**Supplement to**

Impact of US Food and Drug Administration registration of antiretroviral drugs on global access to HIV treatment

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# Data extraction, quality checks and standardization

### Data extraction and quality check

Data from all sources were extracted by one investigator. USFDA data were checked for accuracy by USFDA experts responsible for PEPFAR application reviews, by comparing information on each ARV with internal FDA records. WHO/PQP and Global Fund data were quality checked twice by the same investigator who did the initial extraction. This was done by comparing all variables for each drug against public WHO and Global Fund lists using manual checks and automated processes programmed in Excel and Tableau to find inconsistent or mismatching information. In both instances, errors were rare (less than 5% of all data) and when found were corrected.

### Standardization of data sources

Scheme for standardizing drug product attributes for comparison and analysis across multiple data sources is described below. For the purposes of this study, drug listings are standardized using the following convention:

1. "+" means combination product, both fixed-dose combination (FDC, co-formulated) and Co-Packaged product (i.e. co-blister)
2. A + B means A and B are in a fixed-dose formulation
3. [A + B] + C means A and B are in a fixed-dose formulation and C is Co-Packaged drug
4. Drugs are alphabetized from left to right, by FDC products and Co-Packaged product
5. Manufacturer names were limited to first word of the name when applicable and excluded distinctions such as Inc., Ltd., etc.
6. Manufacturing sites were standardized by city, state, postal code and country and, when applicable, specific plant name.

# Method Details

### Uptake analysis

To determine uptake of USFDA-registered ARVs, we matched the products across the three lists. The primary matching method was to use USFDA registrations as the base-line and cross-match the products to WHO/PQP and Global Fund lists. An ARV product was considered to be matched if the drug active ingredient, strength, dosage form, sponsor and manufacturing site were identical. It is important to note that in limited cases the review dossiers submitted to PEPFAR and WHO/PQP may not be the same, despite being the same in terms of name, strength, manufacturer name and manufacturing site. In some cases, the review dossier submitted to PQP may have different formulation, manufacturing process, and/or standard (specification of active pharmaceutical ingredient (API), finished pharmaceutical product (FPP), or excipients) than what was submitted to USFDA. While the authors took into account potential formulation (dosage form) changes, we could not conduct in-depth reviews of drug dossiers to determine changes to API, FPP, or excipient specifications of the drug. Such in-depth evaluations of drug dossiers is beyond the scope of this study. It is not known how many products fall into this category, however, the number of products is expected to very small, as such they are not expected to affect the overall findings of this study.

If the product was on the WHO/PQP or Global Fund lists, we determined the quality assurance mechanism with which the product was added to the respective lists. We included ARV products in active status with the USFDA at the time of analysis (**Supplement Table 1**) and excluded those that were once registered have since been withdrawn, either by the USFDA or the drug manufacturer (**Supplement Table 2**).

WHO/PQP list identifies whether the product was added on the basis of USFDA review by using one-way recognition or another process, such as prequalification review, European Medicines Agency or Health Canada. ‘Uptake’ of USFDA product was achieved if the product was added to the WHO/PQP list using USFDA one-way recognition. If the product was on the PQP list by another mechanism or not on the list at all, it was considered ‘non-uptake’ of USFDA-registered product. We found three products on the PQP that were both prequalified and listed as using the USFDA as quality assurance mechanism (**Supplement Table 3**). We considered such products to be prequalified and USFDA-registered, but did not consider them for direct one-way reliance or uptake by WHO.

The Global Fund list states if a product is added using quality assurance by WHO/PQP, an SRA, by an SRA and WHO/PQP, or by its own Expert Review Panel. The Global Fund, however, does not specifically indicate which SRA is used to support its list. To determine if USFDA was the supporting SRA, we matched products on the lists using the five drug characteristics listed above. If the Global Fund listed WHO/PQP and SRA as the quality assurance mechanisms, we cross-checked to determine if WHO/PQP used USFDA as the source of the product. If the WHO/PQP used USFDA registration for one-way recognition and that product was subsequently added to the Global Fund list, we considered that Global Fund product to be supported by USFDA. All products on the Global Fund list under the SRA or WHO/PQP and SRA that matched with USFDA-registered products were considered to meet the criteria for uptake. And if a USFDA-registered product was added to the Global Fund by another mechanism or not at all, it was considered non-uptake.

### *Temporal analysis*

For USFDA-registered drugs that were also on the WHO/PQP list, but were added to the WHO list following a review by the Prequalification of Medicines Program, we determined the temporal relationship between registrations. Temporal analysis was limited to PQP products that were registered after December 2004, when USFDA’s PEPFAR process began. We compared the first positive USFDA action date (tentative approval or full approval) and the WHO prequalification date to determine if the product was added to the PQP list 1) before USFDA registration; 2) after USFDA registration; 3) if the date of PQP was more than 180 days after USFDA registration; and 4) if the date of PQP was more than 365 days after FDA registration. All analyses were conducted with median number of days with an inter-quartile range (IQR).

### *Overlap of review analysis*

To see if there may have been an overlap in reviews between WHO and USFDA, we conducted an analysis to determine the number of products that were either prequalified or USFDA-registered within 180 days of each other. This analysis was conducted by using USFDA registration date as the baseline. All analyses were conducted with median number of days with an inter-quartile range (IQR).

### *Analysis of WHO preferred first-line treatment options*

We analyzed USFDA PEPFAR ARV registrations to determine the extent to which they support WHO-recommended *preferred* first-line HIV treatment options. This was done by identifying each USFDA-registered product that could be a part of the HIV treatment regimens. The options included all single, fixed-dose or co-packaged products that were available for procurement at the time of analysis. A product was considered “supportive” of WHO’s preferred first-line option if it could, either by itself or in combination with other ARVs, constitute an HIV therapy option. We then determined how many and types of USFDA products supportive of first-line therapy were either matched or not matched to the WHO/PQP or Global Fund lists. We also determined if the supportive products were added to the PQP list using a prequalification review before or after FDA registration. The products that matched or did not match with WHO/PQP and Global Fund lists were categorized into four non-overlapping population-based groups: these were products that supported treatment in 1) children from birth to 3 years of age; 2) children from 3 to 10 years; 3) all children from birth to 10 years; and 4) adults, pregnant and nursing women, and adolescents.

### Relative Risk tests conducted

We conducted relative-risk calculations between adult versus pediatric ARVs and fixed-dose/co-packaged versus single-active ingredient formulations to determine if there was an association between uptake or non-uptake of certain products by WHO or the Global Fund. Specifically, we conducted the following five categories of tests (result in **Supplement Section III**):

* 1. Association between WHO/PQP uptake and USFDA registration:
		1. Test to determine association between pediatric and non-pediatric products.
		2. Test to determine association between fixed-dose combination and single drug product.
	2. Association between the Global Fund uptake and USFDA registration:
		1. Test to determine association between pediatric and non-pediatric products.
		2. Test to determine association between fixed-dose combination and single drug product.
	3. Association between WHO/PQP NON-uptake and USFDA registration:
		1. Test to determine WHO omission of USFDA fixed-dose combination drugs compared to single drugs.
		2. Test to determine WHO omission of USFDA-registered pediatric products compared adult products.
	4. Association between the Global Fund NON-uptake and USFDA registration:
		1. Test to determine Global Fund omission of USFDA fixed-dose combination drugs compared to single drugs.
		2. Test to determine Global Fund omission of USFDA-registered pediatric products compared adult products.
	5. Association between listing of preferred WHO first-line therapies registered by USFDA on the WHO/PQP list:
		1. Test to determine association between pediatric vs adult products for inclusion on the PQP list.

Supplement Table 1: USFDA-registered active ARV products and their matching to WHO/PQP and Global Fund Lists, by population

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ARV Name** | **ARV Strength** | **ARV Dosage Form** | **Manufacturer** | **PQP List Match** | **GF List Match** | **PQP and GF Lists Match** |
| **Adult ARV Products** |
| [Atazanavir + Ritonavir] + [Lamivudine + Zidovudine] | [300 mg + 100 mg] + [150 mg + 300 mg] | Tablet | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Emtricitabine + Tenofovir DF] + Nevirapine | [200 mg + 300 mg] + 200 mg | Tablet | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Stavudine] + Efavirenz | [150 mg + 40 mg] + 600 mg | Tablet | Strides | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Stavudine] + Nevirapine | [150 mg + 40 mg] + 200 mg | Tablet | Strides | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Tenofovir DF] + Nevirapine | [300 mg + 300 mg] + 200 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Tenofovir DF] + Nevirapine | [300 mg + 300 mg] + 200 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Tenofovir DF] + Nevirapine | [300 mg + 300 mg] + 200 mg | Tablet | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Abacavir | [150 mg + 300 mg] + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Efavirenz | [150 mg + 300 mg] + 600 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Efavirenz | [150 mg + 300 mg] + 600 mg | Tablet | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Efavirenz | [150 mg + 300 mg] + 600 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Nevirapine | [150 mg + 300 mg] + 200 mg | Tablet | Aspen Pharmacare | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Nevirapine | [150 mg + 300 mg] + 200 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| [Lamivudine + Zidovudine] + Nevirapine | [150 mg + 300 mg] + 200 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 300 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 600 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 600 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 600 mg + 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 600 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine + Zidovudine | 300 mg + 150 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 150 mg | Capsule | Aspen Pharmacare | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Atazanavir | 200 mg | Capsule | Aspen Pharmacare | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Atazanavir | 200 mg | Capsule | Aurobindo | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 300 mg | Capsule | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 300 mg | Capsule | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir + Ritonavir | 300 mg + 100 mg | Tablet | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir + Ritonavir | 300 mg + 100 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Darunavir | 75 mg | Tablet | Cipla | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Darunavir | 150 mg | Tablet | Cipla | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Darunavir | 400 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Darunavir | 600 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 250 mg | Capsule, Delayed Release | Barr | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 400 mg | Capsule, Delayed Release | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 400 mg | Capsule, Delayed Release | Barr | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 400 mg | Capsule, Delayed Release | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Dolutegravir | 50 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Edict | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Micro | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Efavirenz | 600 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 600 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Lamivudine + Tenofovir DF | 400 mg + 300 mg + 300 mg | Tablet | Mylan | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine | 200 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine | 200 mg | Capsule | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine | 200 mg | Capsule | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine + Tenofovir DF | 200 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine + Tenofovir DF | 200 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine + Tenofovir DF | 200 mg + 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine + Tenofovir DF | 200 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Emtricitabine + Tenofovir DF | 200 mg + 300 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Centaur | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Micro | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 150 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 300 mg | Tablet | Micro | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Lamivudine | 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 300 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | Tablet | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 40 mg | Tablet | Emcure | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 40 mg | Tablet | Strides | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Stavudine | 150 mg + 30 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Stavudine | 150 mg + 30 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Stavudine | 150 mg + 30 mg | Tablet | Mylan | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Stavudine | 150 mg + 40 mg | Tablet | Mylan | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Ranbaxy | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Aspen Pharmacare | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 150 mg + 300 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 100 mg + 25 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 200 mg + 50 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 200 mg + 50 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 200 mg + 50 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 200 mg + 50 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 200 mg + 50 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Huahai | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Micro | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | ScieGen | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 200 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 400 mg | Tablet, Extended Release | Cipla | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Nevirapine | 400 mg | Tablet, Extended Release | Mylan | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Ritonavir | 100 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 15 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 15 mg | Capsule | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 20 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 20 mg | Capsule | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 30 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 30 mg | Capsule | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 30 mg | Capsule | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 30 mg | Solution, Oral | Strides | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Stavudine | 40 mg | Capsule | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 40 mg | Capsule | Emcure | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 40 mg | Capsule | Hetero | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 40 mg | Capsule | Mylan | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Stavudine | 40 mg | Solution, Oral | Strides | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Tenofovir DF | 300 mg | Tablet | Aspen Pharmacare | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Tenofovir DF | 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Tenofovir DF | 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Tenofovir DF | 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Tenofovir DF | 300 mg | Tablet | Macleods | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Tenofovir DF | 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Tenofovir DF | 300 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 300 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 300 mg | Tablet | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 300 mg | Tablet | HEC | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 300 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 300 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| **Pediatric ARV Products** |
| Abacavir | 20 mg/mL | Solution, Oral | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 20 mg/mL | Solution, Oral | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 60 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir | 60 mg | Tablet, Oral Suspension | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet, Oral Suspension | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet, Oral Suspension | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Abacavir + Lamivudine | 120 mg + 60 mg | Tablet, Oral Suspension | Mylan | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Atazanavir | 100 mg | Capsule | Aurobindo | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 100 mg | Capsule | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 150 mg | Capsule | Aurobindo | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 150 mg | Capsule | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 150 mg | Capsule | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 200 mg | Capsule | Emcure | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Atazanavir | 300 mg | Capsule | Aurobindo | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 10 mg/mL | Powder for Solution, Oral | Aurobindo | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Didanosine | 100 mg | Tablet, Oral Suspension | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 125 mg | Capsule, Delayed Release | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 125 mg | Capsule, Delayed Release | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 150 mg | Tablet, Oral Suspension | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 200 mg | Capsule, Delayed Release | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 200 mg | Capsule, Delayed Release | Barr | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 200 mg | Capsule, Delayed Release | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 200 mg | Tablet, Oral Suspension | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 250 mg | Capsule, Delayed Release | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Didanosine | 250 mg | Capsule, Delayed Release | Mylan | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 50 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 50 mg | Capsule | Micro | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Efavirenz | 50 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 100 mg | Capsule | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 100 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 200 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 200 mg | Capsule | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 200 mg | Capsule | Micro | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Efavirenz | 200 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Efavirenz | 200 mg | Tablet | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 10 mg/mL | Solution, Oral | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 10 mg/mL | Solution, Oral | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine | 10 mg/mL | Solution, Oral | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 30 mg + 50 mg + 6 mg | Tablet, Oral Suspension | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Stavudine | 60 mg + 100 mg + 12 mg | Tablet, Oral Suspension | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 30 mg + 50 mg + 60 mg | Tablet, Oral Suspension | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 30 mg + 50 mg + 60 mg | Tablet, Oral Suspension | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Nevirapine + Zidovudine | 30 mg + 50 mg + 60 mg | Tablet, Oral Suspension | Strides | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Stavudine | 30 mg + 6 mg | Tablet, Oral Suspension | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Stavudine | 60 mg + 12 mg | Tablet, Oral Suspension | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet, Oral Suspension | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet, Oral Suspension | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 40 mg + 10 mg | Pellets, Oral | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 100 mg + 25 mg | Tablet | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Lopinavir + Ritonavir | 100 mg + 25 mg | Tablet | Hetero | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 10 mg/mL | Solution, Oral | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 50 mg | Tablet, Oral Suspension | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 50 mg | Tablet, Oral Suspension | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Nevirapine | 100 mg | Tablet, Oral Suspension | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Rilpivirine | 25 mg | Tablet | Strides | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Ritonavir | 25 mg | Tablet | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Ritonavir | 50 mg | Tablet | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 1 mg/mL | Powder for Solution, Oral | Aurobindo | PQP List Match | No GF List Match | ARV on PQP OR GF Lists |
| Stavudine | 1 mg/mL | Solution, Oral | Cipla | No PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 50 mg/5mL | Powder for Solution, Oral | Cipla | No PQP List Match | No GF List Match | ARV NOT on PQP or GF Lists |
| Zidovudine | 50 mg/5mL | Solution, Oral | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 100 mg | Capsule | Aurobindo | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 100 mg | Capsule | Cipla | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| Zidovudine | 100 mg | Tablet | Mylan | PQP List Match | GF List Match | ARV on PQP OR GF Lists |
| **Number Matching** |  |  |  | **173** | **185** | **204** |

Supplement Table 2: USFDA ARV products not currently active, excluded from analysis

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Current USFDA Regulatory Status** | **Application Type** | **Application Number** | **ARV Name** | **ARV Strength** | **ARV Dosage Form** |
| Complete Response\* | ANDA | 206584 | Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet |
| NDA | 204119 | Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet |
| Withdrawn | ANDA | 77327 | Zidovudine | 300 mg | Tablet |
| 77357 | Lamivudine | 150 mg | Tablet |
| 77429 | Nevirapine | 200 mg | Tablet |
| 78348 | Abacavir | 20 mg/mL | Solution, Oral |
| 90433 | Lamivudine | 150 mg | Tablet |
| 91203 | Lopinavir + Ritonavir | [80 mg + 20 mg]/mL | Solution, Oral |
| 204538 | Zidovudine | 10 mg/mL | Injection |
| NDA | 21838 | Lamivudine + Stavudine | 150 mg + 40 mg | Tablet |
| 21969 | Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | Tablet |
| 21969 | Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 40 mg | Tablet |
| 21974 | Lamivudine + Stavudine | 150 mg + 30 mg | Tablet |
| 21974 | Lamivudine + Stavudine | 150 mg + 40 mg | Tablet |
| 22293 | Abacavir | 60 mg | Tablet |
| 22294 | Zidovudine | 60 mg | Tablet |
| 22297 | Efavirenz | 100 mg | Tablet |
| 22346 | Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | Tablet |
| 22346 | Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 40 mg | Tablet |
| 22347 | Lamivudine + Stavudine | 150 mg + 30 mg | Tablet |
| 22347 | Lamivudine + Stavudine | 150 mg + 40 mg | Tablet |
| \*Complete Response implies that the USFDA has reviewed the product and found it to be non-satisfactory due to safety, efficacy or quality concerns. These products received USFDA registrations but were subsequently rescinded and issued “complete response letter.” These products are not available for procurement.One additional ARV product, although USFDA-registered and currently available, was excluded due to inconsistencies in public and internal listings of the product. |

The following three ARV products (**Supplement Table 3**) on the WHO list were determined to be both USFDA-registered and prequalified by WHO/PQP. Therefore, for the purposes of this study, they were analyzed as both USFDA-registered and WHO prequalified.

Supplement Table 3: ARV products on the WHO/PQP list determined to be USFDA-registered and WHO prequalified

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Current FDA Regulatory Status** | **FDA Application Type** | **FDA Application Number** | **WHO/PQP Reference Number** | **PQP ARV Name** | **PQP ARV Strength** | **PQP ARV Dosage Form** | **PQP ARV Sponsor** |
| Fully Approved | ANDA | 91560 | HA575 | Abacavir | 300 mg | Tablet | Hetero |
| Tentatively Approved | NDA | 204568 | HA593 | Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet | Cipla |
| NDA | 22459 | HA448 | Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | Hetero |

# Additional Results

### Overall summary of WHO/PQP, the Global Fund and USFDA drug lists

**Table 1** in the main paper shows number of active ARV products available on the WHO prequalified medicines list, the Global Fund procurement list and USFDA ARVs list for PEPFAR. The products on the WHO and Global Fund are limited to manufacturers who have also submitted ARVs to USFDA under the PEPFAR process. The data are listed by each type of quality assurance program employed by either WHO or the Global Fund. WHO uses two sources of quality assurance: 1) WHO Prequalification of Medicines Programme (WHO PQP); and 2) The Alternative Listing Procedure, which uses drugs reviewed by Stringent Regulatory Authorities (SRAs), such as USFDA.[1] For the purposes of this study, we limited the analyses to USFDA-registered drugs only. The Global Fund uses four quality assurance mechanisms to add drugs to its formulary for procurement: 1) SRAs such as USFDA; 2) WHO PQP; 3) SRA and WHO PQP; and 4) WHO’s Expert Review Panel (ERP) which reviews necessary drugs not quality assured by other sources and adds them to the Global Fund formulary on a temporary basis. The last column of the table shows USFDA-registered ARV products under the PEPFAR program. The data are presented by drug type – either single ARV product, 2 drug fixed-dose combination (FDC), 3 drug FDC, or co-packaged drugs. **Supplement Table 2** shows a cross-walk of the USFDA 221 active products to the two WHO quality-assurance mechanisms and the three Global Fund mechanisms.

WHO/PQP list had 234 ARVs listed through two quality assurance mechanisms from PEPFAR manufacturers: 128 ARVs (55%) underwent WHO’s own prequalification review and 106 were based on one-way recognition of USFDA registrations (**Supplement Table 4**). There was a 77% (173/224) overlap of the products registered by USFDA and their availability on the WHO/PQP list through the two quality assurance mechanisms. Six of the 106 USFDA-registered products have been withdrawn by USFDA; although listed on the WHO list, these six products were excluded from subsequent analyses.

The Global Fund listed a total of 270 ARV products on its procurement list from PEPFAR manufacturers: 116 products were based on reviews by SRAs, 91 were based on both WHO/PQP and SRAs, 62 were based solely on review by WHO/PQP and one was added to the list based on its own Expert Review Panel (**Supplement Table 4)**. Seven products on the Global Fund list that were coded as both WHO/PQP and SRA quality assured had to be recoded to SRA only because they were not found on the WHO list but matched fully to all drug characteristics on USFDA list. There was an 83% (185/224) overlap of the products registered by USFDA and their placement on the Global Fund procurement list through the four quality assurance mechanisms.

Supplement Table 4: Disposition of USFDA-registered ARVs, cross-tabbed by the WHO/PQP and the Global Fund ARVs list, by quality assurance mechanisms of each entity

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | WHO/PQP Quality Assurance Mechanism # of ARV products (#Adult ARVs; # Pediatric ARVs) |  |
|  |  | Not on WHO/PQP List | USFDA Registered | WHO PQP | Total |
| GF Quality Assurance Mechanism | Not on GF List | 20 (A14; P6) | 16 (A10; P6) | 3 (A3) | 39 |
| USFDA Only (Direct Reliance on USFDA) | 24 (A10; P14) | 71 (A47; P24) | - | 95 |
| WHO/PQP and USFDA (In-Direct Reliance on USFDA) | 7 (A4; P3) | 13 (A10; P3) | 63 (A50; P13) | 83 |
| WHO/PQP Only | - | - | 7 (A6; P1) | 7 |
| Total | 51 | 100 | 73 | 224 |
| WHO: World Health Organization; PQP: Prequalification of Medicines Program; USFDA: US Food and Drug Administration; GF: Global Fund; A: Adult; P: Pediatric |

Supplement Table 4 caption: The table shows a cross-tab between the WHO/PQP list (columns) and the Global Fund list (rows). The cells contain the number of active USFDA-registered ARVs according to the quality assurance mechanism employed by WHO/PQP and the Global Fund.

Color scheme for Supplement Table 5 is as follows:

**Red**: Not used for one-way recognition by the Global Fund or the WHO.

**Purple**: Directly used by WHO via one-way recognition.

**Green**: Directly or Indirectly used by Global Fund via one-way recognition.

**Blue**: Directly used by WHO and directly or indirectly used by Global Fund via one-way recognition.

**Supplement Figure 1** below shows the number of USFDA-registered products that were added to the WHO prequalification list or the Global Fund procurement list, by drug type and patient population. The figure also shows the number of products that are on USFDA-registered ARVs list but were added to the WHO or the Global Fund lists by other quality assurance mechanisms.

Supplement Figure 1: Number and type of USFDA-registered ARVs on the WHO PQP and the Global Fund procurement lists, by the quality assurance mechanism and population

**Supplement Figure 1 abbreviations:** USFDA: US Food and Drug Administration (approved and tentatively approved products); WHO: World Health Organization; PQP: Prequalification of Medicines Program; SRA: Stringent Regulatory Authority; ARV: Anti-retroviral.

### Relative Risk calculation results

* 1. Association between WHO/PQP uptake and USFDA registration:
		1. There was **no association** between pediatric and non-pediatric products (relative risk (RR) 1.08, 95% confidence interval 0.8 to 1.5)
		2. There was **no association** between fixed-dose combination and single drug product (RR 1.15, 0.86 to 1.54) for uptake by the WHO.
	2. Association between the Global Fund uptake and USFDA registration:
		1. There was **no association** between pediatric and non-pediatric products (RR 1.04, 0.90 to 1.19)
		2. There was **no association** between fixed-dose combination and single drug product (RR 1.12, 0.99 to 1.28) for uptake by the WHO.
	3. Association between WHO/PQP NON-uptake and USFDA registration:
		1. There was **no association** between USFDA fixed-dose combination drugs compared to single drugs (RR 0.63, 0.38-1.05) for not being on PQP list.
		2. There was **no association** for omission of USFDA-registered pediatric products compared adult products (RR 1.39, 0.90-2.17).
	4. Association between the Global Fund NON-uptake and USFDA registration:
		1. There was **no association** for Global Fund omission of FDA registered fixed-dose vs single products (RR 0.55, 0.29-1.05).
		2. There was **no association** for Global Fund omission of FDA registered pediatric vs adult formulations (RR 0.95, 0.51-1.77).
	5. Association between listing of preferred WHO first-line therapies registered by USFDA on the WHO/PQP list:
		1. There was **no association** between pediatric vs adult products for inclusion on the PQP list (RR 1.53, 0.95-2.46).

### Temporal analysis

Table 5: Sixty-Six ARVs registered by both WHO/PQP and USFDA, by population

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **WHO Prequalification or USFDA Registration** | **Population** | **WHO Reference Number** | **ARV Name** | **ARV Strength** | **Date of****WHO Prequalification** | **Date of****USFDA-Registration** | **Days Difference between USFDA Registration and WHO Prequalification** |
| USFDA Registration Before WHO Prequalification | Adult | HA352 | Efavirenz | 600 mg | 12/16/2008 | 5/24/2006 | 937 |
| HA365 | Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | 3/10/2009 | 1/31/2007 | 769 |
| HA371 | Abacavir | 300 mg | 4/23/2008 | 11/6/2006 | 534 |
| HA390 | Efavirenz | 600 mg | 2/24/2009 | 3/26/2007 | 701 |
| HA392 | Lamivudine + Zidovudine | 150 mg + 300 mg | 4/23/2008 | 11/29/2007 | 146 |
| HA396 | Nevirapine | 200 mg | 7/25/2008 | 5/15/2008 | 71 |
| HA399 | Efavirenz | 600 mg | 7/1/2009 | 2/29/2008 | 488 |
| HA401 | Tenofovir DF | 300 mg | 6/30/2009 | 4/29/2009 | 62 |
| HA403 | Efavirenz | 600 mg | 7/25/2008 | 7/12/2007 | 379 |
| HA410 | Tenofovir DF | 300 mg | 10/27/2009 | 11/30/2007 | 697 |
| HA417 | Emtricitabine + Tenofovir DF | 200 mg + 300 mg | 8/20/2010 | 3/30/2009 | 508 |
| HA418 | Emtricitabine | 200 mg | 9/1/2011 | 3/29/2011 | 156 |
| HA424 | Lamivudine | 150 mg | 12/14/2010 | 10/7/2008 | 798 |
| HA425 | Lamivudine | 300 mg | 12/14/2010 | 10/7/2008 | 798 |
| HA426 | Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | 2/24/2009 | 10/21/2008 | 126 |
| HA448 | Lamivudine + Tenofovir DF | 300 mg + 300 mg | 9/1/2011 | 11/5/2009 | 665 |
| HA457 | Zidovudine | 300 mg | 9/29/2010 | 4/25/2008 | 887 |
| HA459 | Lamivudine + Zidovudine | 150 mg + 300 mg | 10/18/2011 | 5/29/2009 | 872 |
| HA465 | Nevirapine | 200 mg | 9/29/2011 | 3/31/2009 | 912 |
| HA489 | Lamivudine + Tenofovir DF | 300 mg + 300 mg | 10/5/2011 | 3/4/2011 | 215 |
| HA492 | Lopinavir + Ritonavir | 200 mg + 50 mg | 1/11/2013 | 5/23/2012 | 233 |
| HA494 | Abacavir | 300 mg | 12/22/2011 | 5/12/2010 | 589 |
| HA498 | Emtricitabine + Tenofovir DF | 200 mg + 300 mg | 6/24/2013 | 12/22/2011 | 550 |
| HA506 | Efavirenz | 600 mg | 12/4/2012 | 8/29/2011 | 463 |
| HA507 | Atazanavir + Ritonavir | 300 mg + 100 mg | 11/28/2011 | 11/18/2011 | 10 |
| HA508 | Tenofovir DF | 300 mg | 10/31/2012 | 4/2/2010 | 943 |
| HA513 | Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | 5/24/2012 | 2/8/2012 | 106 |
| HA514 | Lamivudine + Tenofovir DF | 300 mg + 300 mg | 4/10/2014 | 11/8/2012 | 518 |
| HA524 | Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | 6/13/2014 | 12/22/2009 | 1634 |
| HA535 | Tenofovir DF | 300 mg | 10/21/2013 | 5/25/2011 | 880 |
| HA538 | Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | 2/19/2014 | 10/31/2013 | 111 |
| HA552 | Emtricitabine + Tenofovir DF | 200 mg + 300 mg | 2/18/2015 | 7/31/2013 | 567 |
| HA563 | Ritonavir | 100 mg | 12/16/2015 | 3/27/2015 | 264 |
| HA570 | Nevirapine | 200 mg | 2/19/2014 | 4/30/2012 | 660 |
| HA575 | Abacavir | 300 mg | 8/13/2015 | 9/29/2010 | 1779 |
| HA593 | Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | 4/16/2015 | 12/30/2013 | 472 |
| HA611 | Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | 6/4/2015 | 8/14/2014 | 294 |
| HA635 | Abacavir + Lamivudine | 600 mg + 300 mg | 12/16/2015 | 3/30/2009 | 2452 |
| HA644 | Lamivudine | 150 mg | 10/26/2016 | 5/30/2012 | 1610 |
| Pediatric | HA438 | Efavirenz | 200 mg | 12/14/2010 | 8/3/2009 | 498 |
| HA493 | Abacavir | 20 mg/mL | 11/1/2012 | 7/2/2012 | 122 |
| HA510 | Nevirapine | 50 mg | 2/19/2014 | 4/30/2012 | 660 |
| HA511 | Nevirapine | 100 mg | 2/19/2014 | 4/30/2012 | 660 |
| HA518 | Abacavir + Lamivudine | 60 mg + 30 mg | 1/8/2014 | 5/12/2011 | 972 |
| HA557 | Lamivudine + Nevirapine + Zidovudine | 30 mg + 50 mg + 60 mg | 10/24/2014 | 9/21/2012 | 763 |
| HA572 | Lamivudine + Zidovudine | 30 mg + 60 mg | 4/10/2014 | 2/4/2014 | 65 |
| WHO Prequalification Before USFDA Registration | Adult | HA153 | Lamivudine | 150 mg | 5/29/2007 | 1/29/2008 | 245 |
| HA268 | Nevirapine | 200 mg | 4/1/2005 | 8/11/2006 | 497 |
| HA275 | Lamivudine + Nevirapine + Zidovudine | 150 mg + 200 mg + 300 mg | 5/23/2006 | 11/18/2011 | 2005 |
| HA277 | Lamivudine + Nevirapine + Stavudine | 150 mg + 200 mg + 30 mg | 12/21/2005 | 9/10/2010 | 1724 |
| HA291 | Lamivudine + Zidovudine | 150 mg + 300 mg | 6/30/2006 | 10/18/2010 | 1571 |
| HA411 | Lopinavir + Ritonavir | 200 mg + 50 mg | 2/19/2009 | 3/10/2009 | 19 |
| HA439 | Emtricitabine + Tenofovir DF | 200 mg + 300 mg | 10/5/2011 | 2/26/2014 | 875 |
| HA500 | Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | 12/8/2011 | 2/27/2012 | 81 |
| HA516 | Tenofovir DF | 300 mg | 5/23/2013 | 8/5/2014 | 439 |
| HA562 | Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | 11/17/2014 | 11/28/2014 | 11 |
| HA573 | Lopinavir + Ritonavir | 100 mg + 25 mg | 9/9/2015 | 3/7/2016 | 180 |
| HA574 | Lopinavir + Ritonavir | 200 mg + 50 mg | 9/9/2015 | 3/7/2016 | 180 |
| HA588 | Tenofovir DF | 300 mg | 12/7/2016 | 12/29/2016 | 22 |
| HA627 | Darunavir | 400 mg | 12/21/2016 | 3/16/2017 | 85 |
| HA628 | Darunavir | 600 mg | 12/21/2016 | 3/16/2017 | 85 |
| Pediatric | HA389 | Efavirenz | 200 mg | 2/24/2009 | 2/12/2010 | 353 |
| HA433 | Lamivudine + Nevirapine + Zidovudine | 30 mg + 50 mg + 60 mg | 10/26/2009 | 7/8/2010 | 255 |
| HA437 | Lamivudine + Zidovudine | 30 mg + 60 mg | 5/25/2009 | 1/5/2011 | 590 |
| HA464 | Zidovudine | 100 mg | 3/30/2010 | 2/23/2011 | 330 |
| HA488 | Abacavir | 60 mg | 8/20/2010 | 3/4/2011 | 196 |

Supplement Table 6: Number of products and median number of days to prequalification of ARVs by WHO/PQP after USFDA-registration (for products registered after December 2004 only)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **All ARVs** | **ARVs for Adults** | **ARVs for Pediatrics** |
|  | **Number of Products** | **Median Number of Days (IQR)\*** | **Number of Products** | **Median Number of Days (IQR)\*** | **Number of Products** | **Median Number of Days (IQR)\*** |
| **All drugs that were prequalified by WHO any time after USFDA registration** |
| Single Drug | 25 | 660 (463-880) | 21 | 697 (463-887) | 4 | 579 (310-660) |
| 2 Drug FDC | 13 | 518 (215-665) | 11 | 518 (224-616) | 2 | 519 (65-972) |
| 3 Drug FDC | 8 | 383 (119-766) | 7 | 294 (119-621) | 1 | 763 (N/A) |
| Overall | 46 | 559 (233-798) | 39 | 550 (249-835) | 7 | 660 (310-712) |
| **Drugs that were prequalified by WHO more than 180 days after USFDA registration** |
| Single Drug | 21 | 534 (488-798) | 18 | 750 (534-912) | 3 | 660 (579-660) |
| 2 Drug FDC | 10 | 567 (513-922) | 9 | 550 (508-665) | 1 | 972 (N/A) |
| 3 Drug FDC | 5 | 618 (434-793) | 4 | 621 (383-1202) | 1 | 763 (N/A) |
| Overall | 36 | 663 (503-884) | 31 | 665 (408-884) | 5 | 660 (660-763) |
| **Drugs that were prequalified by WHO more than 365 days after USFDA registration** |
| Single Drug | 20 | 699 (562-900) | 17 | 798 (589-912) | 3 | 660 (579-660) |
| 2 Drug FDC | 8 | 616 (534-922) | 7 | 567 (534-769) | 1 | 972 (N/A) |
| 3 Drug FDC | 4 | 766 (618-1202) | 3 | 769 (621-1202) | 1 | 763 (N/A) |
| Overall | 32 | 699 (542-900) | 27 | 701 (542-900) | 5 | 660 (660-763) |
| \*All number of days rounded to the nearest whole dayARV: Anti-retroviral; IQR: Inter-quartile range; FDC: Fixed-dose combination; WHO: World Health Organization; USFDA: United States Food and Drug Administration |



Supplement Figure 2: Difference in registration timelines between WHO/PQP and USFDA, by category

**Supplement Figure 2 description**: The box plots, in five distinct categories, indicate the timing of WHO prequalification in relation to USFDA registration. Each dot depicts an ARV product.



Supplement Figure 3: Box-plot of ARVs prequalified by WHO before USFDA-registration

USFDA: US Food and Drug Administration; WHO: World Health Organization; PQP: Prequalification of Medicines Program; ARV: Anti-retroviral; IQR: Inter-Quartile Range

**Supplement Figure 3** caption: The box-plot shows the median number of days, the interquartile range in days and spread of products (color-coded dots by USFDA application number) that were prequalified by WHO before USFDA registration took place.

### Overlap of review analysis

Supplement Table 7: Number of products and median number of days to prequalification of ARVs by WHO/PQP and USFDA registration within 180 days of each other (for products registered after December 2004 only)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **All ARVs** | **ARVs for Adults** | **ARVs for Pediatrics** |
|  | **Number of Products** | **Median Number of Days (IQR)\*** | **Number of Products** | **Median Number of Days (IQR)\*** | **Number of Products** | **Median Number of Days (IQR)\*** |
| **Drugs that were prequalified by WHO within 180 days (before or after) of USFDA registration** |
| Single Drug | 7 | 71 (51-139) | 5 | 71 (62-162) | 2 | 81 (61-102) |
| 2 Drug FDC | 6 | 106 (31-172) | 5 | 146 (19-180) | 1 | 65 (N/A) |
| 3 Drug FDC | 5 | 106 (81-111) | 5 | 106 (81-111) | 0 | N/A |
| Overall | 18 | 99 (57-149) | 15 | 106 (62-156) | 3 | 65 (53-94) |
| **Drugs that were prequalified by WHO within 180 days after USFDA registration** |
| Single Drug | 4 | 97 (67-139) | 3 | 71 (67-114) | 1 | 122 (N/A) |
| 2 Drug FDC | 3 | 65 (38-106) | 2 | 78 (10-146) | 1 | 65 (N/A) |
| 3 Drug FDC | 3 | 111 (109-119) | 3 | 111 (109-119) | 0 | N/A |
| Overall | 10 | 108 (65-126) | 8 | 109 (67-136) | 2 | 65 (65-122) |
| **Drugs that were registered by USFDA within 180 days after WHO prequalification** |
| Single Drug | 3 | 85 (54-85) | 3 | 85 (54-85) | 0 | N/A |
| 2 Drug FDC | 3 | 180 (100-180) | 3 | 180 (100-180) | 0 | N/A |
| 3 Drug FDC | 2 | 46 (11-81) | 2 | 46 (11-81) | 0 | N/A |
| Overall | 8 | 83 (21-133) | 8 | 83 (21-133) | 0 | N/A |
| \*All number of days rounded to the nearest whole dayARV: Anti-retroviral; IQR: Inter-quartile range; FDC: Fixed-dose combination; WHO: World Health Organization; USFDA: United States Food and Drug Administration |

### *Analysis of WHO preferred first-line treatment options*

**Supplement Table 8** shows the number of USFDA-registered ARVs for WHO preferred 1st line HIV therapies, stratified by age categories. **Supplement Table 9** shows the number and type of ARV products that are considered WHO preferred 1st line HIV therapies that were both USFDA-registered and WHO prequalified.

Supplement Table 8: USFDA-registered ARVs supportive of WHO 1st line preferred, by Age Category

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Age Category** | **ARV Name** | **ARV Strength** | **ARV Dosage Form** | **Number of USFDA-Registered ARVs** |
| Less than 3 years of age | Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet | 3 |
| Lamivudine + Zidovudine | 30 mg + 60 mg | Tablet, Oral Suspension | 2 |
| Lopinavir + Ritonavir | 40 mg + 10 mg | Pellets, Oral | 1 |
| Lopinavir + Ritonavir | 100 mg + 25 mg | Tablet | 2 |
| Ritonavir | 25 mg | Tablet | 1 |
| Ritonavir | 50 mg | Tablet | 1 |
| Zidovudine | 50 mg/5mL | Powder for Solution, Oral | 1 |
| Zidovudine | 50 mg/5mL | Solution, Oral | 1 |
| Zidovudine | 100 mg | Capsule | 2 |
| Zidovudine | 100 mg | Tablet | 1 |
| 3 to 10 years of age of age | Efavirenz | 50 mg | Capsule | 2 |
| Efavirenz | 50 mg | Tablet | 1 |
| Efavirenz | 100 mg | Capsule | 1 |
| Efavirenz | 100 mg | Tablet | 1 |
| Efavirenz | 200 mg | Capsule | 3 |
| Efavirenz | 200 mg | Tablet | 2 |
| 0 to 10 years of age | Abacavir | 20 mg/mL | Solution, Oral | 2 |
| Abacavir | 60 mg | Tablet | 1 |
| Abacavir | 60 mg | Tablet, Oral Suspension | 1 |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet | 3 |
| Abacavir + Lamivudine | 60 mg + 30 mg | Tablet, Oral Suspension | 2 |
| Abacavir + Lamivudine | 120 mg + 60 mg | Tablet, Oral Suspension | 1 |
| Lamivudine | 10 mg/mL | Solution, Oral | 3 |
| Adults, Pregnant and Breastfeeding Women, and Adolescents | Efavirenz | 600 mg | Tablet | 9 |
| Efavirenz + Emtricitabine + Tenofovir DF | 600 mg + 200 mg + 300 mg | Tablet | 5 |
| Efavirenz + Lamivudine + Tenofovir DF | 400 mg + 300 mg + 300 mg | Tablet | 1 |
| Efavirenz + Lamivudine + Tenofovir DF | 600 mg + 300 mg + 300 mg | Tablet | 4 |
| Emtricitabine | 200 mg | Capsule | 3 |
| Emtricitabine + Tenofovir DF | 200 mg + 300 mg | Tablet | 5 |
| Lamivudine | 150 mg | Tablet | 7 |
| Lamivudine | 300 mg | Tablet | 6 |
| Lamivudine + Tenofovir DF | 300 mg + 300 mg | Tablet | 6 |
| Tenofovir DF | 300 mg | Tablet | 7 |
| Total |  | 91 |
| ARV: Anti-retroviral; DF: Disoproxil Fumarate |

Supplement Table 9: Number of WHO preferred 1st line HIV therapies and median number of days to prequalification of ARVs by WHO/PQP and USFDA-registration (for products registered after December 2004 only)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **All ARVs** | **ARVs for Adults** | **ARVs for Pediatrics** |
| **Type of Product** | **Number of Products** | **Median Number of Days (IQR)\*** | **Number of Products** | **Median Number of Days (IQR)\*** | **Number of Products** | **Median Number of Days (IQR)\*** |
| **Drugs that were prequalified by WHO after USFDA registration** |
| Single Drug | 14 | 697 (421-839) | 13 | 701 (463-880) | 2 | 310 (122-498) |
| 2 Drug FDC | 8 | 534 (362-616) | 6 | 534 (508-567) | 2 | 519 (65-972) |
| 3 Drug FDC | 3 | 294 (203-383) | 3 | 294 (203-383) | 0 | N/A |
| Overall | 26 | 513 (294-798) | 22 | 534 (379-798) | 4 | 310 (94-735) |
| \*All number of days rounded to the nearest whole dayARV: Anti-retroviral; IQR: Inter-quartile range; FDC: Fixed-dose combination; WHO: World Health Organization; USFDA: United States Food and Drug Administration |

# References

1. World Health Organization. *Prequalification of medicines by WHO*. 2016 [cited 2016 August 18]; Available from: http://www.who.int/mediacentre/factsheets/fs278/en/.