Human Development Network

Access to Medicines in Low and Middle Income Countries: Goals and Challenges

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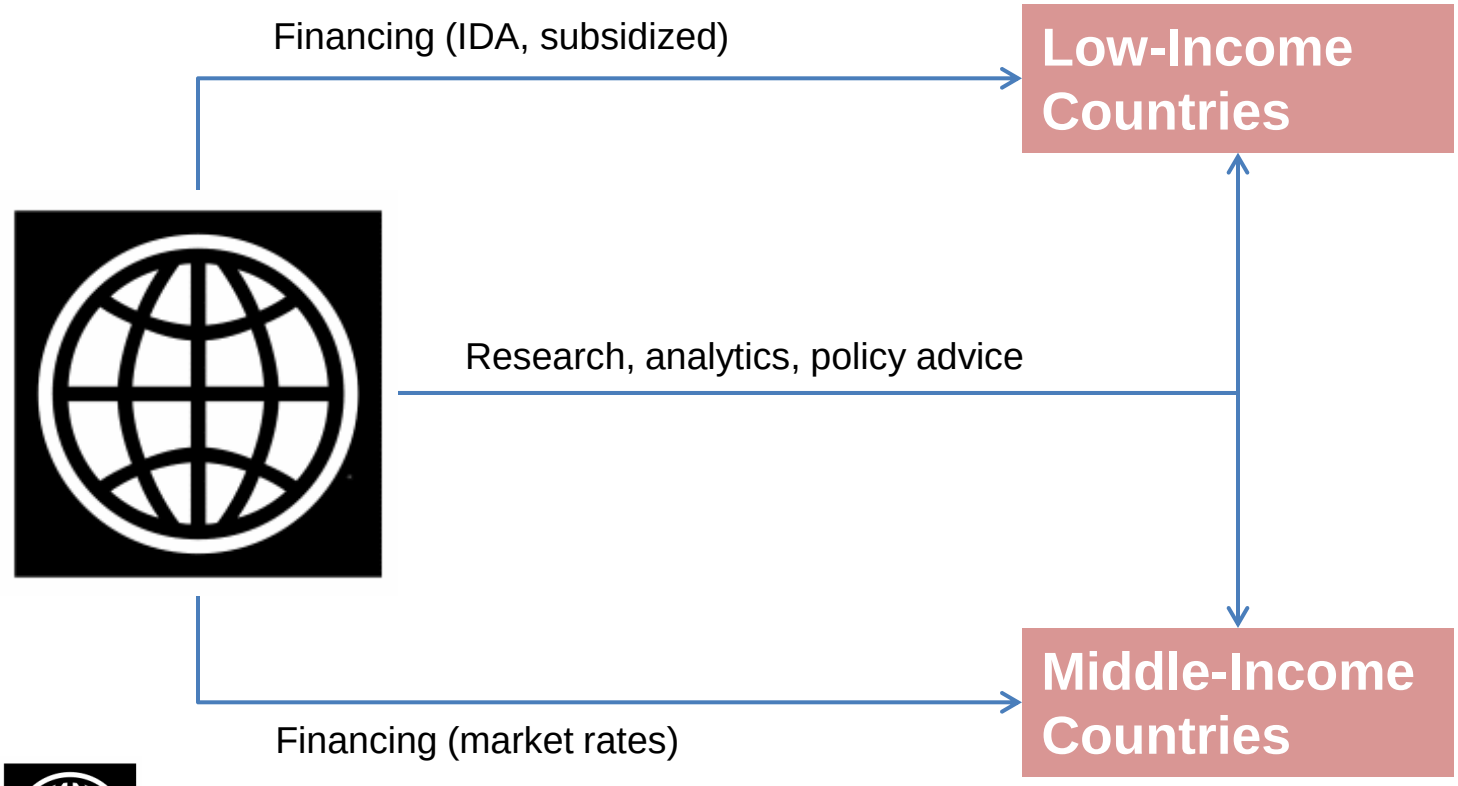
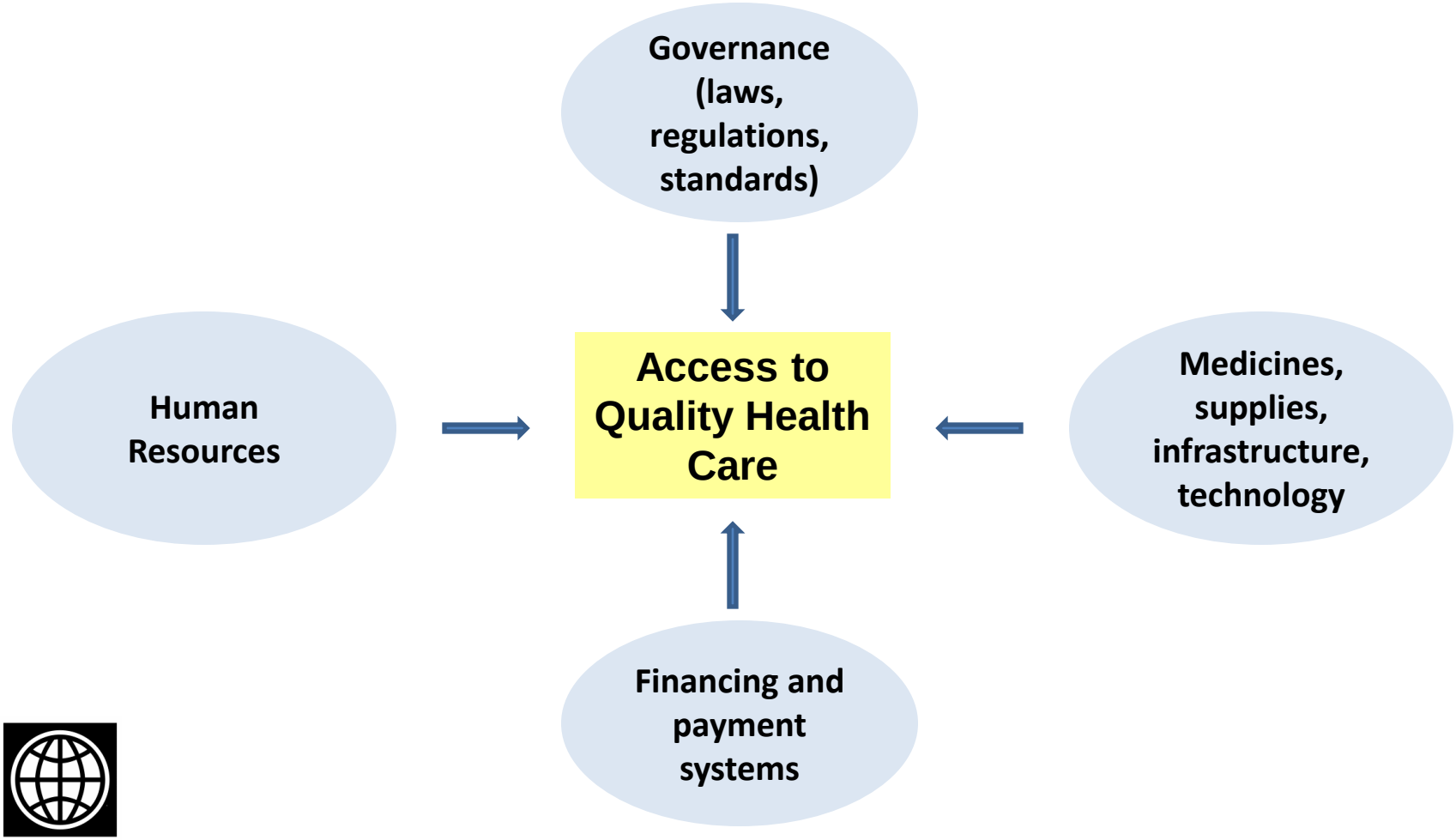
The World Bank
August 2013

The World Bank and its clients



Overall goal: reduce poverty, increase equity

Health Systems focus



Core challenges for policy makers

Low income

- Availability
- Quality
- Affordability
- Adherence
- Lack of resources requires prioritization of life-saving treatments with high public health impact

Middle income

- Equitable access
- Rational use
- Perception of quality
- Financial protection
- Affordability of innovative treatments

Systemic issues

Market failure

- Fragmented buyers
- Uninformed consumers
- Biased professionals
- Conflict between public health and private incentives

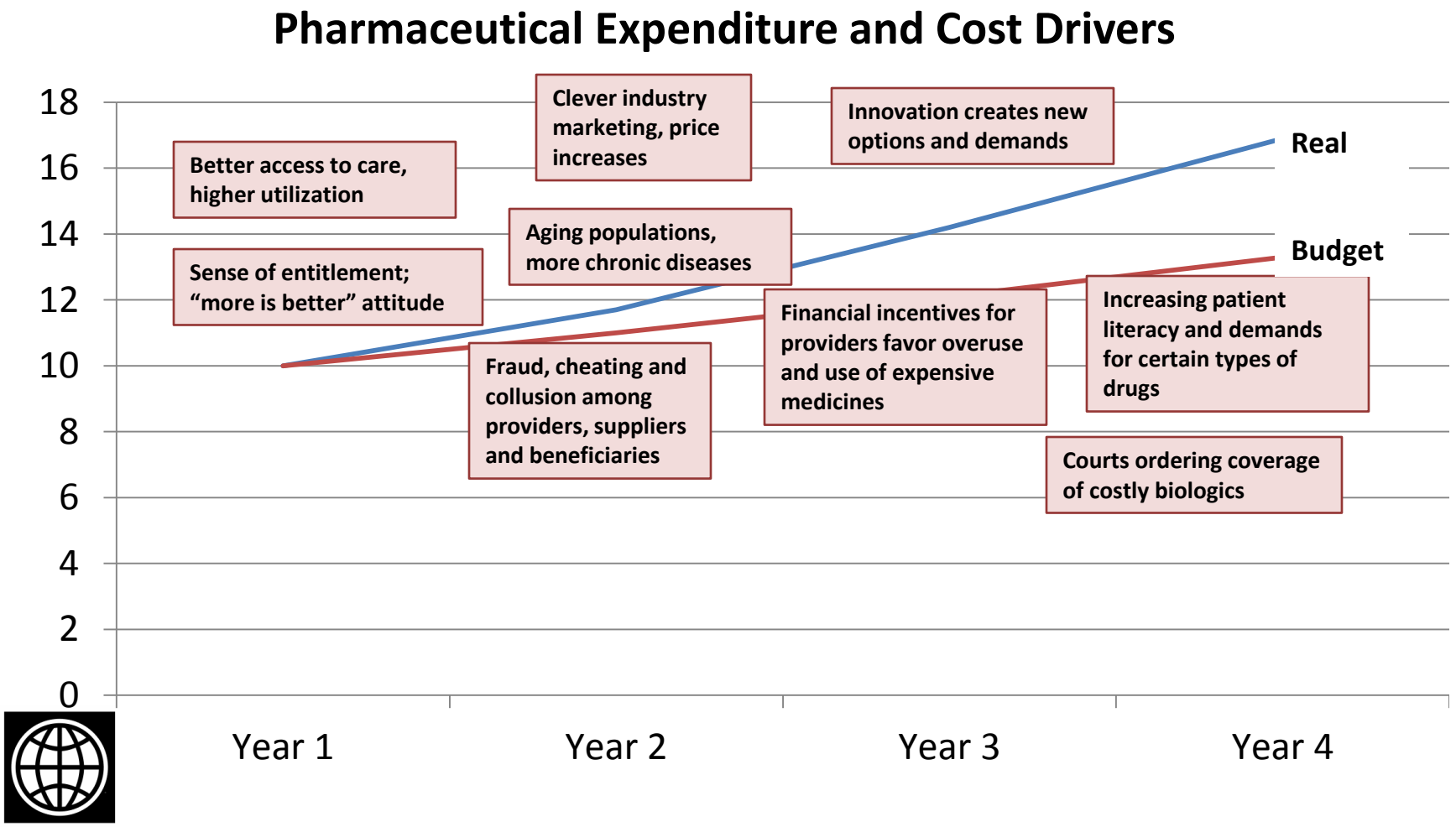
Weak governance and management

- Lack of accountability
- Outdated HR policies
- Fragmented decision making
- Corruption
- Lack of business skills
- Lack of technical skills
- Lack of data and transparency

Innovation dilemma

- Novel, potentially life saving medicines developed by large multinational companies come at a high cost
- Insurance funds and other payers with pooled funding are interested in offering new technologies but need to contain costs, the relevant factor being budget impact
- Individual patients from low-income households may not be able to afford new medicines even if they are priced far below the developed country price level
- **Manufacturers of such products face an ethical dilemma between shareholder interests (cost recovery, profit) and patient interest (access for all who could benefit from a new medicine)**

Drug budget overruns are the norm…



Once established, bad habits are not easy to break

Payers often find it hard or impossible to crack down on abuse and enforce restrictions against the combined political power of healthcare professionals, patients and a well organized industry

Rationale for Price Regulation

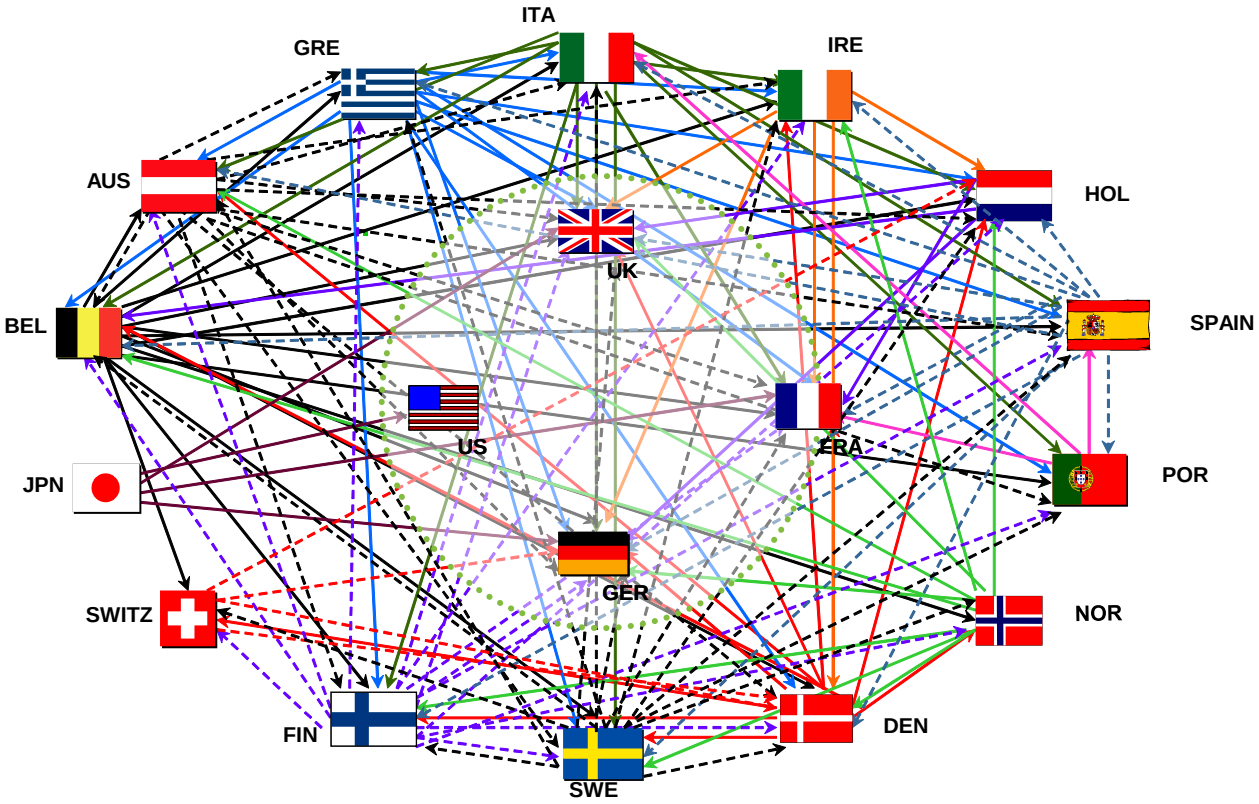
- Protecting consumers (vulnerability in the case of illness)
- Staying within limited budget
- Getting more value/volume for the money
- Improving access for the poor
- Protecting domestic industry, stimulating R&D investment (?)

- But price regulation alone is not sufficient to achieve any of these objectives!

Standard Pricing Tools

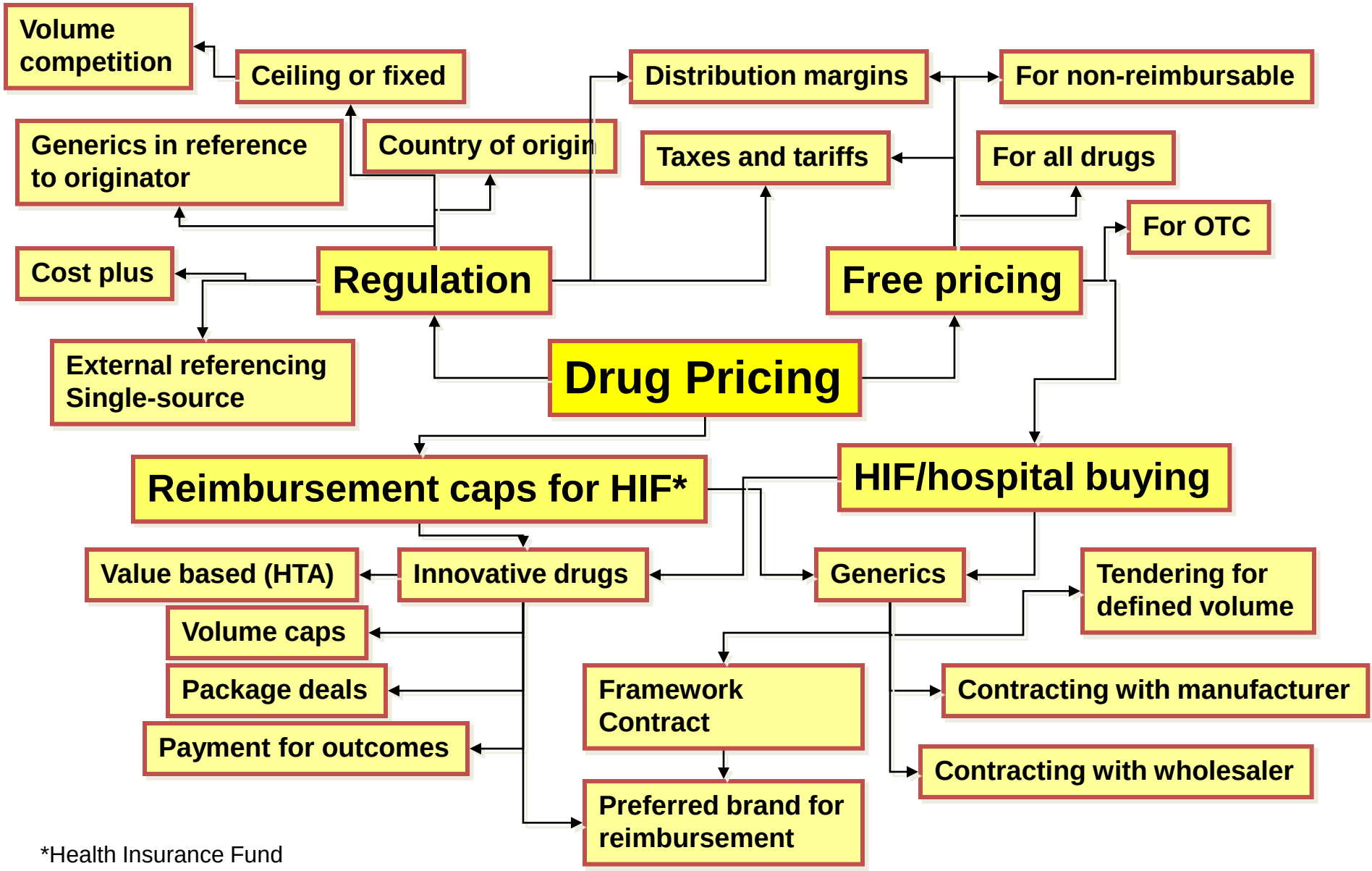
- Reference pricing (innovator, generic)
- Reimbursement ceilings (internal referencing)
- Pooled purchasing/contracting

External Referencing



Self-limiting concept? What happens once all countries are referencing to each other?

Drug Pricing "Mind Map"



*Health Insurance Fund

Core areas for policy innovation – Low income

Supply chain integration

- So far, procurement and supply chain logistics are often treated as separate system components
- Fragmentation is the rule
- Establish “Good Practices” for supply chain management as integral part of development cooperation?

Financing systems

- Public, top-down funding systems often ineffective, strangled by bureaucracy
- “Money-follows-patient” principle with focus on the poor
- Opening the door for more participation of private sector (combined with better regulation)

Strengthen regulators

- Current procurement systems potentially undermine regulators
- Patients using private providers exposed to significant risks due to weak enforcement
- Long-term solution has to rely on competent regulators to ensure quality of medicines in the market

What about rational use?

- Any evidence for successful, cost-effective, sustainable strategies to change provider and patient behavior ..
- .. in the absence of a strictly managed pharmaceutical benefit provision with third party payment mechanism?

Core areas for policy innovation – Middle income

Universal Coverage…

Typically includes coverage for a range of pharmaceutical products:

"Pharmaceutical Benefit Management" or "Pharmacy Benefit Management" is the set of rules, controls and enforcement tools that define how eligible beneficiaries can obtain third party payment for prescription medicines under a public budget or insurance funded healthcare program

Defining rules and developing tools upfront…

- Restrictive – stay on the safe side; later more benefits can be added
- Enforceable – have all management tools in place before benefit is implemented

Setting parameters for a pharmaceutical benefit

Reimbursement list: which medicines are covered

Patient eligibility (sub-population, condition, age, gender etc.)

Reimbursement rates, prices, discounts, budget caps etc.

Patient co-payment; exemptions, limits

Compensation for distributor, pharmacist; substitution rights

Assessment and decision making on inclusion of new technologies

Case management for high-cost patients

Negotiation strategies for deals with industry

Medical and economic assessment

Publicly available data & analysis (example NICE)

Decisions made by other countries

Manufacturer provided data

Considering

- Health priorities
- Applicability of data
- Available funds
- Economic impact
- Subjective suffering
- Delivery capacity
- Other relevant factors

Rejection

or

Go-ahead for negotiations with supplier

Countries that cannot afford a full scale Health Technology Assessment body still need a mechanism to assess available information on new medicines/technologies and make rational decisions on spending priorities for a pharmaceutical benefit package

Negotiation goals and strategies

Innovative, patented, expensive

Price per unit versus total budget impact

Cost-sharing or price-volume agreements

Generic, multi-source

Competitive pressure on generic drug prices

"Preferred brand" model, eliminating bonus to supply chain

Optimizing "value for money" requires different negotiation strategies for dealing with manufacturers of innovative (patented) versus generic medicines. Price regulation or fixed reimbursement rates alone will lead over time to sub-optimal outcomes. This issue can be tackled after a benefit scheme is implemented.

Investing into data collection and management

- Provider and patient level data on utilization are needed to manage the main cost drivers
- Transaction monitoring produces lots of data every day; significant computing power is needed to process data and generate meaningful reports
- Confidentiality of personal data is an issue that needs to be addressed and communicated well

Patient	Product	Service Provider
Unique identifier	Unique identifier	Unique identifier
Diagnosis (code)	Dosage form, dosage	Date of transaction
Eligibility criteria (example age, gender)	Units dispensed	Units prescribed

Using data to adjust rules and inform negotiations

(Examples)

- Expenditure tracking against budget
- Performance against agreed goals for rational use
- Flagging potential fraud
- Identifying patterns of abuse, overuse
- Measuring cost-effectiveness of prescribing
- Enforcement of price-volume agreements

Options for a frugal approach

In a low income environment or if political will for upfront investment is missing, a benefit package under a defined budget cap could be implemented as follows:

- Coupon system
  - Offering coupons for eligible beneficiaries and specific products; coupons are handed out by providers and can be cashed in by pharmacists
  - Data collection at payer level, based on reimbursed coupons
- Budget holding at health facility level:
  - Each facility gets a defined budget allocation for reimbursement through a single contract pharmacy. Once budget is used up, patients pay out of pocket
  - Pharmacy keeps record and informs health facility management of remaining budget

Downsides: Benefit may be captured by people with “connections” or higher literacy levels, who learn how to play the system

Ensuring access for the poor

- Manufacturers should make a commitment to working with their national counterparts on a solution that maximizes access to novel medicines for which the need exceeds ability to pay
- Different medicines and different countries will require a range of strategic options to optimize access without eroding profitability in the high-income segment, such as
  - Compassionate need programs
  - Collaboration with service providers that treat mainly poor patients and offering the medicine for free
  - Voluntary license to a generic drug company

Technology offers innovative solutions

Management of the provider-patient transaction with a smartphone app, that

- Verifies patient eligibility
- Guides the provider through the intervention based on a defined protocol
- Verifies identity with a photo and barcode reader
- Transmits transaction based data to a central server for analysis
- Pays the provider through an “m-pesa” like service as soon as transaction is complete

In this setting, the type and number of transactions can be pre-defined and controlled server-side. Each type of service has its own app. The risk of budget overruns is minimalized.