MEAs in China: current status and implications for CEA

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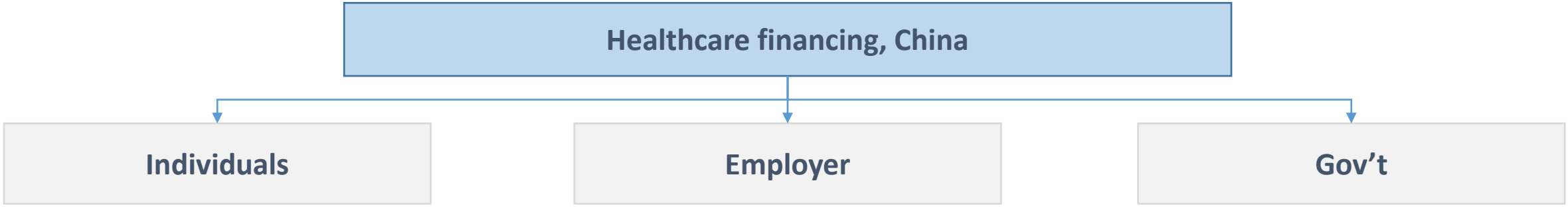
Study objective, frameworks, and methodology

- **Study objective**: to identify current status of MEA policy and operation in China, for the fulfillment of Master's dissertation at the Department of Social Policy, London School of Economics
- **Framework**
    1. **Equity**
        - Equity in access
            - Equal access across geographies and different insured populations
        - Equity in financing
            - Vertical equity – populations with higher incomes required to pay a greater % of income for accessing MEA contracted drugs versus populations with lower incomes
    2. **Efficiency**
        - Technical efficiency – producing the same outcomes for equal or less input
        - Administrative efficiency – transaction costs associated with the use of of MEAs
    3. **Quality**
        - Governance structure - representation of interests, and accountability and responsibility structures
- **Methodology**
    - Literature review – Chinese journal publications, policy documents, and media sources

Healthcare financing in China is based on social health insurance (SHI) principles



- **Formal sector**
  - Urban Employees Basic Medical Insurance (urban formal sector) - e.g. 2% of wage goes towards personal Medical Savings Account
- **Informal sector**
  - Urban Residents Basic Medical Insurance (urban informal sector)
  - New Rural Cooperative Medical Scheme (rural sector)

- **Formal sector**
  - Urban Employees Basic Medical Insurance - e.g. 6% of employee wage goes towards personal Medical Savings Account & Pooled Account

- **Gov't subsidies**
  - Enrollees of Urban Residents Basic Medical insurance
  - Enrollees of New Rural Cooperative Medical scheme

Official figures show, >95% of Chinese population are covered by 1 of 3 gov't health insurance scheme

Barriers in China's pharmaceutical policy – the context against which MEAs are implemented

BARRIERS IN CHINA'S PHARMACEUTICAL POLICY

For insurees	For pharma co's	For insurers

• Unequal pharmaceutical benefits across insurance types, with Urban Employees > Urban Residents > New Rural Cooperative	• Significant time delays across all post-licensing bottlenecks
	• Post-licensing access for pharmaceutical products is defined by multiple bottlenecks, including:
	  • Reimbursement
	  • Public insurer tendering
	  • Hospital formulary listing
	  • Hospital performance metrics
		• Fragmented power
		• Public insurer has little to no power in controlling pharmaceutical spending

For insurees, policies and historical insurance spending have granted Urban Employees favorable pharmaceutical benefits

Insurees

UNEQUAL PHARMACEUTICAL BENEFITS

	Urban Employees	Urban Residents	New Rural Cooperative
Pharmaceutical benefits	• **National reimbursed drug list (NRDL)** – centrally issued list • **Provincial reimbursed drug list (PRDL)** – provincial supplementation of the NRDL, based on regional need • NRDL houses **2127 molecules**, separated in to List A (more basic molecules) and List B (more innovative molecules) • Provinces have the legal mandate to supplement the NRDL; wealthier provinces found to supplement greater # of molecules		• **Essential Medicines List** (EML) – centrally issued list • **Provincial Essential Medicines List** (PEML) – provincial supplementation of the EML, based on regional need • EML houses **520 molecules**, which are even more basic than NRDL A list • Wealthier provinces found to supplement greater # of molecules

Pharmaceutical spending	• Total public health insurance spending for the three schemes in 2012 was 115 billion USD, with 67% of spending attributable to urban schemes, despite the schemes covering only 40% of total insured lives
	• Total insurer spending on pharmaceutical spending is not reported, but difference in benefits can be inferred from insurers' total healthcare spending, which includes spending on all reimbursed services and drugs
	  • 139 USD per urban insuree
	  • 46 USD per rural insuree		

For pharma co's, costly access bottlenecks, littered throughout the access value chain, slowly whittle away effective patent life (1/2)

Pharma

ACCESS BOTTLECKS

Value chain	Licensing	Reimbursement	Tendering	Hospital listing	Prescription

Description of bottleneck	• *Not in scope*	• Different central ministries manage different public insurance schemes
		  • **MoHRSS** – Urban Employee & Urban Residents
		  • **MHFPC** – New Rural Cooperative
		• National and provincial stakeholders
		• Not friendly towards high-priced therapies
		  • E.g. no TTD's on NRDL or EML
			• All drugs sold through public hospitals must go through collective provincial procurement, under the mandate of the Ministry of Health and its provincial counterparts
			• Different provinces have different tendering cycles and policies
				• Winning provincial tenders is necessary but not sufficient in getting contracts
				• Pharma co's (who have been granted provincial tenders) must also fight for hospital contracts
				• Hospital contracts are largely determined by hospital formularies
					• Historically, hospitals have abused the legal 15% markup on drugs – epidemic of opportunistic prescribing – e.g. antibiotic resistance
					• Hospital performance now subject to performance metrics
					  • For pharmaceutical products, ratio of drug revenue to total hospital revenue is the most detrimental metric

For pharma co's, costly access bottlenecks, littered throughout the access value chain, slowly whittle away effective patent life (2/2)

Pharma

ACCESS BOTTLECKS

Value chain	Licensing	Reimbursement	Tendering	Hospital listing	Prescription
Description of bottleneck	• *Not in scope*	• National and provincial stakeholders • Different formularies for different schemes	• All drugs sold through public hospitals must go through collective provincial procurement	• Pharma co's (who have been granted provincial tenders) must also fight for hospital contracts	• Hospital performance now subject to performance metrics
Time delays		• NRDL was last updated in 2009 – longest cycle is 6 yrs • EML was last updated in 2012 – longest cycle is 3 years	• Provinces have different tendering cycles, • Typically, tenders are held once every 13 months	• Hospital formularies controlled by hospital-specific formulary committee • On average, committees meet every 1-2 years	• Expensive drugs are not prescribed for fear of performing poorly on the metric

For insurers, policy landscape in China means that public insurers have little to no control over determinants of cost

Insurer

Total public pharmaceutical expenditure is a function of the quantity of drugs dispensed and their prices, with influence from changes in demographic patterns, product mix, the introduction of new medicines, and the number of 'me-too' drugs

- Mossialos et al., Regulating pharmaceutical prices in the European Union, 2004

CONTROL OVER ASPECTS OF PUBLIC PHARMACEUTICAL EXPENDITURE

	Quantity of drugs	Prices of drugs	Demographic patterns	Product mix	New medicines	# of me-too drugs
Does insurer have influence?	✕	✕	✕	✕	Some (via formulary)	Some (via formulary)
Stakeholder with influence	Hospitals	NDRC (ceiling price)*, MHFPC (tenders)	MHFPC	Hospitals	CFDA	CFDA

*recent reforms in 2015 abolished the price ceiling

Key finds of study – key characteristics of MEAs in China

Key characteristics of MEAs

- **Categorization:** financial-based schemes, mainly aimed to address impact to public budgets. Drugs are contracted on average, 4.3 years after they launch and the range of being 0-10 years
  - **Most contracts structured on Patient Assistance Programs (PAPs): 65% of contracts**
- **Geographic implementation:** a total of 25 regions have implemented MEAs
  - 20 individual provinces (total of 31 provinces in China)
  - 5 municipalities
- **# of drugs contracted per region:** large range (1-24 brands), with 76% of regions contracting between 1-5 drugs
- **Drugs contracted:** 41 different brands and 37 different molecules across all geographies. 27% (11 drugs) were drugs manufactured locally, and the rest were foreign brands
  - 73% of drugs were antineoplastic and immunomodulating agents (ATC1 class L)
  - 12% of drugs, namely those produced by local Chinese suppliers, were not classifiable according to WHO's ATC system
- **Earliest recorded year of implementation:** 2005/2006 PRDL update cycle for Urban Employees and Urban Residents Basic Medical Insurance schemes

Key study finding – implications on equity

Equity in access

- **Geographic access**
  - Only 20 provinces and 5 municipalities have implemented MEAs - patients in some provinces cannot access MEA drugs; provincially implemented MEAs confer benefits to broader populations than municipality implemented MEAs
- **Access for different insurance groups**
  - Information only available for 8 regions – access is granted to all three insurance types
  - Access for remaining 16 regions unknown

Equity in financing

- **Regressive financing**
  - Information only available in 5 regions, which suggests financing mechanism was regressive
  - E.g. In Jiangsu province (wealthy eastern coast)
    - Urban Employees & Residents: 25% co-insurance, average annual incomes of 5,600 USD
    - New Rural Cooperative: 30% co-insurance, average annual incomes of 2,000 USD

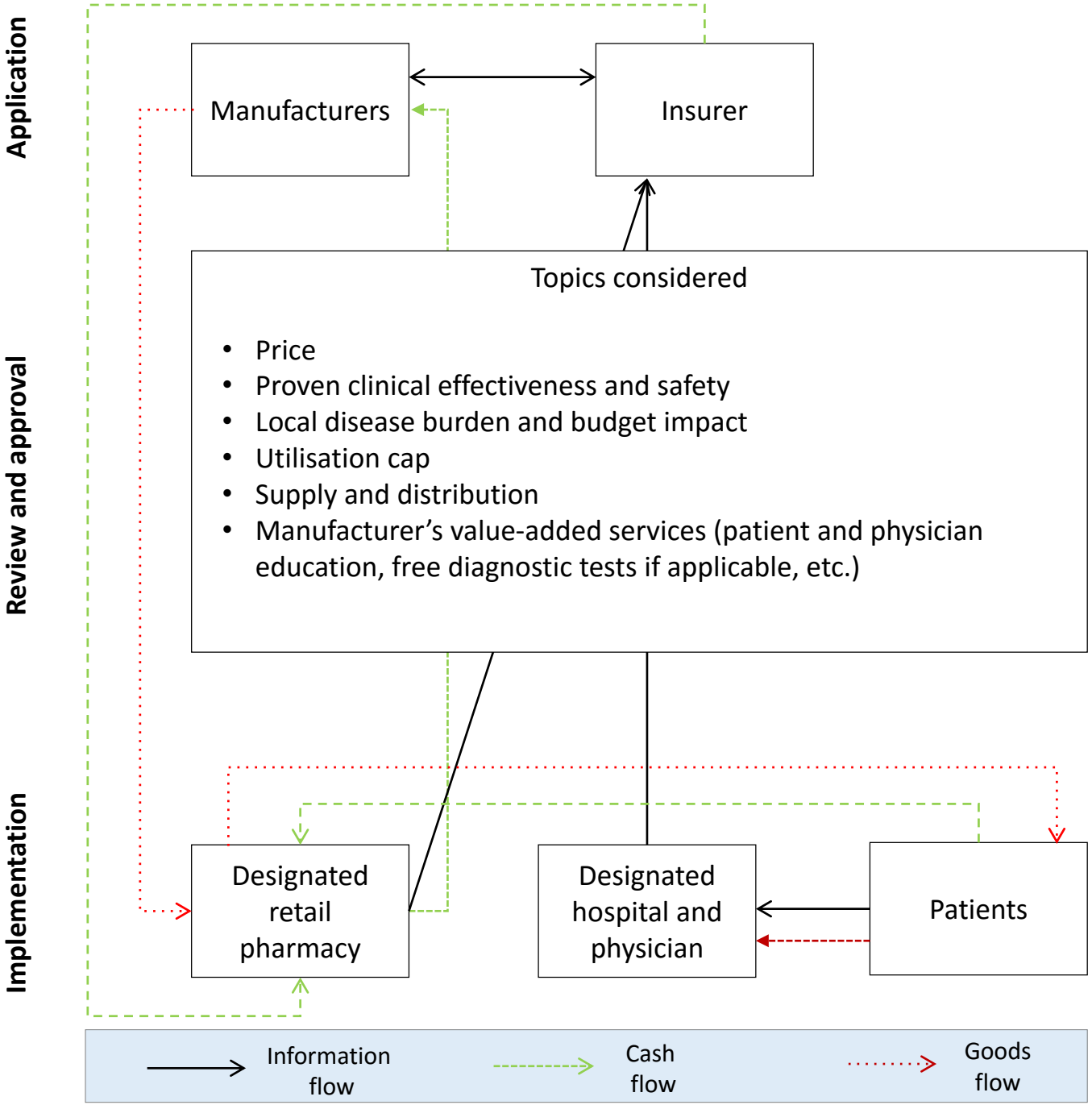
Key study finding: implications on efficiency

Technical efficiency

- **Limited use of generics/biosimiliars**
  - 11 of 41 drugs were locally produced generics/biosimiliars, which are usually cheaper than originator brands
  - These 11 generic/biosimilar drugs were contracted a total of 18 times (14%) across all regions
    - 8 drugs contracted in one province
    - 2 drugs in two provinces
    - 1 drug in four provinces
  - Evidence of regions not contracting generic/biosimiliars, even when they are available → could more savings be extracted or have originators offered large discounts?

Administrative

- **Some administrative efficiency gains**
  - Hub model – designated hospitals (and physicians) and retail pharmacies where MEA contracted drugs can be prescribed and obtained, respectively
  - Suggests administrative burden to be concentrated in certain hubs, which lessens overall burden
  - Equity trade-off's however
- **Some administrative efficiency losses**
  - No central review body nor formulary
  - No evidence of formal referencing of neighboring provinces or collective procurement/price negotiations



Key study finding: implications on efficiency and the use of PAP

- **Use of Patient Assistance Programs (PAPs) extract large discounts for insurers**
  - E.g. Glivec™ for the treatment of CML
  - Prior to MEA: PAP of buy 6 donate 6
  - As part of MEA: PAP of buy 3 get 9
    - Buy 3 portion: insurer reimbursement of 70 to 75%; patient co-insurance of 25 to 30%
    - Donate 9 portion: manufacturer must honor
  - From the perspective of the patient:
    - 100% OOP (no MEA, no PAP) → 50% OOP (no MEA, PAP) → 7.5% OOP (MEA, PAP)
- **Administrative efficiency gains**
  - PAPS executed in collaboration with Charity Organizations, which provides administrative support
  - Charity Organizations remain part of the MEA contract → administrative efficiency gains
  - Hub model → administrative efficiency gains

Key study findings: implications on quality, defined as governance

Interest representation

- Limited patient representation
  - 1 region solicited input from the general public as to which drug(s) should be contracted
- Significant clinical representation
  - Physicians / specialists
  - No nurses, primary care
- Significant gov't representation
  - Insurer
  - Representatives of local chapters of other government bodies, i.e. NCP and CPCC

Responsibility structures

- Pharma co's & designated medical institutions
  - Responsible for monitoring volume usage
  - Responsible for reporting spending and budgets
- Designated hospitals
  - Responsible for ensuring suitable patients (e.g. those with right biomarkers) undergo therapy

Accountability structures

- Local insurers
  - Operation of the scheme, including the financial health of the local health insurance risk pools
- No formal review processes, timelines or monitoring structures outlined

MEAs resolve historical barriers in pharmaceutical policy for insurers and pharma co's

- **For insurers – enables greater accumulation of power**
  - Grants legal mandate over pricing and volume to insures, which have historically fallen with other stakeholders
- **For pharma co's – resolves commercial and market access barriers**
  - Reimbursement – circumvents long formulary delays observed
  - Tendering – circumvents the need to tender, as contracts are signed between insurers and manufacturers
  - Hospital listing – circumvents the need to list in hospital formulary, as contracts are signed between insurer and manufacturers
  - Hospital performance metrics – protects MEA contracted drug from being considered in hospital performance metrics (as it is now sold through retail pharmacies, rather than hospital pharmacies)

Learnings for EEA, based on China MEAs

Equity	Efficiency	Quality

• Access
  • Geographic and populations
• Financing
  • Vertical equity
	• Central HTA review processes
	• Hub model for implementation – administrative efficiency
		• Transparency?
		• Governance, responsibility and accountability structures