

Takeda's Position on Intellectual Property for Access to Medicines

Key message

It is Takeda's vision to serve the needs of our patients wherever they are. That is why we are committed to providing the broadest possible access to our innovative medicines and vaccines through our Access to Medicines strategy. We believe that Intellectual Property should not be considered a barrier to patients gaining access to medicines.

This position is aimed at expanding patient access to innovative medicines and vaccines globally. It consists of the following:

In least developed countries (LDCs)¹ and low-income countries (LICs)², covering Takeda products already on the market as well as our future products, we will:

1. Either not file patents, nor enforce them.
2. Where necessary, support voluntary licenses and non-assertion declarations or clauses to improve patient access to medicines.
3. Offer under appropriate terms, licenses to manufacturers that can provide patients with low-cost access to our medicines, on a selective basis.
4. Make our patent information available, upon request, to the public.

Additionally, Takeda acknowledges the transition period that LDCs are exempted from obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) regarding pharmaceutical patents until January 1, 2033.

Background

Our mission is striving towards better health and a brighter future for people worldwide through leading innovation in medicines and vaccines. Takeda is committed to addressing unmet medical needs through continuous innovation, and to helping to ensure patients with access to high-quality healthcare.

An intellectual property (IP) system that encourages the creation of new technologies by allowing a defined period of exclusivity in return for the disclosure of the latest inventions to the public is critical to all industries striving for

innovation. This creates an ecosystem that encourages further efforts and investments in future medicines and vaccines while ensuring the diffusion of innovation that benefits society as a whole. This ecosystem is critical for medicines and vaccines due to the extremely challenging and costly nature of drug discovery and clinical development, which takes, on average, more than 10 years of dedicated effort and investment.

Innovation in medicines and vaccines has always driven the fulfillment of unmet medical needs, increases in life expectancy, and improvements in quality of life for patients. It has significantly reduced health and economic burden by preventing illness, premature disability and death due to infectious and chronic diseases. Without the encouragement provided by an effective IP system, the world would not have many of the remarkable, life-saving medicines and vaccines that it has today.

Even though the majority of medicines and vaccines on the WHO's essential medicine list are off-patent, there are many other barriers to access such as regulatory and supply chain challenges, and a relative lack of financing within some healthcare systems. These factors seriously limit patient access even to generic medicines and vaccines. Ensuring patients get access to medicines in these countries is a shared responsibility among governments, civil society and the private sector and each can contribute in their own way.

Takeda is committed to contributing through our comprehensive Access to Medicines strategy to strengthen global health systems, which covers programs such as capacity building, patient assistance, corporate social responsibility as well as our approach to IP.

(Learn more about our Access to Medicines Strategy [here](#))

Takeda's position

In line with our corporate mission, Takeda's approach to IP aims to accelerate patient access to medicines while fostering the development of new, potentially life-saving medicines and vaccines over the long-term.

It is Takeda's vision to serve the needs of our patients wherever they are. That is why we are committed to providing the broadest possible access to our innovative medicines and vaccines through our [Access to Medicine strategy](#). We believe that IP should not be considered a barrier to access to medicines as this access is often hindered by other barriers (listed above).

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Additionally, Takeda acknowledges the transition period that LDCs are exempted from obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) regarding pharmaceutical patents until January 1, 2033. This will not affect our position on not filing or not enforcing patents in LDCs and LICs.

Takeda aims to improve access to medicines for patients where it is most needed. LDCs and LICs are the world's most impoverished and economically vulnerable countries. Lack of healthcare resources, including medicines and vaccines, remains a key challenge and affects the lives of millions of people in these countries.

Our position on patenting and licensing provides opportunities for qualified generic companies to manufacture and deliver our innovative medicines and vaccines. This is an important component of our Access to Medicines Strategy and provides a foundation for our ongoing efforts to deliver innovative medicines and vaccines to patients in these countries.

As to Compulsory Licensing:

We are committed to delivering our innovative medicines to patients worldwide through our day-to-day dedicated efforts and our comprehensive Access to Medicines strategy. Despite such efforts, we acknowledge that there may be circumstances in which patients have emergent and serious difficulties in accessing life-saving medicines. In such cases, we do not rule out that a compulsory license could be a realistic option. We also recognize that the TRIPS Agreement 31bis allows the export of products under compulsory license to countries where there is limited or no existing pharmaceutical manufacturing capacity.

However, we do not believe that compulsory license provides a sustainable solution, but rather a short-term measure that does not address the root causes of the challenges patients face in accessing medicines. We believe and understand that this is a part of the reason why neither the TRIPS Agreement, nor the Doha Declaration permit unlimited use of compulsory licenses. Excessive use of compulsory licenses will hinder patient access to innovative medicines as it weakens the IP system, which plays a key role in the creation of an ecosystem for the sustainable Research & Development of those innovative medicines and vaccines.

Closing

IP protection creates an ecosystem for continuous innovation and the diffusion of innovative technologies across the globe. However, there are serious barriers to access to medicines in LDCs and LICs for complex, multifaceted reasons which can only be addressed through public-private cooperation and long-term commitment. Takeda's mission is to strive towards better health for people worldwide through leading innovation in medicines and vaccines. Takeda believes our Access to Medicines strategy and our IP initiatives will bring us one step closer to improving peoples' lives worldwide.

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This position will be reviewed on an annual basis.

¹ Least Developed Countries defined by the United Nations (as of December 2018)

https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf

² Low Income Countries defined by the World Bank (FY 2020)

<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>