Market Access: Understanding the Private Sector

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TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Access Challenge

- Make sure that new regimens reach patients

- AAA Mandate
  - **A**ffordability
  - **A**vailability
  - **A**doptability

New Regimen Adoption Needs Help of SHA

- Timing of past regimen change

- Process & timing for revising global guidelines

- Feasibility of early diagnosis of TB & resistance

- Quality of treatment delivery system

- Champions of new regimens

TB Alliance's
Market Access Strategy

- **Know the TB market**
- Form partnerships
- Learn from other product introductions
- Prepare for moxifloxacin introduction
- **Develop MDR strategies**
  - Help launch planning of TMC 207
  - Publicize economic case for new regimens

Understanding the TB Market

- **Pathway to Patients** (with IMS, 2006)
  - Understand flow of TB drugs in high burden & high income countries
  - Size the 2007 global TB drug market

- **Value Proposition Study** (with IMS, 2007)
  - What TB stakeholders would value, tolerate, or reject with regards to a new, shorter first-line TB regimen

- **Country Introduction Study** (with MSH, 2008/09)
  - Key issues in 22 High Burden Countries
  - Understand process of regimen change

- *Patient Study* (2010-11)
  - Document patient opinion about current and future regimens

Private Sector Study (2010)

- All high burden countries with IMS' private sector drug sales data (except Brazil)
  - India, China, Indonesia, South Africa, Bangladesh, Pakistan, Philippines, Russia, Vietnam & Thailand

- All 1st and 2nd line drugs on WHO list plus ciprofloxacin, gatifloxacin & clofazamine

- Seeking information about affordability, uptake, availability of WHO recommended treatments in private sector

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1st line cases treated in private market

 # Cases potentially covered by pvt market

Countries (left to right): India, Indonesia, China, Pakistan, Philippines, Bangladesh, Russia, Thailand, South Africa, Vietnam
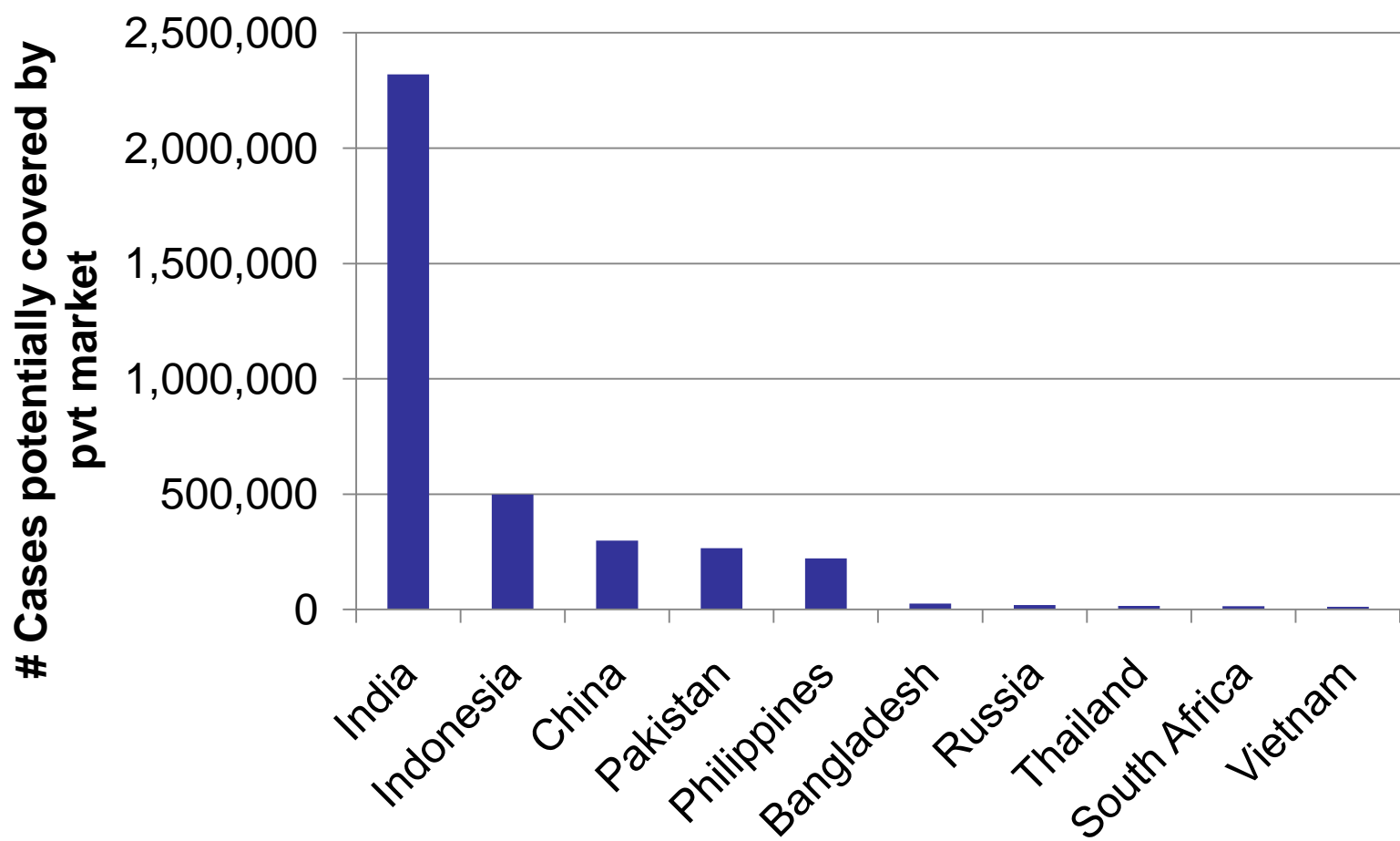
4 Manufacturers Make Most FDCs

Top 10 manufacturers make 87% of FDC volume in 10 countries;
top 4 manufacturers make 69%

MNF	Country of Coverage	Total FDC Volume	% FDC Vol
LUPIN	India, Vietnam	**232,678,238**	28.3%
MACLEODS PHARMA	India	132,452,038	16.1%
WYETH	Philippines, Pakistan	101,865,910	12.4%
SANDOZ	**India, Indonesia, Philippines, Bangladesh, SA, Thailand, Vietnam, Pakistan**	98,503,468	12.0%
CONCEPT PHARMA	India	40,115,330	4.9%
SCHAZOO ZAKA PVT L	Pakistan	31,391,860	3.8%
MEDICHEM PHARM	Philippines	24,025,800	2.9%
NATRAPHARM	Philippines	22,686,800	2.8%
PLETHICO	India	19,407,291	2.4%
OVERSEAS	India	14,655,442	1.8%

69%

87%
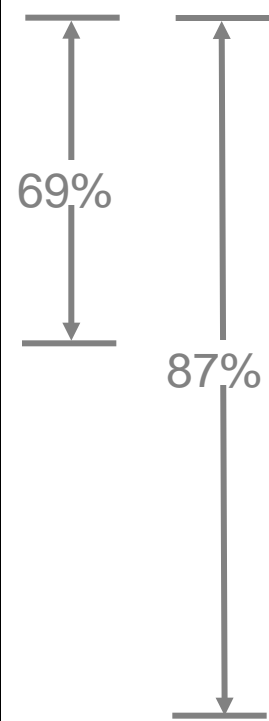
Major Manufacturers <u>Capable</u> of Quality If Purchasers/Regulators Demand It

% of FDCs that could be made to WHO-PQ Standards

MNF with WHO-Prequalified FDC Products
LUPIN
MACLEODS PHARMA
SANDOZ

56%

By MNFs that are not pre-qualified by WHO

"Best-case" Scenario – Ceiling %

Not all strengths by the same MNF are prequalified

Not all facilities by the same MNF are prequalified

Not all production lines in these facilities are high quality

Actual % of WHO-prequalified products

<4%
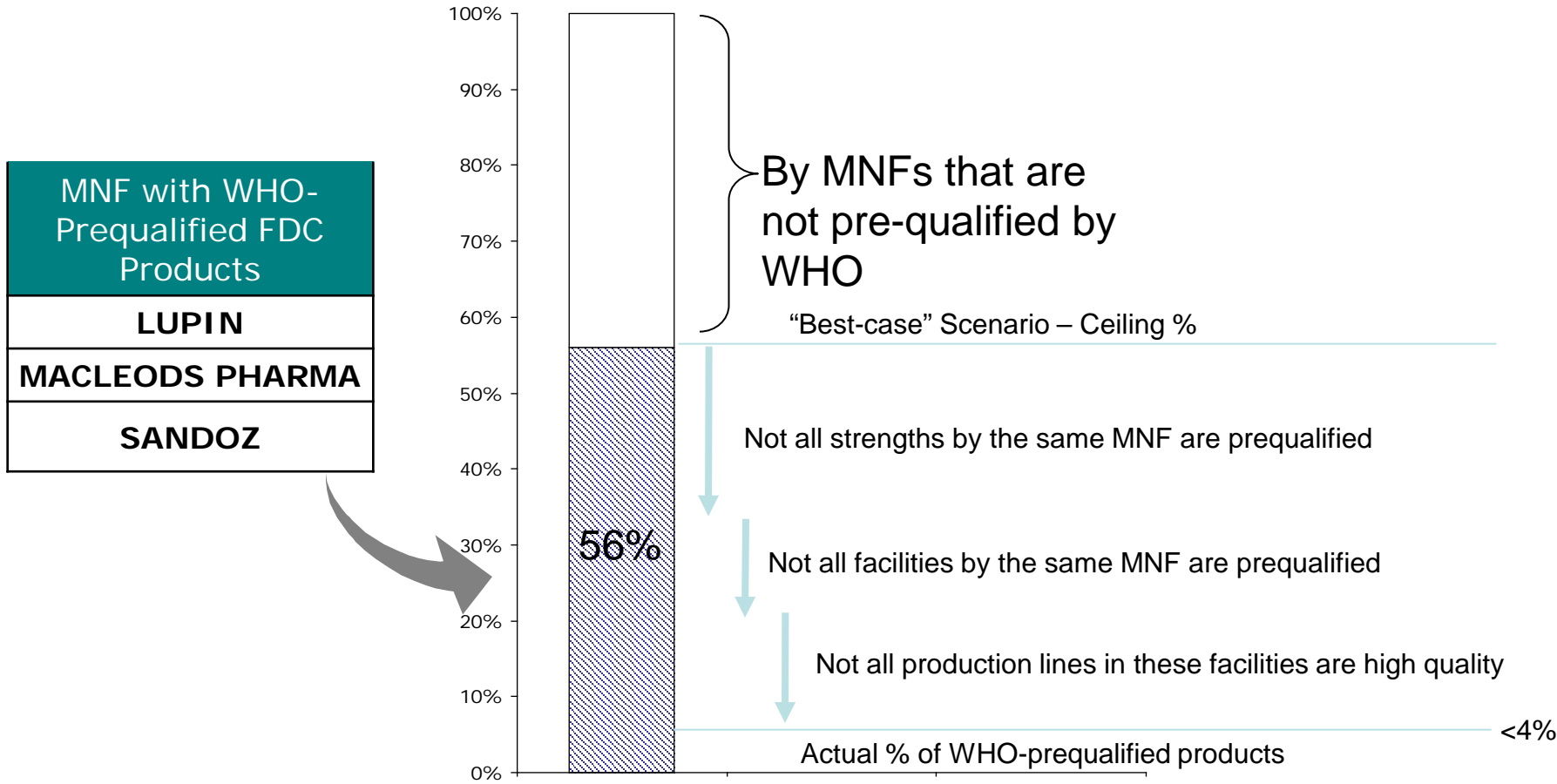
of FDCs of Different Strengths

Country	RH	HE	HZ	RHE	RHZ	RHZE	Total in Country
India	15	2		8	15	8	48
Philippines	7	4		3	3	2	19
Pakistan	5	3		3	4	2	17
Indonesia	3	6			1	1	11
Bangladesh	5				4	1	10
Vietnam	3	1		1	1	1	7
South Africa	4				1	1	6
Thailand	2				1	1	4
Russia	1	1	1			1	4
China	1				1		2
10-country Total	20	13	1	11	18	11	74

Some 2ⁿᵈ line drugs are missing

Category	API	Bangladesh	China	India	Indonesia	Pakistan	Philippines	Russia	SA	Thailand	Vietnam
Injectable agents	Streptomycin	■	■	■	■	■	■	■	■	■	■
	Capreomycin	□	■	□	□	□	□	■	■	□	□
	Amikacin	■	■	■	■	■	■	■	■	■	■
	Kanamycin	■	■	■	■	■	□	■	■	■	■
Fluoroquinolones	Ofloxacin	■	■	■	■	■	■	■	■	■	■
	Moxifloxacin	■	■	■	■	■	■	■	■	■	■
	Levofloxacin	■	■	■	■	■	■	■	■	■	■
Oral bacteriostatic agent	Protionamide	□	■	■	□	□	□	■	□	□	■
	Ethionamide	□	□	■	□	■	□	■	□	■	■
	Terizidone	□	□	■	□	□	□	□	■	□	□
	Cycloserine	□	□	■	□	■	□	■	□	■	□
	Aminosalicylic Acid	□	■	■	□	■	□	■	□	■	■

Grey= units available; White= units not available

- Capreomycin and the oral bacteriostatic agents are often not available, for any indication.

Private Sector Market

First Line

- Private sector provides large volume of treatments and can't be ignored

- Capability to make quality FDCs is there, but only if demanded by purchasers or regulators

- Small number of manufacturers influence most of the FDC market

Second Line

- Not too many MDR patients being treated in the private sector, at least with a full regimen

- Scale up a real challenge in some countries due to lack of availability

Scale up Costs of MDR-TB

- Cost of MDR-TB drugs per patient $2000-9000

- WHO projected cost of treating 357,000 people with MDR-TB in 2015: US$2.7 b

- Lower cost of a new MDR regimen is crucial to effective scale up

Savings with New MDR-TB Regimen

- Cost of new regimen would be no more than 10% of current drug costs

- Potential to save billions on drug treatment costs alone

- Further savings on health systems costs from shorter treatment, no hospitalization

- Could provide complete regimen to at least 1.2 million patients for the same cost as drugs for 150,000 patients today