

# Malaysia

Government investment will support future growth of the Malaysian pharmaceutical and healthcare industry

## Risk and reward index

**44.4**  
Industry Rewards

**80.9**  
Industry Risk

**8**  
Regional Rank

**41**  
Global Rank

Note: Scores out of 100; higher score = lower risk. Source: Fitch Solutions' Innovative Pharmaceuticals Risk/Reward Index

## Key foreign players

- 1 AstraZeneca
- 2 GlaxoSmithKline
- 3 Merck & Co
- 4 Novartis
- 5 Pfizer
- 6 Sanofi
- 7 Takeda

## Strengths



**Progressive government policy** aimed at attracting international investment



Improving **local manufacturing standards**



Commitment to **biotech development**



Sizeable and **growing generic drugs market**



Manufacture of **halal medicines** improving access to other global Islamic markets



New regulations for **halal drug market**

## Challenges



**Low per capita pharmaceutical expenditure** and **foreign direct investment**



**Lax patent law** remains conspicuously below international standards



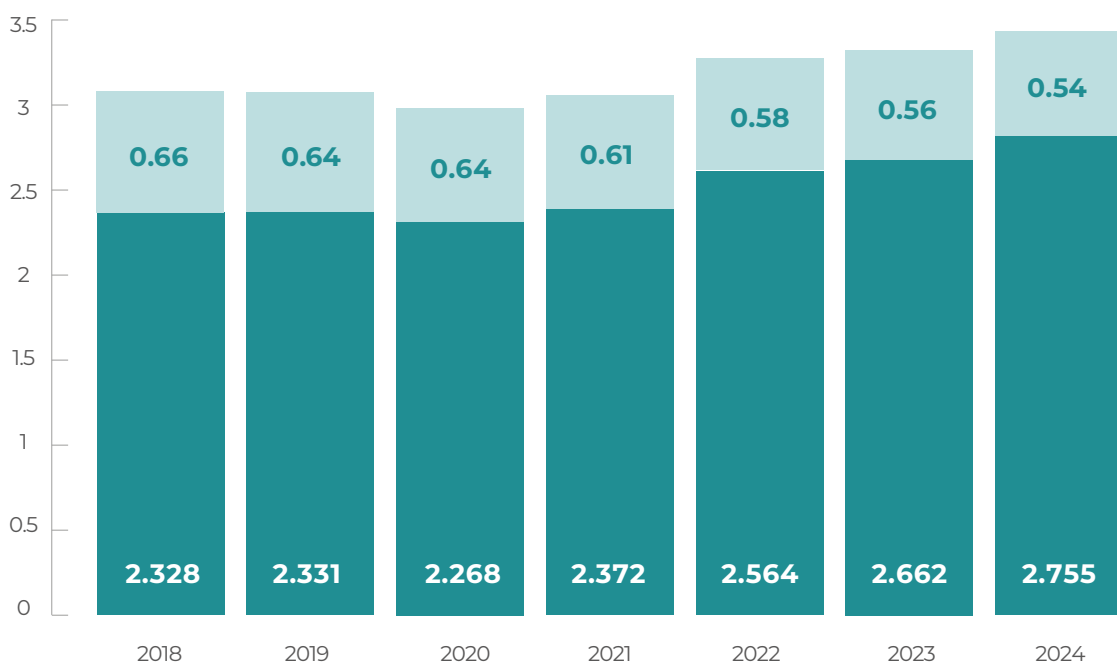
Strict government **drug pricing policy** heavily **biased towards local drug producers**



**Market reliant on imports**, particularly at the hi-tech end of the scale, placing pressure on government finances

## Forecast

■ Pharmaceutical sales, USDbn ■ Pharmaceutical sales, % of GDP



Source: Malaysia Pharmaceuticals & Healthcare Key View, May 2020 Review, Fitch Solutions  
Source: Malaysia, Pharmaceuticals & Healthcare Report Q2 2020, Fitch Solutions

## Regulations

The **Drug Control Agency (DCA)**, under **Malaysia's Ministry of Health (MOH)**, oversees **drug registration**.

In Malaysia, many **high-end drug products** are imported. **Robust government spending** on healthcare and attractive government **tax incentives** for foreign drug companies operating in the country lead to **increased growth and opportunities** for prospective foreign pharmaceutical companies.

Applications can be submitted to the DCA online via the **Quest 2 system**. There are four categories of pharmaceuticals in Malaysia: **biologics, new drug products, over the counter (OTC) generics** and **generics**. Although certain types of OTC products are eligible for an abridged evaluation, all other pharmaceutical products must undergo an **entire evaluation** via the **DCA prior to approval**. The estimated **timeline** for abridged evaluations is around **180 days**; full evaluations can extend up to a year or more. **Registrations are valid for 5 years** and can be renewed.