

Position on Access to Health

Background

Advances continue to be made in technology and medicine that address unmet medical needs. However, there still remain barriers for many people who have difficulty accessing the healthcare they need due to the 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 for patients. Astellas also works to advance Access to Health by engaging in initiatives in areas where improvements are needed for healthcare. To improve Access to Health, Astellas has identified four areas where we can leverage our strengths, technologies and expertise to contribute to better global health. These areas are “creating innovation”, “enhancing availability”, “strengthening healthcare system” and “improving health literacy”.

1. Creating Innovation

- Innovative medicines to satisfy unmet medical needs
Astellas' primary contribution to improve 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.
- Social benefit-driven research and development
Astellas endeavors to accelerate social benefit-driven research and development, i.e., to research and develop products for diseases which Astellas believes have high unmet medical needs but have been neglected or less prioritized for commercial reason. These activities include drug discovery research, formulation development and new indications for existing products for patients suffering from such diseases.

2. Enhancing Availability

- 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 some developing countries need special consideration. Astellas commits to not file nor

enforce patents in select countries with significant economic challenges considering the importance of improving Access to Health. These select countries will be decided by referring to those designated as Least Developed Countries (LDCs)^{*1} defined by the United Nations or Low Income Countries (LICs)^{*2} defined by the World Bank.

- **Expanded access to investigational medicines**
The general approach for making our medicines available to patients in need is through the conduct of clinical trials and subsequent registration and commercialization of our products. However, Astellas recognizes that patients with serious or life-threatening diseases may have exhausted all of their available treatment options, may not qualify for a clinical trial and may seek access to investigational medicines. As appropriate, Astellas commits to establishing expanded access plans for investigational medicines and patients that satisfy certain defined conditions in compliance with local regulations.
 - **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 medicine to patients and customers. Astellas maintains strict quality standards and effective supply chain management to ensure the safety and continued availability of our products.
 - **Patient assistance/access program**
In some markets, Astellas will implement programs which enable patients, who meet predetermined criteria, to obtain assistance in gaining access to select Astellas' medicines. These programs should include a fair and transparent application process, rational criteria and an effective distribution mechanism relevant for the local market needs.
3. **Strengthening Healthcare System**
- **Improving medical infrastructure, services and quality of care**
Astellas seeks to contribute to improvements in the healthcare system through initiatives that benefit public health, enhance the quality of healthcare being provided, and bring overall value to patients, other stakeholders, and the healthcare system as a whole. Our goal through these efforts is to make a lasting improvement in local capacity.
 - **Technology transfer including capacity building**
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.

4. Improving Health Literacy

- Increasing awareness and patient support

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 works, within many different regulatory environments, to provide appropriate information and opportunities for patients, families, caregivers and other stakeholders as appropriate to understand diseases and the proper use of pharmaceutical products. In addition, Astellas supports patient groups working to improve health literacy for patients. Interacting with patient groups also helps us to better understand the needs of patients.

Each of these initiatives helps facilitate Access to Health. At the same time, we believe that these initiatives will lead to enhancement of 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 Expanded Access to Investigational Medicines
5. Position on Intellectual Property in Developing Countries