

Position on Human Rights

Background

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. Astellas believes that the rights and dignity of the people using our products both during and after development are paramount. Astellas recognizes it has a responsibility to respect human rights of our stakeholders.

Our Position

Astellas is committed to respecting the human rights of all people (within and outside the Company) and upholding high labor standards. Wherever we operate, we comply with applicable local labor and employment laws and respect internationally-recognized basic human rights and labor standards, such as the International Bill of Human Rights, the UN Guiding Principles on Business and Human Rights (UNGPs), and the International Labour Organization's (ILO's) Declaration on Fundamental Principles and Rights at Work. In addition, Astellas is a signatory of the UN Global Compact, endorsing the Ten Principles and supports the transparency requirements of the UK's Modern Slavery Act and similar legislation.

Astellas respects children's human rights such as those enshrined in the Children's Rights and Business Principles in not only prohibiting child labor but also conducting pharmaceutical research and development related to the development of pediatric formulations.

We also expect our business partners to meet basic human rights and labor standards.

When violations of these rights occur, Astellas recognizes the need and right for victims to have access to effective remedies (judicial and non-judicial).

1. Human Rights to Which Astellas Pays Special Attention

While Astellas is committed to respecting all human rights, we pay particular attention to the rights on which our business activities can have a significant impact:

- **Human Rights in Clinical Trials and Other Research and Development Activities**
Astellas is committed to maintaining the highest scientific and ethical standards in our pharmaceutical research and development. We comply with internationally-accepted standards for non-clinical and clinical research, including the International Council for

Harmonization Guidelines and the ethical principles articulated in the Declaration of Helsinki, as well as applicable laws, regulations and industry codes.

In our clinical trials (including post marketing clinical trials), we put the health and safety of trial subjects first, ensuring the respect and protection of their human rights, including rights to dignity, self-determination, privacy and confidentiality of personal information. We obtain appropriate informed consent from everyone taking part in Astellas-sponsored clinical trials.

We handle human biological samples (e.g. blood, tissues and cells) and associated data in a highly responsible and ethical manner. We ensure that appropriate informed consent is obtained from donors (or parents, custodian, or legal representative), as required by relevant local laws, regulations, guidelines or industry codes.

- **Counterfeit Drugs and Product Safety**

Astellas is committed to ensuring an uninterrupted supply of high-quality products for our patients around the world. We maintain strict product quality standards and a robust supply chain across the world to ensure the efficacy, safety and supply of our products. Our efforts toward patient safety also include implementing appropriate measures against medical errors and drug counterfeiting.

In recognition of the fact that the safety profile of products can continue evolving post marketing, we are also dedicated to monitoring the safety of our products continuously throughout their lifecycles, according to applicable laws, regulations and industrial codes, such as the Good Pharmacovigilance Practices (GVP). We collect, evaluate, and timely report product safety information to health authorities around the world in compliance with applicable laws and regulations.

- **Access to Health**

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 a lack of available treatments, poverty, healthcare system challenges and insufficient healthcare information. While the protection of the right to health is primarily the responsibility of states, pharmaceutical companies like Astellas can play a role in contributing toward improving the health of people by expanding access to health.

To this end, we are working on a range of initiatives including: aiming to achieve the United Nations Sustainable Development Goals, combating diseases which have been commercially neglected, preventing and controlling non-communicable diseases, and supporting technology transfer.

Astellas believes intellectual property enhances innovation and discovery and is committed to enhancing access to health through innovation, especially in developing countries. Astellas commits to not filing or enforcing patents in Least Developed Countries (LDCs)*1 defined by United Nations or Low Income Countries (LICs)*2 defined by the World Bank. We recognize that these countries can be the subject of flexibilities allowed in Declaration on the TRIPS agreement and public health (Doha Declaration) in order to address social and economic concerns. For more details about our policy and position of intellectual property, please find “Policy on Intellectual Property” and “Position on Intellectual Property in Developing Countries”.

*1: [LDCs defined by United Nations](#)

*2: [LICs defined by World Bank](#)

- **Human Rights in the Workplace**
Employees are a core of our operations, as they enable all we do and are the driving force to realize our mission. Astellas respects the human rights of our employees, including the rights to non-discrimination, freedom of association and collective bargaining, freedom from forced labor and privacy. In addition, we work to promote diversity and inclusion in the workplace and provide a safe and rewarding work environment for our employees. We promote respect for these rights in our business partners.

We comply with child labor laws and regulations and support all ILO labor standards outlined in ILO Conventions (C138 and 182).

- **Human Rights in the Community and Environment**
Astellas respects the human rights of our neighbors in areas where we operate or have business office and facilities. We continuously monitor and address the environmental impacts of our business operations on our neighbors.

2. Implementation

This position statement applies to Astellas’ worldwide operations. Astellas continues to execute the commitments made herein and to fully embed respect for human rights within all areas of the company. Astellas also works to employ our position on human rights in local context through implementation of relevant policies and procedures.

Astellas also expects our business partners to respect human rights in their own operations through our Business Partner Code of Conduct.

We understand the need for employee feedback and the right to remedy, and so we have reporting mechanisms through which employees can file complaints, without fear of reprisal or retaliation and on a confidential basis. This system can be used by both employees and external stakeholders. It allows users to report concerns through telephonic and web-based applications, and it allows anonymous reporting wherever such reporting is allowed by law.

3. Stakeholder Engagement

Astellas believes that corporate respect for human rights is an ongoing and evolving process. Astellas is committed to ongoing engagement with relevant stakeholders to continue to understand and address human rights impacts linked to our business from the perspective of those affected. For example, Astellas' third-party lifecycle management program reviews key attributes of our significant business partners. We will continue to build upon these efforts and improve our overall human rights performance through public reporting on our approach.

4. Governance

This position statement has been developed by the Corporate Advocacy Department, which is responsible for providing strategic direction and oversight for Astellas' human rights work, with the input from cross-functional departments within the Astellas group. It has been approved by the Chief Executive Officer (CEO).

References

1. International Bill of Human Rights (consists of the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, and the International Covenant on Civil and Political Rights and its two Optional Protocols)
<https://www.ohchr.org/Documents/Publications/FactSheet2Rev.1en.pdf>
2. UN Guiding Principles on Business and Human Rights (UNGPs)
http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf
3. International Labour Organization's (ILO's) Declaration on Fundamental Principles and Rights at Work
<https://www.ilo.org/declaration/lang--tr/index.htm>
4. Ten Principles of the United Nations Global Compact
<https://www.unglobalcompact.org/what-is-gc/mission/principles>
5. Children's Rights and Business Principles
<https://www.unglobalcompact.org/take-action/action/child-rights>
6. Declaration of Helsinki
<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

7. ILO Conventions
[https://www.ilo.org/moscow/areas-of-work/gender-equality/WCMS_249143/lang--en/index.htm](https://www.ilo.org/moscow/areas-of-work/gender-equality/WCMS_249143/lang-en/index.htm)
8. Astellas Group Code of Conduct
9. Astellas Business Partner Code of Conduct
10. Policy on Respect in the Workplace/Prevention of Discrimination and Harassment
11. Position on Access to Health
12. Position on Counterfeit Medicines
13. Policy on Intellectual Property
14. Position on Intellectual Property in Developing Countries