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BUILDING INSTITUTIONAL / HUMAN CAPACITY TO REVITALIZE HEALTH MARKETS FOR REGIONAL COOPERATION AND TRADE

Final Report – Project Code: 10F198220

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Contents

I. Executive Summary

Covid-19 type crises lend evidence to the fact that social and industrial development outcomes converge in healthcare. Even high-income countries lack core human and institutional resources and capacity for efficient and resilient production, equitable access and economic distribution of essential medicines, vaccines and critical inputs to meet their own needs – let alone for export and trade. Mega trends in climate change and digitalization mean dealing in the $1.65tn global Therapeutic Goods Health Markets ("**TGHM**") also oblige stakeholders to design, apply and measure mutually reinforcing environmental, social, governance and industrial policy that leads to greater resilience, human dignity, and a healthier planet.

Indonesia, Nigeria and Turkey (the "Pilot Countries") carry potential to establish resilient and effective heath markets by investing in and developing policy for the industrialization and trade in HS 3003 Unpackaged Medicaments and HS 3004 Bandages. Developed through natural resource value-add processing for APIs, generics and medical devices value chain and manufacturing assets, the Pilot Countries could establish and contribute to self-reliance and strategic regional and

global positioning in critical input supplies – together with their South-South and High-Income Country partners.

The Pilot Countries have potential to leverage existing capacity to leapfrog into advanced medical and therapeutic goods production, and intellectual property rights commercialization through forward and reverse linkages that account for product and economic complexity.

For example, 'low-hanging fruit' opportunities exist in integrating national and regional capacity and gaps in strategic value chain and manufacturing assets derived from each country's endowment of human and natural resources and institutional capacity for HS 3003 and HS 3004, for extraction and value-add processing of Nigeria's health-grade Colloidal Kaolin assets with national incumbents, emerging and global leaders such as Dangote or BUA, with R&D, development and licensing or offtake agreements with Biovaccine Nigeria Ltd., could establish a domestic integrated supply chain in API precursors, excipients, drug delivery and other medical bioproducts derived from mineral resources.

Potential 'Tipping Point' leadership from private sector firms such as Sinar Mas, APP / Paper Excellence and PT Biopharma could contribute to unlocking Indonesia's influence in TGHM by developing its rights, property and interests in forestry, botanical and agriculture natural resources under its ownership and control which can be developed and commercialized into PPE, medical textiles and respiratory therapeutic applications. Renewable and sustainable bioproducts such as nano-lignocellulose, gas substrates and chitin could be developed as non-petrochemical substitutes to China imports of melt blown or spunbond polypropylene polymers as critical input supplies in PPE such as masks, gowns, and bandages.

Figure 1. Country Linkages and Regional Value Chain Asset Development Opportunities

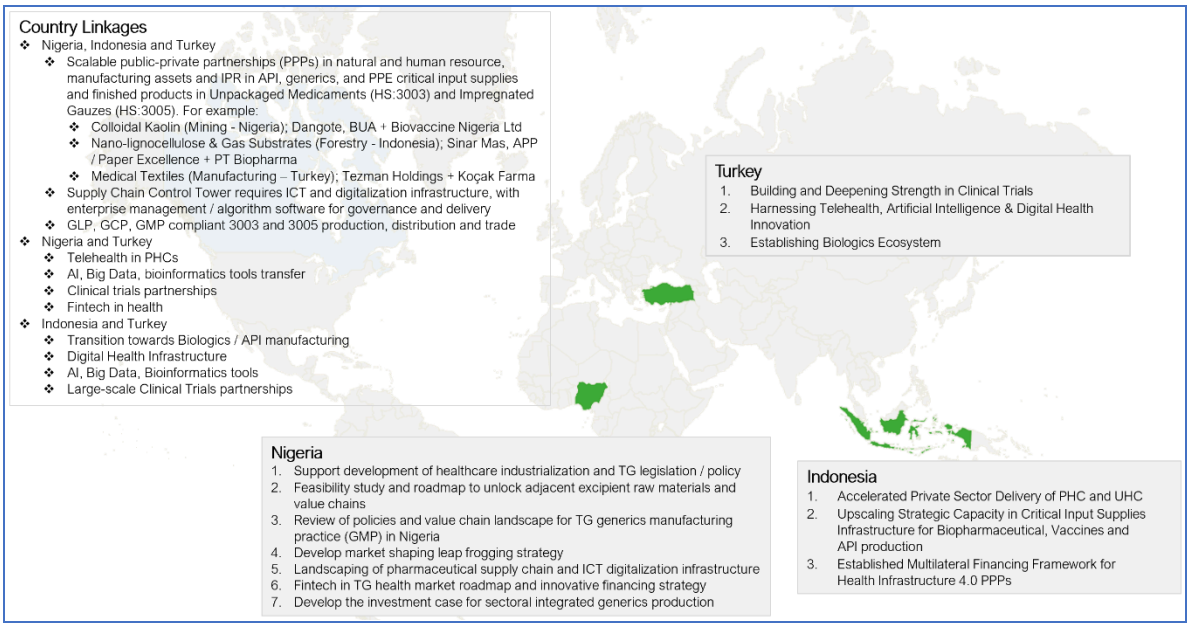

Figure 1. Country Linkages and Regional Value Chain Asset Development

Further, Turkey's existing capacity in generics and PPE production with firms such as Tezman Holdings + Koçak Farma could provide material contributions to value-add critical input supplies and finished products such as impregnated gauzes, and advanced medical devices with controlled release for anti-viral, antimicrobial or immunological effects unmet needs in infectious respiratory diseases or conditions.

II. Context and Introduction

Islamic Development Bank Group (IsDBG) and Developing 8 (D-8) member countries have committed to achieving the targets within the 2030 Sustainable Development Goals (SDGs). Among these Goals, SDG 3, "ensure healthy lives and promote wellbeing for all at all ages" includes targets related to the progressive provision of Universal Health Coverage (UHC), research and development, trade, intellectual property rights, health financing of therapeutic goods and services, and capacity strengthening for early warning, risk reduction and management of national and global health risks.

Even before the COVID-19 pandemic, member countries had undergone fundamental demographic, epidemiological, social, economic, and technological transformations that touch every dimension of daily life. In all but a handful of countries, COVID-19 pandemic exploited weaknesses across health markets and supply chain systems, cumulatively creating the conditions for a preventable catastrophe. At the height of the COVID-19 pandemic, primary healthcare (PHC) cessations were further exacerbated by disruptions to global supply chains for therapeutic goods (TGs) and essential medicines.

Insufficient stockpiling, suboptimal inventory management and contingency planning, and fragmented TG supply chains across regional, national, and international public health platforms led to shortages of essential supplies and equipment, sparking bidding wars and in some cases, leaving health workers without appropriate protective gear. Even high-income countries lacked the domestic capacity to produce many Therapeutic Goods (TGs) for their own needs – let alone for export and trade.

As the world emerges from the pandemic, the crises offers a compelling opportunity to think creatively, break out of established paradigms, and build more effective, resilient therapeutic goods manufacturing and supply chain systems that are fit-for-purpose in the modern era, with potentially huge knock-on benefits across health and non health markets. Governments, policy makers, industry leaders, investors, academics, and practitioners are recognizing the need to work together to marry a forward-looking Therapeutic Goods Health Market (TGHM) vision for their regions, with transformational shifts and institutional reforms driven by a demand led approach.

III. Rational and objectives

The Organisation of Islamic Cooperation (OIC) and D-8 member countries (MCs) have opportunities to leverage momentum from renewed private, public and partner commitments to participate, shape and revitalize the global US$680 – 1,250 billion Therapeutic Goods Health Market. For example, global partners and investors such as the International Monetary Fund (IMF), World Bank, World Health Organisation (WHO), World Trade Organisation (WTO) have called for $50 billion in investment to generate $9 trillion in global economic returns by 2025: by boosting therapeutic goods

manufacturing capacity, supply, trade flows and the equitable distribution of diagnostics, oxygen, treatments, medical supplies and vaccines.

The call to action highlighted the compelling social, commercial and economic opportunities in unlocking integrated value chains in TG raw materials and precursors, bulk and packaged medicines, biologics and biosimilars, medical devices and PPEs, estimated at US$680 – 1,250 billion. Rethinking development assistance can drive private sector investments and capacity building needed to deliver on the promise of 'equitable access to medicines and healthcare commodities'. A new era of development assistance will require shifting from investing in specific disease programs towards investing in integrated systems and institutional capacity strengthening.

To harness the momentum from global engagement opportunities and advance the achievement of SDG goals for MCs, the Islamic Development Bank Group (IsDBG) and Developing 8 Health and Social Protection Secretariat (D8 HSP) have conducted a study to support IsDBG/D8 member countries – starting with Turkey, Indonesia and Nigeria – to revitalize and shape their respective therapeutic goods (TG) health markets, in order to build more sustainable and integrated health systems that are accessible, equitable and affordable to populations.

The TGHM Assessment used a market-led, private sector lens to diagnose why and where key fractures, capacity gaps and opportunities exist within the US$680 – 1,250 billion global addressable market – using Nigeria, Turkey and Indonesia as case studies. The study responded to the following research questions:

- *What are the characteristics of the Therapeutic Goods Health Market in Nigeria, Turkey and Indonesia and what are the major institutional, human and market capacity constraints that impede the growth and viability of Therapeutic Goods Health Markets?*
- *What are the opportunities for Therapeutic Goods Health Market in regional trade, cooperation and creating integrated TG value chains (and blended financing mechanisms) between ISDB / D8 MCs and regions?*

This report summarizes the findings of the study and proposes evidence-based capacity building (phase 2) investments required to unlock health market industrialization opportunities, country and reverse linkage programs and public private partnerships in Therapeutic Goods Health Markets in the three countries. Unlocking social, economic and commercial returns from these opportunities will require bold institutional and country leadership from key stakeholders. For example, the COVID-19 mRNA vaccine technology transfer hub offers a unique window of opportunity and template for private sector, civil society, and government partner collaboration to scale up global production capacity in essential medicines and related infrastructure.

What follows are the study methodology, situation assessment findings, capacity gaps, capacity building priorities and country linkage opportunities to inform a phase 2 scope of work that operationalizes key recommendations.

IV. Study methodology and conceptual framework

The study is a capacity readiness assessment that focuses on gaps, constraints and capacity building opportunities for private sector engagement, innovative financing, and trade development in Therapeutic Goods Health Markets - ultimately contributing to more sustainable and resilient health systems as well as growth in regional and global trade in D-8 and OIC Member Countries. The study was designed to emphasize a market-led approach for private sector engagement and regional partnerships for trade and development, with a view to strengthening the competitiveness and capacities of member countries in the strategic industries in which they have a comparative advantage, by creating local value chains, leveraging innovative blended financing instruments, and building the human capital base for sustainable economic growth.

The study methodology was based on; a) desk research, b) semi-structured interviews, and c) regional consultative sessions with over 55 key stakeholders from (i) private sector TG value chain actors, (ii) investors and financing partners, (iii) payers, (iv)

policy makers and regulators (v) service providers and (vi) trade and regional bodies. In addition, stakeholders from multi-lateral organizations and development partners working on Health, Trade, Finance and Economic Development as well as IsDB and D-8 operational staff in regional hubs and practice units were interviewed or consulted as part of the study.

For the purpose of the study, Therapeutic Goods are broadly defined as products or services for use in humans in connection with (i) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury, (ii) influencing, inhibiting or modifying a physiological process (iii) testing the susceptibility of persons to a disease or ailment, and (iv) influencing, controlling or preventing conception or testing for pregnancy. Therapeutic Goods Health Markets encompass direct inputs that support the health system, such as intangible assets in knowledge, know-how and intellectual property for the supply, production, distribution and delivery of physical therapeutic products and services, and intermediate or indirect inputs such as the policies/legislation, institutional programmes that deliver therapeutic goods for PHC, and the enabling ICT support, healthcare infrastructure, market and trade related value chains, among others.

The study focused on the main TG categories; including (i) Active Pharmaceutical Ingredients (“APIs”), which are the biologically active components of the finished drug product, (ii) Formulation and finishing of generics, patented and branded products, over-the-counter and complementary medicines, (iii) Biologicals products manufactured in, extracted from, or semi-synthesized from biological sources e.g. vaccines, and (iv) Medical devices including diagnostic instruments, implants and appliances such as pacemakers, treated or impregnated gauzes or bandages, and medical textiles or PPE (i.e. masks, gowns, drapes).

The study further delineates production and manufacturing activities of TG into three categories; (i) primary production which encompasses the processing of raw materials into Active Ingredients, additives and excipients used in drug formulation; (ii) secondary production which covers processing of finished dosage form such as tablets, capsules, and vials for injection; and (iii) tertiary production which includes packaging and labelling

of finished products from primary and secondary sources into bulk goods for wholesale and final packaging for retail distribution and individual use such as blister packs, or bottles of nasal spray.

The study utilized a 3 part analytical framework to develop a capacity gap assessment and propose priority interventions. The 3 part framework focused on conducting a SWOT analysing for: (i) Firms and Markets; (ii) Trade and Regional Cooperation; and (iii) Universal Health Coverage (UHC) indicators in the three countries, across six capacity domains: (i) Manufacturing / R&D, (ii) Supply Chain Infrastructure, (iii) Access to Capital, (iv) Governance / Institutional (v) Health Systems and (vi) Trade Cooperation. The 3 part framework and 6 capacity domains informed the development of a composite index that aggregates and benchmarks selected proxy UHC, PHC health systems, Therapeutic Goods Health Market and trade indicators – in order to establish a baseline for Nigeria, Turkey and Indonesia.

A three part analytical framework has informed the gap analysis and composite indexing

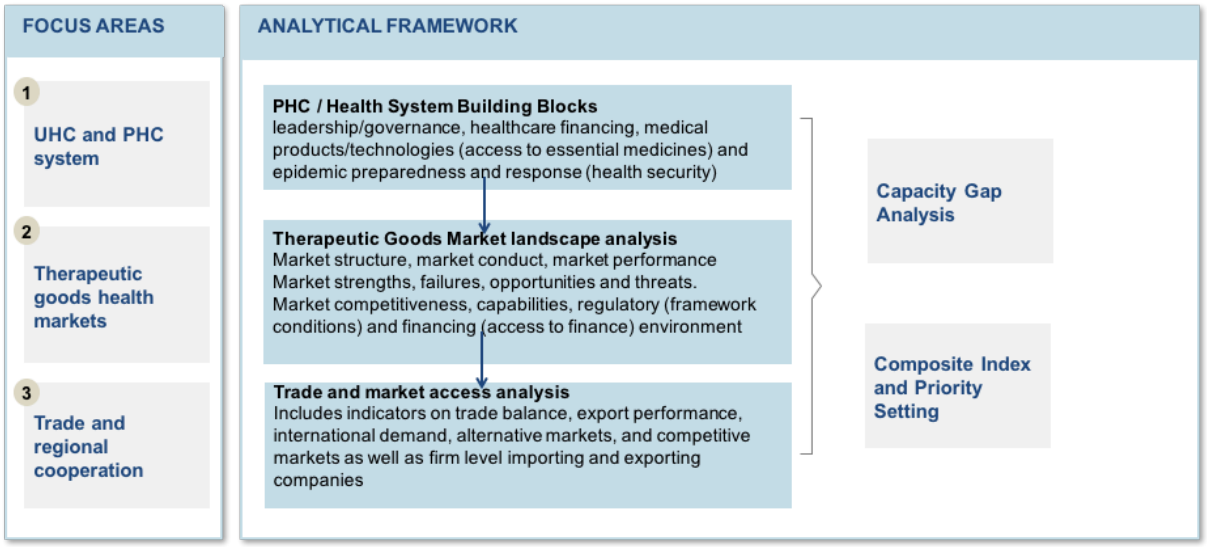

Figure 1: study three-part analytical framework

V. Country summary situation assessment

I. Nigeria summary diagnostic findings

Policy goals

- Nigeria has outlined the following policy goals related to TGHM including; (i) to increase local production capacity to a level where 70% of total output satisfies at least 60% of national drug requirements of essential drugs while the balance is exported by 2023; (ii) to commence the local production of COVID-19 vaccines by 2025; (ii) to establish regional vaccine manufacturing hub capacity for West Africa by 2030; (iii) by 2030, to improve annual pharmaceutical/Therapeutic Goods trade balance to $200 million; and (iv) to develop a health market industrialization policy for the TG Industry and a drug pricing policy; and (v) to coordinate the commencement of harmonisation of laws in the ECOWAS sub-region by 2023; amongst others.

UHC, TGHM and trade assessment

- The state of the Nigeria health system is characterized by suboptimal health outcomes, poor quality of care and lack of protection from financial risk as a result of the cost of care. Nigeria reports a suboptimal UHC effective coverage index of 38.3 and low coverage of health insurance at < 5%. The country is experiencing an epidemiological shift in the burden of disease from communicable diseases to non-communicable diseases. The availability or access to Essential Medicines (EM) is low; at 36% in private facilities and 26% in public facilities. The out of pocket expenditure as a percentage of Total Health Expenditure (THE) is high at 71% and total pharmaceutical expenditure (TPE) as a percent of total health expenditure is low at 9%.

- There are 130 registered drug manufacturers, 1,534 retail pharmacies, 724 drug distributors and 292 drug importers in Nigeria. Only 10 drug manufacturers are quoted on the Nigerian Stock Exchange. With a population of over 200 million people, Nigeria is Africa's largest consumer market, expected to grow by $94

billion over the next ten years. The addressable market for Therapeutic Goods is estimated at $1.4 billion; with a 13% Compound Annual Growth Rate (CAGR), of which generic medicines accounts for 38.9% share. The contribution of pharmaceutical manufacturing to GDP was 0.3% in 2019. The medical device market is expected to reach $201.8 million by 2023, (CAGR 9%), even as 90% of equipment are imported.

- Nigeria had three Essential Medicines related trading partners among the D8 and OIC member countries in 2019 – all of which were import partners. Nigeria's sub-regional trade partners in 2019 to which she exported therapeutic goods were Ghana with 62.8% volume valued at US$118,000, and Benin with 35.1% volume valued at US$66,000. According to trademap.org Nigeria did not export EMs to any D8 or OIC member country during this period.

Nigeria TGHM capacity constraints and gaps

- Nigeria has a low manufacturing capacity utilization of 40 percent. The TGHM industry is only able to meet 25 per cent of the local demand for drugs and has a fragmented market structure with multiple supply chains. The market has significant exposure to APIs and pharmaceutical imports (>70% of pharmaceuticals are imported and >90% of APIs are imported).
- There is no dedicated healthcare industrialization and trade policy focused on the health sector. The country has an outdated TG regulatory framework. National regulators such as NAFDAC, NIPRID, Africa CDC, Africa Medicine Agency, and Africa Free Trade Agreement Directorate face capacity constraints particularly in bio equivalency lab, GMP and clinical science capacity.
- There is a dearth of skilled technical personnel in drug development and manufacturing as well as low investments in Research and Development (R&D). Most employees in local pharmaceutical manufacturing sector are semi-skilled workers who acquire their skills on the job.

- There is also limited financing for health SMEs, primarily due to perceptions of high cost of capital, limited financial management capacity and unclear business case articulation.
- There is limited application of innovation and technology in supply chain and inventory management as well as a lack of supply chain infrastructure for warehousing.
- There is an untapped trade potential in the TGHM with inadequate trade supply-side capacity and trade-related infrastructure constraints. There was no export of TG to D8 and selected OIC members in 2019. Nigeria recorded a TG net trade deficit of -$1.74 billion in 2018 and TG export of $4.3 million 2019. There is limited financing for exports for precursors and therapeutic goods (TGs).

Nigeria TGHM strengths and opportunities

- Nigeria has the potential to be a regional manufacturing hub for West Africa. Approximately 60% of drug manufacturing in ECOWAS takes place in Nigeria. With an estimated population of about 700 million, the ECOWAS sub-region represents additional market potential. It is estimated that $422 million was spent on routine vaccines through Global Alliance for Vaccine (GAVI) in 2016. The GAVI subsidy for vaccine imports is expected to end by 2022.
- Federal Executive Council ratified Nigeria's membership in African Continental Free Trade Area (AfCFTA) in 2019.
- The Central Bank of Nigeria launched a N100 Billion Credit Support Scheme for pharmaceutical companies, medical device companies and supply chain companies; and the Nigeria Sovereign Investment Authority with $ 2 Billion Asset Under Management is prioritizing investments in generics and vaccine manufacturing related investments in Nigeria.
- Untapped and undeveloped precursor/adjacent markets in Minerals, Mining, Agriculture and Petrochemical value chains for APIs.
- Growing local industries such as Dangote Group and BUA, with capacity to manufacture petroleum biorefinery derivatives and by-products; including TG precursors, excipients, resins and intermediate inputs e.g for kaolin production or starches for non-internal preparations, gums etc.

- Emerging players such as, May and Baker and Emzor have also developed some fill and finish, drug-product formulation, generics manufacturing capacity to develop local inputs for production.

II. Indonesia summary diagnostic findings

Policy goals

- The following 2025-based objectives and targets could be used to track Indonesia's Health Market Industrialization policy: Increase the UHC Effective Index to 65 (2019 baseline: 57); Improve private sector participation in PHC goods and services delivery to 50% (2020 baseline: 35 - 40%); Increased annual health Industrialization related FDI to $5 billion by 2025 (2015–2019 baseline average: ~$1 billion); Reduced import 35% by 2025 (2020 baseline: $3.4 billion domestic expenditure in therapeutic goods); increased volume and Return on Invested Capital (ROIC) in TGHM by 10% CAGR (2020 baseline: unknown); and have issued at least one (1) commercial scale Shari'a, IFRS, ESG / 'Operational SDG' compliant bond

Indonesia UHC, TGHM and trade assessment

- With a population of ~ 269 million, Indonesia has a UHC coverage of 82% (as of 2020) and effective coverage index of 57. Indonesia operates the world's largest insurance ('Jaminan Kesehatan Nasional' (JKN)) UHC programme. Out-of-pocket health care expenditure in Indonesia has declined from 57% of THE in 2010 to 35% in 2018 and availability and access to essential drugs and vaccines is ~ 60.6% in private facilities and 76.6% in public facilities, below the country 90% target. Since 2017, JKN has operated with an annual $750 - $900M operating deficit (>0.05% of total 2021 State Budget).

- The 2025 forecasted pharmaceutical and medical devices addressable market is $18 – $22 Billion (6 - 10% CAGR). Indonesia imports >90% of raw material APIs (60% from China), and 95% of medical devices. In addition, 70% of ~210 firms are domestic, supplying 75% of country medication needs. The State Owned Enterprise, PT Biofarma aims to achieve 25% domestic raw material supply &

production capacity, and achieve 7.5% domestic market share. In addition, 22 of the 50 largest pharmaceutical and medical device companies (i.e. Sanofi, Pfizer, GSK, J&J, Siemens, Bayer, Takeda, Novartis) have local manufacturing, sales, or distribution infrastructure in the country.

- Essential Medicines trade accounts for 40-50% of total Therapeutic Goods exports, expanding at 11% CAGR. Since 2015, Nigeria has been the primary export destination (2020: 2,271 Tons, $27.6M Trade Value, 4.67% of Indonesia's global TG trade; 5 yr, 7-10% CAGR). The 2022 National Economic Recovery Strategy targets a 35% import substitution and 85% utilisation capacity in Chemical, Pharmaceutical and Medical Devices sectors. According to trade.org, Indonesia imported $912M worth of TG and exported $556M worth of value.

Indonesia TGHM capacity constraints and gaps

- Indonesia has a low base capacity for API production as well as GLP, GCP and GMP for biologics production. In 2019, the estimated government spending on R&D was 0.2% of GDP, compared to an average of 1.0% for MIC, and >2% for HIC;
- Indonesia imports >90% of raw material and APIs, for drugs and medicines production.
- Inconsistencies in healthcare industrialization and raw material import policies.
- The poor health information system interoperability and limited ICT infrastructure (66.4% internet access, less in remote regions) pose key infrastructural and health system challenges. Archipelago amplifies gaps in ICT, Health Information Systems infrastructure that lead to inefficiencies in cold/ supply chains and distribution.
- Limited data in actual and potential domestic production and knowhow for vaccines biologics, and biosimilars production.
- Foreign ownership limits Medical Devices (49%), Generic/ Biosimilar production and Service Delivery (0%) investment participation, effectively shutting out private sector investments and partnerships relative to regional peers (Vietnam, Malaysia, Singapore).

- Indonesia has a structurally weak position relative ASEAN competitors in technology transfer and IP asset commercialization; and has limited participation in international IP treaties and enforcement of biopharmaceutical patentability standards;
- According to trade.org, Indonesia's global untapped trade potential is estimated at $550 - $625M as at 2019. Its 2018 Share of Essential Medicines trade balance as a percent of total trade value is low 11.56%, while its therapeutic goods net trade was -$277 - $356M in 2019.

Indonesia TGHM strengths and opportunities

- Indonesia appears to have the best short-term potential to support generics-led export growth strategies. With pro-generic policies and cost-containment initiatives in place, demand for solid dose formulations as well as newer emerging export markets for cheaper and branded generics offer opportunities for the country.
- There is also the potential to boost local pharma sector by buying newly established JV facilities as API CMOs for wider global market. There are already some CMOs for finished products established in the region.
- Mandatory UHC establishes a captive domestic market of ~270M people, 39% of the total population of the 10 South-East Asian (ASEAN) countries.
- Indonesia's economic and technological complexity shows production of vaccine / biologics, and unpackaged / packaged medicaments are in reach.
- By 2050, prepaid private healthcare spending is expected to increase from $21 to $77 per capita, (4.14% CAGR).
- There are opportunities to diversify, relocate supply chains from China or India for brownfield and greenfield capital investment in relocated or newly established intermediate API manufacturing, and downstream production and export.
- The Omnibus law provides for 100% foreign and private ownership in raw material, API, intermediates production ($175 - $210M annual domestic production value). For example, State Owned Enterprise PT Biofarma aims to achieve 7.5% domestic market share.

- Newly established (2021) Sovereign Wealth Fund ($30B) specifies legal / commercial structure for MDB, private and institutional investment in Health Sector PPPs.
- In 2018, nearly 70% of health expenditure was spent on medicines. The 2050 forecasted prepaid private healthcare spending is estimated at $77 per capita (4.14% CAGR).
- Indonesia is in advanced discussions on bilateral and multilateral trade agreements with OIC / D8 member countries and HIC countries to develop capacity and promote technology transfer in TG supply / value chain.
- Aligning 2022 import substitution strategy and utilisation targets with FDI and PPP investments can diversify or relocate regional API supply chains for newly established generics, vaccines and patented production for domestic consumption and export.

III. Turkey summary diagnostic findings

Policy goals

- Turkey has outlined the following policy goals related to TGHM including by 2030 to; (i) achieve a 8.9 skilled researchers per 1000 employees target, (ii) achieve 85% capacity utilization; (iii) increase pharmaceutical related FDI by 20%, (iv) perform > 600 clinical trials, (v) increase by more than 5%, the private sector market share in health insurance; (vi) establish an expedited registration pathway for SMEs; and (vii) realize 10% CAGR and 10 % Intra-trade volume in selected OIC / D-8 MCs; amongst others.

Turkey UHC, TGHM and trade assessment

- Turkey's UHC Effective Index is 69.2 based on UHC 2030 data, with a progressive improvement of 6 points between 2010-2015. The coverage of essential health services, as defined by the UHC service coverage index of Turkey was 74.7% in 2017. Economic growth and a broadened tax base has provided Turkey's government with the means to expand its non-contributory insurance scheme, while rising employment levels helped increase coverage

through contributory health insurance. Turkey's availability of Essential Medicines (EM) is estimated at 55% while out of pocket expenditure as % of Total Health Expenditure is estimated at 17%.

- The Turkish pharma industry is mature, but it is only in the last decade that the market has migrated from a low-margin, mass generics model to chronic therapies and biologics in a trend that aspires higher-value products. The pharma market is forecasted to grow to US$15bn in 2025 (10.3% CAGR). Generics (13.7B TL) and bio-similar (0.6B TL) continue to gain market share. In the last 10 years, 200 new companies forced their entry into the generics market at a time when the government gave away generous incentives to kick-start a biotech sector including rolling out a localization policy.
- In 2019, Turkey exported $1.5Bn in pharmaceutical products, making it the 29th largest exporter. Turkey imported $5.06B in pharmaceutical products, becoming the 22nd largest importer. Pharma sector is the third largest contributor to Turkey's trade deficit i.e pharmaceutical trade deficit of US$3.8 billion. Turkey has $1.8 billion in untapped export potential, according to trade.org. About 39% of manufacturing sector consists of medium to high tech players. Global market share of chemicals exports from Turkey is 0.4% with a trade deficit in the balance of chemical intermediate goods.

Turkey TGHM capacity constraints and gaps

- Low APIs and pharmaceutical manufacturing capacity utilization and high reliance on raw material / APIs inputs from HICs.
- Skilled research (R & D) capacity below OECD average as a result of the lack of depth of expertise in pre-clinical / clinical studies.
- Outdated bilateral investment treaties with 75 countries. Turkey only has treaties with Egypt and Malaysia within D-8 member countries. Delays in the registration process remain a challenge for early-stage start ups and SMEs.
- The TG market in Turkey is distorted and dominated by two incumbents with 70-80% market share; 4,000 pharmacies (out of 26,000) represent 40% of total turnover.

- There are limited convergence platforms and innovative financing instruments to support, incubate and commercialize early stage pharma and biotech start ups, from Turkish universities, investors and research centers.
- Relatively low health worker density (52.6/10,000), uneven distribution of PHCs in provinces and relatively low usage of referral system.
- Absent and inimical regulatory system for pharmaceutical and precursor manufacturing and trade. Unattractive pricing policy of national payer and lack of coordination among regulators for the implementation of incentives are barriers to the production of high valued medicinal products.
- According to trade.org, Turkey's global untapped trade potential is estimated at $1.8 Bn as at 2019. TG production reached $5.3 Bn in 2020. As at 2019, Turkey had a TG trade deficit of $3.8 Bn and $0.99 Bn for medical device products.

Turkey TGHM strengths and opportunities

- Increased local production of higher-value products – notably biosimilars – represents the most likely contributor to a significant rise in export values.
- Localization policy has led to more interaction between local and foreign players and a rise in collaborations for contract manufacturing.
- Localizing R&D and API production could be the next relevant step in localization efforts.
- Turkey can leverage comparative advantages in terms of production, logistics, and clinical studies.
- Turkey is currently working on investment incentives, technology transfer, digitalization in healthcare and health tourism to encourage more foreign participation.
- Successful models of PPP projects that lead to advanced health outcomes have been deployed. There is an opportunity to replicate elements of a government-private sector coalition and technology exchange programs in other D8 countries.

  Although, Turkey joined PIC (S)- Pharma Inspection Co-Operation Agreement (in 2018), Turkey must further develop bilateral agreements with the different countries that are members, which would boost Turkish exports to double-digit

growth. The markets with greatest potential for Turkey's exports of pharmaceutical components within D8 are Egypt, Iran, and Nigeria.

VI. Consolidated gaps

The country diagnostic and desk review findings were further interrogated through interviews with country stakeholders. The stakeholder interviews revealed common themes, gaps, linkages and opportunities across the three countries. The interviews validated identified capacity gaps and framed hypothesis of priority interventions to revitalize therapeutic goods health markets in the three countries. The consolidated findings were triangulated and vetted where possible with stakeholder interviews to inform a synthesized reference.

Below is a brief diagnostic description of the consolidated gaps through six capacity domains. In the consolidated gap analysis, crosscutting factors and issues are highlighted that form the basis of establishing and populating a composite index; and developing a capacity building framework and strategy to revive TGHM in the three countries.

R&D / Manufacturing

Consolidated gaps or unmet capacity needs in R&D / Manufacturing across the countries include; (i) low APIs and pharmaceutical manufacturing capacity utilization e.g 40 percent in Nigeria; (ii) untapped and undeveloped precursor markets in Minerals, Mining, Agriculture & Petrochemical value chains for APIs and (iii) few firms participate in the WHO Prequalification of Medicines Programme (PQP) due regulatory compliant hurdles that help ensure that medicines supplied by procurement agencies meet acceptable standards of quality, safety and efficacy.

Supply Chain Infrastructure

Consolidated gaps in supply chain infrastructure include; (i) high reliance on foreign sourced raw material and APIs inputs e.g up to 90% of APIs and over 70% of pharmaceuticals are imported in Nigeria. Indonesia also imports over 90% of raw materials and API inputs, for drugs and medicines production; and (ii) Inadequate cold chain infrastructure, storage and logistics capacity in Nigeria and Indonesia.

Access to Finance

Constraints include; (i) limited financing for local manufacturing in Nigeria and Indonesia; (ii) major drug pricing policy issues in Nigeria and Indonesia; Limited financing for health SMEs, primarily due to perceptions of high cost of capital, limited financial management capacity and unclear business case articulation, particularly in Nigeria and Turkey's biotech start up clusters; (iii) limited financing for exports for precursors and therapeutic goods (TGs) in Nigeria and Indonesia; and (iv) low public sector spending for TG R & D; poor actuarial data on health financing in Nigeria and Indonesia.

Governance / Institutional

Consolidated capacity gaps in this critical domain include; (i) absent and inimical regulatory system for pharmaceutical and precursor manufacturing and trade in all three countries; (ii) low regulatory capacity or alignment as well as weak policies on drug pricing and trade in Indonesia and Nigeria; (iii) vaccine nationalism and trade restrictions in Therapeutic Goods; and (iv) outdated or absent health market industrialization and trade policy that impedes viable market access and competitive pricing.

Health Systems

Common gaps in the health systems in all three countries include; (i) low Health worker density, expertise, and capacity in Good Laboratory, Clinical and Manufacturing Practices (GLP, GCP, GMP respectively or GxP in general) domains; and (ii) poor Health Information Systems interoperability and limited ICT infrastructure for data intelligence and management in Nigeria, Indonesia and Turkey.

Trade Cooperation

Capacity gaps related to enhanced trade and regional cooperation include; (i) The APIs and TGs trade deficit for Nigeria, Turkey and Indonesia is significant; (ii) dormant or outdated technical agreements to govern increase in trade, cooperation and

partnerships; and (iii) minimal Bi-Multilateral (MFN) or Free Trade Arrangements with select countries and trade blocs.

VII. Consolidated composite index

The country diagnostic and consolidated gap analysis helped inform a monitoring and evaluation framework and performance benchmarking system for the proposed capacity building interventions. A composite index was developed to include 15 relevant and representative indicators in the 3 domains of UHC, TGHM and trade. The index consists of the following indicators.

- Universal Health Coverage/PHC systems
    - UHC Effective Coverage Index
    - Out of pocket expenditure as a % of current health expenditure
    - Private expenditure on health as a share of total health expenditure
    - Availability of EM in health services
    - Total Pharmaceutical Expenditure (TPE) as a % of Total Health Expenditure (THE)
    - Number of health workers per 10,000

- Therapeutic Goods Health Markets
    - R&D % of GDP
    - Household Expenditure (HHE) on pharma as a % of total HHE on health
    - Country involvement in open innovation models and technology transfer
    - Return on Invested Capital and Volume in Therapeutic Goods

- Trade and Regional Integration
    - Therapeutic Goods net trade balance
    - Share of TGs trade balance as a % of country total trade balance
    - Share of OIC/D8 TG export as a % of total export
    - Share of OIC/D8 TG import as a % total import
    - Revealed Comparative Advantage in Essential Medicines
    - Incentive schemes for Research, Innovation and Development

A proposed proforma Health Market Industrialization Composite Index of the three pilot countries is outlined below in figure 2. The Health Market Industrialization Composite Index serves a baseline and is consistent with the priority pillars of the three government's strategic plans. They focus on continuing efforts to control COVID-19 while prioritizing the crosscutting issues in health, markets, trade and industrial policy.

Proforma 2021 Therapeutic Goods Health Markets Composite Index

Index Item	Nigeria	Indonesia	Turkey	Indicator Description
Universal Health Coverage				**Universal Health Coverage**
UHC Effective Coverage Index	38.0%	57.0%	74.7%	UHC Effective Coverage Index: Scaled 0-100 Coverage index for essential health services (based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, noncommunicable diseases and service capacity and access)
Current Health Expenditure (% of GDP)	3.9%	2.9%	4.1%	Current Health Expenditure (% of GDP): Level of current health expenditure expressed as a percentage of GDP. Estimates of current health expenditures include healthcare goods and services consumed during each year. This indicator does not include capital health expenditures such as buildings, machinery, IT and stocks of vaccines for emergency or outbreaks.
Out of pocket expenditure as a share of current health expenditure	77.0%	34.9%	17.0%	Out of Pocket Expenditure (OOP) as a share of current health expenditure: OOP payments refer to the portion of healthcare costs not covered by insurance, covered from available disposable income
Private expenditure on health as a share of total health expenditure	77.0%	50.3%	22.0%	Private expenditure on health as a share of total health expenditure: Indirect measure of UHC and also availability of private insurance system in developed health systems
PHC systems				**PHC systems**
Availability of EM in health services	52.0%	Public: 76.6%, Private: 60.6%	55%	Availability of EM in health services: % availaibilty of Essential Medicine vis a vis WHO List, by comparing available product number in EML list of the country compared with WHO list
TPE as a % of THE	26.0%	33%	26%	TPE as a % of THE: Total Pharmaceutical Expenditure as a share of total health expenditure; as an indirect measure of availability therapeutic goods and financial support, also valued expenditure vs other health services
Number of health workers per 10 000	17	42	52	Number of health workers per 10 000: Direct indicator of health capacity, min recommended number >50
Therapeutic Goods Health Markets				**Therapeutic Goods Health Markets**
R & D % GDP (PPP)	0%	0.2% / 55th	1.1%/14th	R & D % GDP (PPP): the share of R&D spending in GDP. Indirect indicator of potential innovation growth of the country TGs
Therapeutic Goods Market Share by volume and value (in public and private sector);	14%	33%	23%	Therapeutic Goods Market Share by volume and value (in public and private sector); relative value of therapeutic goods , indicator of differential pricing in the private and public sector
Household exp on pharma as a % of total household exp for health	80%	N/A	30%	Household exp on pharma as a % of total household exp for health: The burden of pharmaceutical expenditure on private health spendings
Country involvement in open innovation models and technology transfer	None in Therapeutic Goods	Yes. Omnibus Law (No. 11 of 2020), and new BITs offer enhanced protection for domestic / foreign IP, and R&D / commercialization in greenfield / brownfield FDI.	YES, As of 2020, 86 Technolpolis' technology development centers (18 under construction) allied with universities and industrial centers.	Country involvement in open innovation models and technology transfer: Potential for in-country innovative health solutions and export
Volume and ROIC in Therapeutic Goods (CAGR)	NA	NA	NA	Volume and ROIC in Therapeutic Goods (CAGR): Annual compound growth rate in production volume and Return On Invested Capital
Trade and regional integration				**Trade and regional integration**
Therapeutic Goods trade balance net import / export TG	Imports: $1.75B Exports: $.43M Trade Balance: -$1.74B (100% yoy increase)	Import $912M Export $556M Trade Value: -$356M (25% decrease)	Import: $5.06B Export $1.4B Trade Value: -$3.5B (1.5% increase)	Therapeutic Goods Export, Import, Trade value: Current year country data
Share of Pharmaceutical trade balance as a percent of total trade balance (2020)	-23.22%	9.91%	6.28%	Share of Pharmaceutical (HS2: 30) trade balance as as percent of Country total trade balance - The sum of annual HS2:30 trade balance divided by the annual all trade balance
Share of Essential Medicines (HS4: 3003 - 3006) trade balance as a percent of total trade balance	-14.92%	11.56%	3.06%	Share of Essential Medicines (HS4: 3003 - 3006) trade value as a percent of total trade value: The sum of annual HS4:3003-3006 Trade Value divided by the annual all Trade Value
Share of select OIC countries' exports as percent of total global exports	0.00%	11.34%	3.45%	Share of select OIC countries' exports as percent of total global exports: Indicator for the benefit of potential cross country collaboration
Share of select OIC countries' imports as percent of total global imports	0.05%	1.22%	0.33%	Share of select OIC countries' imports as percent of total global imports: Gap indicator for D8 collaboration
Revealed comparative advantage (RCA) in Essential Medicines	0.00	0.09	0.22	Revealed comparative advantage (RCA) in Essential Medicines: Ability to close the know-how gap in national Essential Medicines production
Incentive schemes for Research, Innovation and Development	TBD	YES. R&D activities may qualify for deduction of 300% of the R&D costs incurred, w/ bonus 50% deduction if patent or plant variety protection rights (PVT rights) are registered in Indonesia. Direct, non-competitive R&D funding in universities; technology insurance scheme for activities in Techno Parks and Business Innovation Centres.	YES. EU-Turkey "Technology Transfer Accelerator Turkey" for technology commercialization developed at Turkish universities and research centers. 2018: Patent and Trademark Office established "Turkish IP Valuation Engineering and Consultancy Services Corporation" for IP commercialization.	Incentive schemes for Research, Innovation and Development: Country political and economic will for innovation

Figure 2: Health Market Industrialization Composite Index of the three pilot Countries

VIII. Country priorities and linkages

The findings from the country situation analysis, consolidated capacity gap analysis and composite index were also validated during a virtual consultation attended by over 55 stakeholders from Nigeria, Turkey and Indonesia, that consisted of; (i) private sector TG value chain actors, (ii) investors and financing partners, (iii) payers, (iv) policy makers and regulators (v) service providers and (vi) trade and regional bodies. The consultation also informed the prioritization of low lying fruits and cross country opportunities. The following summary outlines the country priorities and capacity building strategic pathways identified during the consultation.

Nigeria stakeholders identified three priority interventions in the following sequence.

- API precursor market industrialization program to develop and unlock adjacent excipient raw materials and value chains in Minerals, Mining, Agriculture & Petrochemical segments (such as kaolin, petroleum derivatives) to build TG health markets e.g Nigeria government's focus on processing of Kaolin for pharma grade precursors.
- Upscaling generics, vaccines, supply chain and ICT Infrastructure to accelerate Nigeria's transition from a focus on imports, package and labelling, fill and finish; towards generics manufacturing leveraging innovation and technology emerging platforms that present new opportunities for leapfrogging.
- Support development of ICT for health program to scale up innovation in PHC service delivery, develop Fintech in TG health market to reimagine healthcare payments for Nigeria; and leverage innovative financing instruments to provide credit line financing to SMEs and underwriting risks for health SMEs.

Indonesia stakeholders also identified three priority interventions including;

- Accelerating private sector delivery of primary healthcare through leveraging innovation and technology including increasing R&D spend in telehealth, ICT Infrastructure (satellite, base receiver stations), labs and R&D facilities, and focusing on skills and technology transfer initiatives with HICs and LMICs.

- Upscaling biopharmaceutical, vaccines and supplies infrastructure by focusing on developing a 20-yr strategic roadmap in critical input supply (human and natural resources that includes botanicals, agriculture, mining, forestry, etc.,) for development, manufacturing, and IPR in APIs, generics, patented drugs, and bioproducts; diversifying the supply and production of APIs and TG precursor inputs; transitioning from a focus on generics to API / biopharmaceutical manufacturing; and developing a supply chain control tower to monitor and plan supply and distribution of TGs.
- Establishing multilateral financing framework for health infrastructure PPPs as part of the Indonesia Investment Authority's SWF 'Managed Fund for Health Sector'. Leverage existing key structural reforms for increased economic competitiveness and reduced barriers to doing business, by investing in indigenous natural and human resources, R&D, production, and trade that unlocks $600 mn in untapped annual exports; and expand country complementarity and trade with key partners such as Nigeria (5 percent of country total 2020 therapeutic goods trade (7-10% CAGR).

Turkey stakeholders identified the following priority interventions including;

- Building and deepening strength in clinical trials through enhanced coordinated management of clinical research and development of large-scale clinical trial design, deployment, reporting and regulatory framework.
- Harnessing telehealth, Artificial Intelligence & Digital Health Innovation by establishing dedicated bodies and governance mechanisms to support planning, budgeting and implementation of scalable digital health innovation, technology and production platforms; and supporting master skills and training capacity building for policy development in AI, Big Data / bioinformatics tools for epidemiological forecasting, and large-scale clinical trials design, deployment, reporting and regulatory compliance.
- Establishing Biologics Ecosystem by supporting biologics / biosimilars innovation with HIC and private sector partners, with a focus on pricing policies, trade

financing for timely and guaranteed payment and market access provisions in bi-multilateral trade agreements.

In sum, all three countries demonstrated the potential for national and regional product and market innovation, and industrial capacity development in API precursors, excipients, bulk and packaged medicines, biosimilars, mRNA and PPE technologies and associated supply chains.

As a result of the virtual consultation, country breakout sessions and discussion, and the country group presentations held in plenary, the following country linkage and global engagement opportunities were identified. From the perspective of private sector and investors, the following items could also be positioned as 'Thematic Opportunities in Health Market Industrialization & Regional Value Chain Asset Development'. They include:

1. Nigeria and Indonesia
    a. Business to business (B2B) partnerships to secure adjacent excipient raw materials (e.g , plant and mineral resources).
    b. Reverse linkage for ICT digitalization infrastructure to include pharmaceutical supply chain control tower.
    c. Nigeria Sovereign Investment Authority interest in Generics manufacturing capacity support between Nigeria and Indonesia.
    d. B2B with Biovaccine Nigeria Limited and Biopharma in Indonesia (proposed); Dangote/BUA - Sinar Mas / Paper Excellence (indicative Petroleum and Forestry derived health biotechnologies and bioproducts).
2. Nigeria and Turkey
    a. Telehealth in PHCs.
    b. AI, Big Data, bioinformatics tools transfer.
    c. Clinical trials partnerships.
    d. Fintech in health.
3. Indonesia and Turkey

a. Transition towards API manufacturing.
b. Mobile and Telehealth, ICT, AI, Big Data, bioinformatics tools.
c. Accelerating Private Sector Delivery of PHC and UHC..
d. Large scale clinical trials partnerships.

Several best practices and global engagement opportunities were highlighted including;

1. Engagement with global funders (e.g., Nigeria Sovereign Wealth Fund, Indonesia Sovereign Wealth Fund, Gavi, EU, Africa Development Bank, G7+,) on catalyze sustainable international financing for health security capabilities for future pandemics and high consequence biological threats, including sustainable support for a global health security financing mechanism, such as a Financial Intermediary Fund, to support metrics-driven approaches to country capacity for countering biological threats.
2. Commitment from Indonesia Ministry of Health to support the inclusion of the TGHM program on the G20 global agenda
3. Finalization and set up of the African Medicines Agency (AMA) and its strategic plan, that includes a vaccine- specific plan.

IX. Draft capacity building framework and theory of change

The consultation also led to the co-creation of a Capacity Building Framework and theory of change – see figure 3 and 4 - which provides, in visual form, a snapshot of the levers by which Therapeutic Goods Health Markets can be revitalized to achieve impact level goals in IsDBG/D8 member countries. The goal statement is the overarching aim of the proposed initiative, which will be achieved through successfully attaining the three outcomes through the implementation of the program. As is indicated, the confluence of these three outcomes will yield the proposed goal with Firms and Markets, Trade and Regional Cooperation and Universal Health Coverage in tandem providing the requisite conditions for efficient and resilient Therapeutic Goods Health Markets. It is also important to highlight that the outcomes are also mutually reinforcing in support of the goal, as shown through the arrows between the outcomes. For example, Firms and Markets are stronger with greater Trade and Regional

Cooperation; and Universal Health Coverage is buttressed by efficient and resilient supply, as well as access to global value chains.

It is also important to recognize the linkages with the 2030 SDGs agenda, to ensure alignment with international best practice. The relevant SDGs into which this initiative will impact are highlighted in figure 3. These SDGs show how revitalized Therapeutic Goods Health Markets not only benefit IsDBG/D-8 member countries and their citizens but also aligns with and contributes to regional and global development agenda

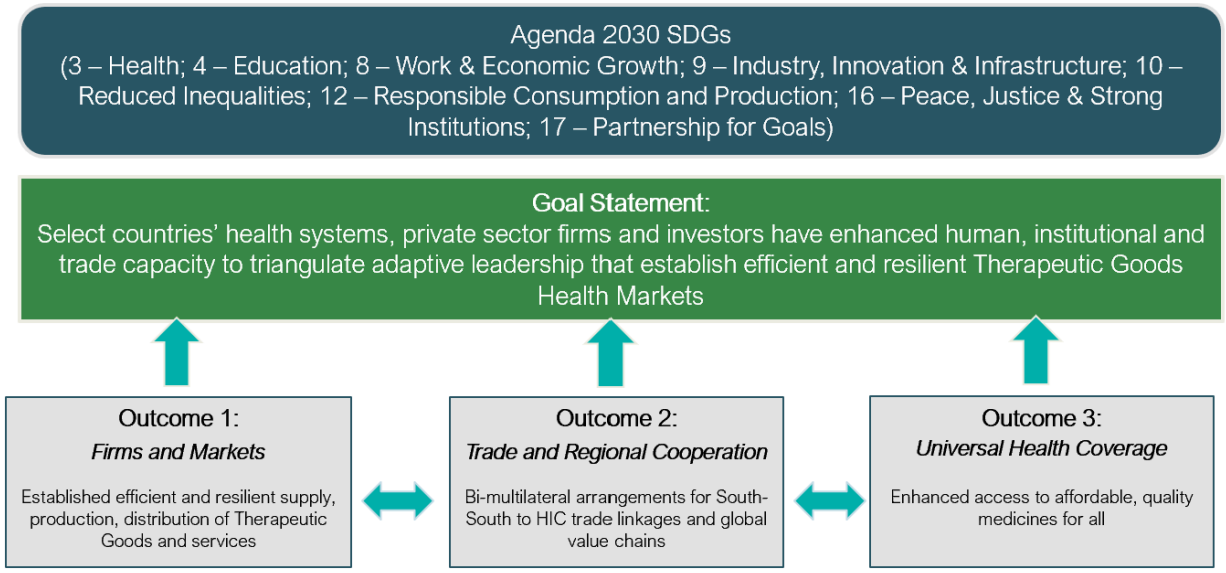

Figure 3. Draft Capacity Building Framework

The Program Theory of Change expands on the capacity building framework outlined above. For clarity, the impact is synonymous with the goal from the framework and the outcomes are also the same. What the theory of change is able to do however, is to add more specificity through proposed indicators that go with each of the applicable outcomes. In addition to the outcomes and impact, which have already been expanded upon in some detail, this also outlines a level below with outputs and the associated indicators. These outputs will feed into the outcomes, not necessarily in a one-to-one fashion but still linearly in those programmatic activities that will result in these outputs, which will then lead to the outcomes and ultimately the proposed impact. Finally, on the far left-hand side, the capacity gaps show the current deficiencies.

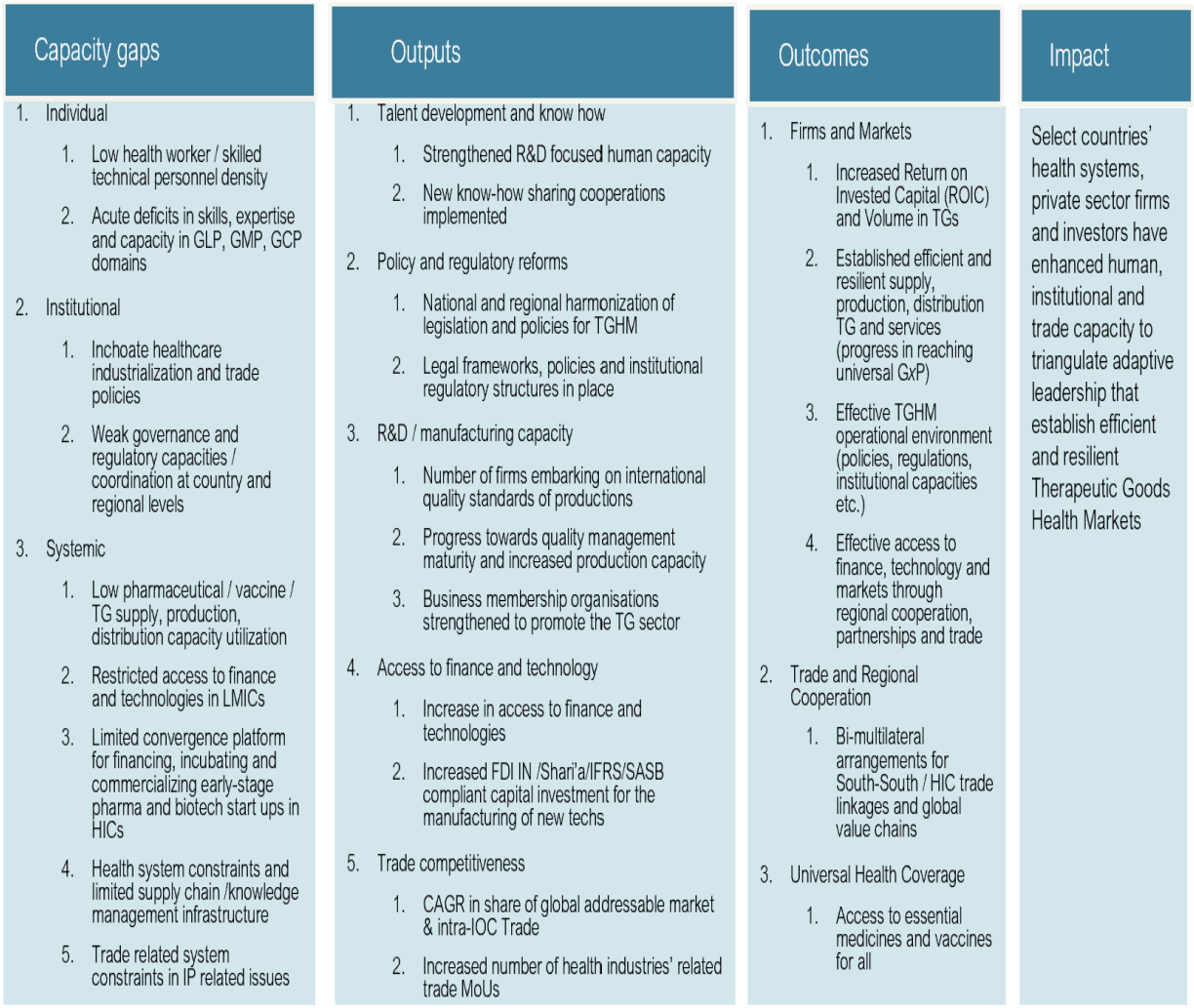

Figure 4. Program Theory of Change