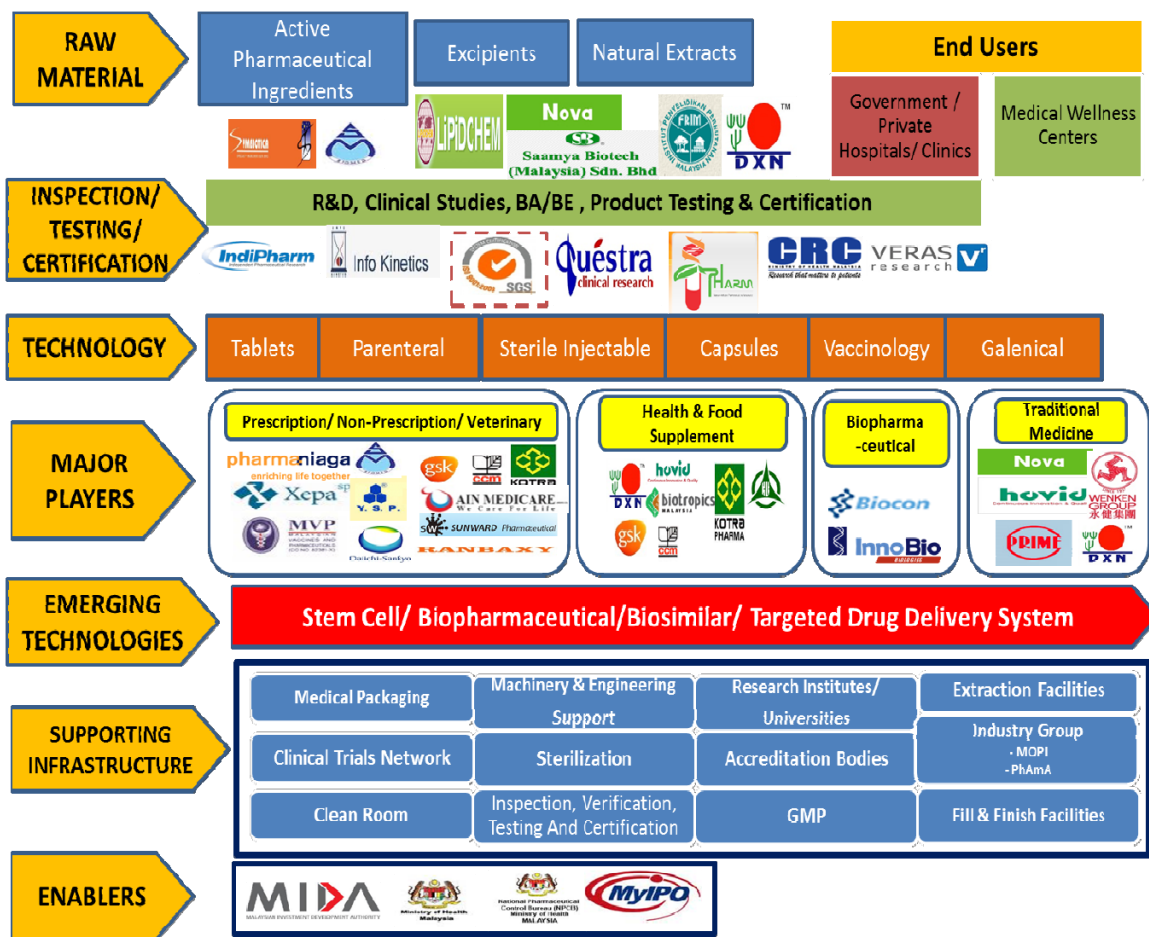


## **PHARMACEUTICAL INDUSTRY**

- The pharmaceutical products in Malaysia can be broadly classified as:
  - i. New Drug Product (NDP)
  - ii. Biologics
  - iii. Generic products
    - Prescription medicine
    - Non-prescription medicine (Over the Counter, OTC)
  - iv. Health and food supplements
  - v. Traditional medicine
  - vi. Veterinary products
  
- In 1984, drug registration was introduced in Malaysia and the Drug Control Authority (DCA) established. All drugs/medicine in pharmaceutical dosage forms and cosmetics have to be registered and notified before sale and marketing is permitted in the country. To date, a total of 266 pharmaceutical premises with Good Manufacturing Practices (GMP) certification have been registered with DCA.
  
- Of these, a total of 89 premises are licensed to manufacture modern medicines (analgesics, antacids, anti-hypertensive, diuretics, antibiotics and anti-histamines in the form of tablets, capsules, drops, powders, creams, ointments, injectable, syrups, ophthalmic and nasal preparations). 172 premises are licensed to produce local traditional and herbal medicines. The remaining 5 are veterinary premises.
  
- Major MNCs such as Glaxo Smith Kline, B.Braun, Y.S.P Industries, Ranbaxy and Sunward Pharmaceutical have established their production facilities in Malaysia, while Pharmaniaga, CCM Pharmaceutical, Kotra Pharma, Hovid and Xepa-Soul Pattinson represent some top local pharmaceutical companies in Malaysia. The current ecosystem of pharmaceutical industry is as shown:



| No. | Raw materials / Services Providers | Major Companies/ Agencies/ Parties   |
|-----|------------------------------------|--|
| 1.  | Active Pharmaceutical Ingredient   | <input type="checkbox"/> Symbiotica Specialties Sdn Bhd.<br><input type="checkbox"/> SM Biomed Sdn Bhd.  |
| 2.  | Excipient/ Natural extracts        | <input type="checkbox"/> Saamya Biotech (Malaysia) Sdn Bhd<br><input type="checkbox"/> DXN Pharmaceutical Sdn Bhd<br><input type="checkbox"/> Nova Laboratories Sdn Bhd  |
| 3.  | Research Institutes                | <input type="checkbox"/> Forest Research Institute of Malaysia (FRIM)<br><input type="checkbox"/> Institute for Medical Research (IMR)<br><input type="checkbox"/> Malaysian Agriculture Research and Development Institute (MARDI)<br><input type="checkbox"/> Malaysian Institute of Pharmaceuticals & Nutraceuticals (IPHARM)<br><input type="checkbox"/> Center for Natural Products Research and Drug Discovery (CENAR) |

|   |                             |   |
|---|-----------------------------|---|
| 4 | Clinical Research           | <input type="checkbox"/> Clinical Research Malaysia (CRM)<br><input type="checkbox"/> Clinical Research Centre (CRC)  |
| 5 | Bioequivalence Centre       | <input type="checkbox"/> Info Kinetics Sdn Bhd<br><input type="checkbox"/> Pusat Pengajian Sains Farmasi, USM<br><input type="checkbox"/> University of Malaya Biequivalence and Testing Centre (UBAT)<br><input type="checkbox"/> Clinical Investigation Centre, University Malaya Medical Centre                                      |
| 6 | Logistics                   | <input type="checkbox"/> DKSH (Supply Chain/ Logistic)<br><input type="checkbox"/> Zuellig Pharma (Supply Chain/ Logistic)  |
| 7 | Associations / Institutions | <input type="checkbox"/> Malaysian Organisation of Pharmaceutical Industries (MOPI)<br><input type="checkbox"/> Pharmaceutical Association of Malaysia (PhAMA)  |
| 8 | Utilities/ Infrastructures  | <input type="checkbox"/> TNB (Energy), State Water Consortium<br><input type="checkbox"/> KLIA & KLIA2 (International Airports)<br><input type="checkbox"/> Seaports<br><input type="checkbox"/> Industrial Parks<br><input type="checkbox"/> TM (Telecommunication)<br><input type="checkbox"/> Streamyx, Maxis, Celcom, P1 (Internet) |

Pharmaceutical industry in Malaysia is currently scattered across the region but prominent in two main clusters in Klang Valley.



Major foreign and local pharmaceutical companies operating in Malaysia:

Local companies:

| No | Company                                | Products   |
|----|--|--|
| 1  | Pharmaniaga Manufacturing Bhd          | Tablets, capsules, liquids, ointments & creams, cephalosporin  |
| 2  | CCM Pharmaceuticals Sn Bhd             | Tablets, capsules, liquids, syrup, granules, sterile ear/ eye drop, softgel, cephalosporin   |
| 3  | Hovid Berhad                           | Ethical drugs, nutritional health supplements, herbal remedies, enhanced absorption formulations and slow release formulations, soft gels, capsules, tablets, granules and creams. |
| 4  | Kotra Pharma (M) Sdn Bhd               | Tablets, capsules, liquids, ointments & creams, sterile and small volume injectables, cephalosporin  |
| 5  | Xepa-Soul Pattinson (Malaysia) Sdn Bhd | Tablets, capsules, liquid preparations, creams, ointments and sterile eyedrops   |
| 6  | Ain Medicare Sdn Bhd                   | IV solution, haemodialysis concentrates and peritoneal dialysis solution   |

Foreign companies:

| No | Company   | Country of Origin | Products  |
|----|---|-------------------|---|
| 1  | Sterling Drug Malaya, manufacturing arm of Glaxo SmithKline (GSK) | United Kingdom    | General oral solid pharmaceutical products  |
| 2  | B. Braun Medical Industries Sdn Bhd                               | Germany           | Large volume parenterals, hemodialysis concentrates, peritoneal dialysis solution   |
| 3  | Ranbaxy (M) Sdn Bhd   | India             | General oral solid pharmaceutical products  |
| 4  | Y.S.P Industries (M) Sdn Bhd                                      | Taiwan            | Tablets, capsules, suppositories, liquid preparations, powders, gels and creams including veterinary and aquatic products |
| 5  | Biocon Sdn Bhd  | India             | Insulin   |
| 6  | Sunward Pharmaceutical  | Singapore         | Uncoated tablets, capsules, liquids, and creams   |

- List of Associations for Pharmaceutical Industry as below:

|                                  | <b>Malaysian Organisation Of Pharmaceutical Industries (MOPI)</b>   | <b>Pharmaceutical Association of Malaysia (PhAMA)</b>  |
|----------------------------------|---|--|
| <b>Name of Current President</b> | Mr. Diong Sing Peng   | Mr.Muru Annamalai  |
| <b>Membership</b>                | 42 members  | 39 members   |
| <b>Address</b>                   | Global Business & Convention Centre<br>Mezzanine Floor, Block A,<br>No. 8, Jalan 19/1, Section 19,<br>46300 Petaling Jaya<br>Selangor   | C-37-3, BlockC, Jaya One,<br>72A, Jalan Universiti, 46200<br>Petaling Jaya, Selangor Darul<br>Ehsan.   |
| <b>Contact Detail</b>            | T: 03-7931 9003<br>F: 03-7932 2730<br>Email: <a href="mailto:admin@mopi.org.my">admin@mopi.org.my</a>   | T: 03-7960 8322/23<br>F: 03-7960 8324<br>Email: <a href="mailto:phama@phama.org.my">phama@phama.org.my</a><br><a href="mailto:janice@phama.org.my">janice@phama.org.my</a>   |
| <b>Roles</b>                     | AMMI continue to be the growth base of the medical device industry in Malaysia and consist of three main types of industry players: manufacturers; suppliers of raw materials and services to the medical devices manufacturing companies; and importers and exporters of medical devices, all of whom employ a sizable workforce in their production facilities. | The Malaysia Medical Device Association or commonly known as MMDA has a diversity of members comprising of local manufacturers, local authorised representatives, importers, suppliers, distributors, multi-national corporations and service providers involved in the distribution and sales of medical devices and related healthcare products and equipment within Malaysia. |

## **I. INCENTIVES**

- Incentives for Manufacturing Companies
- Incentives for High Technology Companies
- Incentives for Strategic Projects
- Reinvestment Allowance (RA)
- Accelerated Capital Allowance (ACA)

## **II. PROMOTED PRODUCTS/ ACTIVITIES UNDER PROMOTION OF INVESTMENT ACT (1986)**

- General List
- High Technology List
- Growth Areas

### III. REGULATION AND ENFORCEMENT

- Drug Control Authority (DCA)
- Control of Drugs and Cosmetic Regulations (CDCR) 1984

### IV. TRADE PERFORMANCE FOR PHARMACEUTICAL PRODUCTS

#### • Export

| Year   | Total (RM million)      |
|--|-------------------------|
| 2013   | RM 982                  |
| 2014   | RM 1,130                |
| 2015   | RM 1,308                |
| 2016   | RM 1,456                |
| Top 5 Major Export Items   | Total (RM million) 2016 |
| 1. Medicament mixtures (not 3002, 3005, 3006), put in dosage       | RM 690                  |
| 2. Glycosides & their salts, ethers, esters & other derivatives    | RM 402                  |
| 3. Provitamins & vitamins, natural/reproduced by synthesis         | RM 99                   |
| 4. Pharmaceutical goods, specified sterile prod sutures, laminaria | RM 73                   |
| 5. Hormones; their derivatives; steroids                           | RM 62                   |

#### • Import

| Year  | Total (RM million)      |
|---|-------------------------|
| 2013  | RM 5,008                |
| 2014  | RM 5,602                |
| 2015  | RM 5,976                |
| 2016  | RM 6,160                |
| Top 5 Major Import Items  | Total (RM million) 2016 |
| 1. Medicament mixtures (not 3002, 3005, 3006), put in dosage                | RM 4,542                |
| 2. Human & animal blood; antisera, vaccines, toxins, micro-organism culture | RM 493                  |
| 3. Glycosides & their salts, ethers, esters & other derivatives             | RM 280                  |
| 4. Provitamins & vitamins, natural/reproduced by synthesis                  | RM 212                  |
| 5. Antibiotics  | RM 187                  |

- In terms of trade, total trade for pharmaceutical was RM 7.6 billion in 2016. Exports of pharmaceutical products amounted to RM1.5 billion in 2016, an increase of 11% as compared to RM1.3 billion in 2015. Major exports were:
  - medicament mixtures (RM690 million);
  - glycosides and their salts, ethers, esters and other derivatives (RM402 million);
  - provitamins and vitamins, natural/reproduced by synthesis (RM99 million);
  - pharmaceutical goods, specified sterile product sutures, laminaria (RM73 million); and
  - hormones, their derivatives, steroids (RM62 million).
- Top 5 export destinations in 2016 were the Singapore (RM194 million), USA (RM155 million), Brunei (RM120 million), Indonesia (RM94 million) and Hong Kong (RM91 million).
- In 2016, imports totaled RM 6.2 billion. Major imports were:
  - medicament mixtures (RM4,542 million);
  - human and animal blood, antisera, vaccines, toxins, micro-organism culture (RM493 million);
  - glycosides and their salts, ethers, esters and other derivatives (RM280 million);
  - provitamins and vitamins, natural/reproduced by synthesis (RM212 million); and
  - antibiotics (RM 187 million).
- Top 5 import destinations in 2016 were the Germany (RM861 million), China (RM822 million), USA (RM593 million), France (RM479 million) and Switzerland (RM397 million).

## V. INVESTMENT

- In term of investments, 12 projects with investments worth RM940 million were approved by MIDA in 2015. Of this, 9 projects (RM144 million) have been implemented. While in 2016, a total of 9 projects were approved with investment value of RM916 million.

### Approved Investments

| <b>Year</b>  | <b>No. of Projects</b> | <b>Domestic<br/>(RM mil.)</b> | <b>Foreign<br/>(RM mil.)</b> | <b>Total<br/>(RM mil.)</b> |
|--------------|------------------------|-------------------------------|------------------------------|----------------------------|
| 2013         | 12                     | RM201<br>(37%)                | RM338<br>(63%)               | RM539                      |
| 2014         | 15                     | RM260<br>(24.8%)              | RM487<br>(65.2%)             | RM747                      |
| 2015         | 12                     | RM564<br>(60%)                | RM376<br>(40%)               | RM940                      |
| 2016         | 9                      | RM272<br>(30%)                | RM644<br>(70%)               | RM916                      |
| <b>Total</b> | <b>48</b>              | <b>RM1,297</b>                | <b>RM1,845</b>               | <b>RM3,142</b>             |

Source: MIDA