



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

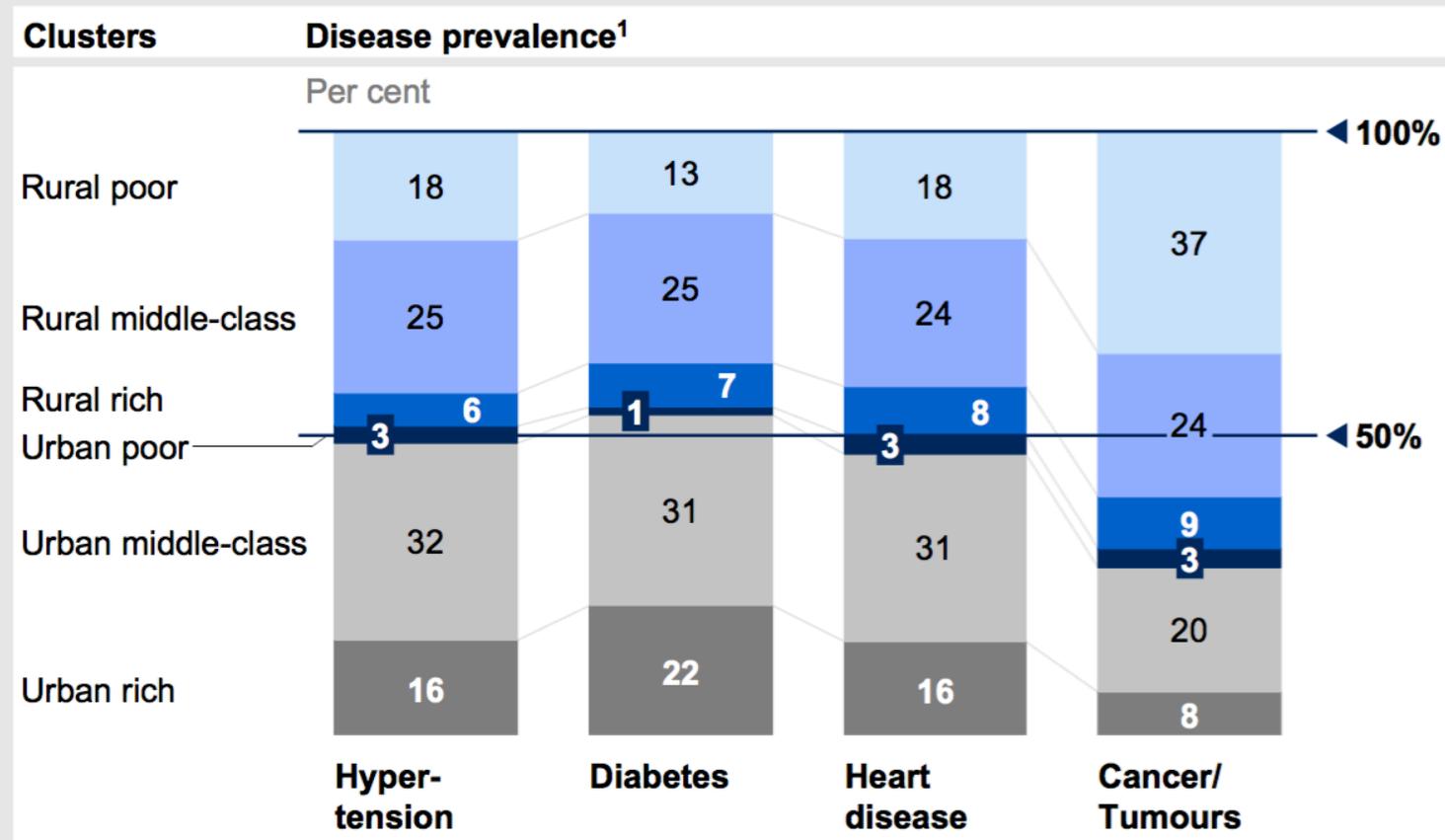


- A sub-center serves about 5000 people in general
- We have 1 primary health center for 30,000 people in rural populations in plains, 1 for every 20,000 people in hilly and tribal areas
- Community health center serves about 80,000 to 1.2 lakh people

Disease burden



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



¹ Defined as cases per 1,000 population

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

Key Message



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">• Synthesis (material, process, controls)• Specification (Structure and Identification)	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.

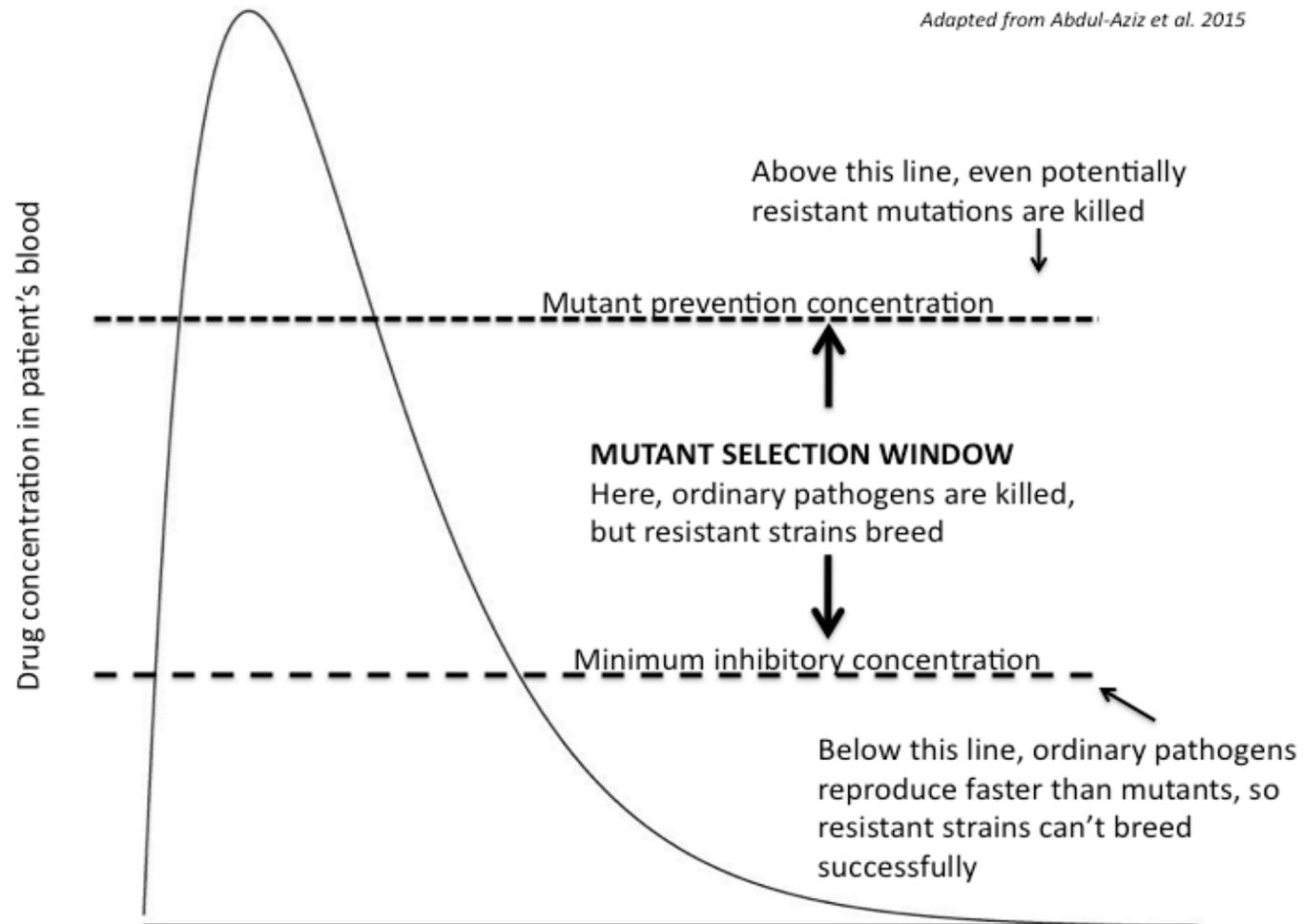
Classification of quality



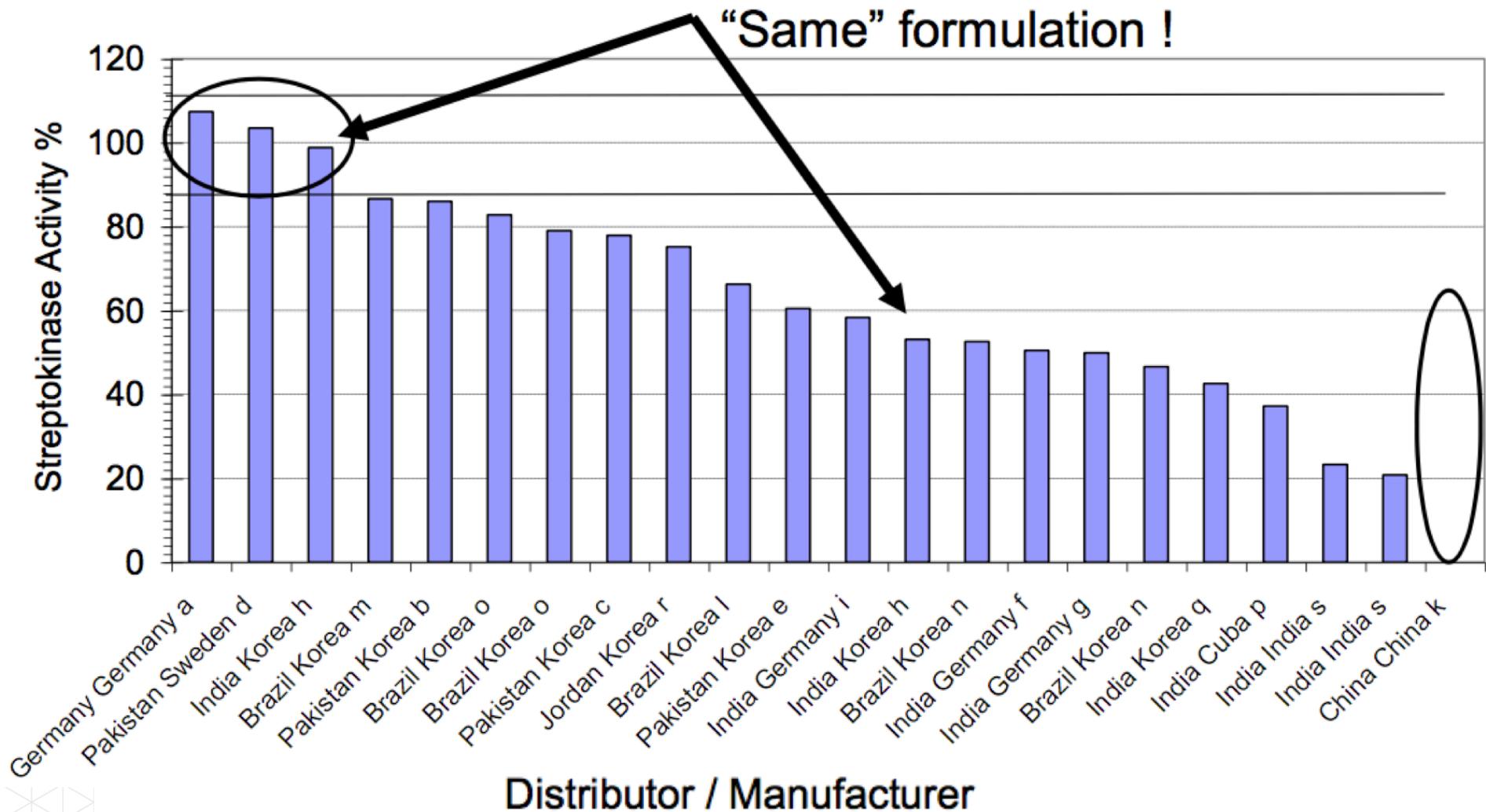
		LIMITED THREAT TO PUBLIC HEALTH	MAJOR PUBLIC HEALTH THREAT			
LEGAL		Registered manufacturer, good quality			LEGAL	
				Registered manufacturer, degraded		
				Registered manufacturer, accidental production error		
FALSIFIED		Registered manufacturer, good quality but stolen/ diverted/ falsely packaged/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



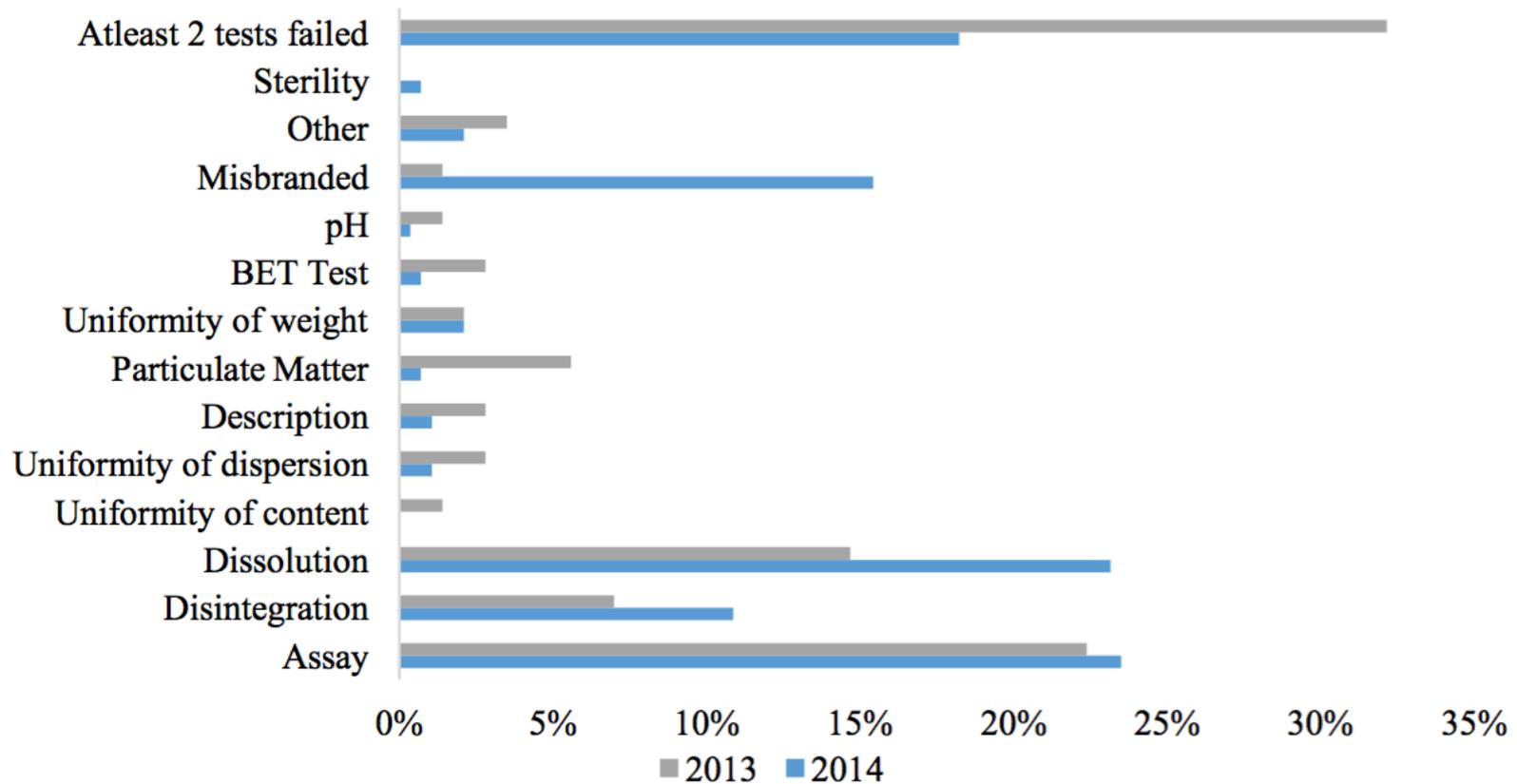
A real world example



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

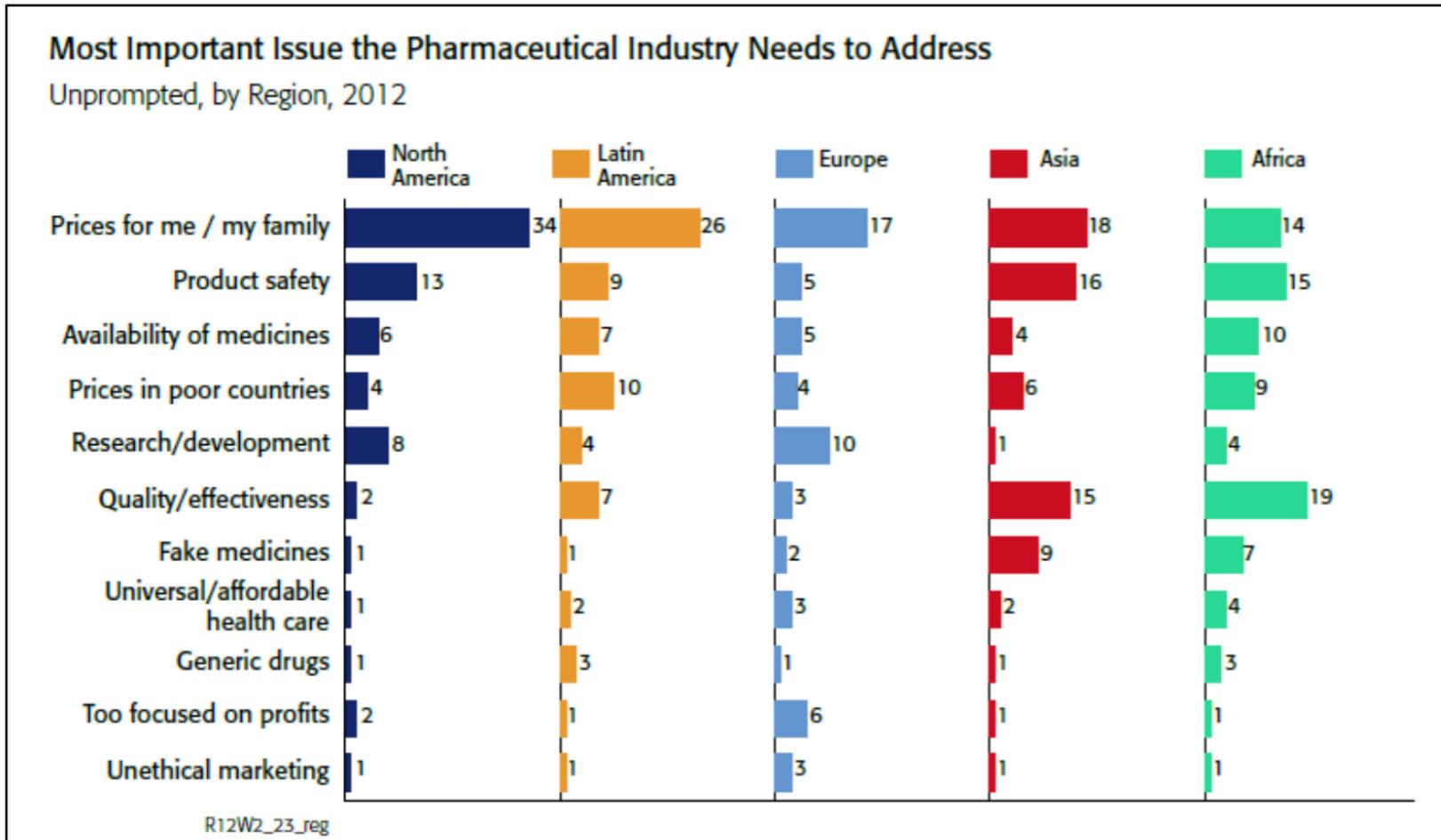


Figure 4: Causes of Drug Alerts



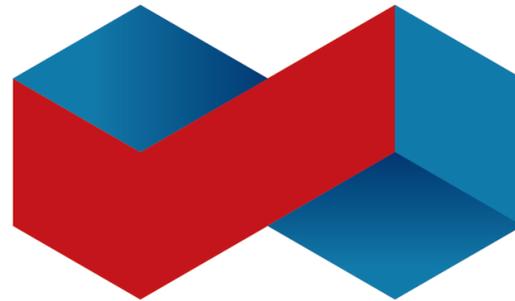
Source: Working paper #30, Indian council for research on international economic relations, September 2015

Effect of a strong regulator on public health



Source: GlobeScan Stakeholder Intelligence eBrief

Thank you



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