From the outset, the report analyses the Mauritian BioPharma Ecosystem and its Key Proposals. It namely highlights the impactful role of Centers of Excellence. A combination of critical factors of success is further outlined: regulatory, strategic projects, investment, partnerships, human capital, infrastructure and speed.

Thereafter the report focuses in depth on the building blocks of a pharmaceutical and biotechnology hub. It develops main aspects such as the regulatory framework, the skills needs and the different fields of research and manufacturing of services and products. Emphasis is laid, in parallel to the strategic market positioning of Mauritius, which is a member of the African Union and various African trading blocs such as the SADC and COMESA.

Lastly, the third part of the study emphasises on the Institutional and Governance framework. The pivotal roles of the Mauritius Life Science Authority (MLSA) and of the Mauritius Institute of Biotechnology (MIB) are highlighted as well as the necessity for regular appraisal of performance, for example through Hard KPIs (Key Performance Indicators).

The feasibility and framework study uncovers concrete strategic opportunities for research, development and investment and actionable levers for efficient and profitable trade. A key take-away is a 6-pronged framework geared towards short term, medium term and long term outcomes.

The six components of the framework are (1) Skills and capabilities, (2) Legal, Regulatory and Compliance Framework, (3) Animal Research (4) Clinical Research (5) Manufacturing and (6) Investment and Incentives.

In the short to medium term, the focus of this multi-faceted approach is to develop and establish Priority Products and Services for export, update Legal and Regulatory and IP framework to ensure global standards are met and build capacity and infrastructure to become a Biopharma hub. In the medium to long term, the report proposes a coordinated approach from each angle to ensure establishing Mauritius as a centre of Excellence for Clinical Trials, R&D and manufacturing.
The European Union’s Africa RISE (Reform for Investment and Sustainable Economies) programme is a demand-driven regional technical assistance facility to promote business development and improve the investment climate in Eastern Africa, Southern Africa, and the Indian Ocean. It supports the EU partnership with Africa in 25 countries on sustainable investments and jobs, inclusive green growth, and decent work. Africa RISE is financed by the European Union and implemented by Landell Mills in partnership with Adam Smith Europe, Imani Development, and International Economics Consulting.

Africa RISE has conducted a comprehensive feasibility study for the establishment and focused strategic positioning for Mauritius as a pharmaceutical and biotechnology hub.

Government of Mauritius’s Vision of a Regional Pharmaceutical Hub

This study is key to the vision of the Government of Mauritius to make the pharmaceutical and biotechnology industry become an economic pillar. The government thereby aims at increasing exports while ensuring job creation in the country. Mauritius offers enormous potential such as educated workforce, a modern infrastructure and a small but thriving clinical research industry.

Furthermore, the Government of Mauritius envisions positioning the country as a Biopharmaceutical and Pharmaceutical hub for the African continent. To quote an October 2021 study, “the objective of Government is to establish a vaccines and pharmaceutical manufacturing industry in Mauritius, with the aim of developing the country into a medical hub for the African continent.” The National Budget FY2021/2022 commits to the establishment this hub with the aim of serving the African continent and beyond.

Mauritius Institute of Biotechnology

In line with this policy objective, Government has established the Mauritius Institute of Biotechnology (MIB) to lead the development of this industry with its key objectives:

- To promote, develop and accelerate the manufacturing of pharmaceutical products including vaccines and other drugs in Mauritius;
- To negotiate and secure licensing agreements with international vaccine and pharmaceutical companies;
- To conduct and promote high level research in various fields of biotechnology, including food technology;
- To develop and facilitate the commercialization of Mauritian made vaccines and pharmaceuticals, through collaboration with regional institutions, reputed universities, and other international organisations such as the World Health Organisation.
Existing Biopharmaceutical Ecosystem

In 2020, the country, which is highly dependent on imports purchased USD 207 million worth of biopharmaceutical goods. However, the country has an existing biopharmaceutical ecosystem which comprises of 75 institutions. Amongst others, it comprises of 25 enterprises in the biotech sector engaged in various operations such as clinical trials, primate breeding for export, fish oil manufacturing, and biofuel production and 5 Clinical Research Organisations (CROs) operating in Mauritius employing over 1000 workers.

Furthermore, Mauritius is the leading exporter of live primates in the world with three major local companies that raise live primates. The exports reached USD 48.7 million in year 2021.

Nonetheless, the report notes that despite the existence of institutions such as the Mauritius Research and Innovation Council, the Centre for Biomedical; Biomaterials Research, and the Food and Agricultural Research & Extension Institute, patents, company creation and product creation for local and regional markets are next to nil.

The report views the ecosystem as having great scope for growth at regional level after overcoming existing bottlenecks. Indeed, statistics for 2020 indicate that African countries have imported USD 31 billion of biopharmaceutical products, which represents a 63 percent increase from 2010 to 2020. Likewise, global biomanufacturing has an expected growth rate at a CAGR of 14.85% during the forecast period 2021-2031 and is expected to reach a value of USD 85,201 million in 2031.

International Trade Agreements

A founding member of the African Union, Mauritius is also a signatory of key continental, regional and international free-trade agreements. These agreements place the country – which is already geographically well placed along trade lines - in a particularly enviable position with regards to incentives, taxation and business development. These include the CECPA agreement with India, the FTA agreement with China, the AfCFTA agreements amongst others.

Business Opportunities

Benchmarking allows to identify main products and services which Mauritius could swiftly scale up to meet international needs. They are as follows:

<table>
<thead>
<tr>
<th>Products</th>
<th>Services</th>
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| 1. Biological Drugs, Biosimilars, Including Vaccines, Hormones, Antibodies, Cells  
2. Therapeutics, Generics, and novel formulations  
3. Nutraceuticals and Products, Incorporating Food Technologies, Food Ingredients, Dermo-cosmetics, Medical Aesthetics  
4. Oceanic Research Products  
5. Medical devices including innovative products | 1. Pre-clinical Research services/studies with Investigational Medicinal Products (IMPs) including long term toxicology studies  
2. Phase II and Phase III Clinical Trial Studies  
3. Non-Communicable Diseases Research Centre of Excellence  
4. Exploratory Drug Development Centre (EDDC) |
Top Export potential

Top products which Mauritius could export globally have the potential to generate an income of more than USD 50 million. These include:

1. Instruments used in medical sciences (HS 901890),
2. Medicaments consisting of mixed or unmixed products (HS 3004), and
3. Medical, surgical instruments and appliances (HS 901839).

Mauritius has excellent opportunities, according to the experts, to export biopharmaceutical products to the United States, Singapore, China, Vietnam, and India.

Other eurocentric exports with a potential of generating USD 3.8 million income are: (1) Reagents; diagnostic or laboratory reagents (HS 382200) and (2) Ophthalmic instruments and appliances (HS 901850)

Products which can be targeted for the United State Market are: (1) Medicaments consisting of mixed or unmixed products (HS 3004) and (2) Instruments used in medical sciences (HS 901890)

Benchmarking Models, Job Creation and Competitiveness

The report outlines a few key findings while benchmarking biopharmaceutical hubs such as those found in India, Singapore and South Africa. One of the key conclusions is that countries that invest in advanced high-tech services, advanced bio-manufacturing and R&D, and both pre-clinical and clinical research are the ones that are most valuable in a shorter period. Moreover, countries that invest more in synthetic manufacturing and less technology services as it is the case of India, are more profitable on the longer term.

The experts note that despite market size differences with India, keeping in mind the demands of the lower income market segments of Africa, Mauritius can learn from India’s best practices around frugal innovation and manufacturing. These are essential to build affordable medicines, products, and services.

The report furthermore recommends building an ecosystem model that combines Singapore’s model of high-tech and remote and local labour of highly skilled foreigners, as well as advanced biomanufacturing. And to develop a manufacturing industry that considers digital transformation and automation.
The report however forewarns that local incentives to replace imports should ensure sustainable job creation whilst ensuring competitiveness. For that purpose, the incentives should be balanced with high tech, highly qualified human capital and the highest regulatory and quality standards to build a highly competitive model. The report indicates the necessity for identifying cut off thresholds for manufacturing plants. For example, for countries such as Mauritius, the cut-off for a tablet-based product should be around 500 million tablets.

Furthermore in terms of building a marketing and sales force, the promotion of Mauritius as a hub for global or regional pharmaceutical administrative headquarters and/or distribution could generate activity and revenue.

**Centers of Excellence**

To support the process of developing Mauritius as a biopharmaceutical hub, the experts advise that the country can provide an institutional platform for the setting up of Centers of Excellence to build capacity as highly specialized training centers, attract investments and materialize products and services with global quality standards while enabling public, private and international collaborations.

The report recommends the creation of Seven Centers of Excellence to develop a concrete and continuous sustained collaboration between Academia, Industry, and the needs of the Mauritian population along with best practices from leading international institutions:

1. High Tech Commercialization
2. Natural Products, Drug Discovery, and Innovation Devices
3. Clinical Research and Decentralized Digital Services
4. Community Research; Patient Recruiting
5. Bio manufacturing
6. Synthetic Manufacturing and Innovative Formulation
7. Innovation and manufacturing Medical

It is also highlighted in the report that while some of these centers will leverage on existing infrastructure and lower investments for setting them up (1.5M to 2M USD), others would require medium to larger investments to remain competitive in the long run (2.5M to 15M USD).

A platform of Centres of excellence is proposed to create a conducive environment to attract international investment by delivering products and services with the highest standards, and promoting the creation of private public and international partnerships. This will allow companies to co-invest, and achieve a significant improvement in communication, empathy, and the democratization of projects, products and data, thus optimizing and synchronizing processes, services and supply chains. It will also make operations flexible and production proactively responsive to change.

Centers of excellence are responsible for creating standard processes that, together with automation, and specialized training programs will enable a highly competitive technological framework for Mauritius to compete and collaborate to produce high quality medicines for Mauritius, Africa and the world. Centres of excellence present an opportunity to consolidate best practices and new technologies at the heart of production and innovation while certifying efficient processes and creating a conducive environment to attract foreign investment.
Investment and Funding Mechanism

A detailed list of potential collaborators, partners both academic, corporate and investors is provided in the report. Depending on the level of investment funding available to the MIB, consultants see a potential for the MIB to invest in specific projects which are important in achieving its objectives. The proportion of funding and dynamics of collaboration with each potential investor will depend on the scope of investment.

The following is a list of institutions and stake holders that could enhance the implementation and staged funding of both institutions and projects proposed in this report.

- Seed funding from both public and private institutions would enable the development of early-stage research projects for example in university institutions or start-ups with promising projects.
- Venture and Scale-Up Capital participation would be more appropriate to encourage the growth of small-medium enterprises and start-ups already established in Mauritius.
- Co-investment with corporate funds represent an opportunity for the development of large companies as well as manufacturing and institutional projects in the health sector, including the centres of excellence.
- Co-investment with local funds and international funds such as African Union, European Union and International Financing Corporations are attractive in leveraging their funding for specific programs, and the development of institutional capacity to create the biotech hub in Mauritius.

Follow up to investment should be enhanced by technical, professionals and the network of centres of excellence which will help in developing a minimum viable product, incubating, or accelerating project, therefore decreasing the risk in the creation of tangible products and services on behalf of Mauritius and its biopharmaceutical industry.

Smaller Regional Clusters

While the report stresses on the necessity to enhance diplomatic and commercial ties to highlight the presence of Mauritius on the biopharmaceutical map, it also proposes the way forward by harmonizing regulations and creating small clusters of biopharmaceutical hubs.

It notes that sub-Saharan African countries could work together to encourage a handful of globally competitive industry clusters. They would stand better chances of producing affordable, high-quality drugs. And, with proper regulatory harmonization, smaller countries could experience faster lead times and more responsive supply chains by mostly relying on local suppliers.

Legal and Regulatory Framework and Regulatory Body

It is proposed to create a Mauritius Life Science Authority (MLSA) that will have the authority to govern activities across the biopharmaceutical value chain.

The Clinical Trials Act of 2011 provides a legal framework that makes provisions for three responsible bodies that oversee the conduct of clinical trials in Mauritius in accordance with the principles of GCP: (1) The Clinical Research Regulatory Council (CRRC) (2) The Ethics Committee (3) The Pharmacovigilance committee.
The experts recommend a new bio-pharmaceutical law in Mauritius, called the Bio-Pharmaceutical Act with a broader remit than the existing laws on clinical trials and on Animal Research. The new Act would replace the Clinical Trial Act of 2011 and integrate part III of the Animal Welfare Act of 1983, thus providing a unifying law that governs both preclinical and clinical research.

The new Act will include provisions to conduct clinical trials with a range of biotechnology product areas, including investigational medicinal products (both chemical entities and biologics), vaccines, and medical devices.

A Clinical Trial Committee (CTC) and an independent Ethics Committee (EC) would have the responsibility to ensure that Clinical Trials are conducted in accordance with internationally accepted standards, as defined by Good Clinical Practice.

A similar parallel structure will be created to oversee Animal Research. A Committee on Animal Research and Ethics (CARE) will ensure that animal research is conducted in accordance with Good Laboratory Practice.

Skills Gaps Analysis and Capacity-Building

Regarding job creation, the report highlights the potential for highly paid and highly skilled jobs. Additionally, the Biopharma manufacturing sectors will be able to provide good and decent employment for less skilled people.

It notes that the biopharma sector will act as a catchment area for STEM students and encourage careers as scientists, engineers, biostatisticians, bioinformaticians amongst others. Life science talents will be better retained and relocated diaspora can play a pivotal role in the training, mentoring, “reskilling”, and “upskilling” of fresh scientific graduates in this sector. Furthermore the MIB can attract more foreign talent and also serve as an international platform to attract expatriates.

Infrastructural Needs

The report identifies infrastructural needs to support growth:

- Streamlined services- a green channel developed for the export of the biopharma products, specially for those with limited shelf life
- Temperature controlled storage
- Fast delivery- by flight or by sea route
- Dedicated location- Production, export and biosafety
- Export of data- Highly secured telecommunication connectivity.
- International recognition of Mauritian products (mutual recognition agreements)
- Sanitary and Phytosanitary norms (to avoid non-tariff barriers).
- Electricity- Ensuring a good, and stable electricity supply even during cyclones
Intellectual Property


The Industrial Property Act of 2019 has a wide scope that covers several elements that will provide a legal framework for researchers, investors, and entrepreneurs who need to protect their IPR.

The Act makes provision for Mauritius to adhere to the World Intellectual Property Organization (WIPO) administered Treaties. The report recommends that Mauritius should introduce laws that protect intellectual property rights in the bio-pharmaceutical industry, in line with knowledge-based economies. An option would be to amend the current act and add a section on Intellectual Property protection specific to the Bio-Pharmaceutical Industry. The European Framework would be suitable for Mauritius as it includes both patent protection and data exclusivity.

A Six-Pronged Practical Framework

The report synthesizes key elements, forecasts and recommendations for the short term, medium term and long term via a six-pronged practical framework.

It considers:

- Skills and Capabilities & institutions
- Legal, Regulatory and Compliance Framework
- Animal Research
- Clinical Research
- Manufacturing
- Investment and Incentives
The vision of Mauritius as a regional biopharmaceutical hub can become a reality with numerous layers of benefits for the country but also for the African region and also to address global needs. However, there is a need for collaboration with various partners at the government level with AU, EU, and the global organisations such as WHO as well with the global pharmaceutical and API companies in order to fund and establish supplies for manufacturing capacity in Mauritius. Creating alliances with public and private sectors to mitigate costs while adding value, and enhancing diplomatic ties and leveraging on trade agreements are steppingstones towards strengthening this economic pillar sustainably in Mauritius. Africa Rise is also supporting Botswana and the SADC region in advancing the Biopharma agenda and build regional synergies across the value chains in sector.

### Outcomes

#### Short-term (1 to 2 years)

- The Mauritian Biopharma Industry Model (Hub or Ecosystem)
- Priority Products and Services to address export potential; local, regional and global demands
- Regulatory and Administrative Consolidation
- Promotion and Commercial Efficiency
- Capacity Building and Institutional Excellence through a platform of centres of excellence that use existing infrastructure with global standards
- Developing Markets

#### Midterm (2-5 years)

- Attracting investors and partnerships to materialize investments, industry infrastructure, and offer tangible products and services to replace imports and materialize potential exports.
  - Staged Public and Private Investments
  - Increased offering of products and services
  - Industry Infrastructure through new centres excellence
  - Community building (Partners, Investors and Collaborators)

#### Long-term (5 years)

The report forecasts that the Short term and Mid-term outcomes will allow Mauritius biopharma industry to increase export products by at least 100M. Thus setting the pace for the expansion and growth of the sector.

### Conclusion

The vision of Mauritius as a regional biopharmaceutical hub can become a reality with numerous layers of benefits for the country but also for the African region and also to adress global needs. However, there is a need for collaboration with various partners at the government level with AU, EU, and the global organisations such as WHO as well with the global pharmaceutical and API companies in order to fund and establish supplies for manufacturing capacity in Mauritius. Creating alliances with public and private sectors to mitigate costs while adding value, and enhancing diplomatic ties and leveraging on trade agreements are steppingstones towards strengthening this economic pillar sustainably in Mauritius. Africa Rise is also supporting Botswana and the SADC region in advancing the Biopharma agenda and build regional synergies across the value chains in sector.