



Impact of regulatory framework and its  
implementation on quality of medicines in India

National Institute for Public Finance & Policy

New Delhi

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# Topics



- Role of medicines in primary healthcare in India
- Background to medicine quality
- Understanding the current system
- Voices in the current system
- Why the PIL route?
- What next?

# Healthcare Services Delivery in India



## **Public Health Sector**

### (a) Primary Health Care

- Primary healthcare centers & sub-centers

### (b) Hospitals/Health Centers

- Community Health Centers
- Rural Hospitals
- District hospital/health center
- Specialist hospital
- Teaching hospitals

### (c) Health insurance schemes

- Employees state insurance
- Central Govt. health scheme

### (d) Other agencies

- Defense services
- Railways

## **Private Health Sector**

(a) Private hospitals, poly-clinics, nursing homes & dispensaries

(b) General practitioners & clinics

## **Indigenous system of medicine**

- Ayurveda, Unani, Homeopathy

## **Voluntary health agencies**

## **National Health Programs**

## Interesting metrics

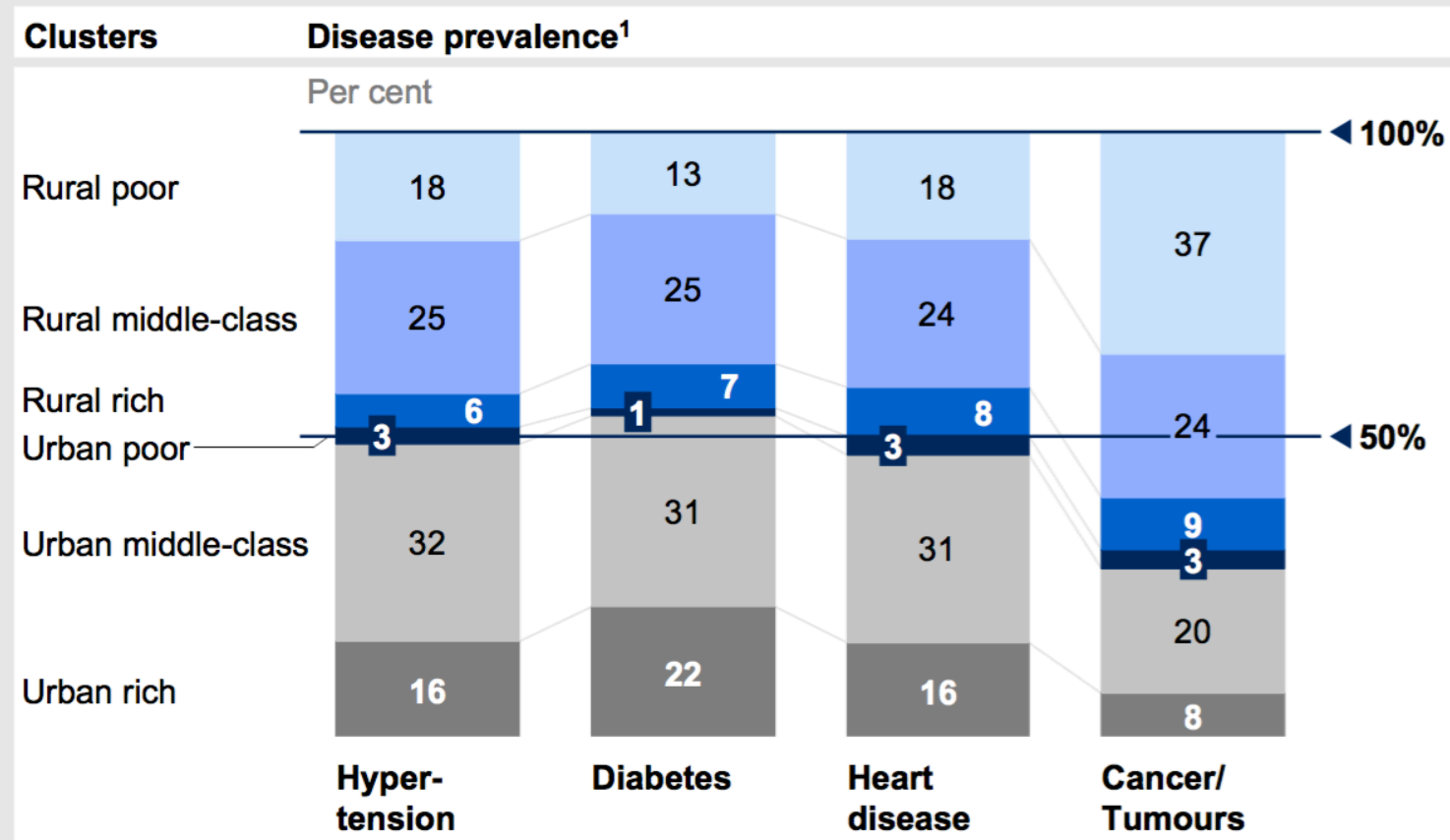


- A sub-center serves about 5000 people in general
- We have 1 primary health center for 30,000 people in rural populations in plains, 1 for every 20,000 people in hilly and tribal areas
- Community health center serves about 80,000 to 1.2 lakh people

# Disease burden



## Rural India accounts for 50–70% of non-communicable diseases



<sup>1</sup> Defined as cases per 1,000 population

SOURCE: NSSO Morbidity and Health survey, 2004; McKinsey analysis



Good quality, safe and effective medicines become the first armament in our quiver for delivery of effective healthcare services

# Background to drug quality



- A pharmaceutical company's fundamental responsibility is to deliver drugs that ensure:
  - Identity
  - Purity
  - Strength
  - Quality
- Pharmaceutical companies use specifications, process controls, procedures, tests and acceptance criteria to ensure that drugs meet all the above criteria

# What makes a drug usable?



	Drug Substance (API)	Drug Product
Identity	<ul style="list-style-type: none"><li>• Synthesis (material, process, controls)</li><li>• Specification (Structure and Identification)</li></ul>	Specification (Specific identification tests)
Purity	Isolation and purification, residual solvents, process impurities, degradation products, manufacturing process	Degradation products, oxygen / moisture permeation, leachables and extractables
Strength	In-process uniformity , closure, stability assays, date of expiration	Dosage uniformity, stability assays, date of expiration
Quality	Particle size distribution and polymorphs	Dissolution, hardness, viscosity

The above level of detail has not been specified for excipients.



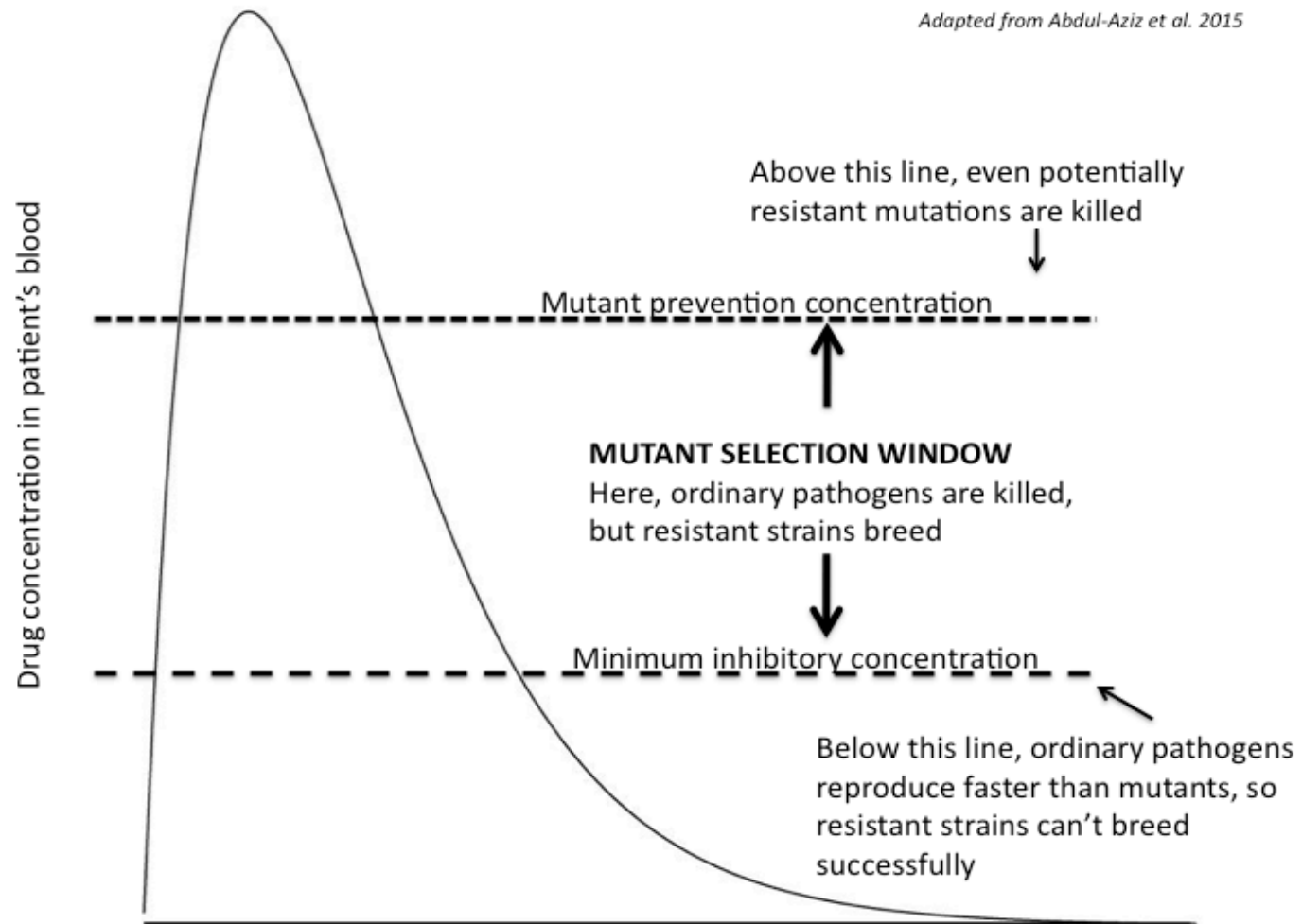
# Classification of quality



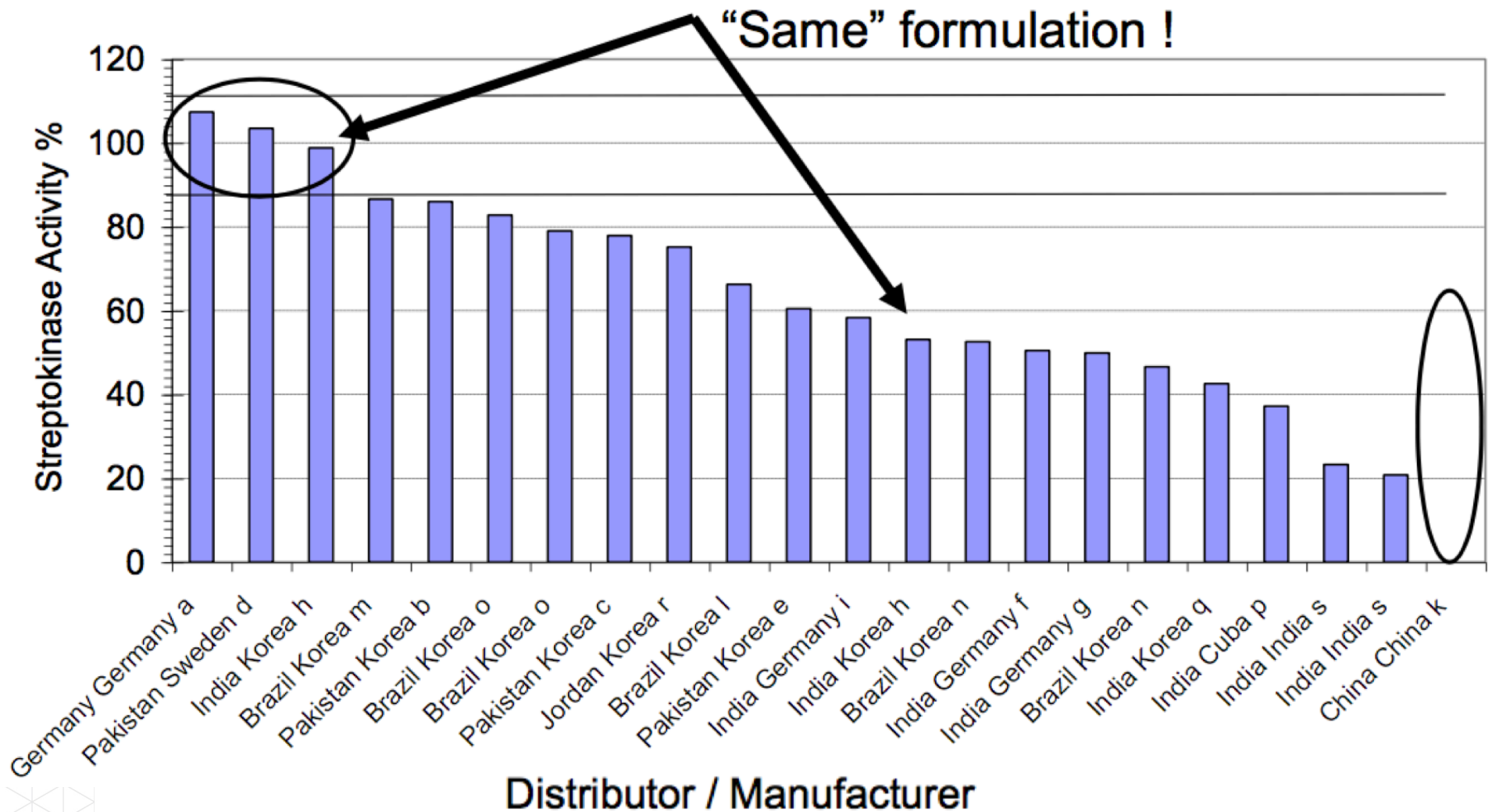
	LIMITED THREAT TO PUBLIC HEALTH	MAJOR PUBLIC HEALTH THREAT	
LEGAL	Registered manufacturer, good quality	Registered manufacturer, degraded Registered manufacturer, accidental production error	LEGAL
FALSIFIED	Registered manufacturer, good quality but stolen/ diverted/ falsely packaged/ unregistered in this market Unregistered manufacturer, good quality	Registered manufacturer, grossly negligent production error Registered manufacturer, intentionally poor quality production Unregistered manufacturer, poor quality production	FALSIFIED
	LIMITED THREAT TO PUBLIC HEALTH	MAJOR PUBLIC HEALTH THREAT	

Source: Antimicrobial Resistance and Medicine Quality. Pisani for AMR Review, November 2015

# Why does quality matter?



# A real world example

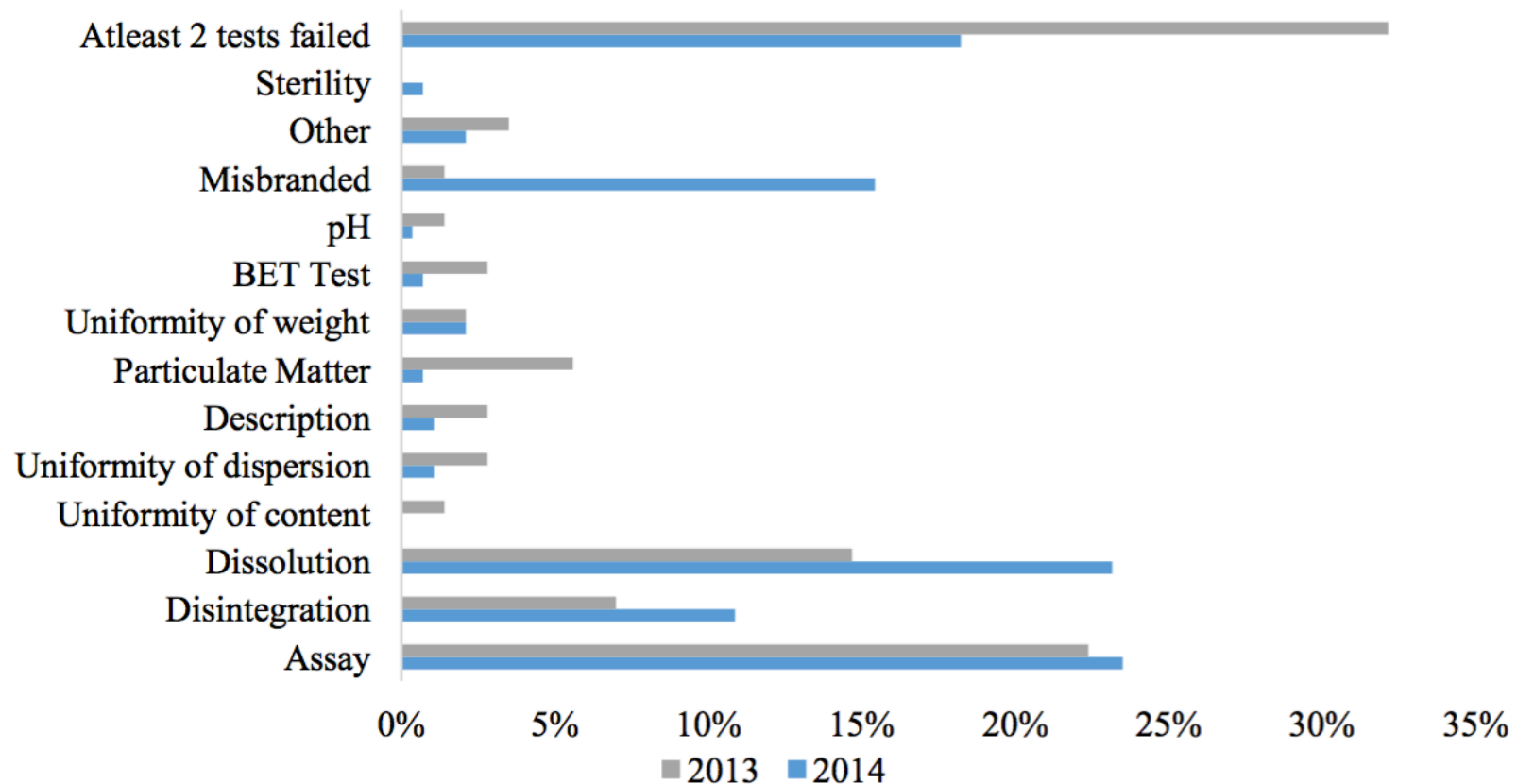


Hermentin *et al*, European Heart Journal (2005) 26, 933–940

# CDSCO says substandard medicines are not a real problem

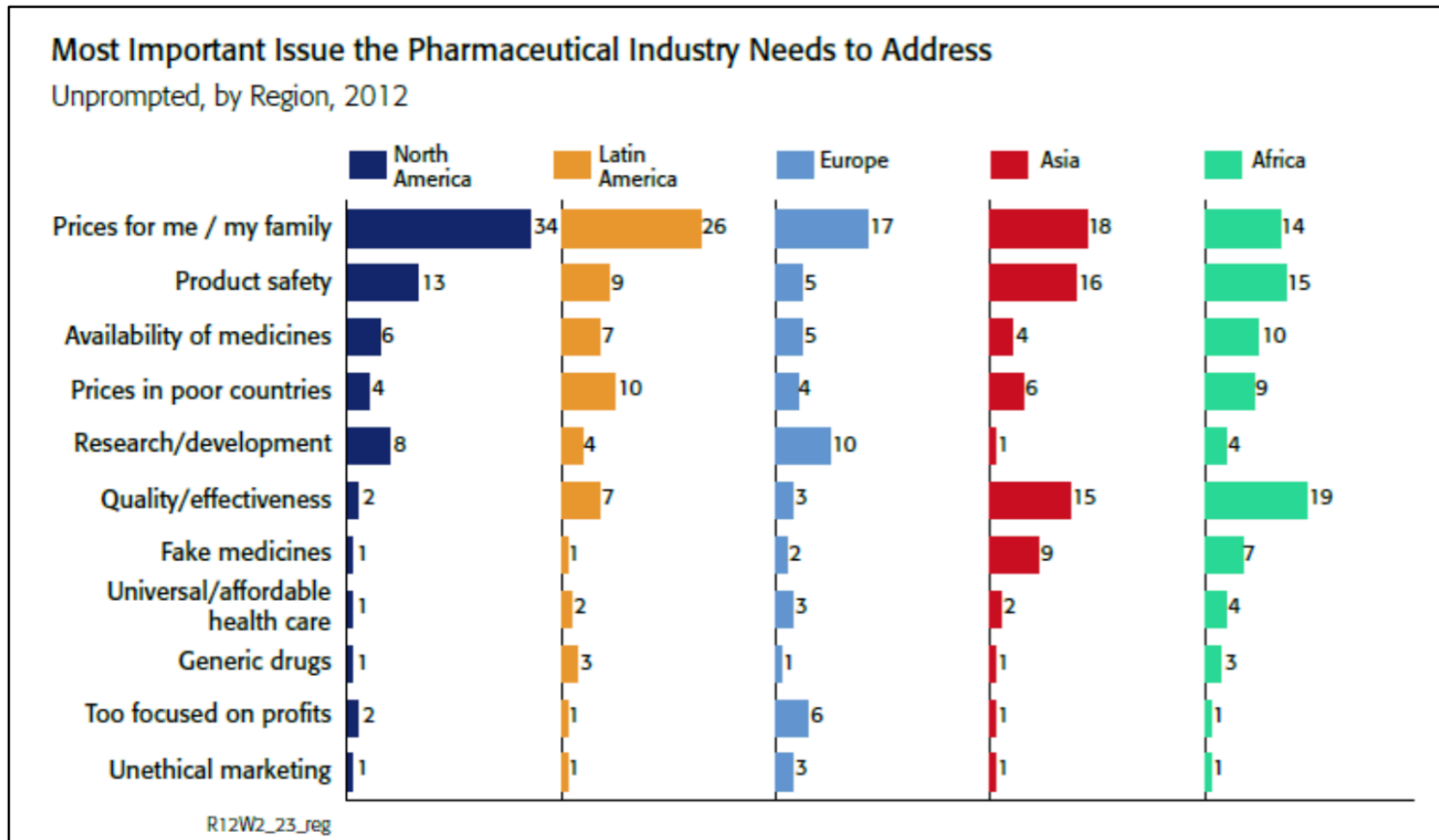


**Figure 4: Causes of Drug Alerts**



Source: Working paper #30, Indian council for research on international economic relations, September 2015

# Effect of a strong regulator on public health



Source: GlobeScan Stakeholder Intelligence eBrief

Thank you



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