

Innovative packaging for ARVs

Options presented by manufacturers

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DISCLAIMER

“Products presented in this document are for illustrative purposes only and do not represent an endorsement of any sort by the Global Fund of particular products”

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1) Background

WHO Guidelines on differentiated care

Table 6.1. Diversity of care needs for people living with HIV

People living with HIV	Care package elements
People presenting when well	Adherence and retention support
People with advanced disease	Clinical package to reduce mortality and morbidity
Stable individuals	Reduced frequency of clinic visits and community ART delivery models
Unstable individuals	Adherence support, viral load testing, switch to second- or third-line ART if indicated, monitoring for HIV drug resistance (HIV-DR)

6.7 Frequency of clinical visits and medication pick-up

NEW

Recommendations

- Less frequent clinical visits (3–6 months) are recommended for people stable on ART (strong recommendation, moderate-quality evidence).^a
- Less frequent medication pickup (3–6 months) is recommended for people stable on ART (strong recommendation, low-quality evidence).^b

^a When routine clinical consultations are due, they should be coordinated with planned medication pickup to reduce visit frequency.

^b ARV supply management should be strengthened to ensure availability of ARV medicines and prevent stock-outs in the context of less frequent medication pickup.

2) Shrink wrapping and multi-month packaging

- **Shrink wrapping**
 - Innovative packing mechanism where tablet bottle packs are packed without outer/secondary cartons
 - Can be multi-month packaging or monthly packaging
- **Multi-month packaging**
 - Packing of 90's count or 100's count of tablets in one bottle to cover a three month period of treatment

Shrink wrapping

- 12 bottles in ONE tray shrink wrapped



New pack: Efavirenz 600mg + Lamivudine 300mg + Tenofovir 300mg tablets

Courtesy of Aurobindo

Shipper Packing

- 8 trays in a shipper (i.e. 96 bottles in a shipper)
- 10 leaflets bundled and on top of E-flute box (which is around 10% of the total quantity)



New pack: Efavirenz 600mg + Lamivudine 300mg + Tenofovir 300mg tablets

Courtesy of Aurobindo

3) Overall benefits of shrink and multi-month packaging

- **Clinical**
 - Less clinical visits to pick up medication
 - Reduced financial costs of travelling to the clinic
 - Higher retention in care for stable patients
 - Indirect cost savings i.e. medical personnel would be able to attend to other patients
- **Environmental**
 - Minimize the use of materials and resources throughout the product lifecycle
 - Green packaging
 - Reducing paper consumption
- **Economic**
 - Savings in terms of transportation costs including freight cost, inland transportation, handling and clearance charges etc
 - Number of packs per 40 ft container can be increased up to 42% i.e. for every 3 containers you can save 1 container in transportation
 - Savings in terms of space in the warehouse
 - In transit damage can be minimized as no monocarton is used
 - Easy to handle shrink packaging



Advantage of Shrink Packing over Present Packing

Particulars		Present Packing	Shrink Packing - Option 1**	Shrink Packing - Option 2**
No. of packs per Shipper		90	96	96
No. of Pallets per container		46	46	46
Volume utilized		53 CBM	53 CBM	53 CBM
Stacking per container	1 st Layer	23 pallets x 24 shippers x 90 pack = 49,680 packs	23 pallets x 24 shippers x 96 packs = 52,992 packs	23 pallets x 24 shippers x 96 packs = 52,992 packs
	2 nd layer	23 pallets x 12 shippers x 90 pack = 24,840 packs	23 pallets x 18 shippers x 96 packs = 39,744 packs	23 pallets x 24 shippers x 96 packs = 52,992 packs
Maximum shippers per Container		828	966	1104
Total packs per container		74,520	92,736	105,984

**Stacking customization is possible as per the shelf space in warehouse.

Container size: 40 Ft.

Pallet & container packing – saving space

- Maximum of packs that can be filled in one 40ft' container are either 92'736 or 105'984 packs



Courtesy of Aurobindo



Courtesy of Aurobindo

*New pack: Efavirenz 600mg + Lamivudine 300mg + Tenofovir 300mg tablets

Estimated volume enhancement for TLE with and without carton

	Existing (With Carton) Standard TLE shipment	Proposed (Without Carton)
Packs per Shipper	84 (7X6,2 Layers)	112 (8X7,2 Layers)
Length of Shipper	415	415
Width of Shipper	370	360
Height of Shipper	280	255
Pallets Per Container	46	46
Container	Reefer 40FT Container	Reefer 40FT Container
Total No. of Shipper/Pallet	18	24
Pallet Size	120X80	120X80
No. of shippers /Container	46 x 18 = 828 shippers	1104
Packs per 40 feet container	828 x 84 = 69'552	1104 x 112 = 123'648

** The volume increase per 40ft container is more than 75% which is significant

Tray packing

- Removing carton to tray packing of containers.



Courtesy of Hetero

TENOFOVIR /Emtricitabine/Efavirenz (300/200/600 mg) tabs of 28's being supplied to South Africa in carton less packing.

Earlier Packaging Configuration

A) Product with mono Carton and with a leaflet inside



Courtesy of Mylan

Current Packaging Configuration

A) Product without Carton



Courtesy of Mylan

TENOFOVIR /Emtricitabine/Efavirenz (300/200/600 mg) tabs of 28's being supplied to South Africa in carton less packing.

Earlier Packaging Configuration

B) Cartons are packed loose or Shrink Bundle in shipper



Courtesy of Mylan

Current Packaging Configuration

B) Shrink Bundle configuration



Courtesy of Mylan

TENOFOVIR /Emtricitabine/Efavirenz (300/200/600 mg) tabs of 28's being supplied to South Africa in carton less packing.

Earlier Packaging Configuration

C) 108 bottles per shipper



Courtesy of Mylan

Current Packaging Configuration

C) 144 bottles with one PAD per shipper



Courtesy of Mylan

4) Regulatory variation approval

- Suppliers are required to file for regulatory variation approval at global and national level
- Various suppliers have already filed for these variations and approvals are in process
- Filing initiated in the following countries: Malawi, Zimbabwe, Zambia, Kenya, Ethiopia, Uganda, Nigeria, Tanzania, Mozambique, Ghana
- Multi-pack filing also initiated for some countries
- Hetero – Re-submission of TLE to WHO and USFDA. Studies for additional pack sizes are running in parallel

Approval status filed by Mylan

TLE	Shrink pack / Multi-month packs			Approved		Approval Date of submission
	30's Carton Less – Approved	100's Carton Less – Approved	90's Carton Less – Approved	WHO/FDA	Country Regular Authority	
Ethiopia	Yes	Yes	No		FMAHACA	Carton less variation sent on 6/5/16
Ivory Coast	Yes	Yes	No		DPML	Carton less variation sent on 31/5/16
Kenya	Yes	Yes	Yes		PPB	Carton less variation sent on 9/9/16
Malawi	Yes	Yes	Yes		PMPB	Carton less variation sent on 14/6/16
Mozambique	Yes	Yes	Filed		DPML	Carton less variation sent on 11/5/16
Namibia	Yes	Yes	Yes		NMRC	Intimation is required. Already Done
Tanzania	Yes	Filed	Filed		TFDA	Carton less 100's hard copy of variation sent on 6/5/16. Submission Proof awaited
Uganda	Yes	Yes	Yes		NDA	Variations Sent & Intimated as approvals
Zambia	Yes	Yes	Yes		ZAMRA	Carton less variation sent on 2/8/16
Zimbabwe	Yes	Yes	Filed		MCAZ	Carton less variation sent on 24/6/16
Nigeria	Yes	Filed	Yes		NAFDAC	30's approved on 5/8/16 ,90's submitted on 15/7/16.100's will be filed in Nov

Picture illustration with regulatory leaflet attached on individual bottle



Courtesy of Aurobindo



Courtesy of Aurobindo

5) Next steps

- Confirmation from PRs that they are ready to implement the shrink packaging and/or the multi-pack packaging
- Manufacturers to work with PRs for registration in the countries