

**Licensing of Generic Products
Needs and Expectations of Industry**

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Strasbourg, France
13 May 2016

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**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

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Needs of Industry – *Cost Containment*

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

Facilitate Access to Affordable Medicines

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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

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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

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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

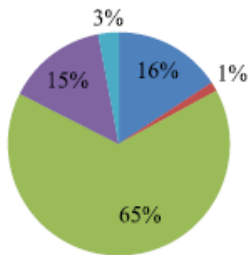
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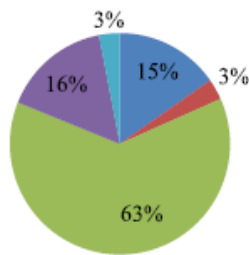
Medicines Shortages

Causes

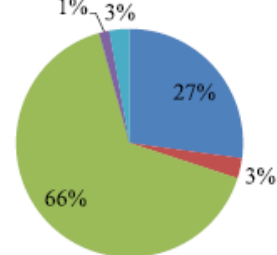
a Overall Drugs



b Essential Drugs



c Oncology Drugs



■ Production Problem ■ Economic Reasons ■ Unknown ■ Other ■ Multiple

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: Suzzane Hill, WHO

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Medicines Shortages

Findings

Country	Total Products Listed as Shortages	EML/Total
Canada (2012-Current)	800	82/800
US FDA (Current)	101	29/101
TGA (Current)	150	19/150
ASHP (Current)	160	47/160

Note: TGA Total Includes Allergens for Skin Testing

Courtesy: Suzzane Hill, WHO

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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"

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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"

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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”

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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”

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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”

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THANK YOU

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