

Agencia Nacional de Regulación, Control y Vigilancia Sanitaria

Global Regulators Conclave

India sourced Generic Medicines – Global Expectations

23 september 2022

Country facts

ECUADOR



Ecuador is located in the western corner at the top of South America

Population: 18 million
(2022)

Capital: Quito

Currency: U.S
Dollar



National Regulatory Agency competences



Regulation



Control



Surveillance



Products for human use and consumption

- ✓ **Medicines**
- ✓ Medical devices
- ✓ Natural products for medical use
- ✓ Processed food
- ✓ Cosmetics
- ✓ Biochemical reactives
- ✓ Domestic pesticides

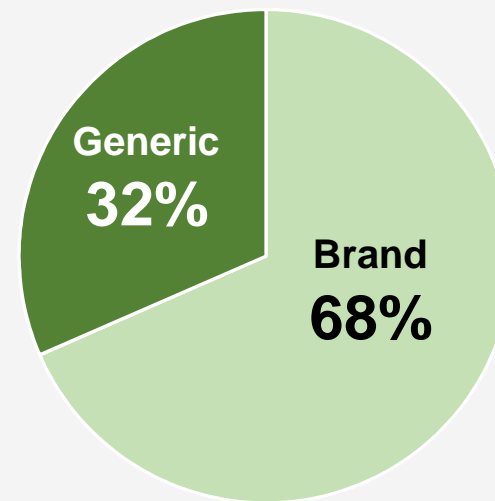
Establishments

- ✓ **Produce**
- ✓ **Export**
- ✓ **Import**
- ✓ Store
- ✓ Transport
- ✓ Distributes
- ✓ Commercializes

Control / Certification Department

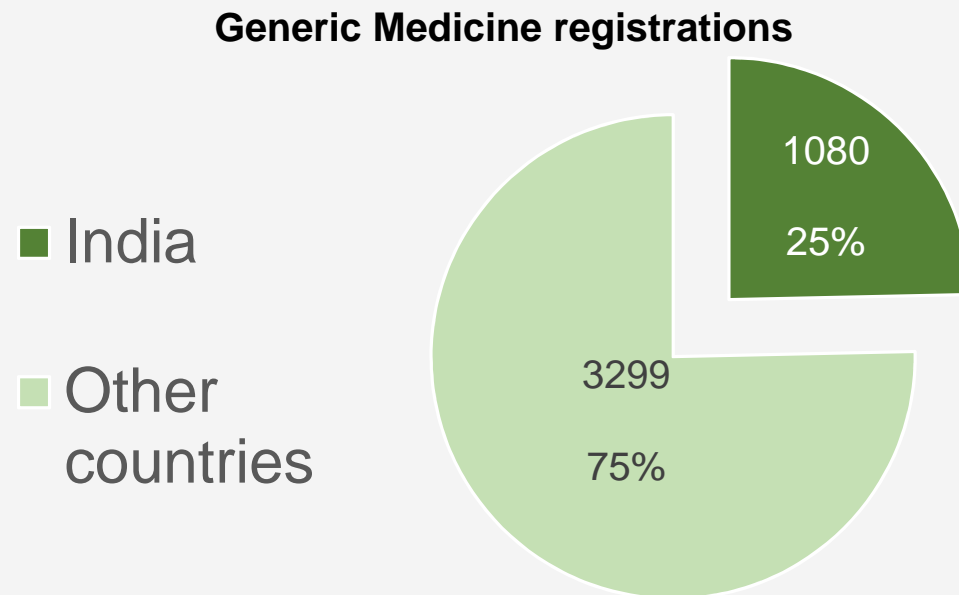
- ✓ Coordinates the certification process (Registration certificates)
- ✓ Updates the risk profile of products and establishments.
- ✓ Elaborates and updates the certifications and clinical trials.

Brand medicines vs Generic medicines



13.880 current medicine registration certificates in Ecuador from all over the world

Generic medicine registrations

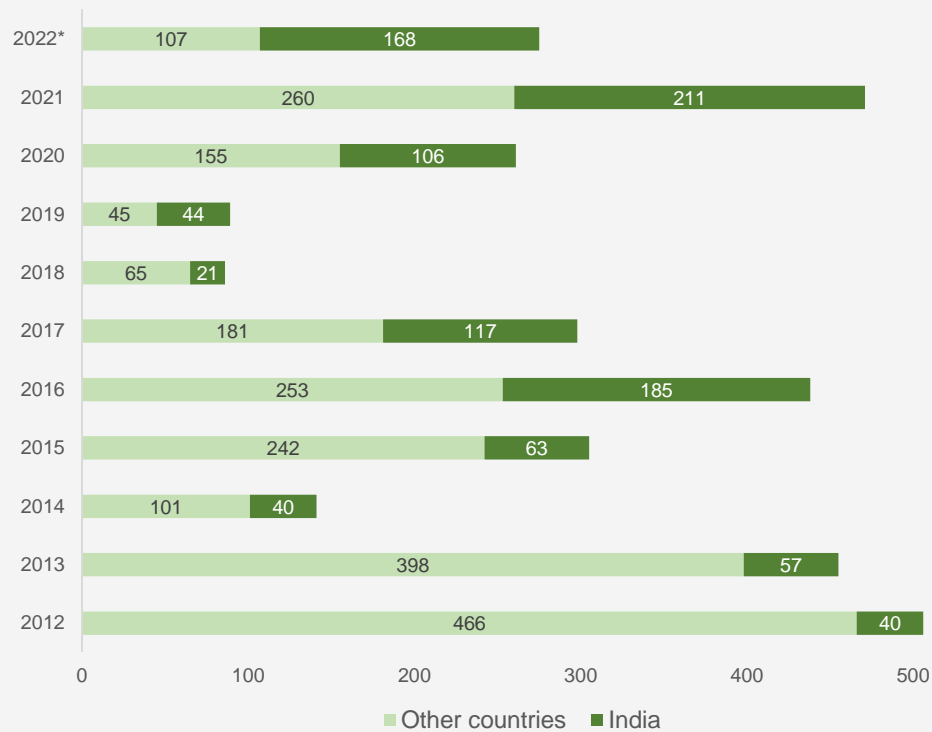


✓ India is the main issued generic medicine registration country

4.379 current generic medicine registration certificates from all over the world

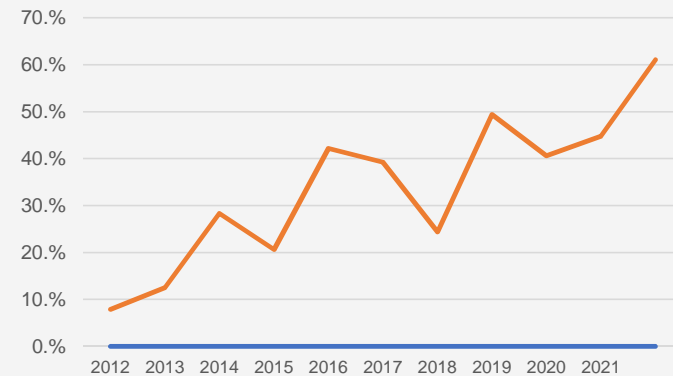
Generic medicine registrations - Market share

Generic Medicine Registration Certificates by year
Other Countries-India



*until 14 september 2022

Market share trending by year



- ✓ India went from 10% in 2012 to 61% in 2022 registrations issued
- ✓ India is the main single country producing Generic Medicines to Ecuador

Expectations



Improve control and regulations

Share experiences and information between Regulatory Agencies from India and Ecuador



Reliance

According to Ecuadorian regulation, Indian products can be homologated if have EMA/FDA (or equivalent) registrations.



Good Manufacturing Practice

Ecuador is implementing a Good Manufacturing Practice inspection to products and establishments from different countries, including India in 2023.

Countries, establishments and products are ranked to inspect in order to potential risk level.

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Thanks!