



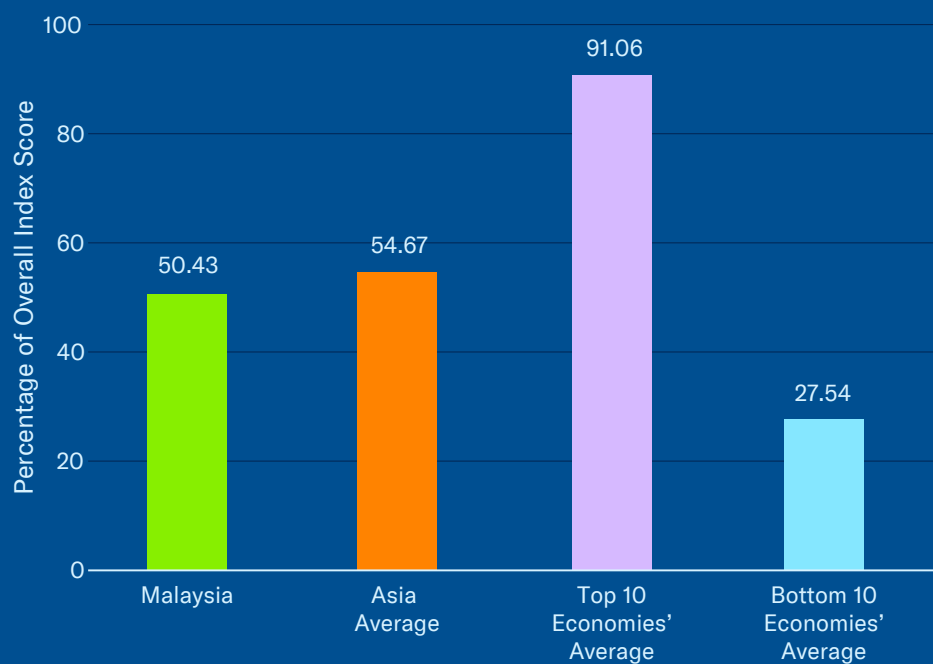
Malaysia

Rank
28/55

Category Scores



Overall Score in Comparison





Malaysia

Rank
28/55

Key Areas of Strength

- Strong enforcement efforts against infringing set-top boxes continued through Malaysian Communications and the Multimedia Commission and Ministry of Domestic Trade and Consumer Affairs
- 2022 amendments to the Patent Act provide for a defined pathway of postgrant opposition proceedings
- 2020 Trademark Act amendments strengthen the enforcement environment
- Generous R&D and IP-specific tax incentives are in place
- The Intellectual Property Corporation of Malaysia has PPH agreements in place with both EPO and JPO
- Strong focus by the Malaysian government on IP as a commercial asset and technology transfer

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- A government use license (the equivalent of a compulsory license) was issued in 2017 for sofosbuvir, a breakthrough medicine to treat hepatitis C
- *De facto* RDP full term of protection is not offered to new products
- Patent term restoration is not offered

Percentage of Overall Score: 50.43% • Total Score: 26.73

Spotlight on the National IP Environment

Past Editions versus Current Score

Malaysia's overall Index score has increased from 26.72 out of 50 indicators in the twelfth edition to 26.73 out of 53 indicators. This reflects a score increase for indicator 32.

Copyrights and Limitations; and Enforcement

14. Scope of limitations and exceptions to copyrights and related rights:

Like many other Index economies, the use of machine learning and AI-based technologies and applications is increasing in Malaysia. Over the past few years, the Malaysian Government has responded with several new initiatives aimed at establishing an appropriate legal and policy environment for the use and application of these technologies. This includes, for example, the Ministry of Science, Technology and Innovation's *Malaysia National Artificial Intelligence Roadmap 2021–2025*. This roadmap sets out the overarching policy objectives of developing and harnessing the power of AI and machine learning technologies to help boost Malaysia's economic development, innovation capacity, and international competitiveness. These efforts continued in 2024 with the government announcing that a designated "National AI Office" would be established together with a code of ethics and governance. At the time of research, no draft policy had been published or made available to the public. As noted in the Index, AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, concerns exist about how the development, application, and use of these technologies will affect creators and rightsholders across the world.

Given the existing dynamics of the Internet and the volume of infringing content available online—much of it made available without rightsholders' permission or even their knowledge—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in Malaysia and around the world. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in the Asia-Pacific region. In 2017, the Asia-Pacific Economic Cooperation (APEC) forum (of which Malaysia is a member) announced a new initiative geared specifically toward rare diseases, the "APEC Action Plan on Rare Diseases." The plan's primary aim is to "address barriers to the diagnosis and treatment of rare diseases in the region."

The plan consists of 30 individual targets across 10 pillars, including the promotion of innovative R&D through financial incentives, expedited market review procedures, and support for domestic R&D.

In Malaysia, too, policymakers and the government are increasingly focused on addressing rare diseases and improving patient access to care and treatments. Since 2012, the Malaysia *National Medicines Policy* has included reference to orphan drugs stating, “There shall be appropriate procedures to enhance accessibility of life-saving products and orphan medicines without compromising safety, quality and efficacy.” More recently, in 2021, the Ministry of Health issued an *Orphan Medicines Guideline* that reaffirms the Ministry’s commitment to rare diseases within its national health policy and includes policies on the registration and designation of orphan medicines. The guideline also included a national list of rare diseases recognized by the Ministry with an updated list published in 2023. However, Malaysia does not offer any special IP-based market exclusivity incentives for orphan medicinal product development.