Latin American countries – Regulatory requirements overview

M.R.Syam Sundar – Director, Global Regulatory Affairs

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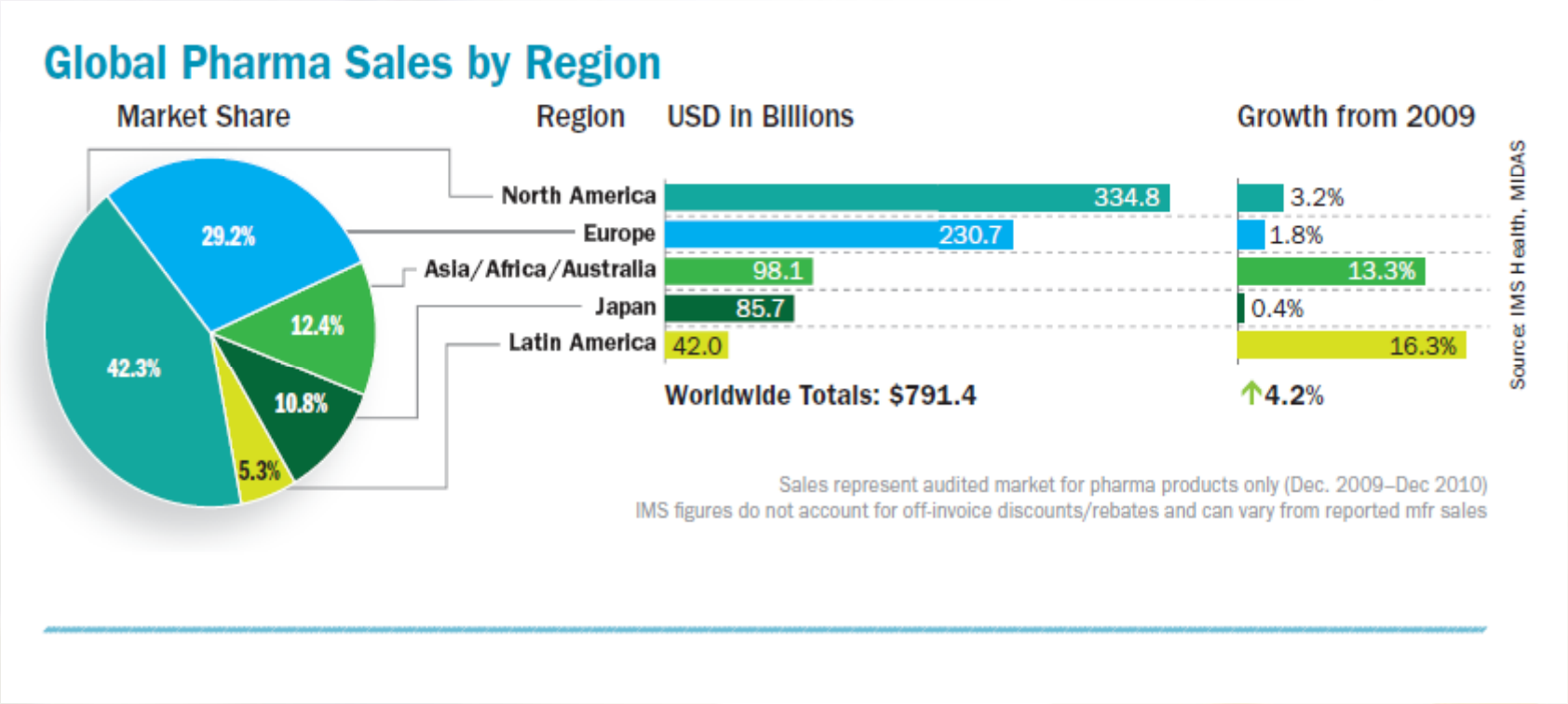
Pharmaceutical Market



- Block buster are going off patent.
- Opportunity for Generic Market.

Key Market

Key Drivers

- Brazil
- Mexico
- Argentina
- Venezuela
- Chile
- Colombia
- Peru
- Cuba

- As of 2010, total population of **600 million**

- **Key driver** of global pharmaceutical markets

Market Advantages

- Market growing at the rate of at the rate of about 15%.
- 4th Largest pharmaceutical market.
- Strong economy growth and next 10 years good market / economy prospects.

Important Market Scenario

Brazil:

- Largest Market
- Govt. increases the health budget.

Mexico:

- 2nd largest market.
- Patent registration norms in place.

Argentina:

- Demand continues to grow.

Venezuela:

- Good market but the economic stability is a concern due to recession.

Regulations for Generics drugs

- Brazil
- Panama
- Peru
- Bolivia
- Ecuador

Generic Drugs

These are interchangeable with the reference drug and have been proved to have the same efficacy, security and quality. They are produced after patent expiration and are identified with an INN or nonproprietary name

Similar Drugs

- Argentina
- Brazil
- Mexico

These have the same active ingredient, concentration, pharmaceutical form and dosage and same indications as the innovative product. They may be differ in size, shape, packaging and period of activity. These are pharmaceutically equivalent to the innovative drug. May use a brand name

- Mexico

Encourages **interchangeable** approved by health authorities and indentified by INN

Registration requirements: **BE / CoPP/ Inspections.**

Country	BE studies	CPP	Plant Audit
Argentina	Yes	Yes	No
Brazil	Yes. ANVISA approved lab, Brazil – Reference product.	Yes	Yes
Chile	No	Yes - Conditional	No
Colombia	Required as per INVIMA guidelines	Yes - Conditional	Yes / International approved certification.
Mexico	To be in done in Mexico	Yes	Yes / International approved certification.
Peru	No	Yes	No
Venezuela	Yes – MR Mandatory PE – Specific conditions.	Yes	No
Ecuador	No	Yes	No

Dossier requirements for submission to Regulatory bodies

- Dossiers to be submitted in local language
- CPP / WHO GMP / Manufacturing license
- Free Sale Certificate
- Letter of Authorization / Power of Attorney
- Legalization of administrative documents from the embassy
- API Technical package (Brazil, Mexico)
- Specification and methods
- COA of API and Excipients from vendors
- Manufacturing procedure and controls
- Executed Batch manufacturing records / Batch Numbering system.
- Stability data on three batches – Stability conditions – as per zone definations.

Recommendations for important requirements.

Brazil:

Requirement: PE – (Pharmaceutical equivalent study to be performed in Brazil).

Recommendations: ANVISA to accept the Pharmaceutical equivalent study generated by the Manufacturer as the facility and lab is inspected by the ANVISA.

Benefits: Time.

Mexico:

Requirement: BE Study to be done in Mexico

Recommendations: COFEPRIS to accept the BE - study performed in India against Mexico reference product. The USFDA / ANVISA / UK MHRA approved lab.

Benefits: Time.

Chile:

Requirement: Process validation completion before BE – Batch.

Recommendation: Acceptance of process validation / evaluation report on exhibit batches.

Other General recommendations:

1. Incase the manufacturing plant is approved by USFDA / UK MHRA / ANVISA, LatAM countries to accept the dossiers along with and FSC. (Eg. Colombia and Chile).

Thanks

M.R.Syam Sundar
Director – Global Regulatory Affairs
Dr.Reddy`s Laboratories Limited,
Hyderabad, India.
E mail: shyamsundarm@drreddys.com