Patterns of Dysfunction in Effective Use of Pharmaceuticals

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HEALTH, NUTRITION, AND POPULATION
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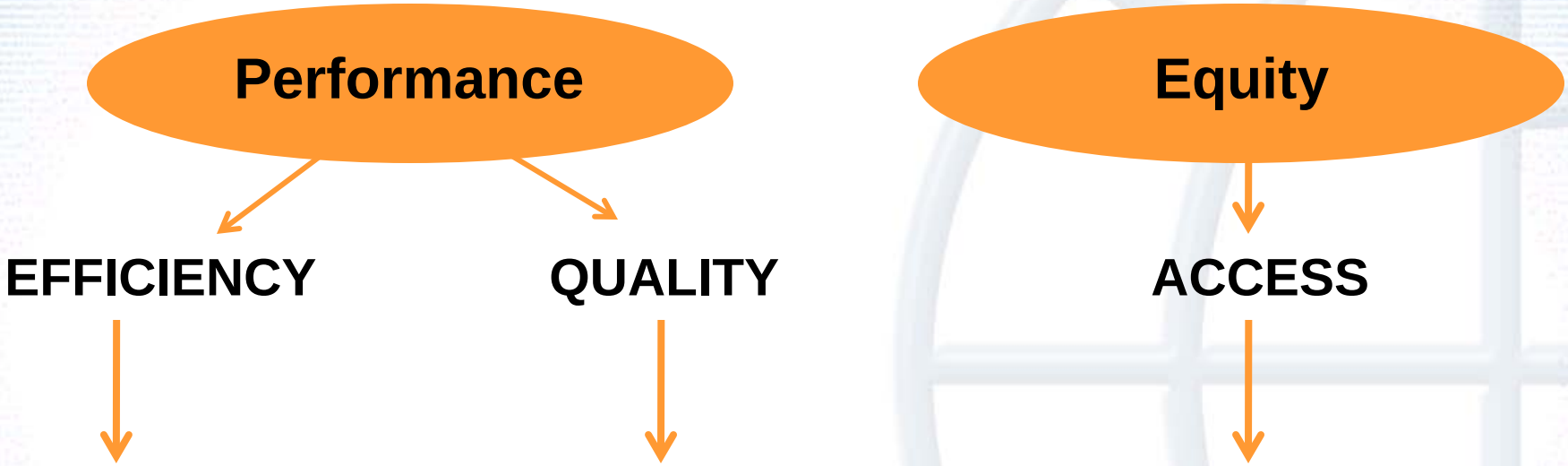
Pharmaceuticals …. The jewels of the Health Sector

Are your Medicines Supporting Health Outcomes?

What do we want from the Health System?



- **Availability**
  Functioning market
  Procurement, supply chain

- **Utilization**
- **Acceptability**

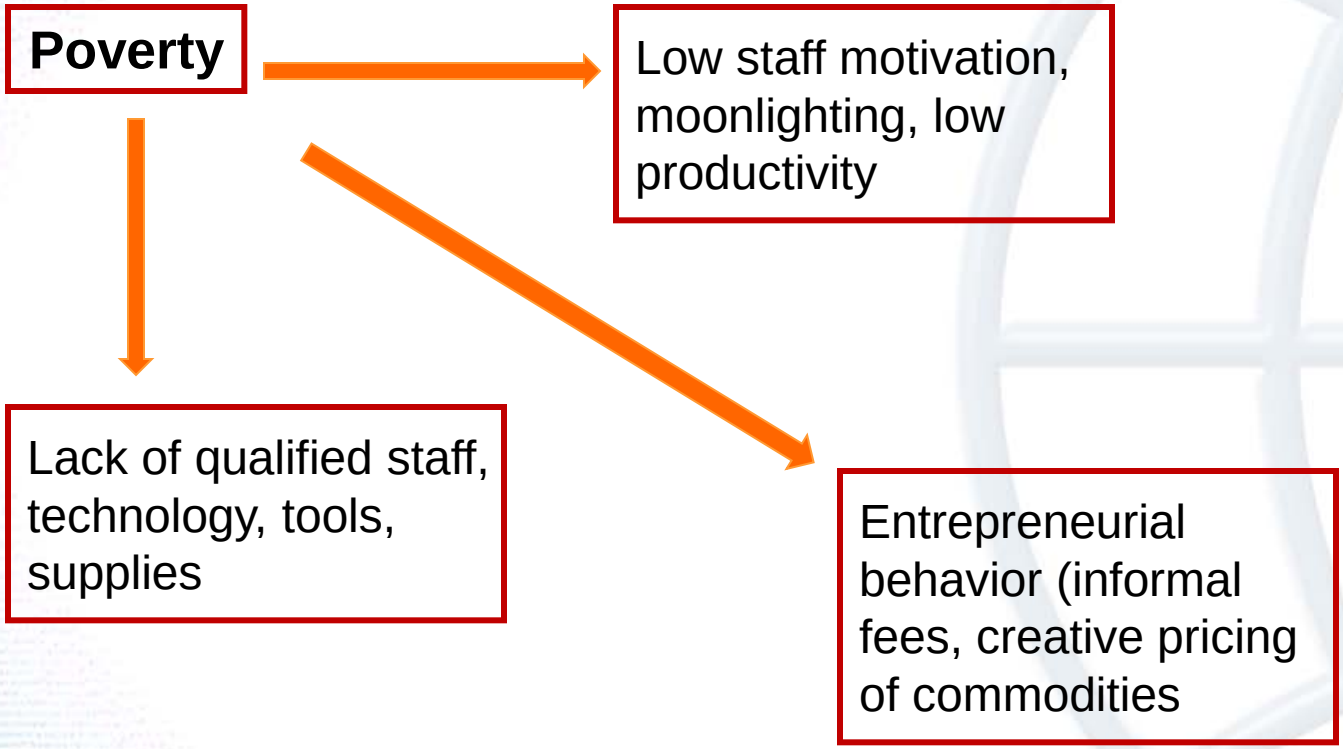
- **Affordability**
- **Accessibility**
  Geographical proximity, Transport costs, service hours

Factors Limiting Access to Medicines

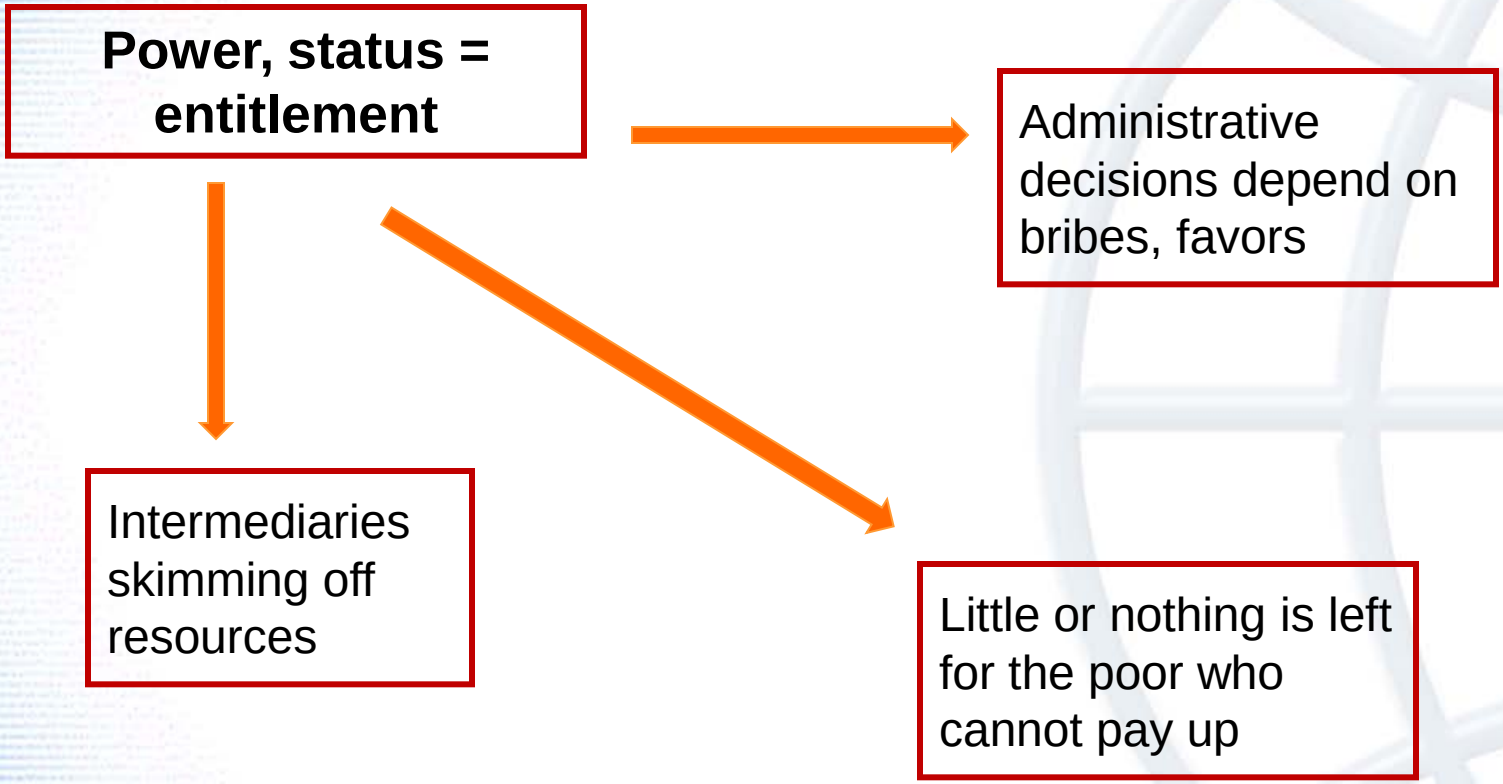
- No cash: patient cannot pay for consultation or buy adequate dose of the right type of medicine
- No access to facility: too far, waiting time too long, no transport, discrimination
- No product: market failure, regulation, procurement failure, bad planning, theft, financing problems
- No knowledge: health worker or patient are not aware of adequate treatment options or don't believe in them; medicines are not used appropriately
- No regulation: no laws or no enforcement, no political interest/ support

➢ Consequence: people go untreated, get inadequate treatment, seek treatment from traditional healers, self-medicate with OTC products or with dubious (smuggled, sub-standard, counterfeit) products from the informal market

Resource limitation causes dysfunction

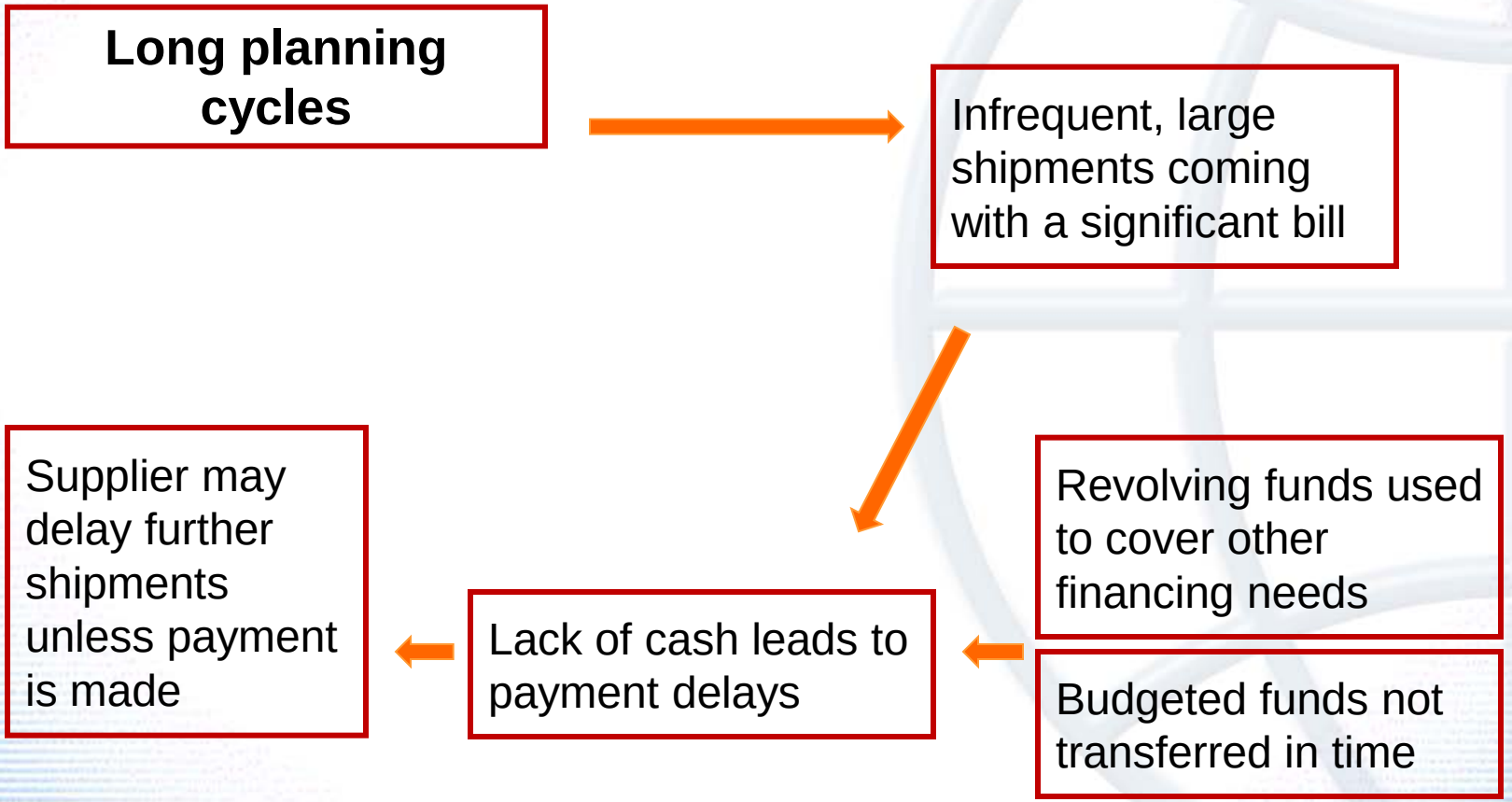


Entitlement culture* causes dysfunction



*In contrast to a culture in which power and status are mainly identified with the responsibility to serve the common good. Legal systems generally demand such a system, but in real life there are significant differences between countries.

Payment problems cause dysfunction



“Market Failure” causes dysfunction

- Experts make decision on behalf of patients
- No accountability for costs and economic consequences
- Incentives usually in favor of overuse of drugs, use of more expensive drugs
- Individual consumers have no power, knowledge or bargaining position
- Pooled purchasers (MOH, insurance funds) sometimes captured by supplier/provider interests, often not well equipped to match the sophistication of suppliers/providers

Information asymmetry causes dysfunction

- Complex issues such as the supply of effective, affordable medicines involves many different interest groups and individuals who see problems and solutions only from their own perspective.
- The resulting clash of interests often leads to the emergence of a dominant group, which imposes its favored policy.

-- MeTA, the UK-funded Medicines Transparency Alliance, recognized the importance of a multi-stakeholder approach.

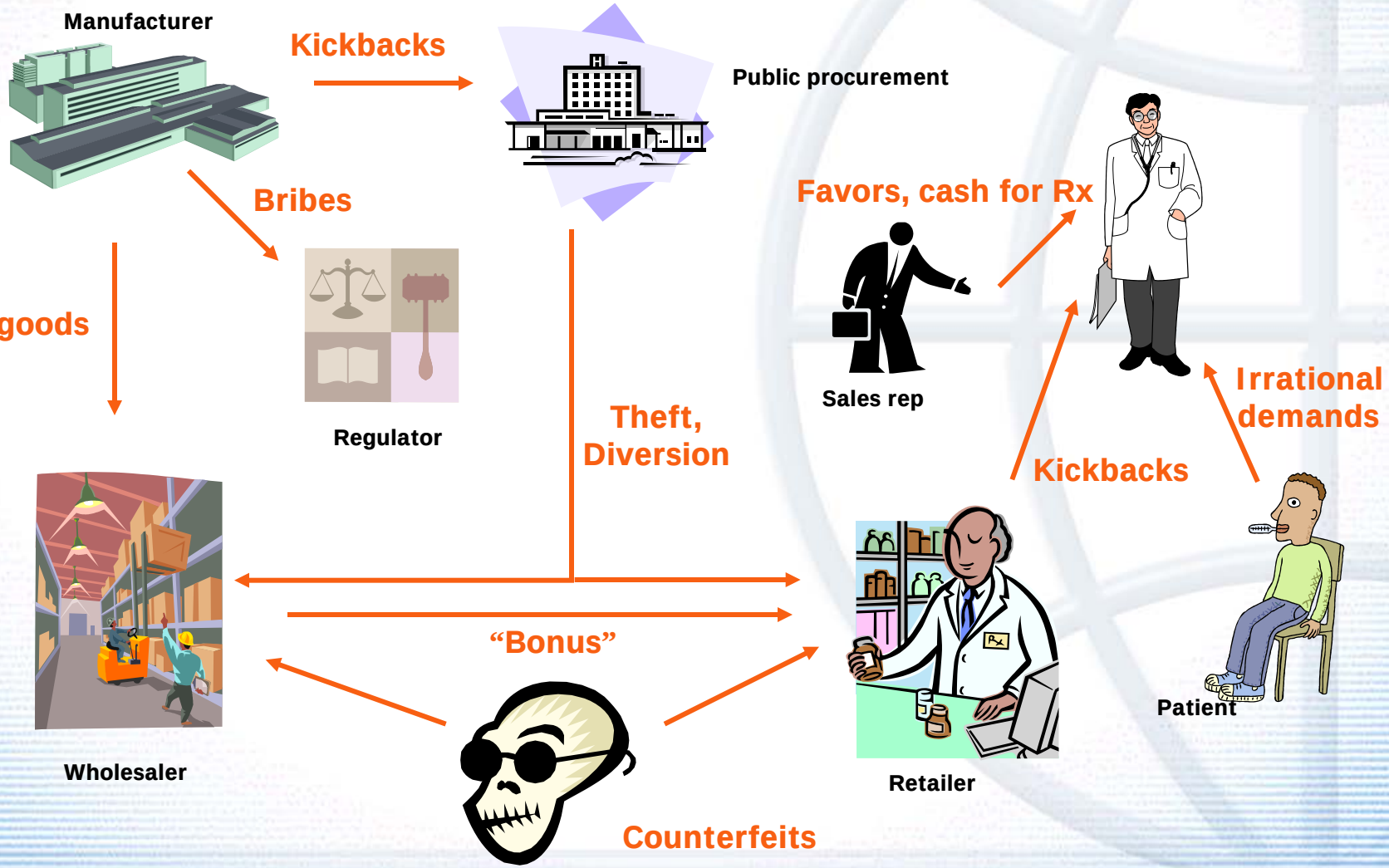
-- MeTA enables various stakeholders to agree to work together on an equitable basis, recognizing the validity of others' interests, sharing information and views.

-- This can include establishing a forum for representatives of everyone involved in the medicines supply chain – manufacturers, governments, international organizations, traders, medical workers, academics, the media, and patients.

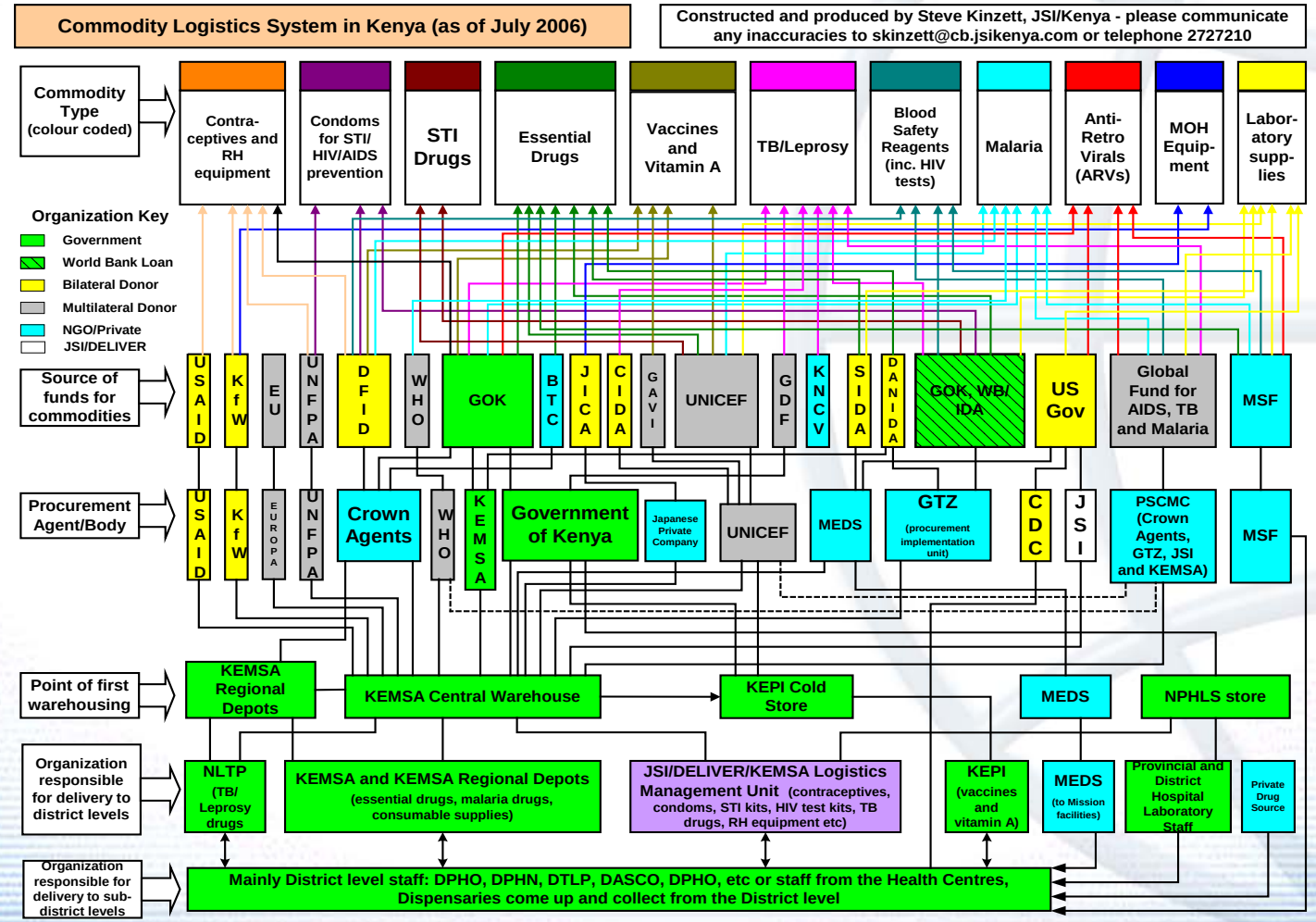
Lack of regulation and enforcement of rules creates dysfunction

- In a lawless environment, personal relationships and interdependence become the stabilizing factor
- Economic efficiency becomes secondary – first is safety: I did something for you, now you owe me..
- Political power and economic power are closely linked – politicians need to provide for their followers to maintain their powerbase
- “Tribal” thinking: keeping power and resources within the “family” is rational behavior in a hostile environment – creation of monopolies (example: drug gangs)
- Cartels become a way to split the market and keep the peace among competitors

Kickbacks, leaks and schemes



Fragmentation – Example Kenya



What can be changed to improve access?

1) Analytical Framework for the Health Sector: "Control Knobs"

- Financing – are there user fees? are there insurance schemes?
- Payment – are doctors, hospitals and other providers adequately paid – are there incentives to improve access?
- Organization – who does what? is there a functioning supply system?
- Regulation – is there a functioning drug regulatory authority, are there sanctions for counterfeiters?
- Persuasion – have there been efforts to influence behaviors both of providers and consumers, have there been steps to improve political will?
- Others??

What can be changed to improve access?

2) Analytical Framework for the Pharmaceutical Sector

- ✓*Incentives*
- ✓*Processes*
- ✓*Systems*

Commercial interests

Policy and politics

Market

Regulation, administration

Financing

Use of drugs

Patient perceptions

Payment mechanisms

PSCM*

*Procurement and supply chain management

Practical Steps for Improving Pharmaceutical Supply and Rational Use

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Case study: MEDS Kenya

- First Faith-based organization to have WHO prequalified lab
- 4th prequalified lab in sub-Saharan Africa
- How did this improve pharmaceutical access?

Case study: NAFDAC - NIGERIA

- Nigeria is one of a number of countries whose pharmaceutical system has been impacted by corruption and has struggled to curtail the production and trafficking of substandard drugs.
- In 2001, the National Agency for Food and Drug Administration and Control (NAFDAC) underwent an organizational restructuring resulting in reforms to reduce counterfeit drugs and better regulate pharmaceuticals.
- Have these changes led to improvement?

- Video…http://www.youtube.com/watch?v=Tooxeb3Byrg

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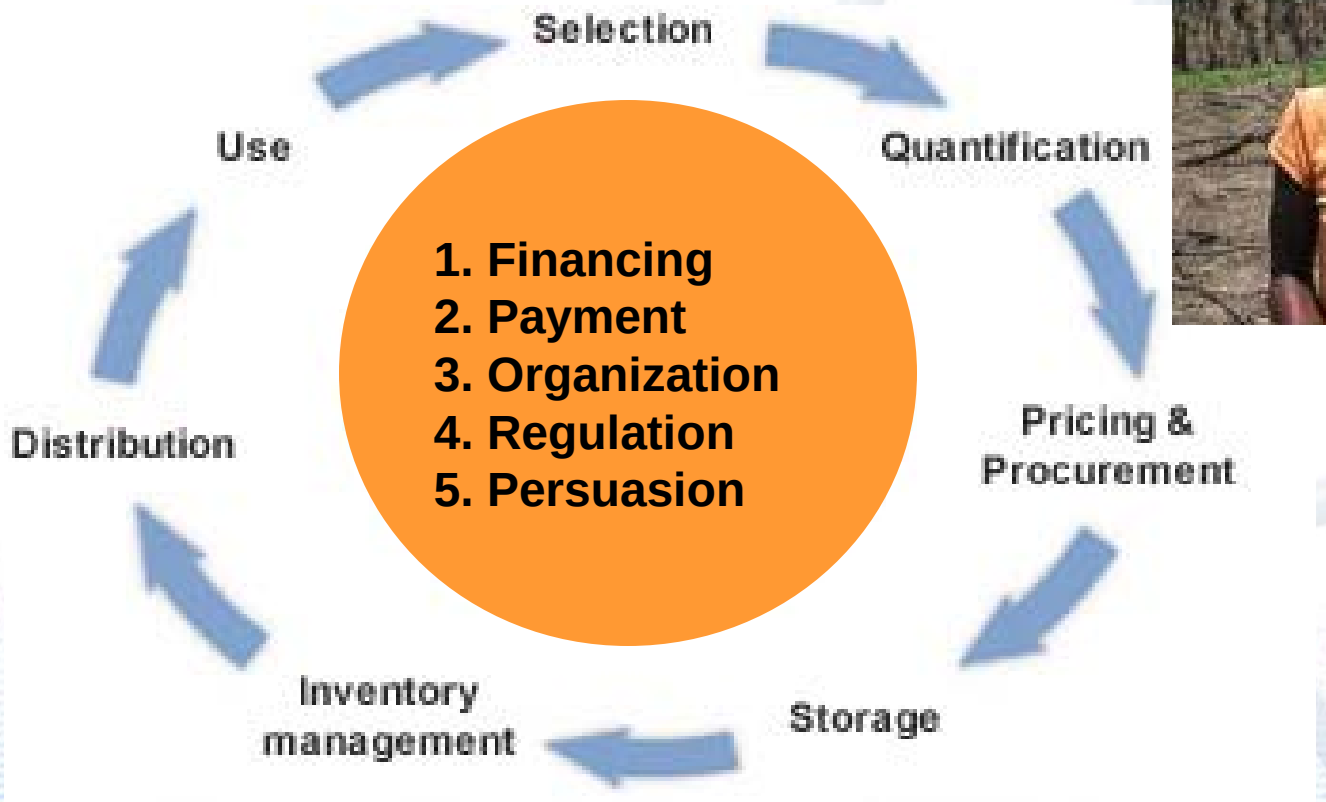
How can we overcome these problems?

Use Health Systems Controls to Affect the Procurement and Supply Chain Cycle



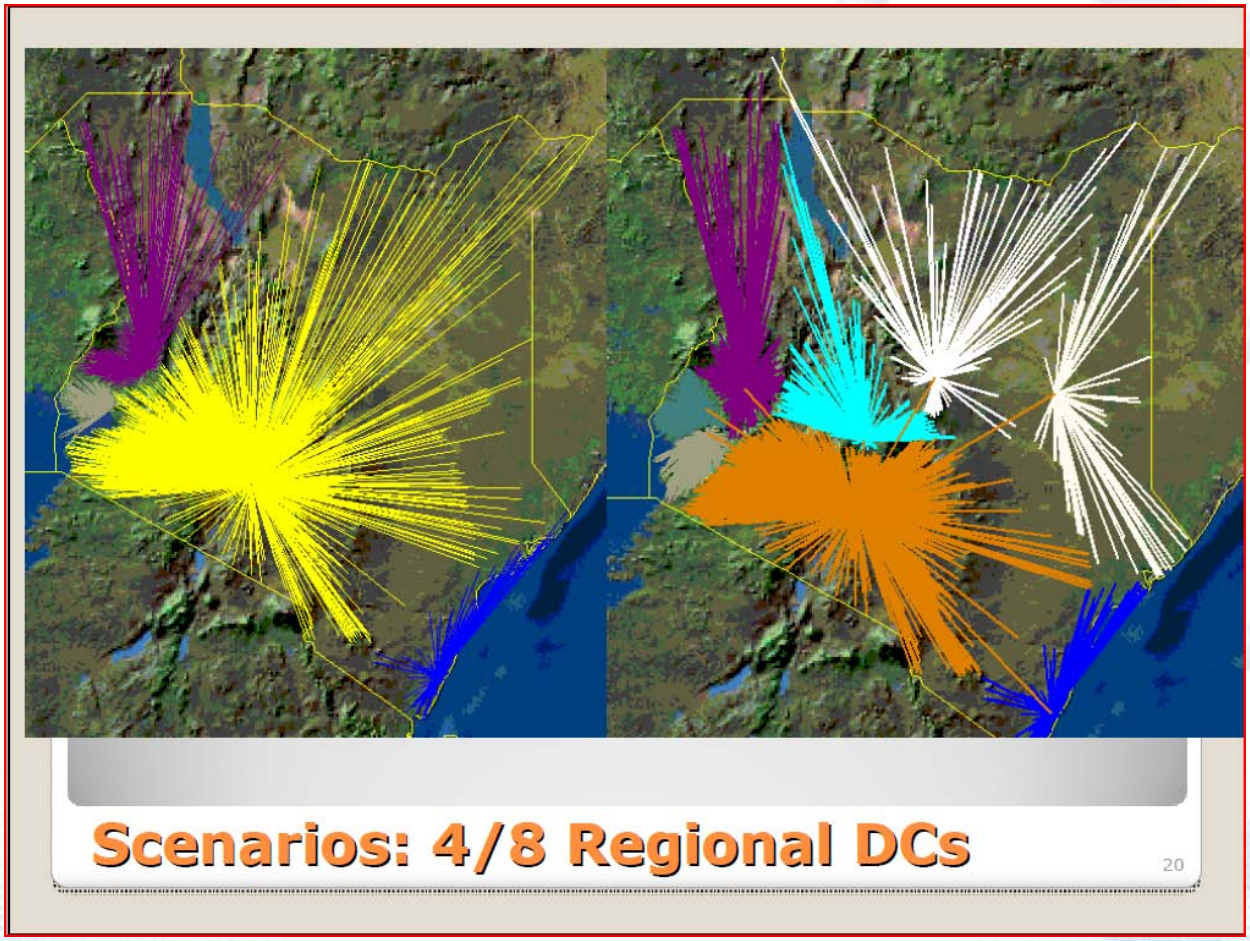
1. Financing: Empowering consumers through alternative payment mechanisms

- Consumer entitlement through vouchers or benefit schemes (for example by handing out a smart card, using cell-phone based payments?)
- Facilities get reimbursed for certain drugs and services (abuse potential!)
- Pooled demand creates bargaining power that individual consumer are lacking
- Goods will “chase the money”, meaning the market will develop capacity to supply if steady demand is ensured by adequate financing
- “Pharmacy Benefit Management” creates pressure to collect utilization data and can be used to support rational use of drugs

2. Payment: Using contracting and incentives to overcome capacity problems

- Public hospitals/clinics could form a “buyer club” to purchase supplies in the private sector, using framework contracts (complementary to the top-down public supply chain)
- Supply chains could be partially or completely outsourced, changing from physical to “virtual” procurement with more resources for contract oversight at the center
- Quality control and assurance can be governed by the purchasing contract to compensate for absence of regulatory oversight (for example in post-crisis situations)
- Incremental public funding can be made conditional on provision of good quality performance data and adherence to certain performance standards (treatment guidelines, rational use)
- Elimination of unnecessary rules and restrictions, for example broadening of OTC market to decrease pressure on health system

3. Organization: using modeling tools to identify cost-effective designs (example: KEMSA decentralization)



4. Regulation
Knowing what the situation is: data & transparency

- Availability of tracer drugs at facility level
- Presence of unlicensed, fake or substandard drugs in the market
- Time required to get licenses etc.
- Drug prices in the market
- % of funding that reaches community level
- Prescribing behavior at facility level, adherence to treatment guidelines
- Regular reports, ranking lists
- Hotline for consumers and whistleblower protection/reward scheme to identify cases of abuse, fraud, corruption

Regulation: Strength in numbers?

How would harmonization impact the registration process?

Today's current environment	A harmonized future environment
~ 50 National Medicines Regulatory Authorities (NMRAs) governing drug registration across Africa	8 regional economic communities (RECs) covering the entire African continent
Paperwork, technical requirements, and other registration steps differ across NMRAs	Common documentation, procedure, and decision-making framework across all RECs
Manufacturers must invest significant time and effort in each registration, so a limited set of countries are targeted	Low cost to register in each additional country, so coverage is more broad and equitable
No clear timelines for a drug to clear registration and be ready for the marketplace	Streamlined process that is faster and easier... starting first with generics
Little transparency before or during the process	Clear understanding of the process by all parties involved

5. Persuasion: Using data to get political attention and focus resources on the most promising targets

- Highly visible regulatory crack-downs
- Creating a platform for data sharing and discussion (Example MeTA, www.medicinestransparency.org)
- Unblocking administrative decision-making to address bottlenecks and re-allocating resources to more productive areas
- Highlighting good performance and “name and shame” of bad performance in public media

In summary….

good governance means understanding influencing factors

‘consumer (patient) is king’ – must be involved in decision making

Despite abundant literature on the spectrum of issues relevant to pharmaceutical policy—including regulation, pricing, financing, reimbursement, procurement, and distribution—what has been lacking is a practitioner's guide for navigating this complex field while considering the various challenges and limitations that characterize political reality.

There is no "one-size-fits-all" approach to pharmaceutical policy. Even two countries with similar objectives may need to apply different sets of policies, depending on their starting positions, preexisting laws and regulations, perceptions among providers and patients, and implementation capacity. Developed countries may find it hard to reconcile industrial policy and innovation with cost containment in the health sector. Middle-income countries may have to bridge the divide between a demanding urban population and large numbers of poor people in peri-urban and rural areas. Low-income countries may struggle to provide basic essential drugs to their population through inefficient delivery systems that are still largely state run, while their growing private markets may be flooded with drugs of dubious origin and quality. In each case, policy makers and implementing agencies need to select and combine their policy measures in a way that not only conceptually addresses the main problems but also is practically viable and sustainable.

A Practical Approach to Pharmaceutical Policy discusses the wide range of challenges facing policy makers, presents the current know-how, and provides specific examples of policy packages that can be used in defined circumstances. The book, which focuses on developing countries, equally addresses the issues faced by low-income and middle-income countries. It concludes with a prognosis of how things might evolve in the longer term, assuming convergence toward models that work to reduce the fragmentation of policies and enhance regulatory and economic efficiencies. Such an evolution to a sustainable platform would benefit all stakeholders, but particularly those who, as patients, do not have reliable access to effective and safe medicines.

A Practical Approach to Pharmaceutical Policy will be of interest to pharmaceutical policy makers and advisers in developing countries; people in related fields such as health financing, health service delivery, and health insurance management; representatives of the pharmaceutical industry and associations; academics and students of public health policy, pharmacy, and health economics; and undergraduate and graduate students in related fields.

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