Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Focus on the Role of Finance

Addenda to Final Report

March 2021

List of Addenda

1. Inception Report
2. Survey Questionnaires
3. Binit Agrawal - Sovereign Wealth Funds As Potential Investment Partners In Developing Pharmaceuticals Manufacturing Capacity In Africa
4. Nanditta Batra - The Contribution of Government Policies to Growth and Development of Pharmaceutical Industry in India
5. Rajashri Seal - Background Research on Financing Activities of the African Union and Others for Local Production of DVT

Prepared for the Open Society Foundations – Public Health Program

Nova Worldwide Consulting®

Addendum 1

Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharma Manufacturing in Africa: With a Focus on the Role of Finance

Inception Report
23rd November 2020

Frederick M. Abbott

Ryan B. Abbott

Joseph Fortunak

Padmashree Gehl Sampath

David Walwyn

A landscape mapping and analysis of financing for African manufacturing of COVID-19 diagnostics, vaccines, therapeutics and essential PPEs

Prepared for the Open Society Foundations – Public Health Program

Nova Worldwide Consulting®

Table of Contents

List of Figures

List of Tables

List of Abbreviations

DVTs	Diagnostics, vaccines and therapeutics
OSF	Open Society Foundations
PHP	Public Health Program
PPE	personal protective equipment

Background to the Assignment

Recognizing that the COVID-19 pandemic provides a decisive moment for the Open Society Foundations (OSF) to push for change that is structural, impact-focused, and aligned with its long-term economic and social justice aims, the foundation is seeking to use this opportunity to mobilize people, politics and movements to promote equitable and affordable access to life-saving diagnostics, vaccines and therapeutics (DVTs) for COVID-19, as well as those needed in future health crises.

More specifically, the OSF's Public Health Program (PHP) wishes to support the urgent need for increased manufacturing capacity in Africa, Asia and Latin America, both to respond to the pandemic and, over the longer term, to increase research and manufacturing power in the Global South. As part of this focus, the OSF-PHP has engaged Nova Worldwide Consulting (Nova) to undertake a landscape mapping of financing for DVT and essential personal protective equipment (PPE) manufacturing in Africa.

This mapping must provide an analysis on how these funds are structured (including co-financing requirements), what guidelines are used for their utilization, and what blockages or barriers may exist in accessing financing. The mapping must also identify areas where civil society advocacy and influence could result in more successful technology transfer and rapid scale-up of manufacturing capacity to enhance equitable access to DVTs and essential PPE/health technologies.

In this Inception Report, Nova's proposed scope of work and approach to the OSF-PHP's requests have been detailed.

Scope of Work

Nova will undertake the following scope of work:

- Prepare this Inception Report for consideration by OSF-PHP and the attendees of the Learning Event (Phase 1)
- Undertake an initial mapping of financing for DVT and PPE in Africa based on secondary data sources (Phase 2)
- Conduct a series of interviews with stakeholders in connection with the core problem statement (local DVT and PPE manufacturing is constrained by limited availability and the high cost of finance) (Phase 3)
- Develop the list of opportunities for advocacy groups and others to address the financial constraints and hence unlock pharmaceutical industrialization (Phase 4)
- Draft a list of recommendations for civil society based on the perceived opportunities (Phase 5)
- Finalize the list subsequent to a discussion of the draft proposals in a workshop (Phase 6).

Approach and Methodology

Overall Approach

The project will be completed in six phases as shown in Figure 1.

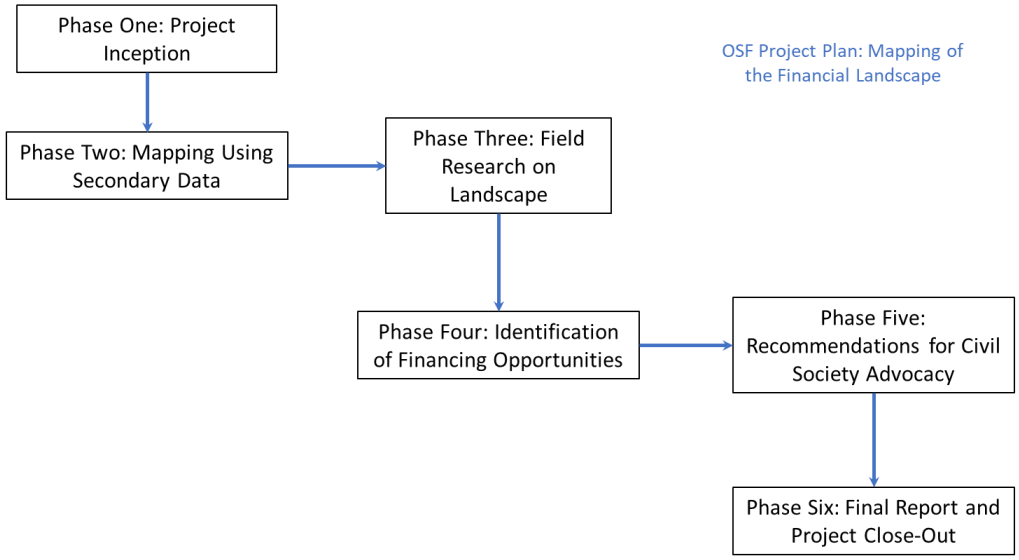


Figure 1. Overall phasing of the approach

In the mapping of funding streams, the project will assume that the financial ecosystem is broadly configured as shown in Figure 2.

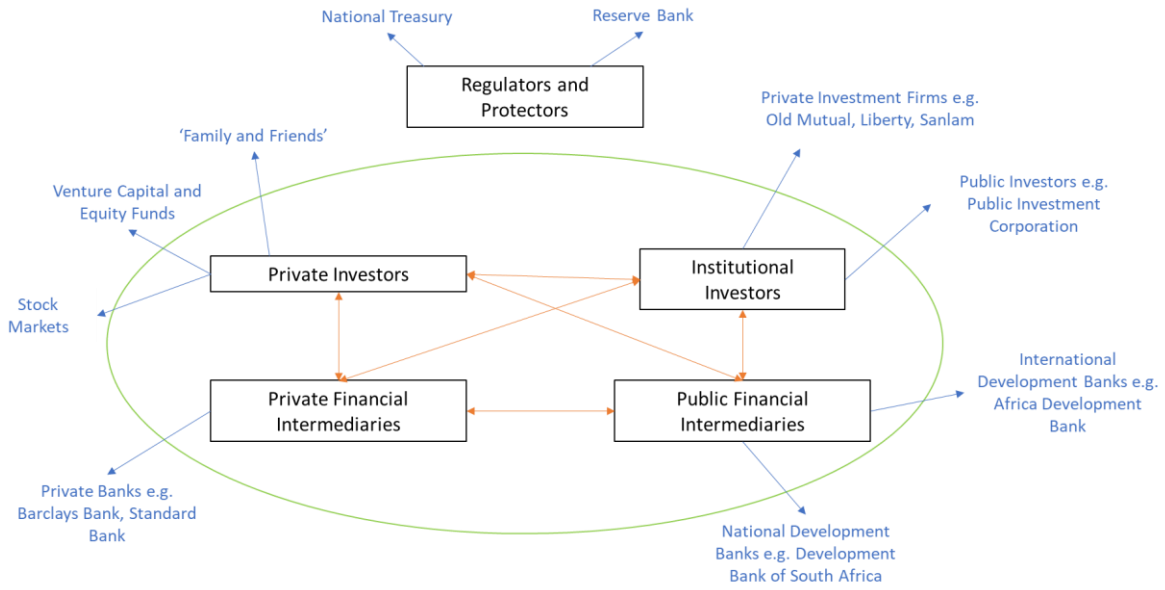


Figure 2. Structure of the African financial system

Phase 1: Inception Report

Phase 1 will consist of the development of this report and the facilitation of the Learning Event.

Phase 2: Mapping Using Secondary Data

In Phase 2, Ryan Abbott will study secondary data on the availability of financing from multilateral institutions, such as the World Bank, the International Finance Corporation, Asian and African Development Banks, and the New Development Bank, as well as from bilateral contributions, philanthropic foundations.

Phase 3: Field Research on Landscape

Scoping Interviews with Stakeholders

Primary data for the project will be gathered using two separate approaches. In the first part of the work, two to three members from each of the stakeholder groups will be interviewed about the financial landscape for local DVT and PPE manufacture. Altogether around 20 interviews will be completed as shown in Table 1. The respondents are expected to be a mix of financial intermediaries and firms located on the continent.

Two questionnaires (one aimed at the companies, and one structured to elicit responses from financial intermediaries) will be structured based on the following sequence of 'thought processes':

- Hypothesis (relating to the problem statement): The availability and cost of finance plays a fundamental role in preventing the localization of DVT and PPE manufacture on the continent.

- The outline for the interview questions, to be asked of the pharmaceutical firms, will be:
    - Experience of Finance: What is the evidence for the role of finance, especially lack of availability of public finance intermediaries and private financial intermediaries, in hindering the localization of production in Africa?
    - Impact of Financial Constraints: Does this lack of finance impinge upon other factors of production (such as technological intensity of production), and market access, and if so, how?
    - Stages of Financial Bottlenecks: At which particular stage does the lack of financial intermediaries begin to hinder the localization of production?
    - Source of Finance: To what extent do successful firms rely largely on institutional investors in addition to private capital for their success? Have any 'out-of-the-ordinary' solutions been adopted by firms, in any instance?

- The outline for the interview questions, to be asked of other stakeholders, will be:
    - Available Options: To what extent do private financial intermediaries exist as financiers of localization in the pharmaceutical sector in Africa? What is the extent of public sector intermediary presence and support to overcome these hurdles (e.g. the presence of regulatory incentives, grants)?
    - Awareness by Stakeholders: To what extent has financing been a core component of local production programs and projects in Africa? What existing models have been used to overcome the problem of finance, other than Product Development Partnerships? What are the trends in the financing of local production?

    - Nature of Action: Does finance act alone, or is there a more systemic connection that needs to be factored into production capacity building approaches? What is the influence of finance on technology transfer and/or technology development? Are political actions necessary?
    - Targets: What should be the end-goal of the Action once it has been implemented?

It is acknowledged in this survey that there are a broad range of previously identified non-financial factors potentially constraining local production, including limitations in infrastructure (such as transportation and electricity supply); regulatory obstacles, including limited regulatory personnel; limitations in technical training; intense competition from foreign based low-cost producers; intellectual property-related barriers; tariff and related trade policies; consumer preferences for well-known branded products; physician prescribing practices; limitations on demand from internationally financed procurement; and limited progress on regional market integration. These issues will not, however, form part of this study, except in an ancillary role.

A range of stakeholders have been identified for the interviews including relevant international or regional financial institutions, government officials, Africa CDC, international and national civil society groups and donors (see Table 1). The interviewees have been selected based on their role in the financial ecosystem (regulator, investor, intermediary, public or private) and their experience in the pharmaceutical/financial sectors. No attempt will be made to achieve comprehensive or random sampling. Instead, a purposive strategy will be followed in order to get maximum value within the short research period of the study.

Table 1. List of interviewees based on representation within the financial/pharmaceutical ecosystem

Stakeholder Group	Organization	Interviewee	Interviewer
Foundation Financing	Gates Foundation	TBD	Abbott, F
Foundation Financing	Rockefeller Foundation	Jono Quick	Abbott, F
Higher Education/Research	Open University	Maureen Macintosh	Abbott, R
Institutional Investors	African Development Bank	TBD	Gehl Sampath
Institutional Investors	International Finance Corporation	TBD	Gehl Sampath

Stakeholder Group	Organization	Interviewee	Interviewer
Institutional Investors	Industrial Development Corporation (South Africa)	Skakel Meer, Sonia Keulder	Walwyn
International Agencies/Local Production	UNCTAD	Christoph Spennemann	Abbott, R
International Agencies/Local Production	NEPAD/AU	Skumbozo Ngozwana	Fortunak
International Regulation/ Technology Transfer	Medicines Patent Pool	Chan Park	Abbott, F
International Regulation/ Technology Transfer	TRIPS Division at WTO	Tony Taubman, Maegan McCann	Abbott, F
Multilateral Financing	World Bank	TBD	Abbott, R
Multilateral Financing	International Finance Corp (Social Investment)	TBD	Abbott, R
Multilateral Financing	African Development Bank	TBD	Gehl Sampath
National Technology Strategy/ Regulation	Nigeria Regulatory Authority	TBD	Gehl Sampath
National Technology Strategy/ Regulation	National Treasury	Devan Naidoo	Walwyn
National Technology Strategy/ Regulation	dti, South Africa	Andre Kudlinski (former)	Abbott, F
National Technology Strategy/ Regulation	Nigeria Central Bank	TBD	Fortunak
National Technology Strategy/ Regulation	dti, South Africa	Marumo Nkomo	Abbott, F
Private Pharmaceutical Sector	Quality Chemicals, Uganda	TBD	Gehl Sampath, Fortunak
Private Pharmaceutical Sector	Biovac Institute	Morena Makhoana	Walwyn
Private Pharmaceutical Sector	Biovac Institute	Selwyn Kahanowitz	Walwyn
Private Pharmaceutical Sector	Nigeria: Emzor	TBD	Fortunak, Gehl Sampath
Private Pharmaceutical Sector	Nigeria: Neimeth	TBD	Fortunak, Gehl Sampath
Private Pharmaceutical Sector	Ethiopia: Kangle, Cadila	TBD	Fortunak, Gehl Sampath
Private Pharmaceutical Sector	Ghana: LaGray	TBD	Fortunak, Gehl Sampath
Public Pharmaceutical Sector	Ketlaphela (Pelchem)	Benji Steynberg/ Petro Terblanche	Walwyn

Case Studies

Two case studies will be undertaken in Phase 3 of the project. Both studies will draw on more detailed research which has already been undertaken. The results of the previous work will be

updated using interviews and more recent secondary data (such as company reports and public documents).

In the first study, the development and implementation of the Biovac Institute will be covered. Biovac is the only successful human vaccine manufacturer currently operating in Africa. Established in 2003 as a public-private partnership covering vaccine research and development, manufacturing and supply, the Biovac Institute has grown from an initial base of 24 staff and a revenue of R188 million to an organization of 250 people and an annual revenue of R1.8 billion (as of January 2018) (Walwyn and Nkolele, 2018). The case study will investigate how funding has been raised for the entity and to what extent the PPP has hindered or assisted access to finance.

In the second study, the project initiative known as Ketlaphela will be covered. Ketlaphela was developed to manufacture antiretroviral active pharmaceutical ingredients in South Africa, but failed to raise finance or secure government support. As a result, the initiative has never materialized into a manufacturing facility (Tomlinson, 2020).

The case studies will be supported by past data collection efforts and evidence (as substantiated by secondary literature) from Bangladesh, India and Uganda, and other countries as possible.

Survey of Pharmaceutical Manufacturers

In addition to the interviews with stakeholders and the two case studies, Drs Fortunak and Gehl Sampath will also undertake a comprehensive survey of the Association of Industrial Pharmacists of Nigeria on the issue of financing for DVT and PPE manufacturing facilities.

The survey will be online, and will use a similar set of questions to those being proposed for the scoping interviews. However, the questions will be designed to ensure that the survey can be completed with minimum effort and hence achieve a high response rate. Such approaches include the use of multiple-choice questions, tick boxes, no written answers unless essential, branching if appropriate and a maximum of 20 questions. The content of the questions will be completed once Phase 2 has been completed.

Phase 4: Identification of Financing Opportunities and Relationship of Finance to Other Variables

In Phase 4, the project team will synthesize the results from the case studies and the interviews with key stakeholders in order to develop suitable models and identify opportunities for financing the local production of DVTs and PPE.

Fred Abbott will explore mechanisms for sustainable and resilient financing adapted to localized production of COVID-19 diagnostics, vaccines and treatments (DVTs), taking account of current trends in institutional investing. This includes instruments such as “social bonds” and third-party

guarantee instruments. Exploration will include consideration of existing PDP models adapted to local production.

Joe Fortunak will address whether new chemical formulations and production process technologies, including advances in manufacturing equipment technology, create opportunities for improving global competitiveness of local African manufacturing. Implementation of such advanced technologies development requires capital investment as well as access to underlying IP. Can the current technological environment advance the prospects for successful development of African local manufacturing?

Alternative and/or holistic variables: to what extent can improved financing options overcome other factors that have inhibited development of local production in Africa?

Has the COVID-19 pandemic and present or potential restrictions on sources of DVT supply altered the political dynamic in Africa that may increase priority of financing local production?

Phase 5: Recommendations for Civil Society Advocacy and Intervention

Phase 5 will cover the development of recommendations for civil society in promoting DVT and PPE manufacturing in Africa. This phase will specifically address the objective of identifying specific recommendations and discussion points for influencing financing DVT and PPE manufacturing in Africa.

The discussions points will cover both ways for stakeholders to shape financing streams (for example, the new IFC Global Health Platform); suggestions for specific manufacturing proposals at country or regional level; and monitoring of investments against stakeholder-agreed outcomes.

These recommendations and discussion points will then be submitted to the OSF and other attendees of the Discussion Workshop, the latter to be nominated by the OSF in the third phase of this project, for their input and critique. The attendees of the Discussion Workshop may include all or some members of the Learning Group, depending on the OSF's requirements. The Discussion Workshop to be convened at the end of Phase 5 of the project.

Phase 6: Final Report and Project Close-Out

In the final phase, the draft recommendations for civil society advocacy and intervention will be revised based on the feedback from the attendees of the Discussion Workshop and the OSF.

The final set of recommendations will then be issued to the OSF. The timing of the workshop and the submission of the Final Report is given in the Project Programme.

Project Structures

Project Team

The project team will consist of the following members:

- Team Leader and Project Management - Frederick Abbott
- Project Team - Joseph Fortunak, Padmashree Gehl Sampath, David Walwyn and Ryan Abbott

Details on each team member follows.

Frederick Abbott

Professor Abbott has a background in law and economics. He has focused much of his career on promoting equitable access to health technologies, including pharmaceuticals, vaccines, diagnostics and medical equipment. As a consultant for the World Health Organization (WHO), he prepared three detailed studies examining legal and economic frameworks for promotion of local production, the first study focusing on Africa, and subsequent studies focusing on China and India. In the context of his work for WHO and UNDP he has participated in the organization and conduct of workshops regarding local production in Africa, Asia and Latin America. Prior to undertaking studies for WHO, he prepared a study for the Government of Colombia (funded by USAID) focusing on enhancing local production, including research on the production framework of Brazil. In 2003, he worked with a group of experts on an Initiative for Pharmaceutical Technology Transfer (IPTT) which had as its objective "Stimulating African production of affordable medicines for HIV, TB, malaria and other endemic neglected diseases". Each of the referenced studies and presentations addresses questions of financing. They are available here: https://frederickabbott.com/local_production

Joseph Fortunak

Professor Fortunak has developed and launched processes to manufacture 50+ new and generic drugs with total sales of over USD$200 Bn as a scientist in the pharma industry. As a professor he has developed and transferred technologies to support local pharmaceutical manufacturing in India, China, Brazil, and African countries. He teaches a postgraduate degree program in Nigeria for drug manufacturing at the University of Ibadan, and has worked with dozens of multinational companies and NGOs to promote WHO Prequalification of medicinal products for GFATM, USAID/PEPFAR and to implement quality-assured manufacturing with maximum efficiency. Examples include contributions to processes that lowered the Active Pharmaceutical Ingredient pricing of tenofovir disoproxil fumarate from USD$900 to USD$100/kg and the API pricing of efavirenz from USD$1100 to USD$100/kg.

Padmashree Gehl Sampath

Professor Gehl Sampath has a background in development economics, working currently as Senior Advisor of the Global Access in Action Program of the Berkman Klein Center, Harvard University. She has worked for over two decades on access to medicines and health, particularly pharmaceuticals and vaccines, from the perspective of developing and coordinating programs that engage in technology transfer, financing and alleviating other innovation constraints to enterprises in the developing world. She has served as a team head and coordinator of several United Nations inter-agency programs in this context, first at the World Health Organization and then at the United Nations Conference on Trade and Development. As part of these programs she has engaged extensively in preparing detailed studies on alleviating constraints to local production for greater access in Africa and Asia, organized region-wide and national workshops to engage policy makers and other stakeholders, and structured policy advocacy and training courses. Her other work in this area includes detailed sector-wide studies of the experiences of countries such as India and Bangladesh, to extract lessons on what works and what does not, and analyses that pertain to highlighting the changing context for local production in developing countries., She has worked with several development banks, including the African Development Bank, World Bank, Asian Development Bank, and the Asia Infrastructure Investment Bank engaging on how financing for innovation can make a large difference in the way countries can boost their local production capabilities. All of her work on the topic can be found at: https://rights2100.org/pharmaceuticals-vaccines-and-health-care

David Walwyn

Professor Walwyn has a background in engineering economics, chemical engineering, chemistry and science and technology policy. He worked for twenty years in South Africa's chemical and pharmaceutical industry, with a focus on the development of novel processes for the local manufacture of a range of active pharmaceutical ingredients including naproxen, penicillin and stavudine. Since 1995, he has also worked closely with local government departments on the localization of pharmaceutical production, with a particular focus on antiretrovirals and TB drugs. This work resulted in the development of a number of policy documents for the local pharmaceutical industry. In 2007, he started a small company, Arvir, which was focused on the establishment of local antiretroviral manufacture. In 2010, he worked for a company attempting to develop novel therapies for TB. Since 2012, he has been a full-time academic at the University of Pretoria, where he has continued working on the conditions necessary to progress pharmaceutical manufacture. Further details of his academic publications are available from the ResearchGate site at www.researchgate.net/profile/David_Walwyn.

Ryan Abbott

Professor Abbott is Professor of Law and Health Sciences at the University of Surrey School of Law, Adjunct Assistant Professor of Medicine at the David Geffen School of Medicine at UCLA, and Partner at Brown, Neri, Smith & Khan, LLP. He has published widely on issues associated with

life sciences in leading legal, medical, and scientific books and journals. Professor Abbott has extensive experience with local production of medicines from serving as outside general counsel to biotechnology companies and from work as a consultant to organizations including the United Kingdom Parliament, the European Commission, the World Health Organization, and the World Intellectual Property Organization. He is a licensed physician and patent attorney in the United States, and a solicitor advocate in England and Wales. (Additional details at https://ryanabbott.com/)

Project Interns

In addition to the senior project team members, at least six interns will be appointed to assist with key aspects of the work. The details are as follows.

India

2-4 researchers from India are expected to assist in extracting learnings from local production experiences in other countries, with a view to contribute to how finance links to other factors of production. They will also support work on new mechanisms for financing from the perspective of extracting social value. These researchers will work with two of the team members.

South Africa

Two interns will be appointed to assist with the case studies to be undertaken as part of Phase 3. The interns will complete a high-level cost/benefit analysis of each case study and collate the results of the interviews in order to generate the overall conclusions from the two studies. The interns are students of a course in Engineering Economics and also work within the university technology transfer sector. The experience will be useful in developing necessary skills to support their work in raising finance for university spin-offs in the pharmaceutical sector

Nigeria and Ethiopia

Two interns will be appointed to assist with the case studies to be undertaken as part of Phase 3 and Phase 4. These interns will be selected based on the ability to gather learnings from local pharmaceutical production. The interns will manage logistics for stakeholder interviews, provide an interface between local participants and the Team, and gather information relevant to matching the overall hypothesis with operating principles for the stakeholders. The interns are students in Pharmacy or medicine in Nigeria and Ethiopia. The experience will be useful in developing skills to support public sector involvement in supporting the emergence of local pharmaceutical manufacturing.

Learning Group

The Terms of Reference require Nova to "organize a small group of experts with experience in advocacy for local production and access to medicines to provide input regarding proposed project work program, including to identify potential research gaps and areas of opportunity".

Accordingly, Nova has compiled a list of potential invitees to the Learning Event. The list has already been finalized and the nominations have been approached to attend the event; further details are given in Table 2. (It is noted that the status as acceptance is reflected as of the date of this report and this information may still change before the event.)

Table 2. List of invitees for the Learning Group

Individual	Organization	Status of Acceptance
Banji Oyelaran-Oyeyinka	African Development Bank	Yes
Jorge Bermudez	Fiocruz	Yes
Carlos Correa	South Centre	Yes
Jicui Dong	WHO	Yes
Nick Drager	TBVi	Yes
Ellen 't Hoen	Medicines Law and Policy	Yes
Yoke Ling	TWN	Yes
Precious Matsoso	former South Africa DG Health	Yes
Cecilia Oh	UNDP	Yes
Bernard Pecoul	DNDi	Yes
Rangarirai Machemedze	EQUINET (Regional Network for Equity in Health in East and Southern Africa)	Yes
Seth Berkley	GAVI/Covax	Pending
Rosalind McKenna	OSF-PHP	Yes
Roxana Bonnell	OSF-PHP	Yes

Project Programme

The project will extend over three months as shown in Table 3.

GANTT Chart

Table 3. Schedule of activities (GANTT)

	Status	October				November				December				January				February			
Week ending Friday		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Phase 1: Inception																					
Inception meeting					1																
Inception report																					
Phase 2: Mapping Using Secondary Data																					
Desk research (literature)																					
Preparation of interim report																					
Re-scoping based on secondary data																					
Learning Event									2												
Phase 3: Field Research and Landscape																					
Finalisation of questionnaire																					
Interviews and engagements																					
Coding of interviews																					
Case studies																					
Final report on Phase 3																					
Phase 4: Development of Financing Opportunities																					
Analysis of Phase 3 results																					
Draft report on financing opportunities																					
Phase 5: Recommendations for Advocacy and Intervention																					
Draft report on recommendations																					
Workshop on key findings																				3	
Phase 6: Final Report and Project Close-Out																					
Preparation of final report (draft)																					
Presentation to OSF																					
Revision of report and close-out																					4

Project Deliverables

The main deliverables of the project will be as follows:

- Inception Report (this document), and organization of Learning Event and will serve to fine-tune the problem statement, the key assumptions and the scope of the mapping to be undertaken and will serve to fine-tune the problem statement, the key assumptions and the scope of the mapping to be undertaken
- Literature Report; containing an analysis of the current and emerging landscape of existing and new financing mechanisms for DVTs and PPE manufacturing in Africa, including the sources of funding, the targeted investment opportunities, the make-up of public and private finance and of domestic and development finance, the priority geographies, and the outcomes identified for such financing
- Opportunities and Recommendations Report; containing in draft format a list of opportunities for influencing financing DVT and PPE manufacturing in Africa either through stakeholder engagement to shape financing streams (for example, the new IFC Global Health Platform), input to specific manufacturing proposals at country or regional level, or monitoring of investments against stakeholder-agreed outcomes
- Discussion Workshop; this event will be held at the end of Phase 5, and will allow the Project Team to solicit input to the draft recommendations as developed in Phases 4 and 5.
- Final Report; the final report will consist of a set of discussion points, developed through the project and enriched by the Discussion Workshop inputs, which can be used to inform civil society advocacy.

Background References

General

Abbott, Frederick M. 2007. Comparative Study of Selected Government Policies for Promoting Transfer of Technology and Competitiveness in the Colombian Pharmaceutical Sector (USAID/MIDAS).

African Union Commission. 2007. Pharmaceutical manufacturing plan for Africa. African Union: Addis Ababa.

BiotechEast. 2015. Taiwan and China biotechnology, medical devices, pharmaceuticals: Government development strategy and investment incentives, 2015

EIU/ IFC. 2019. Improving Access and Affordability for Biopharmaceuticals in Emerging Markets, Geneva.

Gehl Sampath, P. Pharmaceutical Manufacturing in Bangaldesh- A success Story. 2018. What can we learn? Federation of East Asian Manufacturers Issue Paper 1.

Gehl Sampath, P. 2009. Reconfiguring global health innovation, Routledge (UK).

IFC, 2020. Social Bonds, Illustrative Use-of-Proceeds Case Studies: Coronavirus.

IMAP. 2011. Pharma & Biotech Industry Global Report.

Invest Korea. 2014. Biopharmaceutical

McKinsey & Co. 2020. Reopening and Reimagining Africa.

OECD. 2020. OECD Business and Finance Outlook 2020: Sustainable and Resilient Finance, OECD Publishing, Paris, https://doi.org/10.1787/eb61fd29-en.OECD Sustainable and Resilient Finance 2020.

PMGMAN. 2012. Nigerian Pharma Industry – Progress Towards Prequalification.

PWC, Pharma. 2009. Taxing times ahead: Which path will you take?

Steele, Pamela, et al., 2020. A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic.

The AfCFTA and Transformative Industrialization Webinar Series. 2020. Webinar 1: Pharmaceuticals, Health Care Value Chain and Health Resilience.

Tomlinson, C. 2020. In-depth: What ever happened to Ketlaphela?, Spotlight, June 5.

UK BIS. 2011. Strategy for UK Life Sciences.

UNCTAD. 2009. Local Production of Pharmaceuticals and Related technology Transfer in Developing Countries, UN: Geneva.

UNIDO. 1980. Appropriate Industrial Technology for Drugs and Pharmaceuticals, Monograph UNIDO (Vienna).

UNIDO, AVMi, WHO. 2017. Vaccine Manufacturing and Procurement in Africa.

Walwyn, D. R. & Nkolele, A. T. 2018. Coordinating health and industrial policy in South Africa; a case study of the vaccine public-private partnership. *South African Journal of Infectious Disease,* 33(3)**,** pp 39-48.

WHO

- China policies to promote local production of pharmaceutical products and protect public health, 2017
- Increasing Access to Vaccines Through Technology Transfer and Local Production, 2011
- Indian policies to promote local production of pharmaceutical products and protect public health, 2017
- Local Production for Access to Medical Products: Developing a Framework to Improve Public Health, 2011
- Local Production for Access to Medical Products: Developing a Framework to Improve Public Health, Policy Brief 2011
- National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015–2025)
- Trends in Local Production of Medicines and Related Technology Transfer, 2011

World Bank. 2020. Saving Lives, Scaling-up Impact and Getting Back on Track COVID-19 Crisis Response Approach Paper.

Methodology

Geels, F. W. 2020. Micro-foundations of the multi-level perspective on socio-technical transitions: Developing a multi-dimensional model of agency through crossovers between social constructivism, evolutionary economics and neo-institutional theory. Technological Forecasting and Social Change, 152, pp 119894.

Grace, C. 2010. Product Development Partnerships (PDPs): Lessons from PDPs established to develop new health technologies for neglected diseases. Department for International Development: London.

Hall, D. 2015. Why Public-private Partnerships Don't Work: The Many Advantages of the Public Alternative. Ferney-Voltair.

Hay, C. & Wincott, D. 1998. Structure, agency and historical institutionalism. Political Studies, 46(5), pp 951-957. doi: 10.1111/1467-9248.00177

Hekkert, M., Negro, S., Heimeriks, G. & Harmsen, R. 2011. Technological Innovation System Analysis. A manual for analysts, Universiteit Utrecht.

Malerba, F. 2005. Sectoral Systems of Innovation: A Framework for Linking Innovation to the Knowledge Base, Structure and Dynamics of Sectors, Journal of Economics of Innovation and New Technology, Vol. 14. https://doi.org/10.1080/1043859042000228688.

Mazzucato, M. and Semieniuk, G. 2017. Public Financing of Innovation: New Questions *Oxford Review of Economic Policy*, Volume 33, Issue 1, pp 24-48. doi.org/10.1093/oxrep/grw036.

Weinstein, N. D. 1988. The Precaution Adoption Process. *Health Psychology,* 7(4)**,** pp 355.

Weinstein, N. D., Sandman, P. M. & Blalock, S. J. 2008. The Precaution Adoption Process Model. *In:* Glanz, K., Rimer, B. K. & Viswanath, K. (Eds.) *Health Behavior and Health Education: Theory, Research and Practice.* 4th ed. San Francisco: Jossey-Bass, Ch 3, pp 123-147.

Yescombe, E. R. 2011. *Public-private partnerships: principles of policy and finance*, Oxford: Butterworth-Heinemann.

Addendum 2

Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Specific Focus on the Role of Finance

Addendum

31st January 2021

Survey Questionnaires for Firms and Financial Intermediaries

Prepared for the Open Society Foundations – Public Health Program

Nova Worldwide Consulting®

Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Specific Focus on the Role of Finance

A Study for the Open Society Foundations – Public Health Program

Survey Questionnaire for Firms

This survey is part of a wider study for the Open Society Foundations- Public Health Program. The study aims to understand the hindrances to local production of diagnostics, vaccines and pharmaceuticals in the African continent, with a particular focus on finance. Particularly, the focus is on how financial constraints manifest at the firm level, what blockages or barriers may exist in accessing financing, and what can be done to address those in order to support manufacturing capacity in Africa.

- The information required is for the year 2019, unless otherwise stated.
- Complete confidentiality is assured with this survey. The information that you provide us will be used in an aggregate form only. Individual firm data and firm identity will be completely anonymous.
- All participating firms will be given complimentary copies of the final draft of this study.

NOTE: Please attach a copy of your visiting card to the completed questionnaire.

1. Firm Demographics

1.1. Name of firm: _____ Year established_____

1.2. What is the nature of your firm's main business activity (You may tick more than one)?

(a) API/ Bulk drug supplier □ (e) Formulations manufacturer □
(b) Medicinal tool kits and diagnostics □ (f) Packaging □
(c) Vaccines production □ (g) Others (*please specify*) □
(d) Distribution □

1.3. In which categories do your products fall (You may tick more than one)?

(a) Analgesics and Anti-Pyretics □ (g) Cardiac therapy □
(b) Antibiotics □ (h) Corticosteroids □
(c) Anti-Tuberculosis □ (i) NSAIDs, Anti-rheumatic □
(d) Anti parasitic and anti-fungal □ (j) Other therapeutic Segments □
(e) Vaccines □ (k) HIV/AIDS □
(f) Antimalarials □ (l) Diabetes □

1.4. Around what percentage of your firm's output is sold in the domestic market?
_____(*please give exact percentage)*

1.5. How many products do you presently sell in the national market?

(a) 1-10 □ (b) 10-20 □ (c) 20-40 □ (d) Above 40 □

1.6. Does your firm export? Yes □ No □

If yes, how long has the firm been exporting? _____(*Please specify number of years*)

1.7. How does your firm sell its main export product? (*please tick the appropriate box*)

Method of exporting	**% of your exports using this method in 2019**
a. Export directly to client overseas	
b. Sell to overseas agent / distributor	
c. Sell to domestic export agent/ distributor	
d. Sell to equity partner overseas	
e. Others (*Please specify*)	

1.8. What is the ownership structure of your firm?

(a) State owned (100 %) □
(b) 100 Percent foreign owned □
(c) 100 Percent locally owned □

(d) Joint venture □ → Local equity _____%
Foreign equity _____%

1.9. If your firm is part of a larger group, or a joint venture, what are the main activities of your firm's foreign affiliate in your country? *(You may choose more than one answer)*

(a) Production □ (b) R&D □ (c) Marketing and distribution □

2. Capacity, Skills, Process and Product Technologies

2.1. What was your firm's total employment (full time)?

2016	2017	2018	2019	2020

2.2. What is the highest academic qualification at your organization?
(a) Ph.D □ (b) M.Sc □ (c) B.Sc □

2.3. Education level of staff of personnel *(approx.. % of total staff)*

(a) PhD holders Number ☐ ☐ %

(b) Masters degree Number ☐ ☐ %

(c) Bachelors degree Number ☐ ☐ %

(d) Others Number ☐ ☐ %

2. 4. Do you engage in any kind of R&D in your firm? Yes □ No □

If yes, name the number and proportion of persons engaged in R&D in your firm *(Total full time equivalent):*

	2015	2016	2017	2018	2019
a. Number of people engaged in R&D					
b. % of total workforce					

2.5. Does your firm carry out/ engage in new product development?
(a) No □ (b) Yes □ → No. of times in the past 5 years? _____(*Please specify number*)

2.6. Does your firm carry out/ engage in new process development?
(b) No □ (b) Yes □ → No. of times in the past 5 years? _____(*Please specify number*)

2.7. How was the new product obtained?

(a) Licensing? □ (c) Own development? □

(b) Foreign subsidiaries? □ (d) Others (*please specify*):_____

2.8. Were the new products new to:

(a) Your firm □ (b) Local market □ (c) Regional market □ (d) Global market □

2.9. Are your new products and processes registered under intellectual property rights (IPR) instruments?

(a) Copyrights □ (b) Industrial designs □ (c) Patents □ (d) Trademarks □ (e) Others □

If others, please specify _____

2.10. What is the intensity of product/ process development in your prime areas of focus (*you may tick more than one*):

(a) APIs production/ Bulk Antigen production □

(b) Formulations □

(c) Clinical trials support □

(d) Production of diagnostics/ PPE/ Others □

2.11. Was the new process/ product development based on:

(a) In house R&D □ (d) Collaboration within industry association □

(b) Adapted from competitors □ (e) Support from intermediary organization □

(c) Licensed from technology supplier □ (f) Others _____ (*please specify*)

2.12. What % of your firm's gross inputs was sourced domestically?

2015	2016	2017	2018	2019

2.13. How do you rate the contribution of the following to new product or process development at your firm? ***Please circle your rating for each point from 1 (weakest) to 5 (strongest)***

Statement	Rating				
a. Government incentives for innovation	1	2	3	4	5
b. Scientific/skilled manpower	1	2	3	4	5
c. Local universities for R&D collaboration	1	2	3	4	5
d. Local R&D institutes for R&D collaboration	1	2	3	4	5
e. Intellectual property protection	1	2	3	4	5
f. Quality of local infrastructure services	1	2	3	4	5
g. Availability of capital	1	2	3	4	5
h. Lack of government sponsored R&D schemes	1	2	3	4	5
i. Technology transfer from other firms	1	2	3	4	5
j. Transfer of personnel to local firms or R&D institutions (for training and manpower exchange)	1	2	3	4	5
k. Access to foreign exchange	1	2	3	4	5
l. Availability of raw materials at an acceptable price	1	2	3	4	5

m. Ability to price competitively with imports	1 2 3 4 5
n. Lack of obvious demand	1 2 3 4 5
o. Time/difficulty with National Drug Regulatory approvals	1 2 3 4 5

2.14. What is your firm's main source of new technology over the last 5 years?

Please circle your rating for each point from 1 (weakest) to 5 (strongest).

Source of technology	**Rating**
a. Technology licensing	1 2 3 4 5
b. From firms you sell your output to	1 2 3 4 5
c. Joint venture R&D	1 2 3 4 5
d. Strategic partner	1 2 3 4 5
e. Turnkey contract	1 2 3 4 5
f. Transfer from parent firm	1 2 3 4 5
g. Hiring of managers & skilled employees	1 2 3 4 5
h. Suppliers of equipment or components	1 2 3 4 5
i. Local universities & public research institutes	1 2 3 4 5
j. Reverse engineering and copying	1 2 3 4 5
k. Informal sources	1 2 3 4 5
l. Others (*please specify*)	1 2 3 4 5

2.15. How would you rate the average quality of your firm's production capacity (*please tick one only*)?

(a) World class □ (b) Highly advanced (c) Advanced □ (d) Not very advanced □ (e) Dated □

2.16. Does your firm have the internal capacity to manufacture drugs if the government issued a compulsory license on anti retroviral drugs, or drugs for Tuberculosis, Malaria or COVID-19 related health emergencies?

Yes □ No □

2.17. If your answer to Q. 2.16 is yes, do you think this option to produce drugs through compulsory licensing for the local market or other markets in Africa is an attractive option to retain your export sales?

Yes □ No □

Please give reasons for your position:

_____

_____

2.18. How much of your staff is primarily engaged in Quality Assurance and/or Regulatory activities?

(a) Number _____ (b) %_____

2.19. What is the status of your GMP certification?

(a) National □ (b) International □

If International (tick as many as applicable):

(a) WHO PQ □ (b) PIC/S □ (c) EMA □ (d) USFDA □

2. 20. Has your firm been through a regulatory national inspection for GMP or new approvals in the last two years?

Yes □ No □

If you answered YES, did you receive any major/critical observations resulting from this audit?

_____
_____

2.21. Has your firm been through a regulatory international inspection for GMP or new approvals in the last two years?
Yes □ No □

If you answered YES, did you receive any major/critical observations resulting from this audit?

_____
_____

2.22. How does the the emerging regulatory harmonization processes of NEPAD and the African Union impact on your business

1 2 3 4 5

(Rate from 1 to 5, where 1 is not highly unfavourable and 5 is highly favourable)

3. CAPITAL, SPENDING AND FINANCE

3.1. What accounts for most of the spending in your firm for 2019? ***Please rank as applicable from 1 (does not utilize much of the annual budget) to 5 (utilizes a significant part of the annual budget)***

FIRM PURCHASES	Rating
a. API/ bulk antigens	1 2 3 4 5
b. Sourcing other supplies (excipients, packaging, etc)	1 2 3 4 5
c. Installing new production equipment	1 2 3 4 5
d. Payments to ports, licensing authorities and regulatory inspectors	1 2 3 4 5
e. Distribution and marketing	1 2 3 4 5
f. Land and utility payments	1 2 3 4 5

3.2. Over the last 5 years (2001-2005), has your firm *(you may choose more than one)*

(a) Brought new capital equipment? □ (c) Put in new production system? □

(b) Set up new production line? □ (d) Put in new ICT components □

3.3. What is your firm's average capacity utilization rate? *(tick where appropriate)*

Capacity utilization	*2015*	*2016*	*2017*	*2018*	*2019*
(a) Up to 50%					
(b) 51-70%					
(c) 71-90%					
(d) Over					

90%					

3.4. What accounts for a low capacity utilization rate, if you answered (a) or (b) in Q. 3.3.

(a) Low market demand □ (d) Preference for foreign products □
(b) Outdated, poor quality products □ (e) Lack of distribution and marketing □
(c) Too much competition □

3.5. What were your firm's main sources of finance (%)?

Source of finance for firm level operations	2015	2019/2020
a. Domestic banks		
b. Foreign/ regional banks		
c. Other non-bank lenders		
d. Family/friends		
e. Partner firms		
f. Equity market		
g. Government grants		
h. Venture capital		
i. Other (*specify)*		
T O T A L	1 0 0%	1 0 0 %

3.6. Over the last five years, have you made an effort to enhance the capital base of your firm?
(a) Yes □ (b) No □

If yes, tick the new sources of finance:
(a) Domestic banks □ (e) Partner firms □
(b) Foreign/ regional banks □ (f) Equity markets □
(c) Non-bank lenders □ (g) Government grants □
(d) Family/ Friends □ (h) Venture capital □

3.7. If not, do you rate financial support as a constraint to expand production at the firm level?

1 2 3 4 5

(Rate from 1 to 5, where 1 is not severe at all and 5 is extremely severe)

3.8. Are there new production ideas/ R&D projects/ new market entry that you have abandoned or not undertaken in the last five years?

(a) Yes □ (b) No □

If yes, rank the reasons for abandoning the projects:

(Rate from 1 to 5, where 1 is not severe at all and 5 is extremely severe)

Issue	**Rating**
a. Lack of access to financing through banks	1 2 3 4 5
b. Inability to access institutional/ donor financing	1 2 3 4 5
c. Lack of relevant technology/ partners needed for production	1 2 3 4 5
d. Lack of skilled R&D personnel	1 2 3 4 5
e. Lack of good infrastructure facilities to conduct R&D	1 2 3 4 5

f. Difficulties to penetrate the local/ regional market	1 2 3 4 5
g. Too much competition	1 2 3 4 5

3.9. Have you approached local banks to tackle these issues and raise finances for your firm?

(a) Yes □ (b) No □

If yes, rate your experience in accessing finance (from 1 = easy to 5 = highly difficult)

1 □ 2 □ 3 □ 4 □ 5 □

3.10. Has your firm participated in any government-sponsored R&D program during the last 5 years? (a) Yes □ (b) No □

3.11. Did your firm receive any government assistance *(direct grants, subsidies)* for R&D over the last 5 years?

(a) Yes □ (b) No □

3.12. To the best of your knowledge, how have the following changed over the past five years (2015-2019)

++ increased significantly, + increased, = remained the same, - decreased, -- decreased significantly

	++	+	=	-	--
a. Support received by public research institutions					
b. Government grants and subsidies for production Industry Associations					
c. Support for regulatory processes					
d. Financial support through banks					
e. Financial support through public sector intermediaries, like regional banks or international donors					
f. Technology transfer or technology collaborations with foreign firms					
g. Competition for markets by foreign firms					

3.12. How much do you think will the following factors help your firm's ability to compete better?

Please circle your rating for each point from 1 (weakest) to 5 (strongest)

a. Science and technology support institutions	1 2 3 4 5
b. Testing and quality evaluation facilities	1 2 3 4 5
c. Market research and intelligence	1 2 3 4 5
d. Greater access to regional markets	1 2 3 4 5
e. Export credit programs	1 2 3 4 5
f. Financial incentives for expansion/ R&D	1 2 3 4 5
g. SMI support and inter-firm collaboration schemes	1 2 3 4 5
i. Others (please specify)	1 2 3 4 5

Thank you for your valuable input and kind cooperation.

As a token of our appreciation for your kind assistance, we would like to send you a copy of the findings of this study. Could you please provide us with your address.

Mail to: _____

_____

_____

_____

Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa:
With a Specific Focus on the Role of Finance

A Study for the Open Society Foundations – Public Health Program

Survey Questionnaire
Financial Intermediaries

This survey is part of a wider study for the Open Society Foundations- Public Health Program. The study aims to understand the hindrances to local production of diagnostics, vaccines and pharmaceuticals in the African continent, with a particular focus on finance. Particularly, the focus is on how financial constraints manifest at the firm level, what blockages or barriers may exist in accessing financing, and what can be done to address those in order to support manufacturing capacity in Africa.

- The information required is for the year 2019, unless otherwise stated.
- Complete confidentiality is assured with this survey. The information that you provide us will be used in an aggregate form only. Individual firm data and firm identity will be completely anonymous.
- All participating firms will be given complimentary copies of the final draft of this study.

NOTE: Please attach a copy of your visiting card to the completed questionnaire.

1. Agency Demographics

1.1. Name of the organization: _____ Year established_____

1.2. What kinds of activities do you support?

1.3. To the best of your knowledge, to what extent do your sectoral investments go to the pharmaceutical sector in Africa?

1.4. While making a decision to finance firms in expanding production, what are the factors you consider (tick more than one if applicable):

(a) Firm size ☐
(b) Firm's partners ☐
(c) Firm's R&D capacity ☐
(d) Social contribution/impact ☐
(e) Capital structure of firm/investors ☐
(f) Procurement/off-take commitments ☐
(g) Geographical location/market size ☐
(h) Product basket ☐
(i) History of operations ☐
(j) Increasing local employment ☐
(k) Co-financing ☐
(l) Sectoral risks, e.g., duration, rate of return ☐
(m) Others: _____
_____

1.5. While making investment decisions, for portfolio investors for instance, are pharmaceutical investments considered more risky than investing in other sectors?

(a) Yes ☐ (b) No ☐

If yes, why? _____

Can you cite one or more critical factors you evaluate when considering finance for pharmaceutical production in Africa? _____

1.6. Would you be more likely to engage in financing, if the local firms had foreign partners?

a) Yes ☐ (b) No ☐

If yes, why? _____

1.7. Do you offer or do you provide financing for the following kinds of services:

(a) Technology acquisition ☐
(b) Market acess/ tendering support ☐
(c) Human resources identification/hiring ☐
(d) Market analysis/pricing ☐
(e) Identification of potential partners ☐
(f) Offering other services ☐

If you ticked others, please specify…….

1.8. How often do pharmaceutical firms approach you for financing?
(a) Often □
(b) Rarely □
(c) All the time □
(d) Never □

1.9. In your experience, is lack of adequate financing a constraint to expanding production in the pharmaceutical sector at the firm level?

1 2 3 4 5

(Rate from 1 to 5, where 1 is not severe at all and 5 is extremely severe)

1.10. In your experience, does an elevated cost of capital in Africa (as compared with higher-income regions) hinder expansion of local production of pharmaceuticals?
(a) Yes □ (b) No □

1.11. What is the ownership structure of your organization?
(a) State owned (100 %) □
(b) 100 Percent foreign owned □
(c) 100 Percent locally owned □
(d) Joint venture □ → Local equity _____%
Foreign equity _____%
(e) International organization □
(f) Publicly traded shares □
(g) Foundation or other non-profit □

1.12. In your experience, do you think there are enough incentives for firms to expand production in the African context?
(a) Yes □ (b) No □
If not, give reasons why not----------

1.13 What, in your view, is the main hindrance to production expansion/ new product and process introductions?

(Rate from 1 to 5, where 1 is not severe at all and 5 is extremely severe)

Issue	Rating
a. Lack of access to financing	1 2 3 4 5
b. Inadequate or under-developed structures of venture capital and private financing	1 2 3 4 5
c. Lack of relevant technology/ partners needed for production	1 2 3 4 5
d. Lack of skilled R&D personnel	1 2 3 4 5
e. Lack of governmental support and grants	1 2 3 4 5
f. Difficulties to penetrate the local/ regional market	1 2 3 4 5
g. Too much competition	1 2 3 4 5

h. A lack of market acceptance by consumers	1 2 3 4 5

1.14. Do you provide financing for the following kinds of services:

(a) Technology acquisition □
(b) Market acess/ tendering support □
(c) Human resources identification/hiring □
(d) Market analysis/pricing □
(e) Identification of potential partners □
(f) Offering other services □

If you ticked others, please specify……..

1.15. Has your agency/ organization changed its financing policy for firms in the past five years? If yes, how do you think it impacts on the costs of capital in the African context?

1.16. Do you believe that African firms can build local capacity to capture revenues in key segments of local production?

(a) Yes □ (b) No □

1.17. Do you have experience of financing local production in the African continent?

(a) If yes, how many firms have you financed? _____
(b) In how many countries _____
(c) What is the financing arrangement _____
(d) What were the underlying reasons for financing _____
(e) If you declined to finance, please cite reasons: _____

1.18. In your experience, are there other sources of finance that firms can access?

(a) Yes □ (b) No □

If Yes, please specify the sources:
……
……..

1.19 Have you been involved in any bond issuance or other fixed interest offerings specifically directed toward initiating or expanding pharmaceutical manufacturing in Africa?

(a) Yes □ (b) No □

1.20. If you answered yes to Q. 1.19, please specify:
……
……..

1.21. If you answered no to Q. 1.19, do you think there might be a market for such offerings to finance pharmaceutical manufacturing in Africa? If no, please explain why not

1.22. Has your agency any experience in new models of financing in recent years? If yes, please specify

……
……..

1.23. Do you believe that local pharmaceutical manufacturing is an important factor towards increasing access to medicines in Africa?

(a) Yes □ (b) No □

If you answered yes, can you elaborate on what steps could be taken to ensure greater financing of this sector:

……
……..

Thank you for your valuable input and kind cooperation.

As a token of our appreciation for your kind assistance, we would like to send you a copy of the findings of this study. Could you please provide us with your address.

Mail to: _____
_____
_____
_____
_____
_____

Addendum 3

Sovereign Wealth Funds As Potential Investment Partners In Developing Pharmaceuticals Manufacturing Capacity In Africa

Addendum Report

31st January 2021

Binit Agrawal

Prepared for the Open Society Foundations – Public Health Program

Nova Worldwide Consulting®

Summary

Sovereign Wealth Funds (SWFs), with their long-term investment horizons, would be suitable investors for African pharmaceutical manufacturing infrastructure.1 They are increasingly taking into account SDGs and Environmental, Social and Governance (ESG) risks in their investment decisions.2 Some other SWFs, like those from MENA region, are also foregoing returns in favour of securing domestic interests like health security.3 COVID-19 has also moved SWFs to seriously consider health-risk as a strategic issue and invest in pandemic-preparedness.4 Hence, African pharmaceuticals manufacturing industry, given its long-term growth potential, developmental dividends, and ability to reduce the impact of future pandemics, would be an important investment destination for SWFs.

There is also a rise in moralist SWFs (e.g. the Australian Future Fund) and Sovereign Development Funds (e.g. the Abu Dhabi Fund for Development), which consider developmental dividends an important part of their investment decisions.5 These funds could be important source of investment in pharmaceutical manufacturing infrastructure in Africa.

Furthermore, African countries have also become more stable, democratic and development oriented in recent times. This makes them, along with their bounty of natural resources, an attractive investment destination. The important catalyst in this process of improving the investment environment are African SWFs, which now number to over 14. They can be an important source of initial investment, and then attract other SWFs and private investors as co-investors.[6]

---

[1] Rajiv Sharma, Sovereign Wealth Funds Investment in Sustainable Development Sectors: Background studies in support of the High-Level Conference on Financing for Development and the Means of Implementation of the 2030 Agenda for Sustainable Development (Nov. 13, 2017) (Conference Report), https://www.un.org/esa/ffd/wp-content/uploads/sites/4/2017/11/Background-Paper_Sovereign-Wealth-Funds_16-Nov.pdf; *Investment Objectives of Sovereign Wealth Funds—A Shifting Paradigm* 5 (International Monetary Fund, Working Paper No. 11/19, 2011).

[2] Lina Saigol, *The world's biggest sovereign-wealth fund wants to rid itself of poor ESG performers*, MARKETWATCH (Oct. 08, 2020), https://www.marketwatch.com/story/the-worlds-biggest-sovereign-wealth-fund-wants-to-rid-itself-of-poor-esg-performers-11602084190.

[3] Jeanne Amar, et. al., *GCC Sovereign Wealth Funds: Why do they Take Control?* (HAL-SHS, 2018), https://halshs.archives-ouvertes.fr/halshs-01936882/document; Basil MK Al-Ghalayani, *Exploring opportunities in global pharmaceuticals sectors*, ARAB NEWS (Aug. 23, 2020), https://arab.news/p4zjg.

[4] Matt Craven, et. al., *Not the last pandemic: Investing now to reimagine public-health systems*, MCKINSEY (July 13, 2020), https://www.mckinsey.com/industries/public-and-social-sector/our-insights/not-the-last-pandemic-investing-now-to-reimagine-public-health-systems; COMMISSION ON A GLOBAL HEALTH RISK FRAMEWORK FOR THE FUTURE, THE NEGLECTED DIMENSION OF GLOBAL SECURITY: A FRAMEWORK TO COUNTER INFECTIOUS DISEASE CRISES 17-23 (2016).

[5] Joseph A. Kéchichian, *Sovereign Wealth Funds in the United Arab Emirates*, in THE POLITICAL ECONOMY OF SOVEREIGN WEALTH FUNDS (Xu Yi-chong & Gawdat Bahgat, eds., 2010) 90; GORDON CLARK, ET. AL., SOVEREIGN WEALTH FUNDS: LEGITIMACY, GOVERNANCE, AND GLOBAL POWER 42 (2013).

[6] Juergen Braunstein, *Financing Africa's Infrastructure Gap through New Forms of Co-Investments and Partnerships with Sovereign Wealth Funds*, AFRICA AT LSE (Nov. 21, 2014), http://blogs.lse.ac.uk/africaatlse/2014/11/21/financing-africas-infrastructure-gap-through-new-forms-of-co-investments-and-partnerships-with-sovereign-wealth-funds.

Thus, SWFs and SDFs which have long-term investment goals and do not seek short-term profits, in addition to African SWFs, would be suitable candidates for investments in the African pharmaceutical infrastructure. Initial interest would be to invest in countries which already have some established manufacturing setup and distribution channels (e.g. Kenya, Nigeria, South Africa, and Morocco). The products of interest would be blockbuster drugs whose patents have recently expired or are about to expire, as it would help internal affordability and would also be suitable for export to home countries (e.g. MENA region). In due course, investments would also have to be made into manufacturing of feeder materials like API, to bring down costs. These efforts must be complemented by the development of medical research institutes and labs, which are important to improve R&D and develop human resources. Vaccine manufacturing, while important, is significantly more complex and expensive. Thus, it would not generate immediate interest from SWF investors.

Table of Contents

List of Figures

No table of figures entries found.

List of Tables

No table of figures entries found.

List of Abbreviations

DVTs	Diagnostics, vaccines and therapeutics
OSF	Open Society Foundations
PHP	Public Health Program
PPE	personal protective equipment

1 Sovereign Wealth Funds As Potential Investment Partners In Developing Pharmaceuticals Manufacturing Capacity In Africa

When the term Unicorn (referring to startups with a valuation of over USD 1 billion) was coined in 2013 there were merely 40 of them in existence. Today, there are over 400 startups which are classified as unicorns. Credit for this surge in the number of unicorns is given to Sovereign Wealth Funds ('SWFs'), their corpus of over USD 40 trillion,[7] and their long-term horizon.[8] While the debate on the definition of SWFs continues to rage, it is broadly agreed that SWFs are special-purpose vehicles that invest sovereign assets in private financial markets.[9] Their investment cycles tend to be long-term in nature, with a focus on creating economic clusters, and hence, their risk appetite is higher.[10] Thus, SWFs are considered to be suitable investors for infrastructure projects with developmental goals.[11]

In recent times, there have been three key palpable changes in how SWFs invest: *first*, they have shifted their focus away from investing through public markets, choosing instead to become active investors, who support the very creation and management of new firms;[12] *second*, they have an eye on entering into sectors which have a demand-supply mismatch, e.g. their investments in the internet sharing-economy;[13] *third*, they are increasingly incorporating sustainable development goals (SDGs) in their investments, partly because of a realisation that fossil and commodity prices are going to remain low for the foreseeable future.[14]

---

[7] Marco Kamiya and Winston Ma, *Sovereign investment funds could be the answer to the SDGs*, WEFORUM (Dec. 04, 2019), https://www.weforum.org/agenda/2019/12/sovereign-wealth-funds-sdgs/.

[8] WINSTON MA AND PAUL DOWNS, THE HUNT FOR UNICORNS: HOW SOVEREIGN FUNDS ARE RESHAPING INVESTMENT IN THE DIGITAL ECONOMY (2020).

[9] GORDON CLARK, ET. AL., SOVEREIGN WEALTH FUNDS: LEGITIMACY, GOVERNANCE, AND GLOBAL POWER 14 (2013).

[10] Indranil Ghosh and Matthias Lomas, *How Sovereign Wealth Funds Can Catalyse Investments into the SDGs*, ILFSWF REVIEW, https://ifswfreview.org/2019/our-partners/how-sovereign-wealth-funds-can-catalyse-investments-sdgs; Peter Kunzel, et. al., *Investment Objectives of Sovereign Wealth Funds—A Shifting Paradigm* 5 (International Monetary Fund, Working Paper No. 11/19, 2011).

[11] Rajiv Sharma, Sovereign Wealth Funds Investment in Sustainable Development Sectors: Background studies in support of the High-Level Conference on Financing for Development and the Means of Implementation of the 2030 Agenda for Sustainable Development (Nov. 13, 2017) (Conference Report), https://www.un.org/esa/ffd/wp-content/uploads/sites/4/2017/11/Background-Paper_Sovereign-Wealth-Funds_16-Nov.pdf; Cody Feldman, *Sovereign wealth funds could increase equality in a post-COVID world*, WEFORUM (June 19, 2020), https://www.weforum.org/agenda/2020/06/sovereign-wealth-funds-could-increase-equality-in-a-post-COVID-world/.

[12] Sharma, *Id*.

[13] Patrick Schena and Asim Ali, *Sovereign Wealth Fund Investment in Economic Transformation: Toward an Institutional Framework*, 18(1) WORLD ECONOMICS JOURNAL 123, 133-134 (2017).

[14] Javier Capapé, et. al., *Sovereign Wealth Funds – 2017 Annual Report* 63-80 (IE Sovereign Wealth Labs, 2017), https://sites.tufts.edu/sovereignet/files/2018/06/SOVEREIGN-WEALTH-LAB-REPORT-2017.pdf

Until before COVID-19, the focus of SWFs was still on the internet economy, natural resources, and energy. COVID-19 has brought into limelight the next big industry: healthcare.[15]

While healthcare industry across the world, including pharmaceuticals manufacturing, would receive significant investments in the new decade, Africa would be one of the most attractive destinations, given its strong demographics and a high burden of diseases.[16] For SWFs, pharmaceuticals manufacturing in Africa would be a natural match to their investment goals: it has long-term return potential; will help them cater to the huge demand for affordable drugs; will allow them to scale the numerous small firms in this field; and will enable them to integrate developmental goals in their investments. While the major pharma companies continue to have an appeal, the focus has now shifted to smaller firms, which will yield outsize returns over the longer period.[17]

2 Sustainable Development As An Investment Objective For SWFS

SWFs are now seriously considering divesting out of projects which have Environmental, Social and Governance (ESG) Risks. Norway's USD 1 Trillion SWF, world's largest, is leading in such divestments.[18] However, it is not alone. The New Zealand Superannuation Fund and the Swedish Public Pension Fund too have divested out of fossils.[19] ESG's not just dent the public profile of investors, but are also unsustainable in the longer term due to rising public pressure. Commentators have noted that after COVID-19, there would be increasing pressure on SWFs to

[15] Emma Stevenson, *What are the long-term prospects for healthcare investing post COVID-19?*, SCHRODERS (July 03, 2020), https://www.schroders.com/en/insights/economics/what-are-the-long-term-prospects-for-healthcare-investing-post-COVID-19/; *Investing for Resilience: IFSWF Annual Review 2019* (IFSWF, June 09, 2020), https://www.ifswf.org/publication/investing-resilience-ifswf-annual-review-2019; Holly Ellyatt, *Here's why some sovereign wealth funds could outperform despite the coronavirus crisis*, CNBC (June 09, 2020), https://www.cnbc.com/2020/06/09/sovereign-wealth-funds-investments-helped-by-coronavirus-crisis.html; Basil MK Al-Ghalayani, *Exploring opportunities in global pharmaceuticals sectors*, ARAB NEWS (Aug. 23, 2020), https://arab.news/p4zjg.

[16] R. Logendra, D. Rosen, and S. Rickwood, *Africa - A ripe opportunity: Understanding the pharmaceutical market opportunity and developing sustainable business models in Africa* (IMS Health, White Paper, 2013), https://marketbookshelf.com/wp-content/uploads/2017/06/IMS_Africa_Opportunity_Whitepaper.pdf.

[17] Claire Milhench, *Cash Injection: Sovereign Funds Target Healthcare*, REUTERS (Oct. 06, 2017), https://www.reuters.com/article/us-global-swf-healthcare-analysis/cash-injection-sovereign-funds-target-healthcare-idUSKBN1CB0EB.

[18] Lina Saigol, *The world's biggest sovereign-wealth fund wants to rid itself of poor ESG performers*, MARKETWATCH (Oct. 08, 2020), https://www.marketwatch.com/story/the-worlds-biggest-sovereign-wealth-fund-wants-to-rid-itself-of-poor-esg-performers-11602084190.

[19] *Preqin Special Report: Sovereign Wealth Funds* (Preqin, Aug, 2018) 6-7, https://docs.preqin.com/reports/Preqin_Special_Report_Sovereign_Wealth_Funds.pdf; *Swedish Public Pension fund divests from fossils*, GREENPEACE (Mar. 16, 2020), https://www.greenpeace.org/sweden/pressmeddelanden/6102/swedish-public-pension-fund-divests-from-fossils/.

move away from commodities towards investments in public goods, with environment and health risk management being the most prominent ones.[20] Similar to ESG risks, due to COVID-19, the global North has also realised the cost of the pandemic risk, something Africa has continuously witnessed in the last few decades.[21] Thus, investors are being advised to invest in pandemic-preparedness to avoid future pandemics and ensure global economic stability.[22] Going ahead, SWFs would be more open to addressing pandemic risks, which would require investments to improve local capabilities across continents to address possible pandemics swiftly, curbing their global spread. Pharmaceutical production infrastructure in Africa, thus, would be an important means to address pandemic risks and would invite natural interest from SWFs.

In addition to SWFs, there is also a whole group of emerging Sovereign Development Funds (SDFs), whose aim is to invest in projects which support sustainable development. While the profit motive is not lost, as it is in case of charities, development is given a high weightage. One such fund is the Abu Dhabi Fund for Development, which manages over USD 10 billion in assets, in over 52 countries, many of them African.[23] The fund targets developing countries, especially those with a Muslim population and has a strong focus on Africa. SDFs also have a higher risk appetite. One example is the Khazanah Fund of Malaysia. Over the course of 10 years, the fund invested USD 50 billion in the Iskandar region of Malaysia, a region which was considered extremely backward and unsuitable for investments.[24] The efforts of Khazanah transformed Iskandar into the Shenzhen of Malaysia. Some other SWFs, with a focus on SDGs and intergenerational equity, have also been referred to as moralist SWFs, and it has been noted that their number and financial power is growing.[25] For example, the incorporation charter of the AUD 100 billion Australian Future Fund specifically requires its investments to mandatorily take into account intergenerational equity. It also provides that investments should be long-term, with their objectives being assessed first in 2020, and then in 2040. Such moralist SWFs and SDFs can be important supporters of pharmaceutical manufacturing infrastructure in Africa.

---

[20] Daniel Wilde, *Should Sovereign Wealth Funds Invest to Achieve the Paris Agreement?*, IFSWF REVIEW, https://ifswfreview.org/2019/our-partners/should-sovereign-wealth-funds-invest-achieve-paris-agreement.

[21] *When will we learn our lesson on pandemics?*, AVIVA INVESTORS (July 21, 2020), https://www.avivainvestors.com/en-gb/views/aiq-investment-thinking/2020/07/pandemic-lessons/.

[22] Matt Craven, et. al., *Not the last pandemic: Investing now to reimagine public-health systems*, MCKINSEY (July 13, 2020), https://www.mckinsey.com/industries/public-and-social-sector/our-insights/not-the-last-pandemic-investing-now-to-reimagine-public-health-systems; COMMISSION ON A GLOBAL HEALTH RISK FRAMEWORK FOR THE FUTURE, THE NEGLECTED DIMENSION OF GLOBAL SECURITY: A FRAMEWORK TO COUNTER INFECTIOUS DISEASE CRISES 17-23 (2016).

[23] Joseph A. Kéchichian, *Sovereign Wealth Funds in the United Arab Emirates*, in THE POLITICAL ECONOMY OF SOVEREIGN WEALTH FUNDS (Xu Yi-chong & Gawdat Bahgat, eds., 2010) 90.

[24] Caroline Nowacki & Ashby H. B. Monk, Bridging Institutional Logics to Lead Regional Development: The Case of Khazanah in Iskandar Malaysia (Feb. 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3346100.

[25] CLARK, *Supra* note 9, at 42.

3 Africa as a Destination and Source of SWF Investment

Africa has become an important investment destination for SWFs generally. Many of these countries were politically unstable for most of the 20th century, making them unsuitable for long-term investments. However, they have not just become more stable, but are also increasingly becoming more democratic and development-oriented.[26] This has made Africa, with its rising population and ample availability of land and raw resources, a suitable destination for investment.

Furthermore, the notion that capital can only flow from North to South has been shaken up by the rise of African Sovereign Wealth Funds, which are capitalized through the surplus from commodities trade. Now numbering to over 14, these SWFs are divided into smaller funds with various goals, including sustainable economic development.[27] Ghana's SWF for example is sub-divided into Ghana Stabilization Fund, the Ghana Heritage Fund, and the Infrastructure Investment Fund.[28] The existence of African SWFs can become an important catalyst to support the development of pharmaceuticals manufacturing infrastructure. They can be an important source of initial investment, and then attract other SWFs and private investors as co-investors.[29] Already continent-wide effort is being undertaken to mobilize resources through the initiatives of African Development Bank.[30] Furthermore, as early as 2007, Heads of State of 54 African nations endorsed a Pharmaceutical Manufacturing Plan for Africa which consists of a package of technical solutions to some of the critical challenges confronting the continent's pharmaceutical industry.[31] There is a consensus amongst the leaders that Africa should manufacture its own drugs, and African SWFs could be major investors in a concrete and effective plan.

[26] Javier Santiso, *Sovereign Development Funds*, 58 OECD POLICY INSIGHTS (2008).

[27] *Africa's Sovereign Wealth Funds are a Source of Development Finance*, UNITED NATIONS INFORMATION CENTRE (Sept. 24, 2020), https://namibia.un.org/en/92450-africas-sovereign-wealth-funds-are-source-development-finance; Julia Chen, *Financing The Sustainable Development Goals: The Role Of African Sovereign Wealth* Funds, 51 INTERNATIONAL LAW AND POLITICS 1259, 1267-1269 (2019).

[28] *Sovereign Wealth Funds as a Driver of African Development* (Quantum Global, 2014) 10, http://quantumglobalgroup.com/wp-content/up loads/2017/10/Sovereign-Wealth-Funds-as-a-driver-of-African-develop- ment.pdf.

[29] Juergen Braunstein, *Financing Africa's Infrastructure Gap through New Forms of Co-Investments and Partnerships with Sovereign Wealth Funds*, AFRICA AT LSE (Nov. 21, 2014), http://blogs.lse.ac.uk/africaatlse/2014/11/21/financing-africas-infrastructure-gap-through-new-forms-of-co-investments-and-partnerships-with-sovereign-wealth-funds.

[30] Rabah Arezki & Amadou Sy, *Financing Africa's Infrastructure Deficit: From Development Banking To Long-Term Investing*, BROOKINGS (2016), https://www.brookings.edu/research/financing-africas-infrastructure-deficit-from-development-banking-to-long-term-investing/.

[31] Janet Byaruhanga, *The Pharmaceutical Manufacturing Plan for Africa*, AFRICAN UNION DEVELOPMENT AGENCY (Aug. 24, 2020), https://nepad.org/news/pharmaceutical-manufacturing-plan-africa.

4 South-South Investments

African nations may also benefit from investments made by SWFs of major developing nations like China and India. China has already set-up an Africa specific SWF christened as the China Africa Development Fund.[32] Chinese capital has also moved from its other SWFs and public banks into various African countries. However, China has usually focused on securing access to resources and energy, as against projects with a developmental angle. It has also been accused of acting as a rentier, trying to take permanent control of resources like land and water.[33] India, on the other hand, has focused on investing in consumer utility and developmental infrastructures like telecom and healthcare.[34] Pharmaceuticals are a key component of India-Africa relationship, and there is active interest in the governmental level to further expand this relationship.[35] Today, 20% of pharmaceuticals in Africa are of Indian origin, comprising 40% of all total exports from India to Africa. India is also the global leader in vaccine and generic drugs manufacturing. It accounts for over 10% of global drug manufacturing by volume and merely 1.5% by value, pointing towards the affordable nature of Indian drugs.[36] While China has been catching up with India in the pharmaceuticals sector, the growth has been through a big-push by the state. Few African countries can give that big-push, and must rely on organic growth. Given India's learning curve in organic growth, its experience can be extremely useful for African governments and entrepreneurs. However, India does not have any active SWF which invests internationally. Nonetheless, its public banks, like the Export-Import (Exim) Bank and other public enterprises are major investors in Africa and can be a source of funding for pharmaceutical infrastructure.[37] In the recent past, Exim Bank has seriously considered major investments in healthcare

[32] Sven Grimm & Elizabeth Schickerling, *The China-African Development Fund (CADFund) As A Sovereign Wealth Fund For Africa's Development* (Stellenbosch University, July 2013), http://hdl.handle.net/10019.1/85284.

[33] Elirehema Doriye, *The next stage of sovereign wealth investment: China buys Africa*, 18 Journal of Financial Regulation and Compliance 23 (2010).

[34] Abhishek Mishra, *How Indian and Chinese involvement in Africa differs in intent, methods and outcomes*, OBSERVER RESEARCH FOUNDATION (Sep. 17, 2019), https://www.orfonline.org/expert-speak/how-indian-and-chinese-involvement-in-africa-differs-in-intent-methods-and-outcomes-55574/#:~:text=Currently%2C%20for%20the%20year%202017,has%20reached%20US%24%2069%20billion.

[35] C.J. Murray, et al., *Development assistance for health: trends and prospects*, 378(9785) THE LANCET 8 (2011); Oomen C. Kurien & Kriti Kapur, *Africa as an export market: An analysis of Chinese and Indian pharmaceutical industry*, OBSERVER RESEARCH FOUNDATION (Apr. 01, 2020), https://www.orfonline.org/expert-speak/africa-as-an-export-market-an-analysis-of-chinese-and-indian-pharmaceutical-industry-63930/

[36] *Pharma Industry Promotion*, DEPT. OF PHARMACEUTICALS, https://pharmaceuticals.gov.in/pharma-industry-promotion.

[37] Malancha Chakrabarty, *Indian investments in Africa: Scale, trends, and policy recommendations*, OBSERVER RESEARCH FOUNDATION (May. 19, 2017), https://www.orfonline.org/research/indian-investment-africa-scale-trends-and-policy-recommendations/; India: Partnership Overview, AFRICAN DEVELOPMENT BANK GROUP, https://www.afdb.org/en/countries/non-regional-member-countries/india#:~:text=The%20partnership%20between%20India%20and,African%20Development%20Bank%20in%201983.

infrastructure in Africa and has regularly extended Line of Credits.[38] However, the strong pharmaceuticals lobby in India can be a roadblock to any major investment from India. Indian generic manufacturers have grown due to their exports to Africa, which is relatively easy compared to directly investing there, given the free trade regime.[39] Thus, more often than not the Indian industry has been against the idea of investing in Africa, and this may mean that investments from India would only be symbolic.[40]

5 What To Manufacture?

There are various categories of pharmaceutical products including feeder materials like excipients and APIs, and end-products like vaccines, tablets and so on. Even within end products, there are many categories of medicines dealing with minor ailments like common cold to those used for the treatment of diseases like Cancer. Currently, Africa has basic manufacturing capacity for old and commercial drugs like nutraceuticals, cough & cold preparations, simple analgesics & sedatives, antimalarials, older generation antibiotics, antihelminthics, 1st generation anti-hypertensives, anti-diabetics, etc. Even within Africa, 80% of the total capacity is located in South Africa and Morocco, and a further 20% in Ghana, Kenya and Nigeria.41 Thus, intra-Africa inequality in pharmaceutical infrastructure is very prominent. Furthermore, Africa has close to no facility to manufacture feeder materials like APIs, over 95% of which is imported. R&D facilities too are non-existent and there is no reverse engineering set-up.

Any investment, thus, must support a competitive and enduring integrated manufacturing pharmaceutical industry to be successful. This would require, first, setting up facilities to exploit blockbuster drugs whose patents have recently expired or are about to expire. Every year the patents of many important drugs expire. For example, in 2020, 18 drugs having sales of USD 17 billion, lost their patents.42 If Africa gains the ability to develop those drugs, it would help create the capacity to respond to many diseases, reduce import dependency and improve drug

[38] David Rasquinha, *Healthcare in Africa, built by India*, EXIM BANK (2016), https://www.eximbankindia.in/blog/blog-content.aspx?BlogID=7&BlogTitle=Healthcare%20in%20Africa,%20built%20by%20India; TC James & Apurva Bhatnagar, *Together Towards a Healthy Future India's Partnerships in Healthcare* (Research & Information System for Developing Countries, 2019) 35, http://ris.org.in/sites/default/files/Together%20Towards%20a%20Healthy%20Future-India%E2%80%99s%20Partnerships%20in%20Healthcare.pdf

[39] Sudip Chaudhuri, *Can Foreign Firms Promote Local Production of Pharmaceuticals in Africa?*, in MAKING MEDICINES IN AFRICA (M. Mackintosh, et. al. eds., 2016) 111-114.

[40] *Id.*

[41] Oomen C. Kurien, *Expanding pharmaceutical local production in Africa: An idea whose time has come?*, OBSERVER RESEARCH FOUNDATION (APRIL 10, 2019), https://www.orfonline.org/expert-speak/expanding-pharmaceutical-local-production-in-africa-an-idea-whose-time-has-come-49805/.

[42] *These drug patents are expected to expire in 2020*, MEDCITY NEWS (JAN. 31, 2020), https://medcitynews.com/2020/01/these-drugs-have-patents-expected-to-expire-in-2020-and-some-will-face-generic-competitors/.

affordability. In due time, Africa may also gain price competitiveness to export to other continents. Since this can yield results without significant R&D costs, it should be a priority area for investors.

Secondly, any manufacturing effort must be complemented by the development of medical research institutes and labs, which can support reverse engineering efforts. Without these, projects would have to rely on expensive foreign workers, and may prove to be inefficient. Indeed, investment in training and education itself can become a profitable venture.43 Further, these institutes can also create future entrepreneurs, who are key to ensure the deepening of the manufacturing industry once it is established.

Thirdly, investments must achieve the economic scale necessary to offer price competitiveness over cheap imports from India. A report found that currently, manufacturing is unable to take root because of their inability to reach the scale of production and sales required to make them affordable.44 Thus, investments must be planned well to take advantage of established distribution channels. This would mean that initial investments must be made in countries like Nigeria, Kenya, South Africa or Morocco, as they already have some sort of manufacturing setup. The focus must be on scaling and upgrading those setups, so that these countries can become exporters. This is imperative because, in the last few years, SWFs have become inward-looking, seeking to invest strategically so as to secure domestic goals.45 SWFs from the MENA region, for example, have focused on investing in food security. In fact, one study found that when strategic interests are in question, SWFs are ready to forego profit-maximization and high returns.46 Post COVID-19, MENA countries have started to consider pharmaceuticals as another key area of domestic interest.47 Thus, investments in the pharmaceutical industry in Africa would garner more interest if they could offer export value to these countries.

---

[43] Pamela Steele, et. al., *A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic* (PSA, July 2020) 6, https://www.pamsteele.co.uk/wp-content/uploads/2020/07/20200715_LocalPharmaManufacturingInAfrica.pdf.

[44] Michael Conway, et. al., *Should sub-Saharan Africa Make its own drugs?* (McKinsey, Jan. 10, 2019), https://www.mckinsey.com/~/media/McKinsey/Industries/Public%20and%20Social%20Sector/Our%20Insights/Should%20sub%20Saharan%20Africa%20make%20its%20own%20drugs/Should-sub-Saharan-Africa-make-its-own-drugs.pdf.

[45] Arman Sidhu, *GCC Sovereign Wealth Funds Reinvent Themselves In COVID Era*, EURASIA REVIEW (Jan. 19, 2021), https://www.eurasiareview.com/19012021-gcc-sovereign-wealth-funds-reinvent-themselves-in-COVID-era-analysis/; Bernardo Bortolotti, et. al., *Sovereign Wealth Funds and the COVID-19 shock: Economic and Financial Resilience in Resource-Rich Countries* (BAFFI CAREFIN Centre Research Paper No. 2020-147, Aug 2020), http://www.bernardobortolotti.com/wp-content/uploads/2020/08/SWF-and-COVID19.pdf.

[46] Jeanne Amar, et. al., *GCC Sovereign Wealth Funds: Why do they Take Control?* (HAL-SHS, 2018), https://halshs.archives-ouvertes.fr/halshs-01936882/document.

[47] Al-Ghalayani, *Supra* note 15.

Fourthly, investments in manufacturing of feeder materials like API would also be profitable, and must complement the manufacturing of final drugs. Without easy access to APIs, final goods would be costly, defeating the purpose of manufacturing affordable drugs.

Vaccine manufacturing, on the other hand, is significantly more complex and is often reliant on latest innovations. Thus, large-scale vaccine manufacturing would require a minimum level of industry maturity, which can be acquired only after a few decades of experience in the manufacturing space. While governments do have the right to invoke compulsory licensing and gain access to the latest R&D, it would still be difficult to manufacture vaccines without the necessary human resources and industry experience. However, this should not dissuade investors from setting up capacities for older vaccines like those used to fight polio or malaria. It would go a long way in displacing these diseases from their last few bastions.

Addendum 4

THE CONTRIBUTION OF GOVERNMENT POLICIES TO GROWTH AND DEVELOPMENT OF PHARMACEUTICAL INDUSTRY IN INDIA

Addendum Report

7th February 2021

Nanditta Batra

Prepared for the Open Society Foundations – Public Health Program

Nova Worldwide Consulting®

Contents

INTRODUCTION:

The modern system of allopathic medicine depends upon a robust supply of drugs and other pharmaceutical products. This makes pharmaceutical industry crucial to the health goals of a nation. However, pharmaceutical substances are unique than other manufactured merchandise. Their manufacture requires requisite scientific knowledge and skills. It is technology based capital intensive industry. However, finance is required not only for manufacturing the known products but also for innovation of novel products. It then becomes crucial for countries to frame their policies strategically that promote both the innovation of new drugs and the manufacture of essential medicines; that advance the public health concerns while protecting to a limited extent the commercial interests of financers and investors. What strategies are suited to a developing country that seeks to establish a sustainable domestic pharmaceutical industry? Should it rely on cheap exports or go for import substitution? If yes, then what policies are needed to complement import substitution that provides impetus to local and foreign entrepreneurs to invest in pharmaceutical manufacture? This paper aims to answer these questions by exploring the policies adopted by the Indian government since 1947 that have revamped its pharmaceutical sector since then. From being a nation dependent upon imports to becoming 'the pharmacy of the world' India has come a long way. I have discussed the evolution of pharmaceutical industry in 4 phases. The phases are chosen so as to coincide with important legal or political development that cusp the pharmaceutical sector. As the years 1970, 1991 and 2005 (for reasons discussed later in this paper) are determinative and definitive of the fate of the pharmaceutical industry in

India, I have chosen them to be the turning points for my analysis. The discussion on phase wise development of pharmaceutical sector is followed a section giving an overview of general policies relating to bank credits, taxation and small and medium industries that have impacted its growth.

1. PHASE 1: FROM 1947 TO 1970

When the Industrial Policy Resolution was promulgated in 1956 industries were divided into three categories. Category A was reserved exclusively for government; In Category B both State and private enterprises were allowed and Category C was primarily meant to be developed by the private sector. As per this policy the pharmaceutical industry was put in category B where both State and private participation were allowed. Primarily there were four types of players in Pharmaceutical Industry during that period which is the foreign subsidiaries, joint ventures of foreign pharmaceutical firms with Indian partners, Indian enterprises and Public sector undertakings. However, post independence the pharmaceutical sector in India was dominated by the presence of foreign firms and their products (Ramachandran, P.K. and Rangarao, 1972). India was import dependant (Greene, 2007). This was primarily due to lack of technological knowhow and the patents on medicines under were permitted under 'The Indian Patents And Designs Act, 1911'. As the patents were held mainly by foreign companies and bulk drugs imported from other countries the drug price in India was among the highest in the world.(Kamble et al., 2012) (Ghosh, 2019). The Indian government tried to solve the problem by stepping in the industry itself and establishing public sector enterprises like Hindustan Antibiotics in 1954 and Indian Drugs and Pharmaceuticals Ltd in 1961 to manufacture special pharmaceutical products with main objectives of creating self-sufficiency in respect of essential life saving medicines, to free the country from dependence on imports and to provide medicines to the millions at affordable prices and not to make millions from the medicines.[1] To achieved this the technology was imported. While United Nations International Children's Emergency Fund ['UNICEF'] and World Health Organisation ['WHO'] provided the technology to Hindustan Antitbotic Limited for manufacturing 'Penicillin' the then Union of Soviet Socialist Republics ['USSR'] provided basic technologies for manufacturing certain other drugs, supplied plant and machinery and helped start operations at Indian Drugs and Pharmaceuticals Ltd. The first drug

price control order was also imposed during this period in the wake of Indo China war in 1963. Subsequently, concerted policy and legislative actions were taken to break the monopoly of foreign players and make the medicines affordable by stressing on self-reliance through local production in phase 2.

2. PHASE 2: FROM 1970 TO 1990

The major bottleneck that prevented the small Indian firms from expanding their manufacturing capability was the product patents for medicines. This was sought to be done away with on the basis of recommendations of the Ayyangar committe report[2]. The provisions of the Indian Patents and Designs Act, 1911 in so far as they pertained to patents were repealed by enacting Patents Act, 1970[3] and Section 5 of the 1970 Act forbade product patents for food, medicines while allowing process patents for the same. This allowed for drugs to be reverse engineered and promoted small scale manufacturers to produce formulations. Indigenous production was further expanded by clipping the wings of foreign firms under the stringent provisions of Foreign Exchange Regulation Act, 1973. The Hathi Committe, 1975 in its report had observed that despite small scale manufacturers, a large number of bulk drugs were imported and it therefore recommended incentivising local manufactures.[4] However, the committee did not recommend nationalization of pharmaceutical industry but recommended that foreign shareholding be reduced from 40% to 26%. The Drugs Policy, 1978 which was based on the recommendations of the Hathi Commission incentivized Indian drug manufacturers by relaxing the provisions of the licensing policy, and by imposing conditions on foreign-controlled firms to ensure that they created linkages within the economy. (Dhar & Rao, 2002). The changes specifically made are:

> Indian enterprises were given two major incentives. First, these enterprises were allowed to produce formulations up to 10 times the value of bulk drugs. The Indian drug manufacturers were thus allowed to produce a relatively higher proportion of non-basic drugs in a regime that laid emphasis on the production of bulk drugs. Further, to encourage consumption of indigenously produced bulk drugs, only such formulation capacity was sanctioned in which the formulation turnover was based on a ratio of 2:1 between indigenous bulk drugs and imported bulk drugs. Foreign firms on the other hand faced relatively tighter controls in respect of their expansion in production of formulations. Three conditions were imposed on the foreign drug firms

intending to expand their operations in India. These were: (i) the ratio between production of bulk drugs and formulations allowed in their output mix was 1:5, as against 1:10 allowed to the Indian firms; (ii) licences to foreign firms were provided only if the firms agreed to supply 50 per cent of their production of bulk drugs to non-associated formulators; and (iii) foreign firms producing formulations based on imported bulk drugs and intermediates had to start manufacturing from the basic stage within two years. The policies in respect of the foreign firms were thus aimed at utilizing the strengths of these firms for creating linkages within the industry for fostering an increase in downstream capacities.(Dhar & Rao, 2002)

3. PHASE 3: FROM 1991 TO 2005

The year 1991 signifies a dramatic shift in economic and fiscal landscape of India. Due to balance of payment crisis India undertook to implement structural reforms (World Bank Report No. 9412-IN) and liberalise its economy (Basu D and Miroshnik V, 2016). The New Economic Policy, 1991 marked a momentous shift in dismantling the license Raj. The Industrial licensing was abolished for all new, expansion, and diversification projects regardless of size, except in 18 designated industries. It is noteworthy that "Drugs & Pharmaceuticals" was one of those designated industries that still required a compulsory license. However, in 1994 industrial licensing for all bulk drugs and their formulations and for intermediates stood abolished except for the five bulk drugs and products produced by re-combinant DNA technology[5].Even those five drugs were delicensed and taken out of the purview of the Industries (Development and Regulation) Act in 1999. [6] Other factors that boosted the manufacturing capacities and contributed to the development of pharmaceutical sector in India are:

3.1. Capital inflows through Foreign Direct Investment in Pharmaceutical Industry, since 1991:

With the adoption of New Economic Policy, 1991 foreign direct investment in pharmaceutical was permitted. The limits of foreign direct investment in pharmaceutical sector have increased over a period of time. As per the current Indian FDI policy, 2020,[7] 100% Foreign Direct Investment is allowed in pharmaceutical sector in both 'Greenfield' and 'Brownfield' projects. However, under Brownfield only 74 % is under automatic route

and beyond that government route[8] but there are other general conditions that apply in both Greenfield and Brownfield FDI relating to essential medicines. The FDI inflow in pharmaceutical sector during the past 3 years has been as following:

Year	***Amount in Indian Rupees in Crores (in US$ Million)***
2018-19 (April – March)	1,842 (266)
2019-20 (April – March)	3,650 (518)
2020-21 (April – September	2,715 (367)
Cumulative Sector- wise FDI equity inflows (from April, 2000 to September, 2020)	**90,529 (16,868)**
% age to total Inflows (In terms of US$)	**3%**

[Source: Department for promotion of industry and internal trade, Government of India][9]

3.2. Foreign Portfolio Investment since 1993

As per SEBI (Foreign Portfolio Investors) Regulations, 2019[10]foreign portfolio investors are categorised into two types. Category I: Includes "Government and Government related investors such as central banks, **sovereign wealth funds**, international or multilateral organizations or agencies including entities controlled or at least 75% directly or indirectly owned by such Government and Government related investor(s); **Pension funds and university funds**; Appropriately regulated entities such as insurance or reinsurance entities, banks, asset management companies, **investment managers, investment advisors, portfolio managers,** broker dealers and swap dealers; Entities from the Financial Action Task Force member countries which are appropriately regulated funds; unregulated funds whose investment manager is appropriately regulated and registered as a Category I foreign portfolio investor: Provided that the investment manager undertakes the responsibility of all the acts of commission or omission of such unregulated fund; university related endowments of such universities that have been in existence for more than five years;" [11] Category II includes "endowments and

foundations; charitable organisations; corporate bodies; family offices; Individuals; appropriately regulated entities investing on behalf of their client, as per conditions specified by the Board from time to time**; Unregulated funds in the form of limited partnership and trusts;"**

They can invest only in listed securities.[12] In case they invest in unlisted holdings then the same is treated as Foreign Direct Investment and Foreign Portfolio Investment.[13]As per fortnightly data latest for 15 January, 2021 the Foreign Portfolio investment in pharmaceuticals and biotechnology is as under

[amount is in Indian Rupees in Crores]

Equity	**Debt**	**Debt VRR**	**Hybrid**	**Total**
1,66,625	0	0	0	1,66,625

[Source: NSDL[14]]

3.3. Drugs and Pharmaceutical Research Programme since 1994

Soft Loan for Pharmaceutical Industrial research and development projects are made available by the government at concessional rate of 70% of the project cost at a simple interest of 3% on reducing amount. Repayment is to be done in 10 annual equal instalments after the project period. Interest during the implementation period will be amortized and will be payable in maximum of 5 instalments after the project period along with the instalment of principal amount.[15]

3.4. Schemes by Technology Development Board since 1995

The Technology Development Board provides financial assistance to Indian industrial concerns and other agencies, attempting development and commercial application of indigenous technology, or adapting imported technology to wider domestic applications.[16] The Fund receives the proceeds from Research and Development Cess on the import of technology imposed under The Research & Development Cess Act, 1986.[17]

The mode of financial assistance is one of the following:

- Loan @ 5% simple annual interest; (upto 50% of the project cost);

- Equity; (upto 25% of the project cost); and
- Grant; (specially in the projects having national importance).[18]

In past it has given assistance to healthcare and pharmaceutical sector.[19] A scrutiny of agreements from 2016 to 2020 show that Technology Development Board has unrelentingly supported pharmaceutical and medical device manufacturing by entering into the finance/loan agreements with following :

- M/s DiabetOmics for development of three point-of-care tests for # Diabetes 1 & 2 and # Pre-eclampsia[20]
- M/s Iatome for portable #X-Ray machine for multi-purpose investigations[21]
- M/s. Renalyx Health Systems Private Limited, Bangalore for financial assistance for "Development of an affordable connected Haemodialysis Machine for Rural Public Health Centres".[22]
- M/s Shree Coratomic Limited, Pithampur (M.P.) for Manufacturing of 50 IRS units (critical component of Cochlear Implant system) for supplying to DEBEL, DRDO for clinical trials"[23]
- M/s OmniActive Health Technologies Limited, Mumbai for Establishing Commercial Plant using Congealing Technology to produce Lutein and other Carotenoids[24]
- M/s Panacea Medical Technologies Pvt. Ltd., Bangalore for IMRT/IGRT based Treatment Planning System (TPS) for 6MV Medical LINAC[25]
- M/s Mobilexion Technologies Pvt. Ltd, Thiruvanthapuram for "Development and Commercialization of Ubimedique Acute Care System (UCMAS)"[26]
- M/s Incredible Devices Pvt. Ltd., Chandigarh for "Development and Commercialization of Catheter Reprocessing System (C.R.S)"[27]
- M/s MSV Laboratories Pvt. Ltd[28]
- M/s Panacea BiotecPvt Ltd, New Delhi to complete the late stage development of first Indian Dengue Vaccine[29]
- M/s Epygen Biotech Pvt. Ltd, Navi Mumbai for 'Epygen Phase I Funding[30]
- M/s Yashraj Biotechnology Limited, Mumbai[31]
- QuNu Labs Pvt Ltd, Bengaluru[32]

- M/s Medzome Life Sciencez Pvt. Ltd. , New Delhi[33]

Ministry of Commerce and Industry, Government of India has established Pharmaceuticals Export Promotion Council of India to harmonise pharmaceutical exports from India.[34] It has various schemes that provide technical and financial assistance for export related activities. I have listed some of the features of the schemes that provide financial assistance:

3.5. Market Development assistance scheme since 2001[35]

Under this scheme financial assistance is provided for Marketing Projects Abroad, capacity building, support for statutory compliances, conducting studies and project development. Individual exporters are eligible for support for statutory compliances which includes:

- **Charges/expenses for fulfilling statutory requirements in the buyer country including Registration charges for product registration abroad for select priority product group**: On **Reimbursement basis** to individual exporters for charges/fees paid by an Indian exporter for fulfilling the statutory requirements in the buyer country e.g. registration charges paid in case of pharmaceuticals, bio-technology and agrochemical products. Includes the following

- Expenses made for carrying **out clinical trials; data validation** etc. for pharmaceutical products, equipments, medical consumables/disposables etc. shall also be covered for assistance.
- Level of Assistance: For statutory charges/expenses on statutory compliances of the products allowed by the Empowered Committee, assistance under the Scheme would be **50% of the charges/expenses** and the total ceiling for each exporter shall be **Rs.50 lakhs per annum.**[36]

- **Testing charges for engineering products abroad:** Under the Scheme, the assistance at the rate of 50% of the testing charges will be provided subject to the condition that an exporter can apply for maximum five tests in a year and the total ceiling for each exporter would be Rs.10 lakhs per annum.

- **Anti Dumping, Anti Money Laundering and other investigations/ compliances**: Assistance for contesting litigation (s) in the foreign country concerning restrictions/anti dumping duties/Anti Money laundering Law compliances etc. on particular product (s) of Indian origin shall be provided under the scheme. The support shall not exceed 50% of the actual expenditure subject to an upper ceiling of Rs.200 lakhs in each case.

Total assistance provided under this scheme for product registration to pharmaceutical companies is as follows:

	Total assistance (In INR)
2018-2019	22,00,67,290[37]
2017-2018	Data not available
2016-2017	19,06,64,102[38]
2015-2016	14,87,59,331[39]
2014-2105	2,54,65,801.00[40]

[Source: PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA][41]

3.6. Market Access Initiatives (MAI) Scheme since 2003:

Assistance is provided to exporters for export promotion activities abroad by participation in Export Promotion Council etc. led Trade Delegations/BSMs/Trade Fairs/ Exhibition by way of travel expenses by air and expenses on stall.[42]

4. PHASE 4: FROM 2005 TILL DATE

To meet its international obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights which forms part of the Agreement establishing the World Trade Organisation, India had to amend its Patent Law in 2005 and grant patents for drugs and pharmaceuticals once again. It was rightly speculated by many scholars that patents on medicines might lead to increased consumer prices for the drugs due accumulation of patents by pharmaceutical firms, coercive bargaining, hold-up effects, and unfair terms in license agreements and cooperative licensing aimed to curb competition (Sampath, 2005). However, the Indian Government has tread cautiously in wake of product patent regime and refocused

on the need to innovate domestically and provide incentives to domestic firms that can compete with global giants in open market. In this regard some of the notable schemes of the Government are:

4.1. Schemes by Biotechnology Department since 2008:

The Department of Biotechnology has set up Biotechnology Industry Research Assistance Council to empower the emerging Biotech enterprises to undertake strategic research and innovation, addressing nationally relevant product development needs.[43] It provides assistance at various stages of product development including from the incubation to commercial launch of product. Some of the flagship programs are:

4.1.1. *Bioincubators Nurturing Entrepreneurship For Scaling Technologies ('Bio-Nest'):*

Incubation space is provided to innovators to test their ideas, run their operations, have access to high end instrumentations and locate in a place where they connect with other start ups and mentors.[44]

4.1.2. *Biotechnology Ignition Grant Scheme (BIG):*

The innovators receive up to INR 50 lakh for research projects with commercialization potential with duration of up to 18 months.[45]

4.1.3. *Biotechnology Industry Partnership Programme (BIPP):*

It supports the development of appropriate technologies in the context of recognized national priorities. Proposals are invited under 7 broad themes: a.) Drugs including drug Delivery, b.) Vaccines and clinical trials, c.) Biosimilars & stem cells, d.) Devices & Diagnostics, e.) Agriculture, f.) Industrial Biotechnology including Secondary Agriculture and g.) Bioinformatics & facilities that virtually cover every aspect of Biotechnology. Biotechnology Industry Partnership Programme is an advanced technology scheme only for high risk, transformational technology/ process development. It is for high risk futuristic technologies and mainly for viability gap funding.[46]

4.1.4. *The Small Business Innovation Research Initiative (SBIRI)***:**

It provides early stage funding for high risk innovative research in small and medium companies led by innovators with science backgrounds to get them involved in

development of products and processes which have high societal relevance.[47] The assistance to a start-up will be up to INR 7 crores against equity.[48]

4.1.5. *Accelerating Entrepreneurs (ACE) Fund*

It is equity "Fund of Fund" exclusively for Biotech Start-ups. ACE daughter funds are registered with Securities and Exchange Board of India as private funds. They invest equity in start-ups for providing the risk capital to undertake innovation, research and product development.[49]

4.2. Schemes by Department of Pharmaceuticals

4.2.1. Assistance to Pharmaceutical Industry for Common Facilities, 2014

To improve the infrastructural facilities, environmental compliance and improve waste management within a pharma manufacturing cluster, the scheme proposes to set up common facilities centre which will include Common Testing Centres, Training Centres, R&D Centres, Effluent Treatment Plants, Common Logistics Centres. Maximum limit for the grant in aid under this category would be Rs 20.00 crore per cluster or 70% of the cost of project whichever is less. [50]

4.2.2. Pharmaceutical Technology Up gradation Assistance Scheme, 2014

This scheme is intended for Small and Medium Pharma Enterprises so that they may be able to upgrade their plant and machinery to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards. [51] Assistance is in the form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution both in Public and Private sector will be provided to 250 Small and Medium Pharma Enterprises of proven track record. The upper limit of interest subvention on loans for technology/ infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 crore, availed by the concerned small and medium enterprises for purpose of upgradation to WHO-GMP norms. [52]

Total Budgetary allocation: Rs 144 crore.

The Budget expenditure on select schemes is as follows[53]:

Budget Expenditure: 2020-21 (in Indian Rupees in Crores)				
Name of Scheme	**Actual 2019-20**	**BE 2019-20**	**RE 2019-20**	**BE 2020-21**
Cluster Development	2.23	6.23	2.23	12.00
Pharmaceuticals Technology Up gradation Assistance Scheme(PTUAS)	0.00	0.02	0.02	0.02
Assistance to Bulk Drug Industry for Common Facilitation Centre	0.00	0.02	0.02	21.52
Development of Pharmaceuticals Industry (North Eastern Region) (MH 2552)	0.00	0.01	0.01	0.01

[Source: Department of Pharmaceuticals]

4.2.3. Production Linked Incentive Scheme for promotion of domestic manufacturing of critical Key Starting Materials/ Drug Intermediates and Active Pharmaceutical Ingredients In India, 2020

[Financial Year 2020-21 to Financial Year 2029-30]

The scheme was launched vide notification dated 21st July, 2020 of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers to reduce dependence upon the import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. 53 critical APIs were identified for the purpose of the schemes that are intended to be now domestically produced. However, the scheme is limited only to Greenfield projects. Under the Scheme, financial incentives shall be given for six years based on sales made by selected manufacturers for 41 products (the list of 41 products cover all the identified 53 APIs). The rates of financial incentive are:

- For fermentation based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%.
- For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%.[54]

The total financial incentives amount to Rs. 6,940 crore.

4.2.4. Scheme for Promotion of Bulk Drug Parks, 2020[55]

[FY 2020-2021 to FY 2024-2025]

The financial assistance under the Scheme will be provided for creation of common infrastructure facilities in three Bulk Drug Parks proposed by State Governments and selected under the scheme. Financial assistance to a selected Bulk Drug Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost[56]. Common facilities include: central effluent treatment plant, solvent recovery and distillation plant, steam generation and distribution system, common cooling system and distribution network, common logistics facilities, advance laboratory testing centre, emergency response centre, centre of excellence. [57]

Maximum assistance under the scheme for one Bulk Drug Park would be limited to Rs. 1000 crore. Total assistance is Rs 3000.

4.3. Merchandise Exports from India Scheme, 2015

[Under the Foreign Trade Policy 2015-2020]

The Pharmaceutical Products exported to both category A and B countries have 3% reward.[58] Export of goods through courier or foreign post office, as notified in Appendix 3C, of FOB value upto Rs 5,00,000 per consignment shall be entitled for rewards under MEIS.[59] If the value of exports is more than Rs 5,00,000 per consignment then MEIS reward would be calculated on the basis of FOB value of Rs 5,00,000 only.[60] The duty credit scrips so generated as rewards are freely transferable and can be used for:

" (i) **Payment of Basic Customs Duty** and Additional Customs Duty specified under sections 3 (1), 3 (3) and 3 (5) of the Customs Tariff Act, 1975 for import of inputs or goods, including **capital good**s, as per DoR Notification, except items listed in Appendix 3A.

(ii) **Payment of Central excise duties on domestic procurement** of inputs or good

iv) Payment of Basic Customs Duty and Additional Customs Duty specified under Sections 3 (1), 3 (3) and 3 (5) of the Customs Tariff Act, 1975 and fee as per paragraph 3.18 of this Policy."[61]

Please note that the scheme has been withdrawn w.e.f 1st January, 2021.[62] It was held by WTO dispute settlement panel not to be in compliance with WTO's Agreement on Subsidies & Countervailing Measures.[63]In *"India- Export related measures*" cases[64], by US the panel held that Merchandise Exports from India Scrips do not meet the conditions of the Agreement on Subsidies and Countervailing measures.[65] It was held by the panel that, "the duty credit scrips awarded under MEIS are subsidies contingent upon export performance, inconsistent with Articles 3.1(a) and 3.2 of the SCM Agreement."[66]

Please also note that other schemes including .the Export Oriented Units (EOU) Scheme and Sector-Specific Schemes, including the Electronics Hardware Technology Parks (EHTP) Scheme and the Bio-Technology Parks (BTP) Scheme (the EOU/EHTP/BTP Schemes) have been held to be not in compliance with SCM agreement.

4.4. Remission of Duties and Taxes on Exported Products, 2021:

It has been introduced as a replacement to MEIS to refund the embedded duties suffered in export goods. [67]Instead of reward system under MEIS it aims to refund actucal duties. "The RoDTEP scheme would refund to exporters the embedded Central, State and local duties/taxes that were so far not being rebated/refunded and were, therefore, placing our exports at a disadvantage. The refund would be credited in an exporter's ledger account with Customs and used to pay Basic Customs duty on imported goods. The credits can also be transferred to other importers."[68]

5. OTHER POLICIES

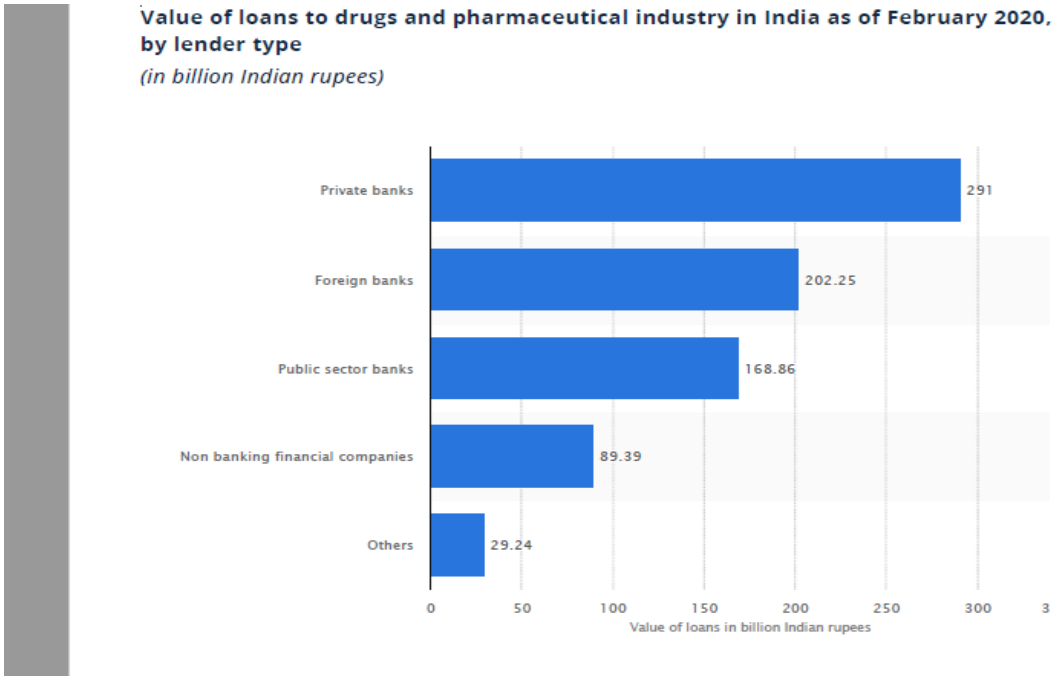
5.1. Bank Credit:

Bank credit is required to meet the working capital requirement and even expansion of industry into new product segments. Banks offer current account facility, short and long term loans, letters of credit, and bridge financing facilities. Loans can also be taken from foreign banks and financial institutions as "External Commercial Borrowings".[69]

As per RBI data, the bank credit collected from select 33 scheduled commercial bank for pharmaceutical sector is as follows[70]:

Statement 2: Industry-wise Deployment of Gross Bank Credit										
(Rs.crore)										
							Variation (Year-on-Year)		Variation (Financial Year)	
Sr. No	Industry	Nov. 23, 2018	Mar. 29, 2019	Nov. 22, 2019	Mar. 27, 2020	Nov 20, 2020	Nov.22, 2019 / Nov.23, 2018	Nov.20, 2020 / Nov.22, 2019	Nov.22, 2019 / Mar.29, 2019	Nov.20, 2020 / Mar.27 2020
							%	%	%	%
	Drugs & Pharmaceuticals	50814	50500	48501	53427	48875	-4.6	0.8	-4.0	-8.5

[Source: Reserve Bank of India] [71]



[Source: Statista Research Department][72]

As per Industry Spotlight report on Indian Drugs & Pharmaceutical Industry (September, 2020) by Small Industries Development Bank of India "Public sector banks are the largest contributors in providing finance to the drugs and pharmaceutical industry with a share of 36.8% in volume as of Feb 2020, followed by private banks (35.4%), NBFCs (16.5%), foreign banks (8.1%) and others (3.0%)."[73]Further in terms of value, 68% of loan went to large corporates while only 23% went to Micro and Small Medium Enterprises.[74]

5.2. Special Incentives to Micro Small and Medium Enterprises

A micro enterprise is one where the investment in Plant and Machinery or Equipment does not exceed one crore rupees and turnover does not exceed five crore rupees; a small enterprise, where the investment in Plant and Machinery or Equipment does not exceed ten crore rupees and turnover does not exceed fifty crore rupees; a medium enterprise, where the investment in Plant and Machinery or Equipment does not exceed fifty crore rupees and turnover does not exceed two hundred and fifty crore rupees.[75] A plethora of schemes[76] have

been launched by Ministry of Micro and Small Medium Enterprises to provide infrastructural and financial assistance to them. Some of them are:

5.2.1. Micro & Small Enterprises Cluster Development:

The Ministry of Micro and Small Medium Enterprises has adopted cluster development approach for enhancing productivity and competitiveness as well as capacity building of Micro and Small Medium Enterprises. The Scheme supports financial assistance for establishment of Common Facility Centres for testing, training centres, Research and development, Effluent Treatment, raw material depot, complementing production processes etc. and to create/upgrade infrastructural facilities in the new/existing industrial areas/clusters of Micro and Small Medium Enterprises such as power distribution network, water, telecommunication, drainage and pollution control facilities, roads, banks, raw materials, storage and marketing outlets, common service facilities and technological backup services for Micro and Small Medium Enterprises in the new/ existing industrial estates/areas.[77]

5.2.2. *Credit Linked Capital Subsidy for Technology Upgradation*:

15% subsidy for additional investment up to ₹ 1 cr for technology upgradation by Micro and Small Medium Enterprises is provided.

5.3. Tax benefits:

The Income Tax Act, 1961 provides various rebates and deductions to entities engaged in research activities. Some of the notable sections of particular relevance to pharmaceutical sector are:

5.3.1. Development rebate under Section 33 for acquisition of new machinery/plant.

5.3.2. Deduction for expenditure on scientific research under Section 35

5.3.3. Deduction to Indian Companies in respect of profits retained for export business [Section 80 HHC]:

In computing the total income of the assessee, a deduction to the extent of profits derived by the assessee from the export of such goods or merchandise is permitted.

5.3.4. Area based exemptions:

from paying central excise (and now refund of GST)[78] were available to hilly states and State of Jammu and Kashmir. This has led to proliferation of pharma clusters in Baddi in Himachal, Ponta Sahib in Uttrakhand and Sikkim.

CONCLUSION:

The Government of India to boost the expansion of Indian pharmaceuticals industry and to ensure the availability of drugs in the country at reasonable prices and further to promote research and development has taken various initiatives towards that end. While the Central government also has five public sector enterprises[79], for manufacturing pharmaceuticals only of them i.e. Karnataka Antibiotic & Pharmaceuticals Limited is the only profit making rest are in losses. Also as the public sector enterprises cannot meet the pharmaceutical demands of a large population, therefore the Government of India has supported a private domestic industry by providing direct financial assistance, indirect support through tax concessions and infrastructural support through capacity building. The Central Government routes its financial assistance to pharmaceutical sector through the Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers, Department of Biotechnology under the Ministry of Science and Technology, Technology Development Board, Department of Science and Technology. The Indian experience is a testament to the fact that the support of government is crucial to the development of indigenous pharmaceutical industry. The lacks of patents augur well to the growth of domestic players and gives them necessary manufacturing experience before venturing into new products.

References

Dhar, B., & Rao, C. N. (2002). *Transfer of Technology for Successful Integration into the Global Economy: A Case Study of the Pharmaceutical Industry in India*. https://unctad.org/en/Docs/iteipcmisc22_en.pdf

Ghosh, P. K. (2019). Government ' s Policies and Growth of Pharmaceutical Industry in India 1947-2018 : A Review. *Research and Information Systems for Developing Countries*. http://ris.org.in/sites/default/files/Publication File/DP 236 P K Ghosh DP-min.pdf

Greene, W. (2007). The Emergence of India ' s Pharmaceutical Industry and Implications for the U . S . Generic Drug Market The Emergence of India ' s Pharmaceutical Industry and Implications for the U . S . Generic Drug Market. *U.S. International Trade Commission*, 36.

Kamble, P., Ghorpade, S., Kshirsagar, R., & Kuchekar, B. (2012). Progress of the Indian pharmaceutical industry: a shifting perspective. *Journal of Intellectual Property Law & Practice*, *7*(1), 48–51. https://doi.org/10.1093/jiplp/jpr177

Ramachandran, P.K. and Rangarao, B. V. (1972). The Pharmaceutical Industry in India. *Economic and Political Weekly*, *7*(9), 27–36. https://doi.org/10.1111/j.1747-1796.1999.tb00056.x

Sampath, P. G. (2005). Economic Aspects of Access to Medicines after 2005 : United Nations University-INTECH. *Access*, *May*, 1–111.

World Bank, Report No. 9412-IN, *India 1991 Country Economic Memorandum* available at http://documents1.worldbank.org/curated/en/962181468033534646/pdf/multi0page.pdf.

---

[1] http://www.idplindia.in/about.php
[2] http://www.delhihighcourt.nic.in/library/reports/Rajagopala_Ayyangar_Report_Report_on_patent_law.pdf.
[3] Section 162, Patents Act, 1970.
[4] Hathi Committee Report (1975), 104-107.
[5] Press Note No.4(1994 Series) dated 25.10.94 issued by the Ministry of Industry.
[6] PRESS NOTE NO.3 (1999 SERIES), Government of India, Ministry of Industry, Department of Industrial Policy & Promotion, available at https://dipp.gov.in/sites/default/files/pn13_0.pdf.
[7] https://dipp.gov.in/sites/default/files/FDI-PolicyCircular-2020-29October2020_0.pdf.
[8] *Id.* Paragraph 5.2.27, pages 65-68.
[9] https://dipp.gov.in/sites/default/files/FDI_Fact_sheet_September_20.pdf.
[10] Available at https://www.sebi.gov.in/legal/regulations/sep-2019/securities-and-exchange-board-of-india-foreign-portfolio-investors-regulations-2019_44436.html.

[11] Regulation 5, SEBI (Foreign Portfolio Investors) Regulations, 2019.
[12] Regulation 20 (1)(a), SEBI (Foreign Portfolio Investors) Regulations, 2019.
[13] Proviso to Regulation 20 (4) (d) (x), SEBI (Foreign Portfolio Investors) Regulations, 2019.
[14]https://www.fpi.nsdl.co.in/web/StaticReports/Fortnightly_Sector_wise_FII_Investment_Data/FIIInvestSector_Jan152021.html.
[15] https://www.startupindia.gov.in/content/sih/en/government-schemes/drugandpharma_research.html.
[16] http://tdb.gov.in/.
[17] http://tdb.gov.in/downloads/.
[18] http://tdb.gov.in/modes-financial-assistance/.
[19] From 1997 to 2014, 79 projects in healthcare sector has been provided assistance. The details of the approved projects are available at http://tdb.gov.in/wp-content/uploads/2017/02/Health-projects.pdf.
[20] http://tdb.gov.in/agreement-2016-2017/.
[21] *Id.*
[22] *Id.*
[23] http://tdb.gov.in/agreements-2017-2018/.
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] http://tdb.gov.in/agreements-2018-19/.
[31] http://tdb.gov.in/agreements-2019-2020/.
[32] http://tdb.gov.in/agreements-2020-2021/.
[33] *Id.*
[34] https://pharmexcil.com/.
[35] https://pharmexcil.com/v1/docs/MDA/mai_guide_2007.pdf.
[36] Para 7.3.1 of the REVISED MARKET ACCESS INITIATIVE (MAI) SCHEME, Ministry of Commerce And Industry Department of Commerce, E&MDA Section dated 4th Jan, 2007 available at https://pharmexcil.com/v1/docs/MDA/mai_guide_2007.pdf.
[37] https://pharmexcil.com/data/uploads/MAIPRFEE201819.pdf
[38] https://pharmexcil.com/data/uploads/MAIBeneficaries201617.pdf.
[39] https://pharmexcil.com/data/uploads/MAIBeneficaries201516.pdf.
[40] https://pharmexcil.com/uploadfile/ufiles/MAI_2014-2015.pdf.
[41] https://pharmexcil.com/relevent-members-forms.
[42] https://pharmexcil.com/v1/docs/MDA/MDA_April2006.pdf.
[43] https://www.birac.nic.in/desc_new.php?id=89.
[44] https://www.birac.nic.in/bionest.php.
[45] https://www.birac.nic.in/big.php.
[46] https://www.birac.nic.in/desc_new.php?id=216.
[47] https://www.birac.nic.in/desc_new.php?id=217
[48] *Id.*
[49] https://www.birac.nic.in/aceFund.php.
[50] https://pharmaceuticals.gov.in/sites/default/files/Cluster%20Development%20Scheme.pdf.
[51]https://pharmaceuticals.gov.in/sites/default/files/Pharmaceutical%20Technology%20Upgradation%20Assistance%20Scheme%20%28PTUAS%29.pdf.
[52] *Also see* Annual Report, 2019-2020, Department of Pharmaceuticals available at https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf.
[53] https://pharmaceuticals.gov.in/sites/default/files/Budget%20Expenditure.pdf.
[54] *Id. See* paragraph 4 of the scheme on Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates(DIs) and Active Pharmaceutical Ingredients (APIs) In India, No. 31026/16/2020. (CG-DL-E-21072020-220616 dated 21st July, 2021).

[55] Scheme for Promotion of Bulk Drug Parks, vide notification dated 21st July, 2021 available at https://plibulkdrugs.ifciltd.com/docs/Gazettee%20notification%20of%20bulk%20drug%20schemes.pdf, 13-14.
[56] *Id,* Paragraph 4.
[57] *Id,* Paragraph 5.
[58] See Appendix 3B, MEIS Schedule Table 2,ITC (HS) code wise list of products with reward rates under Merchandise Exports from India Scheme (MEIS) available at http://dgftcom.nic.in/Exim/2000/PN/PN15/pn0215.pdf, P 78-85.
[59] Chapter 3, Exports from India Schemes, *Foreign Trade Policy 2015-2020.* Available at https://content.dgft.gov.in/Website/FTP%20Chapter%203%20as%20on%20June%2030%202019.pdf.
[60] *Id. Para 3.05.*
[61] *Id. Para 3.02.*
[62] https://www.indiantradeportal.in/vs.jsp?lang=0&id=0,25,857,3901.
[63] https://www.indiatoday.in/business/story/wto-rules-against-india-s-export-subsidies-all-you-need-to-know-1614635-2019-11-01.
[64] WT/DS541/R. Report of panel available at https://www.wto.org/english/tratop_e/dispu_e/541r_e.pdf.
[65] Id. P 69.
[66] *Id.* P 111.
[67] https://fieo.org/uploads/files/file/Final%20Press%20Release%20RoDTEP_V1_4(1).pdf.
[68] *Id.*
[69] Foreign Exchange Management (Borrowing and Lending) Regulations, 2018, para 2 (iv) defines "External Commercial Borrowings (ECB)" as borrowing by an eligible resident entity from outside India in accordance with framework decided by the Reserve Bank in consultation with the Government of India.
[70] https://www.rbi.org.in/Scripts/BS_PressReleaseDisplay.aspx?prid=50891
[71] https://rbidocs.rbi.org.in/rdocs/PressRelease/PDFs/PR8650E9CECE0CF8140A285C2159DCA50C3D3.PDF.
[72] https://www.statista.com/statistics/1179061/india-value-of-loans-to-drugs-and-pharmaceutical-industry-by-lender-type/.
[73] SIDBI and CRII Report, Industry Spotlight report on Indian Drugs & Pharmaceutical Industry (September, 2020) pg 5 available at https://www.sidbi.in/files/article/articlefiles/CRIF-Industry-Spotlight-Vol-I-Drugs-Pharmaceutical-Industry.pdf.
[74] *Id.* P 8.
[75] Notification dated 1st June, 2020, *Ministry of Small, Micro and Medium Enterprises,* CG-DL-E-01062020-219680 available at https://msme.gov.in/sites/default/files/MSME_gazette_of_india.pdf.
[76] http://www.dcmsme.gov.in/SAMACHAR/eBook%20of%20Schemes%20for%20MSMEs.pdf.
[77] https://msme.gov.in/infrastructure-development-program
[78] https://www.cbic.gov.in/resources//htdocs-cbec/excise/area-baesd-exemption/Annex-E-GST_Gazette_Nofication-circular.pdf
[79] ANNUAL REPORT OF DOP 2019-20, available at https://pharmaceuticals.gov.in/sites/default/files/UPDATED%20ANNUAL%20REPORT%20OF%20DOP%202019-20.pdf. [Five CPSEs are Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL) and Karnataka Antibiotic & Pharmaceuticals Limited (KAPL)] .

Addendum 5

BACKGROUND RESEARCH ON FINANCING ACTIVITIES OF THE AFRICAN UNION AND OTHERS FOR LOCAL PRODUCTION OF DVT

Addendum Report

7th February 2021

RAJASHRI SEAL

Prepared for the Open Society Foundations – Public Health Program

Nova Worldwide Consulting®

Background

The 2012 business plan of the Africa Union's Pharmaceutical Manufacturing Plan for Africa ('PMPA') states that:

> This Business Plan does not represent a source of funding for public or private sector players but is a package of technical assistance which countries can access. Initial discussions with the World Bank have suggested that there could be interest in supporting investment in, for example, National Medicines Regulatory Authorities (NMRAs) although ultimately it will be the responsibility of *individual countries* to finance the recommended investments (whether in terms of bricks and mortar or through support to the industry in the form of incentives) (emphasis mine).

There is no specific step with respect to local pharmaceutical production for Covid-19 that specifically flows out of the PMPA. Having said that, the pandemic has demonstrated the urgent need to implement the PMPA by all countries within the African Union ('AU') and the need to harmonise the standards of pharmaceutical products across the AU in line with the Africa Continental Free Trade Area (AfCFTA) plan. While limited yet concrete efforts have been made to achieve the former, decisive steps have been taken to achieve the latter.

While I could not find any funding *specific* to bolster the implementation of the PMPA for pharmaceutical manufacturing for Covid-19 in particular, there have been many responses from the AU to strengthen health systems across Africa and to give an impetus to local manufacturing within the AU, across all sectors. The scope of such interventions has been quite general. Only very few projects directly tackle the question of local manufacture of pharmaceuticals in Africa head-on. Other projects are either not specific or assume that the PMPA will be tackled through trickle-down effects and hence, there is no concerted effort to finance the PMPA through directly tailored interventions.

Covid-19 interventions by the AU and related bodies

This Section will describe the kinds of specific projects that have been implemented by the AU to respond to Covid-19 generally, the scope and purpose for each such project, the main donors/financing sources behind such projects, how they have been utilized so far and how they tie in/relate to the goals of the PMPA, if at all they do.

1. **The AU-Covid Response Fund (with respect to procurement and distribution of essential Covid-19 medical supplies)**:

The African Union and the Africa Centres for Disease Control and Prevention (Africa CDC) launched a public-private partnership with the *AfroChampions Initiative*, known as the Africa COVID-19 Response Fund. The AfroChamps Initiative is a set of public-private partnerships that brings together both business and political figures, and is co-chaired by former South African President Thabo Mbeki and Nigerian businessman Aliko Dangote. The fund aims to raise the following: USD 150m "*to prevent transmission*", USD 170m "*to prevent deaths*", $30m to "*prevent social harm and for crosscutting measures*" (prevention campaigns, supply chain management), and USD 50m for economic support to vulnerable populations.[1]

It aims to raise an initial US$ 150 million for immediate needs to prevent transmission and up to US$ 400 million to support responses to the pandemic by pooling resources required for the procurement of medical supplies and commodities, and so on. Many African countries have already provided seed funding to the Fund including South Africa, the Democratic Republic of the Congo, Egypt, Kenya and Mali. Private sector partners that have signed up e include: *Africa Health Business*, *Global Infectious Disease Services*, *SpeakUpAfrica* or *Talamus Health Incorporated*; African banks such as *Ecobank*, *Standard Bank* and *Equity Bank*; private equity funds such as RH managers; philanthropic organisations like the *Africa Public Health Foundation*; private leaders from the UNDP African Influencers for Development Group.[2]

The AU COVID-19 Response Fund's aim vis-à-vis pharmaceutical in particular, is to support the *procurement* and *distribution* of essential COVID-19 medical equipment and supplies and mobilize rapid response by Member States. Thus, this Fund will support the pool procurement of diagnostics and other medical commodities by the Africa CDC for distribution across the AU Member States.

There have been several other funding initiatives too. While they do *not* deal exclusively with pharmaceutical production, they are nonetheless being listed out here since, ostensibly the primary aim of such grants is to facilitate and strengthen scientific research on Covid-19 prevention and treatment in Africa. Since such projects deal with studying the scientific bases of Covid-19 in relation to the specific demographics across Africa (which knowledge is essential before developing any proper pharmaceutical product), the knowledge generated out of such projects will perhaps indirectly, or even tangentially benefit potential pharmaceutical manufacturing activities in Africa, whenever they take off.

---

[1] https://ecdpm.org/wp-content/uploads/African-regional-responses-COVID-19-discussion-paper-272-ECDPM.pdf
[2] https://www.africanews.com/2020/04/07/coronavirus-africa-african-union-and-african-private-sector-launch-covid-19-response-fund//

i) The *COVID-19 Africa Rapid Grant Fund* was established to address research questions and implement science engagement activities associated with the pandemic, with an initial total funding of approximately USD 4.75million, close to R80 million. The *National Research Foundation* (NRF), supported by *South Africa's Department of Science and Innovation (DSI); Canada's International Development Research Centre (IDRC); the Fonds de Recherche du Québec (FRQ); the Swedish International Development Cooperation Agency (Sida); the United Kingdom's Foreign, Commonwealth & Development Office (FCDO); United Kingdom Research and Innovation (UKRI) through the Newton Fund; and the Science Granting Councils Initiative in Sub-Saharan Africa (SGCI)* participating councils have collaborated and are funding this initiative, which was conceptualised under the SGCI. The fund is administered by the NRF. The fund aims to support knowledge generation and translation to inform diagnostics, prevention and treatment of COVID-19; strengthening of African regional and continental science engagement efforts in response to the pandemic; and leveraging existing and new multilateral collaborations from international partners. The Research Projects are vast and varied. They include studying the genetic and immunologic factors associated with the severity of COVID-19 in different demographic groups and documenting the lessons which have been learnt from previous infectious disease outbreaks in Africa .[3]

ii) The African response to the Covid-19 epidemic (ARIACOV) project was funded by the French Development Agency (AFD) as part of the "Covid-19: initiative Common health". The two-year project aims to support the authorities of Benin, Cameroon, Ghana, Guinea, the Democratic Republic of the Congo and Senegal in the development and strengthening of national response strategies to the epidemic. Being a collaboration between IRD researchers and their partners working in West (Benin, Ghana, Guinea, Senegal) and Central Africa (Cameroon, Democratic Republic of Congo), ARIACOV relies on International Joint Laboratories (LMI), and other collaborative mechanisms developed by the IRD. With funding of 2.2 million euros, it will enable operational research to be deployed over the next 2 years, in three areas: the setting up of multiple activities that combine training, equipment and consumables, to carry out Covid-19 diagnostics on large scales and to allow the carrying out of sero-epidemic surveys in different demographics,through epidemiological field surveys and quantitative data collection methods.[4]

[3] https://www.nrf.ac.za/media-room/news/projects-announced-covid-19-africa-rapid-grant-fund
[4] https://www.ird.fr/ariacov ; https://www.afd.fr/fr/actualites/initiative-covid-19-sante-en-commun-le-financement-des-premiers-projets-en-afrique

2. Africa CDC's Efforts

The Africa Joint Continental Strategy for COVID-19 Outbreak,[5] developed by the AU and Africa CDC of the African Union Commission, is implemented through two major operational units: the Africa Task Force for Coronavirus (AFTCOR), and Africa CDC's Incident Management System.

a) Ramping up local manufacture of PPE/ventilators

The Africa Taskforce for Novel Coronavirus (AFTCOR) was set up as a continental, collaborative response to COVID-19. The supply chain technical working group (TWG) that operates within this mechanism provides guidance and technical support to Member States on COVID-19 preparedness and containment. The TWG undertook to map the producers of PPE on the continent. They found that: a) existing manufacturers of PPE had limited routes to market their products, b) not all countries and their respective national standards organisations had the skills to be able to accredit new PPE producers, c) there existed very limited post market surveillance of PPE standards, both for locally produced PPE as well as imported PPE at the time, and d) there was limited laboratory testing capacity for new manufacturers to test and accredit PPE in Africa.[6] As a response to this, the following happened:

i. The Nigerian government organized a meeting wherein the promotion of manufacturing of PPE was encouraged. One such solution was local production of PPE. The company was initially producing DVDs and then it converted a part of it to produce masks. The *Transgreen O-Care* medical mask was launched in three months. The company obtained financing from Standard Charted Bank in Nigeria to obtain machines for mask production. At present, the company is able to produce 240,000 masks per day but scalable to reach 300,000 masks in a day.[7]

ii. Hawassa Industrial Park (HIP): The HIP was initially geared towards apparel production. However, the pandemic shrunk apparel demand and increased the demand for PPE, which prompted them to shift to PPE production. Support from Ethiopian airlines by bringing in raw materials, duty free imports, and VAT free local sales of PPE policy by the Ethiopian government provided the impetus.

---

[5] https://au.int/sites/default/files/documents/38264-doc-africa_joint_continental_strategy_for_covid-19_outbreak.pdf
[6] https://africacdc.org/download/medical-ppe-production-in-africa-promoting-local-manufacturers-to-support-the-covid-19-response-workshop-report/

[7] https://africacdc.org/download/medical-ppe-production-in-africa-promoting-local-manufacturers-to-support-the-covid-19-response-workshop-report/

iii. South Africa locally produced 20,000 ventilators at an average cost of R 12,500 each for Covid-19 patients. The machines were manufactured under the 'National Ventilator Project' ('NVP') by the state-owned Council for Scientific and Industrial Research (CSIR) and the SA Ventilator Emergency Project (SAVE-P), a consortium of companies. Individual components for the CPAP-ventilator were manufactured by a consortium of industry partners in Gauteng, KwaZulu-Natal and Eastern Cape, including the Central University of Technology and firms such as Black Capital Systems, Andani Futuretech Manufacturing, UV Tooling, Sola Medical, Gabler Medical and Pitchline Engineering. All manufacturing was done for the CSIR. The SAVE-P consortium incorporates manufacturers located in Cape Town, Pinetown, Durban, Midrand, and Alberton, consisting of MCR Manufacturing, Reef Engineering, Bosch, Executive Engineering, Rhomberg Instruments, Dowclay Products, ISO Health SA, Pegasus Steel, NAACAM, AFRIT, Corruseal, New Age Medical Supplies, Aveti and Non-Ferrous Metal Works. The development, production and procurement costs for the 20,000 units were funded through a R250m donation from the Solidarity Fund, at an average cost of R12,500 per unit. The SA Radio Astronomy Observatory (SARAO) was appointed to manage the national effort.[8]

iv. The African Medicines Quality Forum, a technical working group of the African Union Development Agency, is a continental collaborative that helps national quality control laboratories strengthen their capacity for medicinal quality testing and helps to prevent fake and subpar medicines from reaching consumers.[9]

b) Easing procurement and distribution of essential medical supplies

i. The Africa CDC – in collaboration with *Janngo* (a pan-African tech startup), *Afreximbank*, and 20 international partners and foundations launched a pooled digital purchasing platform – the **Africa Medical Supplies Platform** ('AMSP') – to support African governments ordering diagnostics and medical equipment on the global market. Afreximbank will facilitate payments, and logistics partners will expedite delivery. The AMSP will ensure the availability of vetted critical medical supplies at affordable rates. The Africa CDC will be responsible for providing market intelligence regarding reliable manufacturers and will aid the pooled procurement and

[8] https://www.timeslive.co.za/news/south-africa/2020-12-17-sa-made-20000-ventilators-for-covid-19-patients-at-a-cost-of-r250m/
[9] https://www.devex.com/news/sponsored/opinion-africa-led-solutions-to-expedite-access-to-covid-19-vaccines-98720

distribution of products to African nations. The strategic partners include Novartis,[10] UNECA, the Rockefeller Foundation, Mastercard Foundation, the Susan Thompson Buffet Foundation, Virgin Unite, Bill and Melinda Gates Foundation, Higher Life Foundation, Skoll Foundation, The Elma Foundation, Baobab Circle, Vaya Africa Mauritius Limited, UNICEF, WHO, the GAVI Alliance, Microsoft, and the French, Canadian and Chinese governments.[11] The commercial partners include Alibaba Foundation, FedEx, Ethiopian Airlines, South African Airways, Rwand Air, Kenya Airways, Egypt Air, DHL, ASKY airlines, UPS and Astral Aviation.[12] Philips has also entered into a partnership with the AMSP to allow for a ventilator exchange program wherein healthcare facilities within the AU members states will be able to replace outdated Intensive Care Unit (ICU) ventilators. In addition to sourcing additional equipment via the AMSP platform, hospitals within the chain will also be able to exchange their outdated ventilators for a next-generation Philips hospital ventilator at favorable conditions, within March 31, 2020 .[13]

ii. A consultative meeting of four of the six East African Community ('EAC') Heads of States directed "*partner states to prioritize regional value/supply chains to support local production of essential medical products and supplies including masks, sanitizers, soaps, coveralls, face shields, processed food, ventilators as part of efforts to combat covid-19 in the region*" and directed "*partner states to support agro-processing and value chains as an import substitution measure and establish special purpose financing schemes for small and medium enterprises*". They further underscored the development of a regional mechanism for COVID- 19 testing, certification and harmonization system for certifying and sharing COVID-19 test results.[14]

iii. Former President Olusegun Obasanjo had endorsed the launch of the 'Connecting the Dots' Initiative (CDI). The initiative is promoted by DFS Africa, a London based and Africa focused transaction advisory and strategic implementation firm, in collaboration with a consortium of partners, including the Tony Blair Institute for Global Change (TBI), the Federation of African Pharmaceutical Manufacturers

---

[10] https://www.novartis.com/news/media-releases/new-collaboration-between-novartis-and-africa-medical-supplies-platform-facilitate-supply-covid-19-related-medicines (Portfolio of 15 generic and over-the-counter (OTC) medicines from Sandoz division will be sold at zero-profit to governments through Africa Medical Supplies Platform (AMSP) to 55 African and 15 Caricom eligible countries)

[11] https://amsp.africa/strategic-partners/#

[12] https://amsp.africa/commercial-partners/

[13] https://www.philips.com/a-w/about/news/archive/standard/news/press/2020/20201105-philips-and-the-african-union-join-forces-to-create-access-to-healthcare-solutions-for-covid-19-and-beyond.html

[14] https://www.eac.int/communique/1725-communiqu%C3%A9-heads-of-state-consultative-meeting-of-the-east-african-community

Association (FAPMA), African Pandemic Response Alliance (APRA), and Kenya Manufacturing Association. The Initiative is designed to ease supply chain challenges in the procurement of COVID-19 essential products.

c) Pandemic Preparedness in general

i. The Skoll Foundation earmarked a total of $7 million to support COVID-19 preparedness and response activities in Africa. The Africa CDC, the SACIDS Foundation for One Health (SACIDS), and the East African Integrated Disease Surveillance Network (EAIDSNet), through this funding, have agreed to collaborate for better preparedness and response to Civid-19. The partnership will be focused on diagnosis and subtyping, enhanced surveillance and risk communication in several AU Member States. It will build on existing systems for monitoring influenza-like illnesses and SARIs.

ii. The European Centre for Disease Prevention and Control (ECDC) and Africa CDC launched a partnership initiative to strengthen the capacity of Africa CDC for public health emergency responses. The 4 year project called 'EU for health security in Africa: ECDC for Africa CDC', funded by the EU, will aid in harmonised surveillance and disease intelligence, and support the implementation of the public health workforce strategy of Africa CDC. The project will help to exchange experiences and lessons across Member States on: disease surveillance, early detection of threats, data sharing, and risk assessment and response. All these areas include capacity-building components, which will be integrated in the existing Africa CDC initiatives. A grant of EUR 9 million and a complementary grant of EUR 1 million was made to Africa CDC to cover its staffing costs under this project. The project is funded under the European Development Fund by DG DEVCO.[15]

Major Donors to the Initiatives:

- As on April 22, 2020, the following countries and organizations had made the following financial contributions to the AU-Covid 19 response fund and the Africa CDC respectively:[16]

[15] https://www.ecdc.europa.eu/en/news-events/eu-and-au-sign-partnership-scale-preparedness-health-emergencies#:~:text=Entitled%20'EU%20for%20health%20security,intelligence%20of%20prioritised%20outbreak%2Dprone

[16] https://au.int/sites/default/files/pressreleases/38401-pr-sc26713_e_original_-_communique_of_the_bureau_of_the_assembly_held_on_22_april2020.pdf

	Country/Organisation making the financial commitment	Amount of Financial Commitment to the AU-Covid 19 response fund (in US dollars)	Amount of Financial Commitment to the Africa CDC (in US dollars)	Total Financial Commitment (in US dollars)
1.	Egypt	$4 million	$2 million	$6 million
2.	Kenya	$2 million	$ 1 million	$ 3 million
3.	Mali	$1.5 million	$ 500 000	$2 million
4.	South Africa	$4 million	$2 million	$ 6 million
5.	DRC	$2 million	$2 million	$4 million
6.	Senegal	$ 1 million	$ 1 million	$ 2 million
7.	Rwanda	$ 500 000	$ 500 000	$ 1 million
8.	Zimbabwe	$ 1 million	$ 1 million	$ 2 million
9.	African Development Bank:	$1 million	$25 million	$26 million
10.	Motsepe Foundation	$4 million	$ 2 million	$6 million
11.	Afrexim bank	$3 million	-	
12.	Trade and Development Bank of Southern Africa:	-	US $500 000	

While latest data is unavailable and it is unclear how much of such funding was actually devoted to bolster local pharmaceutical production in Africa, these sources especially (Sources 9-12) in the Table above gives us an idea about the organizations who have supported Covid-19 amelioration efforts in the past and can be potential sources for future investment in the pharmaceutical industry.

- Furthermore, Wellcome and the United Kingdom Department for International Development (DFID) had awarded a grant of EUR 2.26 million to Africa CDC to implementation of the Africa Joint Continental Strategy for COVID-19 outbreak. The strategy aimed to enhance coordination, collaboration, cooperation and communication across AU states and focusses on laboratory and subtyping, surveillance, infection control, clinical case management, risk communication, and supply chain management. It will also

help in stockpiling and distributing essential commodities needed by AU Member States.[17]

3. Country Specific Interventions for increasing manufacturing, distribution and financing of pharmaceutical products

i. In **Nigeria**, the Dangote Group, Access Bank, Zenith Bank, Guaranty Trust Bank, MTN, and KPMG came together to form the Coalition Against COVID-19 (CACOVID) that will provide funds for immediate purchase of medical supplies and the creation of isolation centers. Guaranty Trust Bank worked quickly to transform a stadium into a 110-bed isolation center within five days in partnership with Lagos State.
In order to boost testing capacity, 54gene, which is a genomics research start-up, launched a fund to which donated USD 150,000 and which secured an additional funding of USD 350,000 from partners including the Union Bank. This money was used to increase Covid-19 testing capacity and buying testing equipments, PPE and so on.[18]
The Central bank of Nigeria and its Bankers Committee also pledged to support pharmaceutical companies to boost their local production. While the exact support structure and fund grants would be drawn up with individual banks, the announcement was met with huge support.[19]

ii. In **Kenya**, a team of startups in ecommerce, clean cooking stoves, and micro-distribution came together to Safe Hands Kenya to deploy free soap, hand sanitizer, cleaners and disinfectants, and masks to Kenyans through multiple distribution points. The coalition paired startups with established manufacturers to ensure last mile delivery of essential supplies. There is a zero profit margin on Safe Hands' activities.

iii. **South Africa**, though, is *not* producing any vaccine locally, yet the Aspen institute has tied up with Johnson and Johnson to put the vaccines into vials and then package them for distribution across Africa.

iv. In **Ethiopia**, help came in the form of Chinese investment that was made in 2018. In 2018, Sansheng pharmaceuticals, a firm headquartered in China's Chongqing started an $85mn Ethiopia-based factory, with plans to serve both the Ethiopian market and

[17] https://africacdc.org/news-item/wellcome-and-dfid-support-africa-covid-19-continental-response-with-e-2-26-million/
[18] https://www.forbes.com/sites/tommywilliams1/2020/03/31/nigeria-covid-19-testing-support-fund-launched-by-54gene/?sh=7c30f356ce17
[19] https://www.proshareng.com/news/Monetary%20Policy/COVID-19--CBN--Bankers--Committee-To-Support-Pharmaceutical-Coys/50006

export to other African countries. Sansheng was initially equipped to produce 5 billion solid preparations, 300 million ampoules and 10 million large volume parenteral preparations annually. However, as a Covid-19 response, the company launched a new production line to manufacture 24,000 litres of hand sanitiser daily. This has been possible because the Ethiopian government had launched a 10-year plan in 2015 to raise the share of pharmaceutical and medical products produced locally to 50% by 2025.[20]

v. In **Mauritius,** the Mauritius Investment Corporation (MIC) will reportedly focus more on investing in the pharmaceutical and blue economy as new strategic sectors, in the light of the pandemic.[21] However, the exact financial arrangements are unknown.

vi. In **Ghana**, the Ghana Export-Import Bank has committed $60 million to pharmaceutical companies, in line with the Ghana Government's 'One District, One Factory' policy. The Chief Executive Officer (CEO) of Ernest Chemists Limited, Ernest Bediako Sampong had also reportedly said that this company was looking to increase pharmaceutical production to meet 70% of the essential drugs needed by the criteria within 2-3 years, as opposed to the current pharmaceutical capacity, which is at only 30%. He said that he was looking at government support for financing the same.[22]

vii. In **Senegal**, the Institut Pasteur de Dakar created the Diatropix initiative which is the first non-profit platform for manufacturing fully dedicated rapid diagnostic tests. In collaboration with the Mérieux Foundation, the Institut de Recherche pour le Développement, the Foundation for Innovative and New Diagnostics (FIND), and two industrial partners (Mologic Ltd in the United Kingdom and BioMérieux in France), the platform has been set up to produce rapid diagnostic tests to detect diseases linked to virused such as Covid-19, dengue, Ebola, measles, yellow fever, rubella and meningitis. However, the first product to be manufactured was the rapid diagnostic serological test for COVID-19, as a response to the pandemic.[23]

---

[20] https://chinaafricaproject.com/analysis/can-china-help-build-africas-nascent-pharmaceutical-sector/
[21] https://www.imf.org/en/Topics/imf-and-covid19/Policy-Responses-to-COVID-19
[22] https://www.ghanaweb.com/GhanaHomePage/NewsArchive/Pharmaceutical-companies-to-produce-70-of-country-s-drug-needs-936016
[23] http://www.pasteur.sn/inauguration-de-la-plateforme-de-production-de-tests-de-diagnostic-rapide-a-linstitut-pasteur-de-dakar/

4. **Interventions by the European Investment Bank to Ramp up local manufacturing of API (Active Pharmaceutical Ingredients) within Africa**

The *European Investment Bank* launched the first ever-financing initiative to scale up local production of Active Pharmaceutical Ingredients in Africa.[24] The Active Pharmaceutical Ingredients financing initiative was launched through participation of representatives from the *European Investment Bank, World Health Organisation, EDCTP, Global Access in Action at Harvard Law School and kENUP Foundation*. Kenyan-based non-profit APIFA (API for Africa) contributed their expertise for establishing this financing facility and will act as a non-exclusive promotor to the facility.

Long-term financing will be available in USD, EUR and local currency and can cover more than 50% of the total cost of eligible investment, as a part of the EIB's Covid-19 response. The scheme will enable Africa to benefit from increased local pharmaceutical sales over the next ten years, and improve access to healthcare. Demand for pharmaceutical products in Africa is expected to double to EUR 60 billion by 2020.

This initiative has resulted from the project called CovidX,[25] whose aim is to initiate the production of a select number of APIs to strengthen the supply of drugs needed to fight the Covid-19 pandemic in Sub-Saharan Africa. The API plants will produce non-potent and non-sensitizing APIs for high-volume drugs on the essential medicine list.

The EIB initiative will provide long-term financing for pharmaceutical production across sub-Saharan Africa and specifically target manufacturing of Active Pharmaceutical Ingredients that constitute 45% of final drug costs. It will ensure that African pharmaceutical manufacturing can benefit from technological innovation and digital processes.

5. **Financing Initiatives undertaken by Afreximbank to boost local manufacturing of pharmaceuticals in Africa**

The African Export-Import Bank (Afreximbank) announced a $3 billion Pandemic Trade Impact Mitigation Facility to help central banks in African countries deal with the economic impacts, of the Covid-19 pandemic.[26]

---

[24] https://www.eib.org/en/press/all/2020-377-eib-launches-eur-50-million-africa-pharmaceutical-manufacturing-initiative#:~:text=Demand%20for%20pharmaceutical%20products%20in,EUR%2060%20billion%20by%202030.&text=The%20EIB%20initiative%20will%20provide,45%25%20of%20final%20drug%20costs.

[25] https://www.covidx.eu/projects

[26] https://www.nepad.org/auda-nepad-response/financing-response-against-covid19

The Afreximbank announced a $3-billion facility, named Pandemic Trade Impact Mitigation Facility (PATIMFA), to help African countries deal with the economic impacts of the current pandemic. The joint initiative by *Afreximbank*, *UNECA* and *Africa CDC* will identify and support the capacity of African suppliers, manufacturers and importers that can produce and supply priority healthcare needs, including pharmaceuticals and medical supplies such as face masks, PPE, test kits and ventilators. The three institutions will ensure that countries adopt policies that improve inter-continental trade especially in pharmaceutical products, improve quality control, and harmonise such products.

Under this initiative, $200 million has been earmarked to support food production and the manufacture of, and trade in, medical equipment and supplies. Requests for facilities of $5 million and above will be covered through direct financing by Afreximbank while those for less than $5 million will be handled through on-lending using funds made available by Afreximbank to approved participating local financial institutions.

Thus, the two financing mechanisms are: through Direct Financing and Indirect Financing. As per a document that elaborates the strategies taken by the bank, the following are the financing methods and their respective eligibility requirements, as reproduced verbatim from such document:[27]

> **a) Supporting African Supply Chains and Local Manufactures – Direct Financing**[28]
> -This applies to Financing Requests from Corporates that meet the standard direct financing threshold of Afreximbank i.e. USD 5m and above
> -The standard Eligibility Criteria that applies to manufacturing entities seeking funding from the Bank as required by the Bank's Project Finance & Export Development Departments will apply in this instance viz.,: a) Submission of Facility Application Letter, b) Business Plan, c) Financial Projections, d) Existence of Applicable Licenses, e) 3 Years Audited Financial Statements,
> -Company should have a minimum Annual Turnover of USD10 million and Total Assets of at least USD2 million).
>
> **b) Supporting African Supply Chains and Local Manufactures – Indirect Financing**[29]
> -This category applies to Financing requests from Corporates that are below the minimum threshold for Direct Financing of Afreximbank i.e USD5m (with the Corporates not

[27] https://www.africapharmaconf.com/site/wp-content/uploads/2020/05/Babajide-Sodipo-Afreximbank-AUDA-NEPAD-COVID-19-Presentation.pdf
[28] ibid
[29] supra n(27)

meeting the required Turnover and Asset Size requirements of the Bank – i.e. Annual Turnover $10m and Balance Sheet Size of $2m).

The financing approach under this mechanism shall be in two categories:
1. On-Lending Programme: Under its On-Lending Programme, Afreximbank shall make funds available to approved participating Financial Institutions to on-lend to applicants under a Product Programme Scheme
2. Guarantee Programme: Afreximbank shall provide up to 70% Guarantee to approved Financial Institutions to enable them provide financing to eligible applicants under a Product Programme scheme. Under this product, the Financial Institution shall provide a Local Currency Facility to the borrower.

The eligibility criteria for this mechanism are as follows:[30]

a) Companies to produce COVID-19 relevant materials.
b) Clients associated with helping to tackle Covid-19, including Manufacturers and distributors in the pharmaceutical industry, Healthcare Providers, Non-medical companies that have volunteered to add this capability to their manufacturing output. (The goods in scope include: Protective Personal Equipment (PPEs), Applicable Pharmaceuticals, Medical Supplies, Agro Production, Fertilizers, Ventilators, Face masks, Sanitisers and other high-end consumables.)
c) The company shall be an African Company i.e. registered in Africa (with minimum African Value-add of 35% in production)
d) Companies owned/managed by African Women shall be given preference
e) A Borrower self-certification of Africa content will be required
f) Companies shall possess 3 Years Audited Financial Statements
g) Companies shall assign their Receivables to the participating Local Bank/Financing Institution h) Possess all relevant and applicable regulatory approvals and/or licenses

Reportedly, as part of this initiative, UNECA and Afrexim Bank have compiled a list of fifty local pharmaceutical companies which have the capacity or have shown interest in supplying priority products.[31] However, I could not find the names of such companies that have been identified/benefitted from this initiative and that indeed has been a limitation of my research.

6. Private efforts to ramp up pharmaceutical production in Africa

[30] supra n(27)
[31] https://www.cfr.org/blog/scaling-african-pharmaceutical-manufacturing-time-covid-19

1. In Africa, **Proparco (Group Agence Francaise de Developpement, 'AFD')**[32], as part of their 'Choose Africa' French initiative that aims to earmark EUR 2.5 bn to finance African start-ups and SMEs via AFD Group's tools, has been supporting local start-ups to scale up manufacturing of the following pharmaceutical processes and products:

a. Pass Santé Mousso is an electronic bracelet connected to an application that allows people to carry their personal and medical data on them in the form of jewelry. It was created in Côte d'Ivoire in 2018 by entrepreneur Corinne Maurice Ouattara and its use has boomed with the pandemic. "*With a group of entrepreneurs and support from the African Development Bank [AfDB], we have proposed to boost the Pass to turn it into a pre-diagnosis and follow-up tool for Covid-19 patients*", Corinne explained in Le Monde. Thus, this tool can be used for digitized Covid-19 medical record-keeping and follow up.

b. Some private African players are also setting up systems that connect patients and the medical sector during the pandemic. This is the case with mPharma, which is supported by the Novastar II impact fund which was invested in by PROPARCO in 2019. This start-up, which operates in Nigeria, Ghana and Zambia, has presented mobile Covid-19 screening equipment to the Noguchi Medical Research Institute of the University of Ghana. mPharma was founded by Ghanaian entrepreneur Greogry Rockson and is aimed at building an infrastructure and a drug monitoring system that connects patients, hospitals and pharmacies to a cloud-based software. Doctors know in real-time the exact location and availability of any medication of interest, and patients have a more reliable access to medicines.

c. In Morocco, the ODM Group, which has several clinics and diagnosis centers specialized in oncology, took action by providing Sidi Moumen Hospital in Casablanca with several respirators and monitors. In 2018, PROPARCO, with a consortium of investors, had taken part in the buyout of ODM Group from its historical shareholders. According to Proparco's own claim, this operation has increased the number of cancer diagnostic and treatment consultations in Morocco.

d. On 20th April, 2020, SPE Capital Partners ("SPE Capital") acquired Saham Pharma, the leading antibiotics manufacturer and distributor of injectable solutions in Morocco, along with Proparco as a minority investor. The acquisition constituted the fourth transaction executed through SPE AIF I, a USD 200m Africa-focused private equity fund closed in 2019. It is the second direct equity investment of Proparco within the healthcare sector of Morocco, following group

[32] https://www.proparco.fr/en/actualites/covid-19-africa-private-health-players-mobilized

the ODM group as mentioned above. Nabil Triki, Managing Partner and CEO at SPE Capital had said the following about the acquisition:[33]

> This will be our second investment in Morocco through the fund SPE AIF I and the second in the pharmaceuticals industry, following our investment last year in Future Pharmaceuticals Industry in Egypt. We believe the pharmaceutical sector has strong fundamentals of growth and resilience. Within the sector, players with solid management, manufacturing excellence and strong marketing know-how, like Saham Pharma, can significantly outperform the market.

Proparco claims that nearly 750,000 people will benefit from improved access to essential medicines over the next few years. More than 170 jobs should also be created or maintained in the company.

The project is aimed to help Saham Pharma contribute to the following, which has been reproduced verbatim from the company's website:

i. Improving access to antibiotic drugs and other "life-saving" pharmaceuticals (blood products, painkillers and cancer treatments) reimbursed by the social security system for some 750,000 new patients over the next five years, with a total of over 4.5 million people served annually within five years;
ii. Generating a sixfold increase in the company's antibiotic exports to West Africa over the term of the financing;
iii. Supporting over 170 direct jobs (including 63 held by women) and over 700 indirect jobs over the next five years.[34]

e. On 10.10.2019, Proparco had granted a USD 10 mn loan to the pharmaceutical company Africure Pharmaceuticals, alongside providing technical assistance project to support the company's efforts to comply with WHO Good Manufacturing and Distribution Practices. As per its own claims, Proparco's USD 10 mn loan will allow Africure to increase its production capacity in Africa, by launching two new plants in Côte d'Ivoire and Ethiopia, and the Group to improve its supply options for raw materials. This loan will allow over 2.6m people to benefit from improved access to essential drugs and vaccines by 2024.

   As reproduced verbatim from the website, the Project aims to allow Africure to work towards this objective via:

[33] https://www.proparco.fr/en/node/2580
[34] https://www.proparco.fr/en/carte-des-projets/saham-pharma

i) A USD 10m senior loan for which the loan agreement was signed in October 2019. This loan is financing (i) the construction of two new production plants in Côte d'Ivoire and Ethiopia (USD 7m) and (ii) medium-term working capital requirements to obtain long-term raw materials supply agreements (USD 3m).
(ii) Technical assistance (TA) (EUR 496K) to allow Africure to achieve and maintain international quality standards for its pharmaceutical manufacturing/distribution facilities. The TA covers (i) regular quality audits for existing/new facilities, (ii) training in WHO-GMP standards, and
(iii) the implementation of recommendations from pharmaceutical quality auditors.
The Technical Assistance project focuses on strengthening Africure's quality process to meet international production and distribution standards (WHO's GMP and GDP) for their generic drugs.[35]

While Africure is a medium-sized enterprise with limited production in terms of volume, it is important for Côte d'Ivoire and Cameroon as it will reduce the pharmaceutical import depend of these two countries. Also, the local high-quality producer is able to now produce and distribute the essential pharmaceutical products that the population needs such as antibiotics, antiretroviral and anti-malaria drugs, paracetamol and so on. Thus, while it is perhaps too early to expect Africure to contribute meaningfully to Covid-19 pharma production, nonetheless it can still focus on ensuring the local population continues to have access to basic antibiotics and there is no shortage for them.

7. Financing Initiatives undertaken by Public Development Banks (PDBs)- both international and national

Multilateral PDBs have played a key financing role in supporting Africa's pandemic responses. The key ones will be highlighted below.

a) **IFC**:

i. **Direct Financing Activity**:

IFC created a new private equity fund called 'Health in Africa' Fund that will invest in Africa's health sector. IFC's partners in the Health in Africa Fund are the African Development Bank, the Bill & Melinda Gates Foundation, and the German development finance institution DEG. The fund will target commitments between $100 to 120 million over two closings. The first closing of $57 million includes investments from: AfDB ($20 million), IFC ($20 million), Gates Foundation ($7

[35] http://www.africurepharma.com/proparco-deal.html

million) and DEG ($10 million). The Fund is being managed by Aureos Capital and the fund will invest in SMEs dealing with the health sector, like health clinics and diagnostic centers.

The fund will make about 30 long-term equity and quasi-equity investments that range from $250,000-$5 million, in financially sustainable and socially responsible private health companies. It will invest in companies that deliver: pharmaceutical and medical-related manufacturing companies, health services like labs, diagnostic centres, hospitals and clinics, distribution and retail organizations (like eye clinics, pharmaceutical chains, and logistics companies) and so on. The Health in Africa Fund is part of the IFC-World Bank Health in Africa Initiative under which IFC intends to mobilize up to $1 billion in investment and advisory services over five years, with a focus on improving peoples' lives through partnerships with the private sector.

ii. **Pharmaceutical Access**:

IFC launched a $4-billion Global Health Platform which will help address the severe shortage of medical supplies in developing countries. The platform will provide financing to suppliers of critical raw materials, manufacturers of healthcare products, and to healthcare service providers so that they can expand production capacity. IFC will contribute $2 billion from its own account while mobilizing the other $2 billion from private-sector partners. The financing will be offered to both existing and new IFC clients, mostly in developing countries. To ensure that the the initiative is indeed beneficial to developing countries, companies based in the developed countries which receive funding must commit a share of their supply to developing countries.[36] Thus, this may mean that in the near future, Africa will be able to access medical supplies with ease, by using this Platform.

iii. **More sustained commitment to pharma manufacturing:**

IFC will provide up to $110 million in debt financing to Hikma Pharmaceuticals PLC to help improve access to high-quality generic medicines. Hikma Pharmaceuticals is a leading pharmaceuticals company in the Middle East and North Africa. Its three main business lines include branded generics, injectables, and generics. IFC's investment will enable Hikma to provide accessible healthcare in the region.[37]

iv. **Building hospital chains across Africa**:

[36] https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=17761
[37] https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=23663

IFC is investing $6.75 million in Mauritius-based CIEL Healthcare Limited (CHL) to help the company acquire and operate a chain of hospitals across sub-Saharan Africa. The hospitals will offer high-quality, modern medical services.

CHL will invest in renovating IMG's hospital in Kampala in line with international standards, while also upgrading services in gynecology, general surgery, orthopedics, neurosurgery, critical care, cardiac and renal sciences. CHL is working with Fortis Healthcare, one of India's leading integrated healthcare networks, to transfer skills and develop medical specialties in all its hospitals in Africa.[38] Along with IMG, CHL has also invested in Fortis Clinique Darné in Mauritius and Hygeia Nigeria Limited which owns Lagoon Hospitals in Nigeria.[39]

v. **Opening up of pharmacies and local pharma manufacturing**:

IFC announced a loan of $4.5 million to Goodlife Pharmacy Limited to help the company open a chain of 80 pharmacies across Kenya and East Africa. Goodlife will supply affordable and good quality healthcare products in Kenya, where such products are scarce and there is an abundance of counterfeit products.[40]

b) World Bank

Uganda's The Africa Center of Excellence (ACE) PHARMBIOTRAC (Pharm-Biotechnology and Traditional Medicine) which is funded by the World Bank ran a new project called PharmSan Innovations which was focused on manufacturing of quality hand sanitizers. The entire manufacturing process was fast-tracked and the product was manufactured in accordance with the Uganda National Bureau of Standards (UNBS).[41]

c) International Islamic Trade Finance Corporation (ITFC)

ITFC and the Arab bank for Economic Development in Africa ('BADEA') partnered together to approve the 'Arab Africa Trade Bridges' programme to strengthen the socio-economic resilience of both countries during the pandemic. These measures are aimed at improving the capacities of national pharmaceutical agencies and related institutions in the areas of management, standards and procurement best practices. Immediate measures during the pandemic include supporting the Network of Laboratories in West Africa by supplying COVID-19 testing kits, lab equipment and PPE for medical and para-medical staff. In tandem with material and financial aid, African

[38] https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=18046
[39] https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=18046
[40] https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=24520
[41] https://blogs.worldbank.org/education/world-bank-funded-ugandas-africa-center-excellence-ace-pharmbiotrac-frontline-covid-19

laboratories will also be able to access critical know-how through capacity building and knowledge sharing programs on managing Covid-19.[42]

How far is GAVI extending its purchase commitments to countries in the Global South and improving their manufacturing capacity?

GAVI states that it wants to have a more diversified supply based and that while in 2001, out of five manufacturers who supplied vaccines to Gavi; only one of these was based in Africa, this scenarios has changed considerably over the years. By 2017, nearly two thirds of GAVI's vaccine suppliers were based in Africa, Asia or Latin America.[43] For the Covid-19 vaccine, GAVI has entered into supply arrangements with Glaxosmithkine, Pfizer, and the Serum Institute in India (Pune).[44] It has also entered into a separate deal with AstraZeneca to obtain 300 million doses of the latter's candidate into the COVAX Facility, to be supplied upon licensure or prequalification.[45] It is also in talks with Johnson and Johnson for the same for 500 million doses of the Jannsen candidate vaccine.[46]

One developing country manufacturer that the GAVI has entered into agreements with is the Serum Institute, Pune wherein the latter will provide 200 million vaccine doses for the COVAX facility, which will then be supplied to developing countries. For this, the Bill and Melinda Gates Foundation, GAVI and the SII have entered into an agreement. The collaboration has provided upfront capital to the Serum Institute, India to increase its manufacturing capacity so that the vaccine development process can be smoothened and more doses can be distributed at scale to developing countries.[47] The funding will help in accelerating the manufacturing process by the Serum Institute India for the candidate vaccines which have been licensed from AstraZeneca and Novavax, and which will be procured by the COVAX Facility provided they are successful in attaining full licensure and WHO Prequalification. The vaccines have a ceiling price of US$3 per dose, and the price has been enabled by investments made by Coalition for Epidemic Preparedness Innovations (CEPI), the Bill & Melinda Gates Foundation and Serum Institute, India. To this, Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance had remarked: "*This is vaccine manufacturing for the Global South, by the Global South, helping us to ensure no country is left*

---

[42] https://itfc.africa-newsroom.com/press/arab-africa-trade-bridges-aatb-program-outlines-actions-to-support-developing-countries-cope-with-the-covid19-crisis#:~:text=driven%20business%20environment.-,Since%202008%2C%20ITFC%20has%20provided%20more%20than%20US%2451%20billion,for%20the%20Member%20Countries'%20needs.

[43] https://www.gavi.org/operating-model/gavis-partnership-model/developing-country-pharmaceutical-industry

[44] https://www.gavi.org/investing-gavi/innovative-financing/pneumococcal-amc/manufacturers/supply-agreements

[45] https://www.gavi.org/news/media-room/new-collaboration-makes-further-100-million-doses-covid-19-vaccine-available-low

[46] https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021

[47] https://www.seruminstitute.com/news_sii_gavi_bmgf.php

behind when it comes to access to a COVID-19 vaccine."[48] The CEO of Serum Institute has said that while a certain portion of the vaccines will be reserved for India, the other portion will be given to GAVI. In January 2021, there were reports that GAVI had placed orders for more additional doses with the Serum Institute, India. Apparently, GAVI is also in talks with other Indian vaccine manufacturers to purchase vaccines from them. If this indeed materializes, then needless to say, it would be a big boost to the Indian vaccine manufacturers others than the Serum Institute, which anyway is the world's largest vaccine manufacturer by volume.[49]

GAVI is also in talks with Chinese vaccine companies, to ensure as diverse a pool as possible. There are presently nine vaccine trials in China[50] and the CEPI (which is GAVI's partner), itself is backing two such trials.[51]

However, I could not find any report of any such orders being placed with Africa, so as to give an impetus to local vaccine production in Africa. While the Aspen institute is in talks with Johnson and Johnson for receiving tech transfer for contract manufacturing on the latter's behalf and could reportedly start such manufacturing in late March or April 2021, it is unclear as to what is the present status of this agreement and how much proportion of these doses will South Africa be able to keep for itself, if at all it is able to do so.[52] South Africa has not reportedly signed any deals with any vaccine manufacturers but could get 1.5 million doses from India's Serum Institute.[53] Thus, it seems that as of now, there are no concrete plans on the GAVI's part to boost local vaccine production in Africa.

---

[48] https://www.gavi.org/news/media-room/new-collaboration-makes-further-100-million-doses-covid-19-vaccine-available-low

[49] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/gavi-in-talks-to-make-indian-vaccine-makers-join-covax/articleshow/77321496.cms?from=mdr#:~:text=MUMBAI%3A%20The%20Global%20Alliance%20for,Vaccine%20Agreement%20for%20Covid%2D19.

[50] https://www.gavi.org/vaccineswork/covid-19-vaccine-race

[51] ibid

[52] https://www.news24.com/news24/southafrica/news/covid-19-sas-aspen-could-produce-jj-vaccine-shots-by-end-of-march-20210107

[53] ibid