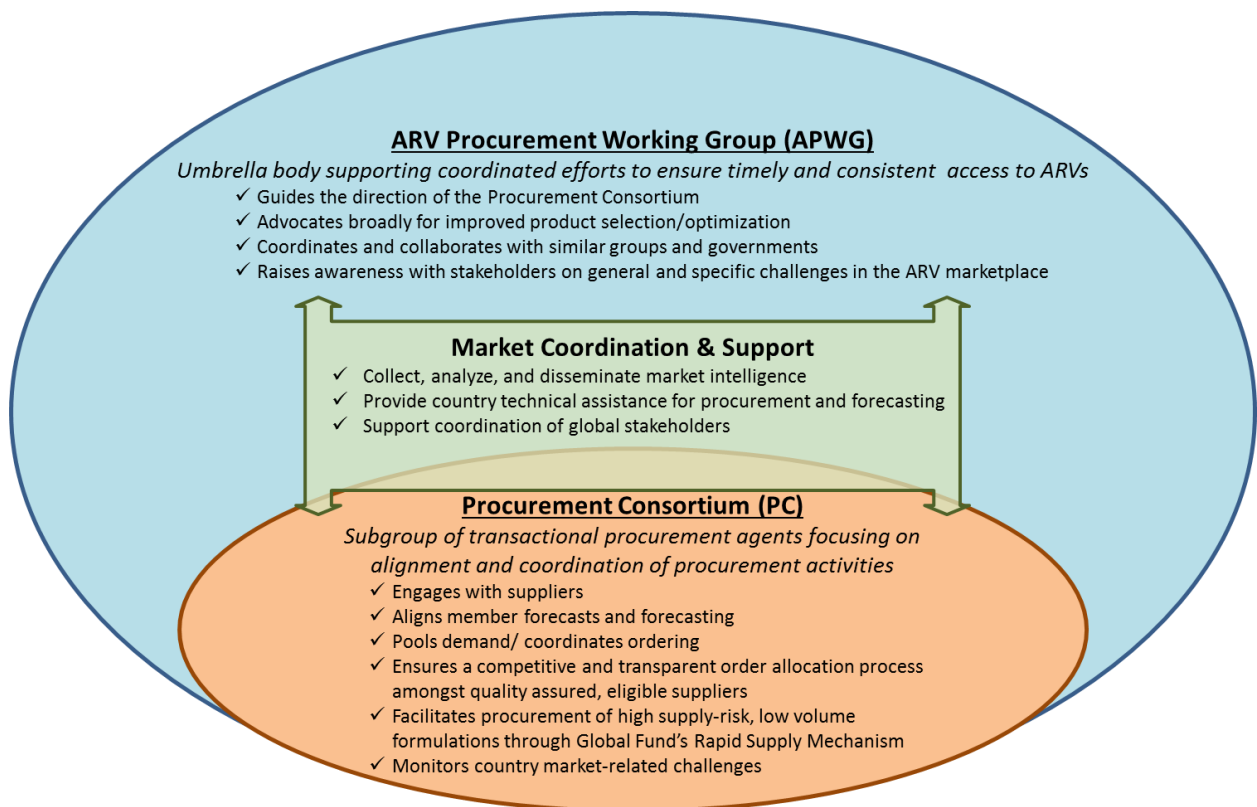
All members of the Procurement Consortium will facilitate the alignment of and/or collaboration on activities related to:

- Forecasting
- Product Selection and Optimization at the transaction level, providing advice on recommended optimal products
- Pooling of procurement and / or coordination of ordering
- Consultations with ARV manufacturers / suppliers on e.g. on lead times, prices
- Targeted support to countries on forecasting and procurement planning. The Consortium will raise flags on specific ARV challenges faced by countries. The Working Group can then discuss possible support to be provided.
- Collecting and disseminating market intelligence within the Consortium and the Working Group. This can be used as part of the advocacy efforts and information sharing by the Working Group.

3.3. *Market Coordination and Support* will be a cross-cutting component to provide the support to both groups to be led by CHAI under its UNITAID funded IPMA project.

4. Roles and Responsibilities

Three core components are identified within the Operational Framework with the defined roles and responsibilities and linkages as illustrated below:



Whilst the roles and responsibilities are defined on the previous page, it is expected that the various organizations involved with this initiative will contribute to all activities as much as possible within their respective mandates to ensure activities are undertaken in a coordinated manner.

For each core component, a lead and support institution is identified for facilitation and coordination of activities identified as the core mandate of the group. It is expected that the lead institution is responsible of coordinating and implementing activities including meetings and reports as defined under each group, with the necessary support from the related institutions.

5. Working Method

5.1. Working Group

Lead: Global Fund supported by UNITAID

The ARV Procurement Working Group will organize one face-to-face meeting per year and regular teleconferences to provide updates.

The Working Group will develop a joint information-sharing platform; the mode, method and frequency will be agreed upon by the Group. The platform will also be used for sharing information on operational procurement activities and market support activities.

Certain Working Group reports could be shared with a wider audience for example on a quarterly or bi-annual basis on behalf of the Working Group and branded as Working Group products. These reports can be made available online via the websites of Working Group members.

5.2 Procurement Consortium

Lead: Rotating between the Procurement Agencies

The Procurement Consortium will organize annual face-to-face meetings back to back with the Working Group and monthly teleconferences in between meetings.

5.3 Market Coordination & Support

Lead: CHAI supported by PFSCM

Market Coordination & Support will be linked to collecting and disseminating market intelligence and providing technical support to countries. CHAI will continue to share their quarterly “Product & Supply update on paediatric HIV commodities” with the Working Group in addition to any other market forecasts developed. Bi-annual APWG Newsletters will be shared with interested stakeholders.

6. Representation

The ARV Procurement Working Group is not a legal body, and membership is based on “collaborative spirit”. Implementation of activities within the Procurement Working Group and Procurement Consortium shall therefore be conducted within the mandate and regulations of the individual organizations.

Representation is by individual organizations and no single member of the group can take over representation of the Working Group or Consortium, without the endorsement of the Working Group and Consortium.

7. Confidentiality

Whilst it is envisaged that most of the documents shared through this Working Group will be public information, each party shall keep confidential, any documents, data and other information provided to it through the Working Group and/or Consortium, if designated "Confidential".