Supporting Sustained Supply through the Coordinated Procurement of ARVs

ARV Procurement Working Group Update

June 2016

Introduction

The Paediatric ARV Procurement Working Group demonstrates how collaboration and coordination amongst global partners can effectively address procurement challenges in a particularly fragile market and achieve tangible improvements to market sustainability. As described further in this newsletter, the group has expanded its scope to include certain adult products and to coordinate procurement volumes to support the scale-up of eagerly awaited new products and formulations for adults and children, some of which are recently approved and others expecting approval over the next few years.

- Christopher Game, Chief Procurement Officer, The Global Fund

New Scope and Expansion of the Working Group

Introducing the APWG

The Paediatric ARV Procurement Working Group (PAPWG) and before it, the UNITAID Paediatric HIV/AIDS Project, were formed with the objective of improving the supply security of paediatric antiretrovirals (ARVs). In response to challenging market conditions the PAPWG aimed to coordinate procurement of paediatric ARVs, strategically manage demand, reduce fragmentation through streamlined product selection, and support transition of countries to the IATT formulary list of optimal and limited-use products.

The PAPWG's approach to improving supply security has been so successful that some paediatric ARVs no longer require the same level of support that they have previously received. Thus, in January 2016, the group approved the expansion of the scope of the PAPWG to include additional products facing similar market conditions. This is aligned with the Global Fund's Market Shaping Strategy and efforts of other member organisations, such as UNITAID and USAID, to support the introduction of new optimal products for both adults and children.

The work of the group will be expanded to include select adult ARVs and will continue to support at-risk paediatric ARVs. The revised list of closely tracked products was introduced ahead of the first 2016 quarterly order cycle. In mid-2017, members will reflect on successes and lessons learned from this expansion to move forward with additional product categories beyond HIV as necessary.

To reflect its broadened mission and scope, the PAPWG has adapted its name from the "Paediatric ARV Procurement Working Group (PAPWG)" to the "ARV Procurement Working Group (APWG)".

New Observing Members

The APWG welcomed four new observing members in 2016:

Enfants et VIH en Afrique (EVA): Réseau Enfants et VIH: EVA is a regional network that brings together paediatricians from francophone Africa and from France. It aims to improve coverage and access to quality ARV for children through research; capacity building of health care providers; advocacy and partnerships or strategic alliances. EVA's current programmes cover: Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Côte d'Ivoire, Mali, Morocco, Niger, Senegal, Chad, and Togo.

United Nations Development Programme (UNDP): UNDP has partnered with the Global Fund to Fight AIDS, TB, and Malaria since 2003, supporting large-scale programs in countries with limited ability to receive and manage health funds. UNDP works with the Global Fund, other key partners such as UNICEF, and national partners to strengthen health systems and ensure effective delivery of HIV, TB, malaria, and other health

program, with a focus on poor and marginalized communities and countries with complex operational environments.

USAID Global Health Supply Chain Procurement and Supply Management Program (GHSC-PSM): USAID's GHSC-PSM provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security. We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, including providing ARVs and other HIV/AIDS-related commodities under PEPFAR and working to ensure their long-term availability.

Medicines Patent Pool (MPP) is a United Nations-backed organization, established in 2010, offering a public-health driven business model that aims to lower the prices of HIV medicines and facilitate the development of better-adapted HIV treatment and special formulations for children, through voluntary licensing, patent pooling and coordinating and product development. More information available at: http://www.medicinespatentpool.org/about/

Procurement Consortium Efforts and Successes to Date

The APWG met in January 2016 in Geneva to review the group's progress and goals and hear the latest updates and market intelligence from APWG stakeholders.

A recent analysis based on agreed upon key reporting indicators demonstrated the significant progress that the group has made since it was founded. For example, optimal and limited-use formulations formed 95% of PAPWG procurement in 2015, compared to 87% in 2012 and only 69% in 2010 (before the creation of the IATT list). Likewise, lead times for optimal products decreased by 26% between 2013 and 2015. These factors have resulted in the decline and even discontinuation of some non-essential products due to the lack of demand and IATT preference for optimal formulations.

In addition, while not explicit goals of the PAPWG, 85% of paediatric formulations are provided by multiple generic manufacturers and the price of leading paediatric ARVs have decreased. There has also been consolidation around fewer products from 31 ordered in 2012 to 29 in 2015.

The APWG continues to share market intelligence and information with stakeholders and participated in the AMDS meeting in March 2016. This meeting brought together major buyers and suppliers of ARVs and exchanges key market and ARV forecast information. During this meeting, the APWG presented its anticipated demand forecast that was developed using consolidated forecast information from member procurement agents.

Quarterly Order Cycle Coordination

The APWG Procurement Consortium consolidates the submissions of ARVs around fixed quarterly order cycle dates. These dates have been agreed upon by the APWG and shared with suppliers and other stakeholders.

The aggregation of orders for at-risk ARVs around this schedule allows manufacturers to plan production accordingly. Furthermore, consolidated product orders are more likely to meet the required minimum batch size and thus, potentially avoid extended lead times associated with sub-batch orders.

Countries procuring these ARVs independently or through non-APWG procurement agents are encouraged to use the quarterly order dates below to ensure a reliable supply of paediatric ARVs.

Deadline for Orders to be placed with Suppliers*	
Q2 2016	**1 July 2016**
Q3 2016	**30 September 2016**
Q4 2016	**20 December 2016**
Q1 2017	**31 March 2017**
Q2 2017	**30 June 2017**
***Orders should be submitted to procurement agents at least 6 weeks before these dates**	

Scheduled ordering four times a year is especially recommended for low volume paediatric and adult ARVs, a list of these prioritised products is provided:

Prioritised Paediatric ARVs (2016 IATT status)	
Optimal	ABC/3TC 120/60mg dispersible
	LPV/r (80/20 mg/ml) solution
	LPV/r (40/10 mg) oral pellets
	NVP (50 mg) dispersible
	RAL (100 mg)
Limited-Use	3TC (50mg/5ml) solution (100ml)
	ABC (60 mg) dispersible
	ATV (100mg)
	AZT (60 mg) dispersible
	RTV (25 mg) tablets
Non-Essential *(limited-use on 2015 list)*	AZT (50mg/5ml) solution (240ml)
	ATV 150 mg

Prioritised Adult ARVS
ABC 300 mg
ATV 300mg
AZT 300mg
DRV 400mg
DTG 50mg*
EFV 400mg FDCs*
RAL 400mg
RTV 100 mg
TDF 300 mg
3TC 150 mg
**when generics are SRA-approved*

IATT Update

Updated Optimal and Limited-Use List to be Available in 2016

The optimal and limited-use formulary list for the selection of optimal paediatric ARVs dosage forms has been revised by the Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children (IATT) following recent updates to the WHO Guidelines. A draft was presented at the March 2016 AMDS meeting in Geneva and the list will be published after launch of the new 2015 consolidated guidelines from WHO.

The optimal list is designed to provide the minimum number of ARV formulations needed to provide all currently recommended WHO paediatric preferred 1st and 2nd line regimens across all paediatric weight bands. Provision for drugs needed for WHO recommended paediatric alternative regimens are no longer provided on the optimal list but were considered for inclusion on the limited-use list. Additionally, the limited-use list includes dosage forms that may be needed during special circumstances such as paediatric 3rd line, alternative 2nd line, TB co-infection and regimen transitions within programmes.

The 2016 Paediatric ARV Optimal Formulary and Limited-use List reflects currently available paediatric ARV dosage forms including newly approved paediatric products. The 2016 IATT Optimal Formulary has been updated to include: lopinavir/ritonavir (LPV/r) 40mg/10mg oral pellets and raltegravir (RAL) 100mg chewable scored tablets. AZT/3TC/NVP triple fixed-dose combination (FDC) scored dispersible tablets have been transitioned from the optimal formulary to the limited-use list to reflect increasing uptake of preferred first line regimens using LPV/r or efavirenz (EFV). The limited-use list has been updated with the inclusion of RAL 25mg chewable tablets for younger children, ritonavir (RTV) 25mg heat stable tablets for the boosting of unco-formulated PI's as well as the removal of TDF 200mg tablets, atazanavir (ATV) 150mg capsules and all etravirine (ETR) containing formulations.

For more details on the revised IATT list please contact Martina Penazatto (penazzatom@who.int), Nandita Sugandhi (nsugandhi@clintonhealthacces.org), or Wesley Kreft (wkreft@nl.pfscm.org).

ARV Supply Updates

Cipla Oral Solution Update

Cipla has moved the production of its paediatric ARV oral solutions to their new facility in Indore, India. Products such as NVP and 3TC oral solution have been successfully transferred and approved by both the US FDA and WHO PQ. For 3TC oral solutions Cipla expects to receive variation approval in June/July of this year. Cipla has decided to discontinue production for the following oral solutions:

- Abacavir (as sulfate), Oral solution 20mg/ml, bottle of 100ml
- Abacavir (as sulfate), Oral solution 20mg/ml, bottle of 240ml
- Lopinavir/Ritonavir, Oral solution 80mg/20mg per ml, bottle of 160ml
- Nevirapine, Oral suspension 50mg/5ml, bottle of 25ml

We also take this opportunity to remind buyers that WHO and the IATT Optimal Formulary List recommend the use of dispersible tablets wherever possible for antiretroviral treatment. Cipla has dispersible tablets for all the oral solutions and has started commercial production for the recently approved LPV/r (40mg/10mg) oral pellets. This situation with the supply of oral solutions could be an opportune time for programmes to consider switching suitable patients to dispersible tablets and the LPV/r oral pellets. Dispersible tablets offer several advantages over oral solutions ensuring better adherence, longer shelf live (in use) and substantially lower transportation costs.

LPV/r Oral Pellet Update

Cipla's new LPV/r (40/10 mg) oral pellets, approved in May 2015, have gained interest in several countries seeking an alternative LPV/r formulation to the existing oral solution and (100/25 mg) non-crushable, non-dispersible, paediatric tablets. Following a positive validation assessment, commercial production for the oral pellets has begun with the first supplies going to those countries with standing orders. A fact sheet detailing product information and a supply planning policy brief are available online for those seeking further information.

ABC/3TC (120/60 mg) Informational Brief Available

In order to disseminate additional information regarding the junior (120/60 mg) FDC of abacavir and lamivudine (ABC/3TC), the APWG has released an informational brief highlighting the key benefits of introducing this product in countries. The brief will be available online shortly.

Using ABC/3TC (120/60 mg) can significantly decrease pill burden in children by at least 50% compared to existing formulations of ABC, particularly when used as a once daily regimen. The reduced pill burden may improve patient adherence, prevent sub-optimal dosing, and simplify the supply chain at no additional cost to national HIV programs.

Supply Security Related to Procurement of Largely Phased-out Products

A number of countries are still procuring ARVs or formulations that have largely been phased out of treatment guidelines and are often no longer recommended by WHO. These include didanosine and saquinavir for adults, as well as several non-essential paediatric formulations (e.g. non-dispersible tablets) or extremely low volume products such as oral solutions for abacavir, efavirenz, and lamivudine (where dispersible fixed dose combinations are preferred).

Programs are reminded that such products or formulation may not only be sub-optimal for patients, but are also increasingly difficult to procure as they are not regularly produced and long lead times could be expected. There is also a risk of discontinuation of some of these products. Programs are urged to proactively consider moving to more optimal formulations where supply can be assured.

New Product Availability

Some new optimal and limited-use products have received SRA approval since last newsletter:

Mylan: RTV 25 mg tablets have received WHO PQ approval. This new dose of RTV has tentatively been classified as limited-use by the IATT formulary committee for the 2016 list.

Macleods: LPV/r (100/25 mg) heat-stable tablets have received US FDA approval. This is the fourth supplier of this optimal product and now has US FDA and WHO PQ approval.

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