

Forecasting Demand for Critical Medical Technologies: Issues & Options



Global Health Forecasting Working Group

Consultation Presentation

Outline

- The Center for Global Development:
 - Who We Are and Why We Are Taking this On
- The Working Group
- Why Demand Forecasting Is Important And Why It's *Really* Important Now
- Demand and Risk: Aligning Incentives
- Building a Foundation for Long Term Access to Medical Products
- Recommendations: What We Can Do Now
 - Take Demand Forecasting Seriously
 - Create Global Health Infomediary
 - Share Risks and Align Incentives
- Next Steps

Center for Global Development Global Health Policy Research Network

- Leading experts in public health, economics and other social science and technical fields
- Original, focused research on high-priority global health policy and finance issues
- Improve the outcomes of donor decision-making in global health with:
 - Expanded evidence-base
 - New people and perspectives
 - Innovative solutions/ approaches
 - Active communication and outreach

Supported with a grant from the Bill & Melinda Gates Foundation



The Big Picture Problem

Despite the influx of substantial new monies

The right products aren't getting to the people who need them when they need them

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CGD Forecasting Working Group Charge

- **Generate critical thinking about:**
 - Magnitude and nature of forecasting challenges
 - Differences across disease & product categories
 - Ways to improve demand forecasting
 - Specific actions and investments by international actors to improve the global demand forecasting framework
- **Resulting in analytically-based policy recommendations for:**
 - Multi- and bilateral funders
 - Technical agencies
 - Policymakers in developing countries

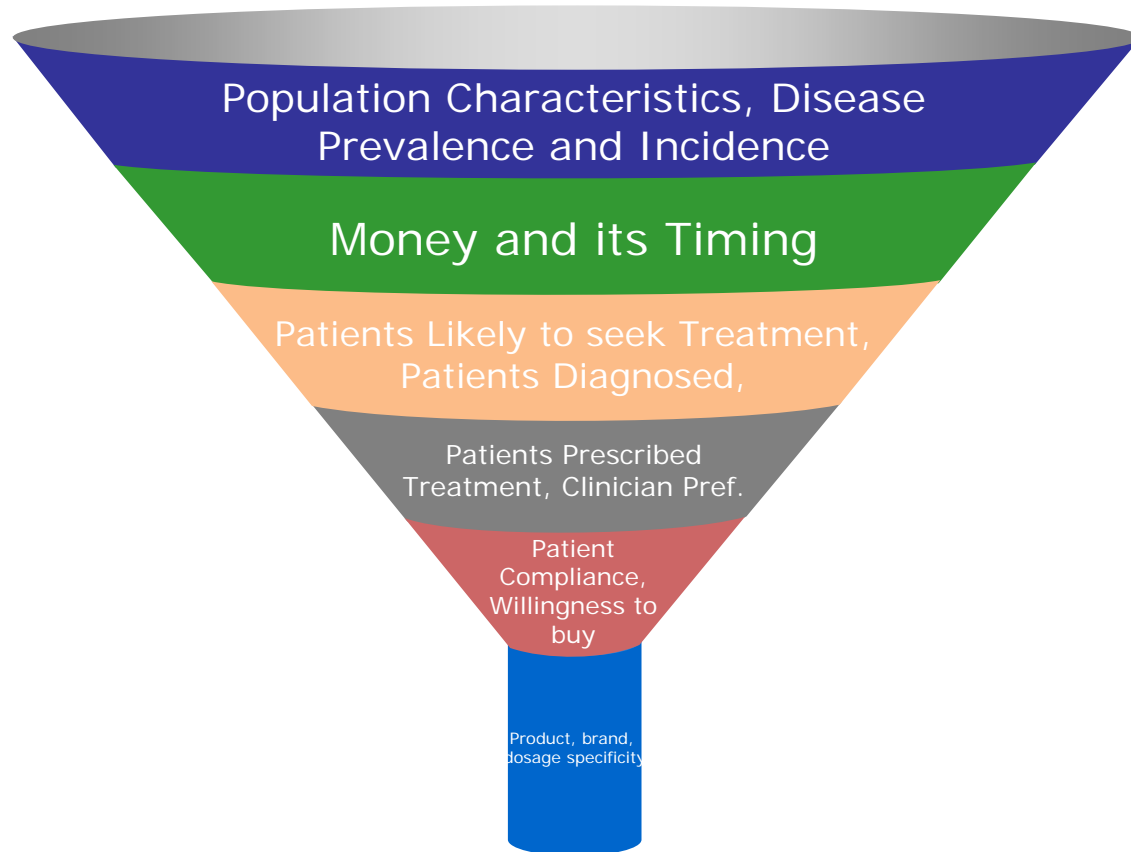
What Is Demand Forecasting?

- Demand Forecasting \neq Needs Estimates
- Demand Forecasting \neq Demand Creation/Advocacy
- Demand Forecasting \neq Target Setting

Estimates “Effective” Market Demand

Product needs which have or will have purchasing power behind them
and will result in actual orders

From Need to Demand



Effective Demand

Why Is Demand Forecasting Important?

- Demand Forecasting is critical bottleneck in supply chains for global health products
 - Limited information about demand for both existing and future products
 - Uncertainty about domestic and donor funding
- Poor forecasting increases risks for suppliers and others
 - Higher costs
 - Supply shortages
 - Concerns about the long-term viability of investing in R&D for developing countries
- Better demand forecasting at the global level urgently needed to improve effectiveness of development assistance for health

Who cares? Forecasting along the Value Chain

	Pre-Product Development	Product Development (Phases I, II)	Large Scale Trials (Phase III)	Product Launch & Post-Launch (Phase IV)	Product Usage
Supplier	Preliminary forecasts drive R&D investment	Product forecasts drive manufacturing & marketing	Regional/ country forecasts drive sales, manufacturing	Regional/ local forecasts drive sales	Regional/ local forecasts drive sales
PDP	Preliminary forecasts drive suppliers/ funders	Product forecasts drive suppliers/ funders	Regional/ country forecasts drive budgets & funders	Regional/local forecasts drive orders & funders	
Funder/ Buyer		New product forecasts drive funding projections	New product forecasts drive short-term funding	Country forecasts drive disbursements	Country forecasts drive disbursements
Global Program		New product forecasts drive funders, approvals	Country forecasts drive funders, approvals	Country forecasts drive funders/ suppliers	Country forecasts drive funders/ suppliers
National Program/ Country Buyers		Country forecasts drive budgets & regulations	Local forecasts drive budgets, regulations & supply chains	Local forecasts drive orders & logistics	Local forecasts drive orders



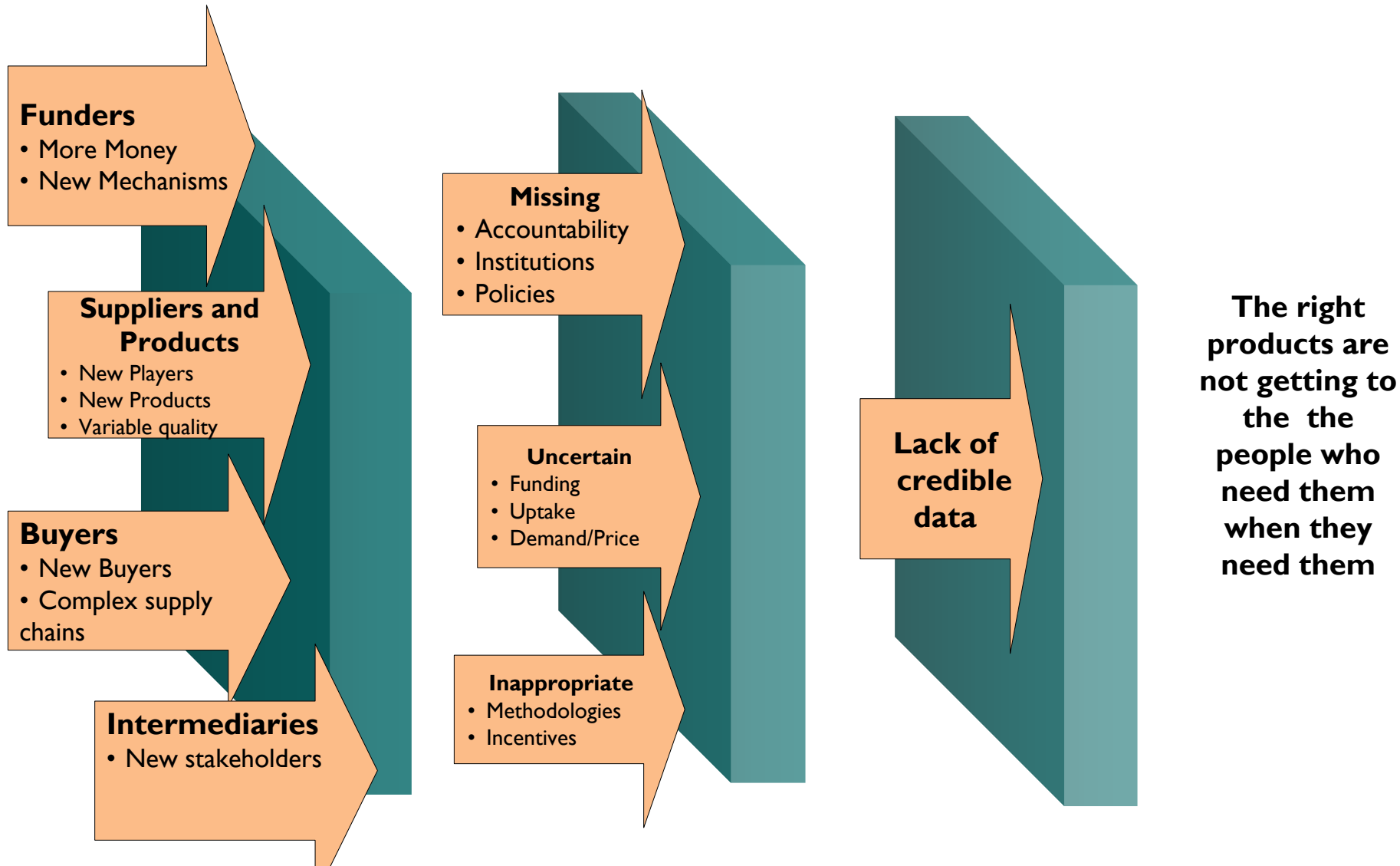
What is Going Wrong and Why

The Changing Global Health Environment

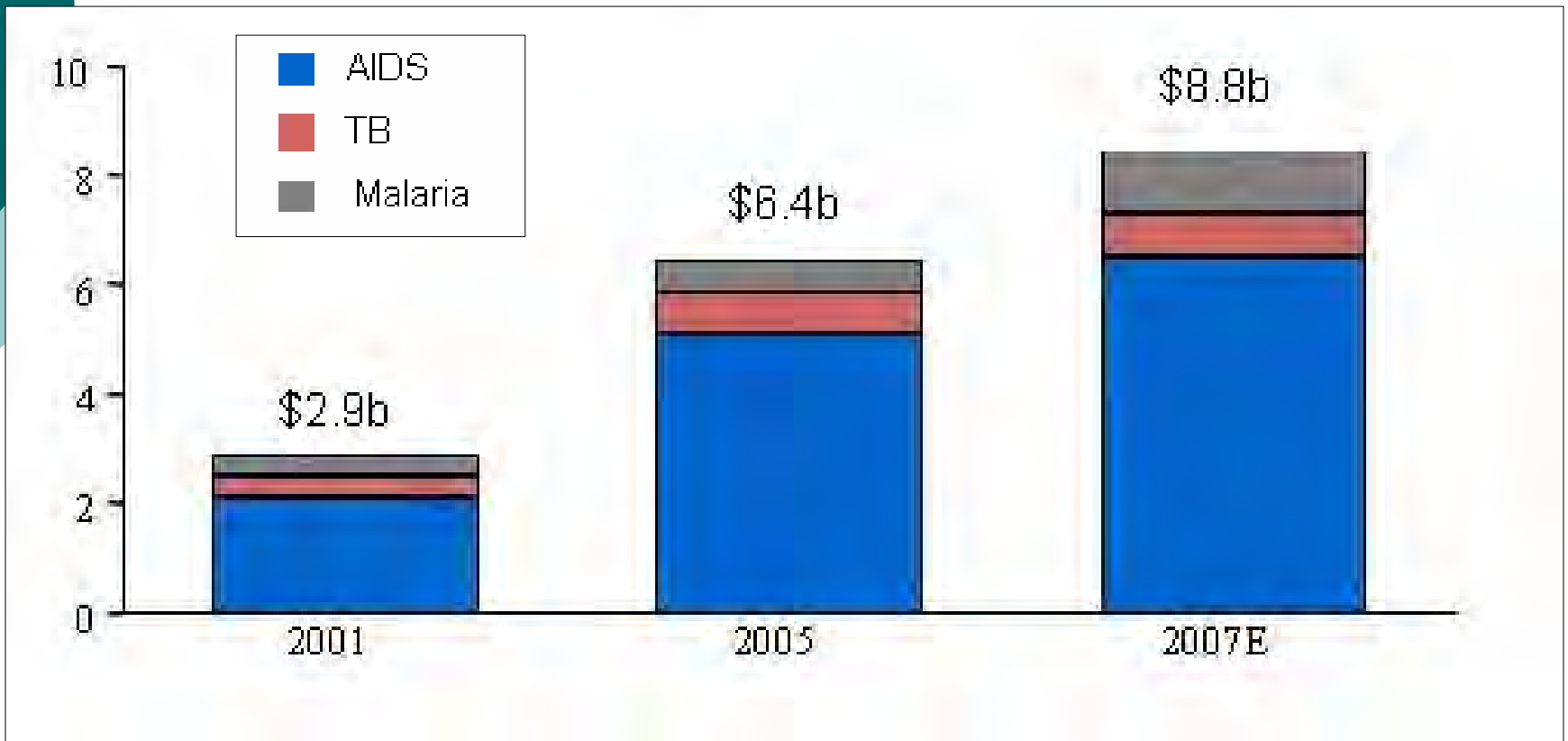
What is Going Wrong?

Complex & Rapidly Evolving Market.....

Leading to Unreliable Demand Forecasts



AIDS, TB & Malaria Funding (2001-2007)



Sources: PEFPAR, Global Fund & World Bank

Suppliers: New players and products

- New suppliers from many countries
- New products with unique characteristics
- Variable quality
- Not viable market for some suppliers



Greater competition and reduced prices in some markets and products

Complexity for buyers

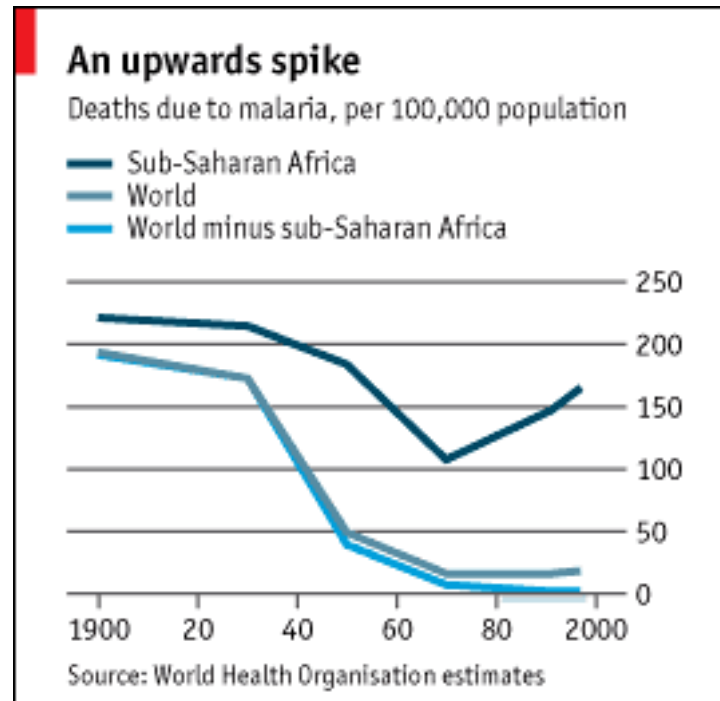
Uncertainty in quality supply

New products

- Lots of first-line, some second-line Products
- Multiple products around the bend:
“technology pile-up!”

Single products	13	ABACAVIR (ABC)
	14	ATAZANAVIR (ATZ)
	15	DIDANOSINE (ddI)
	16	EFAVIRENZ (EFV)
	17	EMTRICITABINE (FTC)
	18	LAMIVUDINE (3TC)
	19	NELFINAVIR (NFV)
	20	NEVIRAPINE (NVP)
	21	RITONAVIR (r or RTV)
	22	SAQUINAVIR (SQV)
Double fixed-dose combinations	23	STAVUDINE (d4T)
	24	TENOFOVIR DISOPROXIL FUMARATE (TDF)
	25	ZIDOVUDINE (AZT, ZDV)
	26	ABACAVIR/LAMIVUDINE (ABC/3TC)
	27	LAMIVUDINE/STAVUDINE (3TC/d4T)
	28	LOPINAVIR/RITONAVIR (LPV/r)
	29	TENOFOVIR DISOPROXIL FUMARATE/EMTRICITABINE (TDF/FTC)
	29	TENOFOVIR DISOPROXIL FUMARATE/LAMIVUDINE (TDF/3TC)
	30	ZIDOVUDINE/LAMIVUDINE (AZT/3TC)
	Triple fixed-dose combinations	31
32		TENOFOVIR DISOPROXIL FUMARATE/EMTRICITABINE/EFAVIRENZ (TDF/FTC/EFV)
33		ZIDOVUDINE/LAMIVUDINE/ABACAVIR (AZT/3TC/ABC)
34		ZIDOVUDINE/LAMIVUDINE/NEVIRAPINE (AZT/3TC/NVP)
Double fixed-dose combinations in co-blister	35	LAMIVUDINE/STAVUDINE + EFAVIRENZ (3TC/d4T+EFV)
	35	LAMIVUDINE/ZIDOVUDINE + EFAVIRENZ (3TC/AZT+EFV)
	36	Table 2: Conditions of offer by company
	38	Table 3: Summary of prices in US\$ quoted by companies for eligible developing countries

Malaria: CQ Resistance and popularity of ACTs

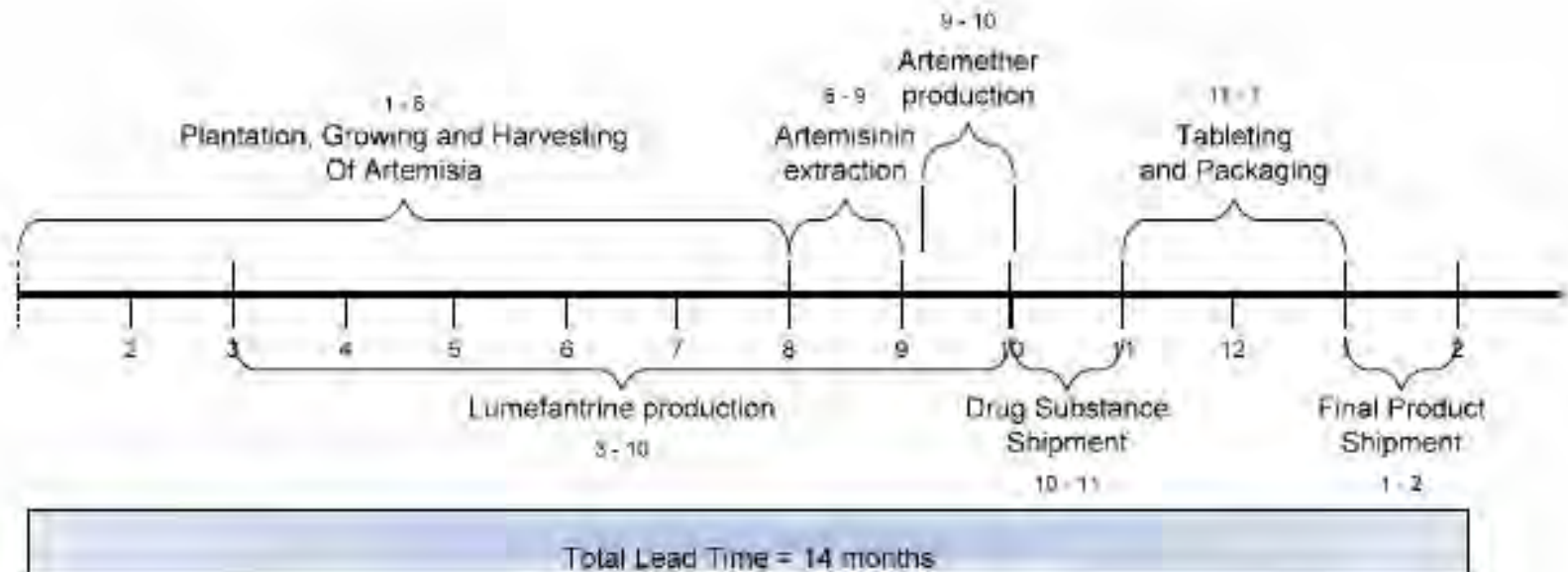


Source: The Economist

Table 1. WHO pre-qualified drugs for malaria as of March 29, 2006

Brand-name®	Compound	Manufacturer	Remarks
Arsumax	Artesunate	Sanofi-Aventis	Mono therapy
Coartem	Artemether/Lumefantrine	Novartis	Approved ACT
-	Artesunate	Guilin Pharma	Mono therapy
Artemotil	Beta-Arterther	ARTECEF	Injectible

ACT Production Process (Based on Coartem)



Tracking Coartem Forecast Performance

All figures in million treatments	2005	2006	2007	2008
Forecast Provided in				
Dec-04	55	106	109	
Dec-05		64	72	80
Sep-06		62 ¹	64	80
Actual Sales	14 ²	55 ³		
Installed Capacity	33	120	120	

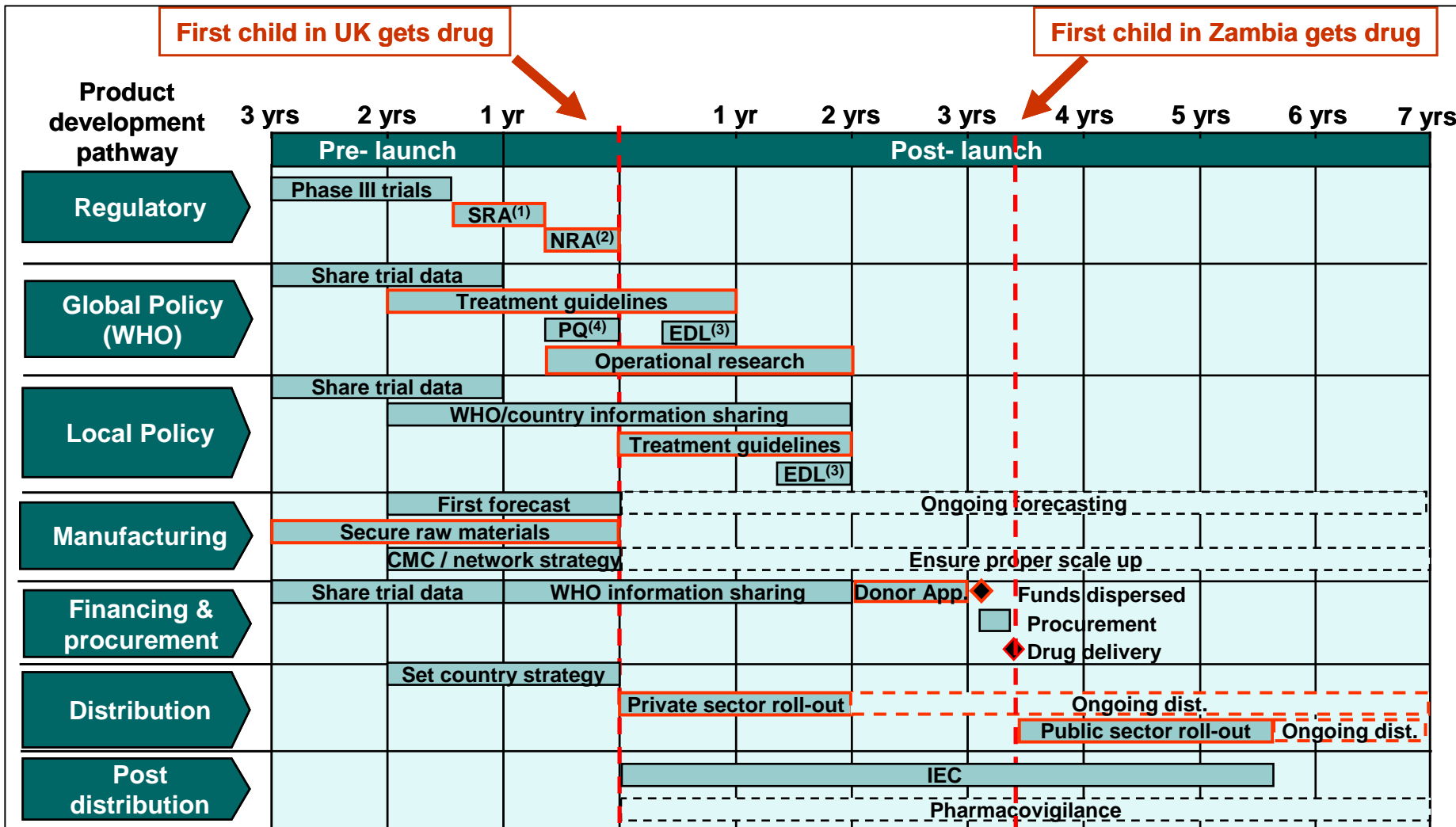
¹ 61.5m =44m treatments actual sales till August 2006 + 17.5m forecasted for Q4 2006

² 9m sold till Dec 2005 + 5m in early Jan 2006 that are counted as 2005 sales

³ 44m sold till August 2006 + 11m expected orders. The manufacturer will carry an additional stock of 5m bringing the total production in 2006 to 59m

MMV Products - Anticipated Regulatory Approval by 2008	R&D Development partners
<p>CDA (Chlorproguanil-Dapsone-Artesunate): a fixed-ratio three-drug combination, being developed to treat uncomplicated <i>P. falciparum</i> malaria.</p>	<ul style="list-style-type: none"> •GlaxoSmithKline UK •Liverpool School of Tropical Medicine UK; •London School of Hygiene and Tropical Medicine, UK •TDR, Switzerland
<p>Eurartesim (Dihydroartemisinin-Piperaquine): a fixed-ratio drug combination being developed to treat uncomplicated <i>P. falciparum</i> malaria in adults and children.</p>	<ul style="list-style-type: none"> •Holley Pharma, China •Oxford University, UK •Sigma-Tau Industrie Farmaceutiche Riunite, Italy
<p>Paediatric Coartem® (Artemether-Lumefantrine): a paediatric dosage suitable for infants and children as small as 5kg.</p>	<ul style="list-style-type: none"> •Novartis Pharma, Switzerland
<p>Pyronaridine-Artesunate: a low-cost, fixed-ratio combination, for the treatment of acute uncomplicated malaria in Africa and Asia (<i>P. falciparum</i> and <i>P. vivax</i> malaria). A paediatric formulation for children of <10kg body weight will also be developed.</p>	<ul style="list-style-type: none"> •Shin Poong Pharm. Inc., Korea

New Buyers Complex Global Supply Chains



(1) Stringent Regulatory Authority (e.g., EMEA, FDA, other)

(2) National Regulatory Authority endemic country; may require additional small scale local studies

(3) Essential Drug List; (4) Pre-qualification

Note: Assumed time-line for next generation ACT

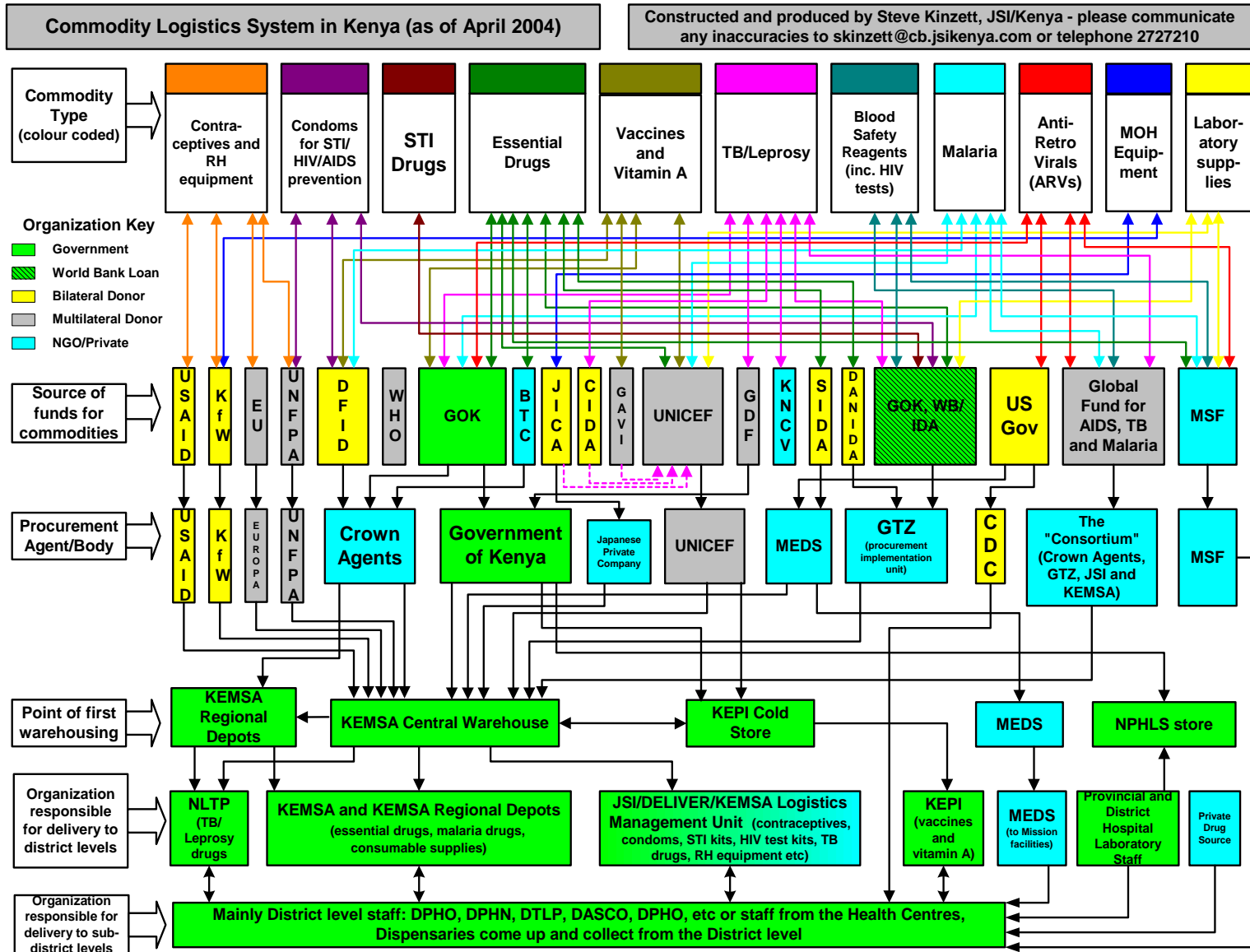
Source: WHO website, GFATM research, interviews

◻ Ongoing activity

◻ Direct uptake impact

New Buyers

Complex In-Country Supply Chains



New Intermediaries

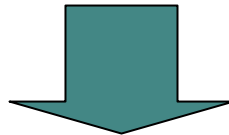
- Product Development Partnerships
 - IAVI, MMV, TB Alliance, IPM
- Public Private Partnerships
 - PneumoADIP, Rotavirus Vaccine Program, Hib Initiative
- Coordinators
 - Roll Back Malaria, Stop TB, UNAIDS
- “Negotiators”
 - Clinton Foundation HIV/AIDS Initiative, Medecins Sans Frontiers
- Procurement Actors
 - UNICEF
- Regulatory, post-regulatory authorities
 - FDA, EMEA, WHO, national regulatory authorities



Risk and Incentives

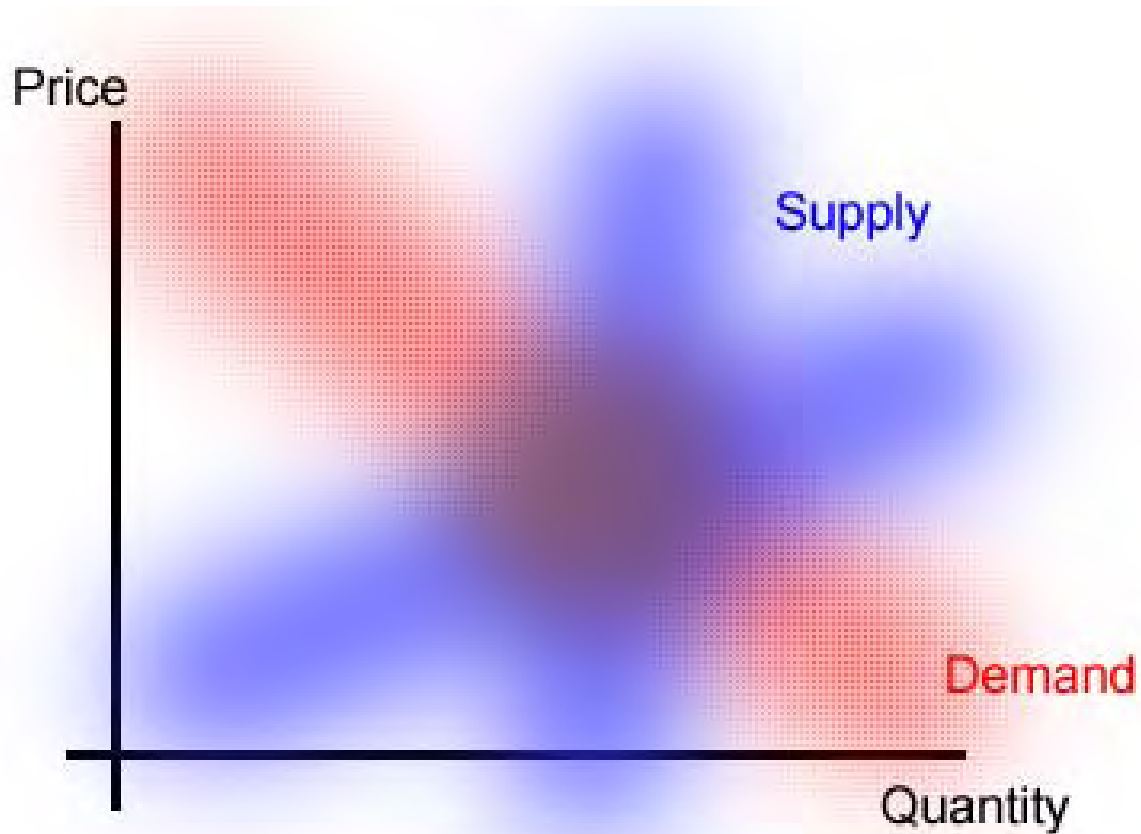
Adds Up To More Risk....

- Risks shift supply and/or demand
 - In ways that cannot be accommodated (price, supply rigidities)
 - Often decreasing the amount that will be demanded (supplied) for a given price



Higher prices to purchasers, lower revenues to suppliers, less access for patients

Supply and Demand with Uncertainty



Sources of risk

- Supply side
 - R&D risk
 - Batch yield/production yield risk
 - Input risk
- Demand side
 - Competition risk
 - Obsolescence risk
 - Policy and preference risks
 - Budget and purchasing power risks
 - Credit risk
- Regulatory risk
 - Regulatory regime risks, regulatory enforcement risks
- Logistics risks
 - Non-timely delivery
 - Losses in distribution chain
 - Complementary inputs

Consequences:

Manufacturers -- Overcapacity, under capacity, reputational costs

Donors -- Less “value for money”

Patients/populations: Poor health outcomes

ACT Risk Allocation Map

	No risk	Moderate Risk
	Low Risk	High Risk

	<i>Supply Side Facilitators</i>	<i>Suppliers</i>	<i>Quality Regulators</i>	<i>Global Technical Agencies</i>	<i>Aggregate Demand Forecasters</i>	<i>Funding Agencies</i>	<i>Procurement Agents</i>	<i>Logistics Providers</i>
SUPPLY-SIDE RISKS								
Batch Yield Risk		Low Risk						
Excess Inventory Risk								
<i>Financial</i>		High Risk				Low Risk		
<i>Reputational</i>					Low Risk			
Long-Term Overcapacity Risk								
<i>Financial</i>		High Risk						
<i>Reputational</i>	Low Risk				Low Risk			
Shortage Risk								
<i>Financial</i>		Moderate Risk						
<i>Reputational</i>		High Risk		Low Risk	Moderate Risk	Low Risk		
DEMAND-SIDE RISKS								
Price Increase						Moderate Risk		
Price Decrease		Moderate Risk						
Grant Approval & Disbursement Timing Risk		High Risk				Moderate Risk		
Sustainability of Funding	Low Risk	Moderate Risk				High Risk		
REGULATORY AND QUALITY RISKS								
Counterfeit product		Moderate Risk						
Safety of approved drugs		High Risk	High Risk			Low Risk		
Lack of approved drugs			Low Risk					
LOGISTICAL AND MISCELLANEOUS RISKS								
Non-timely delivery		Moderate Risk					Moderate Risk	Moderate Risk
Losses in the distribution chain						Low Risk		Moderate Risk
Asset specificity due to early adoption								
Risk of success(vaccine, eradication etc.)	Low Risk	Moderate Risk						

ACT Supply Chain Incentives Map

Disincentive	↓	Indifferent	-
Incentive	↑	Potential Misalignment	

	Supply Side Facilitators	Suppliers	Quality Regulators	Global Technical Agencies	Aggregate Demand Forecasters	Funding Agencies
SUPPLY-SIDE						
Develop Innovative Products	↑	↑	-	-	-	-
Increase size of the supply market	↑	↓	-	↑	-	↑
Decrease supply chain lead time	↑	-	-	↑	-	-
Overforecast in the Short-Term(< 12 months)	-	↓	-	-	↑	↑
Underforecast in the Short-Term(< 12 months)	-	-	-	-	↓	↓
Overforecast in the Long-Term (1-5 years)	↑	↓	-	↑	-	↑
Underforecast in the Long-Term (1-5 years)	↓	↓	-	↓	-	↓
Sharing Information on demand, inventory...	↑	↓	-	-	↑	-
DEMAND-SIDE						
Decrease wholesale price of ACTs	↑	↓	-	↑	-	↑
Decrease retail or end-customer price of ACTs	↑	↑	-	↑	-	↑
Expedite grant approval and disbursement	-	↑	-	-	-	↑
Rapid adoption of ACTs as a treatment option	↑	↑	-	↑	-	↑
Enhance the level and sustainability of funding	↑	↑	-	↑	-	↑
REGULATORY AND QUALITY						
Ensure regulatory compliance and safety	↑	↑	↑	-	-	↑
Expedite regulatory approval of new drugs	↑	↑	-	↑	-	↑
LOGISTICAL AND MISCELLANEOUS						
Improve efficiencies in distribution chain	-	-	-	↑	-	↓
Ensure availability of complementary inputs	-	↓	-	↑	-	↑
Achieve long lasting success(eradication)	↑	-	-	↑	-	↑
Have rigorous accountability in funds usage	-	-	-	-	-	↑

Risk & Uncertainty

- More uncertainty --> Harder to forecast
- Forecasts inaccurate--> More significant financial & health consequences (short- and long-term)

Who could reduce the risk?

○ Supply side

- R&D risk
- Batch yield/production yield risk
- Input risk

○ Demand side

- Competition risk
- Obsolescence risk
- Policy and preference risks
- Budget and purchasing power risks
- Credit risk

○ Regulatory risk

- Regulatory regime risks, regulatory

○ Logistics risks

- Non-timely delivery
- Losses in distribution chain
- Complementary inputs



Donors, Funding Agencies
intermediaries
[systematically over forecast]



WHO [systematically minimize quality-related risk]



National authorities
[systematically over-forecast]



Long-term: Avoiding & reducing risk

- More predictable, reliable donor resources
- Streamlined product approval & regulatory processes
- Product development support that is attuned to market forces (more pull, some push)
- Strengthened health systems / in-country supply chain that feeds info and orders up to suppliers (more pull)



Opportunities for Short Term Action

- Technical constraints
 - Information Gaps
 - Methodologies in the face of market discontinuity
- Structural constraints
 - Asymmetric distribution of risks lead to misaligned incentives



Recommendations

Recommendations Framework

Take Forecasting Seriously

Create Global Health Infomediary

*Share Risk and
Align Incentives through
Contracting*

Increases credibility and transparency of forecasting process through adoption of sound principles

Expands forecasting expertise for global health products

Consolidates disparate information sources

Enables more accurate forecasts

Establishes common baseline forecasts

Shares suppliers' risk

Motivates all players to take forecasting seriously and share information

Motivates funders to reduce risk



**Take Forecasting
Seriously**

Why?

- Impact of Poor Forecasting on Access is Large
- Demand Forecasting Drives Supply Planning
- Forecasting is Unique Expertise



**Take Forecasting
Seriously**

How ?

- Adopt Principles Of Good Forecasting
- Strengthen Technical Forecasting Capability

Principles: Why

Forecasting is a Process, not a Number

- Credibility and Trust In Process
- Increase Confidence and Reduce Market Risk
- Reduce Forecast Variation

Principles of Good Forecasting

- Customer-focused principles
 1. Identify principal customers/decision makers and understand their needs.
 2. Understand and clearly communicate purpose and decisions it will affect.
 3. Create forecasting process independent of planning and target setting.
 4. Protect forecasting process from political interference and ensure transparency.

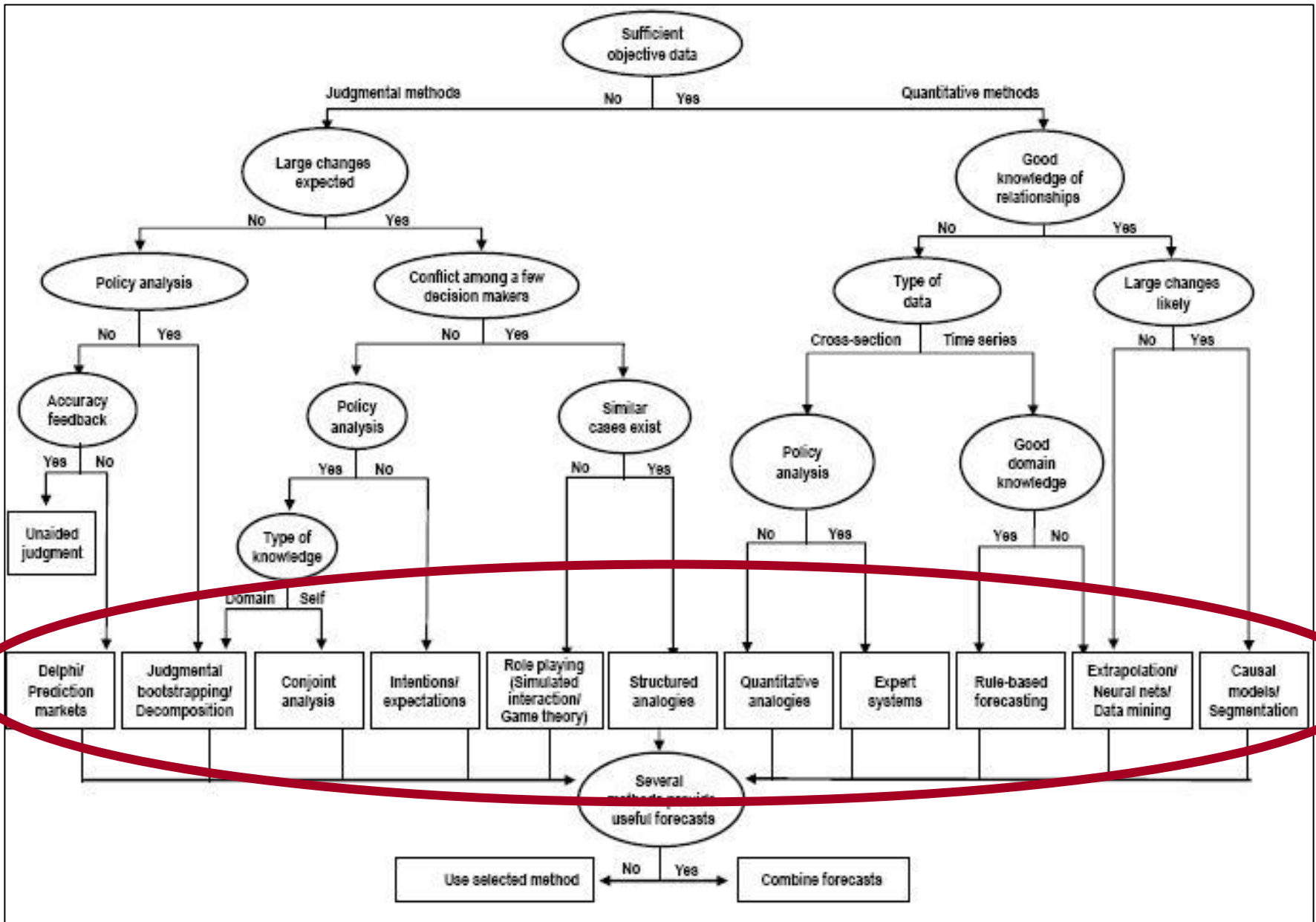
Principles of Good Forecasting

- Process- & context-focused
 - 4. Embed forecast into broader environment taking account of market conditions, public policy, competitive forces, regulatory changes, health program guidelines.
 - 5. Create dynamic forecasting process that continually incorporates and reflects changes in the market, public policy and health program capabilities.

Principles of Good Forecasting

- Methodology- & data-focused principles
 7. Choose the methodologies appropriate to the data and market environment.
 8. Keep methodologies simple and appropriate to the situation. Don't introduce too much complexity, but include sufficient detail to address the level of investment risk and accuracy required.
 9. Make forecast assumptions clear and explicit.
 10. Understand data and their limitations. Use creativity and intelligence in gathering and introducing data into forecasts.

Selection Tree for Forecasting Methods



Develop Technical Capacity

- Recruit students from specialized graduate programs
- Provide extensive training for existing personnel
- Recruit experienced forecasters from industry
- Create forecasting methodology resource base for developing countries



**Create Global Health
Infomediary**

Why?

- Key stakeholders require similar information across variety of diseases & products
- Some data exist but are not shared systematically
- More and better market research is needed

Approaching the Information Gap

Relevant priority data categories

Information sharing
only

- Donor funding

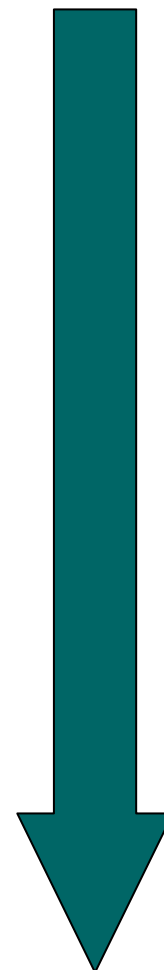
Information sharing
& moderate
improvements in
gathering

- Historical consumption
- Country willingness to pay & adoption preferences

Information sharing
& significant
improvements in
gathering

- Epidemiological data
- Country health infrastructure
- Supply chain/logistics data

*Increasing cost
and complexity*



**Create Global Health
Infomediary**

**Independent
organizations...**

**...with credible processes
and well established
reputations...**

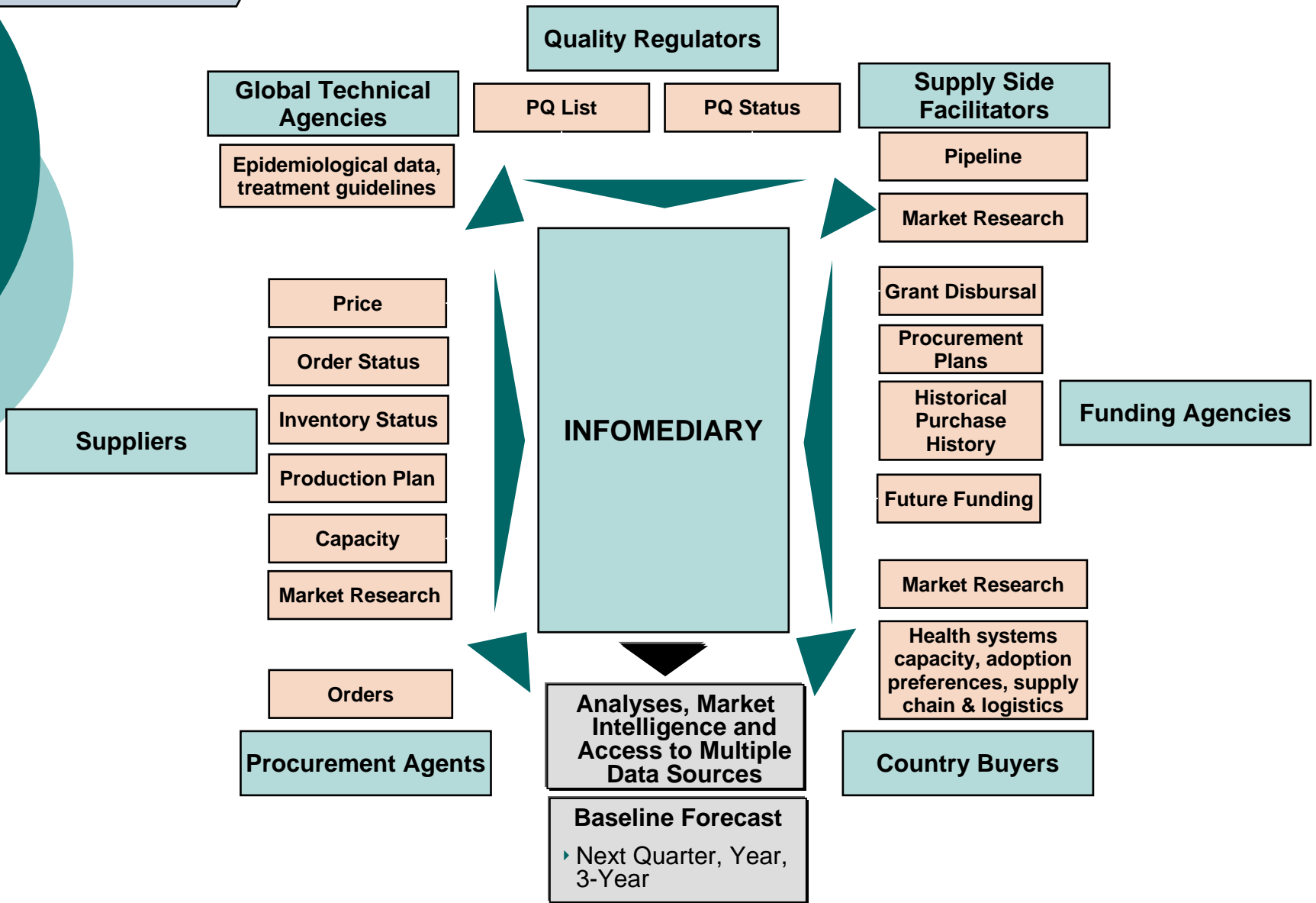
**Provide Information
and Analyses to
Stakeholders**

Developed Country Model

- Market data collected by Infomediaries (ex. IMS Health)
- Customized market information gathering/analysis by many private organizations
- Quality of information and methodologies
- Credibility of information and methodologies
- Market Analyses
- Baseline Demand Forecasts

Create Global Health Infomediary

Global Health Infomediary



Key Functions

Serve as a neutral party that maintains relationships with supply chain partners and has credibility with all stakeholders

- Create and Maintain Central Repository on demand and supply
- Provide Continuous Data Gathering
- Generate Transparent, Baseline Aggregate Demand Forecasts



**Share Risk and
Align Incentives through
Contracting**

Why?

- Funders and Buyers bear limited risk for poor forecasting
- Efficient risk sharing motivates all parties to perform better
- Contracts are important to share risks & align incentives

Creative Contracting

- Minimum Purchase Commitments
- Quantity Flexibility Contracts
- Buyback Contracts
- Revenue Sharing
- Real Options

Recommendations Framework

Take Forecasting Seriously

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Infomediary***

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Increases credibility and transparency of forecasting process through adoption of sound principles

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Consolidates disparate information sources

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Establishes common baseline forecasts

Shares suppliers' risk

Motivates all players to take forecasting seriously and share information

Motivates funders to reduce risk

Building a foundation for long-term access

Building Stronger Supply Chains & Health Systems

Linking Product Development to Market Conditions

Improving the Regulatory & Post-Regulatory Regimes

Increasing Aid Predictability

Consultation and Next Steps

- Soliciting comment and critique through March 23, 2007
- Finalizing the work of the group by April 2007 for May publication and launch