Pharmaceutical Policy in MICs – Challenges and Priorities

September 2015

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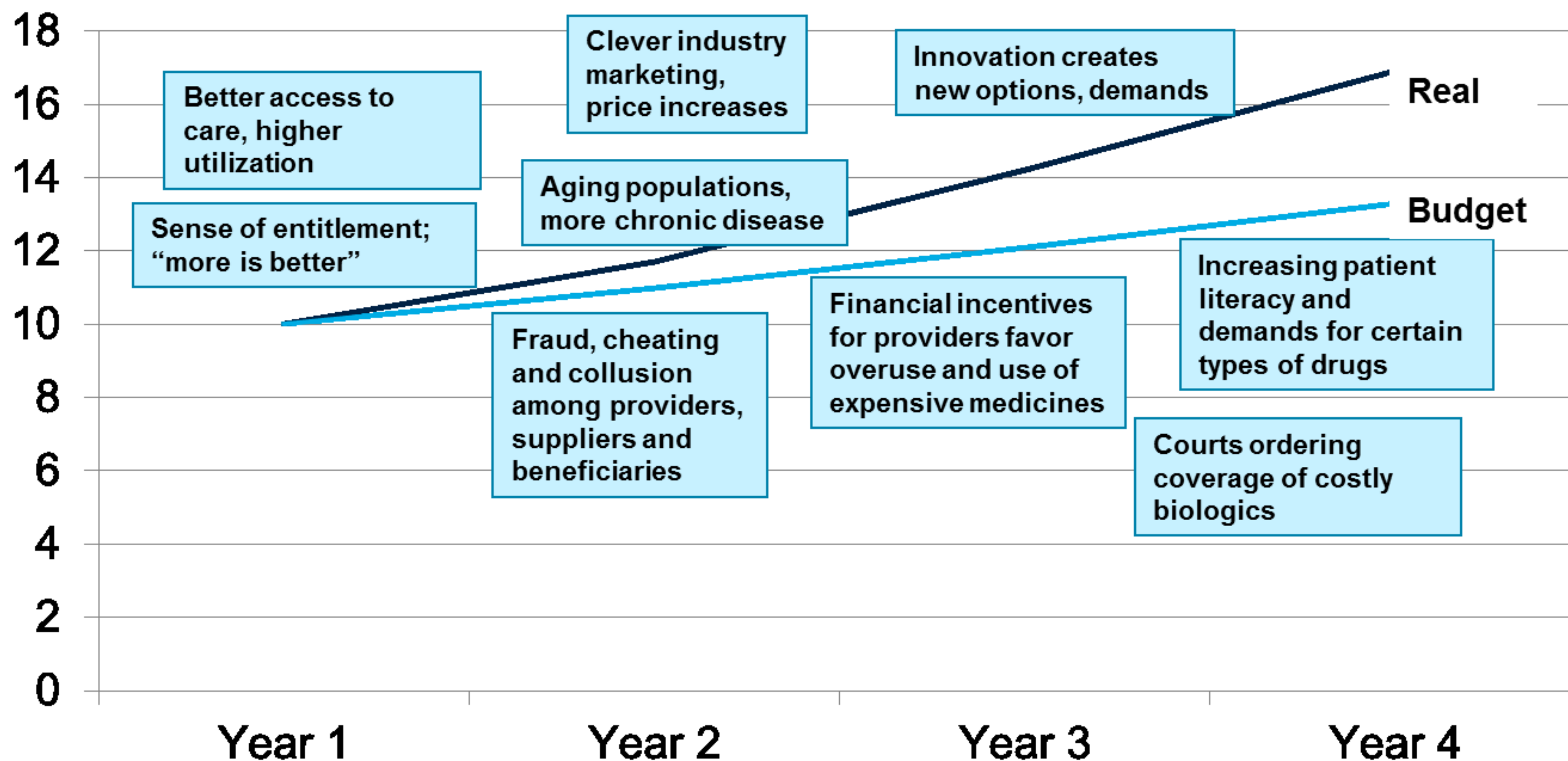
Access challenges

Availability	▪ Certain essential drugs are unprofitable ▪ Public sector rationing (funding, management issues) ▪ Pressure to introduce and finance new, expensive drugs
Purchasing	▪ How to get the best price for quality generics? ▪ Private pharmacy prices/margins difficult to regulate ▪ How to introduce expensive drugs?
Financing	▪ What is the right level of spending for drugs? ▪ Preventing catastrophic expenditure in OOP payments ▪ How to structure co-payments?

Rational use challenges

Polypharmacy	▪ Too many drugs at once ▪ Too many antibiotics ▪ Too many injections
Product mix	▪ Preference for more expensive drugs? ▪ Incentives in the supply chain may antagonize efforts for cost-effective treatment
Under-treatment	▪ NCDs underdiagnosed and/or undertreated ▪ Chronic patients may only get short term treatment (affordability) ▪ Health and economic benefits of adequate treatment not realized

Countries often face cost escalation and drug budget overruns



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Availability and pricing - three "buckets"

Low volume generic	High volume generic	Innovator brand
▪ Availability is key concern ▪ Price needs to be high enough to attract sellers ▪ Active policy needed to ensure supplies (including regulatory side)	▪ Quality and price are key concern ▪ Many competitors in the market ▪ For public sector, better procurement is key ▪ For outpatient drugs, HIF holds key through reimbursement policy	▪ Pressure on budget growing ▪ Priority setting, transparent decision making needed ▪ Active deal making with manufacturers (EU experience)

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)

Pricing Tools

- Reference pricing (innovator, generic)
- Reimbursement ceilings (internal referencing, generics)
- “Preferred brand” strategy in reimbursement
- Pooled purchasing
- “Creative contracting” (innovator, low volume drugs)
- Regulation of margins (wholesale, retail)

Unwanted Effects of Capped Reimbursement

- Fixed reimbursement rates eliminate incentive for price competition
- Generic manufacturers fight for volume instead
- Bonus offers for distributors who push certain brands instead of price cuts
- Winners are wholesalers and retailers, losers are payers and manufacturers

Using Reimbursement Policy to Create Competition Among Generics

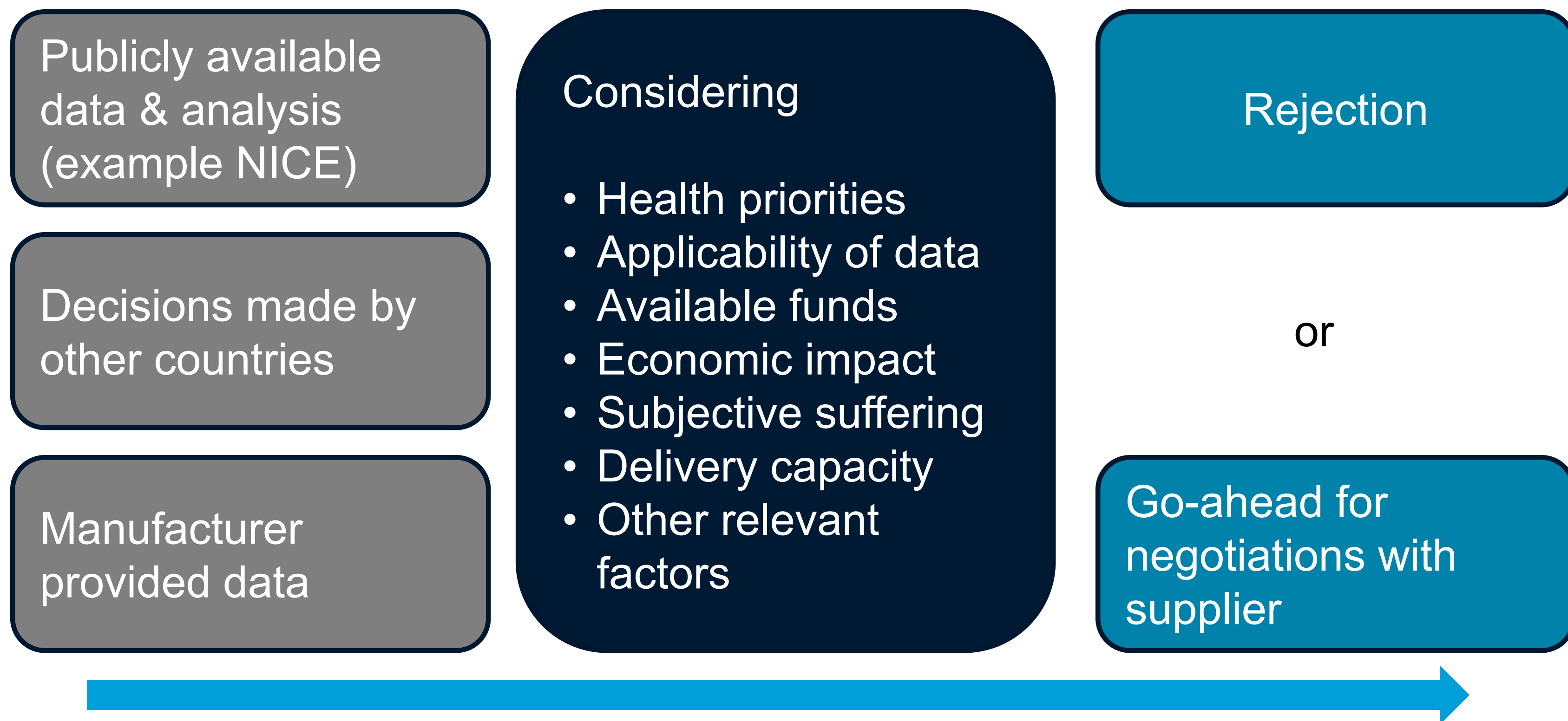
- Letting manufacturers (or their agents) bid for reimbursement status
- Example: only the 2 or 3 lowest price brands will be included in the reimbursement list, all others are not reimbursed at all
- Alternative: waiving co-payment for the cheapest brand(s)

Enforcement of pricing regulation

Controls and inspections can create opportunity for corruption

Electronic transaction system (for tax collection, reimbursement, tracking of products) makes monitoring of compliance with pricing rules easy

Algorithm for medical and economic assessment of new (patented) drugs



Setting parameters for a pharmaceutical benefit

Reimbursement list: which medicines are covered

Reimbursement rates, prices, discounts, budget caps etc.

Assessment and decision making on inclusion of new technologies

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

Patient co-payment; exemptions, limits

Case management for high-cost patients

Compensation for distributor, pharmacist; substitution rights

Negotiation strategies for deals with industry

Static components (although regularly updated)

Dynamic processes

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 strategies for innovative (patented) and generic medicines.

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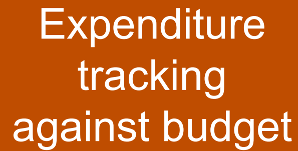
Investing into data collection

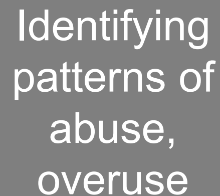
Provider and patient level data on utilization are needed to manage the main cost drivers

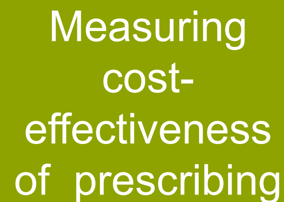
Patient	Product	Service Provider
Unique identifier	Unique identifier	Unique identifier
Diagnosis (code)	Dosage form, dosage	Date of transaction
Eligibility criteria (example age, gender)	Units dispensed	Units prescribed

Using data to monitor rational use, adjust rules and inform policy

(Examples)







Improving rational use

Patient	Prescriber	Facility
▪ Education ▪ Media campaigns ▪ Screening ▪ Disease management programs ▪ Reimbursement policy	▪ Education, training, including academic detailing ▪ Feedback, “naming and shaming” ▪ Incentives ▪ Reimbursement policy	▪ DRGs (can backfire!) ▪ Training ▪ Quality management ▪ Incentives ▪ Reimbursement policy

Once established, bad habits are hard to break…

Policy makers often find it hard to crack down on misuse and enforce better policies, against the combined political power of healthcare professionals, patients and industry