Reaching the 2 billion: The Japanese pharmaceutical industry and access to medicine

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There is an on-going challenge to the global community: ensuring quality, affordable, accessible healthcare to people living in developing countries. It is estimated that two billion people lack access to essential medicines, vaccines and diagnostics, with most of these people living in resource-poor settings. Governments, non-government organisations (NGOs), and private sector organisations need to all coordinate activities to ensure that products and solutions reach the people who need them.

As the innovators and producers of key medicines, vaccines and diagnostics, the pharmaceutical industry has a central role in alleviating this burden. However, industry must be supported in turn by the other stakeholders: governments have a role in creating a supportive environment for companies to development products for the poor, and NGOs identify and communicate pressing issues, and have intimate knowledge of needs and gaps.

The Access to Medicine Foundation stimulates change towards reaching the two billion in three central ways. First, by building consensus, among all stakeholders involved, on what the pharmaceutical industry is responsible for in improving access to medicine. Second, by stimulating a race where companies compete against each other to do well in improving access. Third, by sharing best practices amongst companies: by seeing the practices of competitors, companies find inspiration and direction, and are helped to identify opportunities where they can

contribute to access to medicine challenges based on their unique portfolios, pipelines and expertise.

Japan: Increasing participation in global health issues

"I reiterate that health issues are not purely the domestic concerns of individual countries. Health is a cross-border, global challenge."

These words, from Prime Minister Shinzo Abe, published in the Lancet on December 12 2015, crystallise Japan's recognition that health is a global issue, and its commitment to playing its part to secure the health of the world. Towards this aim, what is the appropriate role of Japanese pharmaceutical companies?

Japan is a world leader in innovation and highquality biomedical research. Through various policy initiatives, the Japanese Ministry of Health, Labour and Welfare has been actively trying to create a hospitable domestic environment for pharmaceutical innovation. This helps position the Japanese industry well to secure its share of the global pharmaceuticals market.

The Japanese market for pharmaceuticals is the second biggest in the world: an estimated 10% of the global total in 2013. Until recently, this \$US 60 billion market provided ample opportunity for Japanese pharmaceutical companies, meaning there was comparatively less incentive for venturing into developing country markets. Companies who had unique products needed outside of the Japanese market would traditionally license these to large Western peers such as Pfizer and AstraZeneca. As a result, Japanese companies

have had less opportunity to build experience in navigating developing markets, and in addressing the variety of challenges involved in bringing medicines successfully to the poor.

However, pharmaceutical markets in developed countries are slowing, and markets in emerging economies – including those that are home to the poorest in the world – are growing. This means that all pharmaceutical companies, including the Japanese, have increasingly been looking outwards to the commercial opportunities these countries present. At the Index, we have learned that humanitarian efforts in these countries go hand-in-hand with long-term economic sustainability for companies. Today's investment in creating relationships with stakeholders in developing countries, building infrastructure and health system capacity, and considering the supply and affordability of innovative products are essential activities in maximising the opportunities of tomorrow's markets.

The engagement of Japanese pharmaceutical companies in global health issues has been exemplified by the welcome participation of several major companies in addressing neglected tropical diseases. Japan has a proud history of research in this area. The 2015 Nobel Prize for medicine, for example, recognised Japanese research excellence in developing solutions for the diseases of the poor: to Professor Satoshi Ōmura (with William Campbell) for his important discovery of ivermectin, a key treatment for lymphatic filariasis and onchocerciasis. This discovery has saved millions of lives. This proud heritage is embodied in the recent creation of the Global Health Innovative Technology Fund (GHIT), where pharmaceutical companies such as Astellas, Chugai, Daiichi Sankyo, Eisai, Shionogi, and Takeda contribute open collaboration and financial capital to drive the Japanese research community towards developing solutions for many other neglected diseases. In only two and a half years, the GHIT Fund has invested in over 40 new products, and progressed six

clinical trials in low and middle-income countries. The GHIT platform continues to demonstrate that Japanese companies, the Japanese Government, and Japanese universities play an important role in the global health ecosystem.

However, the landscape of global health rapidly shifts. While treatments for neglected tropical diseases are an important area of focus (and, given the lack of a viable market, are necessarily a purely philanthropic activity), leading causes of death globally are noncommunicable diseases (e.g., heart disease, stroke, chronic obstructive pulmonary disease, diabetes and cancer). These conditions are becoming more and more common in the developing world. Communicable diseases such as HIV/AIDS and hepatitis also remain serious issues, and antimicrobial resistance is an ever-growing threat. All companies interested in securing their place in developing country markets, and in playing a long term, sustainable role in addressing the needs of the global poor, should consider access in a broader sense than philanthropic initiatives. Companies need to consider how they can serve these markets in a sustainable way, through new business models which consider availability, affordability and accessibility of the full range of their innovative products.

Japanese companies: putting in the groundwork

Based on our 10 years of measuring pharmaceutical companies, we have seen that, while Japanese companies appear to have a smaller access to medicine footprint than many of their western counterparts, key developments have taken place in these companies over time which have increasingly positioned them well to play a significant role in solving access challenges. The first steps have been taken: with their focused participation in initiatives aimed at neglected tropical diseases, Japanese companies have already built important connections, relationships and experience in a range of countries. Furthermore, Japanese companies are starting to restructure how they consider

access internally. For long-term success, it is important that access plans are prioritized, governed and incentivized appropriately throughout the company and – to ensure survival in times of economic stress – are aligned with the overall commercial strategy of the business. Staff must remain motivated, and access priorities should not fall off the radar.

Among the Japanese companies we measure, we see these changes taking place. Japanese companies are establishing clearer commitments on policies valued by the broader access to medicine community, for example, around patent waivers in the poorest countries. While not all companies have a strong portfolio of products needed in the least developed markets, tools like equitable pricing and licensing have enabled some companies to take stronger steps, such as tailoring prices to address affordability in poorer countries.

Senior ownership of access issues is increasing, confirming that access to medicine is not solely seen as an additional philanthropic exercise, but is connected to a broader strategy. Access targets are being defined, and performance is increasingly measured against these targets.

- Astellas: At Astellas, in 2014 we noted that performance in access initiatives were regularly reviewed by their CSR Committee, chaired by their Chief Strategy Officer.
- Daiichi Sankyo: In 2014 we saw that
 Daiichi Sankyo had included global access
 considerations in their business plan,
 indicating that it was being considered
 centrally.
- Eisai: Eisai have a centralised department, Global Access Strategies, responsible for oversight of new policies for improvement of healthcare in the developing world. They also incentivise employees on the basis of access-oriented objectives.
- Takeda: In 2014 Takeda considered access at the senior executive level

through their Global Leadership Committee, and informed us at that stage of plans to restructure and deepen their approach to access, creating a centralized Access to Medicine Office.

Prime Minister Abe, in his commentary to the Lancet, made clear that if we care about global health, we must also care about resilient healthcare systems. He restated Japan's commitment to this goal. Japanese companies have an important role to play in supporting healthcare capacity. This could be in strengthening research and manufacture, in supporting supply chains, and contributing appropriately to healthcare information systems.

We see engagement from all Japanese companies in capacity building in developing countries. While these efforts may remain comparatively narrow when compared to European and US companies, they are important steps. Some important examples are:

- Astellas has supported pharmaceutical manufacturing capacity in Indonesia, engaging in technology transfer to ensure local staff was trained and skilled appropriately.
- Daiichi Sankyo has been active in building local production capacity through technology transfers made to Vietnam, China, and Thailand, and supports local healthcare with mobile clinics in Cameroon, Tanzania, and India.
- Eisai is involved in the Uniting to Combat Neglected Tropical Diseases partnership, which, amongst other things, aims to support supply chains for neglected tropical disease treatments.
- Takeda partners with NGOs to provide support. For example, in maternal and neonatal health in China, Indonesia, the Philippines, and Thailand (with Plan Japan) and in diabetes (with Project Hope).

Key considerations for the industry

As indicated earlier, there are a few key considerations that can help drive a sustainable model for growth, positioning companies for greater economic and accessoriented success. Firstly, strengthening companies' presence in developing countries, building key relationships, and ensuring that solutions are accepted and welcomed by local governments and communities is of paramount importance. Ensuring that the work done has significant impact is critical for success. Any company has to ask itself how best to position in each unique space, and tailor initiatives to the different countries and cultures it sets foot in. For example, driving a sustainable model in Africa requires adapting to different countries, as health is managed, financed and organized differently in each country. A one-size fits all policy will not be successful.

Broader development goals can be served by pharma companies using their expertise to boost healthcare infrastructure. Motivate internal teams to think of solutions to complex supply chain challenges in countries to reach the rural poor. Establish strong relationships with key NGOs, governments and private sector organizations, and align with national and international health priorities with sustainable models to help develop capacity, talent development and infrastructure development. Companies have vast expertise that can be contributed, supporting the relationship building already identified as critical. Manufacturing capacity, pharmacovigilance capacity, research capacity, diagnostic capacity and awareness raising are just some examples.

Companies should consider their specific portfolio of products, and ask how those vital products can be brought to all the populations that need them in a form that is appropriate, when needed, and at the right price. Using your good relationships with local stakeholders, build understanding of barriers

and needs, and then deploy products, solutions and expertise to fill the identified gaps. Consider how products need to be adapted to suit different population needs, how affordability may vary from community to community. Register products rapidly, and make sure supply is front of mind.

The R&D pipeline is also an area where keeping up with both medical need, suitability of products for different environmental, social and demographic uses, and efficient launch of products across different countries and populations is critical. Companies need to ensure that when proof of concept is achieved, there is a valid plan in place for these products to reach the poor. This does not only mean intellectual property considerations, but also working with stakeholders, and planning ahead on supply, affordability and registration targets.

Conclusion

Japanese companies have already demonstrated their willingness and their expertise to support global health needs. The time is right to scale up this commitment, and engage even more closely with the needs of the poorest in the world. There is a clear commitment from the Japan, captured by Prime Minister Abe, to be a significant contributor to global health. Coupled with this, access to medicines is no longer a purely philanthropic exercise, but is part of companies' overall sustainability strategies, both in terms of generating greater health value for patients and economic value for shareholders. With the weight of both government and investors behind them, a decade of experience in engagement with the poorest countries in the world, and their own world-class expertise in product innovation, Japanese companies stand ready to contribute to solving some of the world's biggest access to medicine challenges.