

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

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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

# 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*

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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*

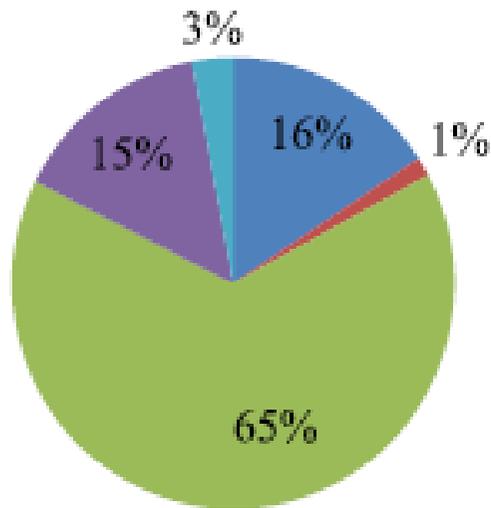
- Prompt Feedback
- Opportunity to Discuss Remedial Actions
- Timely Resolution of Remedial Actions
- Resumption of Supplies

## *Avoid Shortages and Promote Competition*

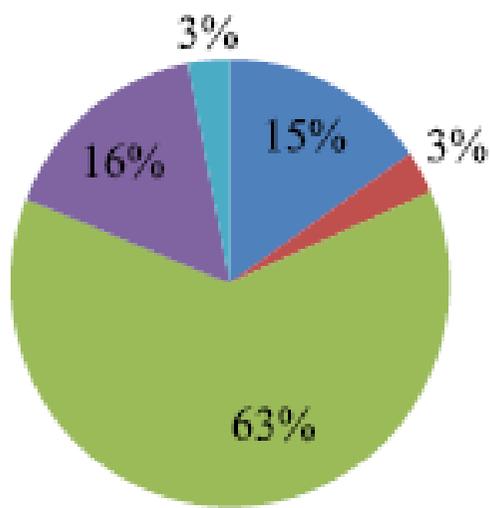
# Medicines Shortages

## Causes

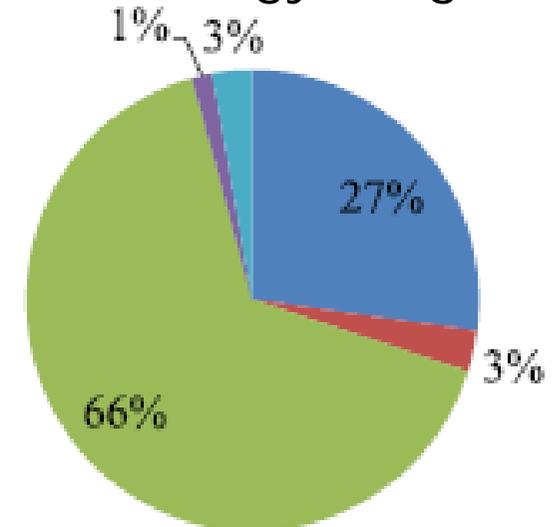
a Overall Drugs



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

# 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

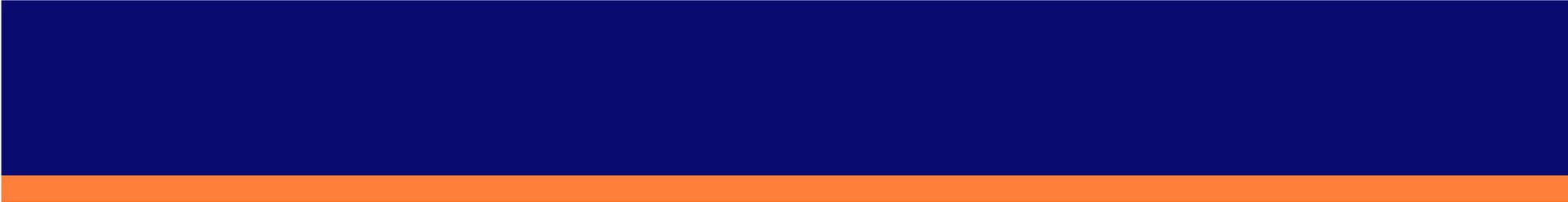
*“Need for Greater Discretion and Information Exchange”*

# 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

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