

Access to Medicines

Progress Report 2018



Better Health, Brighter Future

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Strategic Partnerships



Shaping Public Policy & Patient Advocacy



Innovative Access



Capacity Building

A Message from our CEO



Welcome to Takeda's inaugural Access to Medicines Progress Report. Aligned with our Values and Vision 2025, it has been a priority to expand access to quality care whilst broadening and deepening our commitment to strengthen evolving health systems. To have a real and lasting impact on the lives of patients we serve, we are committed to establish a deeper understanding of the specific needs and challenges of these underserved communities, wherever that may be.

Since launching Takeda's Access to Medicines strategy in 2016, we have learned an enormous amount about how we can be more effective and deliver greater impact to patients in need. Integral to this has been an approach centered on collaboration across sectors and industries. We believe strategic partnerships with governments at both central and local levels, with academic institutions and charities, and with other companies

across our industry are critical to ensure alignment, efficiency and cohesion in addressing patient access barriers. We were delighted to see our progress recognized in the 2018 Access to Medicine Index, with Takeda ranking 5th globally among the leading pharmaceutical companies, rising ten places from 2016. This validation of our efforts has served only to spur our people to even greater aspirations for the future.

While there is clearly still much more to do, we know from our experience to date that we must continue to ensure our programs are both entrepreneurial and accountable. We must address not only the needs of our patients but also the health system gaps that are critical to securing positive and sustainable impact.

As you read the report, I hope you will be encouraged by our progress, engaged by our impact and approach, and optimistic about the prospects for a world with better access to healthcare.

Christophe Weber
President and Chief Executive Officer, Takeda

At a Glance

This Progress Report covers the period from 2016 to 2018.



In 2016

Takeda launched our new global Access to Medicines strategy, focusing on geographies and therapeutic areas with the highest unmet medical need



Over 1.1m patients

have been screened for cancer, hypertension and diabetes



Supported more than 125,000 patients

to receive treatment



Over 4,000 HCPs and CHWs*

have been trained across our therapeutic areas



41 registration filings and 115 approvals

in total have helped accelerate the registration of our medicines



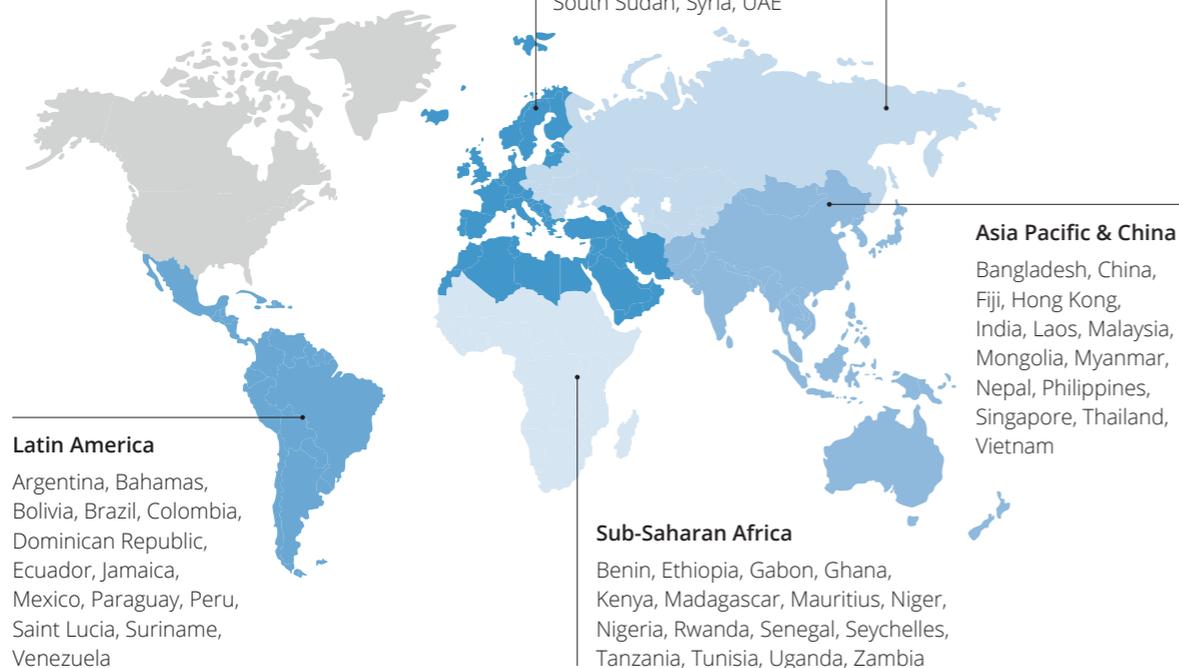
#5

In 2018, Takeda climbed 10 places in the Access to Medicine Index to rank #5 among the leading pharmaceutical companies and was proud to be the Index's biggest 'upward mover'

* Healthcare Providers (HCPs) and Community Health Workers (CHWs).

52

countries and territories with Access to Medicines programs in place



“

The vision we had in 2016 when launching our global Access to Medicines strategy remains: that any patient eligible to receive our most innovative and potentially life-saving medicines should be able to get access, particularly in specialized disease areas where alternative treatment options do not exist. I am proud to see the significant progress our teams and many partners have made since launch.”



Giles Platford,
President, Europe & Canada Business Unit, Takeda

Our Mission

Understanding that access to medicines is a multi-layered challenge, Takeda's strategy is designed to achieve the greatest possible impact, for a high number of patients, aiming for a sustainable approach. Together with strategic partners across multiple sectors, we use our global network and experience to tackle the barriers and gaps in ability and resources that currently prevent patients in underserved communities from accessing the care and treatment they need, not just medicines themselves.

Through key pillars – strategic partnerships, shaping public policy, innovative access and capacity building – we partner with non-governmental organizations, private enterprises and governments in underserved countries to address unmet medical needs throughout the patient journey, from greater awareness and diagnosis to better treatment and support.

Since the launch of our Access to Medicines strategy in 2016, we have made significant progress in improving access to care and treatment, but there is much still to do. We will continue to build on these foundations, expanding our programs to additional disease areas, more patients and a greater number of countries, to provide better health and a brighter future for all. Many thanks to all Takeda colleagues and partners for their commitment and support of our Access to Medicines activities.



Weissbaecker

Dr Susanne Weissbaecker
Global Head, Access to Medicines, Takeda

Our Strategy

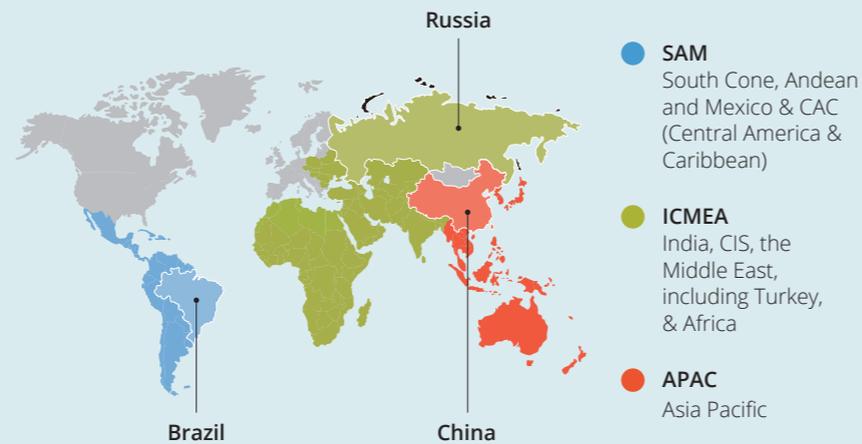
Takeda's Access to Medicines strategy aims to tackle the many barriers that prevent patients from accessing the care and treatment they need, wherever they may live and whatever their circumstances. We approach this challenge by looking at improving the patient journey holistically, and how we can support the strengthening of health systems across the regions and areas in which we operate.

Understanding that access is a multi-dimensional challenge, our Access to Medicines strategy aims to improve the availability and affordability of our innovative specialty care medicines and vaccine candidates, but critically, this is always supported and enabled by building local capacity and enhancing patient support, underpinned by a strategic partnerships approach.

1 Strengthening health systems



2 in underserved communities around the world with a focus on Growth & Emerging Markets*



*The countries and regions reflect Takeda's newly defined Growth & Emerging Markets Business Unit

3 across our chosen therapeutic areas of focus*

* Access to Medicines activities also include strategic initiatives related to Hypertension and Diabetes, as well as for Infectious Diseases, e.g. in Sub-Saharan Africa, reflecting the respective health system and patient needs

** Access to Medicines activities in this report do not focus on rare diseases and plasma-derived therapies as the report covers the period from 2016 to 2018. Some Access to Medicines activities in rare diseases are highlighted on pages 28 and 29 in "A Unified Approach".

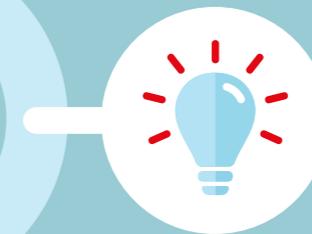


4 and across the complete patient journey



Research & Development

Developing new innovative products and strengthening local R&D capacity to address high unmet patient needs, incorporating access provisions, e.g. Early Access Programs



Awareness

Educating patients, families and community workers about prevention, diseases, symptoms and treatments



Screening & Diagnosis

Supporting healthcare workers to help increase awareness, availability and effectiveness of screening and diagnosis

Prevention & Treatment

Providing healthcare workers with the skills, tools and access to preventive and therapeutic medicines to give the best possible care



Patient Support

Educating healthcare workers, communities, patients and their families on long-term follow up, diseases management, travel support and after care



Our Framework for Access to Medicines

This framework sets out how we work towards strengthening health systems through our global Access to Medicines initiatives.

Ethics and Compliance

Governance and a focus on ethics, compliance and anti-corruption, underpins everything that we do at Takeda, including our Access to Medicines strategy. Takeda's Global Code of Conduct provides a framework for upholding our ethical and moral standards, enabling us to make decisions in line with our values. It sets out the principles we must follow every day and helps us preserve the integrity that is ingrained in our heritage.

All of our initiatives are governed by our Access to Medicines Committee which is overseen by our CEO and his executive team, as well as Access to Medicines working groups to coordinate across business units and functions.

In addition, the Enhanced Patient Access Program Policy defines standard operating procedures and guidelines for addressing scenarios such as Expanded Access Programs and Individual Patient Requests. This consolidated policy has helped ensure that standard terminology is consistent across Takeda and has accelerated how we process requests, allowing us to respond more quickly to patients, communities and organizations to bring real benefits to life.

We regularly assess and evaluate all Access to Medicines initiatives to monitor the implementation and ensure that our high standards for ethics and compliance are adhered to in every single country we reach.

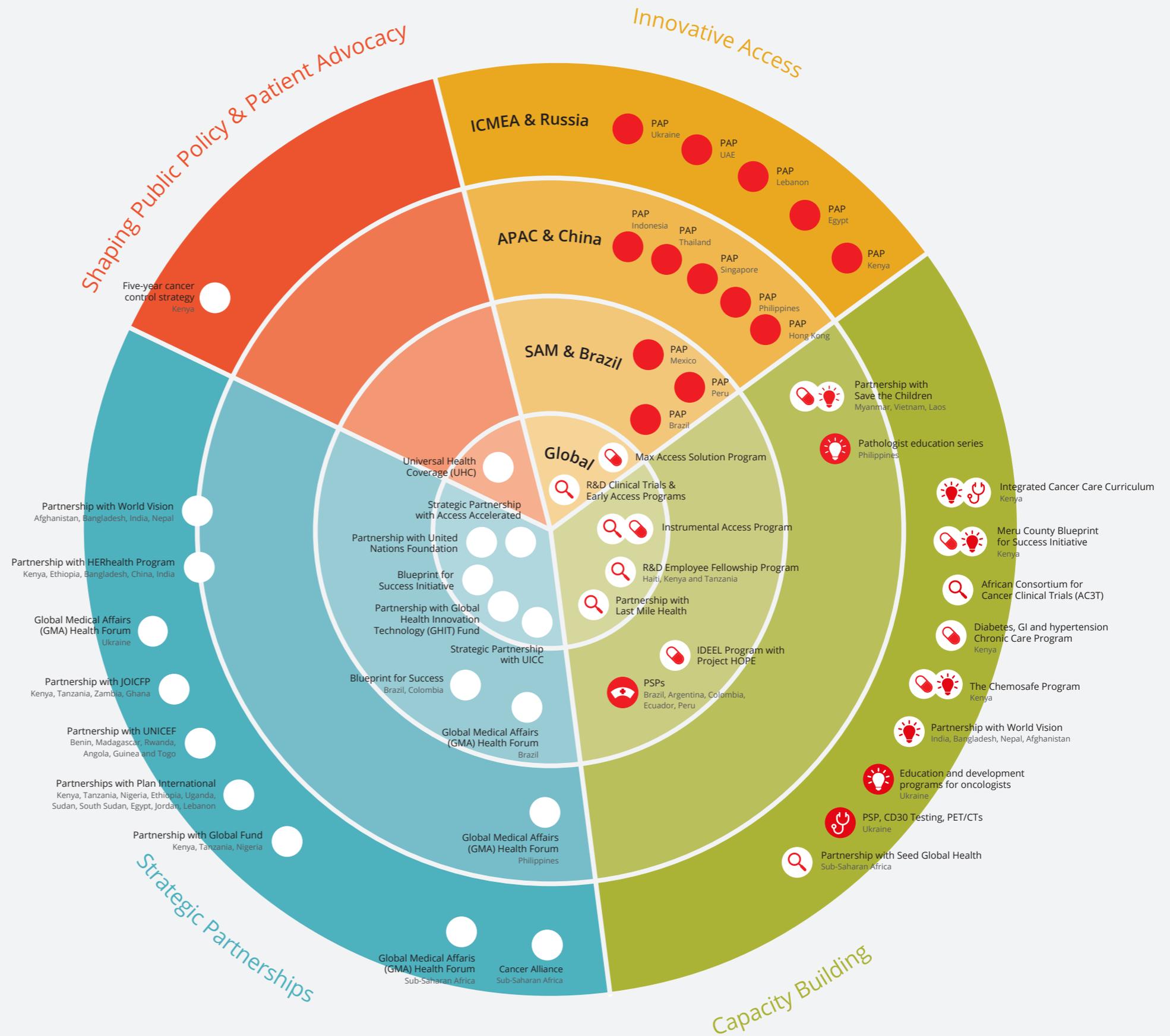
Legend

-  Takeda-Driven Initiative
-  Partner-Driven Initiative
-  Research & Development
-  Awareness
-  Screening & Diagnosis
-  Prevention & Treatment
-  Patient Support

Geographies

- APAC & China:** Asia Pacific, China
- ICMEA & Russia:** India, CIS, the Middle East, Turkey, Africa and Russia
- SAM & Brazil:** South Cone, Andean, Mexico & CAC (Central America & Caribbean) and Brazil
- Global:** All countries and regions in Takeda's Growth & Emerging Markets

Note: PAP and PSP in the wheel refers to Patient Assistance Programs and Patient Support Programs respectively



Strategic Partnerships

Partnerships to strengthen health systems in underserved communities

Takeda's strategic partnerships approach underpins everything we do in our Access to Medicines work. We strive to bring together cross-sectoral stakeholders at both local and global levels. This helps us to identify the critical healthcare gaps and pool resources to provide sustainable solutions. We recognize that we cannot do this alone.

Through our work with leading global and local health experts; academics; development agencies; NGOs; government organizations; healthcare professionals; patient groups; and industry peers, we have learned one of the most fundamental challenges with access programs; they are often developed in silos without a holistic view of the entire healthcare landscape, resulting in overlapping activities and inefficiencies.

Our strategic partnerships approach enables us to work with experienced individuals and organizations in each country. We work to either create programs that address tangible gaps or build on existing initiatives to deliver maximum value to patients, health systems and communities.

We look to engage with partners that will not only enable us to develop innovative solutions, but that will also provide us with new perspectives on local access challenges as well as support and further our long-term strategy to deliver sustainable programs of change.

Programs

Takeda convened a number of partners at our first Blueprint for Success Summit in 2017, bringing together over 300 experts globally from various sectors and industries with the shared ambition to create partnership opportunities and tangible action plans to improve Access to Medicines worldwide. Since the first global Blueprint for Success Summit, we have held various regional forums in Brazil and Colombia, building on this successful concept.

The concept of Blueprint for Success is at the heart of our strategic partnerships approach. Designed and led by Takeda, the first Summit aimed to identify access gaps and learn from the best practices established across different sectors. Together with NGOs, health departments and industry peers, we agreed on initiatives and developed detailed working plans, before implementing a host of projects on the ground.

The theme of our Blueprint for Success concept centers on delivering sustainable and holistic healthcare for patients with non-communicable diseases. The success of the first Summit has led to encouraging pilot programs that include Meru County in Kenya (see page 12 case study), enabling us to apply a global set of principles to local healthcare initiatives, and engaging with the right stakeholders sustainably.

- Other global strategic partnerships initiatives include:
 - Global polio eradication partnership with the Bill and Melinda Gates Foundation
 - US\$5 million contribution to the Global Health Innovation Technology Fund (GHIT Fund), an international public-private partnership
- Our current initiatives in ICMEA (India, CIS, the Middle East, including Turkey, & Africa) include:
 - ¥750 million to the Japanese Organization for International Cooperation in Family Planning (JOICFP) for their work in protecting pregnant women and girls in Africa
 - ¥1 billion to Plan International Japan for health programs aiding the refugee crisis of South Sudan and Syria
 - ¥1 billion to the United Nations International Children's Emergency Fund (UNICEF) to improve maternal, infant and child health through nutrition programs
- In Asia Pacific and China, we have the following initiatives:
 - A partnership and donations to HERhealth Program (also includes ICMEA), which includes factory clinic assessments to improve the healthcare environment of women workers
 - ¥1 billion for measles immunization program with United Nations Foundation (also includes ICMEA and SAM)

Impact

Over 20 strategic partnerships & 50 initiatives

supporting Global Health and Access to Medicines in R&D

Supported the founding of the Hodgkin's Lymphoma Advisory Board in South Africa

Over 250 healthcare

experts were brought together in Takeda's Global Medical Affairs Health Forums organized in Brazil, Kenya, Philippines and Ukraine to identify issues facing healthcare systems



“

We think about partnerships holistically because it is the right approach for patients. This enables us to address the critical healthcare issues affecting society and bring long-term transformative benefits to patients.”



Dr Andy Plump,
President of Research and Development, Takeda

Partnering for a better future – Blueprint for Success pilot in Meru County, Kenya

Africa’s disease burden is expected to increase in the coming decades, especially for non-communicable diseases (NCDs). The present situation is dominated by low public awareness of NCDs, non-existent or inefficient disease prevention, and overburdened, inadequately funded health systems with limited diagnostic capabilities. Where effective treatment is available, high costs often prevent many from accessing such treatment.

Meru County in Kenya was selected as the pilot for the first Blueprint for Success initiative. Launched by Amref Health Africa and Takeda together with local and regional partners, the initiative – a product of the first Blueprint for Success Summit in Geneva – addresses barriers across the entire NCD continuum of care.

The Meru County project brings together the local community, civil society organizations and the Meru County Ministry of Health to strengthen the health systems in the county and surrounding regions by raising public awareness about NCDs, reducing stigma, improving clinical care and delivering better patient support. This includes promoting awareness and understanding of diabetes, hypertension and cancer, including prevention, screening, early detection, and treatment through customized public education, delivered by Community Health Workers (CHWs).

As every healthcare professional in the region needs to provide patient care for life-threatening illnesses such as cancer, we work closely with the county government and Ministry of Health of Kenya to improve such patient support services – increasing the number of trained health workers, refining the quality of service provision and supporting the country in managing the stock of diagnostic equipment, medicines and consumables. In addition to bolstering local healthcare capacity, our collaborations with partners such as the National Health Insurance Fund (NHIF) help to tackle the affordability barriers to treatment.

Together with our partners, we are also working with CHWs in Meru County to improve NCD understanding by collecting data through a mobile community health reporting tool – Mobile Jamii Afya Link (M-Jali) – developed by Amref Health Africa. The objective is to help form a holistic understanding of the local health challenges based on real-time data, and to translate this through policy advocacy in collaboration with local and regional governments.

Our strategic partnerships, formed through the Blueprint for Success Summit, enable us not only to implement global best practices but also ensure that our initiatives are providing high quality patient support for the longer term. We will continue to work closely with local communities, governments and healthcare workers to scale these efforts to other parts of Kenya and Sub-Saharan Africa.



In 2016, NCDs were responsible for 35% of all deaths in Kenya, and 22% of these occurred before the age of 40.

In Kenya, the leading causes of NCD deaths among the poorest quintile were cancers (32.1%) and cardiovascular diseases (26.3%).

The incidence of NCDs accounts for more than 50% of total hospital admissions and over 55% of hospital deaths.

Reference: Kenya National Strategy for the Prevention and Control of Non Communicable Diseases 2015–2020



The initiative aims to achieve the following milestones over the next three years:

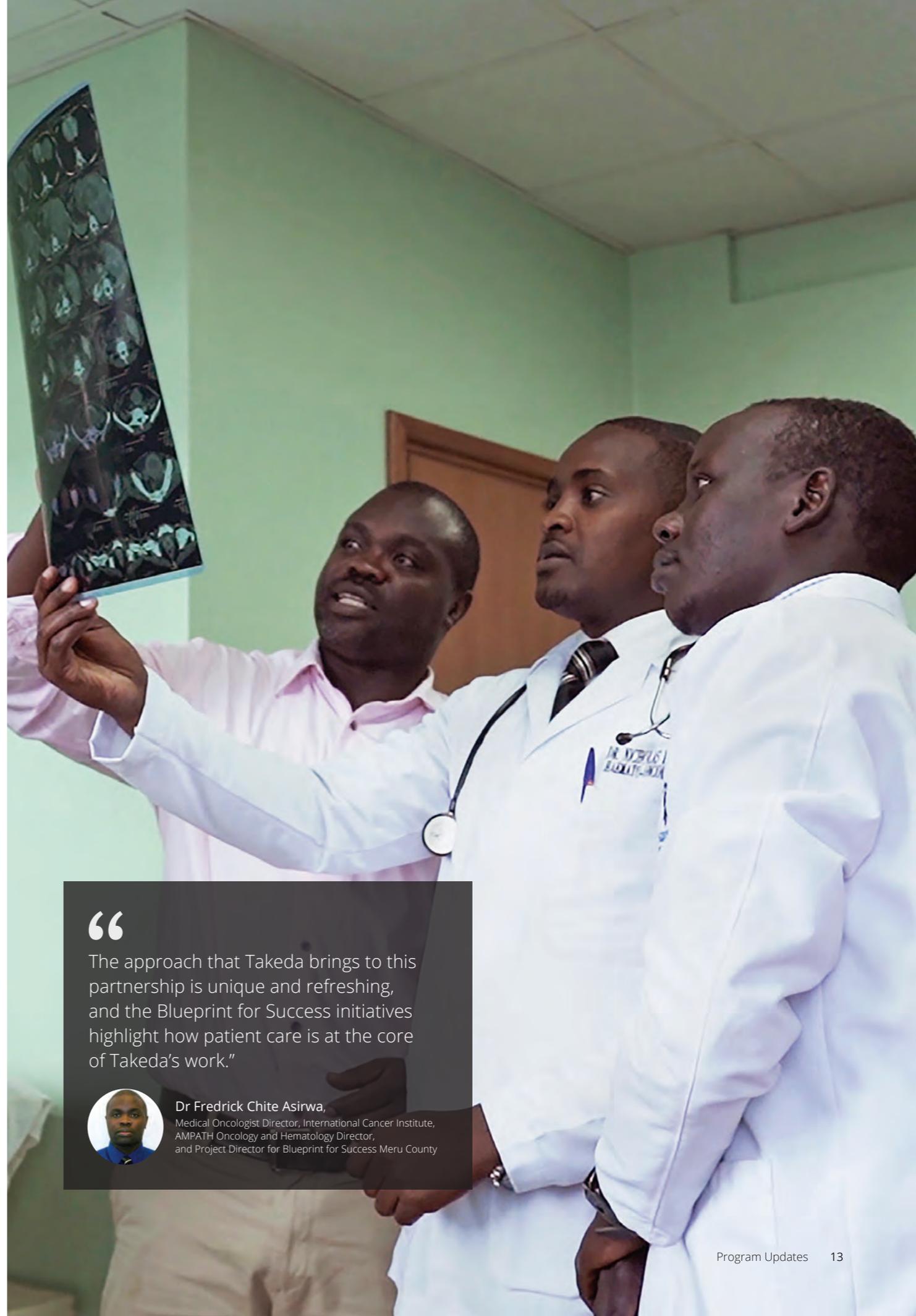
Screen 20,000 women for breast and cervical cancer

Train more than 500 Primary Healthcare Physicians on NCD management

Provide treatment to more than 500 patients with projected breast, cervical and prostate cancer

Screen 1,000 men for prostate cancer to access optimal treatment

Deploy training on diabetes, hypertension, patient support and the Integrated Cancer Care Curriculum to at least 500 Community Health Workers across Meru County



“

The approach that Takeda brings to this partnership is unique and refreshing, and the Blueprint for Success initiatives highlight how patient care is at the core of Takeda’s work.”



Dr Fredrick Chite Asirwa,
Medical Oncologist Director, International Cancer Institute,
AMPATH Oncology and Hematology Director,
and Project Director for Blueprint for Success Meru County

Shaping Public Policy & Patient Advocacy

Shaping the global healthcare landscape through a regional public policy approach

Takeda's partnership approach to shaping public policy is focused on achieving Universal Health Coverage (UHC)¹. We recognize that successfully shaping public policy is not an endeavour for Takeda alone. We work with a coalition of partners in order to improve healthcare in areas with high unmet medical needs and to achieve the following:

- Develop concrete policy proposals to deal with the issues faced by the communities we serve
- Connect governments to NGOs to address emergent health crises
- Work to expand Universal Health Coverage
- Improve health system capacities to identify and manage complex conditions

Key Initiatives

● Cancer Alliance

Takeda is a founding partner of the Cancer Alliance, a group of established organizations and government agencies who have formed a coalition to strive to improve early diagnosis, affordability, quality, and impact of cancer care while enhancing legislation and the public policy environment for patients in Sub-Saharan Africa. As part of this, Takeda was proud to support the drafting of the National Cancer Control Strategy in Kenya (2017-2021) with the Kenyan Ministry of Health and contribute funding, resources and oncology expertise to the program to improve the diagnosis and treatment monitoring of cancer incidences and types.

Endorsed by the Kenyan National Minister of Health and led by the National Cancer Institute (NCI) of Kenya, it involves a coalition of local partners from public, private, and voluntary sectors to coordinate individual cancer care efforts in the region.

The Cancer Alliance aims to develop Nairobi, Kenya into a center of excellence in cancer management for the Sub-Saharan Africa region.

● Partnership with Amref Health Africa

In October 2018, on the sidelines of the United Nations General Assembly (UNGA), Takeda, in partnership with Amref Health Africa, convened global leaders from governments, UN agencies, the donor community, NGOs, and the private sector to investigate best practices to advance UHC in Asia and Africa.

A key discussion outcome was that achieving UHC globally by 2030 will require more effective partnerships to better mobilize and share knowledge, expertise, and financial responsibilities. We look forward to continuing our work with Amref Health Africa and other leading organizations to drive our public policy efforts through sustained dialogue and engagement in order to increase healthcare access to communities.

More broadly, our efforts to shape public policy are focused on strengthening health systems and convening platforms for stakeholders to facilitate dialogue, enhance legislation and align efforts. For example, Takeda has collaborated with other major Japanese pharmaceutical companies to advocate for UHC-focused global policies with organizations such as the World Health Organization and World Bank. We also continue to use our strong research and development capabilities to explore how technological disruption improves local health systems and shapes policies for the future.

Impact

- Achieving UHC is a priority for Takeda, and we are committed to the long-term, continuous efforts it will require. This includes working to align policies and regulations, supporting the implementation of crucial health programs and promoting multi-sector partnerships.
- Public policy also underpins our initiatives in capacity building, innovative access and strategic partnerships.
- A truly successful UHC system requires a concerted and unified effort by multiple stakeholders, including resolute governments and dedicated private companies as well as NGOs, who are attuned to the needs of their communities.

¹ Universal Health Coverage as defined by the World Health Organization: https://www.who.int/healthsystems/universal_health_coverage/en/

² Least Developed Countries (LDC) as defined by the United Nations. October 2014. <https://www.un.org/development/desa/dpad/least-developed-country-category.html>

³ Low-Income Countries as defined by the World Bank. FY2016. <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>

⁴ Pat-INFORMED is an initiative of the World Intellectual Property Office (WIPO) the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and 20 research-based biopharmaceutical companies.

⁵ Established in 2011, WIPO Re:Search is a public-private partnership administered by the World Intellectual Property Organization (WIPO) in collaboration with BIO Ventures for Global Health (BVGH).



“

Since the commencement of Takeda's Access to Medicines strategy, Ethics and Compliance has been integral to enhancing access to our innovative medicines. We remain committed to support patients in need according to the highest possible standards.”



Mwana Lugogo,
Chief Ethics and Compliance Officer, Takeda

A Forward-Looking Intellectual Property (IP) Strategy

Takeda's position on IP for Access to Medicines aims to expand access to innovative medicines and vaccines for patients in the Least Developed Countries² and Low-Income Countries³, where we do not file or enforce patents. We are also proactively engaging with the Patent Information Initiative for Medicines (Pat-INFORMED)⁴ to make Takeda's patents publicly and easily available in such countries.

Today, using our IP assets, we continue to work closely with organizations such as WIPO Re:Search⁵ to contribute to policy efforts and enhance third-party research activities for neglected tropical diseases (NTD) and the development of NTD drugs.

Innovative Access

Sustainable delivery systems to bridge the access gap

Affordable access to quality healthcare is a critical issue for patients, governments and healthcare professionals around the world. An estimated 2 billion people have no access to essential medicines, effectively shutting them off from the benefits of recent advances in modern science and medicine. Pharmaceutical companies must play an important role in building new and more innovative ways to address access and affordability barriers.

Improving access to critical healthcare requires a holistic approach to ensure innovative and specialty care medicines can be matched to the patients who need them most, as soon as practically possible. At Takeda, we are particularly committed to improving the availability of our medicines through R&D clinical trials, Early Access Programs and collaborative financing schemes.

Communities with evolving healthcare systems are a core focus for us. We work in parallel to ensure our innovative medicines and vaccines achieve earliest registration in all countries. To enable this, Takeda has incorporated local and regional registration requirements for emerging markets into global development plans and works to address those requirements earlier in the development of new drugs. For dengue, we are working to seek registration licenses in endemic markets, where the burden of disease is greatest. In addition, we plan to submit for registration in EU and USA to protect their at-risk citizens (including travelers); Takeda will also work with WHO to obtain Pre-Qualification to expand vaccine availability.

We are also focused on establishing Early Access Programs, where allowed, through targeted life-cycle management of existing medicines. For example, we work to provide patient access outside of clinical trials if certain eligibility conditions are met, and if permitted by local law and regulation.

Early Access Programs*

- **Takeda-sponsored and supported clinical trials**
Over 55,000 patients from underserved countries and communities have received access to Takeda's innovative medicines and vaccines through Takeda clinical trials and Early Access Programs. Moving forward, Takeda is exploring ways to enhance the participation of underrepresented patient populations even further.

Communicable Diseases (CDs) and Neglected Tropical Diseases (NTDs) place a disproportionate burden on patients in countries with evolving healthcare systems, which highlights the importance of prevention. Our dengue trials have all been conducted in those countries where the disease burden is greatest and our approach to developing new vaccine candidates is to leverage non-profit, public-private partnerships for maximum impact.

This tailored approach enables us to increase the number of patients that can access our treatments and the related benefits in a sustainable manner.

- **Post-Trial Access Programs (PTAP)**
Patients enrolled in Takeda trials who meet the requirements for PTAP receive further access after the conclusion of trials, until the medicines are made commercially available, via another trial or an expanded access mechanism.
- **Expanded Access Programs (EAP)**
EAPs enable individual patients to gain access to a designated medicine in cases where it is currently not yet licensed or reimbursed in their country and where we have the intent to file.
- **Individual Patient Requests (IPR)**
IPRs are unsolicited requests from healthcare professionals for patients with serious or life-threatening illnesses who are ineligible for trials and have no alternative treatment available.

* Enrollment to Early Access Programs is subject to program rules and guidelines

Impact

Over 55,000 patients received access to innovative medicines and vaccines Focused on 22 countries

Vaccines for Global Impact

Takeda is working hard to develop and deliver innovative vaccines against important diseases such as dengue, norovirus, Zika and chikungunya.

Most of our development vaccines target diseases listed in the Access to Medicine Index. Our key mission is to make these vaccines available in countries with the highest unmet need, fully develop and register them, and build capacity within our facilities to produce the millions of doses that are required to improve global health.



“Vaccines are powerful tools to address inequity. They protect anyone from potentially life-threatening diseases, irrespective of their circumstances. I'm proud that Takeda has made a deep commitment to vaccines, and to making them available to everyone who needs them, wherever they may be.”



Dr Rajeev Venkayya,
President, Global Vaccine Business Unit,
Takeda

Clinical Trials and Early Access Programs



Overcoming barriers to increase access to our innovative treatments – Patient Assistance Programs

In 2017, we pioneered our Patient Assistance Programs (PAPs) which aim to deliver maximum medical benefits to patients through innovative and collaborative financing models. These affordability-based PAPs are holistic and ensure that we help eligible patients who need medical treatment most.

To enable this, we work together with local authorities, foundations, charities, medical associations, governments and other parties to share the cost of treatment with patients. Since inception, almost 700 patients have been treated with some of our most innovative medicines, including Adcetris® and Entyvio®, across 20 PAPs in 14 countries and territories.

Through such collaborative financing, we have increased access to our specialty medicines in areas with high unmet medical need, where Takeda can make a great health impact. We are working to expand our reach into more countries with limited reimbursement or access.

Improving access to our specialty care products for as many patients as possible while ensuring safety and ethical compliance requires the integrity of our programs to be robust. We have a detailed governance process for the consideration, approval and implementation of new programs, and a dedicated governance committee responsible for reviewing and approving our collaborative financing initiatives.

Adcetris®

A treatment for relapsed and refractory Hodgkin's lymphoma and relapsed and refractory systemic anaplastic large cell lymphoma

Entyvio®

A specialty gastroenterology product for the management of Inflammatory Bowel Disease

Knowing that there are significant disparities in healthcare provision both within and between countries, we have adopted a personalized pricing approach rather than providing standard discounts or different tiers of pricing by average gross domestic product per capita. Together with our partners, we have adopted an advanced means-based assessment tool to determine the appropriate individual payment scheme for each patient to ensure they are able to complete their entire course of treatment, even if they cannot pay for it in full.

Partnering with local stakeholders, including government and regulatory bodies, has been a core part of our strategy and will be key to the continued success of our PAPs. We are proud to have developed trusted relationships with many partners from across the public, private and voluntary sectors. In select cases for patients with no ability to pay, we explore routes for them to access medicines included in our PAPs, through donations or additional financial support from local medical societies, charities and NGOs.

While Adcetris® and Entyvio® were our initial focus, we are also working to expand our PAP medicine portfolio to include other diseases with a significant global burden.

“

Takeda's strategy is unique, genuinely patient centric and focuses on achieving the maximum medical outcome for patients, ensuring no one is left behind. The approach to PAPs and the way they have focused on value to patients makes these programs financially sustainable for long-term, lasting impact.”



Dr Joseph Saba,
Chief Executive Officer, Axios International

Active Adcetris® and Entyvio® PAPs

- Adcetris® is live
- Entyvio® is live
- Adcetris® and Entyvio® are live



Capacity Building

Delivering meaningful and sustainable change across the entire patient journey

Providing our medication to patients in underserved communities is not enough.

In many parts of the world it is not just a lack of access to the right medication that is the barrier for patients. Improving the speed of diagnosis is a critical factor in the fight against cancer and other non-communicable diseases – and one that can have the biggest impact on treatment outcomes. The earlier a patient can be diagnosed, the better chances they have of beating the illness, and the greater the impact of the medication.

Having the right infrastructure in place is therefore vital to ensuring that much needed preventative and therapeutic medicines can get to patients where and when they need it. Part of this requires building a network of trained professionals who are able to effectively recognize symptoms, diagnose conditions, treat patients and educate communities on the screening and treatments available to them.

But capacity building is a huge undertaking and something we cannot address as Takeda alone. We are therefore committed to engaging with governments, local healthcare authorities and other partners to understand the needs of local communities and to work with them to provide training programs, early diagnosis, screening, treatment and patient support that will ensure a sustainable healthcare ecosystem that supports both healthcare professionals and patients.

Since we launched our capacity building initiatives in 2016, we have been continually reviewing our impact to explore ways of implementing greater efficiencies to deliver lasting value to the patients and communities we serve.

65%
Approximately 65% of our capacity building initiatives are partnerships

Our capacity building efforts help to provide valuable support and training. We have also integrated initiatives where possible in order to effectively coordinate the activities of our partners. This helps to ensure that resources and programs are developed, delivered and prioritized where, when and how they are needed. Through this approach, we are also able to effectively identify opportunities where partners can share resources and best practices to provide better support to patients.

Takeda's capacity building initiatives are active in the Middle East and Africa, Asia Pacific and Latin America with each developed to address the unique challenges faced by the local health systems, such as the shortage in healthcare professionals, the distance to clinics from patients' homes, and public understanding of treatment options as well as the importance of regular check-ups.

Impact

Over 1,000 healthcare professionals and Community Health Workers have been trained across 20 counties in Kenya

Over 3,000 healthcare professionals and Community Health Workers have been trained across all other countries in Growth & Emerging Markets beyond Kenya

“ Our efforts to support patients in underserved areas mean that we are building capacity across the entire patient journey, beyond traditional perceptions of simply donating medicine. This includes investing in R&D, early disease education, training healthcare workers, screening and diagnosis and more. This is what differentiates our approach to Access to Medicines.”



Dr Wolfram Nothaft,
Chief Medical Officer, Takeda



CASE STUDY #1

Building local capacity in cancer care – Integrated Cancer Care Curriculum

Cancer is the third largest cause of death in Kenya. There is a substantial need for innovative ways of introducing effective and accessible treatments for non-specialists* to assist in care delivery under supervision.

Takeda, together with local partners — the Cancer Alliance (led through the secretariat of Amref Health Africa) and the National Cancer Institute (NCI) of Kenya — identified gaps in cancer care training in Kenya, including around diagnosis, treatment and patient support, that urgently needed to be addressed.

Through collaboration between Takeda, the National Cancer Care Program; Kenyatta National Hospital; Moi Teaching and Referral Hospital; Kenya Hospices and Palliative Care Association (KEHPCA); the Nursing Council of Kenya (NCK); the ELEWA Foundation; Amref Health Africa; Kenyan Network of Cancer Organizations (KENCO); and the Kenya Medical Research Institute (KEMRI), the Integrated Cancer Care Curriculum program was established to address these challenges for patients, commencing with Kenya.

Improving the speed of diagnosis is a critical factor in the fight against cancer in Sub-Saharan Africa. The number of trained professionals, the distance to clinics from patients' homes, public understanding of treatment options and the importance of regular check-ups are all contributing factors that the curriculum specifically seeks to address.

Through innovative training courses and delivery methods that combine in-person training with mobile and online learning, Primary Healthcare Practitioners and Community Healthcare Workers receive training, mentorship and knowledge sharing.

The sustainability of the program depends on the continued commitment of Takeda and our partners, which is why we are working so closely with the government and have made sure that ownership of the program sits with the National Cancer Institute under the National Ministry of Health of Kenya.

The Integrated Cancer Care Curriculum aims to reach 10,000 healthcare workers, to be achieved during 2019, and combines the following Access to Medicines initiatives:

1. Oncology Nurse Training
2. Palliative Care Training
3. Oncology Fellowship
4. Cancer Education for Primary Healthcare Professionals



“

The Integrated Cancer Care Curriculum marks a significant milestone in Kenya's response to the growing cancer burden. The Ministry of Health would like to commend the support Takeda offered us in the development of the Curriculum and cancer screening guidelines, formed in partnership with different key stakeholders across the private and public sector. We believe that it is through such partnerships and scalable models that we will achieve our ambitious goal of securing Universal Health Coverage for our citizens.”

– Dr Kibachio Joseph Mwangi,

Head, Division of Non-Communicable Diseases, Ministry of Health in Kenya

CASE STUDY #2

Strengthening R&D capacity for scientists in developing countries – Instrumental Access Program

The lure of more established countries that can offer more advanced R&D facilities and better career development options for young doctors and researchers is often a challenging issue for developing countries.

Students may travel overseas to receive the best possible education at leading global institutions, but many do not return home due to the opportunities available abroad. This places an enormous strain on health systems in developing countries.

One key factor causing these talents to remain overseas is the lack of access to technology and lab equipment to further their biomedical career research in the developing countries they grew up in.

In 2018, Takeda established a partnership with non-government organization Seeding Labs with a commitment to provide underutilized equipment and instruments from across Takeda to research institutions in developing countries, to help them grow their research capabilities.

One participant in the Instrumental Access Program is the Natural Products Institute at the University of the West Indies in Jamaica. It is estimated that through the institutional participation in this initiative and the instruments provided, scientific advancement capabilities and teaching resources have closed a 10-year gap in research knowledge and sophistication.

Building R&D capabilities in developing countries can transform local healthcare systems. No one is better placed to solve the local challenges that societies face than medical professionals and researchers who live there, have been brought up there, and have a vested interest in solving the unique problems impacting the population. Takeda's Instrumental Access Program therefore does not stop at simply providing underutilized instruments. We help to train medical professionals in how to operate and get the best out of the equipment, we are on hand to assist when they have questions and share the experiences that we and our partners have learned from.

To date, the Instrumental Access Program has:

- Supplied over 250 pieces of equipment to 20 universities in 13 developing countries
- Retained scientific talent, supported attainment of research grant funding, and facilitated the completion and publication of research



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By enabling local research capabilities, you help train these creative, scientific minds to focus on problems facing our community.”

– Dr Rupika Delgoda,

Ph.D, Director of the institute and leading research around mosquito-borne diseases, such as Zika, dengue and chikungunya

“

Beyond the instruments that Takeda provides, it is the expertise exchanged between our R&D colleagues and their counterparts in developing countries that will truly help build capabilities.”

– Dr Chris Reddick,

Vice President, Research and Development Access to Medicines, Takeda

* Non-specialists include Primary Healthcare Practitioners and Community Healthcare Workers

Amref Health Africa's Perspective on Strategic Partnerships

Our partnership with Takeda began in 2016. It quickly became clear that Takeda wanted to do things differently: they wanted to immerse themselves in the challenges throughout the region, well beyond affordability, to deeply understand the critical issues facing health care systems and find the right organizations to partner with to solve them.

A large part of the success of our partnership with Takeda has been a result of their own culture: as a Japanese business, Takeda is meticulous, respectful and fundamentally committed to doing good, not just to doing well. We knew that increasing awareness and building capacity would be key, but we also knew we could not do it alone. From the very beginning, Takeda dedicated a substantial amount of time and resources to studying the healthcare landscape in Africa and made sure to involve all the relevant stakeholders to agree on the full spectrum of challenges before creating an approach for how to address them.

Takeda's Blueprint for Success initiative has been key to mobilizing collaborative action that addresses the challenges of non-communicable diseases. In 2017, the first Blueprint for Success Summit was convened, bringing together over 300 experts from around the world, to create partnership opportunities and enable tangible action plans to improve access to medicines. Since then, we have continued to work together to establish Nairobi, Kenya as a Center of Excellence for oncology in the region.

The roadmap we built together was centered on the patient journey and the inherent challenges faced by patients in Sub-Saharan Africa. Among these, cancer care in particular stood out to us. There is deep lack of knowledge about the disease across the continent – in fact, there is no word for it in most African languages – and yet it is among the biggest killers. Cancer is the third highest cause of death in Kenya.

“

Takeda's mission in Africa has always been about strengthening the healthcare system to benefit society.”

Takeda has played an instrumental role in convening the private sector, which delivers up to 60% of healthcare services in Africa, through establishing the Cancer Alliance – an industry coalition addressing barriers to better cancer care in Africa. Critically, they understood that in order to deliver the most impact to patients, we have to work together across sectors and industries.

As we look ahead, there is much more that we can achieve together to improve access to cancer treatments and raise the standards of health. Our work in Kenya is delivering real, lasting change, and we look forward to continuing our work with Takeda, and other leading organizations, to drive our mission of increasing sustainable health access to communities in Africa.



Dr Githinji Gitahi,
Group CEO, Amref Health Africa



Amref Health Africa, the largest African-led international organization on the continent, provides training and health services to 35 countries in Africa. Founded in 1957 as the Flying Doctors of East Africa to bring critical health services to remote communities, Amref Health Africa works with communities to deliver preventative, community-based health care. They are committed to improving the health of people in Africa by partnering with and empowering communities, and strengthening health systems.

www.Amref.org



Impact Framework

Takeda's Access to Medicines initiatives are currently assessed through monthly dashboards and externally through the bi-annual Access to Medicine Index, and by Boston University's Access Observatory. These assessments allow us to monitor the progress of our projects and ensure that the right medicine, training and support is being administered when, where and how it should be.

We are committed to developing an assessment framework that can be used across the industry, NGOs and governments to evaluate the impact being delivered for patients in an even-handed and comparable manner.

Takeda has partnered with Duke University to create the Access to Health Impact Measurement Framework, a model that is being designed not just to measure the direct impact to patients, but also monitor the difference the programs are making to healthcare systems more broadly.

The Access to Health Impact Measurement Framework considers the impact of initiatives across three categories:

- Health systems context
- Health / therapeutic area
- Patient experience and outcomes

The Impact Framework is bringing together industry peers, healthcare organizations, governments, NGOs and academia to collectively develop a global approach that aspires to provide a single and consistent measurement model for all, and that we believe creates a solid foundation framework to:

- Support a multi-disciplinary approach to tackling global healthcare needs
- Strengthen healthcare systems and improve patient access
- Embed recognition of the need to focus on both capacity and quality
- Present opportunities for collaborative approaches for all stakeholders

We hope this analysis framework will allow Takeda and other organizations to better map Access to Medicines initiatives to clearly show complementary programs and areas for deeper collaboration.

Measuring and benchmarking the impact of our Access to Medicines initiatives in real time is crucial, not just in ensuring the success of our own programs, but in helping communities, societies and healthcare providers to strengthen their health systems across the entire patient journey and guarantee the effective and efficient deployment of resources.

Together with our partners, we are currently trialing the framework, with the aspiration to launch the system within two years, making it publicly available.

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Takeda's commitment to invest in the impact framework and implement it with multiple partners allows significantly stronger program design that goes beyond the many one-off training programs that exist in today's landscape.”

- Dr Krishna Udayakumar,
Executive Director, Innovations in Healthcare, Duke University

“

Responsibility for access to medicine now sits with Takeda's CEO. The company's solid approach to capacity building as well as its deeper approach to equitable pricing were important factors contributing to Takeda rising further than any other company in the Access to Medicine Index 2018, to rank #5.”

- Access to Medicine Foundation



A Unified Approach

In January 2019, we completed our merger with Shire, becoming a global, values-based, R&D-driven biopharmaceutical company. The enlarged business now has an attractive, expanded geographic footprint and leading position in Japan and the U.S., bringing its highly-innovative medicines to approximately 80 countries and regions with dedicated employees worldwide. We remain committed to continuing to respond to the unmet patient needs in underserved communities globally, in an integrated manner.

The integration allows us the opportunity to bring together existing efforts across all the pillars of strategic partnerships, shaping public policy, innovative access, and capacity building to enhance patient access to more life changing medicines and care.

Impact — India Hemophilia Home Care Initiative

In 2015, the team successfully piloted this first-of-its-kind home care model in Mumbai in partnership with the King Edward Medical College (KEM). Initial measured outcome of the patients in the pilot project showed:

| | | |
|---|--|--|
| 50 children with hemophilia on home prophylaxis | 80% reduction in school absenteeism | 18 patients demonstrating an annual joint bleed rate reduction of 77% |
|---|--|--|

The outcomes and tools developed from this pilot have already been shared with the Civil Hospital Surat in Gujarat, and the District Hospital Aluva in Kerala.

We are working to establish further partnerships in India to advance standards of hemophilia care, and exploring how to take these learnings to other access countries.

Shaping Public Policy & Patient Advocacy

Recognizing that health is a key driver of economic growth and prosperity, the Asia-Pacific Economic Cooperation (APEC) has established a Rare Disease Network to increase awareness and shape public policy across the region. Shire was a key member of the Network's leadership, partnering with policy makers as health systems evolve in the region to ensure they adequately address the needs of the rare disease community. We shall continue this important work through our combined Access to Medicines strategy.

We are engaging with Vietnam's government to identify the skills and expertise needed to develop the capacity of Vietnam's healthcare system, and have signed a memorandum of understanding which covers areas including expanding healthcare capacity and education for clinicians and patients. We also work with specific government departments to develop rare disease policies for Vietnam.

The above are two examples of our combined Access to Medicines strategy in shaping public policy.

Innovative Access

The Lysosomal Storage Disorders (LSD) Charitable Access Program (CAP), which was established by Shire, helps to treat patients with three LSD by donating medicinal products for these genetic diseases to non-governmental organizations. In addition to ensuring stable and continuous access, this program also supports capacity building for sustainable, long-term patient care in underserved communities.

Today, the LSD CAP provides Enzyme Replacement Therapy (ERT) to over 200 patients with Fabry disease, Gaucher disease and Hunter syndrome in 12 countries around the world and we are actively exploring the potential of expanding this program.

Capacity Building

Our combined reach will ensure that we are supporting even more healthcare systems and patients across the world.

Launched as an Access Accelerated program, India Hemophilia Home Care enables patients and healthcare professionals to safely and effectively treat hemophilia at home and is a program that we believe has enormous potential under our combined strategy.

According to the World Federation of Hemophilia*, there are an estimated 400,000 people worldwide living with this chronic condition, of which approximately 120,000 are in India alone. Even more concerning, 85% of these persons remain undiagnosed. Many of them are children, so, as well as directly supporting patients, the program actively looks at developing training and support for parents and care givers, to allow these children to be treated at home. Treatment at home helps to prevent and manage bleeds, enabling children to continue going to school (as the reduced school absenteeism of this pilot project demonstrated) and so, this program not only seeks to treat the disease, but creates an environment where children can lead normal and active lives.

* World Federation of Hemophilia: <https://www.wfh.org/en/page.aspx?pid=642>

Strategic Partnerships

A focus on developing strategic partnerships with leading academic centers, technology providers, and biotechnology companies to better understand and address unmet patient needs around the world remains a core focus of our combined Access to Medicines approach. Leveraging the relationships in our combined Access to Medicines strategy will provide greater opportunities to enable access to a wider range of innovative medicines and enhance our ability to bring new specialty treatments to patients with critical conditions. It is estimated that approximately 350 million people are living with severe, life-threatening and complex conditions. Takeda will therefore be investigating how to develop further partnerships, as well as leveraging existing relationships, to bring our life changing medicines to more patients who so desperately need them. Through our combined partnerships, we will continue to strive to solve the most difficult healthcare challenges across public policy, affordability and building local capacity.



The Future

Takeda is deeply engaged in partnerships to address many complex challenges in driving greater awareness, diagnosis, affordability, and patient access to treatments. These span a range of critical healthcare needs across the world. At present, a significant proportion of our work is focused around capacity building and strategic partnerships, and this will continue to be hugely important for us.

However, we see a real opportunity to expand what we have learned in our first two years, not simply to more countries but also to cover a greater number of our most innovative medicines. We firmly believe that Takeda's Access to Medicines initiatives should bring cutting-edge innovative medicines within reach for the world's most underserved patients. Following our recent portfolio expansion, we are excited to introduce additional medicines to our existing initiatives, as well as to build on their work in new countries such as Pakistan.

Looking ahead, we also expect to make available our dengue vaccine in the coming years, which has been delivering encouraging data in ongoing Phase III trials. According to estimates from the World Health Organization (WHO), there may be up to 390 million global dengue infections per year, so the potential impact of this preventative medication is huge. We are currently exploring ways to include dengue and other vaccine candidates in our Access to Medicines initiatives to achieve the greatest health impact for patients in underserved communities.

Shaping public policy is another core part of our strategy that we will look to develop further. Our work to date has involved collaborating with governments in shaping national healthcare policies and approaches to non-communicable diseases, such as cancer. We aim to further enhance our work in this area and are committed to engaging governments to address unique healthcare needs across the world. The true mark of our success will be in creating meaningful and sustainable impact in helping to strengthen health systems.

How we measure our impact is a critical component of our Access to Medicines strategy at Takeda. The Impact Framework we are currently developing with Duke University will ensure a consistent and transparent basis for measuring definitive impact, while also creating a new way of holding ourselves and our partners accountable.

This first report signals the start of a series of progress updates as we grow and learn through our Access to Medicines initiatives. We hope that you have found it both engaging and informative, and we look forward to updating you further as Access to Medicines continues to become even more embedded within Takeda, and continues to shape decision making throughout the organization. Lastly, we urge more partners who share our vision to join us in reaching the world's most underserved patients.



A stylized handwritten signature in black ink.

Ricardo Marek,
President, Growth & Emerging Markets, Takeda



Better Health, Brighter Future



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