

Position on Access to Health

Background

Advances continue to be made in technology and medicine that address unmet medical needs. However, barriers still remain for many people who have difficulty accessing the healthcare they need due to a lack of available treatments, poverty, healthcare system challenges and insufficient healthcare information

Our Position

Astellas' raison d'être is to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Guided by this corporate philosophy, our main efforts to expand Access to Health lie in discovering, developing and providing innovative medicines and medical solutions for patients. Astellas works to advance Access to Health by engaging in initiatives in areas where healthcare improvements are needed. To improve Access to Health, Astellas has identified three areas where we can leverage our capabilities, technologies and expertise to contribute to better global health.

1. Astellas' core business (Rx, Rx+)
 - Creating and delivering innovative medicines and medical solutions to satisfy unmet medical needs
Astellas' primary contribution to improving global health is creating innovative medicines and medical solutions in therapeutic areas with a high level of unmet medical needs and delivering them to patients around the world.
2. Enhancing availability of Astellas products
 - Early Access and Post-Trial Access to investigational therapies
The general approach for making our therapies available to patients in need is through clinical trials and subsequent registration and commercialization of our products. However, Astellas recognizes that patients with serious or life-threatening diseases may not qualify for a clinical trial and may seek access to investigational therapy if they have exhausted all available treatment options. As appropriate, Astellas commits to establishing expanded and early access routes to investigational therapies for patients that satisfy certain defined conditions in compliance with local regulations.
 - International Import Program (IIP) & International Pharmacy Program (IPP)
For some therapies, our international import program supports patients seeking access to medicines after approval and before reimbursement in their country. Additionally, our

international pharmacy program can facilitate access to certain therapies by importing products approved in major countries, in countries where it is not yet approved.

- **Patient Access Initiatives**
In some countries, Astellas will implement programs which enable patients, who meet predetermined criteria, to obtain assistance in gaining access to select Astellas' medicines. These programs include a fair and transparent application process, objective selection criteria and an effective distribution mechanism relevant for the local country needs.
 - **Product Donation and Voluntary Licensing programs via external non-profit organizations**
Astellas considers the feasibility of product donation and voluntary licensing programs, through external non-profit/non-governmental organizations, for certain therapies as a route to make our therapies accessible in countries where they are not commercially available.
 - **Management of Intellectual Property (IP)**
Astellas believes that IP protection of research and development results is essential to continuously creating new drugs and technologies. At the same time, we acknowledge that a variety of inter-related factors in selected developing countries may inhibit access to care, although we do not believe that intellectual property protection is a factor in limiting Access to Health. Astellas commits to not filing or enforcing patents in Least Developed Countries (LDCs)¹ defined by the United Nations or Low Income Countries (LICs)² defined by the World Bank.
 - **Supply chain management**
An effective and responsibly managed supply and distribution system is essential to ensure that high-quality products get to the right patients at the right time. Astellas is committed to ensuring the reliable supply of high-quality, safe and effective medicines to patients and customers. Astellas maintains strict quality standards and effective supply chain management to ensure the safety and continued availability of our medicines.
3. **Collaboration and support for the activities implemented by external partners**
- **Providing Astellas' capabilities and technologies**
In our efforts to improve health issues, we strive to provide cooperation and support for the activities implemented by external partners by combining our capabilities, assets and technologies. Astellas will contribute to the appropriate transfer of technology important to the production of medicines through collaboration with the public and/or private sector. Capacity building, including sharing of know-how, training and education in manufacturing

and quality management of medicines, will be considered to strengthen local healthcare system.

- **Supporting activities to strengthen healthcare systems and improve health literacy**
Astellas seeks to contribute to improvements in healthcare systems through initiatives that benefit public health, enhance the quality of healthcare being provided, and bring overall value to patients, other stakeholders, and the healthcare systems, as a whole. Our goal through these efforts is to make a lasting improvement in local capacity.
Astellas seeks to improve health literacy in the community and believes it is important to undertake initiatives to raise awareness and provide education that will help patients to prevent diseases, or get proper diagnosis and treatment. Astellas supports organizations that work to provide appropriate information and opportunities for patients, families, caregivers and other stakeholders as appropriate to understand diseases and the proper use of medicines. In addition, Astellas supports patient organizations working to improve health literacy for patients. Interacting with patient organizations also helps us to better understand the needs of patients and their caregivers.

Each of these initiatives helps facilitate Access to Health. We believe these initiatives will enhance our enterprise value. In order to develop these activities, Astellas considers working with relevant partners where appropriate and will continue to work with and maintain a close dialogue with stakeholders.

References

1. LDCs defined by United Nations
http://www.un.org/en/development/desa/policy/cdp/ldc_info.shtml
2. LICs defined by the World Bank
<http://data.worldbank.org/income-level/LIC>
3. Policy on Social Contribution
4. Position on Early Access and Post-Trial Access to Investigational Therapy
5. Position on Intellectual Property in Developing Countries
6. Access to Medicines
<https://www.astellas.com/en/sustainability/access-to-medicines>