



Market Access: Understanding the Private Sector

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Access Challenge

- Make sure that new regimens reach patients
- AAA Mandate
 - **A**ffordability
 - **A**vailability
 - **A**doptability



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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



NEW TUBERCULOSIS LONG-DURATION 1-10
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Tuberculosis regimen change in high-burden countries

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SUMMARY

BACKGROUND: Experience with past tuberculosis (TB) regimen changes can guide future regimen changes.

METHODS: To explore the process, major players and procedural success factors for recent public sector TB regimen changes, we conducted 166 interviews of country stakeholders in 21 of the TB high-burden countries (HBCs).

RESULTS: Stakeholders described 40 distinct regimen changes for drug-susceptible TB. These countries committed to considering a change, the average timing was ~1 year for decision-making and ~2 years for rollout. Stakeholders more often cited concerns that were program-based (e.g., inequities and cost) rather than patient-focused (e.g., side effects), and patient representatives were seldom part of decision making. Decision-making bodies in higher-income HBCs had more for-

mulated procedures and fewer international participants. Pilot studies focused on logistics were more common than effectiveness studies, and the evidence base was often felt to be insufficient. Once implementation started, weaknesses in drug management were often exposed, with additional complications if local manufacturing was required. Best practices for regimen change included early engagement of budgeting staff, procurement staff, regulators and manufacturers.

CONCLUSIONS: Future decision makers will benefit from strengthened decision-making bodies, patient input, early and comprehensive planning, and regimens and evidence that address local, practical implementation issues.

KEY WORDS: regimen change, tuberculosis drugs, high-burden countries

THE DEVELOPMENT of new drugs for tuberculosis (TB) is an identified global priority,^{1,2} but adoption will undoubtedly bring challenges. For TB regimen change, existing examples can provide guidance for future efforts. In the present study, we examine recent experience with regimen change in 21 of the 22 high TB burden countries.

Regimens for drug-susceptible TB have been shortened based on clinical trials³ and altered due to widespread human immunodeficiency virus (HIV) infections,⁴ leaving the two main variants as 2HRZE3RIE and 2HRZE4RIE.⁵ The World Health Organization (WHO) initially recommended both,⁶ but then fa-

Some of the resulting changes from 8 to 6 month regimens are documented in this study, as is the adoption of various fixed-dose combinations (FDCs) of TB drugs. FDCs prevent monootherapy^{7,8} and can simplify regimens for patients, physicians, and procurement and distribution systems, thus potentially helping to reduce medication errors and stock-outs.⁹⁻¹¹ FDC use may increase adherence, although supporting evidence for this is scarce.^{12,13} Adoption of FDCs has sometimes been delayed by the lack of access to FDCs with proven bioequivalence to single drug formulations.¹⁴

Decision making during regimen change requires



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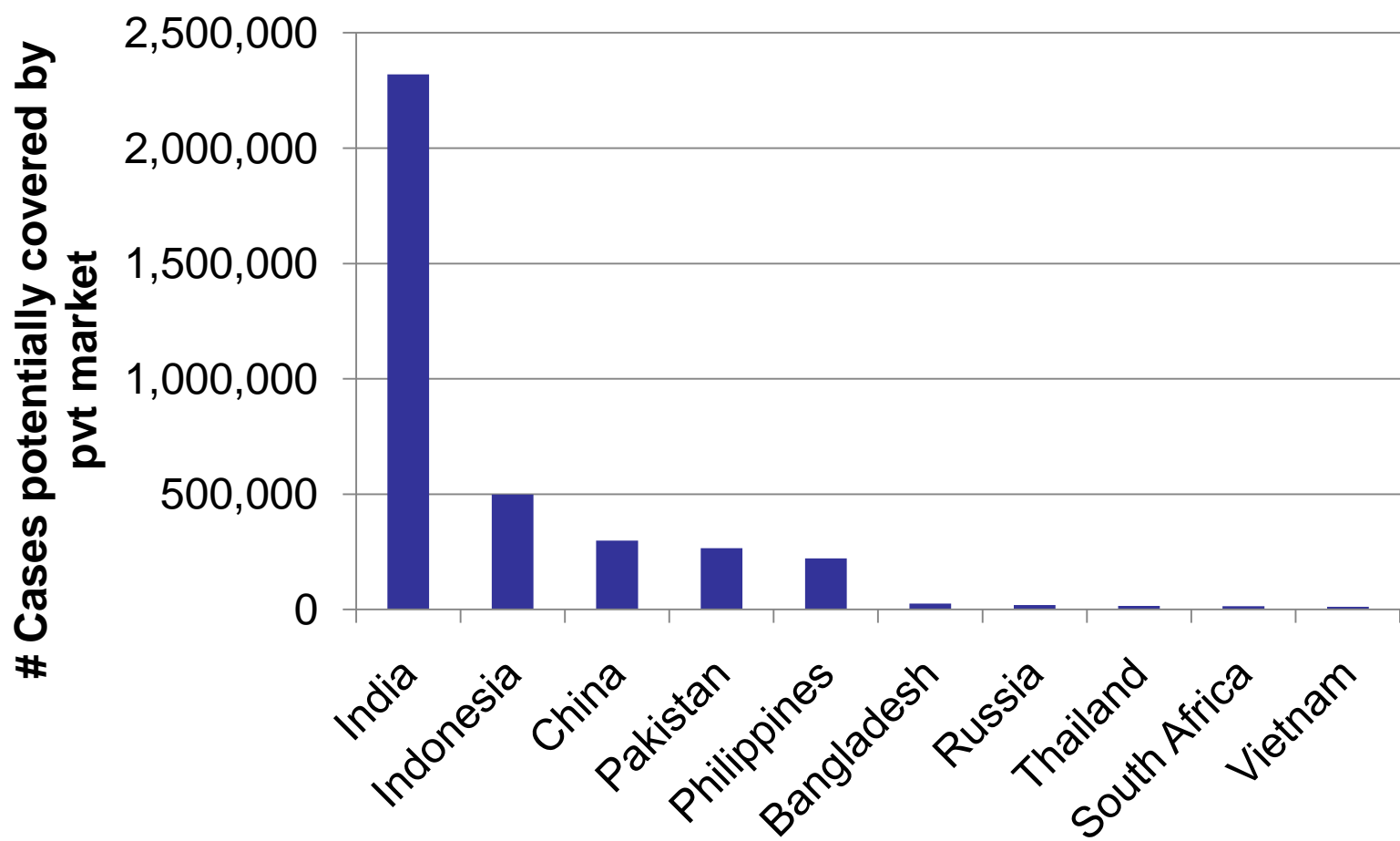
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Private Sector Study (2010)

- 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



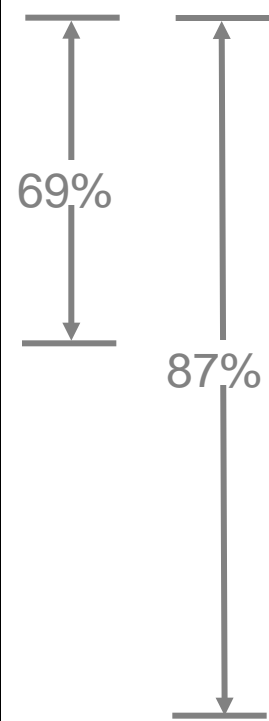
1st line cases treated in private market



4 Manufacturers Make Most FDCs

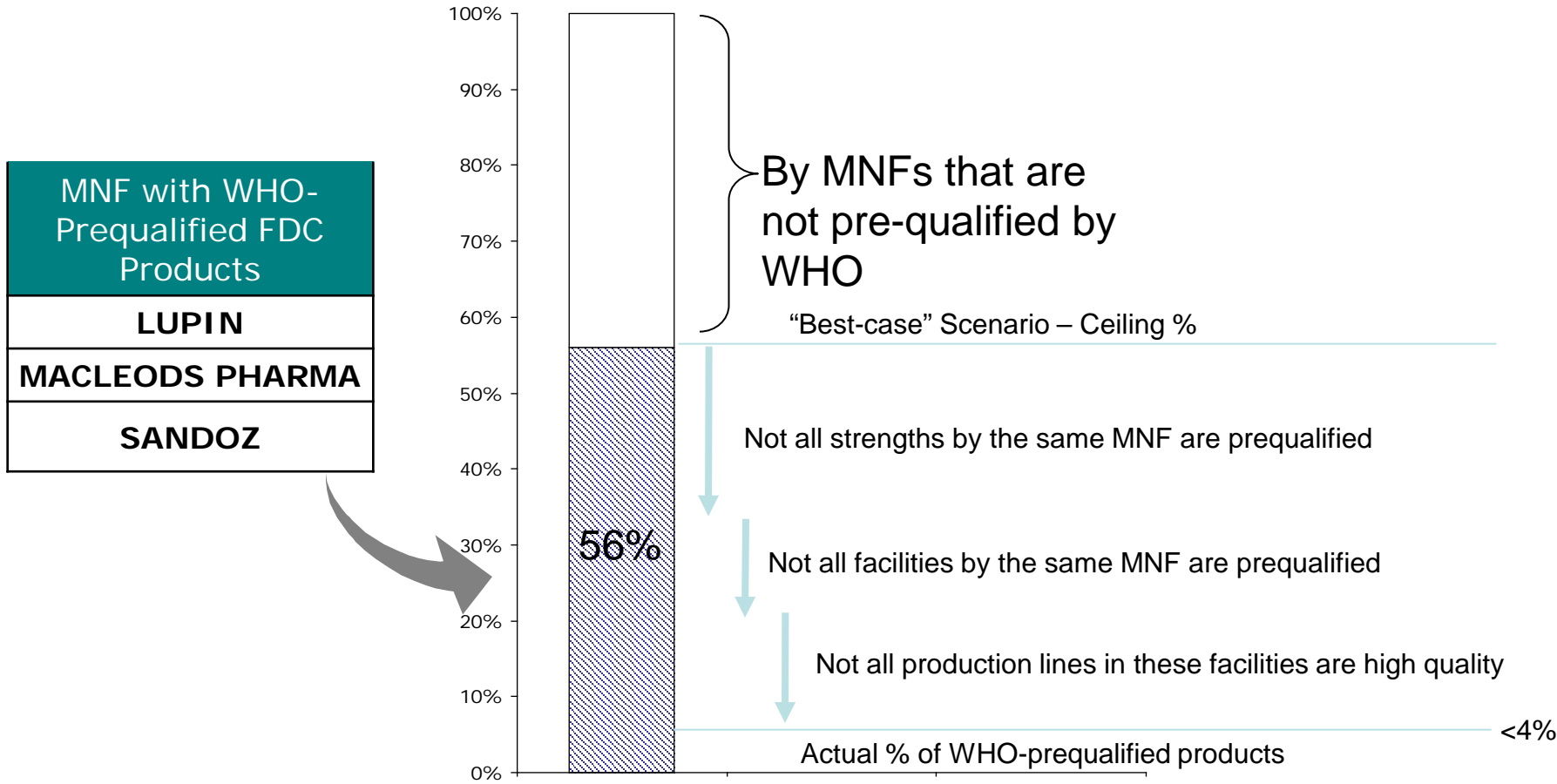
Top 10 manufacturers make 87% of FDC volume in 10 countries;
top 4 manufacturers make 69%

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%



Major Manufacturers Capable of Quality If Purchasers/Regulators Demand It

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



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	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey
	Capreomycin	White	White	White	White	White	White	White	White	White	White
	Amikacin	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey
	Kanamycin	Grey	Grey	Grey	Grey	Grey	White	Grey	Grey	Grey	Grey
Fluoroquinolones	Ofloxacin	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey
	Moxifloxacin	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey
	Levofloxacin	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey	Grey
Oral bacteriostatic agent	Protionamide	White	White	White	White	White	White	White	White	White	White
	Ethionamide	White	White	White	White	Grey	White	Grey	Grey	Grey	Grey
	Terizidone	White	White	White	White	White	White	White	Grey	White	White
	Cycloserine	White	White	White	White	Grey	White	Grey	White	Grey	White
	Aminosalicylic Acid	White	Grey	White	White	Grey	White	Grey	White	Grey	Grey

Grey= units available; White= units not available

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



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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



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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



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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

