

MEDICAL DEVICES INDUSTRY



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STRATEGIES AND POLICIES

TARGETS

1.01 Malaysia has the potential to be a major producer and exporter of medical devices. To achieve this objective, concerted efforts will be undertaken by both the Government and the private sector. During the IMP3 period, total investments in the industry are targeted at RM19.4 billion, while exports of medical devices and products are targeted to reach RM18.4 billion in 2020 (Table 1.1).

TABLE 1.1

	2006- 2010	2011- 2015	2016- 2020	2006- 2020	2006-2020
	(RM billion)				Average Annual Growth (%)
Investments	4.1	6.2	9.1	19.4	9.2
Investments per year	0.8	1.2	1.8	1.3	n.a¹
Exports (end period)	9.0	13.9	18.4	18.4	8.6

PROJECTIONS FOR THE MEDICAL DEVICES INDUSTRY

Note: 1 Not applicable

Source: Ministry of International Trade and Industry

STRATEGIC THRUSTS

- 1.02 Four strategic thrusts have been set for the industry:
 - (1) broadening the range of products towards the higher-end category;
 - (2) promoting FDIs and domestic investments in the industry;
 - (3) expanding the range of support industries and services for the industry; and
 - (4) strengthening the institutional support for enhancing human resource development, R&D and compliance to international standards and regulations.

(1) BROADENING THE PRODUCT RANGE

- 1.03 Further development of the industry will be encouraged, taking advantage of the availability of the potential market, increasing demand for better healthcare products and services, and promotion of health tourism. The focus of the development will be on expansion and diversification. In its efforts to broaden the product range, the industry will take into consideration developments at the global level. Internationally, the industry encompasses a wide range of products, which is changing rapidly, with new developments in medical research and technologies, and increasing consumer demand. In striving for a higher contribution of total factor productivity (TFP) growth to productivity, the industry will be encouraged to diversify into the production of higher value medical devices and products. Areas of focus include the development of own brand names and higher quality and speciality gloves.
- 1.04 Driven by new medical technologies, efforts on developing the capacities and capabilities of skilled personnel will be intensified in the various disciplines, including biomedicine, biotechnology, healthcare and engineering, to facilitate companies in undertaking more capital and technology-intensive operations. The industry will be encouraged to upgrade the technology and ICT applications, moving from basic processes to those involving more innovative and leading edge technologies.
- 1.05 In tandem with the trend in demand, the following growth areas will be promoted:
 - combination products;
 - home-care and self-care products;
 - in-vitro diagnostic devices;
 - cardiovascular devices;
 - orthopaedic devices; and
 - medical and surgical equipment and instruments.
- 1.06 In the short term, the focus of the development of the industry will be on the shift towards higher technology products, where the industry will be encouraged to strengthen its technological capabilities. The areas include:
 - developing new and more sophisticated medical gloves;
 - moving into higher end catheters with improved performance;
 - leveraging upon Malaysia's strength in electronics to fabricate electronicsbased parts for original equipment manufacturers (OEMs) of medical devices; and

 moving into higher end orthopaedic products, contact lenses, and other medical and surgical instruments and appliances.

In the medium to long term, the focus of the product development will be on medical and surgical equipment, high end diagnostic devices, medical imaging equipment and high end hospital and laboratory equipment.

(2) **PROMOTING INVESTMENTS**

- 1.07 Malaysia will be positioned as an outsourcing destination and a major producer of medical devices in the global supply chain. Potential manufacturers will be encouraged to become global suppliers of parts and components for major medical equipment companies. Towards realising this objective, the following strategies will be adopted:
 - promote the development of an integrated cluster of manufacturers of medical devices and medical technology companies, with support services, such as product testing, injection moulding and precision engineering and fabrication;
 - encourage global manufacturers of medical devices to leverage upon the existing domestically available expertise of the plastics, precision engineering and electronics industries to source components and parts from Malaysia, as well as assemble and develop medical sub-assemblies and systems, and undertake the manufacture of diagnostic medical devices;
 - promote and enhance the participation of SMEs in supporting the industry, as sub-vendors to the main suppliers of the MNCs;
 - encourage existing manufacturers of medical devices and manufacturers with related technologies to diversify their product range and develop related products;
 - encourage locally established companies and MNCs to form strategic alliances or joint ventures to invest in the high end range of medical devices and equipment; and
 - strengthen the infrastructure support by making available secure, reliable and cost-effective supply of high quality utilities, including telecommunications, electricity, gas and water, to meet existing and future demands of the industry.

(3) SUPPORT INDUSTRIES AND SERVICES

- 1.08 Efforts will be undertaken to enhance the development of existing support industries, such as precision engineering, electronics, tool and die making, automation support, contract moulding and assembly, and metal and plastic sheet fabrication, to support the growth of the medical devices industry. The efforts include:
 - giving priority to the promotion of the growth of the support services required, in particular, ICT and software development. In addition, support services by local research institutes and universities to the MNCs based in Malaysia, in conducting joint R&D, product designing and testing, and clinical trials for medical devices, will be undertaken;
 - encouraging MNCs to outsource the production of parts and components to local suppliers and transfer technology through strategic alliances, to expand the support industries and services required for the industry;
 - encouraging greater cooperation between the industry and the medical profession, through access to research and testing units, and interactions with medical professionals and inventors of medical equipment and devices; and
 - intensifying the promotion of healthcare services, which include hospital services, and medical and dental services, as well as health tourism, to enhance the overall capacities and capabilities in the industry.

(4) STRENGTHENING THE INSTITUTIONAL SUPPORT

- 1.09 Institutional support will be provided to enhance R&D and human resource development, and assist in the compliance to international standards and regulations. The measures include:
 - providing assistance to encourage R&D activities and the development of product design capabilities, new processing technologies and indigenous medical technologies and devices;
 - encouraging institutions of higher learning, including vocational and technical schools, to include in their curricula relevant courses, such as medical technology, practical biomedical engineering, biophysics, manufacturing of medical devices and materials sciences;
 - fostering greater collaboration between the industry, universities and research institutes to strengthen the development of indigenous technologies and new medical devices;

- encouraging linkages between the medical devices industry and petrochemical industry in the development and application of relevant technologies, such as latex, plastics, and polymer and coating technologies. Linkages with the electronics industry will also be promoted in developing technologies for electro-diagnostic medical devices;
- strengthening the registration of medical devices in Malaysia, with the establishment of a dedicated Medical Device Bureau under the Ministry of Health, to assist, guide and facilitate manufacturers in matters related to the development and promotion of the industry;
- providing support to manufacturers for compliance with local and international standards and regulations to expand exports, including making available information on regulations and requirements overseas;
- reinforcing the maintenance of a national system of controls and regulations relating to the quality, safety, efficacy and timely availability of medical devices, to enhance the perception of the quality of locally produced medical devices;
- further improving the system of registration for patents, trademarks and intellectual properties, based on the World Intellectual Property Organisation; and
- undertaking efforts to remove or minimise the regulatory barriers to trade in medical devices, through expediting the conclusion of mutual recognition arrangements (MRAs) on a bilateral and regional basis.