



Reframing “access to medicines”: Local industrialisation and access to treatment in African contexts

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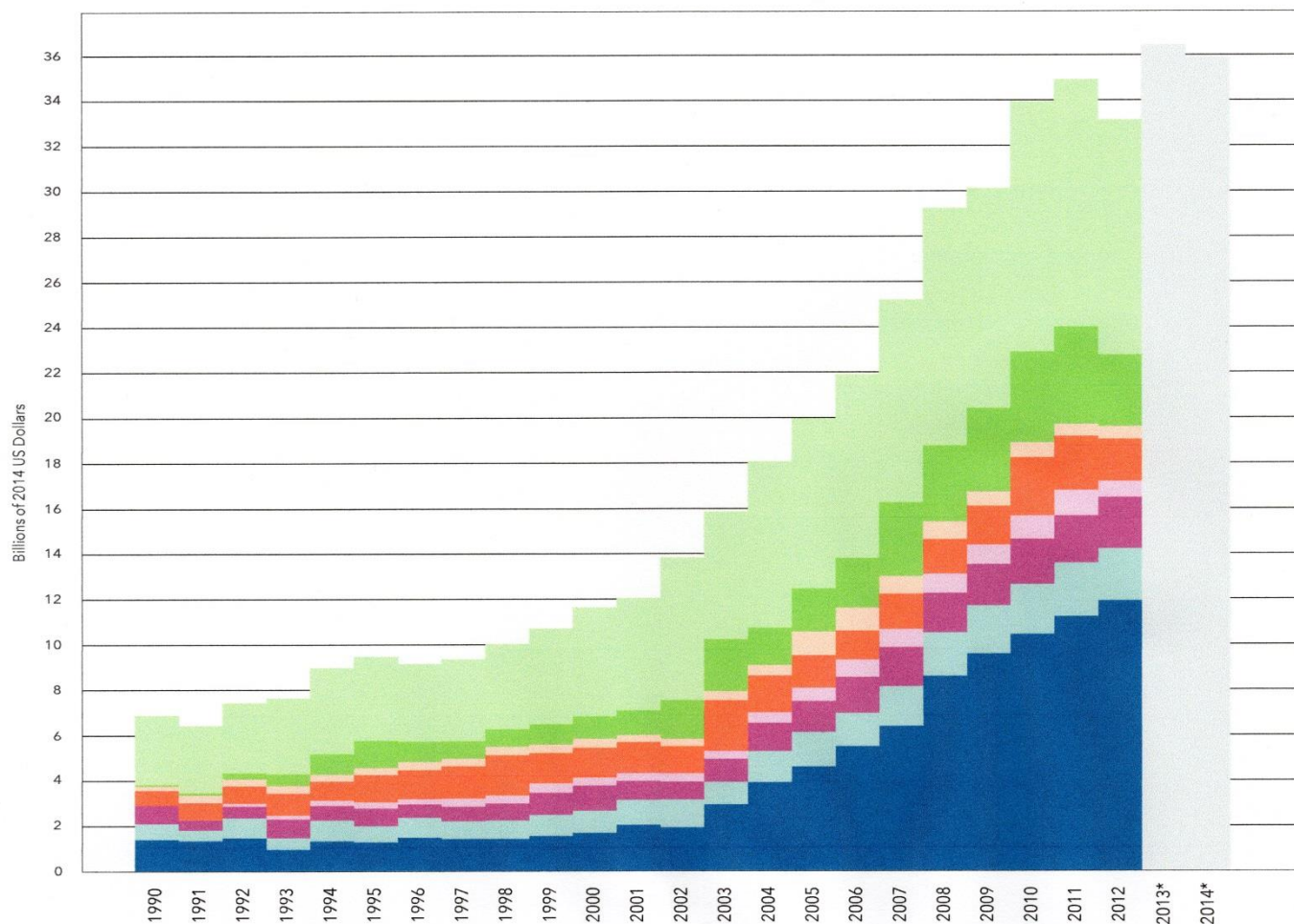


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Concepts of “access to medicines” and international responses

1. “On the shelves” availability e.g. on day of survey (WHO/HAI) (**development aid plus supply chain management**);
2. “Affordability “ : people should not be impoverished by or excluded by price (**price-focused international procurement**);
3. Reliable medicines quality: avoiding substandard and fake medicines (**regulation and WHO pre-qualification**);
4. “Appropriate use”, avoiding misuse e.g. of antibiotics (**provider training, education of the public**).

Huge rise in aid for health in Sub-Saharan Africa: Development assistance for health 1990-2012 by recipient region

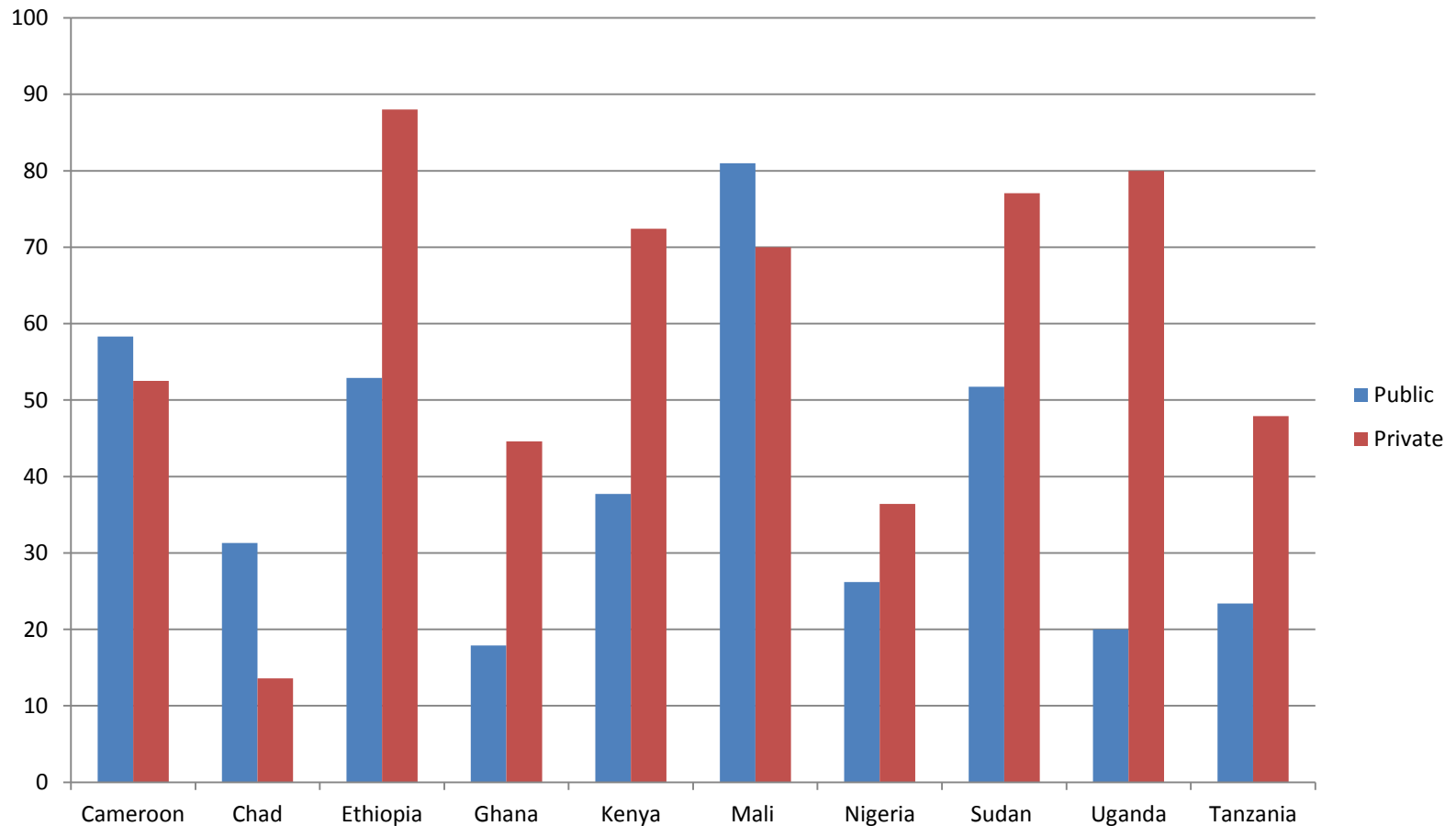


Source: Institute for Health Metrics and Evaluation. *Financing Global Health 2014: Shifts in Funding as the MDG Era Closes*. Seattle, WA: IHME, 2015: 36. SSA is lowest category, dark blue.

Much development aid for health has been for medicines procurement

- Very hard to assess how much of total spent on medicines procurement, and how much of that for SSA.
- Of the large scale aid to health in SSA, 50% currently from USA, focus on HIV/AIDS; also TB and malaria, some maternal health.
- Has had a major impact in saving lives of those with HIV/AIDS and TB.
- Emphasis on international competitive procurement from WHO-prequalified suppliers managed outside SSA, with logistics undertaken locally;
- Development of vertical supply chain management for HIV/TB with some local purchasing of medicines for opportunistic conditions.

Patchy availability of broad spectrum of essential medicines : Median availability of a basket of ~50 medicines, by SSA country



Source: WHO World Medicines Situation 2011: compiled from Statistical annexes

Hence an increasing interest in access to medicines as part of health systems research frameworks

The objective is not “medicines access”, it is rather:

- Access to accurate diagnosis and appropriate treatment
- as a core element of Universal Health Coverage.

Recent WHO health systems work on medicines emphasises:

- Shifting from a supply-side perspective to also tackle demand-side constraints;
- Addressing medicines access barriers at different levels of the health system;
- Better information on medicines as part of health system decision-making;
- An international framework for addressing medicines and health systems.

Argument for a shift away from a purely health systems framing towards a broader developmental and political economy view, reflecting African perspectives

Two key aspects of the political economy of health systems and development in African LICs:

1. *Informalisation* Health systems in LICs are embedded in economies that are highly reliant on cash-based small scale businesses and transactions. The health systems reflect this in their structure and behaviour: the reliance on out-of-pocket (OOP) payments is not something special to the health system.
2. *Externalisation* Many SSA countries have seen waves of industrialisation and deindustrialisation, their pharmaceutical industries reflect that history; contrary to widespread perception, medicines have long been produced in SSA, now are facing increased international competitive pressures.

Informalisation: political economy of OOP payments East African cases

Medicines form a large part of the OOP health care costs of Tanzanians and Kenyans, both medicines purchased at facilities, and those bought from shops.

Data are poor. However two generalisations hold:

- High level of dependence on donor funding
- Most other medicines funding is OOP.

Those two sources now largely fund East African domestic medicines markets. Locally raised tax funding for medicines estimated at <5% of total domestic medicines markets in Tanzania and very low also in Kenya.

Funding for medicines for Tanzanians: a calculation

Shaky data, but robust conclusion: that government tax-funding has little market leverage:

Tanzanian pharmaceutical market	USD million	% of total market
Estimate of total market size *	250	100% (2011/12)
Public wholesaler total sales **	125	50% (2011)
Public wholesaler sales not Vertical Programme/ directly donor funded ***	37.2	15% (2011)
Tax-funded share of Treasury funds for public wholesaler****	11.3	5% (2011/12)
Estimated % share of tax-funded government spending in domestic medicines market		5% (2011/12)

Sources: * Interviews ; ** MSD (2013); ***MSD (2013); ****MoHSW (2013: 4-5)

While donors focus on vertical supply chains, public sector procurement agents see fragmentation

A clinical officer's sources in a Tanzanian public dispensary:

1. Ordering from public wholesaler, plus gap-filling through:

2. Community insurance and user fee funds

... deposited into DMO's account ... used by the DMO to order medicines and supplies especially in case of emergencies

3. Donors: 'basket funds' and equipment donations

... medical equipment even if you order them, you do not get them, so we do not order them.... we ask donors to help.

: thermometers from a Dutch personal donor, BP machine from a friend in the US, stethoscope he had bought himself.

2. Vertical programmes

.... laboratory suppliesfrom the DMO are from a vertical programme and so they are available.

Implications of reliance on OOP are perverse for access to competent diagnosis and appropriate treatment:

- Exclusion of many people from treatment; lack of effective demand reducing on-the-shelf availability;
- Public sector stock-outs and heavy reliance on private shops for medicines, at higher prices than public sector;
- Public facilities rely on medicines sales for petty cash;
- Small scale private dispensaries and shops focus on low cost medicines sales: quality problems and rampant under-treatment: in a 2008 study of FBO and private medicines outlets, selling half-doses was a *norm*;
- Resistance to paying into community insurance schemes because money remains needed for medicines unavailable in the public sector.

Externalisation and fragmentation in Tanzanian medicines supply chains

Donor dependence has brought domestic medicines market disaggregation : loss of domestic market linkages for local pharmaceutical producers.

Sharp decline in local producers' share of domestic medicines market in Tanzania since 2009 (WHO/HAI data):

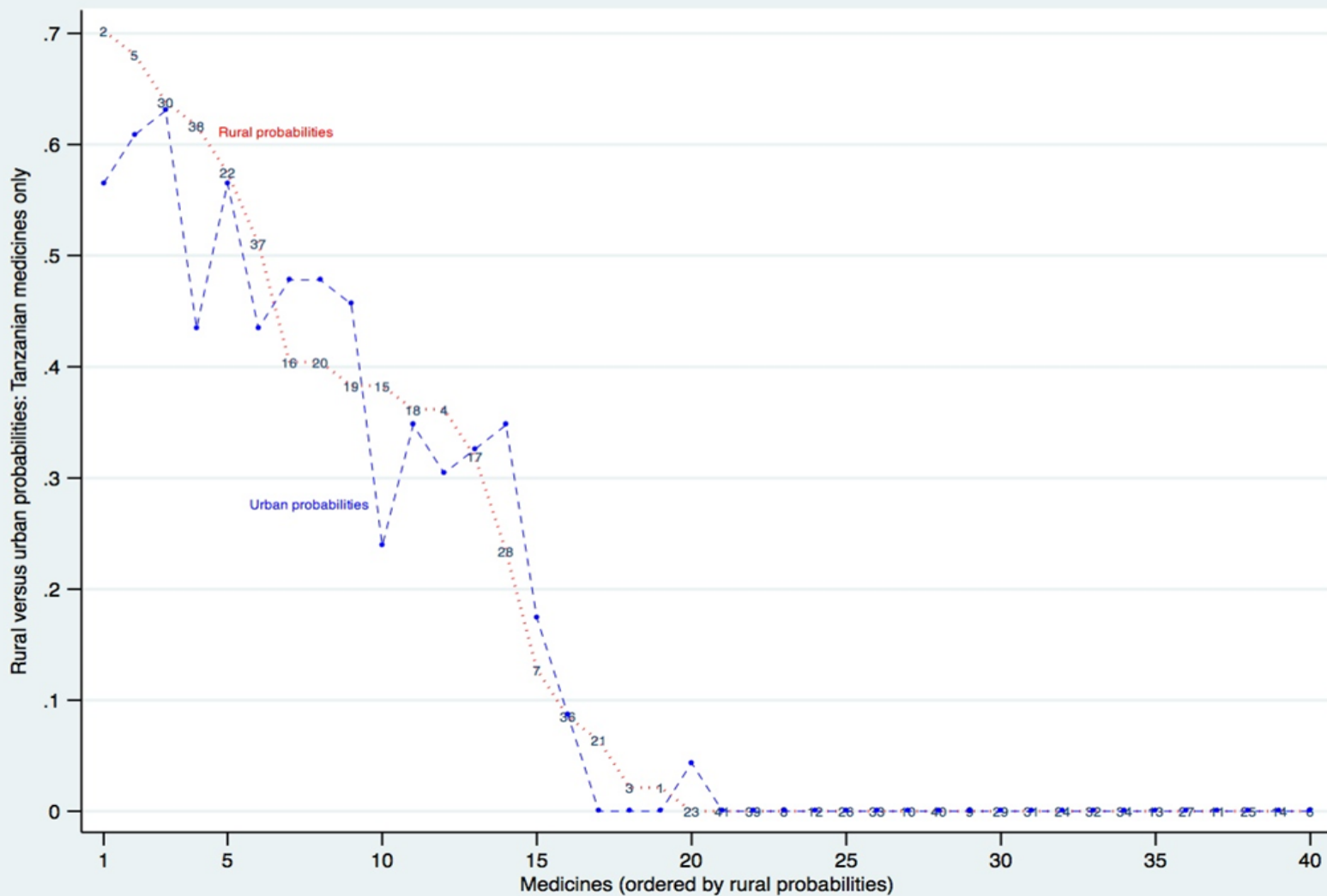
Year	Percent of sample medicines available on day of visit, by country of origin of medicines			
	Tanzania	Kenya	Other	Total
2006	33	14	53	100
2009	21	13	66	100
2012	12	11	78	100

Rising barriers to domestic market entry for local firms:

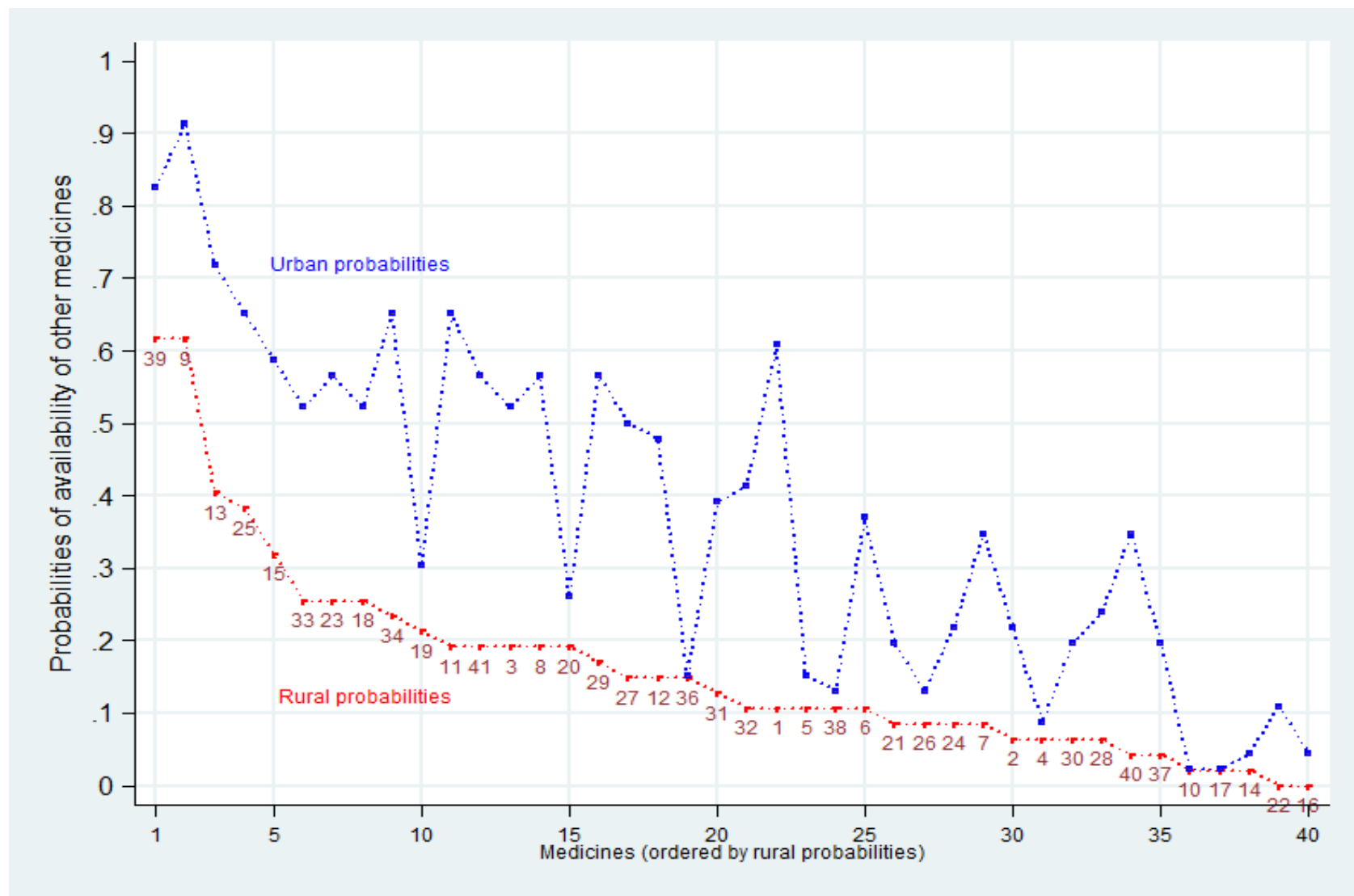
- Loss of industrial protection when tariffs on imported medicines and supplies removed (strong pressure from donors)
- Rising import price competition and some dumping
- Competitive and regulatory pressure to upgrade technological level and quality standards
- Worsening power and infrastructure constraints
- A tightening skills constraint
- Duties and tariffs on imported inputs imply trade policies now favour final goods imports
- Registration delays for new products by local firms
- Weakening local procurement relationships because of large size tenders, short term contracts, no local tenders
- Lack of the public sector support available to competitors.

Should health policy makers care?

**(1) Local firms are better at serving rural demand:
Probability of finding a medicine from Tanzania by rural/urban 2006**



.....while imports tend to “stick” in urban areas:
Probability of finding a medicine from outside East Africa, by rural/urban



Should health policy makers care?

(2) Local production brings health-relevant technical and scientific skills, may change economic and political incentives

For health systems to improve, local expertise and political commitment are essential.

One source of essential skills is industrial: the skills needed to generate locally relevant products and to profit from supplying local needs.

Competition between local industry and imports, in a context where there is some protection against dumping, can keep prices down.

Local producers also constitute a lobby for sustaining and consolidating local public and non-profit procurement.

Public and NGO buyers source more locally than private wholesalers:

Country of origin of tracer essential medicines, by procurement sector, Tanzania and Kenya, 2012/13 (% by sector)

Country	Tanzania		Kenya		
	Public	Private	Public	Faith-based	Private
Wholesale sector/ Source					
Domestic manufacturers	22	11	53	76	33
Other African	10	21	0	0	6
India and Pakistan	49	50	30	11	31
China	6	6	8	1	4
EU and Switzerland	7	11	1	4	19
Other	6	0	7	8	7
Total	100	100	100	100	100

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Total	100	100	100	100	100

Developmental benefits.

To develop, SSA low income countries must industrialise: they need rising productivity.

SSA manufacturing structures – apart from extractive industries - depend strongly on their domestic and regional markets.

Pharmaceuticals have developed in many countries to serve those domestic markets, and among domestic industries, pharma is relatively high skill/ high tech.

Some countries are successfully building pharmaceutical exports onto the domestic market base: Kenya, Ethiopia.

Some are successfully expanding local production and moving up the technology ladder into APIs: Ghana, Nigeria (also South Africa).

Can African countries link industrial development to health system improvement? Three types of policies now in use.

Industrial policies to support local suppliers:

- Revision of taxes and duties to incentivise local production over imports;
- List of products for local supply only, and criteria for retaining or removing items;
- Work with donors to support step-up in technological capabilities of local firms;
- Public pricing policies that ensure local supply can be profitable for basic items, given infrastructure weaknesses and dumping episodes;
- Strategic investments in technical training and support for firms that train effectively;
- Local regulatory and procurement policies that actively support local firms' innovation.

Procurement policies: reducing barriers to entry for local firms, by revising:

- Private sector importer/wholesaler incentives and challenging business links with overseas exporters;
- Public procurement rules and practices : trade credit, tender size, contract length and structure, payment reliability, accreditation of suppliers, decision rules;
- Role of NGO/non-profit/FBO wholesalers;
- Preferences of donors for large overseas orders, and role of donors in setting procurement systems and fragmenting supply chains;
- Involvement of local procurement officers and clinicians in supply chain design.

In health policies, reducing informalisation:

- A much lower proportion of medicines access needs to go through private shops;
- More medicines access has to be free or at very low cost, implying more public and NGO/FBO procurement and supply without charge;
- Access needs to be increasingly associated with proper diagnosis and dispensing;
- Implies pushing the private sector up-market through competition from low cost non-profit/public provision;
- Implies more and more reliable local public as well as donor funding for the whole range of essential medicines and supplies, including antibiotics and chronic disease medicines, gloves and test kits.

Conclusions : combatting externalisation and informalisation

What has happened in health and pharmaceuticals is embedded in the broader political economy of LICs in SSA:

- Sweeping trade liberalisation in recent years
- Externalisation of supply chain linkages
- Informalisation of businesses and payment systems
- Rising inequality and continuing widespread impoverishment.

Universalist health systems can be one force for combatting these trends, linking formalisation of health care provision to industrial and technological improvement and more decent work in the broader economy – and creating lobbies with mutual interests in sustaining domestic linkages.

But note that creating this “health-industrial complex” in Brazil took three decades – it needs to be built institutionally , it can’t be willed into existence.

Acknowledgements, disclaimer, further reading

Project website: iphsp.acts-net.org

Research team members:

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Forthcoming book: Mackintosh M, Banda G, Tibandebage P, Wamae W (eds.) (2015) *Making Medicines in Africa: the Political Economy of Industrialisation for Local Health* Palgrave Macmillan

Other reading: **AUC** *Pharmaceutical Manufacturing Plan for Africa*



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