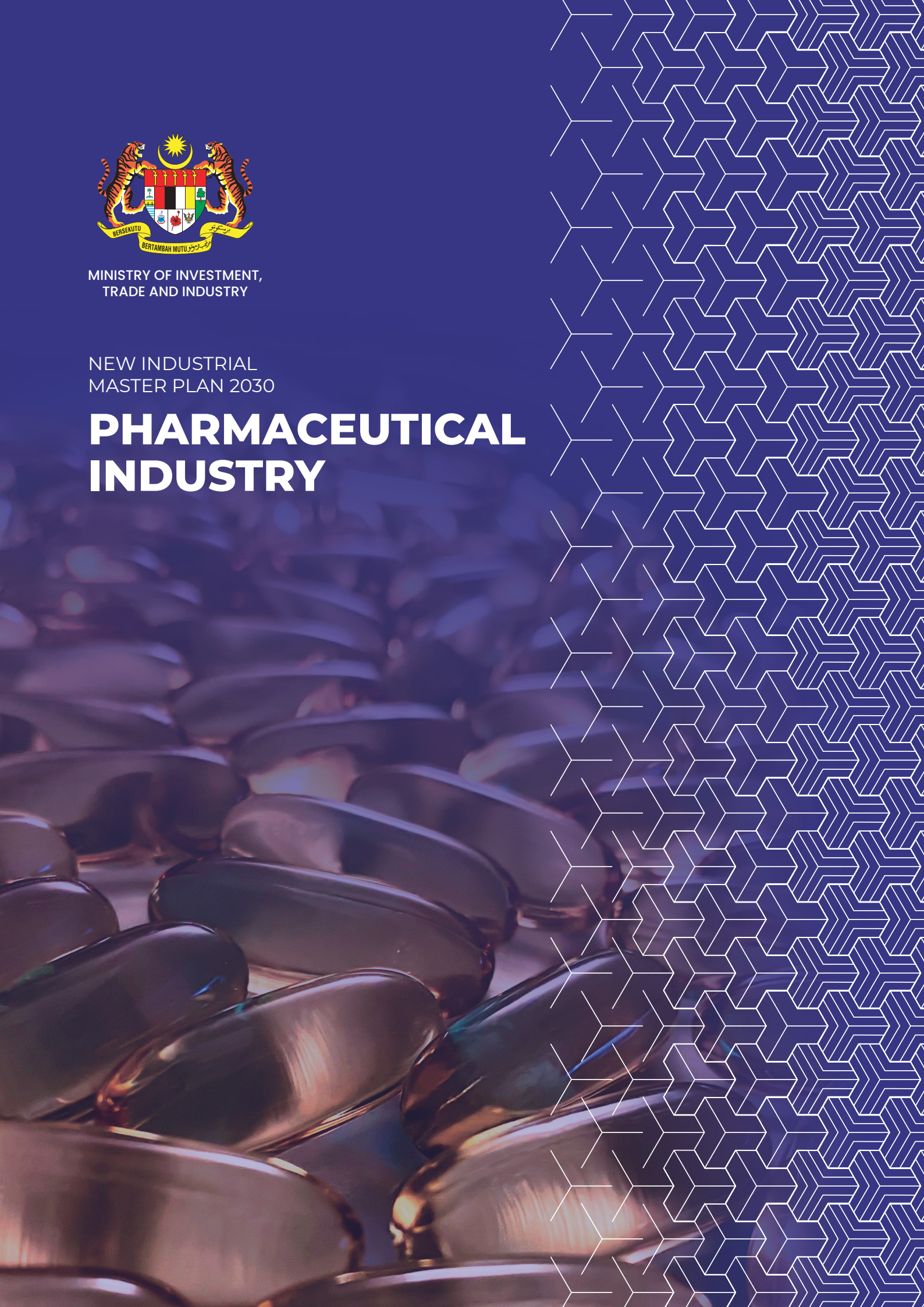
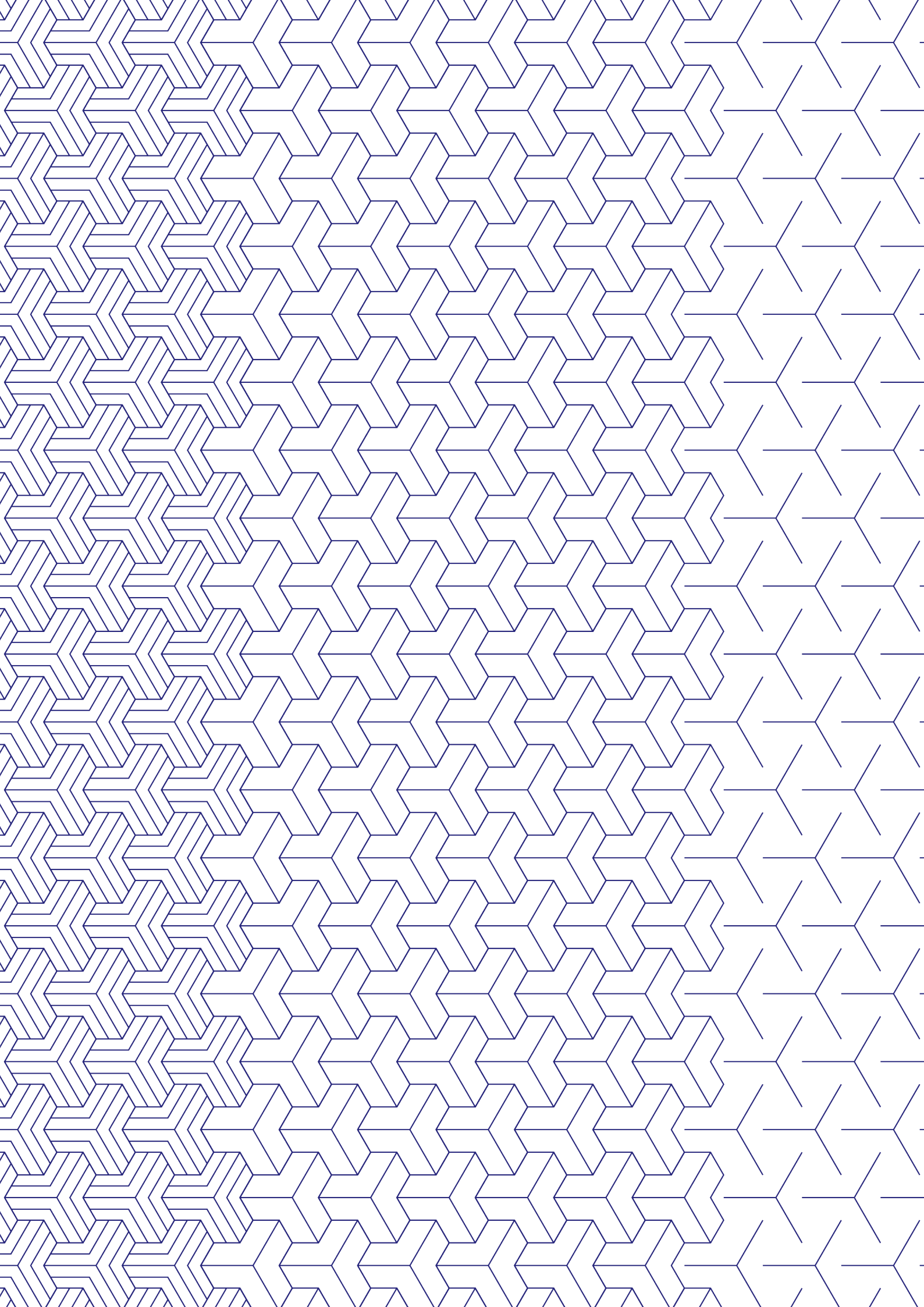
MINISTRY OF INVESTMENT,
TRADE AND INDUSTRY

NEW INDUSTRIAL
MASTER PLAN 2030

PHARMACEUTICAL INDUSTRY





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PREFACE

Malaysia's strength in the manufacturing sector has been significantly driven by the implementation of robust and forward-thinking Industrial Master Plans, first launched in 1986.

The success of the IMP3 (2006-2020) was anchored on innovation, research and development (R&D) and human capital development to drive high value-added industries to transform Malaysia into a knowledge-based economy.

The journey towards formulating the NIMP 2030 is underscored by the need to build a robust industrial sector as an important prerequisite to achieve socioeconomic prosperity. Three previous iterations of the Industrial Master Plans have driven industrial development in Malaysia, with the Government adopting industrial development strategies relevant to the period to transform the economy. Malaysia flourished from a low-productivity agrarian-based economy and is heading towards achieving developed nation status, underpinned by robust manufacturing and services sectors. The strategy has successfully raised the living standards of the Rakyat and propelled remarkable growth in Gross National Income (GNI) per capita, increasing 34 times between 1967 to 2019, making Malaysia one of the fastest growing economies in modern history.

Industrial policies have since become more diverse and complex, incorporating new imperatives including the integration into the global value chain (GVC), development of indigenous capabilities in a knowledge economy, evolution of environmental, social and governance (ESG) criteria and disruptions from the new industrial revolution. The question is not about the necessity of such policies, but rather what new policies are required and how to proceed.

Given the current challenging environment, benchmarking and learning from other country's experiences are no longer sufficient. Malaysia needs to embark on its own path into unchartered territory, to steer the nation into the challenging future. The combined impact of the new imperatives and the recent pandemic has compelled the Government to rethink Malaysia's industrial strategy.

With the NIMP 2030, Malaysia intends to transform the industry into greater heights, capitalising on emerging global trends, supply chain disruptions, current geopolitical landscape, digitalisation and ESG considerations. These trends are moving at an unprecedented pace and Malaysia has to act fast.

Therefore, the NIMP 2030 is designed to achieve the aspirations in a span of seven years and takes on a Mission-based approach for industrial development. This approach unites Malaysia by encouraging collaboration between the Government and the private sector to rally the industries.

Purpose of the NIMP 2030

The NIMP 2030 sets forth Malaysia's future direction in industrial transformation. It provides a national integrated plan for resilient industrial development until 2030 – setting the fundamentals for future policy development and enabling the industry at all levels. It articulates Malaysia's position and participation in the global economic environment.
The NIMP 2030 serves to:

- Provide national strategic direction to lead the industrial development policies;
- Be a conversation piece for investors and other economies on Malaysia's position and direction; and
- Feature the role of the Malaysian Government in shaping the economy.

INTRODUCTION

New Industrial Master Plan 2030

The Missions and Enablers identified will be executed through 21 Strategies and 62 Actions Plans to unlock the needed enabling ecosystems. Several catalytic Mission-based Projects (MBPs) have been identified to catapult the mission-based implementation. The NIMP 2030 strategic framework is illustrated below:

VISION

Our vision for Malaysia is to have:

- Competitive industry with high economic complexity
- High income and skilled workforce
- Strong domestic linkages

GOALS

- **Increase economic complexity**
- **Create high-value job opportunities**
- **Extend domestic linkages**

MISSIONS

MISSION 1
Advance economic complexity

STRATEGIES AND ACTION PLANS

21 Strategies
62 Action Plans

1.1 Expand to high value-added activities of the value chain
1.1.1 Create global IC design champions from Malaysia
1.1.2 Attract global leader to establish wafer fabrication in Malaysia
1.1.3 Shift from basic to specialty chemical
1.1.4 Build Malaysian champions for game changing advanced materials
1.1.5 Identify high value-added opportunities in the aerospace, pharmaceutical and medical devices sectors

1.2 Develop entire ecosystem to support the high value-added activities
1.2.1 Build strong local SMEs in manufacturing and related services to support the industry champions
1.2.2 Integrate value chains between:
- M&E and Medical Devices
- Semiconductor and EV
- Chemical and Pharmaceutical

1.3 Establish cooperative 'vertical integration' for global value chain
1.3.1 Leverage alliance with ASEAN countries to integrate the semiconductor, advanced materials and clean energy value chain
1.3.2 Develop vertical integration programmes through IndustryConnect conferences

1.4 Foster Research, Development, Commercialisation and Innovation (RDCI) ecosystem
1.4.1 Assign specific topics and KPIs to universities for industrial-linked R&D
1.4.2 Digitalise IP application and launch enhanced National IP Policy

1.5 Increase manufacturing exports
1.5.1 Implement national trade advocacy campaign to increase industry utilisation of FTAs
1.5.2 Rejuvenate "Made in Malaysia" branding
1.5.3 Address trade restrictive non-tariff measures (NTMs) and compliance of standards
1.5.4 Update FTA based on geopolitical conditions

5 Strategies, 15 Action Plans

Mission-based Projects:

MBP 1.1 Create global IC design champions in EV, RE and AI
MBP 1.2 Attract new advanced wafer fabrication in Malaysia
MBP 1.3 Deepen to specialty chemical vertical
MBP 1.4 Groom champions in 4 game changing advanced materials

MISSION 2
Tech up for a digitally vibrant nation

2.1 Accelerate technology adoption
2.1.1 Enhance Industry4WRD programmes to increase technology adoption
2.1.2 Accelerate digital infrastructure rollout (JENDELA)

2.2 Shift away from low-skilled labour model
2.2.1 Introduce multi-tiered levy mechanism for low-skilled labour to accelerate automation
2.2.2 Introduce automation condition in new Manufacturing Licence

2.3 Spur technology innovation
2.3.1 Nurture local technology solution providers to support Technology Adoption Programme
2.3.2 Develop generative and industrial AI solution leaders and system integrators
2.3.3 Drive data analytics through a national digital platform for manufacturing

2.4 Accelerate government digitalisation and integration
2.4.1 Digitalise end-to-end government touch points across business life cycle

4 Strategies, 8 Action Plans

Mission-based Projects:

MBP 2.1 Transform 3,000 smart factories
MBP 2.2 Establish Malaysia as Generative AI Hub

- New and existing industry clusters
- Balanced and inclusive participation
- Sustainable development

Develop new & existing clusters | **Improve inclusivity** | **Enhance ESG practices**

MISSION 3
Push for Net Zero

3.1 Accelerate transition towards sustainable practices
- 3.1.1 Develop sectoral decarbonisation pathways to guide transition
- 3.1.2 Decarbonise "hard-to-abate" sectors
- 3.1.3 Introduce carbon policy, accounting and tax
- 3.1.4 Launch iESG framework and transition programmes

3.2 Transition to renewable and clean energy
- 3.2.1 Enhance adoption scheme for energy efficiency or renewable energy
- 3.2.2 Accelerate availability and accessibility of renewable energy source for the industry

3.3 Catalyse new green growth areas
- 3.3.1 Catalyse EV as a key growth driver
- 3.3.2 Grow carbon capture, utilisation and storage (CCUS) as a new sector
- 3.3.3 Develop circular economy framework for the industry

3.4 Shift towards green infrastructure
- 3.4.1 Accelerate transformation of industrial estates into eco-industrial parks

4 Strategies, 10 Action Plans

Mission-based Projects:

MBP 3.1	Create decarbonisation pathway role models
MBP 3.2	Launch locally-manufactured EV
MBP 3.3	Deploy large-scale CCUS solutions

MISSION 4
Safeguard economic security and inclusivity

4.1 Develop resilient supply chain
- 4.1.1 Identify specific supply chain resilience strategies for critical sectors
- 4.1.2 Establish supply chain cooperation and collaboration through G2G and G2B programme
- 4.1.3 Introduce National Mineral Policy for downstream processing of critical minerals

4.2 Foster climate resilient development
- 4.2.1 Develop sectoral adaptation pathways
- 4.2.2 Foster an adaptation industry to provide adaptation products and services (including exports)
- 4.2.3 Instil climate resilience measures for critical economic infrastructure

4.3 Strengthen industrial clusters for regional development
- 4.3.1 Expand clusters for spillover regional impact
- 4.3.2 Align industrial development plan between Federal and States

4.4 Empower *Bumiputera* participation and create inclusive workforce
- 4.4.1 Uplift capabilities of *Bumiputera* companies in manufacturing via *Tindakan Pembangunan Bumiputera 2030*
- 4.4.2 Develop programme to increase women participation in high-skilled manufacturing employment

4 Strategies, 10 Action Plans

ENABLERS

E.1 Mobilise financing ecosystem
- E.1.1 Introduce NIMP Industrial Development Fund and NIMP Strategic Co-Investment Fund
- E.1.2 Boost financing for digitalisation and decarbonisation transition
- E.1.3 Establish green *sukuk* to facilitate transition
- E.1.4 Establish supply chain financing for SMEs
- E.1.5 Increase utilisation of the capital market
- E.1.6 Expand the imSME platform to show all available funding options including government funding and capital market
- E.1.7 Review government funding for consolidation

E.2 Foster talent development and attraction
- E.2.1 Leverage mynext and MYFutureJobs for strategic workforce planning to address long-term demand-supply requirement
- E.2.2 Introduce progressive wage system policy
- E.2.3 Improve policy to enable fast and hassle-free access to high-skilled foreign talents
- E.2.4 Expand TVET programmes for high-skilled jobs in critical sectors
- E.2.5 Raise profile of high-tech manufacturing career to attract interest in STEM subjects

E.3 Establish best-in-class investor journey for ease of doing business
- E.3.1 Establish a unified investment strategy and align investment evaluation to new parameters under NIA
- E.3.2 Harmonise and streamline functions and KPIs across IPA landscape
- E.3.3 Review and design competitive, agile and relevant incentives
- E.3.4 Improve One-Stop Portal for seamless investor experience

E.4 Introduce whole-of-nation governance framework
- E.4.1 Establish public-private collaborative councils
- E.4.2 Set up NIMP 2030 Delivery Management Unit
- E.4.3 Develop NIMP 2030 dashboard system

4 Strategies, 19 Action Plans

NIMP 2030 SECTORAL PLAN

There are individual enclosures of 21 sectors included as a supplementary reference to the main NIMP 2030 document.

They provide a view of the respective sectoral perspective in the context of the main NIMP 2030 document, and were developed with reference to individual sectoral roadmaps, where applicable.

The 21 sectors are:

Category	Industry
Priority Sectors	1. Aerospace 2. Chemical 3. Electrical and Electronics (E&E) 4. Pharmaceutical 5. Medical Devices
Sectors	6. Digital and Information and Communication Technology (ICT) 7. Automotive 8. Food Processing 9. Global Services and Professional Services 10. *Halal* 11. Machinery and Equipment (M&E) 12. Manufacturing-Related Services (MRS) 13. Metal 14. Mineral 15. Palm Oil-based Products 16. Petroleum Products and Petrochemicals 17. Rail 18. Rubber-based Products 19. Shipbuilding and Ship Repair (SBSR) 20. Textile, Apparel and Footwear 21. Wood, Paper and Furniture

This document is the **NIMP 2030 Sectoral Plan – Pharmaceutical Industry.**

OVERVIEW OF THE DOCUMENT

This NIMP 2030 Sectoral Plan – Pharmaceutical Industry (Document) provides insights into the sector and its prospects during the NIMP 2030 period.

This Document offers a comprehensive understanding of the industry's direction during the NIMP 2030 period based on its historical performance, opportunities and strategies to overcome existing challenges and achieve its targets.

The Document is presented in five sections:

1. Background

- This section sets the foundation to help readers understand the industry.
- It delves into the industry's focus area, encompassing its sub-sectors, for a comprehension of the industry's breadth.[1]
- Readers will find details about the industry's value chain and its key players, including the relevant industry associations, in this section.
- The section lists the policies that are related to the industry.

2. Performance

- This section reports the industry's performance during specific periods.
- There are two notable periods for the review of the industry's historical performance:
  - the IMP3 period (2006 to 2020); and
  - from 2021 to 2022.
- The performance review of the industry's development includes its investment trends, export and import dynamics, employment figures, value-added and productivity measures.

3. Trends and Opportunities

- This section highlights the opportunities and potential avenues for growth that the industry can leverage during the NIMP 2030 period.

4. Challenges

- This section provides insights into potential obstacles that could impact the industry's growth and development.

5. Strategies and Action Plans

- The final section of the document outlines the future trajectory for the industry.
- This section provides the Strategies and Action Plans that are intended to catalyse the industry during the NIMP 2030 period.
- The Strategies and Action Plans set in this Document have been aligned to the Missions set in the main NIMP 2030 document.

[1] *Incentives available for this industry as of time of writing can be found in Appendix 1*

SECTION 1 BACKGROUND

Areas Covered

1. Malaysia's pharmaceutical industry consists of four major sub-sectors:
   i. manufacturing of pharmaceutical products;
   ii. manufacturing of health supplements;
   iii. manufacturing of traditional medicines; and
   iv. manufacturing of veterinary products.
2. The products under these categories are illustrated in Table 4.1.

Table 4.1: Sub-sectors of Pharmaceutical Industry

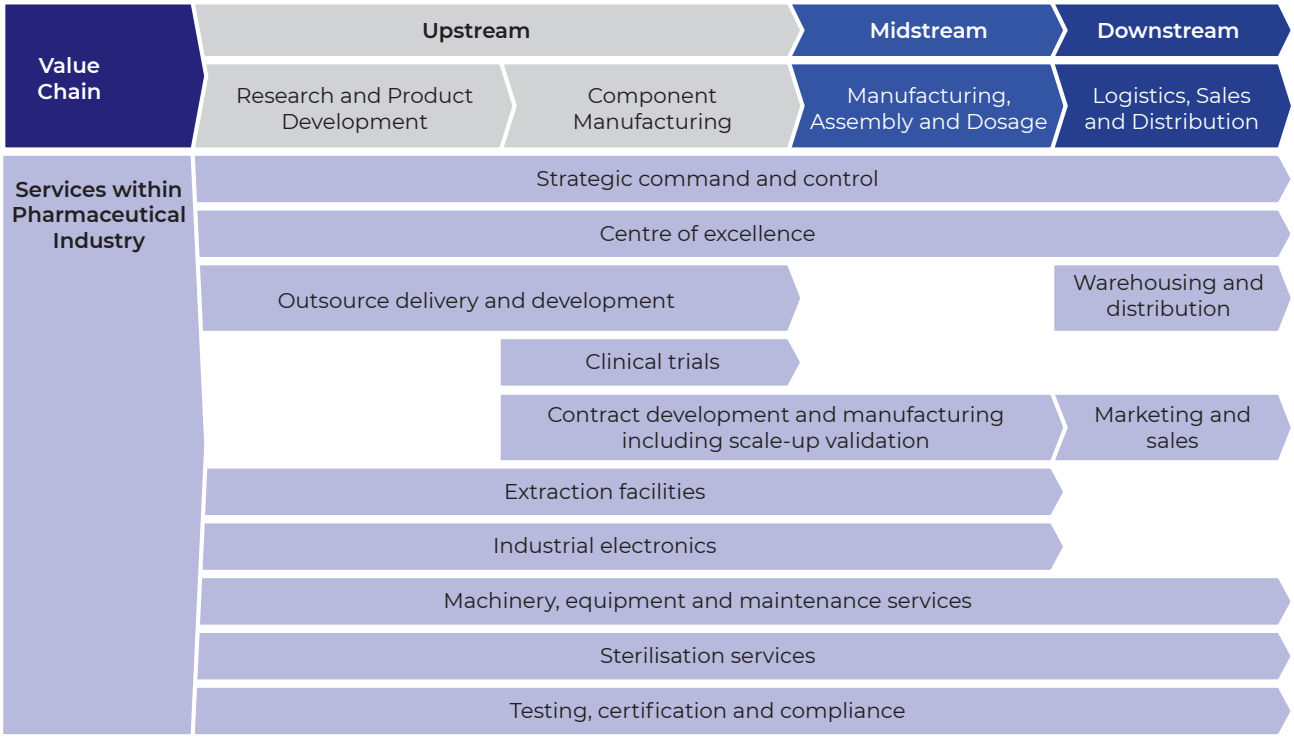
Sub-sectors	Products (Non-exhaustive examples)	
Manufacturing of pharmaceutical products	New Drug Products (NDP)	• Innovator • Originator drugs
	Biologics or biopharmaceutical	• Vaccine • Blood products • Monoclonal antibodies • Insulin • Hormones • Cell and gene therapy products (CGTP)
	Generic products	• Prescription medicine such as antibiotics, analgesics (e.g. morphine), anti-diabetic, anti-asthmatic • Non-prescription medicine or over-the-counter (OTC) medicine such as antiseptic or disinfectants, analgesic (e.g. paracetamol)
Manufacturing of health supplements	Products that are intended to supplement the diet are taken by mouth in forms such as pills, capsules, tablets, liquids or powders and are not represented as a conventional food or the sole item of a meal or diet. Examples include vitamins, probiotics and enzymes.	
Manufacturing of traditional medicine	Any products used in the practice of indigenous medicine in which the drug consists solely of one or more naturally occurring substances of plant, animal or mineral.	
Manufacturing of veterinary products	Any drug which includes any substance, product or article, intended to be used, or capable or purported or claimed to be capable of being used on any animals, whether internally or externally, for a medicinal purpose.	

Source: National Pharmaceutical Regulatory Agency (NPRA)

Value Chain

3. The value chain of pharmaceutical industry (Figure 4.1) includes:
   i. upstream activities – the discovery and development process of pharmaceutical products through research and product development and component manufacturing;
   ii. midstream activities – comprise dosage form selection, formation, packaging and labelling of products through manufacturing, assembly and dosage activities;
   iii. downstream activities – logistics, sales and distribution of pharmaceutical products.

Figure 4.1: Value Chain of Pharmaceutical Industry



Source: New Investment Policy (NIP), Malaysian Investment Development Authority (MIDA)

4. There are various supporting services and infrastructure for the pharmaceutical industry, including:
   i. warehousing and distribution including medical packaging;
   ii. clinical trials;
   iii. extraction facilities;
   iv. industrial electronics;
   v. machinery, equipment and maintenance services;
   vi. sterilisation services;
   vii. testing activities such as bioequivalent and bioavailability studies; and
   viii. certification bodies including the National Pharmaceutical Regulatory Agency (NPRA).

Market Players

5. The stakeholders in Malaysia's pharmaceutical industry can be categorised into four categories:
   i. manufacturers;
   ii. importers, wholesalers, distributors and providers;
   iii. Ministries and Government Agencies and industry associations; and
   iv. academia (public research institutes and higher education institutions).

6. According to NPRA, there are more than 266 licensed pharmaceutical manufacturers in Malaysia as of the point of writing.
   i. 29.0 per cent (77 manufacturers) are producers of pharmaceuticals;
   ii. 66.9 per cent (179 manufacturers) produce traditional medicine and health supplements;
   iii. Remaining 4.0 per cent (10 manufacturers) produce veterinary products.

7. Figure 4.2 maps the presence of the pharmaceutical industry's manufacturers against the activities that they are involved in across the value chain.

Figure 4.2: Presence of Industry Players along the Value Chain of Pharmaceutical Industry

Value Chain

Sub-Sectors		Research and Development (R&D)	Component Manufacturing	Manufacturing, Assembly and Dosage	Logistics, Sales and Distribution
Pharmaceutical Products	Innovator	Low Presence	Low Presence	Low Presence	Low Presence
	Biologics	Low Presence	Low Presence	Low Presence	Low Presence
	Generics	Medium Presence	Low Presence	Medium Presence	Medium Presence
Health Supplement		Medium Presence	Low Presence	Medium Presence	Medium Presence
Traditional Medicine		Medium Presence	Medium Presence	High Presence	Medium Presence
Veterinary Products		Low Presence	Low Presence	Low Presence	Low Presence

Source: MIDA

   i. Pharmaceutical manufacturers are mainly focused on R&D, manufacturing and sales of generics.
   ii. Similarly, health supplement manufacturers are focused on R&D, manufacturing and sales activities.
   iii. In contrast, traditional medicine manufacturers are focused on R&D, component manufacturing and manufacturing and assembly activities.
   iv. There is a limited presence of veterinary product manufacturers across the value chain.

8. Wholesalers, distributors and providers of Malaysia's pharmaceutical industries include retail pharmacies engaged in wholesaling, independent distributors as well as establishments that provide medicines directly to patients such as clinics and hospitals.

9. Industry associations in Malaysia's pharmaceutical industry play a vital role in promoting the interests and growth of the industry. Non-exhaustive examples of these associations include:
   i. Malaysian Organisation of Pharmaceutical Industry (MOPI);
   ii. Malaysian Pharmacists Society (MPS);
   iii. Pharmaceutical Association of Malaysia (PhAMA); and
   iv. Malaysian Association of Pharmaceutical Suppliers (MAPS).

10. Apart from that, Ministries and Government Agencies offer various facilities and initiatives, including testing and certification, licensing, tax incentives and funding assistance, training and consultancy services, and skills upgrading programmes. The Ministries and Government Agencies include:
   i. Ministry of Health (MOH);
   ii. Ministry of Investment, Trade and Industry (MITI);
   iii. National Pharmaceutical Regulatory Agency (NPRA);
   iv. Drug Control Authority (DCA);
   v. Clinical Research Malaysia (CRM);
   vi. Malaysian Investment Development Authority (MIDA); and
   vii. Malaysia External Trade Development Corporation (MATRADE).

11. The pharmaceutical industry in Malaysia is supported by academia that consists of research institutes, private and public universities – playing a part in developing capability for the industry, as well as contribute towards quality research to boost the industry particularly for modern drug discovery.

Policies, Laws and Regulations

12. The industry's development is guided by the following:
   i. Malaysian National Medicines Policy (MNMP)[2] ; and
   ii. National Vaccine Development Roadmap (NVDR).

13. Laws and regulations related to the pharmaceutical industry are:
   i. Poisons Act 1952;
   ii. Dangerous Drugs Act 1952;
   iii. Sale of Drugs Act 1952;
   iv. Medicines (Advertisement and Sale) Act 1956;
   v. Wildlife Conservation (Amendment) Act 2022; and
   vi. Control of Drugs and Cosmetics Regulations 1984.

[2] *Dasar Ubat Nasional (DUNas)*

SECTION 2 PERFORMANCE

IMP3 Focus and Performance

14. During the IMP3 period (2006 to 2020), the industry focused on three growth areas:
    i. production of specialised goods with high margins;
    ii. advancement of drug delivery technologies; and
    iii. entry into biopharmaceuticals, branded generics and biogenerics market.

15. During this period, the industry continued to be a main driver of Malaysia's economic growth, with a CAGR[3] of 8.0 per cent over the last decade up to 2016. It reached a market value of RM9.8 billion in 2020, equivalent to 15.6 per cent of total domestic healthcare expenditure (RM62.8 billion) in 2020.

Investments

16. The investment performance of the pharmaceutical industry for the period of 2006 to 2022 is recorded in Table 4.2 below.

Table 4.2: Approved Investments of Pharmaceutical Industry

Items	Units	IMP3			2021	2022	2021-2022
		2006	2020	2006-2020			
Total Investment	RM million	241.1	152.8	5,291.1	419.5	266.8	686.3
Domestic Investment	RM million	230.7	131.9	2,544.0	380.7	85.9	466.6
Foreign Investment	RM million	10.4	20.9	2,747.1	38.8	180.9	219.7
Number of projects	#	12	12	135	7	5	12
Employment	persons	552	416	7,253	347	187	534

Source: MIDA

17. During the IMP3 period, a total of 135 projects were approved in the pharmaceutical industry with a total investment of RM5.3 billion. These investments committed a total of 7,253 job opportunities.

18. In 2021 and 2022, a total of 12 projects were approved with a total investment of RM686.3 million. These investments committed a total of 534 job opportunities.

19. The investment trends were attributed to:
    i. cautious investment approach taken by investors due to the uncertainties caused by the global pandemic; and
    ii. increased demand for medical products such as medicines and vaccines due to the global pandemic.

20. From 2006 to 2022, 119 (81.0 per cent) of the 147 approved projects were implemented.

[3] *Compound annual growth rate*

Exports

21. The export performance of the pharmaceutical industry during the period of 2006 to 2022 is recorded in Table 4.3 below.

Table 4.3: Exports of Pharmaceutical Industry

Item	IMP3			2021	2022	2006-2020	2020-2021	2021-2022
	2006	2020	2006-2020			CAGR	Annual Growth	
Exports[4] (RM billion)	0.5	1.9	17.4	2.4	2.8	10.3%	24.0%	14.2%

Source: MATRADE

22. During the IMP3 period, the industry's exports grew by a CAGR of 10.3 per cent from RM0.5 billion (2006) to RM1.9 billion (2020).

23. Compared to 2020, total exports of Malaysia's pharmaceutical industry grew by 24.0 per cent to RM2.4 billion in 2021.

24. Subsequently the industry's exports grew by 14.2 per cent to RM2.8 billion in 2022.

25. The industry's export growth was attributed to:
    i. expansion of multinational corporations' (MNC) operations resulting in increased production capacity and generating products more than local consumption; and
    ii. recognition of Malaysia's compliance with international standards through the Pharmaceutical Inspection Cooperation Scheme's (PIC/S) membership.

26. In 2022, Malaysia pharmaceutical industry's products were mainly exported to:
    i. United States (US) (RM0.5 billion, 17.9 per cent);
    ii. Singapore (RM0.4 billion, 12.5 per cent);
    iii. Australia (RM0.2 billion, 7.1 per cent);
    iv. Brunei (RM0.2 billion, 7.1 per cent); and
    v. China (RM0.1 billion, 4.4 per cent).

27. In 2022, main exported products of the pharmaceutical industry were:
    i. medicaments in measured dosage forms (RM0.7 billion, 24.8 per cent);
    ii. insulin in measured dosage forms (RM0.4 billion, 14.3 per cent);
    iii. placebos and blinded or double-blinded clinical trial kits (RM0.4 billion, 14.3 per cent);
    iv. glycosides (RM0.3 billion, 10.7 per cent); and
    v. dressings and other articles with adhesive layers (RM0.3 billion, 10.7 per cent).

[4] *Pharmaceutical products intersect with chemicals and chemical products as well as palm oil-based manufactured products*

Imports

28. The import performance of the pharmaceutical industry for the period of 2006 to 2022 is recorded in Table 4.4 below.

Table 4.4: Imports of Pharmaceutical Industry

Item	IMP3			2021	2022	2006-2020	2020-2021	2021-2022
	2006	2020	2006-2020			CAGR	Annual Growth	
Imports[5] (RM billion)	2.7	8.2	77.0	12.1	10.6	8.2%	48.0%	-13.0%

Source: MATRADE

29. During the IMP3 period, the industry's imports grew by a CAGR of 8.2 per cent from RM2.7 billion (2006) to RM8.2 billion (2020).

30. Compared to 2020, imports grew by 48.0 per cent to RM12.1 billion in 2021. Subsequently, imports normalised to RM10.6 billion in 2022.

31. The import trends were attributed to growth of the Malaysia's healthcare expenditure, especially during the COVID-19 pandemic which led to higher demand for pharmaceutical products such as vaccines.

32. In 2022, Malaysia pharmaceutical industry's products were mainly imported from:
    i. Germany (RM1.6 billion, 15.0 per cent);
    ii. China (RM1.1 billion, 10.4 per cent);
    iii. US (RM0.9 billion, 8.2 per cent);
    iv. France (RM0.8 billion, 7.1 per cent); and
    v. Switzerland (RM0.7 billion, 6.2 per cent).

33. In 2022, main imported products of the pharmaceutical industry were:
    i. medicaments in measured dosage forms (RM5.0 billion, 46.9 per cent);
    ii. placebos and blinded or double-blinded clinical trial kits (RM1.1 billion, 10.2 per cent);
    iii. vaccines for human use (RM1.0 billion, 9.4 per cent);
    iv. immunological products (RM0.5 billion, 4.5 per cent); and
    v. hormones or contraceptives (RM0.3 billion, 2.8 per cent).

[5] *Pharmaceutical products intersect with chemicals and chemical products as well as palm oil-based manufactured products*

Value-added

34. The value-added (GDP) of the pharmaceutical industry for the period of 2006 to 2022 is recorded in Table 4.5 below.

Table 4.5: Value-added of Pharmaceutical Industry

Item	IMP3		2021	2022	2006-2020	2020-2021	2021-2022
	2006	2020			CAGR	Annual Growth	
Value-added[6] (RM billion)	3.4	2.4	3.0	3.4	-2.3%	22.0%	14.8%

Source: Department of Statistics Malaysia (DOSM)

35. During the IMP3 period, the industry's GDP contribution decreased by a CAGR of 2.3 per cent from RM3.4 billion (2006) to RM2.4 billion (2020).

36. In 2021 and 2022, the industry's GDP contribution grew by 22.0 per cent and 14.8 per cent to RM3.0 billion and RM3.4 billion respectively.

37. The GDP contribution of the industry was relatively constant as the industry's production was concentrated on generics manufacturing.

Employment

38. The employment in the pharmaceutical industry for the period of 2019 to 2022 is recorded in Table 4.6 below.

Table 4.6: Employment in Pharmaceutical Industry

Item	IMP3		2021	2022	2019-2022
	2019	2020			CAGR
Employment[7] (persons)	23,320	23,344	25,095	27,325	8.6%

Source: DOSM

39. Industry employment grew by a CAGR of 8.6 per cent from 21,320 persons (2019) to 27,325 persons (2022).

40. The growth trend was attributed to the industry's expansion post COVID-19 pandemic.

[6] Value-added is measured by the GDP of the industry; 2006 GDP data is based on constant 2005 prices, while 2020 to 2022 data are based on constant 2015 prices
[7] This employment data is based on Monthly Manufacturing Statistics December 2022. Due to the change in methodology for employment statistics tabulation in 2019, industry's employment breakdown from 2006 to 2018 is not available

Labour Productivity

41. The labour productivity of the pharmaceutical industry for the period of 2019 to 2022 is recorded as follows (Table 4.7).

Table 4.7: Labour Productivity of Pharmaceutical Industry

Item	IMP3		2021	2022	2019-2022
	2019	2020			CAGR
Labour Productivity[8] (RM)	83,398	104,267	118,317	124,675	14.3%

Source: DOSM

42. The industry's labour productivity grew by a CAGR of 14.3 per cent from RM83,398 (2019) to RM124,675 (2022).

43. The labour productivity growth was attributed to the increased demand for pharmaceutical products such as vaccine and medication during the pandemic.

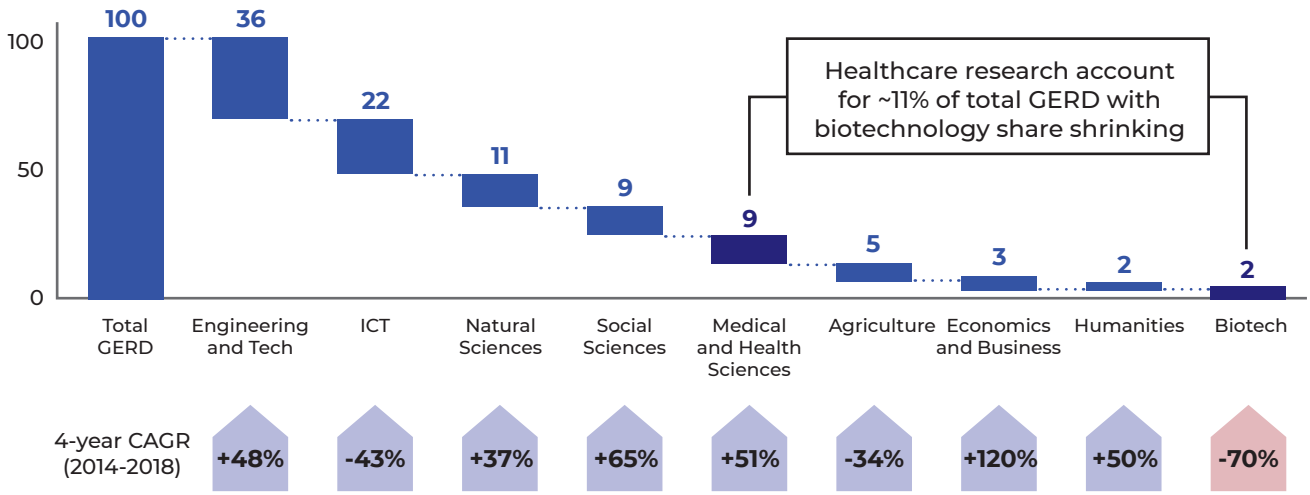
Research and Development

44. Research and Development (R&D) is an important catalyst for local drug innovation. In Malaysia, private and public funding for R&D remains limited as evidenced by the low gross domestic expenditure on R&D (GERD) in this area.

45. From 2014 to 2018, the GERD spending for healthcare research (i.e. medical and health sciences and biotechnology) accounted for 11.0 per cent of total GERD in Malaysia (Figure 4.3).

46. Biotechnology spending which is crucial for new drug development declined by about 70.0 per cent between 2014 and 2018.

Figure 4.3: Breakdown of GERD by field of Research in Malaysia (2014-2018)



Source: Malaysian Science and Technology Information Centre (MASTIC), PhAMA

[8] *Annual labour productivity is derived from value added per employment*

SECTION 3 TRENDS AND OPPORTUNITIES

47. Malaysia's pharmaceutical industry is expected to grow by 5.4 per cent reaching RM9.6 billion[9] by 2027.[10]

48. The pharmaceutical industry is expected to experience significant changes in consumer behaviour. More healthcare treatments are in demand due to several factors including:
    i. ageing population;
    ii. increasing disposable income leading to change in lifestyle and unhealthy eating habits;
    iii. lack of exercises leading to rising of chronic diseases; and
    iv. proactive behaviour that favours prevention than cure.

49. Several opportunities have been identified for Malaysia to leverage and capitalise on the growth potential.

50. These opportunities include clinical research hub, generics hub, biologics and active pharmaceutical ingredient (API) manufacturing of high demand niche botanicals.

Clinical Research Hub

51. Malaysia has the potential to become a clinical research hub for early-stage trials due to its diverse genetic pool – easier for research on rare diseases.

52. Malaysia has a Phase One clinical trial site in Sarawak General Hospital that offers state-of-the-art infrastructure and local talent.

53. Malaysia can serve as a gateway for patient recruitment in ASEAN due to its diverse genetic pool, strong digital infrastructure and strong trade relationships with neighbouring countries.

54. Developing Malaysia's early-stage clinical research can increase access to drugs for non-communicable diseases (NCD) and improve treatment inclusivity for local communities.

55. The development of clinical research in Malaysia contributes to further development of skilled talents, which would attract more research projects to be funded by MNC in Malaysia.

56. Refer to Action Plan 8 (AP8) in Section 5 for specific pharmaceutical industry action plan on clinic research hub.

Generics Hub

57. The Malaysian generics industry has grown significantly over the past decade, reaching 10.0 per cent growth of total local drug sales between 2010 and 2021.

58. This growth is attributed to the presence of established industry players in Malaysia and was further aided by Malaysia's adherence to international manufacturing standards including:
    i. PIC/S; and
    ii. Good Manufacturing Practice (GMP) and Current Good Manufacturing Practice (cGMP) certifications.

[9] USD2.1 billion, converted based on exchange rate USD1 to RM4.48
[10] Source: Statista

59. Moving forward, the focus for the industry is to increase exports and maintain its position as a first mover in generics.

60. As the industry expands, there is a greater need to comply with stricter international standards and produce higher value-added and premium generic products – benefitting local economy by expanding supply chains and domestic linkages.
    i. This growth is expected to benefit the local economy by expanding supply chains and domestic linkages, while increasing the affordability and accessibility of medicines to the public.
    ii. Local production helps to reduce the national pharmaceutical trade deficit and enhance self-sufficiency in the face of potential pandemics or trade disputes.
    iii. It is crucial to create consistent demand to support the industry players to grow. This can be achieved by several approaches such as the facilitation of cross-border trades through mutual recognition agreements (MRA) between targeted countries.
    iv. Other efforts such as improving access to export financing and streamlining regulatory needs between countries help to reduce non-tariff barriers and facilitate cross-border trades.

61. Refer to Action Plan 5 (AP5) in Section 5 for strategies and action plans related to improving exports of Malaysia's products globally.

Biologics

62. Before the pandemic, Malaysia imported most of its biologics, such as vaccines from other countries. However, the pandemic has disrupted global supply chains, making it difficult to obtain biologic products.

63. There is a need for Malaysia to develop its own biologics manufacturing capabilities due to global shortage of biologic products. However, entry into the market is challenging due to high spending on R&D and huge capital requirements as well as availability of niche technical expertise required.

64. To overcome these barriers, leveraging existing manufacturing capabilities will help to accelerate capability building and minimise investment risks. These include manufacturing of biosimilars or contract manufacturing opportunities.
    i. Investing in the bio-based industry can accelerate development of knowledge-intensive talent and supply chain relationships with MNC, contributing to stronger supply chain linkages.
    ii. With increased local production, affordability of life-saving treatments can be enhanced and drive local industry self-sufficiency, in line with the National Vaccine Development Roadmap.

65. It is important to improve existing pharmaceutical related education structure to tackle the challenge of limited industrial pharmacists, which is highly demanded to support R&D of biologics.

66. Refer to Action Plan 3 (AP3) in Section 5 for strategies and action plans related to developing local capabilities to support product innovation and commercialisation.

API manufacturing of High Demand Niche Botanical

67. Malaysia's rich biodiversity particularly in its rainforests, provides a foundation for developmental research in natural medicines.

68. Malaysia has access to a diverse range of medicinal flora with over 15,000 species of vascular plants, allowing for cost-effective extraction and manufacturing.

69. The Government provides strong support through incentives and dedicated policy roadmaps to foster an ecosystem for innovation and growth.

70. Driving investments in the botanical market can create jobs and enhance research capabilities. Therefore, it is imperative for Malaysia to scale up operations by focusing on extraction activities up until production of niche botanical material. This will help to develop traditional medicine products that are being recognized globally such as Ayurvedic in India and Traditional Chinese Medicine in China.

71. Apart from targeting APIs from niche botanicals, Malaysia could attract investment into premium APIs which are chemically-synthesised in particular to treat NCDs such as cardiac, diabetes, oncology and nervous system.

72. Strategic investments are needed to address the import-heavy supply chain risks, focusing on specific APIs or excipients.
    i. However, Malaysia has the potential to focus on premium types of APIs such as those used for NCD medicines and avoid scale or commoditised businesses, in which price competition is high, such as generic API manufacturing where other countries are strong in.
    ii. This allows investments to be inherently more commercially viable and boosts Malaysia's generics market positioning.

73. Refer to:
    i. Action Plan 2 (AP2) in Section 5 for strategies and action plans related to developing local capabilities for API manufacturing; and
    ii. Action Plan 7 (AP7) in Section 5 for strategies and action plan related to improving financing support to explore new areas.

SECTION 4 CHALLENGES

Funding, Procurement and Supply Chain Mechanisms

74. Limited funding for manufacturing activities of higher value-added products has been a challenge in Malaysia. This has become an obstacle for Malaysia to go beyond OTC, limiting its capacity to produce drugs for emerging areas such as NCD.

75. Difficulties in procurement mechanisms and supply chain networks have led to shortages and compromised quality of medicines. The absence of holistic planning in talent development and technology adoption has impeded the industry's progress.

76. Addressing these challenges requires a concerted effort from the Government, private sector players and other stakeholders.

77. Efforts are required to prioritise investments, improve procurement and supply chain mechanisms, and develop strategies for talent development, funding initiatives and adoption of technology.

78. Refer to Action Plan 1 (AP1) in Section 5 for strategies and action plans related to attracting investment for high value-added activities.

Data and Information Sharing

79. The sharing of information mechanisms and facilities is crucial in many industries, including the pharmaceutical sector. Absence of this can lead to duplication of efforts, inefficiencies and missed opportunities for collaboration and innovation.

80. Limitations in electronic medical records (EMR) further compound this problem, as stakeholders involved in clinical research may not have access to updated and comprehensive information about the patients and diseases.

81. This can affect ability to make informed decisions, develop effective strategies and identify emerging trends and opportunities.

82. To address these challenges, it is essential to expand the availability of EMR and to foster a culture of collaboration and knowledge-sharing through a centralised, secured platform or database.
    i. A centralised platform among public hospitals and private research institutes is crucial to monitor supply, distribution and utilisation of data.
    ii. The database needs to be complemented by robust data security policies and protocols to ensure confidentiality of data.
        a. All activities related to patients' data will need to comply with the Personal Data Protection Act 2010 (PDPA).
        b. Any sharing of data must be based on clear policies and protocols agreed by MOH with proper consent and existing Memorandum of Understanding between relevant agencies.
        c. Data and information sharing in clinical research shall comply with guidelines and regulations as stated in the National Institutes of Health (NIH) Guidelines for Conducting Research in MOH Institutions and Facilities, Medical Research and Ethics Committee (MREC), MOH and relevant regulatory bodies.
    iii. By working together and sharing information, stakeholders can overcome these limitations in clinical research and create a more efficient, innovative and sustainable pharmaceutical industry.

83. Refer to Action Plan 6 (AP6) in Section 5 for strategies and action plans related to improving information sharing mechanism within the pharmaceutical ecosystem.

Evergreening

84. The absence of appropriate governance for patents is a significant challenge faced by the pharmaceutical industry, as it can result in unaffordable, ineffective and unsafe medicines.

85. In Malaysia, the Patent Act does not exclude second medical use patent for pharmaceutical products. This can lead to monopolies and high prices for essential medicines.
    i. Some companies may patent a new formulation with slight modifications of existing drugs. This allows the companies to extend its monopoly on the products and prevent generic competition.
    ii. This can be particularly problematic in countries where access to essential medicines is often limited.
    iii. The absence of a mechanism to ensure ethical and professional conduct in the pharmaceutical industry can lead to issues such as corruption, conflicts of interest and the promotion of ineffective or unnecessary treatments.

86. To address these challenges, it is essential for the Government and regulatory bodies to establish appropriate governance frameworks that prioritises affordable, effective and safe medicines.

87. This can involve the development of systems for monitoring patent status which would promote competition, as well as the establishment of codes of conduct and ethical guidelines for industry stakeholders.

88. By prioritising governance and accountability, the pharmaceutical industry can ensure that it operates responsibly and sustainably that patients have access to the medicines they need at prices they can afford.

89. Refer to Action Plan 4 (AP4) in Section 5 for strategies and action plans related to regulating the quality and ethical professional business practices.

SECTION 5 STRATEGIES AND ACTION PLANS

NIMP 2030 Focus

90. During the period of the NIMP 2030, the industry will:

i. strengthen data security policy for sharing information within the pharmaceutical ecosystem;

ii. develop local capabilities in the pharmaceutical industry for innovation and commercialisation;

iii. support clinical research and trials to improve local manufacturing and explore new treatments;

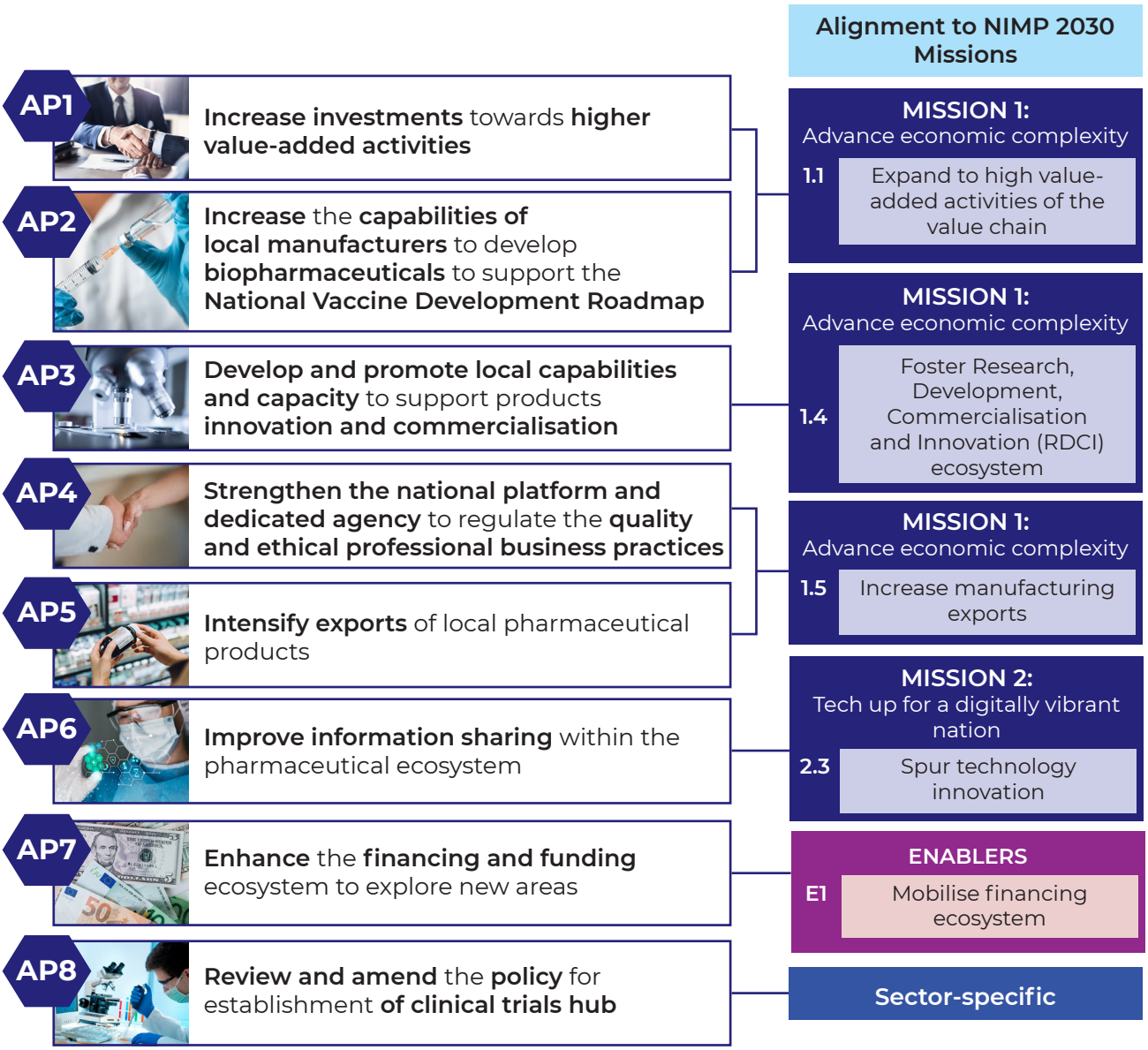
iv. increase visibility of local pharmaceutical products for exports and new markets; and

v. facilitate investment by expanding the pharmaceutical industry.

Action Plans

91. Strategies and Action Plans relating to the NIMP 2030's Missions and Enablers are applicable to this industry (Figure 4.4).

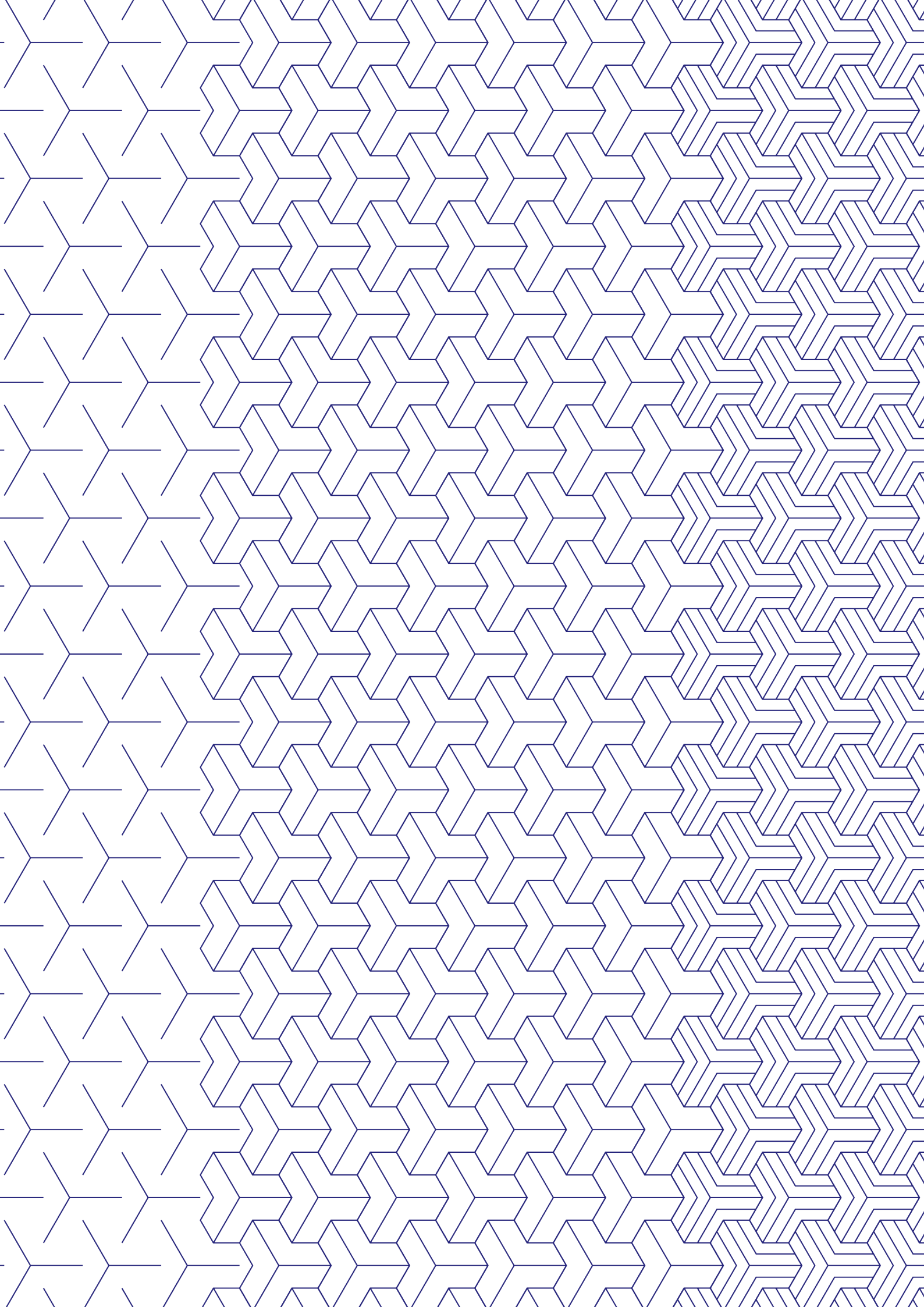
Figure 4.4: Strategies and Action Plans for Pharmaceutical Industry



APPENDIX 1 INCENTIVES

There is an array of incentives offered for key players of pharmaceutical industry, these include the following:

Incentives	Agency
Incentives for General Investment	Malaysian Investment Development Authority (MIDA)
Incentives for High Technology Projects	
Incentives for Strategic Projects	
Special Tax Incentive (Relocation)	
Incentives for Small Scale Companies	
Commercialisation of Public Sector R&D Findings in Resource-based and Non-Resource-based Industries	
Incentive for Research and Development (R&D): • **In-House R&D** • **Contract R&D Company** • **R&D Company**	
Incentive for Automation Capital Allowance (Automation CA)	
Import Duty and/or Sales Tax Exemption on Machinery/ Equipment/ Raw Materials/ Components	
Reinvestment Allowance	Inland Revenue Board of Malaysia (LHDN)



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