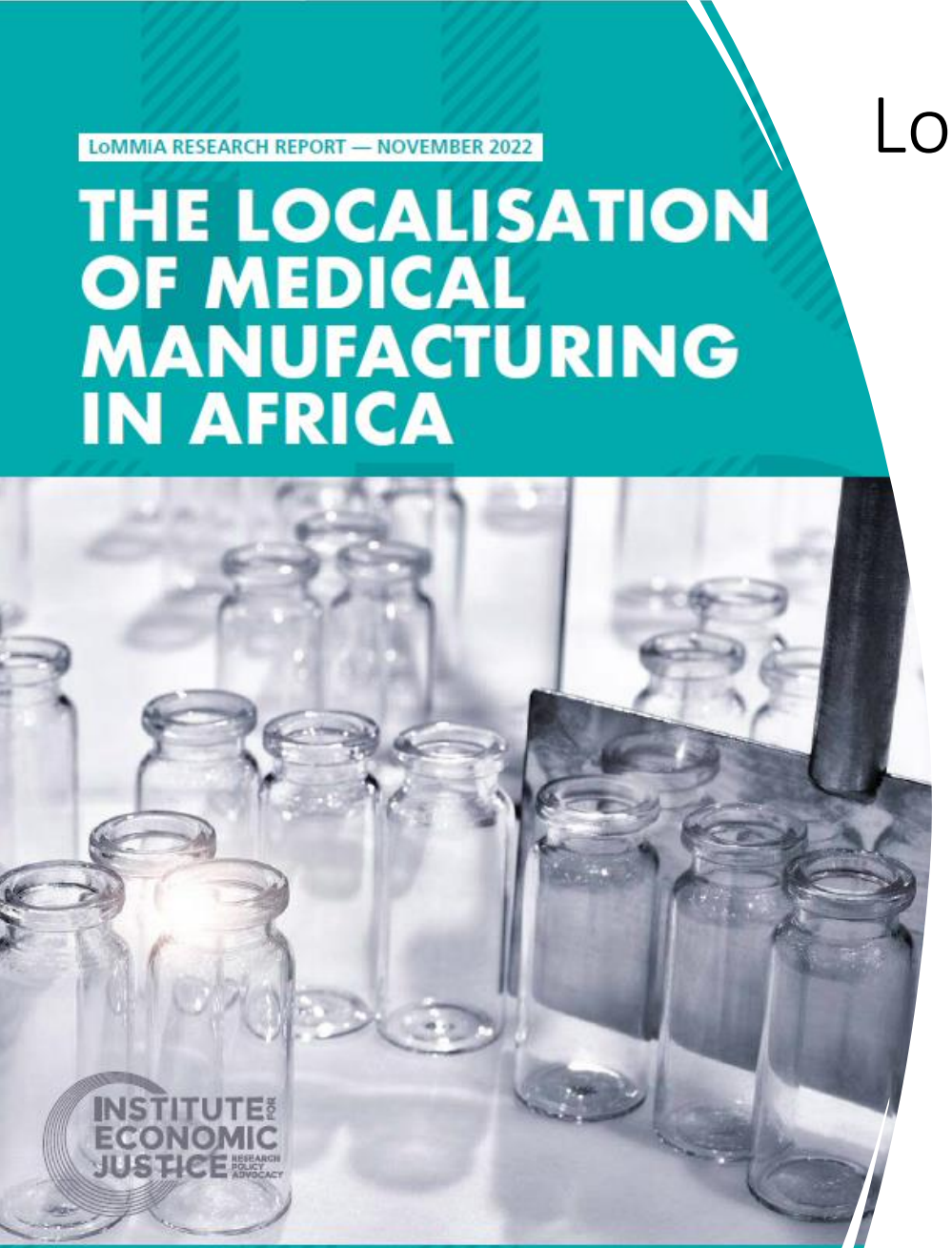

Localisation of Medical Manufacturing in Africa:

Research Report Presentation at the Development Dialogue on the Medical Devices Localisation

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Background and context

- In a majority of African countries, more than 70% of health technology requirements are imported. This situation is untenable both now, and in the long run.
- The advent of the COVID-19 pandemic accelerated the urgency and agency for African governments to seriously consider investing in localisation of medical health technology manufacturing (drugs, vaccines, medical devices, and diagnostics).
- Covid-19 demonstrated that the current African health-industry complex, comprising of local health industrial structures, value chains, and supply chains, and other supporting industries was woefully unprepared to rapidly address fast-moving public health emergencies.

Background and context

- African governments and many agencies and scholars, have been acknowledging, even before Covid-19, the strategic importance of the pharmaceutical sector to local health security and other collateral benefits
- Yet for most African countries, the investment track-record in and design institutional mechanisms to stimulate and sustain technological change in the pharmaceutical sector has remained poor.
- **Will the Covid-19 experience herald a shift in the scenario?**
- It is in this backdrop that the study informing this presentation was commissioned by the IEJ to deepen understandings on key policy, infrastructure, technology, and political economy issues that impact localisation of medical health technologies production.

Project Aims and Objectives

a) Assessing the **current landscape** of medical product manufacturing in Africa

b) Identifying **structural barriers and opportunities** for local manufacturing;

c) **Developing a framework** for assessing the normative elements of the project (that localisation is developmental, ensures better availability of drugs and other medical health technologies and challenges entrenched industrial dominance patterns);

d) Providing policy proposals that promote development, economic recovery, and improved availability of medical health technologies (understood broadly).

Link to the project report [Localisation of Medical Manufacturing in Africa Institute For Economic Justice (iej.org.za)]

Overarching Research Question

How best can African countries harness and deploy lessons from the COVID-19 pandemic and from other relevant local manufacturing experience to develop and enhance sustainable capabilities for local manufacturing of medical health products?

Conceptual underpinnings

- Our understanding of ‘localising medical manufacturing’ in this study derives from a number of standpoints hinged on notions of geography, agency, urgency and proximity.
- We explore overlaps between local as a location versus local as localization, local agency, local urgency, local empowerment and local structural transformations embedded in technological, political, economic and epidemiological transitions.
- These issues elicit various conceptual dimensions, hence this study drew from and interrogated innovation systems and policy architectures, manufacturing, technological capability and business models

Methodology

We used a multi-sited case study approach, with countries, subsectors, companies and products as case studies

We gathered data from primary and secondary sources.

Secondary data collected through desk research into peer-reviewed and grey academic, policy and practice literature.

Primary data gathered through more than 20 semi-structured interviews with key informants in the industry, and policy sectors.

We analysed qualitative data using thematic analysis and for quantitative data sets, we used tabulation and simple statistical analysis.

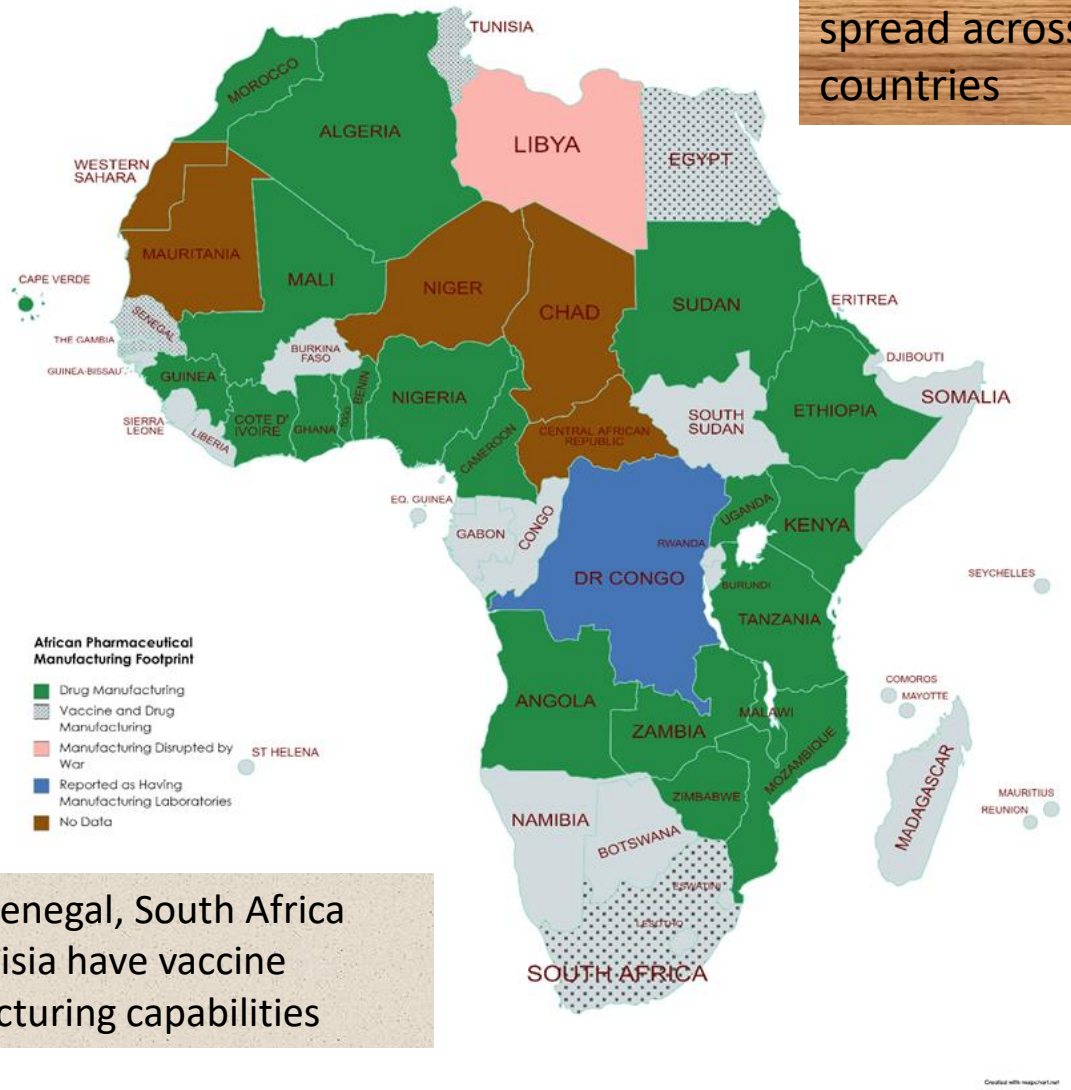
Study findings

- Our findings affirm that the African medical technologies sector is not new
- Study also confirms African countries were neither self-sufficient nor agile enough to repurpose local pharmaceutical capabilities to manufacture medical health technologies at the scale required to expeditiously meet the challenges of the pandemic.
- The study identified and critically examined some regional, country and product-specific case studies of innovative responses to pandemic shortages.

Manufacturing footprint (medicines and vaccines)

Africa has a 125-year pharma manufacturing history

Nearly 650 plants, spread across 29 countries



Egypt, Senegal, South Africa and Tunisia have vaccine manufacturing capabilities

West Africa		East Africa		North Africa		Southern Africa	
Benin	1	Burundi	1	Algeria	55	Angola	2
Burkina Faso	0	Djibouti	0	Egypt	120	Botswana	0
Cape Verde	1	Eritrea	2	Libya	-	Lesotho	0
Cote D'Ivoire	5+	Ethiopia	11	Morocco	33	Malawi	3
Cameroon	15	Kenya	35	Sudan	25	Mozambique	2
Gabon	0	Rwanda	0	Tunisia	39	Namibia	0
Gambia	0	Somalia	0	Western Sahara	0	South Africa	122
Ghana	30	South Sudan	0			eSwatini	0
Guinea	1	Tanzania	4			Zambia	5
Guinea-Bissau	0	Uganda	11			Zimbabwe	5
Liberia	0						
Mauritania	0						
Mali	2						
Niger	?						
Nigeria	115						
Senegal	5						
Togo	3						
Total	178+		64+		272+		139+

Technologies, therapy lines produced on the continent

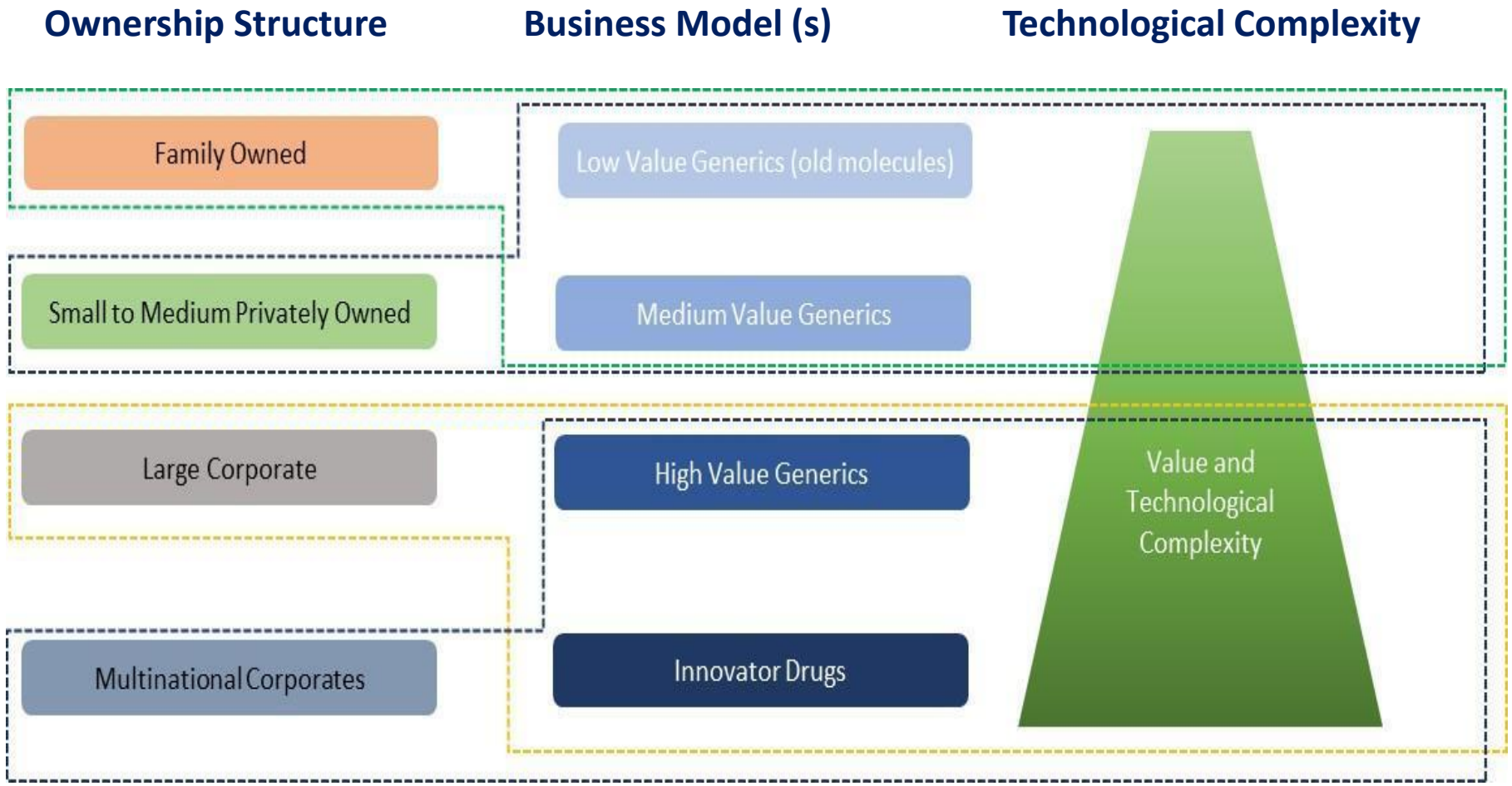
Technologies	Therapy Lines
▪ Tablets ▪ Gelatin capsules ▪ Powders ▪ Injectables ▪ Granules ▪ Ampoules and vials ▪ Effervescent sachets ▪ Syrups and suspensions ▪ Topical preparation ▪ IV fluids ▪ Large-volume parenterals ▪ Sprays ▪ Fixed Dose Combinations ▪ Slow release formulations	**Anti-infectives** ▪ Antibiotics ▪ Antimalarials and other antiprotozoals ▪ Antiretrovirals ▪ Antifungals ▪ Anti-tuberculosis **Other medications** ▪ Antihistamine ▪ Anthelmintics ▪ Analgesics ▪ Gastrointestinal medicines ▪ Erectile dysfunction agents ▪ Anti-hypertensive ▪ Cardiovascular agents ▪ Anti-diabetic ▪ Cold and flu preparations ▪ Asthma ▪ Dermatologics ▪ Anti-nausea ▪ Anti-inflammatory ▪ Antispasmodics ▪ Cough suppressants ▪ Antidepressants ▪ Anti-psychotics ▪ Ophthalmic ▪ Haematology ▪ Radiology ▪ Musculoskeletal ▪ Multivitamins

There is very limited capacity for APIs manufacture on the continent

Focusing on vaccine manufacturing capabilities

Country	Organisation	Established	Vaccines Manufactured
Egypt	Vacsera The only producer of vaccines and sera and one of the main blood banks.	1897	▪ Tetanus Toxoid Vaccine ▪ Diphtheria and Tetanus Toxoid Vaccine [paediatric and adult use] ▪ Diphtheria, Tetanus and Pertussis ▪ Meningococcal Vaccine ▪ Cholera Vaccine ▪ Typhoid Vaccine Planning to produce Sinovac vaccines. A new vaccine facility outside Cairo will have capacity for 1 billion doses per annum.
Senegal	Institut Pasteur de Dak	1896	▪ Yellow Fever – since 1930s One of four WHO approved manufacturers of Yellow Fever vaccine in the world.
South Africa	Aspen	1850 went public in 1997	▪ Johnson and Johnson COVID-19 Vaccine. First Covid vaccines manufactured (fill and finish) on the continent.
	Biovac	2003 as a PPP	▪ BCG for TB ▪ Measles Vaccine ▪ Pneumococcal Conjugate Vaccine ▪ Hepatitis B Vaccine ▪ Hexavalent Vaccine for Diphtheria, Tetanus, Pertussi, Poliomyelitis, Haemophilus influenza B and Hepatitis B ▪ Tetanus Toxoid Vaccine ▪ Agreement to produce Pfizer COVID-19 vaccine (fill and finish). ▪ Guillain-Barre Syndrome (GBS) Vaccine Development.
Tunisia	Institut Pasteur de Tunis	1893- commissioning of establishment	▪ BCG Vaccines – Intradermal BCG and fresh BCG for Immunotherapy (bladder tumours) ▪ Under development – rabies vaccines for human and veterinary use and bacterial vaccines for veterinary use (mixed anthrax and enterotoxemia).

Prevalent Business Models



Medical devices

- The medical devices sector, like the vaccine manufacturing sector, is among the most under-studied on the continent.
- There is a high reliance on imports: in most African countries, over 90% of the medical devices in public hospitals are imported
- Even in South Africa, a country with a well-established medical device sector in terms of companies registered to sell medical devices, only a very small proportion of the manufacturing firms are local.
- The sector faces technological, market and regulatory hurdles
- Currently Africa-based medical device companies depend on European Notified Bodies for certification, and this significantly increases their regulatory compliance costs.

Regulatory capabilities

- The health technologies manufacturing sector is subject to high levels of complex regulation compared to other manufacturing sectors that place their finished goods on the open market
- While drug regulatory capabilities are prevalent on the African continent, institutional capabilities and strengths of regulatory bodies vary across countries.
- According to the WHO, there are 54 National Medicines Regulatory Authorities (NMRAs) in Africa, though only 7% of these have the capacities to perform the core functions expected of NMRAs – momentum from AMA?
- Vaccine regulatory capabilities exist in the four countries that have historically manufactured vaccines
- Medical device regulatory capabilities are weak and in some cases embedded in pharma regulation architectures
- Regulatory capabilities in cell therapies are not yet available, but there are capabilities in monoclonal antibodies (MAbs) regulation in North Africa.

TABLE 6

Medical health technologies governance tools and state of capabilities in African countries

Type of Technology	Characteristics	Governance tools	Capabilities
Biologicals · Monoclonal antibodies (MAbs) · Cell therapies · Vaccines	Produced from living cells, high molecular weight, complex heterogeneous structure, very high process-dependency (the process is the product), propensity for heterogeneity, unstable and very sensitive to external environments, immunogenicity challenges.	· Legislation (law) · Guidelines · Standards	There are vaccine regulatory capabilities in South Africa, Senegal, Tunisia and Egypt. For MAbs, North Africa possesses some regulatory capabilities. No capabilities for cell therapies. The rest of the countries do not possess biologicals regulatory capabilities.
Drugs (small molecules)	Produced through chemical synthesis; low molecular weight, well defined structure, process-independent, stable and non-immunogenic.	· Legislation (law) · Guidelines · Standards	Regulatory capabilities are prevalent across Africa; however regulatory institutional strength varies.

Type of Technology	Characteristics	Governance tools	Capabilities
Medical devices	Medical devices constitute a huge field ranging from spatulas and thermometers to radiation machines and implantable devices. Standards are the general regulatory tool used in this sector.	· Acts · Regulations (law) · EU directives · Local legislation · Standards such as the ISO 13485 and ISO 14971, which provide a management environment that lays a foundation for firms to develop products. The use of harmonised standards can lead to CE mark approval through a notified body. · Guidance documents (which are not legally binding but promote a common approach to the implementation of the procedures). · Technical information reports. · Local and international bodies	Regulatory capabilities for medical devices are scarce on the continent. Local institutions can carry out plant inspections for GMP; however, there is no notified body on the continent and companies depend on Europe for obtaining the CE mark.

Summary: Barriers to Localisation of Medical Manufacturing

- Lack of industrial protection to support local production
- Policy incoherence – industry, STI, education, health
- Limited and/or inappropriate business models and growth options
- Limited access to finance – undervalued strategic importance of the health sector
- Lack of innovative procurement mechanisms
- Weaknesses in generating decent work in/through the sector

Conclusions from the study – an evolving landscape with many positive stories

- The health technologies sector sits at the confluence of politics, public health, manufacturing, business, trade and other sectors of the economy
- This study has confirmed that the African **medical technologies sector is not new,** and that, like elsewhere globally, **deep fragilities** were revealed by the pandemic
- What differs is how countries **respond through harnessing or repurposing available capabilities**.
- Numerous local production efforts were noted, and these had to contend with **various historical and current impediments** to sustainable localisation of manufacturing capabilities
- Countries need a **culture and policies that imbue a 'can-do' attitude**, as seen in countries that led the line in development of various requirements for Covid-19, from ventilators to diagnostic equipment, protective equipment to vaccines.
- **Momentum from the Covid-19 experience** could be harnessed for sustainable transformation of the medical technologies sector

Conclusions and Recommendations

a) Urgent action is needed to build commensurate industrial capabilities. **The state can use its political legitimacy, control of resources**, and ability to exercise immediate agency through public policy to roll out politico-technical projects for this cause

b) One of the greatest shortcomings during Covid-19 was the inability to access APIs. The continent urgently needs to **build API manufacturing capabilities.**

c) In terms of business models, SMEs have served African countries for more than a century, however these **business models are not adequate** for the scale of intervention required to build resilient local health systems that are foundational for global health security and pandemic/epidemic preparedness

Conclusion and Recommendations cont'd

d) There is an urgent need for the local drugs manufacturing sector to **transition to newer technologies**.

e) **Medical devices** are a fledgling industry that requires urgent support which includes availability of finance, standards and other institutional as well as infrastructural support. Lessons can be learnt from the pharma sector

f) The biologics subsector has huge potential in terms of **vaccines and other products such as MAbs (Monoclonal Antibodies).** This is a subsector with tremendous commercial opportunities because of its immediate and future utility

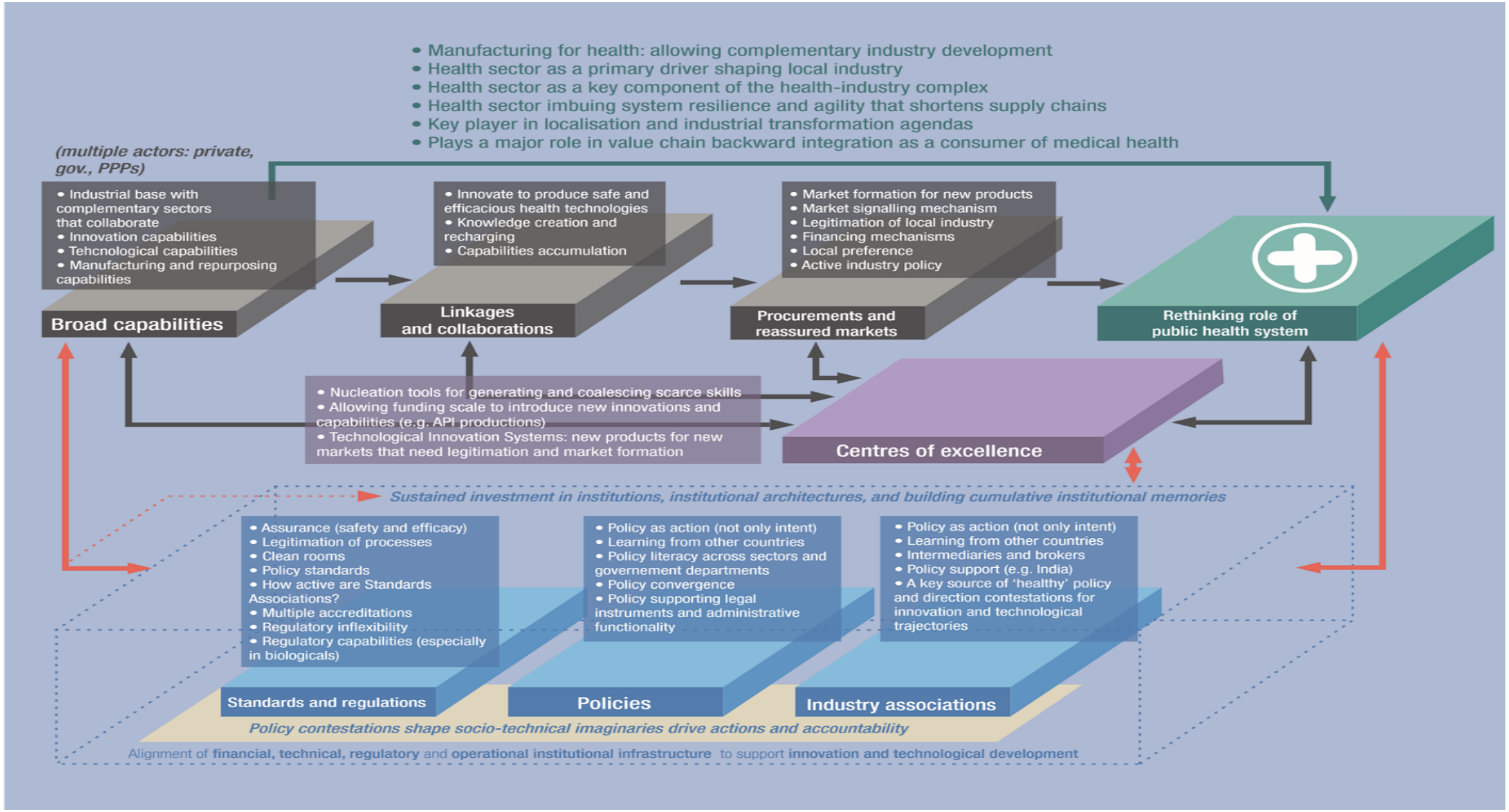
Conclusions and Recommendations cont'd

g) Development of the medical health technologies sector is **long-term in nature**, requires patient capital, and innovative procurement from public health systems as a market signalling mechanism.

h) **Science technology and innovation systems** are a critical component of localisation of medical health technologies manufacturing. Science granting councils have an important role to play here

i) The **localisation challenge is not only technical**, but encompasses local and global power dynamics spanning the political, socio-technical and economic aspects – hence the key role of the state in the medical technologies sector

Proposed Policy Mix to Support Local Manufacturing



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