
Drug Regulatory Database



Our Objective

Promote access to life saving medicines and informed the WHO guideline Process

Work with all concerned parties to remove or minimize obstacles for medicines entering the market and facilitate their uptake

Provide partners and players in the field of SCM with reliable data to inform their decision making process

Who should provide us with data

Manufacturer producing Prequalified and stringent regulatory approved medicines (HIV, TB and ACTs)



WHY

- Limited access to information on ARV marketing authorizations by countries
- Inform stakeholders and WHO management team in their process of making strategic decision and advocacy
- Inform the guideline committee on the status of drug that are/will be included in the guideline
- Inform/made available to state and non state procurement officers, donation programmes, countries using the GFATM grant (options A and B) on medicines registered in their respective country
- Facilitate the procurement of this drugs
- Understand some of the market drivers and procurement behavior



How

- Collect regulatory information and make it available in the public domain as
 - Registered
 - Expired
 - Expiry date not available
 - Under registration renewal
- Contributors: all R&D and generic ARV producers and AMDS partners (SCMS, UNICEF, MissionPharma)

How does the database look like

Therapeutic category:

IN Name:

Strength:

Dosage Form:

Country (multi):

Manufacturer:

Status:

Quality Standards: WHO Prequalification Stringent Regulatory Approved

undefined: 25

Display Columns

- Brand Name
- Company
- Country
- Country of Manufacture
- Dosage Form
- Dosage Form Detailed
- GFQA Standard
- INName
- Manufacturer
- Manufacturing Site
- Pack Material
- Pack Size
- Registration Number

INName	Brand Name	Strength	Country	Status
Abacavir (ABC)	Ziagen	300 mg	Ecuador	Expired
Abacavir (ABC)	Ziagen	300 mg	Brazil	Registered
Abacavir (ABC)	Ziagen	300 mg	Colombia	Under registration renewal
Abacavir (ABC)	Ziagen	300 mg	Chile	Registered
Abacavir (ABC)	Not Applicable	300 mg	Chile	Registered
Abacavir (ABC)	Not Applicable	300 mg	Colombia	Registered
Abacavir (ABC)	Not Applicable	300 mg	Guatemala	Registered
Abacavir (ABC)		300 mg	Ecuador	Registered
Abacavir (ABC)		300 mg	British Virgin Islands	Registered
Abacavir (ABC)		300 mg	Dominica	Registered

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Pack Size
Registration Number

INNName	Brand Name	Strength	Country	Status	Manufacturer
Abacavir (ABC)	Ziagen	300 mg	Ecuador	Expired	GlaxoSmithKline Ltd.
Abacavir (ABC)	Ziagen	300 mg	Brazil	Registered	GlaxoSmithKline Ltd.
Abacavir (ABC)	Ziagen	300 mg	Colombia	Under registration renewal	GlaxoSmithKline Ltd.
Abacavir (ABC)	Ziagen	300 mg	Chile	Registered	GlaxoSmithKline Ltd.
Abacavir (ABC)	Not Applicable	300 mg	Chile	Registered	Aurobindo Pharma Ltd.
Abacavir (ABC)	Not Applicable	300 mg	Colombia	Registered	Aurobindo Pharma Ltd.
Abacavir (ABC)	Not Applicable	300 mg	Guatemala	Registered	Aurobindo Pharma Ltd.
Abacavir (ABC)		300 mg	Ecuador	Registered	Mylan Inc.
Abacavir (ABC)		300 mg	British Virgin Islands	Registered	Mylan Inc.
Abacavir (ABC)		300 mg	Dominica	Registered	Mylan Inc.
Abacavir (ABC)		300 mg	Guatemala	Expired	Mylan Inc.
Abacavir (ABC)		300 mg	Antigua and Barbuda	Registered	Mylan Inc.
Abacavir (ABC)		300 mg	Anguilla	Registered	Mylan Inc.
Abacavir (ABC)		300 mg	Grenada	Registered	Mylan Inc.
Abacavir (ABC)		300 mg	Costa Rica	Registered	Mylan Inc.
Abacavir (ABC)	Abacavir Tablets 300 mg	300 mg	Colombia	Registered	Ranbaxy Laboratories Ltd.
Abacavir (ABC)	Abacavir Tablets 300 mg	300 mg	Colombia	Registered	Ranbaxy Laboratories Ltd.
Abacavir (ABC)	Abacavir Sulfate Tablets 300 mg	300 mg	Costa Rica	Expired	Cipla Ltd.
Abacavir (ABC)	Abacavir Sulfate Tablets 300 mg	300 mg	Ecuador	Expired	Cipla Ltd.
Abacavir (ABC)	Abacavir Sulfate Tablets 300 mg	300 mg	Colombia	Registered	Cipla Ltd.
Abacavir (ABC)	Ziagen	300 mg	Argentina	Under registration renewal	GlaxoSmithKline Ltd.
Abacavir (ABC)	Abacavir Sulfate Tablets 300 mg	300 mg	Chile	Registered	Cipla Ltd.
Abacavir (ABC)	Abacavir Sulfate Tablets 300 mg	300 mg	Dominican Republic	Expiry date not provided	Cipla Ltd.

What Next?

- Expansion to cover TB medicines
- Living database
- Update when information becomes available
- Companies to send their information to dongmonguimfackb@who.int



Thank you!

- <http://www.who.int/hiv/amds/en/>
- http://apps.who.int/hiv/amds/patents_registration/drs/

