

## CASE STUDY:

### Sustaining Paediatric ARV Supply Security with the Paediatric ARV Procurement Working Group

THE PAEDIATRIC ARV MARKET, DESPITE GROWTH OVER THE LAST 10 YEARS, REMAINS RELATIVELY SMALL AND AT RISK. TO ADDRESS PROCUREMENT AND ACCESS CHALLENGES IN THIS PARTICULARLY FRAGILE MARKET, THE PAEDIATRIC ARV PROCUREMENT WORKING GROUP (PAPWG) WAS CREATED TO LEAD GLOBAL COLLABORATION AND COORDINATION AMONGST KEY PARTNERS INCLUDING THROUGH PROCUREMENT PROMOTING OPTIMAL PRODUCTS AND REGIMENS. LEARNINGS FROM THIS WORKING GROUP CAN BE APPLIED TO OTHER COMMODITIES WITH SIMILAR MARKET CONDITIONS. THE GROUP IN FACT EXPANDED ITS MANDATE IN 2016 TO INCLUDE ADULT ARVS WITH SIMILAR CHALLENGES, AND TO SUPPORT THE SCALE-UP OF NEW OPTIMAL REGIMENS AND FORMULATIONS.

#### OVERVIEW

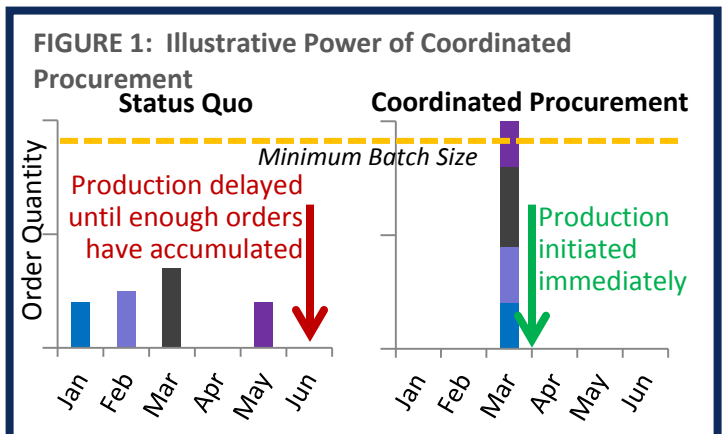
THE SUPPLY OF PAEDIATRIC ANTIRETROVIRALS (ARVS) HAD HISTORICALLY BEEN HIGHLY UNRELIABLE, WITH MANUFACTURING LEAD TIMES RANGING FROM A FEW WEEKS TO MORE THAN A YEAR FOR SOME PRODUCTS, RESULTING IN AN UNRELIABLE SUPPLY AND RISK OF STOCK-OUTS THAT LEFT CHILDREN LIVING WITH HIV WITHOUT TREATMENT, AND HAMPERING EFFORTS TO INCREASE THE NUMBER OF CHILDREN ON ANTIRETROVIRAL TREATMENT (ART):

- Before 2007, procurement of ARVs mostly consisted of fragmented orders from multiple countries for 60+ largely duplicative formulations and dosages
- Beginning in 2007, UNITAID supported the Clinton Health Access Initiative (CHAI) through the Paediatric HIV/AIDS Treatment Project, to make significant progress in stabilizing the global supply of paediatric ARVs and ensuring treatment scale-up
- The theory of change for the effort was that consolidating and coordinating global demand would confirm to generic manufacturers that a commercially viable market existed and encourage production of batches on a regular schedule
- As the UNITAID-CHAI Project progressed, lead times stabilized, optimal formulations for HIV positive children – including dispersible fixed dose combinations (FDCs) – became available, and prices decreased by ~85% for commonly-used paediatric regimens such as zidovudine + lamivudine + nevirapine
- In 2011, the highly centralized ordering that enabled these advances was coming to an end with the completion of the time-limited catalytic UNITAID-CHAI Project
- Funding for paediatric ARVs was taken up by national programs and major donors such as the Global Fund to Fight AIDS, TB and Malaria (Global Fund) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

#### THEORY OF CHANGE

Coordinated procurement with regularly scheduled ordering times can significantly reduce lead times and avoid stockouts. Sharing market intelligence across procurers ensures both visibility and confidence for suppliers in the fragile paediatric ARV market, and supplier accountability. Thus, supply disruptions can be minimized even as the paediatric ARV market is shepherded towards optimal formulations that most benefit patients.

- There was, however, no mechanism to maintain coordination of procurement amongst partners to reinforce and ensure continued market stability
- Recognition of this risk and endorsement of the Global Fund's Market-Shaping Strategy during the 23<sup>rd</sup> Board Meeting in May 2011 led to the creation of the Paediatric ARV Procurement Working Group (PAPWG)
- The PAPWG aimed to maintain and grow the gains made by the UNITAID-CHAI Project, and, by ensuring coordination between a diverse group of major buyers including donors, implementers, and countries
- UNITAID enabled CHAI's continued multi-faceted support for the group through the Innovation in ARV Paediatric Market Access (IPMA) grant. Through the IPMA grant, CHAI's support ranged from analytical to technical and secretarial



## APPROACH

THE PAPWG WAS ABLE TO TAKE A LEADERSHIP ROLE IN MAINTAINING THE PAEDIATRIC ARV MARKET:

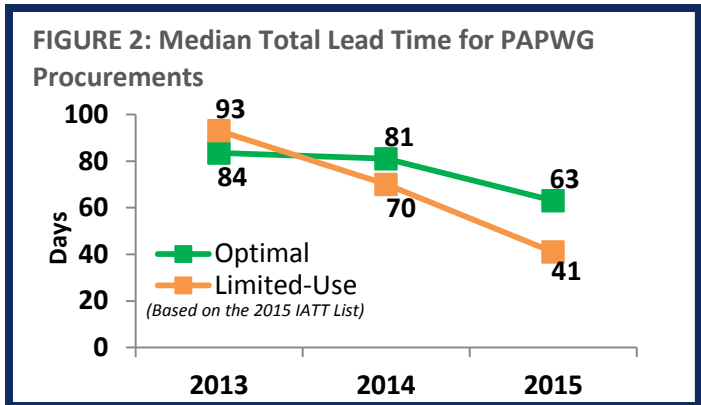
- Although procurement itself was no longer consolidated/pooled in a *centralized* manner, the group sought to ensure that order placement was *coordinated* so that there would not be production delays (*Figure 1*)
- Membership comprises various partners and stakeholders including the major financiers and procurers of paediatric ARVs, as well as technical bodies. This also includes large national procurers like the Kenya Medical Supply Authority (KEMSA) and Ethiopia’s Pharmaceuticals Fund and Supply Agency (PFSA)
- The Procurement Consortium is a sub-group of those PAPWG members engaged directly in transactional procurement or market analysis, such as the Partnership for Supply Chain Management (PFSCM) and the United Nations Children’s Fund (UNICEF)
- The PAPWG adopted many of the same approaches used during the UNITAID-CHAI Paediatric Project, including:
  - **Consolidated ordering** around quarterly calendar dates to ensure any one product had sufficient orders to fulfil a supplier’s minimum batch size
  - **Rolling-up the forecast** across procurers for 12-month anticipated demand to help suppliers with market visibility and production planning
  - **Rationalization of optimal product** selection using the [formulary list](#) developed by the Interagency Task Team (IATT) on Prevention of HIV Transmission in Pregnant Women, Mothers and their Children, and WHO guidelines on ART
  - **Regular communication with suppliers**
  - **Collaboration with partners** to support improvement of country paediatric forecasting, procurement practices, and supply management
- Critical areas of agreement that enabled traction of the PAPWG included:
  - **Building confidence to share** and consolidate procurement data from members for demand transparency
  - Preserving the ability to **adjust buying plans**, while **adhering to individual member policies**
  - Building **consensus on key performance indicators for the group** as a whole

- **Establishing relationships with suppliers as a single entity**, working together to discuss opportunities and challenges in the paediatric market

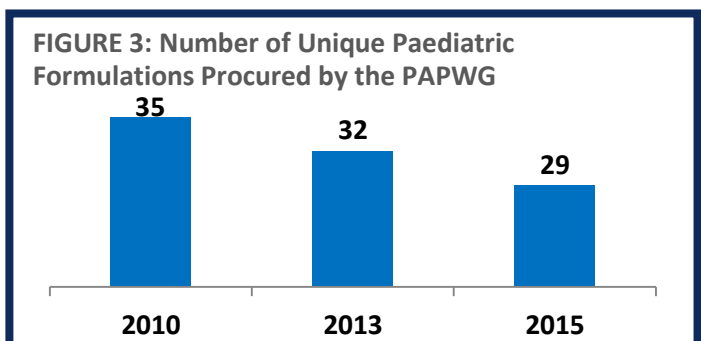
## IMPACT

THE PAPWG HAS ENABLED GREATER VISIBILITY INTO THE PAEDIATRIC ARV MARKET THAN ANY ONE PARTNER COULD ACHIEVE ALONE :

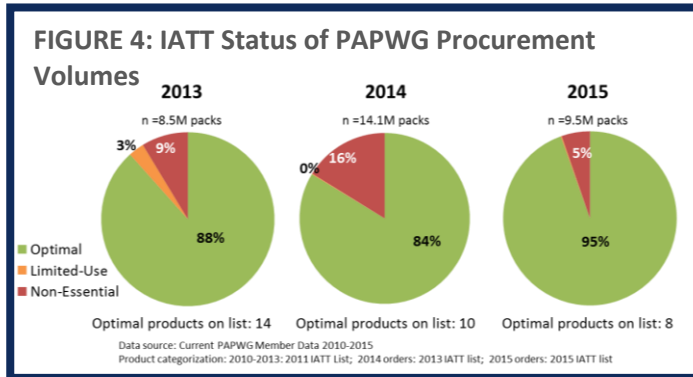
- Anticipated demand forecasts for paediatric ARVs allow the PAPWG to strategically manage demand
- Suppliers are given directional volumes from the group for the **total near-term requirements which allows for commercial planning**
  - This is especially useful for new product introductions and phase-out of legacy formulations based on WHO recommendations
  - Additionally, low-volume ARVs which are clinically important for treatment can be closely tracked for continued availability



- Continued coordination of ordering around the **quarterly order cycle schedule has helped reduce lead times** (*Figure 2*)
  - Set order cycle dates were communicated to a broad group of procurement bodies. Efforts are still underway to ensure consistent and concentrated ordering around these dates
  - Several suppliers have noted the dates and begun to plan production runs around the established schedule



- The PAPWG has continued to **reduce fragmentation through streamlined product selection**, thereby reducing the overall number of formulations in the procurement mix (*Figure 3*)
- Streamlining was accomplished by **guiding procurement towards the IATT formulary list**, and following guidance as updates were published
- The proportion of **optimal ARVs increased to ~95%** of total 2015 procurement volume even as the number of products classified as “Optimal” shrank from 14 to 8 (*Figure 4*)



- The PAPWG has been a **key partner to support the transition** of new ARV treatment formulations and regimens as described by the WHO, IATT, and UNICEF Policy Briefs. Examples include:
  - Phase-out planning for stavudine and didanosine
  - Encouraging use of solid FDCs over oral solutions
  - Supply planning for the new dosage form of lopinavir/ritonavir (oral pellets)
- The PAPWG has been able to effectively **raise awareness** with all stakeholders on general and specific challenges in the paediatric ARV marketplace
- The PAPWG continually aggregates and **disseminates market intelligence information** and collectively acts as one voice to suppliers, as required
  - Countries, suppliers, and other stakeholders can refer to the PAPWG as an authoritative source of market insights regarding paediatric product updates and introduction/discontinuations

## LESSONS LEARNED

AGREEMENT TO WORK WITHIN THE PARAMETERS OF EACH ORGANIZATION WAS A CRITICAL STEP TO THE SUCCESSFUL LAUNCH OF THE PAPWG:

- The broad resolution approved by the Global Fund’s Board in May 2011, needed to be focused in definition so that **each member organization could work within their individual mandates**

- Clarifying that the PAPWG would not act as a single buying group ensured each member could maintain its own policies and contracts

- **Defining data needs with harmonized definitions** from each member was key to establish upfront. The PAPWG established universal definitions so that procurement data and reporting indicators measured were accurate and comparable across organizations
- **Early linkage to the IATT**, a diverse group of technical advisors, ensured that both its optimal formulary recommendations and country procurement decisions were grounded in clinical need and the practicalities of ARV availability in resource-limited settings

## FUTURE OUTLOOK

THE PAPWG CONTINUES TO GROW AND EVOLVE OVER TIME. ITS PRINCIPLES CAN BE APPLIED TO OTHER COMMODITIES WITH SIMILAR MARKET CONDITIONS:

- As a Working Group, the ability to plan, coordinate, and execute on critical activities will lead to better accountability to preserve the integrity of reliable ARV supplies for this fragile market. Showing suppliers that a stable paediatric market exists can help to stimulate innovation of new drugs for children
- Through its newsletter, the Working Group continues to share procurement best practices and market insights for those stakeholders facing procurement challenges, including country programs and procurement systems
  - This includes communication of recommended quarterly order cycle dates
- The approach taken by this Working Group can be applied to other commodities and health interventions and serve as a model mechanism for others to follow
  - The breadth and depth of the intervention can be modulated by size and critical need of the market place
- In 2016, the PAPWG expanded its scope to include additional adult ARVs facing similar market conditions and was renamed the ARV Procurement Working Group (APWG) to reflect the expanded scope and mission
  - The group’s original objectives and operating principles continue to guide the work and ensure increased market stability

<b>Working Group Members (as of July 2016)</b>	<b>Working Group Observers (as of July 2016)</b>
<ul style="list-style-type: none"><li>– Clinton Health Access Initiative (CHAI)</li><li>– Enfants et VIH en Afrique (EVA)</li><li>– Ethiopia Pharmaceuticals Fund and Supply Agency (PFSA)</li><li>– Global Fund to Fight AIDS, TB and Malaria (The Global Fund)</li><li>– Global Health Supply Chain (GHSC) Procurement and Supply Management (PSM) Program</li><li>– Kenya Medical Supply Authority (KEMSA)</li><li>– Organization of Eastern Caribbean States (OECS)</li><li>– Pan American Health Organization (PAHO)</li><li>– Partnership for Supply Chain Management (PFSCM)</li><li>– President’s Emergency Plan for AIDS Relief (PEPFAR)</li><li>– UNITAID</li><li>– United Nations Children’s Fund (UNICEF)</li></ul>	<ul style="list-style-type: none"><li>– Drugs for Neglected Diseases initiative (DNDi)</li><li>– Early Infant Diagnostics Working Group (EIDWG)</li><li>– Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)</li><li>– International AIDS Society (IAS)</li><li>– Medicines Patent Pool (MPP)</li><li>– Médecins Sans Frontières (MSF)</li><li>– United Nations Development Programme (UNDP)</li><li>– World Health Organization (WHO)</li></ul>

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More information on the PAPWG (now APWG) is available [online](#). For further information or assistance please contact:

- [Martin Auton](#) (The Global Fund), APWG Chair
- [Wesley Kreft](#) (PFSCM), APWG Procurement Consortium Chair
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