Dr Milind Joshi
President – Global Regulatory Management
28 June 07

Drug Regulatory Process – Latin America Indian Perspective

J. B. Chemicals & Pharmaceuticals Ltd.

Regulation

Product regulation requires, a balance between protecting public health through an extensive evaluation of a particular product and promoting public health by making needed products available without undue delay.

Latin America – Drug Exports

- Under-served patient population of more than 500 million
- Market worth about USD 41 billion
- Growth rate 8.5% every year
- Growth in Prescription Drugs sales 12.7% to USD 33.6 bn
- Expected to grow to USD 63 billion by 2012
  - Mexico - USD 14.1 bn
  - Brazil - USD 13.6 bn
  - Argentina - USD 4.7 bn
  - Venezuela - USD 4.0 bn
  - Colombia - USD 1.8 bn
  - Chile - USD 1.5 bn
  - Peru - USD 1.0 bn

Latin American Markets

- Brazil, Mexico, Venezuela , Ecuador and Colombia are some of the major pharmaceutical markets
- Brazil and Mexico considered Regulated Markets
- ANVISA : Stringent norms comparable to USFDA
- Brazil : As per ANVISA's norms ,CROs used for BE studies have to be approved and certified by the Brazilian authority. For BE studies, innovator product manufactured in Brazil has to be used for comparison

Latin American Markets

- Mexico : Largest LA Market. Brazil : Total market value of US $5.2 billion. Generic market of approx. US $1 billion. ANVISA has implemented generic law to facilitate generic market entry into the country
- Mexico: Extensive analytical raw data of 3 stability batches.
- Venezuela : Copies of source data

Latin America

1	Brazil
2	Mexico
3	Argentina
4	Venezuela
5	Chile
6	Colombia
7	Peru
8	Ecuador
9	Cuba
10	Guatemala
11	Dominican Republic
12	Costa Rica
13	Trinidad and Tobago
14	Uruguay
15	El Salvador
16	Panama
17	Jamaica
18	Bolivia
19	Honduras
20	Paraguay
21	Bahamas
22	Nicaragua
23	Haiti
24	Barbados
25	Netherlands Antilles
26	Suriname
27	Belize
28	Antigua and Barbuda
29	Saint Lucia
30	Guyana
31	Grenada
32	Saint Kitts and Nevis
33	Saint Vincent and the Grenadines
34	Dominica

Drug Regulation

- Product registration
- Marketing authorization
- Monitoring safety and efficacy post-marketing
- Regulation of drug production, import and distribution
- Drug marketing
- Drug information

Drug Regulatory Requirements - Technical

- Manufacturing Facility Inspections
- Analytical data – API, Finished Product
  - Specifications, MoA, References
- Samples and CoAs
- Analytical Method Validation (API, FP)
- Packaging Material Specifications
- Medical Data
- Product Information
- Dissolution Data
- Bio-equivalence Studies (Study site approval)

Drug Regulatory Requirements - Technical

- Manufacturing Formula and Justification
- Manufacturing Process
- Process Validation
- Batch Numbering
- Batch Records
- Stability Studies (Source Data)
  - Accelerated
  - Long Term

Drug Regulatory Requirements - Legal

- Free Sale Certificate / Product Permission
- GMP Certificate
- Manufacturing License
- Power of Attorney / Contract
- Trademark Registration
- Contract with local quality control facility

Critical Success Factors

- US FDA / UK MCA / TGA approved facilities
- Strong Regulatory Support
- Good Distribution Set up
- Price Competitiveness
- Good Marketing Support
- Strong group for registering products in place
- Expansion in new markets and new products under feasibility studies

Stability Issues

- CTD norms are taken as guidance for regulatory aspects during drug development
- Major discrepancies in requirements of storage conditions for various countries
- Stability studies on three batches - as per ICH guidelines / individual country norms ?
- ICH – Zone IV – 30°C / 70% RH
- Mexico, Costa Rica, Chile, Dominian Republic, Colombia – 30°C / 65% RH
- Venezuela, El Salvador – as ICH


Thank you !!!
milind@jbcpl.com