Licensing of Generic Products
Needs and Expectations of Industry

by
D G Shah
Secretary General
Indian Pharmaceutical Alliance

Strasbourg, France
13 May 2016
Licensing of Generic Products
Needs and Expectations of Industry

Outline of Presentation

- **Needs**
  - Cost Containment
  - Compliance
  - Inspections & Inspectors
  - Maximizing Output

- **Expectations**
  - Dialogue
  - Reputation
  - Fear Psychosis
  - Manipulators
  - Capability

- **Medicines Shortages**
  - Causes
  - Findings
Licensing of Generic Products Worldwide

Needs of Industry - *Cost Containment*

- Single Reference Product
- Uniform Product Standards
- Common Packaging Specifications
- Timely Approvals of ANDAs

*Facilitate Access to Affordable Medicines*
Licensing of Generic Products Worldwide

Needs of Industry - Compliance

- Role of Regulators – Facilitators or Auditors?
- Focus on Capacity Building – Root Cause
- Simple and Practical Guidance to Quality Excellence
- Science-Based Norms
- Avoid Shifting Goal Posts

What Can be Done to Improve Compliance
Licensing of Generic Products Worldwide

Needs of Industry - Inspections & Inspectors

- Need Based Inspections
- Avoid Duplication of Efforts
- Avoid Subjectivity of Inspectors
- Training and Periodic Retraining
- Monitoring and Measuring Performance

Need for Introspection
Licensing of Generic Products Worldwide

Needs of Industry - Maximizing Output

- Prompt Feedback
- Opportunity to Discuss Remedial Actions
- Timely Resolution of Remedial Actions
- Resumption of Supplies

Avoid Shortages and Promote Competition
Medicines Shortages

Causes

a) Overall Drugs
3% Production Problem
16% Economic Reasons
15% Unknown
65% Other

b) Essential Drugs
3% Production Problem
16% Economic Reasons
15% Unknown
63% Other

C) Oncology Drugs
1% Production Problem
3% Economic Reasons
27% Unknown
66% Other

Proportion of the Reported Drugs per Cause for Drug Shortages
a) overall drugs (n=171), b) essential drugs (n=200) and c) oncology drugs (n=71)

Courtesy: Suzanne Hill, WHO
## Medicines Shortages

### Findings

<table>
<thead>
<tr>
<th>Country</th>
<th>Total Products Listed as Shortages</th>
<th>EML/ Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada (2012-Current)</td>
<td>800</td>
<td>82/800</td>
</tr>
<tr>
<td>US FDA (Current)</td>
<td>101</td>
<td>29/101</td>
</tr>
<tr>
<td>TGA (Current)</td>
<td>150</td>
<td>19/150</td>
</tr>
<tr>
<td>ASHP (Current)</td>
<td>160</td>
<td>47/160</td>
</tr>
</tbody>
</table>

Note: TGA Total Includes Allergens for Skin Testing

Courtesy: Suzanne Hill, WHO
Licensing of Generic Products Worldwide

Expectations of Industry - *Dialogue*

- Encourage Open and Frank Communication
- Demonstrate Honesty Pays
- Promote Periodic Meetings with CEOs
- Create a Climate of Mutual Trust

**Message to Industry**

*“Do What You Say; Say What You Do”*
Licensing of Generic Products Worldwide

Expectations of Industry - Reputation

- Protect Reputation to Promote Generic Use
- Weed Out Willful Defaulters
- Check Track Record of Manufacturers
- Differentiate Between Intentional & Unintentional Mistakes
- Ascertain Motive of Action/Inaction

Industry is Aware
“Cost of Compliance is Less than the Cost of Non-Compliance”
Licensing of Generic Products Worldwide

Expectations of Industry - Fear Psychosis

- Remove Barriers to Language
- Understand and Respect Local Culture
- Make an Effort for Fearless Inspections
- Behavioral Changes: Seek Acceptance as “Guide & Helper”

Shared Goals
“Desire to Grow Mandates Patient Safety”
Licensing of Generic Products Worldwide

Expectations of Industry - *Manipulators*

- Identify “Whistleblowers” from “Extortionists”
- Market Manipulators - How to Defuse Them?
- “Consultants” – A Bane or a Boon?

Common Problems
“Need for Greater Discretion and Information Exchange”
Licensing of Generic Products Worldwide

Expectations of Industry - Capability

- Support Capability Enhancing Workshops
- Focus on “Not for Profit” Industry Groups
- Benefit from Two-way Learning
- Rope in Local Regulators & Academics

Work Jointly
“Enhancing Capability is a Lasting Solution”
THANK YOU

dgshah@vision-india.com