

# MAURITIUS

## NATIONAL EXPORT STRATEGY

### MEDICAL DEVICES

#### SECTOR

2017-2021



Republic of Mauritius



International  
Trade  
Centre

This National Export Strategy (NES) is an official document of the Government of Mauritius. The NES was developed on the basis of the process, methodology and technical assistance of the International Trade Centre (ITC) within the framework of its Trade Development Strategy programme.

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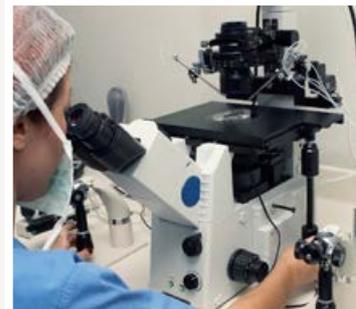
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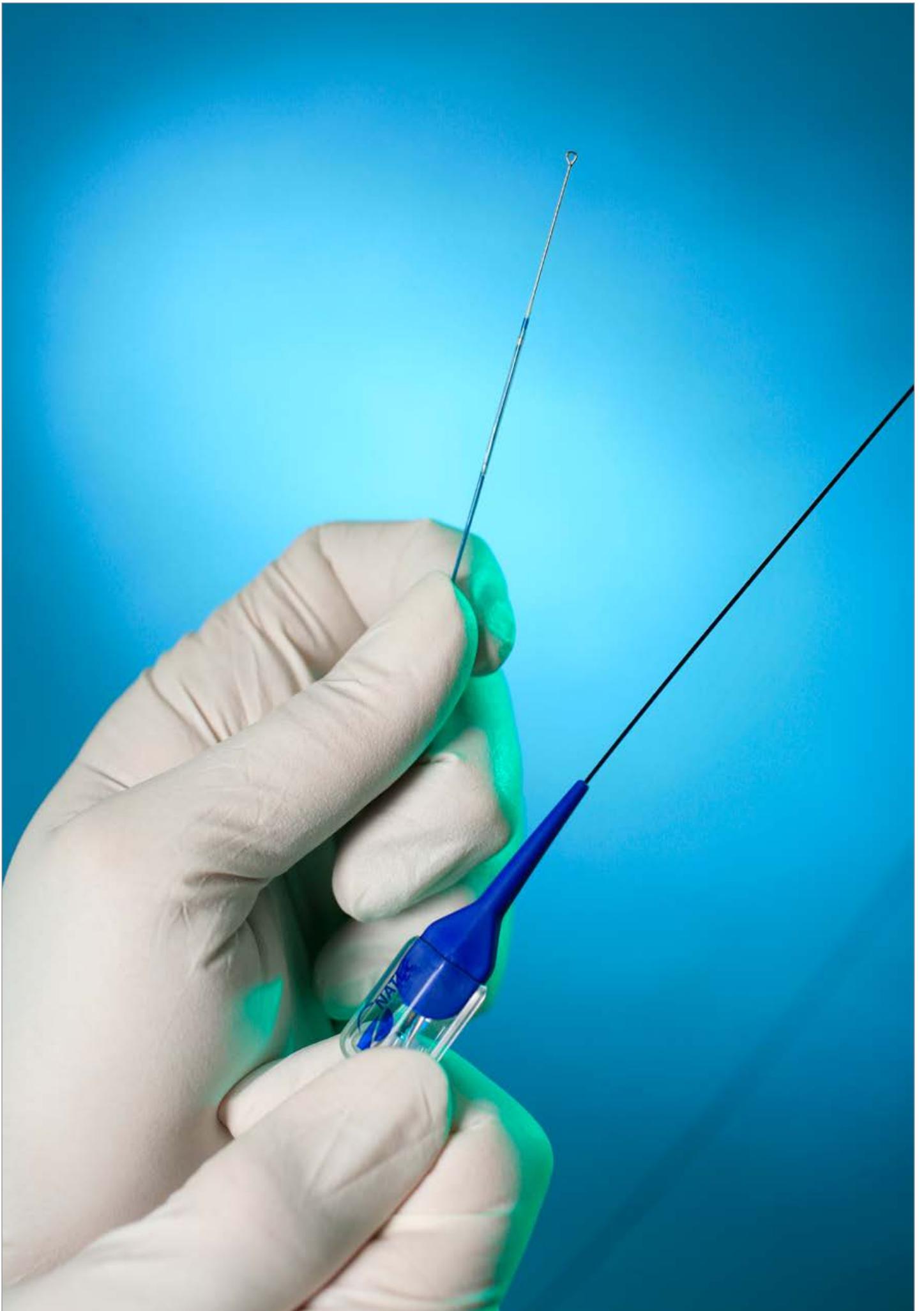


Photo: Medical Devices, Photo 4.JPG

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# EXECUTIVE SUMMARY

The goal of the Mauritius Medical Devices Sector Strategy is to set the sector on the course of strategic development by addressing constraints in a comprehensive manner and defining concrete opportunities that can be realized through the specific steps detailed in its Plan of Action (PoA). The Medical Devices Sector Strategy is an integral part of the NES of Mauritius.

**The sector's strategic orientation** should be geared towards structuring the medical devices sector. Supported by development of an enabling legal and regulatory framework, the strategy for the next five years will be primarily built around a goal of fostering integration and cooperation between the different stakeholders involved in the value chain while strengthening the capacity of local manufacturers to develop innovative products through research and development to generate higher value addition locally and diversify Mauritian products on offer.

The PoA responds to this vision by setting five strategic objectives to support its implementation:

1. Develop an enabling legal and regulatory framework for the medical devices sector
2. Improve the organization of the sector and foster
3. Develop appropriate skills and competencies and foster research and innovation
4. Create a more enabling business environment for the development of the sector and promote FDI
5. Develop markets and strengthen export promotion efforts.

**Mauritius has, since the late 1990s, built a well-developed medical devices industry that produces a wide range of highly sophisticated products**, including an important range of medical implants, catheters and stents. The country has managed to attract several leading industry players from Europe and has progressively established itself as a manufacturing platform for medical devices, exporting the vast majority of its production, notably to France and India. The sector is expected to play a leading role in transforming the Mauritian economy into a high value-added one and will contribute, in particular, to the strengthening of the domestic manufacturing sector.

**The value addition generated by the sector is, however, limited.** If manufacturers are producing highly sophisticated medical equipment, a change in approach is needed as some companies are generating very limited levels of value addition locally. Several manufacturers have indeed

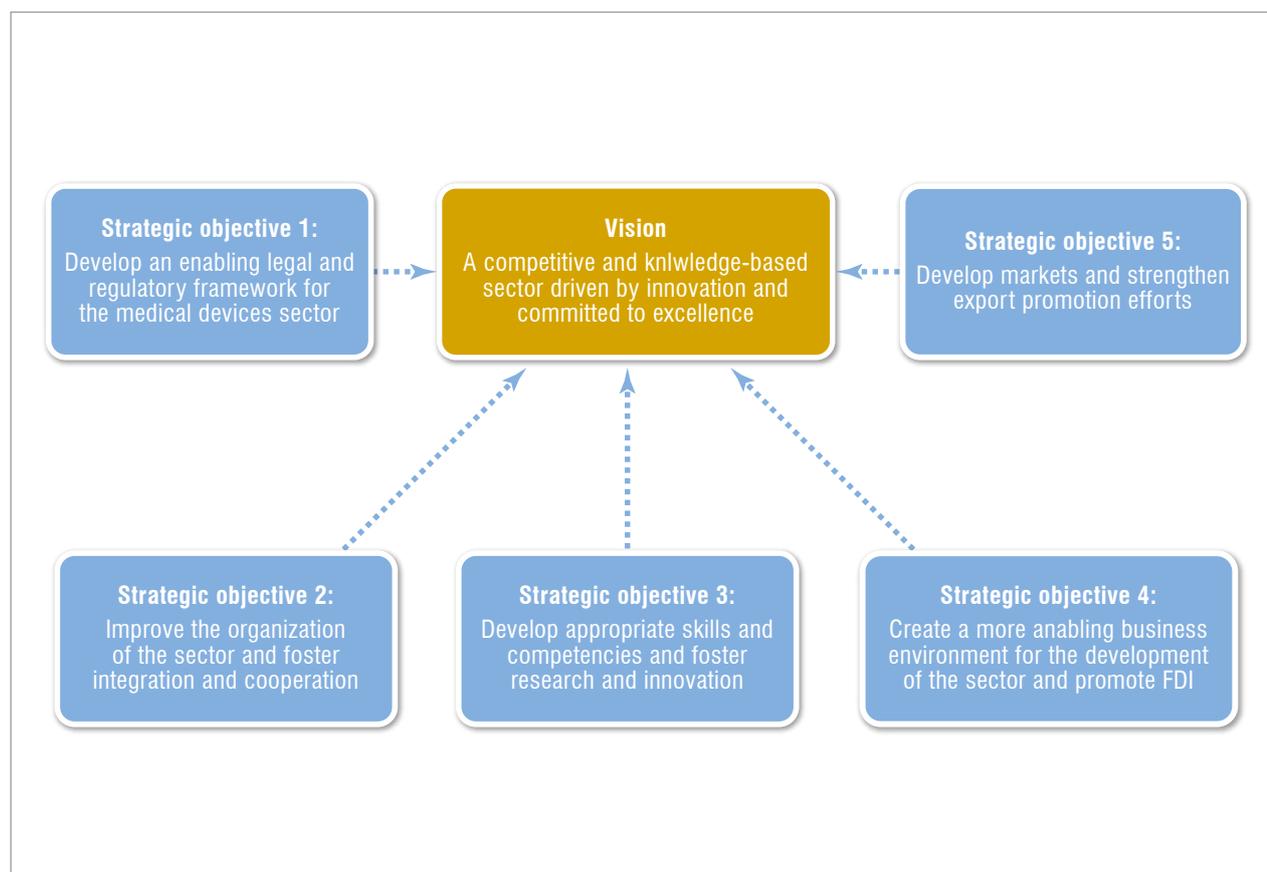
established sites in Mauritius to benefit from the relatively cheap and sufficiently educated labor force to manage simple production processes, therefore playing a very limited role in the global value chains and having a limited impact on value addition. Overall this nascent industry has a limited impact on employment and revenue generation for the country.

**Reinforcing the domestic supply of medical devices components will be one of the main challenges** for the industry in the near future as the sector is currently highly dependent on components imports. Adding value to the production will require a progressive upgrading of the Mauritian sites, gradually moving from the assembly segment of the value chain to the manufacturing of components and, most importantly, research and development. Some manufacturing processes are however being undertaken which can be accentuated through product development.

**The strategy for the next five years will be primarily built around structuring the sector.** Developing a cluster initiative by promoting greater business linkages between companies involved in the value chain will improve the industry's attractiveness and competitiveness. Another important challenge for the future expansion of the industry will be the capacity of local companies to develop innovative products through research and development to generate higher value addition locally and diversify Mauritian products on offer. Improving the knowledge-base of the industry and developing a regulatory framework will be essential in this regard.

**This strategy, the result of extensive consultations with public and private sector stakeholders, led to an invaluable cooperation among sector operators.** Key private sector stakeholders and leading institutions facilitated an exhaustive analysis of the sector. Market-led strategic orientations, prioritized by stakeholders and embedded into a detailed implementation plan, provide a clear road map that can be leveraged to address constraints to trade and maximize value addition. In addition, the inclusive approach ensured that all stakeholders were committed to the process. The Medical Devices Strategy provides Mauritius with a detailed PoA to achieve growth in the sector within the next five-year period. The Strategy is articulated around a unifying vision and five strategic objectives.

Figure 1 : *The strategic scope*



# WHAT IS A MEDICAL DEVICE?

According to the World Health Organization (WHO), 'medical device' means "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body"

The organization indicated further that, typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. A medical device includes everything from highly sophisticated computerized medical equipment down to simple wood-en tongue depressors.

## Distinguish medical devices from biotechnologies

The term "biotechnology" is the use of living systems and organisms to develop or make products, or "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use" (UN Convention on Biological Diversity, Art. 2).

Biotechnology has applications in four major industrial areas, namely health care (also referred to as red biotechnology), crop production and agriculture (green biotechnology), industrial (white biotechnology) as well as marine and aquatic applications (blue biotechnology). The red biotechnology is of particular importance as it



Photo: @iStockphoto

brings together all those biotechnology uses connected to medicine, regrouping four different sub-sectors, namely medical devices manufacturing, pharmaceuticals, clinical trials and breeding for contract research<sup>1</sup>.

However, if a medical device can eventually come in support of a biotechnology activity, and therefore be considered as one component of the biotechnology applied to medical processes, the manufacturing of medical devices cannot be considered as a subfamily of biotechnology, as the sector can operate independently of the biotechnology. Rather, the medical industry should be considered as a specialized industry, a subsector of the broader life sciences.

This functional simplification is useful to understand better the challenges of the medical devices industry, perceive better the investment needed and obtain better visibility on returns that one can hope for.

1. Bol, Biotechnology in Mauritius - Development Perspectives – Industry Report, Bol Mauritius (2014)

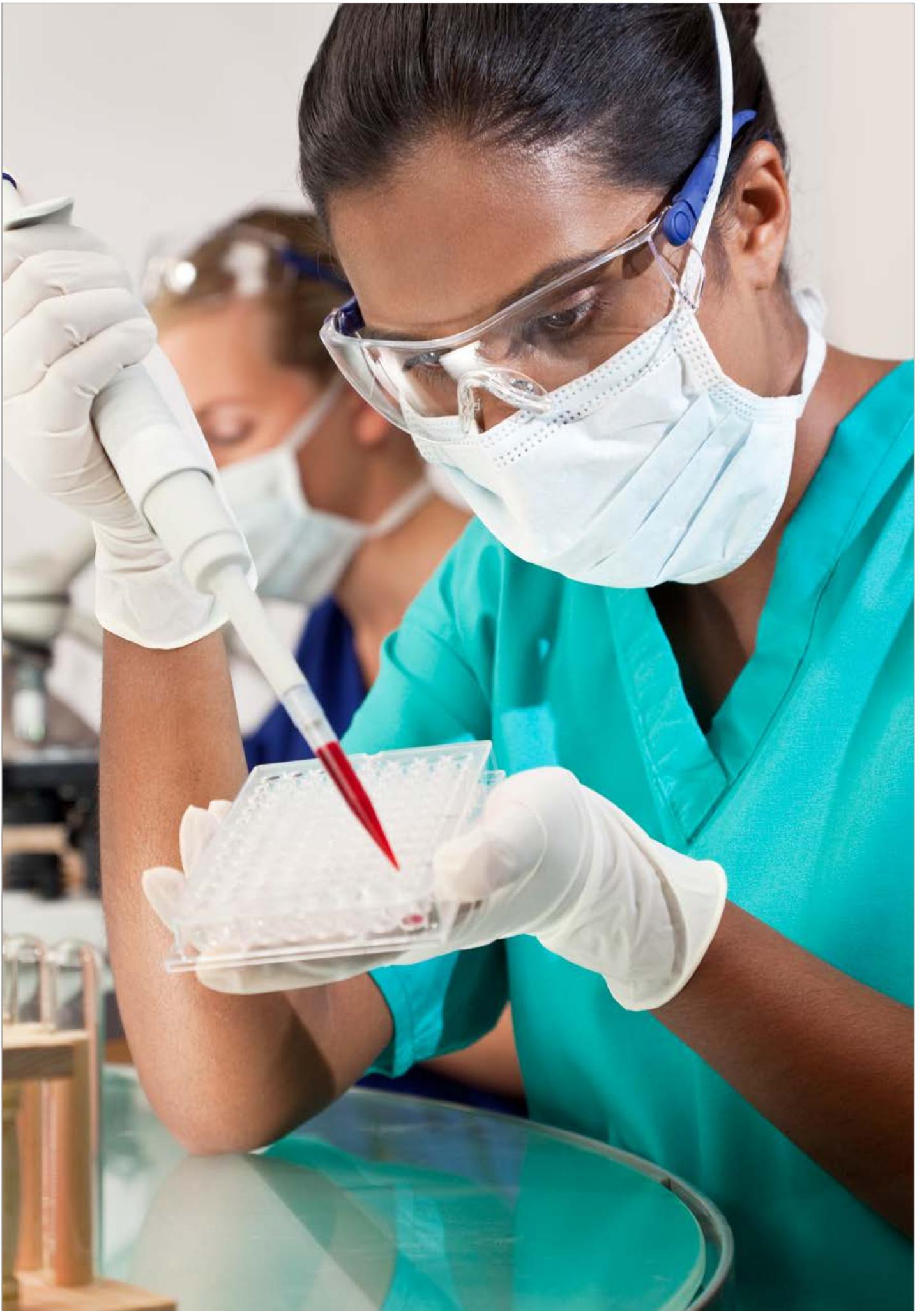


Photo: Medical Devices, Photo 1.jpg

# GLOBAL CONTEXT

According to “MedTech Europe”, more than 500,000 different types of medical devices are produced globally each in service of vastly diverse health objectives<sup>2</sup>, spanning a broad spectrum of products from simple products such as disposable gloves to highly technical complex equipment such as MRI and X-Ray equipment, and pacemakers. Driven mainly by the increase in per capita income, the availability of medical insurance and the development of health-related infrastructure, the global demand for medical devices has grown rapidly over the past decade. The National University of Ireland Galway estimates that the current global market for medical devices is valued at US\$ 228 billion, up from US\$ 164 in 2010.

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2. <http://www.medtecheurope.org/node/679>

More specifically, the global trade of ‘electro-medical apparatus’ (HS 9018), accounting for the bulk of Mauritian exports of medical devices (see box 1), reached an historic high of almost US\$ 111.7 billion in 2014, reflecting a solid annual growth rate of 6.4% over the period 2006-2015, despite a decline of 3.7% reported in 2015. This global market is dominated largely by European and American suppliers, together accounting for almost 80% of the equipment exported in 2015. Almost a quarter of the medical equipment purchased in the world came from the United States (24.2%) that year, driven mainly by the activity of Johnson and Johnson, General Electric and Medtronic, the top three medical device companies in the world. Western Europe represents about 46% of the global medical device market, with Germany leading the market (accounting for 11.7% of the world exports) followed by the Netherlands (7.9%), Belgium (5.8%) and Ireland (5.2%).

## Box 1: Tariff nomenclature used to classify medical devices

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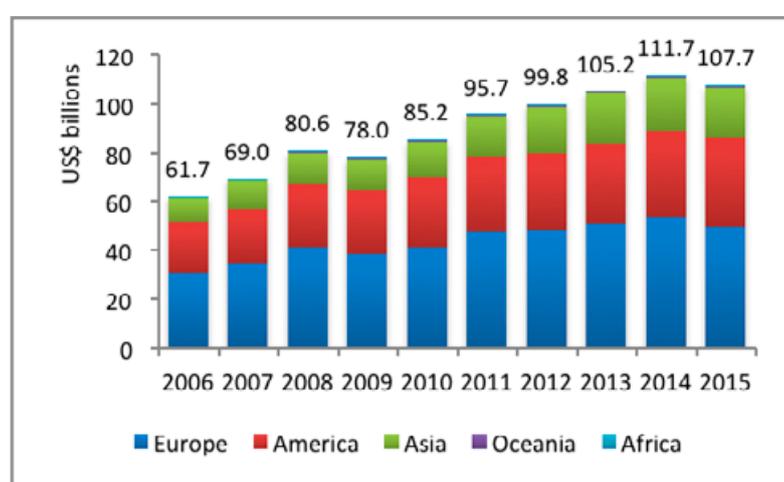
Because medical devices cover a wide range of products classified under different Harmonized System (HS) codes, and particularly under chapter heading 9018 to 9022, it is relatively difficult to capture with accuracy the global trends for all equipment. After a careful analysis of the commodities currently produced in and exported from Mauritius the main tariff nomenclature used for the trade analysis is the following: HS9018 ‘Electro-medical apparatus’.

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If little changes have been observed regarding the origin of exports with a production that is highly concentrated geographically – the top 10 exporters accounted for more than three quarters of the world exports of HS 9018 products in 2015 – significant expansion of the medical devices industry has been observed in several countries, including developing countries (figure 3). Benefitting from an increase in offshore American firms, Mexico has particularly emerged as a key player in the medical devices industry, doubling its exports of medical equipment over the past

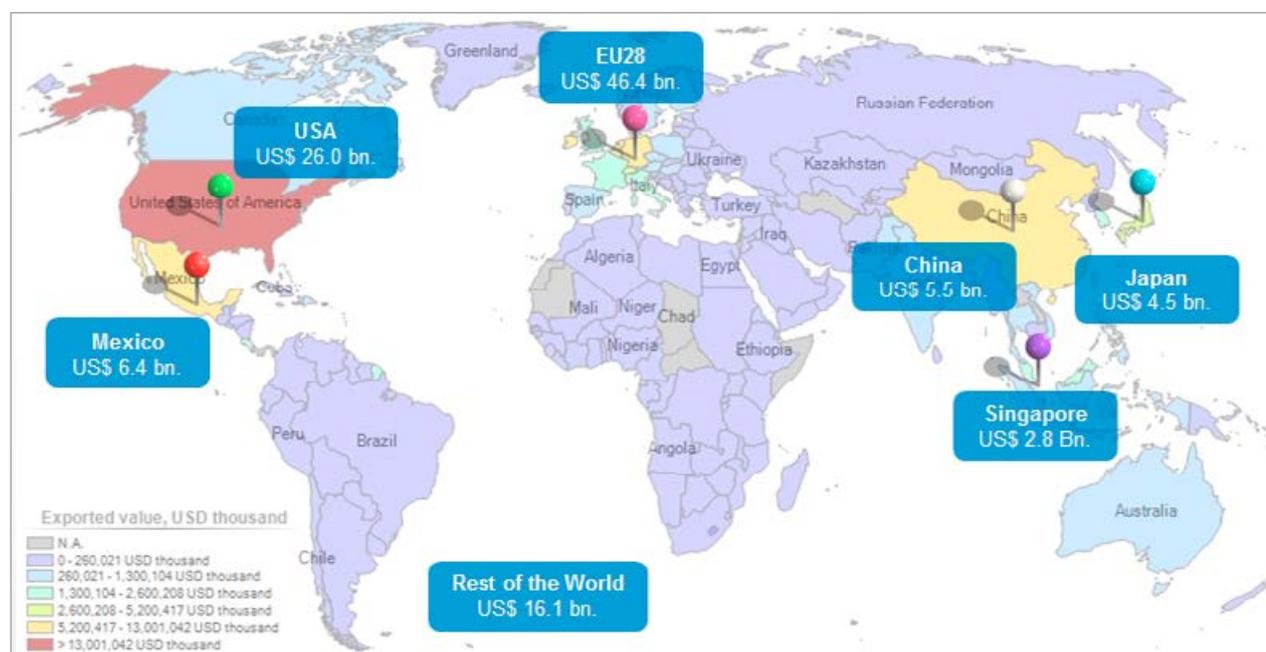
decade and accounting for a market share approaching 6% in 2015. Smaller countries such as Singapore and Costa Rica also rank high in the list of net exporters for HS9018 products, respectively 10th and 14th, with a rapid expansion of their industry in recent years (exports from Costa Rica grew at an annual rate of 19.3% over the period 2011-2015). This situation reflects the fact that these countries have clearly identified the medical devices industry as a national priority listed in their national economic development strategy.

Figure 2: World exports of HS 9018 products by region, 2006-2015



Sources: ITC calculations based on UN COMTRADE statistics

Figure 3: Main exporting countries for HS9018 products in 2015



Sources: ITC calculations based on UN COMTRADE statistics

The global trade of medical devices classified under the HS code 9018 is largely dominated by two categories of products, namely the instruments and appliances used in medical or veterinary sciences (HS 901890) and needles, catheters, cannulae and the like (HS 901839), representing 45.2% and 21.6% respectively, of the world imports in 2015. Electro-diagnostic apparatus (HS 9018) is another important product traded internationally with a share of 8.7% that same year.

Nearly 20% of the medical devices exported globally in 2015 were to the United States which remains by far the largest importer with over US\$ 20.5 billion worth of equipment imported that year. The European demand, representing a share of 43%, was led by Germany (accounting for 7.7% of the world imports), followed by the Netherlands (6.2%), Belgium (5.3%), the United Kingdom and France (3.9% each). Overall, there is high disparity in expenditures between high-income countries and low-and middle-income countries, sales of medical technology being concentrated in high-income nations as highlighted by the fact that Organisation for Economic Co-operation and Development (OECD) countries capture over 75% of world imports of medical devices (HS 9018).

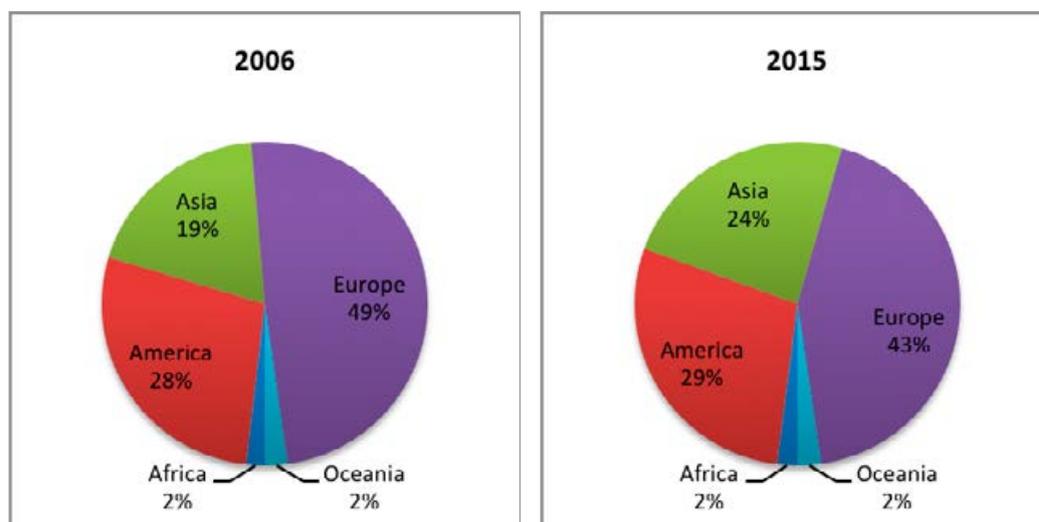
The demand from emerging markets is nevertheless progressively strengthening, notably from Asia. As indicated in figure 4 above, the share of Asian countries in world imports has significantly increased over the past years, from 19% in 2006 up to 24% in 2015, mainly driven by a booming Chinese demand (China reported an annual average growth of 18.4% over the past 10 years) and the



Photo: (cc) pixabay

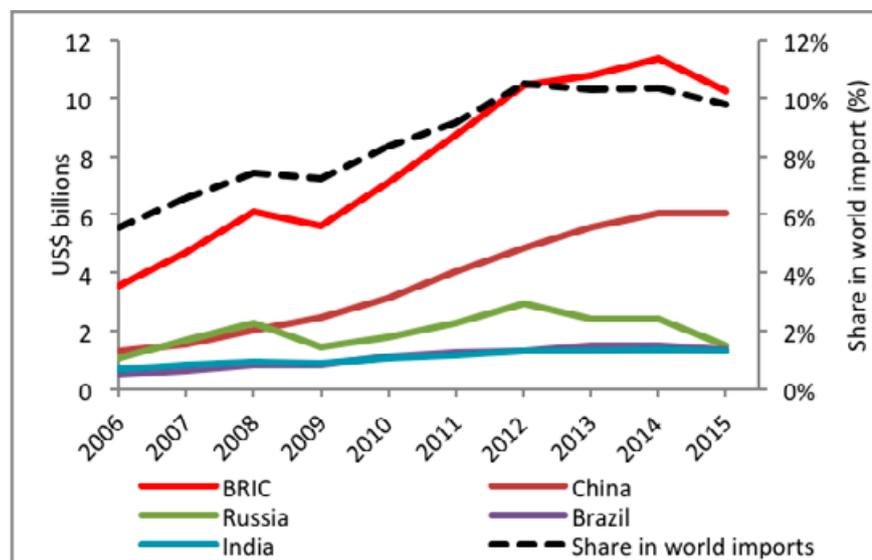
emergence of new actors such as Singapore and India. A strong progression of the demand from BRIC countries (Brazil, Russia, India and China), has also been observed in recent years, together currently capturing about 10% of world imports compared to 5.6% 10 years ago, therefore offering promising prospects for the industry (figure 5).

Figure 4: World imports of HS9018 products 'Electro-medical apparatus', 2006 and 2015



Sources: ITC calculations based on UN COMTRADE statistics

Figure 5: Imports of HS 9018 products from BRIC countries, 2006-2015



Sources: ITC calculations based on UN COMTRADE statistics

## The regulatory environment

As it is related to medical science, the medical devices industry –and the international trade of medical equipment– is highly regulated with well-established standards. Manufacturers operating in the industry are ISO 9001 and ISO 13485 certified and those exporting to the European Union and the United States satisfy the EU Good Manufacturing Practice (GMP) and the US Food and Drug Administration (FDA) requirements:

- **ISO 13485** represents the requirements for a comprehensive QSM for the design and manufacture of medical devices, including all the elements of ISO9001.
- **GMP** is a system for ensuring that products are consistently produced and controlled according to quality standards
- **Specific national or regional QSM requirements:**
  - Regulations of the FDA's Center for Devices and Radiological Health (CDRH)
  - Medical Devices Directives in the EU. The core framework provides for three directives, one for implantable medical devices, another for medical devices and one for in vitro diagnosis medical devices
  - Pharmaceutical and Medical Device Law (PMDL) in Japan
  - Drugs Controller General of India (DCGI), National Health Surveillance Agency ANVISA (Brazil) and China Food and Drug Administration (CFDA)

## Outlook

Despite a recent contraction observed in 2015, the global demand for medical devices is expected to grow over the coming years, driven largely by the emerging demand from developing countries and BRIC countries in particular. According to Espicom Business Intelligence, by 2017, the global medical device market will approach US\$ 434.4 billion, an annual average growth of 7.1% from 2012. Similarly, the National University of Ireland Galway recently indicated that the global market for medical devices is projected to reach US\$ 440 billion by 2018, from US\$ 228 billion today.

This growth in the medical device sector will mainly be achieved through cost containments, better pricing and reimbursement controls and more efficient regulatory issues.

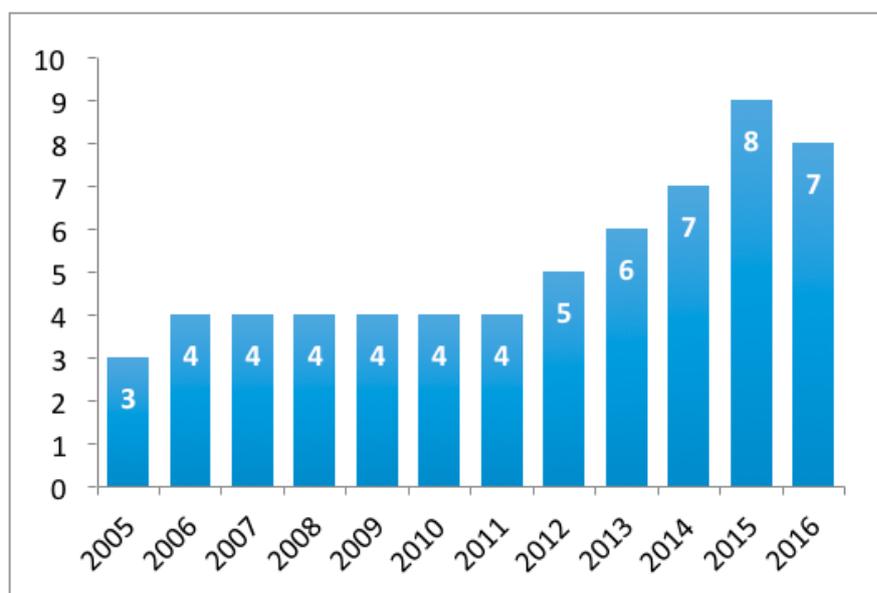
# CURRENT CONTEXT

## HISTORICAL PERSPECTIVE

The Life Sciences industry comprising the pharmaceutical, biotechnology and medical technology segments, is still nascent in Mauritius, and has been growing steadily over the years but has yet to develop to new heights. The development of the medical devices sector is, in particular, very recent. The first company operating in the industry FCI SUD, a French company specializing in ophthalmic implants, was founded in 1997. The company is part of Carl Zeiss Meditec Group, a leading industry player, since 2005. NATEC Medical was the first

Mauritian company founded in 2000 with the first sales realized five years later. Attracted mainly by the competitive tax regime, the stable political and economic environment, the relatively qualified manpower and the enabling business environment, several leading industry players from Europe have established a presence in Mauritius since then. These private actors include Envaste Medical Instruments, Symatese Device, formerly known as Perouse Medical and Kasios, giving greater weight to the Mauritian medical devices sector. On January 1st 2016, seven medical devices manufacturers were operating in Mauritius (figure 6).

Figure 6: Number of medical devices manufacturers operating in Mauritius, 2005-2016



Source: Board of Investment

## DOMESTIC PRODUCTION

Table 1: List of medical devices manufacturers operating in Mauritius as of 1st January 2016

Name of the company	Main products	Status (nationality)	Location
<b>NATEC MEDICAL</b>	Catheters and stents	Autonomous entity (Mauritius)	Réduit
<b>FCI Sud</b>	Ophthalmic implants	Carl Zeiss subsidiary (Germany)	Goodlands
<b>LILMO</b>	Cardiovascular and oncology implants	Pérouse Medical subsidiary (now VYGON since July 2015) (France)	Pamplemousses
<b>SYMATESE</b>	Artificial skins	Pérouse Medical subsidiary, (now VYGON since July 2015) (France)	Pamplemousses
<b>KASIOS</b>	Orthopaedic and dental implants	Kasios France subsidiary (France)	La Clémence
<b>Envaste</b>	Catheters uro & gastroenterology	Autonomous entity (Mauritius)	Ebène
<b>ALPINIA</b>	Biomedical micromechanics	Statice Santé subsidiary (France)	Ebène

With the establishment of these new entities, Mauritius has built a well-developed medical devices industry that produces a wide range of highly sophisticated products. The domestic industry has indeed widened its offerings of products quickly in recent years, currently including cardiovascular and oncology implants, breasts implants, catheters and stents, ophthalmic implants, bone implants and substitutes, artificial skins used in transplant operations, orthopaedic and dental implants as well as sterilization services (table 1). The industry is gaining momentum as further development in the sector is expected in the coming years, particularly as several projects are in the pipeline.

Although these Mauritian-based companies are producing highly sophisticated medical equipment, they are generating very limited levels of value addition locally. So a change in approach is essentially needed to boost levels of value addition.

### Contribution of the sector to GDP and total employment

The Board of Investment (BoI) estimated that the medical devices industry generated a turnover of MUR 750 million in 2015, or US\$ 21 million. According to a report published by the European Union<sup>3</sup> published in 2014, this amount even exceeded MUR 1 billion, or about US\$ 28.5 million, that same year. If it is safe to state that the share of the industry in the economy of Mauritius remains limited, accounting for less than 0.5% of the gross domestic product (GDP), more disaggregated and up-to date information and data would be needed to measure the production and the contribution of the sector to the economy with accuracy.

3. ACP TMS PMU –Developing a Master Plan for the Mauritian Services Sector (2014)

In terms of socio-economic contribution, it is estimated that the medical devices sector currently employs about 550 to 600 people in Mauritius, of whom 95% are Mauritians. It is also estimated that women account for 80% of workforce employed in the industry, and close to 100% of the operatives working on the production lines. The stakeholders involved in the sector indicated further that the workforce employed is relatively young with 50% of our human resources below 30, and 25% below 25 years old.

## VALUE CHAIN MAPPING

The medical devices value chain reflects the complexity and the high level of sophistication of some of the equipment manufactured. It encompasses several distinct key components following the different production stages. Given the high level of integration of the sector internationally, the value chain depicted here is a global value chain.

The challenge for these sites – initially established by leading European firms following a financial strategy aiming at decreasing production costs – and for the industry in general, is to move up the global value chain gradually to maximize gains from participating in the global outsourcing of activities.

### Research & Development

This preliminary stage is critical as it encompasses key activities such as product design, prototyping and process development. Generally, but also depending on the level of complexity of the medical equipment being manufactured, the research and development component of

the medical devices value chain requires highly qualified staff, included specialized scientists and engineers. Highly sophisticated machinery and materials might also be needed to conduct research and development activities. Research and development activities in this highly innovative and technically complex industry must be accompanied by the appropriate level of intellectual property.

The research and development segment of the value chain is currently mainly taken care of, as far as foreign owned subsidiaries are concerned, by the parent companies in Europe. At the moment, only two medical devices manufacturers are conducting part of their R&D activities in Mauritius, namely NATEC Medical and ENVASTE. Several factors can explain the limited development of research activities in Mauritius, chief among them being the lack of appropriately skilled workforce locally and the absence of a legal framework regulating research activities. In this regard, it is to be noted that clinical trials for medical devices are not regulated in Mauritius, hence making pre-clinical testing of medical devices impossible locally. The regulatory approval of the medical equipment, another key element of the research component is made through specialized and internationally recognized certification bodies as such services are currently not available locally.

### Component manufacturing

Once designed, tested and approved, medical devices are manufactured. As the level of technological complexity of medical devices varies greatly, the nature of the different production stages might differ significantly. Generally, though, the production of a medical device requires the manufacturing of different components. Depending on the complexity of the equipment produced, the fabrication of its components might be outsourced by leading industry players.

Component manufacturing comprises a number of diverse activities including the production of electronic, plastic and metal components as well as the development of specialized software. Some companies, such as NATEC Medical, have recently integrated some activities related to the production of parts and components needed to assemble the final product and have developed their own machines<sup>4</sup> as well as software, resulting in greater strategic independence of supply. Even with some degree of vertical integration, component manufacturing in Mauritius is currently limited to the manufacturing, on a small scale, of plastic and metal components.

4. NATEC Medical has developed its Own Brand Labelling - Private Label Manufacturing (OBL – PLM) for PTCA & PTA Balloon and Catheters manufacturing.



Photo: (cc) pixabay

### Assembly

Assembly operations in the medical devices value chain are performed in a clean room and require sterilization and packaging equipment and services. Most production sites in Mauritius were initially established to operate in the “assembly” segment of the global value chain, only dealing with the clean room assembly of final products.

Some development has, however, been observed in several companies in recent years, notably regarding the development of some components and a greater implication in the distribution of the final products.

### Distribution

At this stage, the main operations include kitting, order management, warehousing as well as logistic considerations. If most subsidiaries rely on the company’s sales force and specialized sales departments based in the headquarters in Europe for the distribution and export of the final products, several entities also sell their production to their own network of distributors and resellers.

Looking more specifically at the market distribution channels for medical devices, it appears that most companies adopt an Original Equipment Manufacturer (OEM) strategy, whereby a company buys a product and incorporates or re-brands it into a new product under its own name. The OEM will generally work closely with the company that sells the finished product (often called a “value-added reseller” or VAR) and customize the designs based on the VAR’s needs. The business model is consequently that of a business to business (B2B) whereby sales are made to other businesses, rather than to final users.



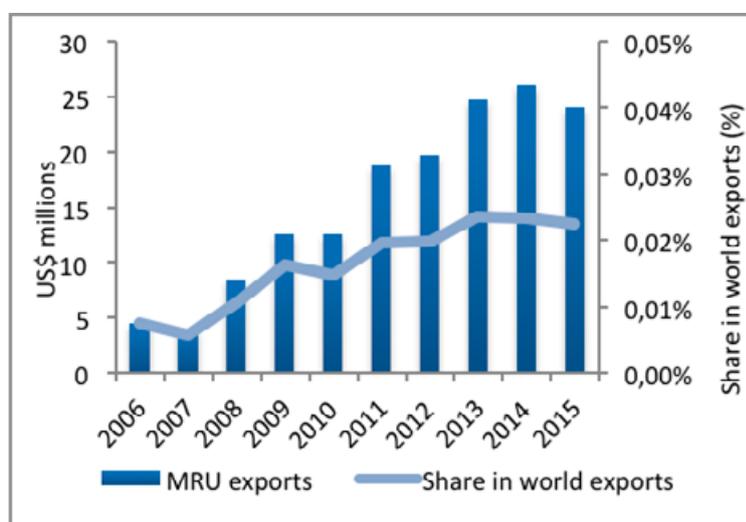
## TRADE ANALYSIS

If Mauritius has managed to establish itself progressively as a manufacturing platform for medical devices, the country remains a small player on the international scene, its exports only representing a mere 0.022% of world exports for electro-medical apparatus (HS9018). The country ranks 59 in world exports. Exports of medical equipment from Mauritius have nevertheless significantly expanded over the years, growing at an impressive Compound Annual Growth Rate (CAGR) of 20.3% over the past decade to reach US\$ 24.1 million in 2015

(figure 8). This amount represents about one percent of Mauritius' total exports that year. Despite a contraction of 7% reported in 2015 compared to 2014, the exported value of the sector has been multiplied by more than five since 2006, though from a very low base.

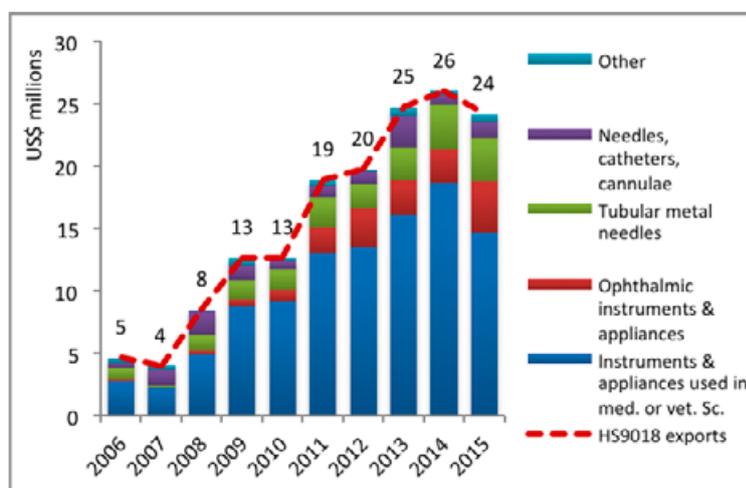
Mauritius' exports are largely dominated by 'instruments and appliances used in medical or veterinary sciences', accounting for 60% of Mauritius' exports of HS 9018 products, followed by ophthalmic instruments and appliances (17%) and tubular metal needles (14%) (figure 9).

Figure 8: Mauritius exports of HS9018 and share in world exports, 2006-2015



Sources: ITC calculations based on UN COMTRADE statistics

Figure 9: Mauritius exports of HS9018, by product, 2006-2015



Sources: ITC calculations based on UN COMTRADE statistics

Exports of Mauritian medical equipment and appliances are concentrated in a limited number of markets with only 11 countries importing more than US\$ 100,000 worth of goods in 2015, France and India being the only two countries importing goods for a value exceeding US\$ 1 million. The French market alone captured about 64% of Mauritius exports of HS9018 products that year, for a total exported value amounting to US\$ 15.4 million. The trade of medical equipment with France is largely dominated by instruments and apparatus for medical surgical sciences, this type of device accounting for almost 80% of the country's imports from Mauritius. This predominance is partly explained by the presence of French subsidiaries that assemble components in Mauritius before shipping them to France for final assembly.

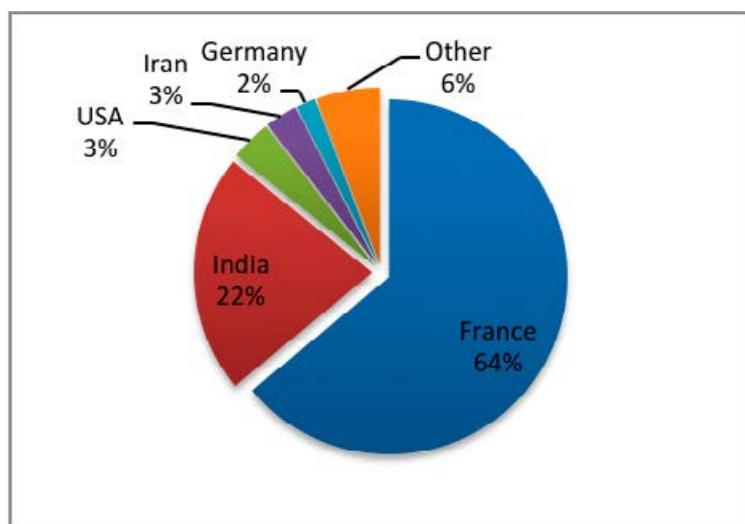
With a continuously increasing share in Mauritian medical devices exports (representing 22% in 2015), India is the second most important market for the domestic industry. The country particularly imports large volumes of tubular metal needles and needles for sutures, this type of equipment accounting for more than 75% of Indian imports of HS9018 from Mauritius for a value exceeding US\$ 4 million. The geographical proximity of the country as well as the historical cultural and commercial linkages that exist between the two countries partly explains this privileged trading relationship. Given its booming demand for medical equipment (India's imports in value have expanded at a CAGR of 7.4% over the period 2006-2015) fuelled by an increasing population and significant increase in per capita income, India offers promising prospects for Mauritius-based manufacturers. The domestic industry has recently penetrated non-traditional markets

such as Iran but the value of the commodities traded remains limited. Apart from the French and Indian markets, the domestic industry has not managed to penetrate international markets yet.

As illustrated in figure 11 below, promising prospects for market diversification, however, exist for medical devices manufactured in Mauritius as most of the key markets in the global trade remain untapped by local firms. In addition to the well-established North American and European markets, the industry could take advantage of the significant growth of imports observed in developing and emerging economies such as China, Mexico, Singapore or Saudi Arabia.

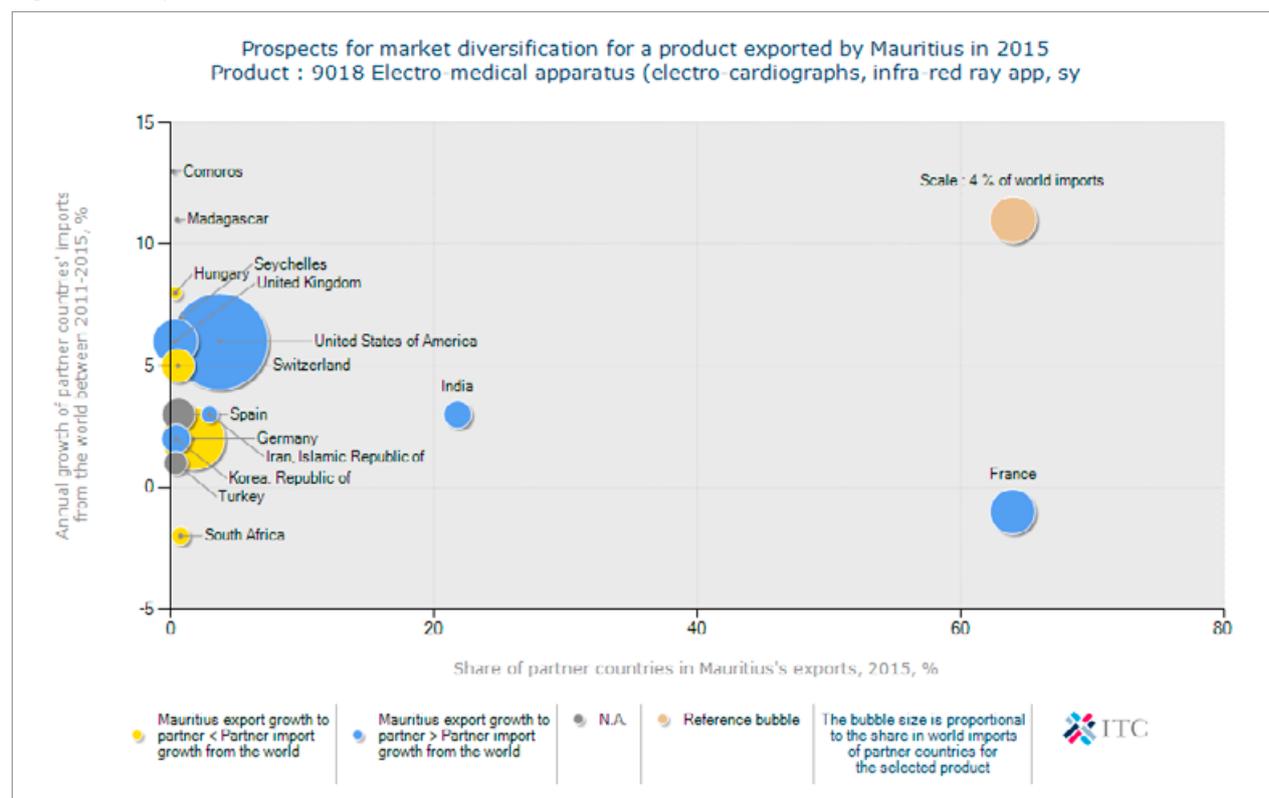
Finally, it is to be noted that most companies operating in the sector do not sell their products to Mauritian buyers. The main reason for this trend is the fact that the Mauritian market is relatively small in size, therefore representing a limited interest for medical devices manufacturers willing to sell large volumes of medical equipment. As further developed under the competitiveness constraints section of this strategy, the phenomenon is reinforced by the burdensome presence of a national preference system, as defined by the National Procurement Act, which does not offer incentives for medical devices manufacturers based in Mauritius to penetrate the domestic market. Mauritius consequently imported significant quantities of medical equipment classified under the HS code 9018 –including instruments and appliances used in medical or veterinary sciences and needles, catheters and cannulae– to a value of US\$ 11.5 million in 2015.

Figure 10: Mauritius exports of HS 9018 products, by country, 2015



Sources: ITC calculations based on UN COMTRADE statistics

Figure 11: Prospects for market diversification



Sources: ITC calculations based on UN COMTRADE statistics

## INSTITUTIONAL FRAMEWORK AND DEVELOPMENT SUPPORT

### The institutional framework

As indicated earlier, it is only recently that the sector received some attention from support institutions, progressively recognizing the growth potential of this high-value activity. If efforts are currently being made the industry has not yet been considered a priority sector and still suffers from a lack of political will demonstrated by the authorities.

Several institutions are directly or indirectly involved in the development of the medical devices industry in Mauritius, including the Ministry of Industry, Commerce and Consumer Protection, the Ministry of Health and Quality of Life, and the Ministry of Finance and Economic Development. Parastatal organizations such as the Bol and Enterprise Mauritius (EM) as well as intermediary organizations such as the Mauritius Chamber of Commerce and Industry (MCCI) are also supporting the development of the industry. Since the support is not provided in a coordinated and articulated manner, there is a lack of

clarity and transparency regarding the respective roles and responsibilities and no clear picture about existing capabilities. Importantly, the lack of coordination between support institutions does not allow for the definition of a clear vision for the industry in Mauritius. As suggested in the Plan of Action, the creation of a dedicated “one stop partner” could be envisaged to reduce complexity, duplication and waste of efforts, and to improve efficiency and responsiveness of the support provided to the sector.

### Development policies

As little attention has been drawn to the medical devices at this stage, no sector development plans have been elaborated at the national level so far. No clear vision, development objectives or orientations have consequently been defined for the industry –and for the life sciences sector as whole– at this point.

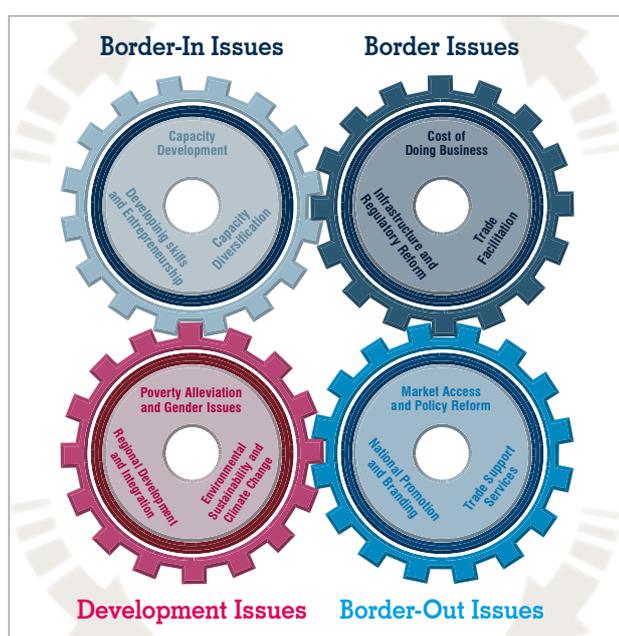
It is, however, to be noted that a high level task force was recently established by the Government and focuses on innovation, including ICT, logistics, Smart Cities, biotechnologies, etc. The Task Force is working on a vision for the development of innovative sectors. It comprises representatives from Bol, MCCI, MCA, ICT, UoM, UoT, and MSB, among others.



Photo: Medical Devices, Photo 6.jpg

## COMPETITIVE CONSTRAINTS AFFECTING THE VALUE CHAIN

Traditionally, the scope of trade strategies has been defined in terms of market entry, such as market access, trade promotion and export development. This ignores several important factors in a country's competitiveness. For an export strategy to be effective it must address a wider set of constraints, including any factor that limits the ability of firms to supply export goods and services, the quality of the business environment, and the development impact of the country's trade, which is important to its sustainability. This integrated approach is illustrated by the four gears framework schematic on the right.



### Supply-side constraints

Supply-side issues impact production capacity and include challenges in areas such as availability of appropriate skills and competencies, diversification capacity, technology and low value addition in the sector's products.

### Business environment constraints

Business environment constraints are those that influence transaction costs, such as regulatory environment, administrative procedures and documentation, infrastructure bottlenecks, certification costs, Internet access and cost of support services.

### Market access constraints

Market entry constraints include issues such as market access, market development, market diversification and export promotion.

### Social and environmental constraints

Social constraints include issues related to poverty reduction, gender equity, youth development, environmental sustainability and regional integration.

## SUPPLY SIDE CONSTRAINTS

### Box 2: Border-In Gear issues

- High dependence on raw materials imports for components manufacturing
- The National Quality Infrastructure is not up to international standards
- No accredited agent to control and calibrate the equipment and machines used for the manufacturing of medical devices components
- The Mauritius Standards Bureau (MSB) does not yet have the capacity to respond to the highly regulated medical devices industry
- Lack of adequate physical infrastructure for the expansion of industry
- Weak business linkages and overall lack of cooperation and coordination between the medical devices manufacturers
- Lack of synergies with potential supporting industries
- Lack of adequate infrastructure to conduct research activities
- The financial products offered by the commercial banks are not adapted to the needs of the medical devices industry
- Shortage of skilled labor, in particular at middle management level
- Strong skills mismatch between the industry and the educational system
- Poor linkages between the industry, academia and research institutions

## CAPACITY DEVELOPMENT

### The high dependence on raw materials imports for components manufacturing generates significant costs for the industry

If some of the components used by the medical devices industry are manufactured in Mauritius, the natural resources required for their production, such as plastic granules, are not available in the country. All raw materials are consequently imported, hence generating significant costs for the companies operating in the sector. The matter is complicated further by the fact that there are currently no distributors of raw materials such as plastic granules in Mauritius owing to the limited number of companies and the small size of the market, making it difficult to achieve economies of scale.

- **Severity:** ● ● ○ ○ ○
- **Value chain segment:** Component manufacturing
- **PoA reference:** Activities 2.2.1 and 2.2.2.

### Medical devices and medical devices components manufactured in Mauritius cannot be certified in the country, owing to a National Quality Infrastructure that is not in line with international standards

Since MAURITAS, the national public accreditation body, is not yet a signatory of the ILAC MRA (Mutual Recognition Arrangement)<sup>5</sup>, final products or components certified by a body accredited by MAURITAS are not accepted by international importers. This situation leaves no other choice to the medical equipment manufacturers but to seek the services of accredited and internationally recognized certification bodies such as LNE/GMED, ITC, SGS, DECRA or TUV. Using these service providers appears to be costly for Mauritian-based companies, all the more so as those entities do not have a local presence in the country.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Component manufacturing and assembly
- **PoA reference:** See National Export Strategy

5. MAURITAS is currently an associate member of ILAC

### **There is currently no internationally recognized accredited agent to control and calibrate equipment and machines used for the manufacturing of medical devices components.**

The complex and sophisticated equipment and machines used by the industry to manufacture and test medical equipment need to be properly calibrated against international standards and controlled and inspected regularly by an accredited and internationally recognized agent. In Mauritius, metrology services fall under the responsibility of the Legal Metrology Services, under the aegis of the MSB, services that are not recognized internationally as they are only accredited by MAURITAS to perform a limited number of tests. Owing to this absence of international recognition, manufacturers have to seek the services of foreign accredited agents, mainly from France, to perform those verifications. In addition, the Legal Metrology Services is not currently prepared to provide such services given the limited knowledge of the department about the industry and the lack of adequate equipment to perform the required tests and controls.

The industry would consequently benefit greatly from a metrology services qualified to validate equipment and machines needed for the manufacture of medical devices as it would reduce the costs associated with those services significantly. A critical first step in achieving this objective is to achieve international recognition of the national accreditation body, MAURITAS.

- **Severity:** ● ● ● ● ○
- **Value chain segment:** Component manufacturing and assembly
- **PoA reference:** Activities 1.2.1. and 1.2.2.

### **The MSB does not yet have the capacity to respond to the highly regulated medical devices industry**

The Bureau is responsible for standardization, quality assurance, testing and metrology and operates a certification marking scheme for products and a national management system certification scheme (including ISO 9001, ISO 14001, ISO/IEC 27001, ISO 22000 and HACCP certification). However, being related to medical science, the medical devices industry is highly regulated and has to comply with specific, strict and well-established international standards that cannot be delivered by the MSB, such as the ISO 13485 certification. Most importantly, and as mentioned earlier in the present strategy, since the MSB is not accredited by an internationally recognized body, i.e. MAURITAS, the tests the entity is accredited to perform cannot, in any case, be used by medical devices manufacturers.

Also, the apparent lack of knowledge among MSB staff about the medical devices industry and its requirements in terms of quality assurance and quality control highlights the need for additional, specific, technical training. Further, the renewal and modernization of some of the equipment used by the MSB also appears to be needed.

Besides, the expertise required to conduct ISO 13485 representing the requirements for a comprehensive Quality Management System (QMS) for the design and manufacture of medical devices is not available locally. This situation has led manufacturers to seek the services of accredited certification bodies in the medical field, such as LNE-GMED, to certify that their QMS for the manufacture of medical devices complies with international standards requirements. The expertise needed to certify and qualify the buildings also appears to be lacking in Mauritius.

- **Severity:** ● ● ● ● ○ ○
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 1.2.3. to 1.2.5.

### **The lack of adequate physical infrastructure for the medical devices industry hampers the expansion of the sector**

Although several facilities are available for new comers in the sector, namely in La Clémence, Rivière du Rempart, where buildings are available for medical devices manufacturers, facilities remain limited in number and, most importantly, do not meet the industry's requirements, particularly for clean-room operations. In these circumstances, establishing a medical devices manufacturing plant requires significant investments and time from potentially interested entities to upgrade the existing infrastructure and to become fully functional. The recent experience of PPSUD, a subsidiary of the American leader Johnson & Johnson involved in the fabrication of breast implants that recently closed down mainly over the difficulties faced in upgrading existing facilities to medical standards, has shown the limit of the model.

The lack of such infrastructure currently dissuades operators from establishing subsidiaries in Mauritius and complicates the expansion of established entities. The creation of physical infrastructures adapted to the industry's needs would unlock the potential of existing entities and would be a starting point for the development of a medical devices cluster, in turn contributing to attracting new manufacturers and startups in particular. The recent launch of two new projects, namely the Rose Belle Business Park and the Rivière du Rempart Technopark, represents a promising opportunity in this regard as medical devices manufacturers could benefit from newly available facilities.

- **Severity:** ● ● ● ● ○
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 2.1.1.



Photo: Medical Devices, Photo 3.JPG

## CAPACITY DIVERSIFICATION

The weak business linkages and the overall lack of cooperation and communication between medical devices manufacturers hinder the development of the industry.

Although synergies could be created between the different manufacturers, business linkages and communication between the different entities appear to be largely underdeveloped. If the fact that the industry is currently relatively small with companies scattered over the territory may partly explain the situation, the absence of a dedicated entity for the sector, the lack of a clear vision on life sciences sector and the absence of a dedicated budget to promote the industry at the institutional level, are also key factors behind the industry's lack of coordination.

The emerging medical devices sector would greatly benefit from a cluster development initiative in order to promote greater business linkages between firms and increase the competitiveness of the local industry. Grouping companies involved in the manufacture of medical equipment to create an operational cluster with rapid access to basic infrastructures could indeed represent a key success factor for the future expansion of the sector. The idea of a "Health Science Techno Park" could be envisaged, for instance, based on the model of the recently created BioPark Mauritius, a dedicated space to biotechnologies for research and development.

- **Severity:** ●●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 2.1.1. to 2.1.3.

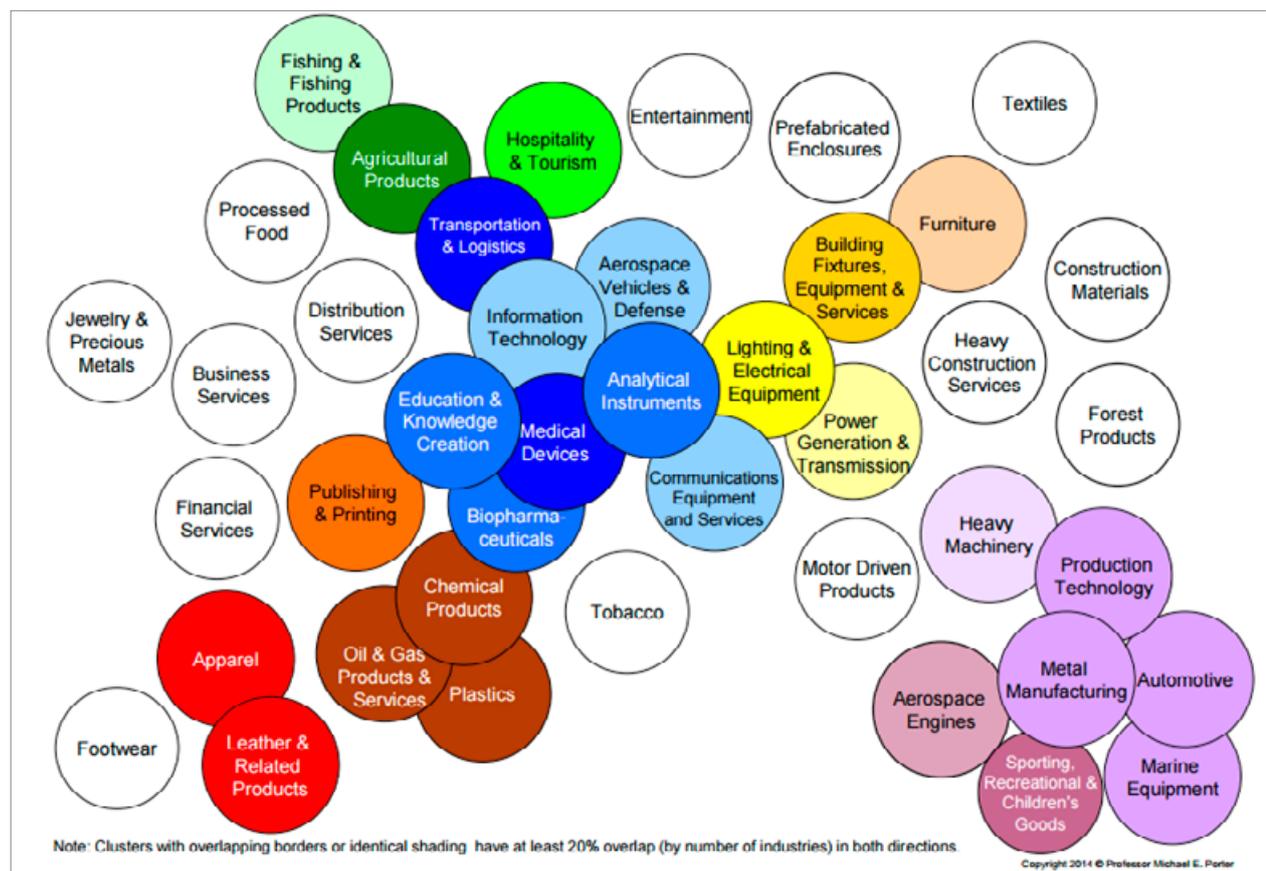
## The lack of synergies with potential supporting industries in Mauritius constrains the expansion of the medical devices sector

In recent years, in addition to the manufacturing of sophisticated medical devices, a few high technology enterprises have been engaged in the production of highly sophisticated products, including watch and watch components manufacturing and high precision plastic products. Synergies between these different activities and medical devices manufacturers exist in various areas, including precision mechanics, industrial design, electro mechanics, and nanotechnology, among others, in particular for the production of medical equipment components. The potential synergies and cluster relatedness are illustrated in figure 12 below. The industry could, for instance, benefit from the expertise and specialized equipment available locally for the molding of high precision plastic components.

Interaction among industry players is currently limited, a key challenge being the lack of an efficient umbrella organization capable of generating synergies through improved collaboration and interaction between those actors.

- **Severity:** ●●●●○○
- **Value chain segment:** Component manufacturing
- **PoA reference:** Activities 2.2.1. to 2.2.3.

Figure 12: Cluster relatedness (Michael Porter)



**Source:** Professor Michael E. Porter (2014). Mauritius Competitiveness Overview. BSP International Conference, Republic of Mauritius, 2nd April 2014. Harvard Business School.

### The present capacity of the medical devices industry to innovate and diversify its production is hampered by the lack of adequate infrastructure to conduct research activities

A gap analysis between the current and the desired state is required to identify the existing research infrastructures operating in the field of the broader Health Science sector and assess their suitability and compatibility with the research activities conducted by the sector. Ultimately, a strategy should be elaborated to optimize the use of existing research infrastructures to respond better to the needs of the sector. The development of new infrastructures could also be envisaged if a need is identified.

- **Severity:** ●●●○
- **Value chain segment:** Research and development
- **PoA reference:** Activity 3.2.3.

### The loans and financial products offered by the commercial banks are not adapted to the needs of the medical devices industry

In particular, manufacturers from the sector have reported a lack of responsiveness from the commercial banks in Mauritius, potentially delaying critical investments. This is all the more important given the rapidly evolving context in which the medical devices manufacturers are evolving. Lack of knowledge and understanding of the sector and of the promising opportunities it offers are preventing financial institutions in granting credit. They are being over-cautious and not currently prepared to provide financial support for innovation to an industry that is not considered a priority by the banking sector. There are, in addition, no advantages or incentives for startups willing to enter the medical devices industry.

Better access to finance coupled with financial incentives and advantages for companies involved in the manufacture of medical tools and equipment would support the expansion of the economic activities of existing

manufacturers, foster innovation and contribute to attracting new actors in Mauritius, including startups with limited financial capacities. The creation of a private equity fund could also represent a viable strategy to support the development of the sector.

- **Severity:** ● ● ○ ○ ○
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 4.3.1. and 4.3.2.

## DEVELOPING SKILLS AND ENTREPRENEURSHIP

### The industry suffers from a shortage of skilled labor, in particular at middle management level

To date, a large proportion of the middle management, i.e. the intermediate management of a hierarchical organization that is subordinate to the executive management and responsible for lower levels of staff, in medical devices companies operating in Mauritius comes from experienced operatives who have been promoted within the company. This process appears to be suboptimal and unsustainable as several years of experience within the companies are required for an operator to be up to the tasks that fall under the responsibility of a middle manager, consequently requiring substantial investment in training. The reason behind this situation is that companies find it difficult to recruit sufficiently qualified middle managers with the necessary business skills locally.

Significant efforts have to be made to develop middle management skills in Mauritian universities but also to attract foreign “brainpower”, namely by increasing the opening up of the country to qualified expatriates and by offering grants.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 3.1.1. and 3.1.3.

### The strong skills mismatch between the industry and the educational system is limiting the medical devices industry potential

Besides the lack of managerial capabilities mentioned above, the industry identified technical skills development as a key success factor and a priority for the competitiveness of the medical devices sector in Mauritius. The education infrastructure (including TVET and tertiary education) is, however, not well-aligned with the requirements of industry with specific needs and shortage of skilled workers identified in the fields of biology, micro-biology, industrial mechanics and maintenance. Recruiting qualified designers, scientists and engineers appears to be particularly challenging for sector’s professionals. The fact that there is no dedicated medical devices curriculum

in Mauritius is largely because the sector still has not reached sufficient critical mass.

Initial training and continuing vocational education and training in these areas, including specific training on clean-room use, need to be developed further in order to align the educational system closely to the industry’s needs. The specialized training courses developed by the Galway Medical Devices Centre of Excellence in Ireland or the Massachusetts Institute of Technology (MIT) in the United States, the world’s references in the field of medical devices, can be used as a source of inspiration in this regard. Significant investment in modern, high technology equipment to be used during the training is also a prerequisite, coupled with theoretical and hands-on practical training on that equipment. It is to be noted here that the Human Resource Development Council (HRDC) Training Fund in place in Mauritius could support such initiatives by reimbursing part of the training costs.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 3.1.1. to 3.1.6.

### Poor linkages between the industry, academia and research institutions

Most companies operating in the medical devices sector do not rely on universities to provide them with the adequately trained workforce, instead internalizing training and research components and elaborating on-board training programmes. As mentioned above, because the medical devices is a relatively new and small sector in Mauritius, it has not yet succeeded in capturing academia and research institutions’ attention. The situation is of particular concern in the field of R&D as the absence of linkages with academia and research institutions makes it difficult for companies to find the expertise needed to conduct such activities. A lack of information on the research carried out by the Mauritius Research Council (MRC) has also been reported by the sector’s professionals.

Establishing a feedback loop between industry and universities would be a critical first step to synchronize the educational system better with the needs of industry. The sector would also benefit from better communication and career guidance on the potential of the medical devices sector. In the field of research, backward and forward linkages need to be developed further with universities and research institutions, such as the MRC, to develop R&D programmes specifically designed for the medical devices industry and targeting different segments of the value chain.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Research and development, component manufacturing and assembly
- **PoA reference:** Activities 3.1.1., 3.2.1. and 3.2.2.

## BUSINESS ENVIRONMENT CONSTRAINTS

### Box 3: Border Gear issues

- Absence of a legal framework for medical devices
- Clinical trials for medical devices are not allowed in Mauritius
- No regulatory framework in place to regulate access to operating rooms in hospitals
- Inadequate protection of intellectual property (IP)
- Difficulties when it comes to dealing with building and land use permits
- Rigid health and safety regulations on industrial materials
- Long customs clearance procedures and customs duties
- Lack of coordination between the supporting services
- Lack of specific expertise and skills of the Trade Support Network
- Lack of incentives for the medical devices sector
- High airfreight costs and limited transport connectivity
- Costly electricity supply
- Limited and expensive Internet access

## INFRASTRUCTURE AND REGULATORY REFORM

### Progress in the sector is hampered by the absence of a legal framework for medical devices in Mauritius

The fact there is currently no specific framework to regulate the activities of the industry in Mauritius contributes to creating an uncertain business environment for risk averse companies not willing to undertake activities that do not fit within a clearly defined regulatory framework capable of protecting them in case of legal action.

A Medical Devices Act could be envisaged, to act as a White Book describing the industrial processes carried out in the medical devices manufacturing industry where guidelines and standard operating procedures (SOP) would be defined clearly. Establishing a regulatory framework would be an important step towards creating a more conducive business environment necessary to attract foreign investors. Further, creating a specific legal framework for medical devices in Mauritius would send a strong signal to key international players in the industry and would position the country on the global stage. Delays in the enactment of such a framework could cause Mauritius to lose business.

- **Severity:** ●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 1.1.2.

### Research activities of manufacturers operating in the sector are constrained by the fact that clinical trials for medical devices are not allowed in Mauritius

The sector value chain cannot be developed fully in Mauritius as conducting clinical trials is not yet permitted because of the absence of a proper legal framework. The industry would greatly benefit from such regulations as it would allow manufacturers to test and validate their medical equipment clinically before they can be put on the market. Though the Clinical Trials Act adopted in 2011 provides for the development of pharmaceutical research, covering both fundamental and applied research, and including pre-clinical and clinical trials, it does not, however, cater for trials of medical devices.

Specific regulations on clinical trials for medical devices should be elaborated along the lines of the Clinical Trials Act for incorporation in the Medical Devices Act. It is also to be noted that a regulatory framework is being developed in Mauritius for pre-clinical trials on monkeys. This is currently a very sensitive topic as voices have been raised against the practice, hence slowing down the adoption of the proposal.

- **Severity:** ●●●●●
- **Value chain segment:** Research and development
- **PoA reference:** Activities 1.1.2. and 3.2.4.

### There is no regulatory framework in place to regulate access to operating rooms therefore impeding research on medical devices

Having access to operating rooms in hospitals and clinics would enable manufacturers to conduct research activities like observing surgical operations with a view to understanding the needs of the surgeons and their medical teams better and the difficulties they might be facing regarding specific interventions. Being in constant contact with medical teams in operation rooms would enable medical devices manufacturers to anticipate those needs by constantly improving and adapting their products to the reality of the operating room. Most importantly, regulating access to such facilities would allow the industry to develop further, in Mauritius, the research and development segment of the value chain, which is currently mainly taken care of, as far as foreign-owned subsidiaries are concerned, by the parent companies in Europe<sup>6</sup>.

More generally, scientific research has to be strictly regulated and controlled to guarantee that the activities are carried out in a safe manner and for very specific purposes. In the case of legal proceedings, regulations would

6. Only two medical devices manufacturers are conducting part of their R&D activities in Mauritius, namely NATEC Medical and ENVASTE.

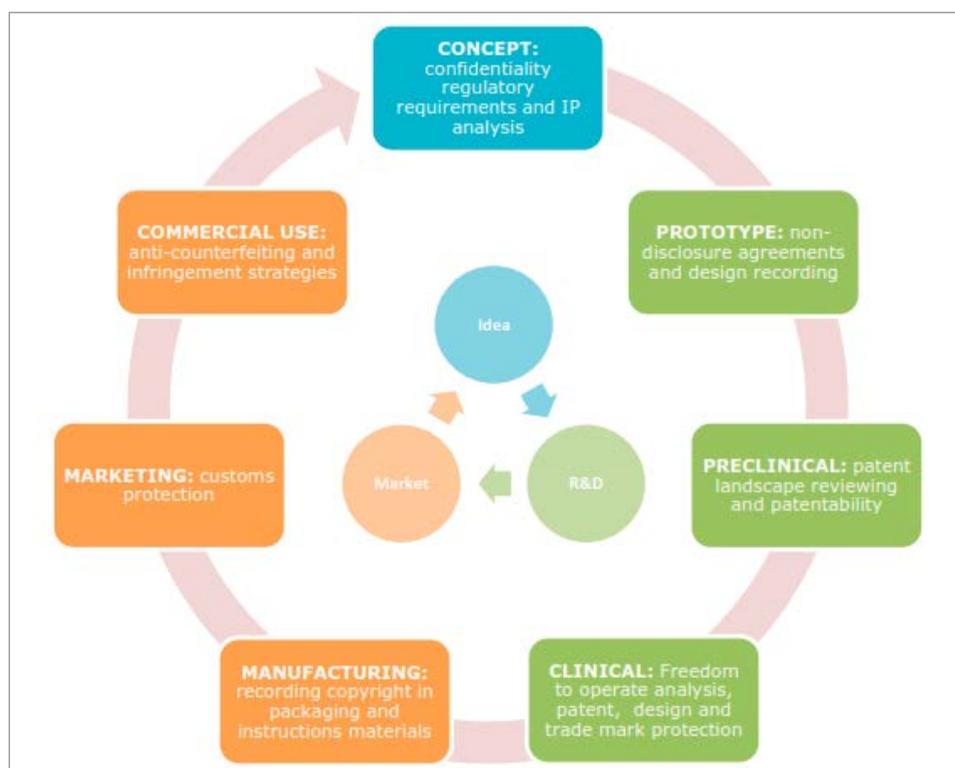
also play a key role in protecting the companies that are undertaking research activities by providing a legal framework that clearly defines their scope of application. For these reasons, a framework to regulate and control research activities in the field of medical devices, including regulations providing for strict regulated third party access to operating rooms, should be incorporated in the envisaged Medical Devices Act.

- **Severity:** ●●●●●
- **Value chain segment:** Research and development
- **PoA reference:** Activity 1.1.2.

### Inadequate protection of intellectual property (IP), patents and brand protection creates unnecessary hurdles to growth

Given the economic value of the industry and the major investments made by companies notably in R&D, it is important that those who retain knowledge are protected through the appropriate laws. As indicated by the EU IPR Helpdesk, placing a medical device on the European market requires consideration of regulatory requirements as well as intellectual property (IP) clearance and protection. As indicated in figure 13 below, IP matters have to be considered at each stage of the product lifecycle of a medical device.

Figure 13: Product life cycle for a medical device



Source: European IPR Helpdesk (2014). Fact Sheet - Intellectual property considerations for medical devices.



Photo: (cc) pixabay

The IP system currently in place in Mauritius, however, does not guarantee the necessary protection for medical devices manufacturers as the national framework for patent protection is not internationally recognized since the country is not a signatory to the Patent Convention Treaty (PCT) under the World Intellectual Property Organization (WIPO). The Patent, Industrial Designs and Trademarks Act 2002, however, provided for the signature of the PCT but the Act is not yet in force and the Treaty has not been signed yet. As a result, patents registered with the Intellectual Property Office (IPO), under the aegis of the Ministry of Foreign Affairs, Regional Integration and International Trade (MoFA), are recognized and protected locally but not internationally. Given the importance of patent protection for medical devices manufacturers the industry has no other choice but to seek IP protection from internationally recognized bodies abroad so that their patents are protected globally.

Similarly, Mauritius is not a signatory to the Madrid Protocol, the International Trademark System under WIPO, a system that allows a trademark owner to seek registration and protection in any of the countries that have joined this protocol. This proves detrimental to operators in the sector in regard to the protection of trademarks. In the same way as for the registration of patents, medical devices manufacturers are forced to register trademarks, including brands, in foreign countries in order to be protected by intellectual property rights. The same observation can be made concerning the protection of industrial design as Mauritius is not part of WIPO's Hague System, the International Design System for the international registration of industrial designs.

- **Severity:** ●●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 3.3.1. to 3.3.3.

### The difficulties faced by the manufacturers when it comes to dealing with building and land use permits make private investment in the medical devices quite risky in Mauritius

A first constraint for investors willing to establish a production site in Mauritius relates to obtaining a building and land use permit. According to data collected by the World Bank's Doing Business 2016 survey, dealing with construction permits in Mauritius requires 15 procedures, takes up to 156 days and costs 0.60% of the warehouse value. Mauritius has made dealing with construction permits easier in recent years but additional efforts are required to reduce the unpredictability of the procedure and increase transparency to attract and reassure potential investors.

In addition, companies willing to invest in the medical devices industry in Mauritius do not receive the support of the public authorities as there is currently no public financing for land and infrastructures that could incentivize the growth of the industry.

- **Severity:** ●●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 4.4.2.

### The rigid health and safety regulations for industrial materials affect the productivity of the sector

The rigid and time consuming procedures for compliance checks for industrial equipment and facilities as provided by the Health and Safety regulations (under the Ministry of Labour, Industrial Relations and Employment) represent an unnecessary burden for medical devices manufacturers. Specific accreditations are, in particular, required for industrial activities. Those procedures could be simplified and streamlined, in line with ILO international standards.

- **Severity:** ●●○○○○
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 4.2.3.

## TRADE FACILITATION ISSUES

### Long customs clearance procedures and customs duties impede imports of inputs

Administrative hurdles in getting customs clearance for imports of specific components remain cumbersome and time consuming for the industry's professionals. In addition, because of a lack of knowledge among customs authorities as well as the absence of clear specifications and HS codes for some imported materials, customs duties are applicable on imports of materials and equipment used for the manufacture of medical devices,

such as alcohols, drugs or solvent. This lack of clarity and the absence of specific regulations on the import of medical devices components can be explained by the fact that the industry is a relatively new business segment in Mauritius, with no historical references.

A list of imported inputs for the broader Health Science sector whereby components would be clearly identified and classified could be envisaged for inclusion in the Mauritius Revenue Authority (MRA) documentation with the view to streamlining customs clearance procedures. The strategy will also support the setting up of an efficient 'National Single Window' system concept under which economic operators give online information on goods to only one contact point, even if the data should reach different administrations/agencies.

- **Severity:** ●●●●○
- **Value chain segment:** Component manufacturing and assembly
- **PoA reference:** Activities 4.1.1. and 4.1.2.

## QUALITY OF INSTITUTIONAL SUPPORT

### Because of their lack of coordination, Trade Support Institutions (TSIs) fail to support the development of the medical devices sector in Mauritius

Several institutions currently have human resources directly or indirectly dedicated to the industry but efforts are not made in a coordinated and articulated manner, with limited communication between the different stakeholders. The ambiguity of the situation results in confused mandates and a lack of clarity of the respective roles and responsibilities with no clear picture about existing capabilities. There is, in particular, some confusion regarding the different Ministries in charge of the medical devices sector, i.e. the Ministry of Industry, Commerce and Consumer Protection, the Ministry of Health and Quality of Life, adding to the complexity and lack of transparency of the system. Importantly, the lack of coordination between TSIs does not allow for the definition of a clear vision for the broader life science sector at the national level.

The creation of a dedicated "one stop partner" contact to act as an umbrella organization dealing with all existing institutions could be envisaged to reduce complexity, duplication and waste of efforts, and to improve efficiency and responsiveness of the support provided to the sector. This entity could take the form of a steering committee that would play an advisory role to the Government and prepare proposals and projects for the industry.

- **Severity:** ●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 1.1.1. and 2.3.1.

### The Trade Support Network (TSN) is lacking the specific expertise and skills required to support the industry efficiently

As the sector is relatively new in Mauritius and has generated limited interest so far, institutions appear to have knowledge and understanding of the nature of the medical devices industry, including its needs and requirements, but lack information on the sector, both from a technical and regulatory point of view. This situation makes it difficult for the industry's professionals to interact with qualified and knowledgeable counterparts at the institutional level.

There is a critical need for capacity building at institutional level required to understand this fast evolving sector better and to improve the quality of the support provided, in particular, in the field of research and development.

- **Severity:** ●●●○
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 2.3.2.

## 'COST OF DOING BUSINESS' ISSUES

### The absence of fiscal incentives for R&D hinders the sector's expansion and limits the industry's potential for innovation and product diversification

The absence of fiscal incentives, such as a research tax credit, for medical devices manufacturers has been identified as a major constraint for the development of the industry in Mauritius as the Government does not currently provide incentives to practitioners to offset some of the costs associated with R&D activities. This limits the development of higher value added and innovative products and processes and does not encourage manufacturers to establish production sites in Mauritius.

To attract investors and medical devices manufacturers to base their research activity in Mauritius, it is essential that the country provides for an R&D Tax credit to businesses. The MCCI believes that, similar to the practice in Singapore, the country should provide for a 400 percent R&D Tax credit to operators involved in the life sciences industry<sup>7</sup>. This will give the necessary impetus to the sector and incentivize companies to locate, or relocate, their research activity in Mauritius.

- **Severity:** ●●●●●
- **Value chain segment:** Research and development
- **PoA reference:** Activities 3.2.1. and 3.2.3.

7. MCCI - Boosting the Life Sciences Industry (December 2015)

Similarly, the lack of tax credit for investment and the lack of incentives for the medical devices sector, make investment in the sector rather unattractive. In addition to the lack of support in the field of research and innovation, the medical devices industry does not currently benefit from incentive mechanisms, such as fiscal incentives, from the local authorities to develop and expand their activities in Mauritius. When the Government declared, in its 2014 budget speech, that ‘an Investment Tax Credit Scheme will be introduced to encourage High-Tech Manufacturing’, the support measure has, to date, not been implemented. Grants and fiscal incentives for exports competitiveness, such as the EM’s Export Credit Insurance Scheme to boost exports to Africa, would contribute greatly to developing the industry and improving the attractiveness of Mauritius for medical devices manufacturers.

- **Severity:** ●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 4.2.1. and 4.2.2.

### High airfreight costs and limited transport connectivity hinders business development

As indicated in the Strategic Trade Development Roadmap (STDR), Mauritius, as a Small Island Developing State (SIDS) with significant distance from its key markets, will always incur the burden of high transportation costs as part of trading costs. This logistical isolation coupled with the lack of economies of scale for the medical devices sector has led to high costs of inputs as well as high costs of exports for the manufacturers. In addition, the issue of air connectivity is particularly prominent for the greater life science sector. As products often need to reach destination in a short time span, the lack of outbound flights from Mauritius limits operators from dealing with such products with high export potential.

Business destinations for air freight could be improved with more frequent air connections to strategic markets such as China or Brazil. In this regard, the incoming Air Corridor between Africa and Asia with Mauritius and Singapore as hubs has the potential to boost the industry<sup>8</sup>. An Air freight rebate scheme on all airlines could also be introduced to improve the competitiveness of the Mauritian medical devices industry.

- **Severity:** ●●●○○
- **Value chain segment:** Distribution, marketing and sales
- **PoA reference:** Activity 4.2.2.



Photo: (cc) pixabay

### The costly electricity supply impacts the overall competitiveness of the sector

As it comprises energy intensive processes such as ventilation and hygiene that require electricity 24/7, the electricity bills of medical devices manufacturers are very high –with no electricity duty exemption schemes in place– representing about 80% of their production costs. High energy costs impact their competitiveness.

Efforts will be made to negotiate an electricity rebate scheme for medical devices manufacturers to encourage the development of the industry.

- **Severity:** ●●●●●
- **Value chain segment:** Component manufacturing
- **PoA reference:** Activity 4.2.2.

### Limited and expensive Internet access impacts the industry’s competitiveness

Although progress has been made regarding the connectivity of the island, Internet services available to firms are currently limited, particularly in terms of upload and download speeds because of a weak bandwidth, and largely uncompetitive in terms of prices. Unstable Internet connection also appears to be a frequently encountered problem. Even though medical devices manufacturers are not highly dependent on Internet connectivity, such level of service and high cost of Internet access affect the competitiveness of the sector.

- **Severity:** ●●○○○
- **Value chain segment:** Entire value chain
- **PoA reference:** See National Export Strategy

8. MCCI, Boosting the Life Sciences Industry (December 2015)

## MARKET ACCESS CONSTRAINTS

### Box 4: Border-Out Gear issues

- High dependence of Mauritian medical devices exports on a few export markets
- Customs duties and taxes imposed by key trading partners on Mauritian exports
- Restrictive regulations to access the domestic market
- Limited visibility of the Mauritian medical devices industry in international trade fairs
- Limited awareness of Mauritius as a destination for investment in the medical devices sector
- Lack of incentives for foreign investors
- Absence of a national strategy for the promotion of the medical devices industry

## MARKET ACCESS AND POLICY REFORM

### The high dependence of Mauritian medical devices exports on a few export markets could represent a threat in the future

With France and India capturing 64% and 22% of Mauritius medical devices exports respectively, in 2015 (UN comtrade), the industry appears to be highly dependent on market conditions and vulnerable to external economic shocks affecting those economies. The predominance of France as an export destination is partly explained by the presence of French subsidiaries that assemble components in Mauritius before shipping them to France for final assembly. In addition, several medical devices production sites based in Mauritius rely on their parent companies' sales force in France to export final products to various parts of the world.

Greater market diversification is, therefore, essential to spread risk and to participate more actively in international trade.

- **Severity:** ● ● ○ ○ ○
- **Value chain segment:** Distribution, marketing and sales
- **PoA reference:** Activities 5.1.1. and 5.2.1. to 5.2.3.

### Customs duties and taxes imposed by key trading partners on Mauritian exports hinder achievement of the broadest possible sustainable access to markets

High tariff barriers imposed by key trading partners on medical devices exported by Mauritius, namely the BRIC countries, affect severely the competitiveness of manufacturers exporting directly from Mauritius. Although

the country currently benefits from the Generalized System of Preferences when exporting to the Russian Federation, no preferential trade agreements have been signed with India, Brazil and China so far. Import duties applied by Brazil and India on tariff line 9018 are particularly high, at 9.25% and 7.5% respectively, while China and the Russian Federation apply lower tariffs of 4.32% and 1.49%, respectively, on those products. It is also important to stress that while Mauritian exporters face tariff barriers from BRIC countries, Mauritius has eliminated all tariff duties on imports of HS 9018 products under the WTO Agreement, making exports of medical devices to the country duty free, irrespective of their origin. This situation of non-reciprocity is perceived as unfair by the industry's professionals.

Given the opportunity that these markets represent for the sector (the annual growth of exports for electro-medical apparatus (HS 9018) in value between 2010-2014 reached 18% in China, 8% Brazil and 7% in the Russian Federation and India, respectively), thorough negotiations of market-entry conditions with those countries are required to obtain significant reductions of the tariff line 9018 and tariff phase-outs periods on imports of Mauritian medical devices. Lowering tariffs on Mauritian exports to BRIC countries will have an immediate positive effect on sales as it would unlock the potential of the industry to penetrate those rapidly growing markets further.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Distribution, marketing and sales
- **PoA reference:** Activities 5.1.1.

### Restrictive regulations prevent medical devices manufacturers from entering the domestic market

Although Mauritius is not considered a key market and is of limited strategic interest to the industry owing to its limited size, operators would, nevertheless, benefit from access to the domestic market. To date, restrictive and cumbersome regulations on medical devices products act as a disincentive for manufacturers considering entry into the Mauritian market. Consequently, the entire production of medical devices is exported.

To develop trade links with Mauritius, a preferential access to the domestic market could be granted to medical devices manufacturers. Overall, conditions to penetrate the domestic market should be reviewed for the sector as they are currently not adapted to the medical devices industry.

- **Severity:** ● ● ● ○ ○
- **Value chain segment:** Distribution, marketing and sales
- **PoA reference:** Activity 5.1.2.

### TRADE AND BUSINESS SERVICES SUPPORT (INCLUDING IN-MARKET SUPPORT)

#### The limited visibility of the Mauritian medical devices industry in international trade fairs hinders the development of the sector

Although efforts have recently been made in this regard, the industry remains insufficiently supported by the authorities to participate in international trade fairs. Such initiatives are currently driven by private sector entities with public authorities only playing a minor role, limited to providing a small financial assistance to the medical devices manufacturers.

A more relevant approach from the authorities to support the participation of the sector in international trade fairs would be to coordinate export promotion activities, identify commercial opportunities, initiate contact with potential buyers, generate interest among prospective foreign direct investors, and provide support to exporters and entrepreneurs visiting the market. The steering committee dedicated to the medical devices industry envisaged earlier could play a key role in conducting those activities.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 5.2.1. to 5.2.3.

Similarly, the limited awareness of Mauritius as a destination for investment in the medical devices sector constrains the expansion of the industry. There is currently no dedicated institutional communication on the industry in Mauritius and no communication campaigns have been undertaken in the country so far. Moreover, there is no national “champion” in terms of communication that is currently recognized at the international level and that could act as a real driving force. As a result, there is a lack of accessible, accurate and understandable information available to prospective entrepreneurs and limited interaction between the different value chain actors, the support institutions and potential foreign direct investors. This lack of awareness may give investors the perception that Mauritius is not a destination for medical devices investment, as investors will most likely focus on markets where they can access information from a mix of official and trade sources.

Significant efforts have to be made to improve communication and create awareness among medical devices manufacturers abroad about the opportunities that Mauritius has to offer for their activities. Increased participation at conferences with international manufacturers for greater exposure to foreign markets could notably be envisaged in this regard. The quality of the support provided to prospective foreign direct investors when visiting the country should also be improved, namely by adopting a more holistic approach.

- **Severity:** ● ● ● ● ●
- **Value chain segment:**
- **PoA reference:** Activities 4.4.1. and 4.4.2.

#### Further, the lack of incentives for foreign investors does not facilitate the expansion of the medical devices industry

To attract prospective foreign direct investors and joint venture partners to establish production sites in Mauritius, targeted and attractive incentive packages should be defined. Measures should in particular be put in place to facilitate the process of obtaining building and land use permits, provide infrastructural incentives and offer financial support for promoting investment by offering subsidized loans and loan guarantees for borrowers willing to invest in the sector.

- **Severity:** ● ● ● ● ●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activity 4.4.3.

## NATIONAL PROMOTION AND BRANDING

### The absence of a national strategy for the promotion of the medical devices industry limits the attractiveness of the sector

There is currently no dedicated budget to promote the medical devices sector in Mauritius and no branding efforts have been made so far to showcase the know-how of local manufacturers. If the industry is to be able to attract the necessary investment for the future, it will be crucial to raise the country's profile by building and reinforcing its international image to boost exports and inward investments. The development of targeted marketing strategies will also be crucial in this regard.

- **Severity:** ●●●●●
- **Value chain segment:** Entire value chain
- **PoA reference:** Activities 5.2.1. to 5.2.3.



Photo: (cc) pixabay

## SOCIAL AND ENVIRONMENTAL CONSTRAINTS

### Box 5: Development Gear issues

- The contribution of the industry to socio-economic development is limited
- The hazardous waste management system is not clearly defined
- The medical devices industry is an energy intensive industry

## POVERTY ALLEVIATION AND GENDER INCLUSIVENESS

### The contribution of the medical devices industry to socio-economic development is not yet visible enough

As the medical devices industry is relatively new and small in Mauritius, only comprising eight companies in 2016, the socio-economic contribution of the sector remains limited. In total, the sector currently employs about 500 people in Mauritius, mainly women, including operators and engineers. The potential for employment creation is, however, significant as the prospects for Mauritian manufacturers are promising in this booming economic sector. The industry will consequently be providing more

employment opportunities and economic spin-offs for the local economy in the near future.

The contribution to socio-economic development is all the more important given that the sector's employees are 95% Mauritians. In addition, the development of the medical devices industry will contribute to gender inclusiveness as women represent at least 80% of the human resources in Mauritian manufacturing and almost 100% of the operators working on the production lines. Finally, it appears that the medical devices industry contributes to a greater integration of youth in employment as it is estimated that 50% of the staff is below 30.

- **Severity:** ○○○○○
- **Value chain segment:** Entire value chain
- **PoA reference:** None (no issues identified)



Photo: Medical Devices, Photo 5.jpg

## ENVIRONMENTAL SUSTAINABILITY

### The hazardous waste management system is not clearly defined for the medical devices industry

There is currently no clear plan for hazardous waste management in place among the manufacturers in Mauritius which raises the question of the environmental sustainability of the sector's activities. Specific investigations would be needed to assess the environmental footprint of medical devices manufacturers' activities and the potential actions that could be taken to reduce it. Overall, there is currently no clear strategy to make sector firms more environmentally friendly.

- **Severity:** ●●●○○
- **Value chain segment:** Components manufacturing and assembly
- **PoA reference:** Activity 1.1.1.

### The medical devices industry is an energy intensive industry

As the manufacturing of medical devices comprises energy intensive processes that require permanent power supply, the electricity consumption of the industry is very high. If little can be done at the manufacture level to reduce that consumption, alternative sources of energy and energy efficiency systems could be developed at the national level, to ensure that economic growth occurs with the environment in mind.

- **Severity:** ●●●○○
- **Value chain segment:** Components manufacturing and assembly
- **PoA reference:** See National Export Strategy

# THE WAY FORWARD

It is only recently that the medical devices industry received some attention from support institutions, progressively recognizing the potential of this high-value activity with a very high growth potential. According to the Bol, the medical devices sector is expected to play a leading role in transforming the Mauritian economy into a high value added and will notably contribute to the strengthening of the domestic manufacturing sector. The development of the sector is indeed very much in line with the government ambition to move towards an economy based on innovation and research and development.

Yet, the potential of the sector has not been exploited fully and significant efforts are needed for the sector to grow and to make the country a leader in the medical devices industry. The industry being in its infant stage of development, the sector's strategic orientation should follow a structural approach. The strategy for the next five years will thus be built primarily around a goal of reinforcing the domestic supply of medical devices components, improving the knowledge-base of the industry and create a more conducive business environment, namely by improving the quality of the institutional support and developing an adapted and targeted regulatory framework. Strong emphasis will also be placed on developing a cluster initiative for the sector with a view to improving the industry's attractiveness and competitiveness by promoting greater business linkages between

companies involved in the medical devices sector value chain in Mauritius, and generating higher levels of vertical and horizontal integration. Another important challenge for the future expansion of the industry will be the capacity of local companies to develop innovative products through research and development with a view to generating higher value addition locally and diversifying the Mauritian products on offer. Adopting an innovative approach will help the industry improve its performance and competitiveness on the international markets, also moving up the global value chain gradually.

## VISION

Though the medical devices sector has shown significant developments in recent years, essentially consolidating its export performance, its contribution to the domestic economy remains limited. To reinforce this contribution further, competitive constraints and structural deficiencies along the four export development gears (supply side, business environment, market entry and development side) will be addressed, and identified opportunities will be leveraged. The following is a delineation of the proposed vision and strategic approach in this direction, agreed with all stakeholders of the medical devices value chain.

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“ A competitive and knowledge-based sector driven  
by innovation and committed to excellence ”

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## STRATEGIC OBJECTIVES

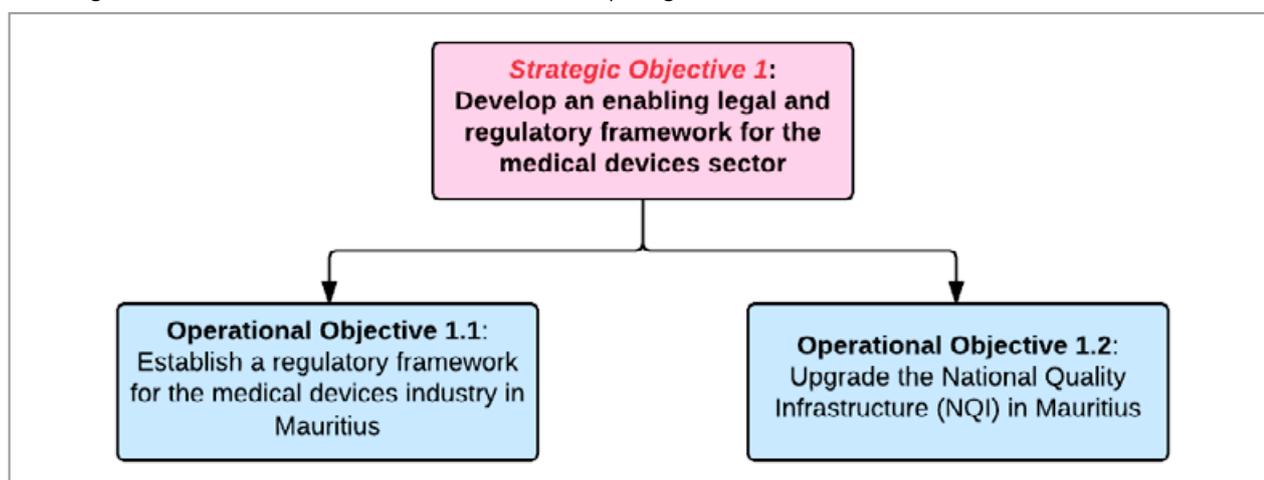
The vision set up for the strategy is delineated in five strategic objectives built around the key areas where action is required over the following five years.

### STRATEGIC OBJECTIVE 1: DEVELOP AN ENABLING LEGAL AND REGULATORY FRAMEWORK FOR THE MEDICAL DEVICES SECTOR

Developing a legal and regulatory framework specific to the medical devices industry, and in line with international practices, is a prerequisite if the sector is to develop in Mauritius in the near future. Being relatively new in Mauritius, the industry does not currently benefit from such a framework, hence contributing to creating an uncertain business environment for manufacturers that might not be willing to undertake activities that do not fit within a clearly defined legal framework. A similar comment applies to the National Quality Infrastructure in place in Mauritius as the NQI, not being in line with international standards, has proven unable to support the activities of the industry.

In operational terms, a first step will be to establish a Steering Committee, to act as a dedicated “one stop

partner” contact that will play a key advisory role to the Government, prepare proposals and projects for the industry and support the decision-making process by pooling the technical or specialist expertise available at national level. The committee will particularly contribute to the elaboration of a comprehensive Medical Devices Act describing the industrial processes carried out in the medical devices industry, while also covering regulatory aspects related to research activities. Upgrading the NQI is also a key component of this strategic objective as it could play a major role in unlocking the potential of the country and investment opportunities. It will particularly be essential to review, upgrade and strengthen the different bodies and laboratories involved in conformity assessment activities, in line with the international practices that govern the manufacture of medical devices.



### STRATEGIC OBJECTIVE 2: IMPROVE THE ORGANIZATION OF THE SECTOR AND FOSTER INTEGRATION AND COOPERATION

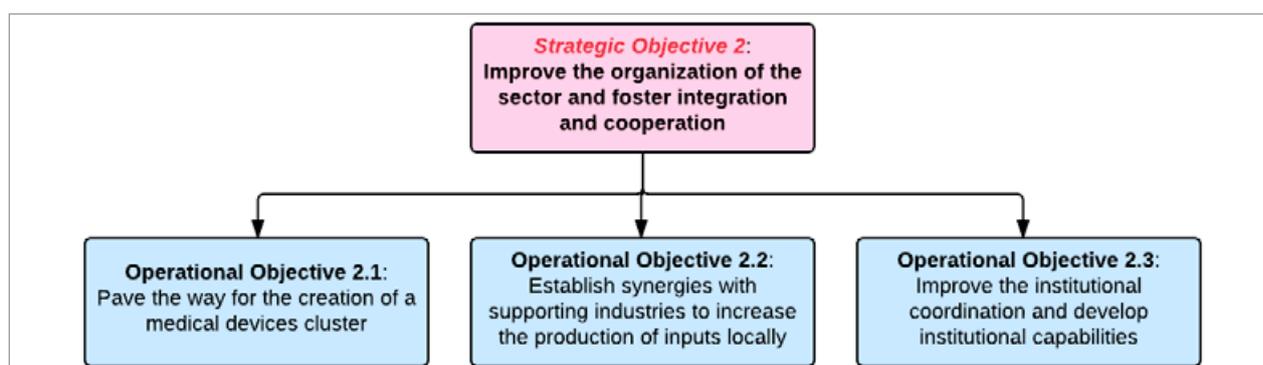
The second strategic objective is aimed at fostering the integration of the medical devices sector in Mauritius by promoting greater business linkages between the different value chain actors. It will include working towards a greater integration of the different stages of production by encouraging the manufacturing of medical devices components locally. Achieving this objective is of utmost importance as it will contribute to increasing the attractiveness of Mauritius as a potential destination for medical devices manufacturers, while improving the

competitiveness of the industry. Improving the structure of the sector should also be accompanied by an appropriate support from the different trade support institutions.

The operation of this objective is put into gear by carrying out preliminary studies aimed at paving the way for the development of a cluster initiative dedicated to the medical devices sector. It is indeed believed that grouping medical devices companies to an operational cluster with rapid access to basic infrastructures represents a key

success factor for the future development of the industry. As medical devices manufacturers operating in Mauritius are currently largely dependent on imports for most of the components, including electronic, plastic and metallic components, the strategy will also work towards establishing synergies with supporting industries to increase the production of inputs locally, notably by promoting greater

business linkages between the manufacturers of medical devices and the supporting industries. Finally, efforts will be made under this objective to improve the institutional coordination and develop institutional capabilities to enhance the understanding and awareness of the medical devices industry and its potential in Mauritius.

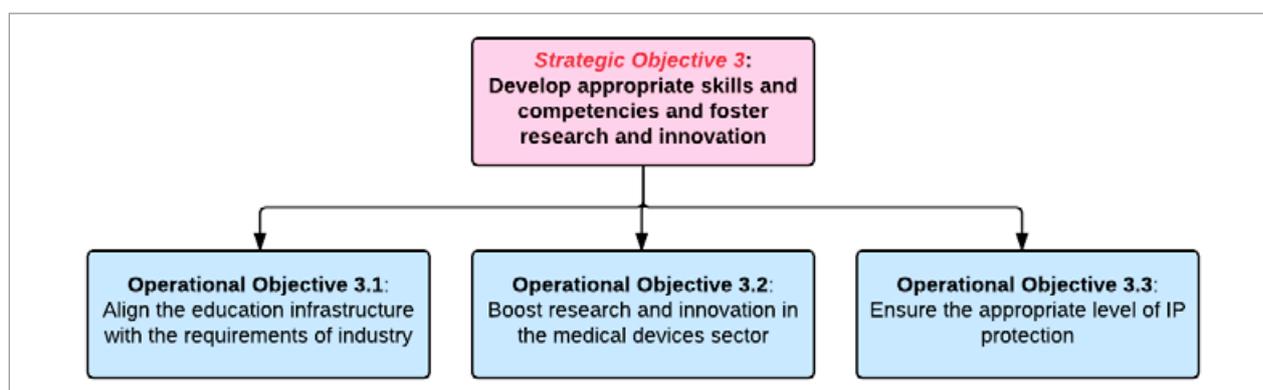


### STRATEGIC OBJECTIVE 3: DEVELOP APPROPRIATE SKILLS AND COMPETENCIES AND FOSTER RESEARCH AND INNOVATION

To have an increased visibility for potential product diversification and to ensure the sustainability of the industry, a big emphasis will need to be put on the building of knowledge and generation of necessary research. These aspects will be absolutely fundamental to ensure the future development of the sector and the production of more sophisticated and higher value added devices in Mauritius. Research and development activities should also be encouraged in order to boost innovation and keep up with the breakneck pace of developments in the medical devices sector.

Operational efforts to complete this objective will first be concentrated on the alignment of the education infrastructure with the requirements of the private sector, in particular, by initiating discussions between medical devices

professionals and research and academia and by gradually translating the industry needs into academic offerings. Also with a view to boosting innovation, specific R&D programmes targeting different segments of the medical devices sector's value chain activities will be elaborated and studies to upgrade research infrastructures in the country conducted. In addition, important efforts will be made through the Steering Committee to establish a system of incentives, such as a research tax credit, to encourage the involvement of the private sector in funding R&D work, while also contributing to developing Mauritius as an attractive destination for medical devices manufacturers. Finally, it will be essential that these measures aimed at boosting innovation are backed with the appropriate level of intellectual property protection.

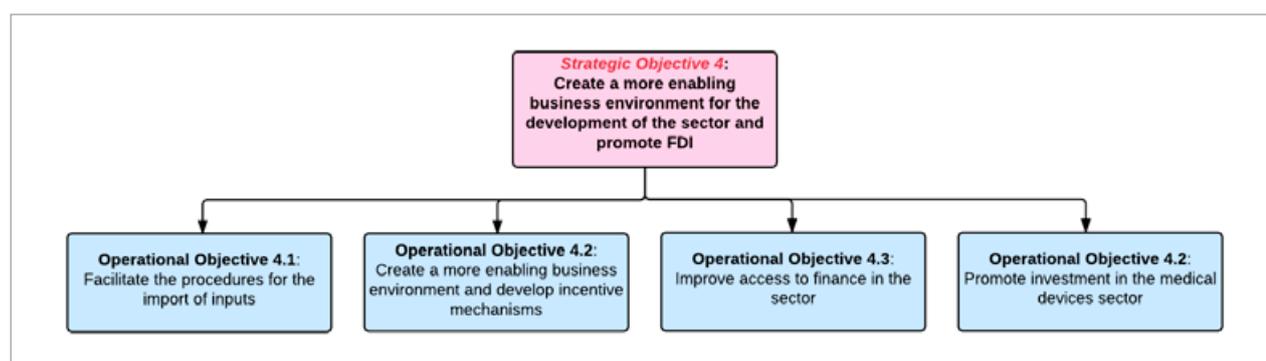


## STRATEGIC OBJECTIVE 4: CREATE A MORE ENABLING BUSINESS ENVIRONMENT FOR THE DEVELOPMENT OF THE SECTOR AND PROMOTE FDI

As the sector is relatively new in Mauritius and has generated limited interest so far, little attention has been devoted to the medical devices industry and the environment in which manufacturers are operating. Yet, the business environment is a critical factor for the expansion of the sector as it plays a key role in manufacturers' investment decision-making process. Significant efforts will therefore, be made to create a more enabling environment for the sector and to promote foreign and domestic investment.

In operational terms, it will, firstly, be important to tackle the issues related to customs procedures for the imports of medical devices components that currently affect the activities of sector. This can be done by raising awareness among all relevant actors and by establishing simplified customs clearance procedures for the industry. Another key component under this strategic objective is to create a

more enabling business environment, something that will be achieved through the setting up of programmes and incentive mechanisms to support the industry, such as grants and fiscal incentives for exports competitiveness, investment tax credit scheme, simplified procedures for building and land use permits, among others. Awareness campaigns on the potential of the sector and the market value of the medical devices manufactures will also be launched targeting financial institutions with a view to ensuring an easy and timely access to finance for businesses. Finally, and in addition to the above-mentioned mechanisms, the strategy envisages the development of an incentive package to encourage more private investment, including Foreign Direct Investment (FDI), in the sector. Particular attention will be paid to improving the quality of the support provided by the support institutions to prospective foreign direct investors.



## STRATEGIC OBJECTIVE 5: DEVELOP MARKETS AND STRENGTHEN EXPORT PROMOTION EFFORTS

Significant market opportunities exist for medical devices made in Mauritius, particularly with a booming demand from BRIC countries, but customs duties and taxes imposed by key trading partners on Mauritian exports affect the competitiveness of the industry and impede export development. This strategic objective is designed to ensure greater market access to the Mauritian manufacturers, including improving entry conditions to the domestic market. In addition, because the Mauritian medical devices sector is still little-known internationally, a key step towards achieving this objective is to ensure structured export development and promotion efforts.

In operational terms, efforts will be made to bring about closer collaboration between Mauritian and key partners' authorities to revisit customs duties and tariffs applied to HS 9018 products on exports to these countries with a view to benefiting from better market access conditions

to these key markets and particularly to BRIC countries. Another key component under this objective will be to ensure structured export development and promotion efforts, mainly through the elaboration of a comprehensive export promotion strategy dedicated to the medical devices sector, including the development of specific market development plans in line with priority target markets identified in the strategy. Building the capacities of commercial attachés concerning the industry will also be conducted in this regard, and regular trade missions to selected target markets for business owners from the sector will be organized.

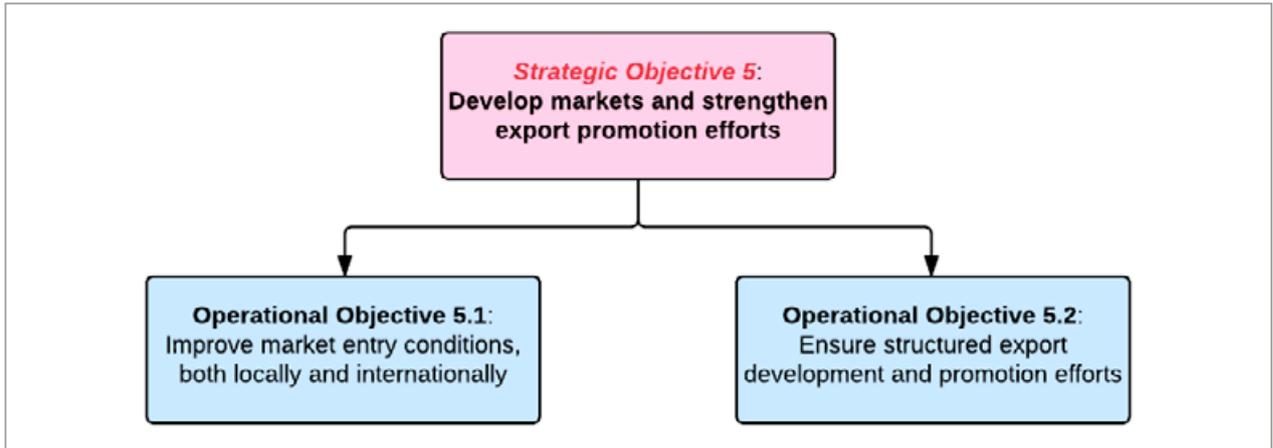
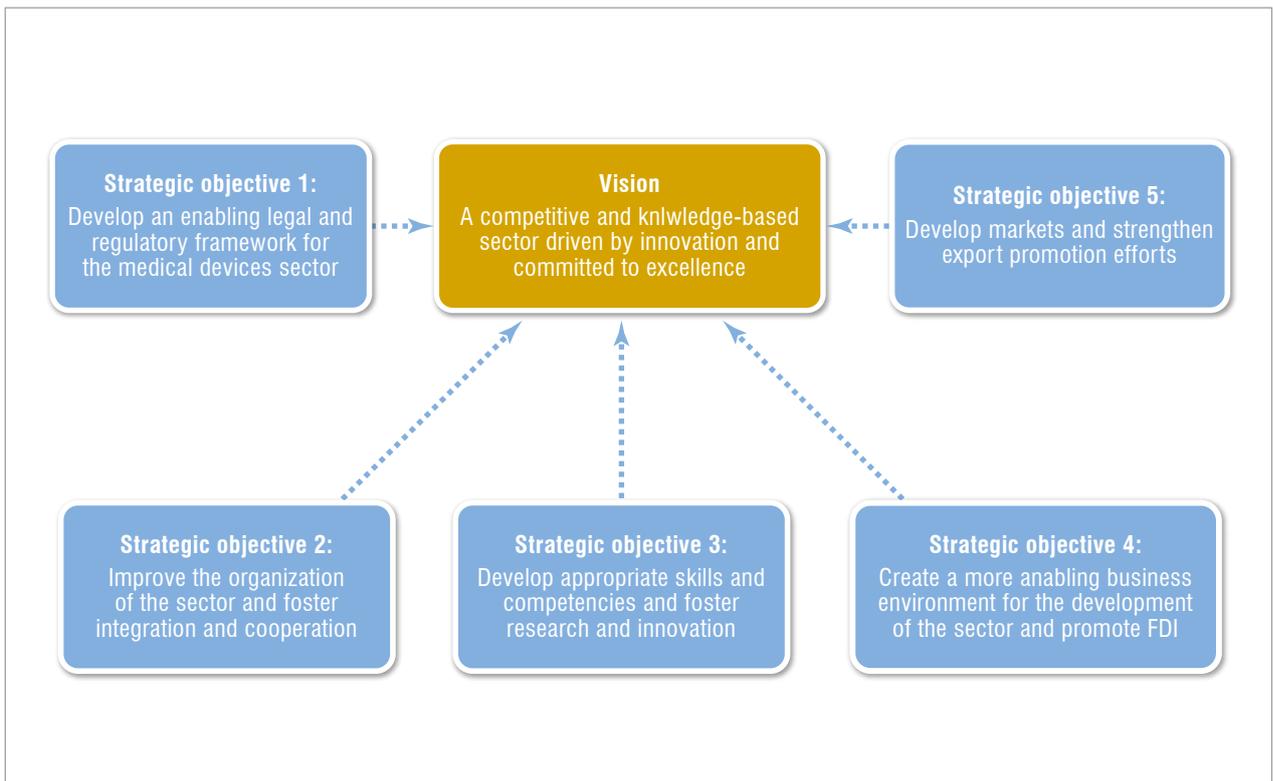


Figure 14: The strategic scope



## LEVERAGING MARKET OPPORTUNITIES

If the global demand for medical devices is expected to grow in the coming years, hence offering promising opportunities for Mauritius manufacturers, the domestic industry is and will be facing fierce international competition, mainly from leading American and European firms. In this constantly evolving environment, securing new

markets and diversifying the production – while maintaining the superior quality of the medical devices manufactured – will be crucial for Mauritian firms to gain market share and improve their competitiveness.

Market diversification possibilities need to be accompanied with careful examination of destination countries’ regulatory environment and quality requirements, and thus will certainly require adjustments of existing products or developing new ones. In this context timely market

intelligence and targeted market development strategies will be required for companies in their diversification initiatives.

The following key orientations are recommended for the sector:

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#### LEVERAGE EXISTING MARKET LINKAGES WITH FRANCE TO BUILD CAPACITIES FOR MORE VALUE ADDED PRODUCTS AND DEVELOP EXPORTS TO THE EU

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Building on the existing trade relationships with France, expanding marketing efforts from Mauritius to this market is a natural step for established manufacturers. However, because the bulk of the sector's exports to France consist of French subsidiaries exporting components or final products to the parent company in Europe, adding value to the production will require a progressive upgrading of the Mauritian sites, gradually moving from the sole assembly segment of the value chain to the manufacturing of components and, most importantly, research and development. Only by developing such activities can local firms truly be able to develop innovative and higher value added products in the country.

In addition to product diversification and the related value addition, there are opportunities for Mauritian firms to penetrate further the broader European market, the leading importing region for medical devices. To do so the industry could build on its solid experience of the French market, which follows EU's Medical Devices Directives. Ensuring the superior quality and safety of the equipment manufactured, guaranteeing the reliability of the supply while remaining competitive in terms of price are prerequisites to penetrate the demanding European market and compete with well-established leading firms.

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#### EXPAND EXPORTS OF EXISTING PRODUCTS TO EMERGING MARKING, TARGETING BRIC COUNTRIES AND INDIA IN PARTICULAR

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As indicated in the global context section of the present strategy, the demand for medical equipment from developing and emerging markets has significantly expanded in recent years, therefore offering interesting opportunities for medical devices manufacturers. Largely driven by Chinese importers, the demand from the BRIC countries has progressed continuously.

In particular, fuelled by an increasing population and significant increase in per capita income, the sustainable demand from India is expected to continue to increase in the near future, therefore offering promising prospects for Mauritian based manufacturers. The geographical proximity of the country coupled with the historical cultural and commercial linkages that exist between the two countries

provides Mauritius with a competitive advantage the sector should capitalize on.

Although efforts and strategies have been developed to penetrate these markets, high tariff barriers imposed by these countries on equipment exported by Mauritius affect the competitiveness of manufacturers exporting directly from the country. In this regard, lowering tariffs on Mauritian exports to BRIC countries would have an immediate positive effect on sales as it would unlock the potential of the industry to penetrate those rapidly growing markets further.

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#### DEVELOP COMMERCIAL ACTIVITIES IN MAURITIUS

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The Mauritius medical devices industry currently exports close to 100% of the medical tools and equipment manufactured locally with virtually no trading relationships with Mauritian buyers. The main factor explaining this disinterest is of a commercial nature as the relatively small Mauritian market only offers limited commercial opportunities for manufacturers. Secondly, restrictive and cumbersome regulations on medical devices products act as a disincentive for manufacturers considering entry into the Mauritian market.

Preferential access to the domestic market could be granted to medical devices manufacturers established in Mauritius to counter balance the limited strategic interest it represents.

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#### DEVELOPING NEW PRODUCTS FOR UNTAPPED MARKETS

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The high dependence of the Mauritian industry on the French and Indian markets could represent a threat in the future, highlighting the need for greater market diversification.

This market development is an inherently riskier approach because Mauritian exporters will need to enter markets in which they have little or no experience. Before doing so, not only do they have to adjust their current offering they must have a clear idea about possible gains and risks, market characteristics and trends as well as the specific quality and safety requirements. In this context the provision of trade intelligence and the elaboration of targeted market strategies will be a key.

During the consultations, stakeholders identified a number of diversification leads, which will need to be analyzed further. Potential markets include Middle East countries such as Iran, Israel and Gulf countries as well as untapped BRIC countries, namely Brazil, Russian Federation and China.

## STRUCTURAL ADJUSTMENTS TO THE VALUE CHAIN – VALUE OPTIONS AND FUTURE VALUE CHAIN

The strategy needs to reach out towards the untapped potential of the sector and identify those opportunities that could improve its performance. The value chain is the appropriate tool to identify those opportunities through the adjustment of the value flows within it.

Unlocking the latent potential of the medical devices sector will require transformations throughout the value chain. These adjustments will allow the sector to improve its horizontal integration and move up the global value chain by generating higher value addition. To this end, the following options for value retention, addition, and creation have been identified.

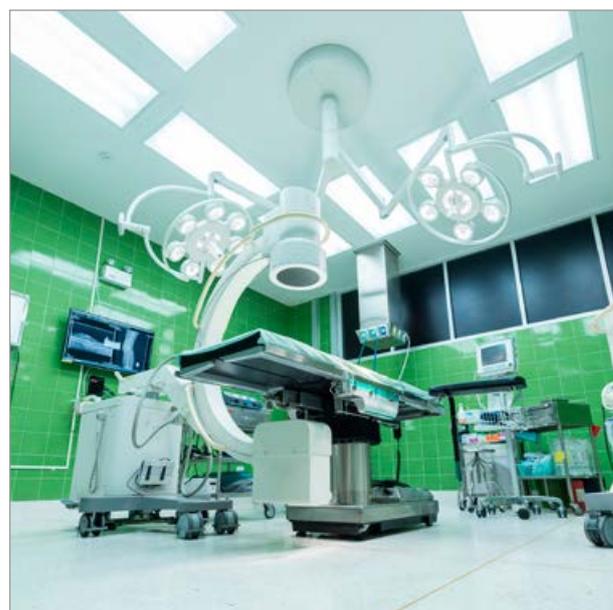


Photo: (cc) pixabay

Table 2: Value options for the medical devices sector

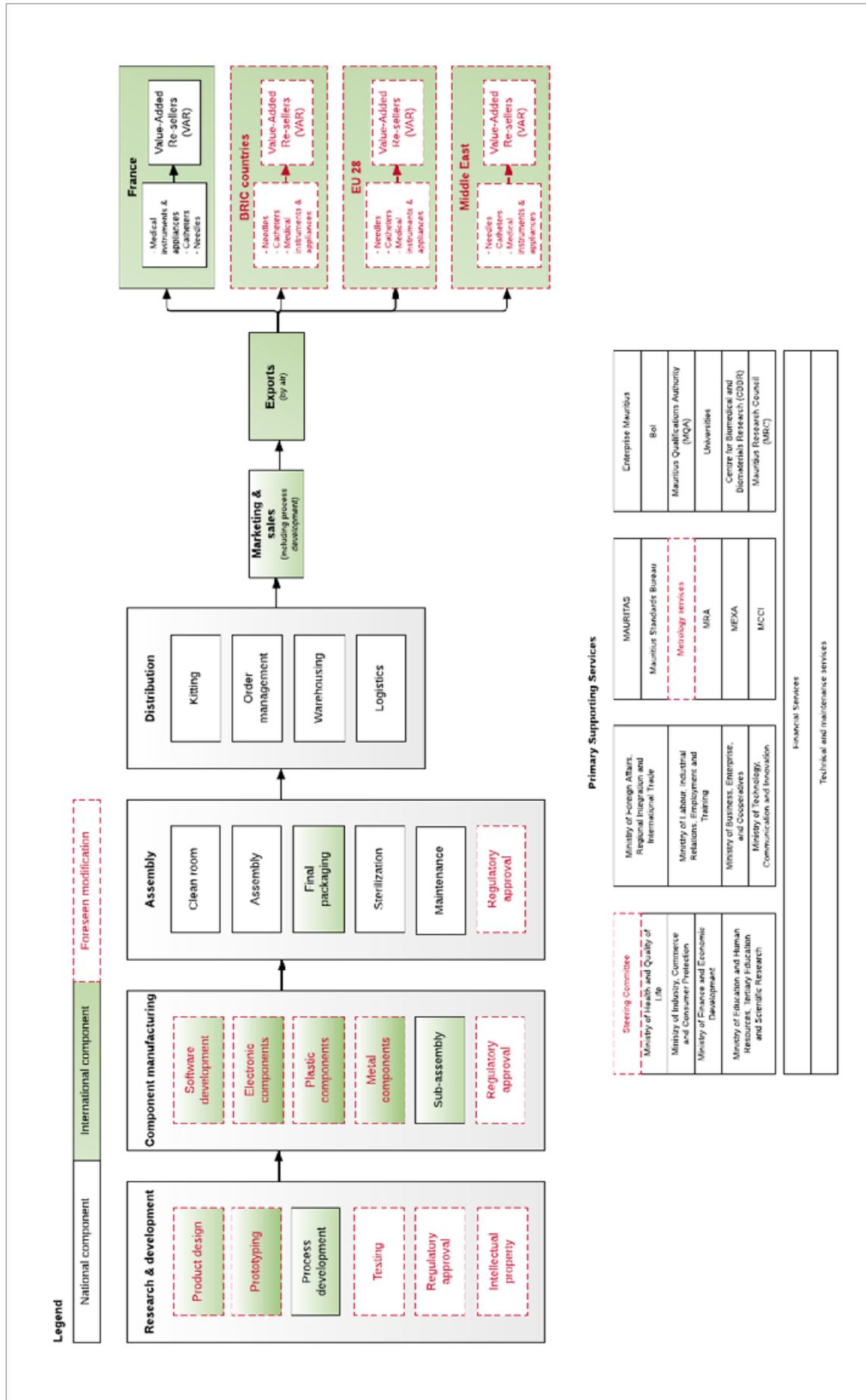
Value retention: "Mauritianized" the supply of medical devices components		
Value Option	How to implement	Timeframe
» Foster linkages with other sectors to secure production inputs and services locally	Undertake a mapping study to obtain a clear picture of the supporting industries that might play a role in the medical devices value chain Promote the development of business relationships between the medical devices and the supporting industries	Long-term
» Local development of software	The production of adapted software for the medical devices industry could be initiated through the development of a dynamic online platform.	Mid-term
» Local manufacturing of electronic components	Envisage the establishment of technology incubators for the development of complex electronic machines and other IT components, also with a view to attracting innovative start-ups.	Mid-term
» Local manufacturing of plastic components	Develop business relationships with private companies engaged in the production of high precision plastic products and benefit from the expertise and specialized equipment available locally for the moulding of high precision plastic components	Mid-term
» Local manufacturing of metal components	Develop business relationships to benefit from the expertise of high technology enterprises engaged in the production of highly sophisticated products, including spare parts for the aerospace industry, watch and watch components manufacturing	Mid-term
» Encourage foreign-owned firms to re-invest profits in the national economy rather than repatriating them	Provide incentives to foreign-owned firms to invest in Mauritius Develop the skills and knowledge necessary to move the global value chain, notably to conduct research and development activities locally Establish a regulatory framework for the medical devices industry in Mauritius	Mid-term
Value retention: Potential synergies with other value chains		
Value Option	How to implement	Timeframe
» Create a connection with the bio-pharmaceuticals sector	The pharmaceutical industry has recently - and rapidly - developed in Mauritius and has reached a certain level of maturity the medical devices manufacturers could learn from, notably regarding the regulatory framework.	Mid-term
» Create a connection with the aerospace industry	Explore potential synergies with the sector, notably regarding the production of high precision metallic elements and in the field of industrial design.	Mid-term
» Create a connection with the watch-making sector	Develop business relationships for the production of medical equipment components using the skills available locally in the field of precision mechanics	Mid-term
» Create a connection with the biotechnology sector	Explore potential product diversification developed with the biotechnology sector and learn from the creation of the BioPark Mauritius dedicated to biotechnologies for Research and Development. Study the development of potential synergies with complementary expertise in the field of research.	Long-term

Value retention: Improve the competitiveness of the sector through the development of a dedicated cluster		
Value Option	How to implement	Timeframe
» Grouping companies involved in the manufacture of medical equipment to create an operational cluster will increase the productivity of the sector	Conduct studies to identify potential locations for the cluster including a cost-benefit analysis, the likely initial investment, recurring costs, and risks and mitigation factors. Prepare and plan the cluster development Provide the cluster members with rapid access to basic infrastructures	Long-term
» A cluster initiative will stimulate new businesses in the field and attract foreign suppliers in Mauritius		
» Promoting greater business linkages between firms will boost innovation in the sector		
Value addition: Develop new, higher-value added, product lines aligned to production capabilities		
Value Option	How to implement	Timeframe
» Develop new, innovative, medical tools and equipment through investment in R&D	Establish a regulatory framework, including regulations for access to operating rooms and to allow clinical trials Establish incentive mechanisms such as a research tax credit Create dedicated research infrastructure Foster linkages with Academia to align the education infrastructure in the field of research	Mid-term
Value creation: Improve market penetration and expand output and capacity		
Value Option	How to implement	Timeframe
» Increase exports to BRIC countries	Improve market-entry conditions with BRIC countries (tariff line 9018)	Mid-term
» Penetrate the Mauritian market	Improve market-entry conditions locally Revise the eligibility criteria of Public Procurement Act for companies registered in Mauritius to qualify for the national preference	Short-term
Value Distribution: increase the sector's contribution to economic and social development		
Value Option	How to implement	Timeframe
» Significant potential for employment creation, notably for the youth, and gender inclusiveness	The industry will be providing more employment opportunities and economic spin-offs for the local economy as it continues to grow	Long-term
» Improve environmental efficiency	Improve the hazardous waste management system Develop alternative sources of energy and energy efficiency systems	Mid-term

Unlocking the potential of the sector will require transformations throughout the value chain. These adjustments, as reflected in the future value chain schematic, are the result of targeted efforts to address the competitive constraints identified and capitalize on structural adjustments required to retain, add and create value in a more effective way. The future value chain will be characterized by:

- i. A “Mauritianization” of the supply of medical devices components
- ii. Improved connections with other national value chains
- iii. Improved regulatory environment and intellectual property protection
- iv. Focus on product and market diversification (with an intention to enter the BRIC markets)

Figure 15: Mauritius medical devices future value chain



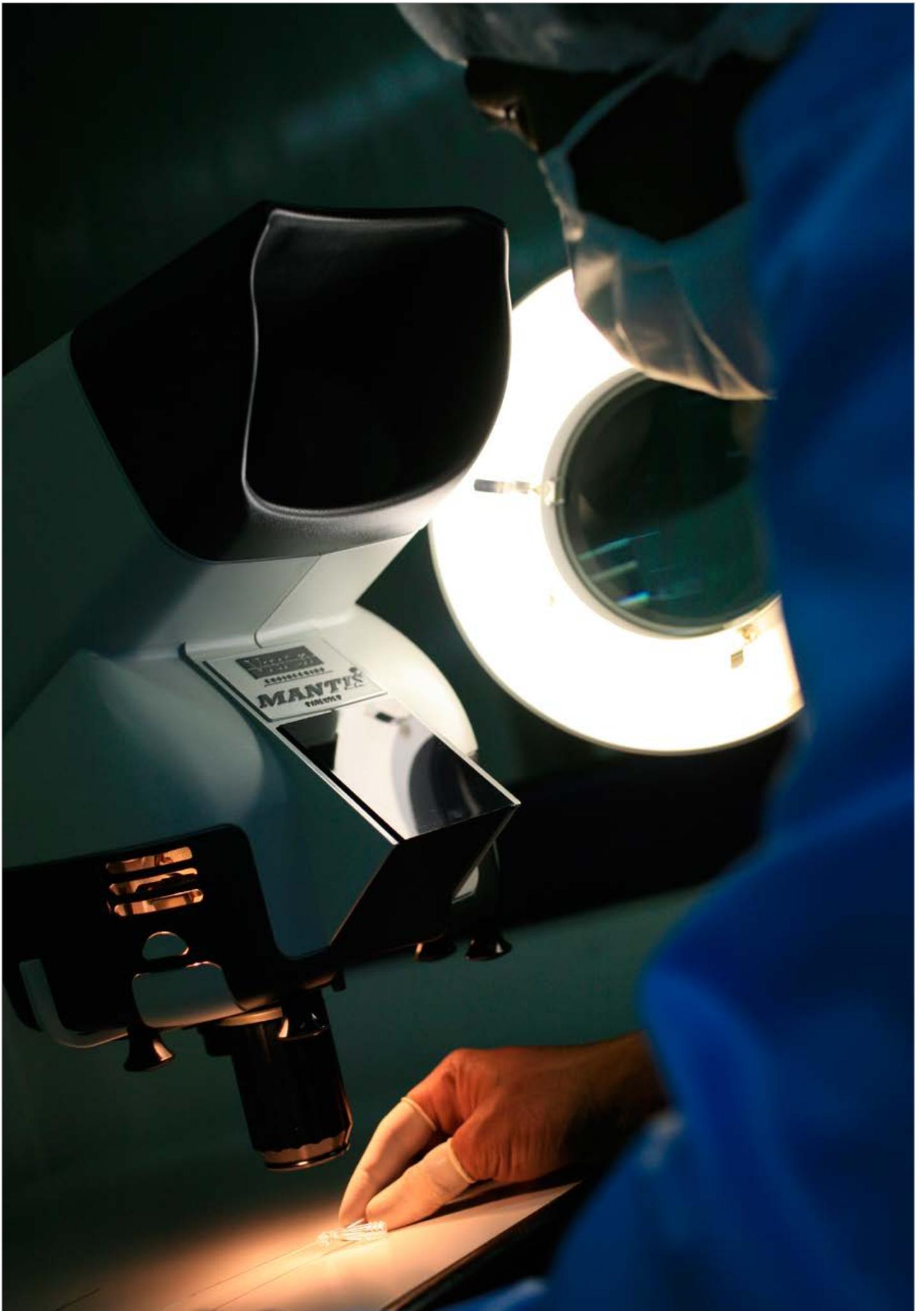


Photo: Medical Devices, Photo 2.JPG

# IMPLEMENTATION MANAGEMENT FRAMEWORK

This comprehensive medical devices strategy, part of the NES Mauritius, endeavours to generate the conditions for a favourable expansion of the industry so as to contribute to overall socio-economic development.

Nevertheless, a strategy in and of itself is not enough to ensure the industry's sustainable development. Such development will require the elaboration and coordination of various activities. While the execution of these activities will allow for the strategy's targets to be achieved, success will depend upon the ability of stakeholders to plan and coordinate actions in a tactical manner.

Indeed, the Medical Devices Strategy is not the strategy of any specific institution. It is the strategy of Mauritius, and to ensure its success, it is necessary to foster an adequate environment and create an appropriate framework for its implementation. The following section presents some of the key success conditions considered necessary for the strategy to be implemented effectively and achieve self-sustainability and long lasting benefits for the country.

## **Establish and operate a public and private coordinating platform, also referred to as a Steering Committee in the present document, and its subsidiary organ**

A key success criterion for the medical devices strategy is stakeholders' ability to coordinate activities, monitor progress and mobilize resources for the implementation of the strategy. It is recommended that the country establishes a sector-specific platform under the NES Secretariat for public-private deliberations that acts in an advisory capacity to the NES Secretariat, the Government and the private sector over issues related to or affecting the medical devices sector and its strategy.

The formal dialogue platform will require a high level involvement of the TSN members (public and private), as their role is crucial and will impact the effectiveness with which the strategy is implemented. Likewise, the ability of the private sector to provide inputs to the strategy implementation process will influence the success of the strategy significantly.

The stakeholders' group consulted during the design process was composed of a panel of representatives from key institutions, involving Ministries and the TSN members, as well as representatives from private medical devices manufacturers. As such, once its mandate is appropriately adjusted, this group of stakeholders, together with additional human resources as required, is best positioned to serve as the public-private platform responsible for the coordination of the strategy implementation. The platform will take the form of a Steering Committee. It will also be required that a nominated Secretariat representative coordinates, monitors and mobilizes resources for implementing the strategy.

The main functions of the public-private platform should be the following:

- i. Act as a consultative group pertaining to the medical devices sector, enabling the private sector and government representatives to identify priority issues;
- ii. Coordinate and monitor the implementation of the strategy by the Government, private sector, institutions or international organizations so as to ensure strategy implementation is on track;
- iii. Identify and recommend allocation of resources necessary for the implementation of the strategy;
- iv. Elaborate and recommend revisions and enhancements to the strategy so that it continues to respond best to the needs and long-term interests of the sector;
- v. Propose key policy changes to be undertaken, based on strategy priorities, and promote these policy changes among national decision makers;
- vi. Guide the Secretariat in its monitoring, coordination, resource mobilisation, and policy advocacy & communication functions so as to enable an effective implementation of the strategy.

As discussed above, the public-private platform should be supported by a Secretariat representative to complete the daily operational work related to implementation and management of the strategy. The core responsibilities of the Secretariat representative should be to:

- A. Support and organise the regular meetings of the public-private platform.
- B. Monitor progress and impact of strategy implementation.
- C. Coordinate strategy implementation partners.
- D. Mobilize resources to implement the strategy.

Specific tasks falling under these broad areas of activities include:

- Formulating project proposals including budgets for implementation of activities of the strategy;
- Developing annual and biannual work plans for approval by the public-private platform;
- Collecting information from project implementation and preparing regular monitoring reports to be submitted to the public-private platform;
- Advocating in favour of the strategy to public and private partners;
- Executing any other tasks given by the public-private platform.

### Private sector support and participation

The private sector should benefit from the strategy implementation through improved productive capacities, reduced costs of doing business, facilitated administrative procedures, enhanced access to finance, etc. However, the private sector clearly expressed during the strategy design process its willingness to contribute, directly or in partnership with public institutions, to the implementation of the strategy. Their implementation efforts can range from providing business intelligence to institutions, contributing to development projects, advocacy, etc. In brief, the private sector's practical knowledge of business operations is essential to ensuring that the activities of the strategy are implemented and targeted effectively.

### Sensitization of implementing institutions to build ownership

The key implementing institutions detailed in the PoA need to be informed of the content of the strategy and the implications for their 2017-2021 programming. This sensitization is essential to building further ownership, and it provides institutions with the opportunity to review the PoA in order to confirm the activities they can implement immediately, in the medium and long term. Such a programming approach will permit better resource allocation within the responsible agencies. This allocation can be formalized by integrating the activity of the strategy in the programme planning of the institution. While the financial dimension is often required, the human resource element is no less important.

### Financial resource mobilisation for implementation

While resource mobilization is only part of the solution, it plays a crucial and indispensable role in supporting the strategy implementation. An integrated resource mobilization plan should be elaborated as soon as the NES is adopted. Resources mobilisation involves planning the sequencing of communications with donors, project

design, project proposals/application and resources collection and management. This should facilitate, leverage and strengthen the impact of diverse sources of finance to support sustainable and inclusive implementation, including national resources, development aid and private investment.

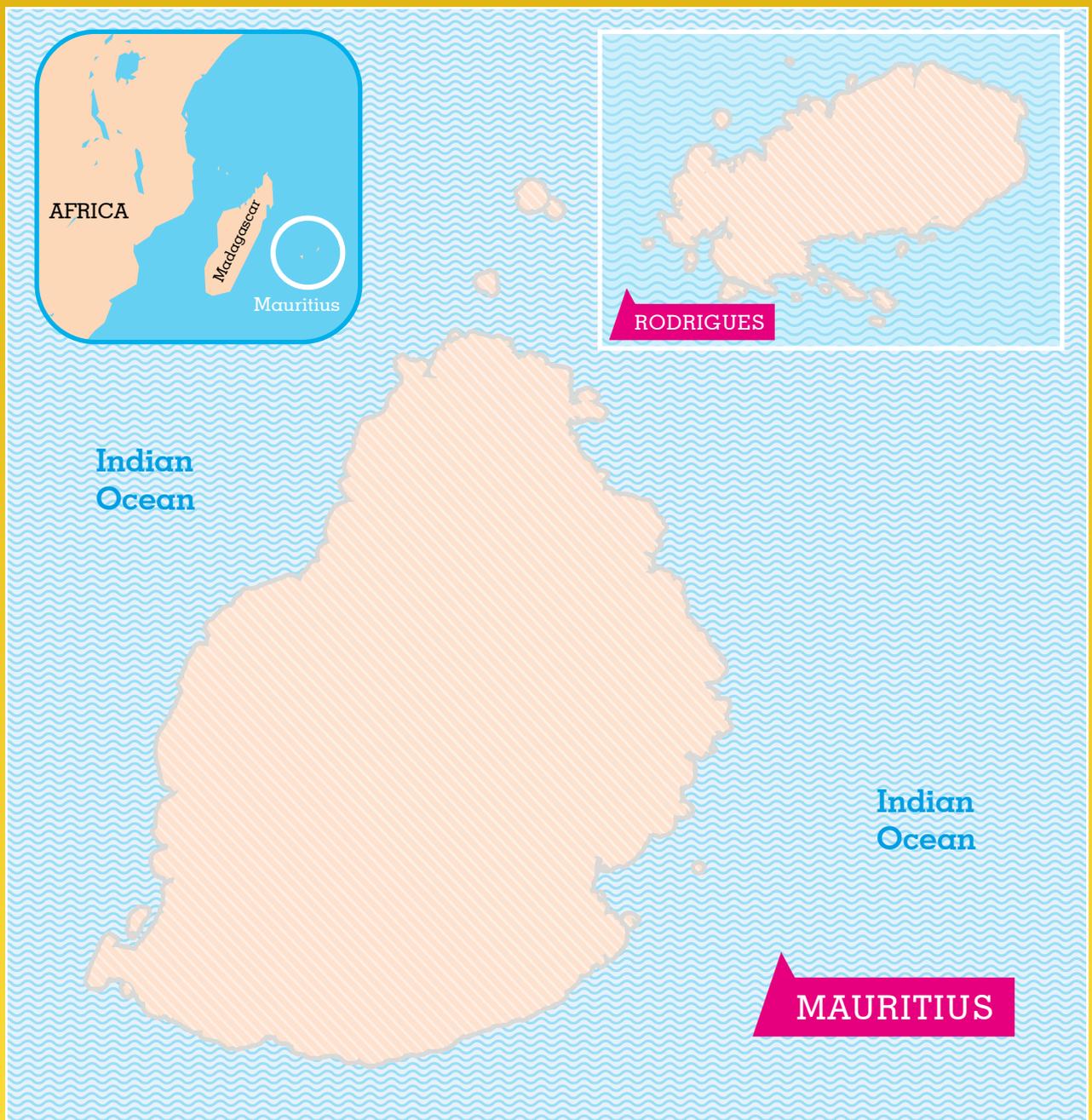
National resources through direct budget and support programme: The Government will need to validate a defined minimum budget support towards the implementation of the different strategy components of the NES, including the medical devices sector. This support for the strategy's activities will demonstrate the government's commitment to the initiatives.

Alignment of donors' support and interventions with the strategy: As the sector is relatively small in Mauritius and because it generates substantial added value, little attention and support have been directed towards the medical devices industry from the international donor community. The public-private platform, together with the authorities, will have to capitalize on the significant momentum gained as part of the strategy design process and leverage it for a smooth and efficient implementation. International development agencies can indeed use the strategy as the logical framework for their programmes as they will surely benefit from its favourable conditions for operation (i.e. political endorsement, private sector buy-in, and improved collaboration with national institutions). The PoA of the strategy should serve the public-private platform as well as the national institutions to improve communication and facilitate the negotiation, planning, coordination and evaluation of commitments made in the context of development aid, in particular through the development of programmes and project proposals aligned with the priorities of the strategy.

National and foreign investment: The strategy design stakeholders' group is composed of representatives from national institutions, the TSN and the private sector. If this group becomes the public-private platform, the strategy should benefit from a solid channel of communication, capable of conveying reliable information to the companies about the export-related opportunities in the industry, and in turn of communicating to the Government the needs that investors have identified to operate successfully. Investment flow in Mauritius could serve as a valuable driver of certain specific areas identified in the strategy and requiring support. Even so, it must be targeted at specific prospects in order to benefit the industry's development as detailed in the future perspective section of the present strategy.

# MAURITIUS NATIONAL EXPORT STRATEGY MEDICAL DEVICES SECTOR

## PLAN OF ACTION



**Strategic objective 1 : Develop an enabling legal and regulatory framework for the medical devices sector**

Operational objective	Activities	Priority 1=high 2=med 3=low	Implementation period					Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020	2021					
1.1. Establish a regulatory framework for the medical devices industry in Mauritius	<p>1.1.1. Establish a Steering Committee, to act as an umbrella organization, a dedicated “one stop partner” contact, dealing with all existing institutions. This entity will play an advisory role to the Government, prepare proposals and projects for the industry and support the decision-making process by pooling the technical or specialist expertise available at national level. More generally, the Committee will ensure that a common agenda is agreed upon and that a long term strategy to support the industry at the national level is defined.</p> <p>Tentatively the Committee could comprise representatives from EM, Bol, Ministries, including MoHQL and MoICCP, SMEDA, MCCI and MEXA, as well as private sector representatives, with a view to generating synergies through improved collaboration and interaction between those actors to achieve greater coordination in the institutional response to the development needs of the industry.</p> <p>It is suggested that the Ministry of Industry, Commerce and Consumer Protection will chair the Steering Committee</p>	1					Entire value chain	Medical Devices Steering Committee established and operational by the end of 2016	Ministry of Industry, Commerce and Consumer Protection (MoICCP)	EM Bol Small & Medium Enterprise Development Authority (SMEDA) MCCI Mauritius Export Association (MEXA) Ministry of Health and Quality of Life (MoHQL)	Government	
	<p>1.1.2. Through technical assistance, draft a <i>Medical Devices Act</i> to provide a regulatory framework for the sector (e.g. Pharmacy Act, or any other relevant Act, that comprises provisions for the manufacture of products as well as their distribution). A first step will be to draft the Terms of Reference (ToR) for the technical assistance. This Act, to act as a White Book describing the industrial processes carried out in the medical devices manufactures, will provide for:</p> <ul style="list-style-type: none"> <li>» the establishment of regulatory framework for medical devices and medical devices components’ testing and certification;</li> </ul> <p><i>Note:</i> when it comes to testing and certification of products, manufacturers should be given the opportunity to choose from more than one laboratory (i.e. <i>GAD / MSB / other Government laboratories or any recognized laboratories</i>)</p> <ul style="list-style-type: none"> <li>» regulations on clinical trials for medical devices in Mauritius to test and validate medical devices clinically before they can be put on the market. Regulations on clinical trials should be accompanied by the appropriate level of patent protection.</li> </ul> <p><i>Note:</i> The Clinical Trials Act adopted in 2011 could be amended to include medical devices trials.</p> <ul style="list-style-type: none"> <li>» a framework to regulate and control research activities in the field of medical devices, including regulations providing for strict regulated third party access to operating rooms.</li> <li>» a plan for an integrated hazardous waste management system</li> </ul>	1					Entire value chain	Medical Devices Act drafted and introduced to the Parliament for enactment by mid-2017	MoHQL	Technical assistance	Government	

**Strategic objective 1 : Develop an enabling legal and regulatory framework for the medical devices sector**

Operational objective	Activities	Priority 1=high 2=med 3=low	Implementation period					Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020	2021					
1.2 Upgrade the National Quality Infrastructure (NQI) in Mauritius	1.2.1. Conduct a gap analysis to determine the calibration requirements of the industry and the services currently provided by the Legal Metrology Services, under the aegis of the Ministry of Industry, Commerce and Consumer Protection (Commerce Division).	2					Entire value chain Legal Metrology Services	Comprehensive gap analysis conducted by the end of 2016	Steering Committee	MolCCP (Commerce Division) Accredited auditors MAURITAS	Donor agencies (UE -ACP TBT Programme?)	
	1.2.2. Based on the outcome of the gap assessment, upgrade the Legal Metrology Services to allow the institution to calibrate equipment and machines needed for the manufacture of medical devices. » acquisition of new calibration equipment » provision of technical training and technical assistance for the Institute's staff related to the use and maintenance of such equipment	2					Legal Metrology Services	The Legal Metrology Services is accredited to calibrate equipment and machines needed for the manufacture of medical devices by the end of 2017	MolCCP	MAURITAS Legal Metrology Services Technical assistance	Government / Donor agencies (EU?)	
	1.2.3. Through technical assistance, establish a list of tests and analyses required by medical devices manufacturers and perform a cost-benefit analysis to assess the relevance and feasibility of conducting such analysis locally, that is, tests that can be conducted in a timely and cost-efficient manner using the services provided by Mauritian laboratories. An analysis of technical and implementation capacities of the MSB and other laboratories to support the medical devices industry in an efficient manner will also be jointly conducted. Draft ToR for the technical assistance.	2					Medical devices manufacturers Laboratories	List of tests and analyses that can be conducted in Mauritius in a timely and cost-efficient manner established by mid-2017 Gap assessment conducted by the end of 2016	Steering Committee	Technical assistance Laboratories Manufacturers	Government	
	1.2.4. Based on the results of the analysis, and supported by the outcome of the cost-benefit analysis (see 1.2.3), undertake targeted capacity building activities for Mauritian laboratories staff focusing on the identified priority areas and related materials.	2					Laboratories	2 training sessions conducted per year, starting 2017	Technical assistance	MolCCP	Government	
	1.2.5. Develop the expertise of MAURITAS to conduct ISO 13485 audits in Mauritius (audit to be conducted once a year)	3					Medical devices manufacturers	A Mauritian certification body is accredited to conduct ISO 13485 audits by 2020	Technical assistance (from accredited auditors)	MolCCP	Government / donor agencies	

**Strategic objective 2: Improve the organization of the sector and foster integration and cooperation**

Operational objective	Activities	Priority 1=high 2=med 3=low	Implementation period					Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020	2021					
2.1. Pave the way for the creation of a medical devices cluster	<p>2.1.1. Conduct a preliminary study for the development of a cluster initiative, such as a "Health Science Techno Park":</p> <ul style="list-style-type: none"> <li>» Identify potential cluster members</li> <li>» Assess the readiness of companies to establish reciprocal trust with other cluster members and to engage in active pooling of knowledge</li> <li>» Ensure clear expectation of and orientation towards benefits as a basis for active involvement of the partners in the cluster</li> </ul> <p>2.1.2. Prepare and plan the cluster development:</p> <ul style="list-style-type: none"> <li>» Conduct an analysis of strengths, weaknesses, opportunities and threats (SWOT)</li> <li>» Formulate themes and rules for cooperation and management of the cluster</li> <li>» Formulation of the specific goals and strategies</li> <li>» Define –and invite– the potential partners needed for the project</li> <li>» Establish the sequence of events and responsibilities</li> <li>» Develop a Business Plan and suitable financing sources (public and private sector funding)</li> </ul>	1					Cluster members	Preliminary study completed by the end of 2016	Steering Committee	Ministry of Finance and Economic Development (MoFED) MoICCP Bol	Government	
	<p>2.1.2. Prepare and plan the cluster development:</p> <ul style="list-style-type: none"> <li>» Conduct an analysis of strengths, weaknesses, opportunities and threats (SWOT)</li> <li>» Formulate themes and rules for cooperation and management of the cluster</li> <li>» Formulation of the specific goals and strategies</li> <li>» Define –and invite– the potential partners needed for the project</li> <li>» Establish the sequence of events and responsibilities</li> <li>» Develop a Business Plan and suitable financing sources (public and private sector funding)</li> </ul>	1					Cluster members	Rules for cooperation established, Goals and strategies elaborated, and Business plan developed by the end of 2017	Steering Committee	MoFED Bol	PPP	
	<p>2.1.3. First steps for the implementation of the cluster development initiative:</p> <ul style="list-style-type: none"> <li>» Establish the organizational structure of the cluster, including its legal form (legal status), structure (competences and communication pathways) and systems (organization of operations)</li> <li>» Develop cluster services (Marketing &amp; PR, export promotion, vocational training and continuing professional education, applied R&amp;D, shared facilities, etc.)</li> </ul>	2					Cluster members	Organizational structure established and cluster services developed by early 2018	Steering Committee	MoFED Bol	PPP	
2.2. Establish synergies with supporting industries to increase the production of inputs locally	<p>2.2.1. Carry out a study to determine supporting services for the medical devices sector and establish a central listing where core competencies and capabilities are referenced.</p> <p>A feasibility study to assess the viability of establishing technology incubators for the development of electronic components, such as the complex electronic machines and other IT components, will also be conducted with a view to attract innovative start-ups.</p>	2					Medical devices manufacturers & supporting industries	Central listing of existing and potential suppliers established by the end of 2016 Comprehensive feasibility study conducted by the end of 2017	Steering Committee	EM MCCI SMEDA Bol MoICCP MRC Mauritius Start-up Incubator (MSI)	Government / private sector	
	2.2.2. Organize inter-professional meetings (B2Bs) to promote the building of business relationships between the medical devices and the supporting industries	1					Medical devices manufacturers & supporting industries	B2B meetings organized on a yearly basis starting 2017	Steering Committee	EM	Government	
	2.2.3. Explore the opportunity to develop sterilized medical devices packaging services for high tech production locally, including design and printing.	2					Packaging companies	Assessment conducted by the end of 2017	Steering Committee	EM MCCI	Government / private sector	

Strategic objective 2: Improve the organization of the sector and foster integration and cooperation											
Operational objective	Activities	Priority 1=high 2=med 3=low	Implementation period				Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020					
2.3. Improve the institutional coordination and develop institutional capabilities	<p>2.3.1. Undertake an institutional assessment to identify the various support actors for the medical devices sector as well as gauge the extent and quality of support to the sector, including:</p> <ul style="list-style-type: none"> <li>» Map support services available to the sector and identify areas of redundancies and overlaps</li> <li>» Assess TSIs' existing capabilities (and skills gap)</li> <li>» Identify the extent to which direct support is available to the sector</li> </ul> <p>Based on the outcome of the study to foster greater coordination among supporting services, set expectations, and clearly define the roles and responsibilities of each institution in supporting the medical devices industry</p>	1					TSIs	Mapping study and gap assessment completed by the end of 2016 Memorandum of Understanding signed by the different stakeholders by the end of 2016	Steering Committee Bol MCCI SMEDA EM MEXA MoICCP MoHQL	Government	
	<p>2.3.2. Based on the results of the institutional assessment (see 2.3.1), conduct capacity building activities to improve the understanding and awareness of the institutions on the medical devices industry.</p>	1					TSIs	Gap assessment conducted by the end of 2016 Seminars conducted once a year for TSIs staff, starting 2017	Steering Committee Bol MCCI SMEDA EM MEXA MoICCP MoHQL	Government	

Strategic objective 3: Develop appropriate skills and competencies and foster research and innovation												
Operational objective	Activities	Priority 1 = high 2 = med 3 = low	Implementation period					Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020	2021					
3.1. Align the education infrastructure with the requirements of industry	<p>3.1.1. Organize a round table gathering industry and academia representatives on medical devices to consolidate industry- research &amp; academia linkages and improve communication</p> <p>» Bridge gaps between industry needs and university training programmes and research</p> <p>» Establish a feedback loop between industry and universities to synchronize the educational system better with the needs of industry and to ensure that information is shared in a more systematic fashion would be a critical first step</p> <p>The objective is twofold:</p> <p>» For the industry: obtain a clear picture of existing training programmes and initiatives in the country</p> <p>» For academia: obtain a clear understanding about the industry's training and research needs</p>	1					Medical devices manufacturers Academia	Organization of one meeting per semester starting second semester 2016	Steering Committee	Universities HRDC Mauritius Institute of Training and Development (MITD) MRC Ministry of Education and Human Resources, Tertiary Education and Scientific Research (MoE)	Government	
	<p>3.1.2. As the sector has not reached a critical mass yet, and before considering developing a dedicated medical devices curriculum in Mauritius in the medium-long term, develop and incorporate specific training courses on the medical devices industry as an option as part of an industrial management curriculum to raise awareness and promote the medical devices industry.</p> <p>The option could provide training courses in micro-biology and clean-room use. Training courses to be delivered by industrial service providers specialized in the manufacturing of medical devices.</p>	1					Medical devices manufacturers Universities (students)	New option developed by early 2017 and operational for the second semester 2017	Steering Committee	Universities MITD HRDC MoE	PPP	
	<p>3.1.3. In the medium to longer term, work towards translating solicited industry needs into academic offerings, including research programmes.</p> <p>» Develop a dedicated medical devices curriculum for students at the faculty comprising initial training and continuing vocational education and training in the area of:</p> <ul style="list-style-type: none"> <li>- biology</li> <li>- micro-biology</li> <li>- clean-room use</li> <li>- chemistry</li> </ul> <p>» Develop practical and interactive middle management training programmes covering the following subjects:</p> <ul style="list-style-type: none"> <li>- Leadership</li> <li>- Conflict management</li> <li>- Marketing management</li> <li>- Financial accounting</li> <li>- Operations management</li> <li>- Decision making and problem solving techniques</li> </ul> <p>The specialized training courses developed by the Galway Medical Devices Centre of Excellence in Ireland or the MIT in the USA, the world's references in the field of medical devices, can be used as a source of inspiration in this regard.</p>	1					Medical devices manufacturers Universities (students)	New curriculums developed by 2018	Steering Committee	Universities MITD HRDC MoE	PPP	
	<p>3.1.4. Once a critical mass of students is reached, provide universities with advanced equipment specific to the medical devices industry and provide students with theoretical and hands-on practical training on that equipment.</p> <p>The provision of equipment will also be supported by the provision of equipment maintenance training to ensure the long term sustainability of such investment.</p>	2					Universities (students)	Equipment purchased and fully operational for the first semester 2018	Steering Committee	Universities MITD HRDC MoE	PPP	

**Strategic objective 3: Develop appropriate skills and competencies and foster research and innovation**

Operational objective	Activities	Priority 1=high 2=med 3=low	Implementation period					Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020	2021					
3.1. Align the education infrastructure with the requirements of industry	3.1.5. Develop internship programmes in medical devices manufactures for students / researchers under the Youth Employment Programme.  3.1.6. Develop linkages between Mauritian universities and specialized universities abroad (such as the Galway Medical Devices Centre of Excellence in Ireland) » Organize a one-week study visit to the Galway University for about 10 students and researchers » Offer the possibility to selected students to spend a year, or at least a semester, at a specialized university abroad	2					Medical devices manufacturers Universities (students)	Create 10 internship positions per year for the entire industry starting second semester 2017  Study visit organized second semester 2017 Exchange programmes operational by 2018	Steering Committee	Manufacturers Universities The Ministry of Labour, Industrial Relations and Employment	Government	
3.2. Boost research and innovation in the medical devices sector	3.2.1. Elaborate an exhaustive list of existing programmes and mechanisms in place to promote R&D activities the medical devices sector could benefit from (such as the MRC's funding schemes) and disseminate information on those programmes. <i>Note:</i> Incubator initiatives have also recently been launched for high-tech and innovative entrepreneurship but have not reached their full potential yet.  3.2.2. Develop backward and forward linkages with universities and research institutes to elaborate specific R&D programmes targeting different segments of the medical devices sector's value chain (also see 3.1.1)	1					Research Institutes Universities Medical devices manufacturers	List of existing programmes established and disseminated to the sector by early 2017	Steering Committee	Universities MRC MSI MoE	Government	
3.3. Ensure the appropriate level of IP protection	3.2.3. Establish a system of incentives, such as a research tax credit, to encourage the involvement of the private sector in funding R&D work. Support mechanisms to help manufacturers offsetting some of the costs associated with R&D expenditure could take the form of a research tax credit on eligible research expenditure, such as high tech machinery investment  3.2.4. Advocate for the enactment of the pending Preclinical Research Bill that will provide the regulatory framework for pre-clinical trials (on monkeys)  3.3.1. Advocate for the signature of the Patent Convention Treaty (PCT) under WIPO, as envisaged under The Patent, Industrial Designs and Trademarks Act 2002, to guarantee the necessary IP protection.  3.3.2. Advocate for the inclusion of Mauritius in the Madrid Union, i.e. as a contracting party to the Madrid Agreement and the Madrid Protocol concerning the international registration of marks (Madrid is the International Trademark System under WIPO).  3.3.3. Advocate for the inclusion of Mauritius in The Hague System, the International Design System, for the international Registration of Industrial Designs	1					Medical devices manufacturers  Min of International Trade and Foreign Affairs  Mauritian Industrial Property Office  Mauritian Industrial Property Office	Inclusion of the Research tax credit in the Budget of the Government of Mauritius for the Fiscal Year 2017  Preclinical Research Bill enacted by 2017  Mauritius signatory state of the PCT in 2017  Mauritius member of the Madrid System in 2018  Mauritius member of The Hague System in 2019	MRA (MoFED)  Steering Committee  Steering Committee  Steering Committee	MoE  MoFA (International Trade Division)  MoFA (International Trade Division)  MoFA (International Trade Division)	Government  Government (on-going)  Government	

**Strategic objective 4: Create a more enabling business environment for the development of the sector and promote FDI**

Operational objective	Activities	Priority 1=high 2=med 3=low	Implementation period					Beneficiaries	Targets	Lead implementer	Supporting implementers	Possible funding source
			2017	2018	2019	2020	2021					
4.1. Facilitate the procedures for the import of inputs	4.1.1. Establish simplified custom procedures and clearly define and streamline the roles and responsibilities of the different institutions involved in customs clearance procedures for the Health Science sector, notably at ministerial level. Advocate for the adoption of a top down approach whereby organizations are registered with customs authorities, describing their activities and imported components.	1					Medical devices manufacturers	New approach adopted by 2018	Steering Committee	MRA MoICCP MoHQL MoFA (International Trade Division)	Government	
							Medical devices manufacturers	List of imported inputs established and included in MRA documentation by early 2017	Steering Committee	MRA	Government	
4.2. Create a more enabling business environment and develop incentive mechanisms	4.2.1. Provide grants and/or fiscal incentives for exports competitiveness, such as the EM's Export Credit Insurance Scheme to boost exports to Africa, to contribute to developing the industry and improving the attractiveness of Mauritius for medical devices manufacturers. 4.2.2. Negotiate fiscal advantages for medical devices manufacturers to improve the competitiveness of the sector. » Explore the opportunity to offer preferential electricity rates to the industry » Introduce airfreight rebate schemes on all airlines	1					Medical devices manufacturers	Incentive mechanisms for exports competitiveness enforced by 2017	Steering Committee	EM	Government	
							Medical devices manufacturers	Rebate schemes introduced in early 2018	Steering Committee	MoFED CEB Airlines	Government	
4.3. Improve access to finance in the sector	4.2.3. Simplify the procedures for compliance checks for industrial equipment and facilities as provided by the Health and Safety regulations (under the Ministry of Labour) and consider reducing the frequency of the controls. Advocate for the alignment of those procedures with ILO international standards	2					Medical devices manufacturers	Health and Safety regulations simplified by 2018	Ministry of Labour, Industrial Relations and Employment	Steering Committee	Government	
							Entire value chain	Awareness campaign conducted by mid-2017	Steering Committee	Commercial banks	PPP	
4.4. Promote investment in the medical devices sector	4.3.1. Conduct awareness and education workshops for bank officers with a view to establishing the potential of the sector and the market value of the medical devices manufacturers and informing financial institutions on the overall value proposition of the sector. 4.3.2. Conduct a feasibility study for the creation of a private equity fund as a viable strategy to support the development of the sector.	2					Entire value chain	Feasibility analysis for the creation of a private equity fund completed by mid-2016	Steering Committee	Private sector		
							Investors	Study completed by the end of 2016	Steering Committee	Bol	Government	
	4.4.1. Conduct a comprehensive review of the current investment promotion activities relevant to the sector in place in Mauritius with the view to: » Assessing the current investment rules and provisions » Formulating recommendations aimed at fostering FDI and innovation in the sector	1					Investors	New communication strategy elaborated by the end of 2017	Steering Committee	Bol	Government	
							Investors	Incentive package developed and implemented by the end of 2017	Steering Committee	Ministry of Local Government and Outer Islands Bol	Government	
	4.4.2. Improve institutional communication with prospective foreign direct investors and create awareness about the opportunities that Mauritius has to offer for their activities. 4.4.3. Develop an incentive package for investors, featuring the following: » Facilitate the process of obtaining building and land use permits » Provide infrastructural incentives » Offer financial support for promoting investment by offering subsidized loans and loan guarantees for borrowers who want to invest in the sector.	2					Investors		Steering Committee	Bol	Government	
							Investors		Steering Committee	Ministry of Local Government and Outer Islands Bol	Government	



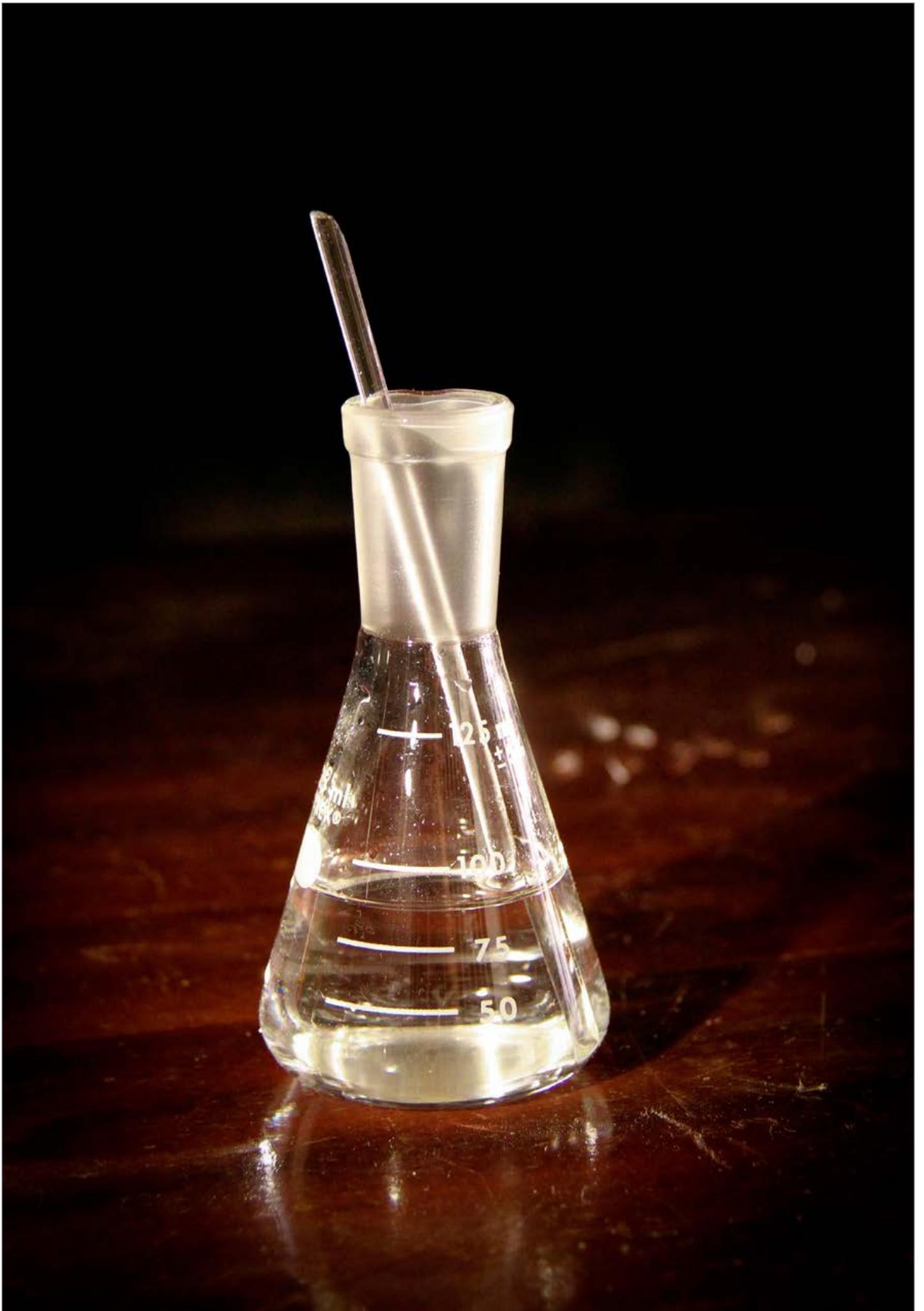


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