

Takeda's Position on Access to Medicines

Key messages

Takeda believes access to healthcare, medicines and vaccines is a priority for people globally. As part of our Access to Medicines strategy, we are committed to addressing the unmet needs of patients wherever they may be, and sustainably strengthening local health systems at every stage of the patient journey. We complement this approach with a commitment towards developing an end-to-end access approach to make our highly-innovative medicines available as soon as practically possible.

Background

The past decade has seen major public health gains and scientific breakthroughs, yet more than two billion people today cannot access the healthcare they need when facing serious, complex and rare diseases. The communities most severely impacted are resource-poor countries with a higher need to strengthen their healthcare systems. This is the frontier in access to medicines that cannot be addressed alone and needs collective action with deep collaboration and lasting commitments between partners across the public and private sector.

Takeda's position

Access to Medicines is deeply embedded within Takeda's vision to serve patients wherever they are, focused on long-term commitments and supported across our organization. We have created a practical framework to increase sustainable access to our medicines through our innovative affordability programs and initiatives that build sustainable capacity across the patient journey, while collaborating with policy makers and experts from NGOs, patient organizations, and governments. Across our programs we have controls in place to mitigate the risk of non-compliance in our operations, including internal controls, risk-based country audits, and formal processes applying to third parties.

Takeda is committed to sustainably strengthen local health systems in low- and middle-income countries at every stage of the patient journey

We have established an implementation model that is fully locally integrated to improve the lives of patients by strengthening the entire healthcare system for NCDs. We aim for earlier diagnosis and local access to consistent high-quality medicines through our innovative affordability programs, while enhancing local standards of care. Our flagship Access to Medicines initiative is the Blueprint for Innovative Healthcare Access in lower middle-income countries (LMICs). It is designed to be sustainable by building a local consortium of expert partners, including governments, who drive implementation. It addresses healthcare access barriers

through sharing resources, expertise and responsibilities, with strong governance, leadership and coordination. This strong local focus strengthens in-country capacities, resulting in sustainably enhanced local health systems. We measure our impact on the lives of patients in a consistent, transparent and independent way to evaluate and hold ourselves and our partners accountable.

Takeda is developing an end-to-end access approach to make our highly-innovative medicines available as soon as practically possible

Takeda's end-to-end access commitments include:

- Embed access principles and plans from early clinical development onwards – with input from stakeholders and patients in resource-poor countries to consider local needs, where appropriate
- Conduct multi-country clinical research – including participants from LMICs in clinical trials for our innovative medicines and novel vaccine candidates, where we intend to register and where appropriate
- Support patient access with Early Access Programs¹, where appropriate and regulatory bodies allow
- Endeavor to implement a global filing strategy for countries in parallel to first major reference country approval to allow faster access in LMICs; focusing on countries with direct or indirect Takeda presence, with high patient need and suitable health system infrastructures
- Follow pro-access IP arrangements in least developed and low-income countries, where we will not file nor enforce patents for Takeda's marketed or future products. Where possible, we support voluntary licenses and offer, under appropriate terms, licenses for low-cost access to our medicines on a selective basis. Learn more about our IP position for access to medicine [here](#).
- We address affordability challenges:
 - Tiered pricing – adjust pricing to a country's socio-economic status and health system maturity
 - Value-based agreements – respond to payer's and provider's needs to manage uncertainty around the real-world outcome and economic impact of our innovative medicines
 - Patient Assistance Programs – increase access, while addressing affordability hurdles. These innovative and collaborative financing models are tailored to a patient and to a country's socio-economic context and local legal health frameworks. It builds on collaborative models between patients, Takeda, at times local authorities, and other parties to share treatment costs.
- Takeda takes a global approach to demand and supply planning for all products to ensure uninterrupted, sufficient, and timely supply. Due to resource constraints in LMICs, we increase our support between global, regional, local functions and local distributors to improve alignment of demand and supply.

Closing

We believe that our strengthened commitment to Access to Medicines will broaden access to our highly-innovative medicines for complex and rare diseases in a sustainable way where the patient need is highest.

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¹ Including post-trial access, named patient programs and individual patient requests