STRATEGIES AND POLICIES

TARGETS

1.01 For the IMP3 period, 2006-2020:

- investments in the pharmaceutical industry have been targeted at RM6.7 billion or RM450 million per annum; and

- exports are targeted to grow at an annual rate of 6.3 per cent to reach RM1.2 billion by 2020 (Table 1.1).

TABLE 1.1

PROJECTIONS FOR THE PHARMACEUTICAL INDUSTRY

Note: [1] Not applicable
Source: Ministry of International Trade and Industry

STRATEGIC THRUSTS

1.02 The industry is expected to develop its own niche products to be able to gain a greater share of the global pharmaceutical market. In the pursuit of this objective, seven strategic thrusts have been set for the further development of the industry:

(1) focusing on developing specific pharmaceutical product groups and services which have the potential for growth;

(2) enhancing exports and diversifying markets;

(3) increasing the economies of scale of the industry through consolidations, re-investments and rationalisation;

(4) promoting foreign direct investments (FDIs) into higher value-added pharmceutical products and services;

(5) encouraging further efforts on R&D and commercialisation;

(6) enhancing the development of expertise, with relevant knowledge and skills for the industry, particularly in drug research; and

(7) strengthening the institutional support in the development and promotion of the industry.

(1) DEVELOPING SPECIFIC PHARMACEUTICAL PRODUCT GROUPS AND SERVICES

1.03 Globally, new factors favour the internationalisation of R&D, as the MNCs reassess their core competencies and undertake vertical disintegration of R&D, product development, clinical trials, manufacturing and marketing activities. A large portion of the expenditures on the development of new chemical entities or new molecular entities are spent on clinical trials. In this respect, clinical trial activities in Malaysia will be promoted, as these activities adhere to the guidelines on Good Clinical Practice (GCP), which adopt the basic principles outlined by the International Committee on Harmonisation of Good Clinical Practice.

1.04 Malaysian pharmaceutical manufacturers which basically produce generic drugs, comprising undifferentiated prescription drugs and over-the counter drugs under their own brands, have developed the capability to launch new off-patent products rapidly. These manufacturers, especially SMEs, are encouraged to explore products which have niche markets, such as nutripharmaceuticals, herbal drugs, products in novel dosage forms and drugs for tropical diseases. To enhance their present market position, the manufacturers will be encouraged to venture into the production of specific pharmaceutical products and the supply of services which have the potential for growth. These include:

- new off-patent drugs;
- biopharmaceutical products;
- niche pharmaceutical products;
- sterile products;
- oncology products;
- clinical trial services; and
- dedicated distribution services.

(2) ENHANCING EXPORTS AND DIVERSIFYING MARKETS

1.05 The present export market base, which mainly covers ASEAN and the less developed countries in Africa and South America, will be expanded to include developed countries, such as the European Union (EU) and the USA. Strategic alliances with these countries will be encouraged. The industry will be encouraged to develop and establish worldwide logistics and marketing networks and linkages to facilitate the expansion into the markets of the developed countries.

1.06 In this respect, measures will be undertaken to encourage Malaysian companies to intensify exports. The measures include promoting Malaysian quality and certification standards, as well as developing Malaysian brands. To enhance the quality perception and image of Malaysian products and brands, pharmaceutical companies will be encouraged to collaborate with domestic packaging companies in the production of a more innovative range of packaging materials, which will result in more convenient, aesthetic and secure packaging. Government-to-Government collaborations, including free trade agreements (FTAs), will be leveraged upon to improve the perception of and gain market acceptance for Malaysian pharmaceutical products. Assistance will also be considered to enable companies to keep pace with global requirements, particularly in the area of compliance with international standards, including those on the environment. In addition, domestic pharmaceutical companies will be encouraged to take advantage of opportunities arising from regional and bilateral trade and investment agreements to invest overseas.

(3) INCREASING ECONOMIES OF SCALE AND EFFICIENCY

1.07 Domestic pharmaceutical companies will be encouraged to operate on a larger scale, to be competitive in the global market. The companies, especially the SMEs, will be encouraged to consolidate with larger local manufacturers, including the MNCs, through mergers or smart partnerships, to improve the economies of scale and be competitive in the global market. Support to these companies will be considered, to create more efficient, globally competitive Malaysian-owned pharmaceutical manufacturers.

1.08 Further re-investments and rationalisation in the industry will be promoted, through the application of information and communication technology (ICT) and improvement in production technologies, to enhance efficiency and quality. Existing pharmaceutical companies will be encouraged to enhance their ICT capacities in areas such as logistics and inventory control. The acquisition of new technologies, including process technology, will be encouraged, through licensing, franchising, or outright purchase from countries which are well established in the production of generics and bio-generics. SMEs will be encouraged to acquire key technologies on GMP to comply with international standards and be able to compete globally.

(4) PROMOTING FOREIGN INVESTMENTS

1.09 Promotion will be intensified to encourage MNCs to establish manufacturing plants with R&D facilities in Malaysia, especially those which have international production networks. Their presence will facilitate the development of the entire pharmaceutical value chain, in terms of production of higher value-added products, technology transfer, support services and employment of highly skilled workforce. MNCs will be encouraged to manufacture products presently not available and undertake activities presently not carried out in Malaysia. These include innovator drugs, active pharmaceutical ingredients, vaccines, inhalation products and novel delivery systems.

(5) ENCOURAGING RESEARCH AND DEVELOPMENT AND COMMERCIALISATION

1.10 Being a research-intensive industry, pharmaceutical companies will require a large allocation of funds for R&D activities, to keep pace with emerging technologies. To reduce the costs of R&D and increase the rate of commercialisation, collaborations will be encouraged between local research institutes, institutions of higher learning and manufacturers.

1.11 For the further development of the industry, local manufacturers are encouraged to undertake innovative drug discovery activities, especially on resource-based new chemical entities and biologics. These manufacturers will also be encouraged to enter into collaborations with foreign companies, especially between small companies having good R&D capabilities and large firms with superior infrastructure. As the development of drugs involves substantive capital expenditures and a long gestation period, support will be provided to encourage research in new chemical entities and biologics. Existing facilities for clinical trials and bio-equivalence studies in various universities, Government hospitals and the private sector will be strengthened and consolidated.

(6) ENHANCING THE DEVELOPMENT OF EXPERTISE

1.12 Productivity in the industry will be further enhanced through a higher contribution from its total factor productivity (TFP) growth. Initiatives on TFP growth include:

- upgrading the quality of the workforce through increasing the number of professional and technical researchers, scientists and pharmacists;

- encouraging the shift from the import-oriented to export-oriented operations of the domestic companies, to take advantage of the growing global demand, and improvements in the operations, including the utilisation of raw materials, and supply chain management;

- promoting the identification of niche products, based on the core competencies of the manufacturers, and their development into high quality products; and

- undertaking coordinated investments in technology and collaborative efforts in R&D.

1.13 Measures will be undertaken to enhance and upgrade the quality of the skilled workforce, in both the short and long terms. A sufficient supply of highly qualified scientists and researchers will be made available to conduct R&D activities in the industry. As a short term measure to overcome the shortage of specific skills, the industry will be allowed to employ foreign skilled personnel, as required. Attachment of pharmacy graduates and post-graduates to the industry will be encouraged to accelerate the transfer of knowledge and the enhancement of technology and skills.

1.14 The content of curriculum in pharmacy in universities will be refocused to reflect the present requirements of the industry. The pharmacy curriculum will be revised to include disciplines relevant to the industry, as well as address key technology needs, including R&D and nurturing of creativity. The intake of students for pharmacy courses will be increased to match the anticipated demand for pharmacists. In the long term, courses on pharmaceuticals and related disciplines will be provided and lecturers made available in both the public and private institutions of higher learning. More sponsorship for post-graduate studies related to pharmaceuticals will be encouraged to increase the supply of qualified researchers for future R&D activities. Greater collaboration will be undertaken between national and international research institutes. With the short and long term measures, it is expected that foreign pharmaceutical companies will be attracted to conduct their clinical trials or bio-equivalence studies in Malaysia.

(7) STRENGTHENING THE INSTITUTIONAL SUPPORT

1.15 Measures in strenghtening the institutional support include:

- reviewing the present assistance programmes, taking into account similar programmes in other competing countries. Support will be provided to:
    - encourage companies to venture into high risk research projects, such as patented and innovator drugs, and active pharmaceutical ingredients;
    - promote accredited testing laboratories, and logistics and sterilisation services; and
    - reduce the costs incurred by intending exporters in the registration of products overseas;

- instituting an effective mechanism, in addition to the present assistance programmes, to promote the conservation of the country's biological diversity and sharing of benefits arising out of the utilisation of genetic resources, in joint research projects, for the further development of the resource-based drugs; and

- expediting, where appropriate, the process of drug registration for local products to enable the domestic manufacturers to take advantage of premium prices, by marketing the newly off-patent products before imports of these products reach the domestic market.