


# Initiatives to Improve Access to Medicines | FY2023 Archive

Despite the rapid progress in technology and knowledge of modern medicine, unmet medical needs remain in a wide range of therapeutic areas, and every R&D-based pharmaceutical company is charged with the mission of addressing these issues by creating innovative new medicines. Furthermore, there are many countries and regions where people are unable to equally access adequate medical treatment due to immature medical systems and/or poverty. To solve these issues, which are recognized as "access to medicines" or "access to healthcare," in addition to our R&D efforts on innovative medicines, we are actively working with international organizations, governments and research institutions, and civil society.

## | Partnership Initiative "Access Accelerated"



Sumitomo Pharma participated in a partnership initiative called "[Access Accelerated](#)."  Access Accelerated is a coalition of more than 20 pharmaceutical companies and several international institutions around the world formed to improve access to healthcare for non-communicable diseases in low- and low-middle-income countries.

Access Accelerated has also worked with Boston University to develop a common measurement framework for individual access programs implemented by each company to promote these efforts effectively. Sumitomo Pharma registered its health improvement program for mothers and children in Cambodia registered under this framework. Sumitomo Pharma participated in Phase 1 from the launch in fiscal 2017 to 2019, and in Phase 2 from fiscal 2020 to 2022.

- Report on activities for the period from fiscal 2017 to fiscal 2022: "[Key Lessons in Advancing Access to NCD Care](#)" 

## | Initiatives to Improve Access to Healthcare in Developing Countries

Sumitomo Pharma supports initiatives to improve access to healthcare in developing countries. The Company cooperated with the NPO Future Code to implement the training and education of nurses in Bangladesh, and in Haiti to implement

regular medical examinations for tuberculosis as well as the training of physicians. We also cooperated in malaria prevention and awareness raising activities, hygiene education, including the installation of toilets, and the operation of an orphanage in Burkina Faso.

## Responding to Demands for Development of Unapproved or Off-Label Drugs

Japan's Ministry of Health, Labour and Welfare (MHLW) invites requests for the development of unapproved or off-label drugs that have been approved for use in Europe and the United States but have yet to be approved in Japan. Upon receipt of such a request, MHLW, through a meeting of the Evaluation Committee on Unapproved or Off-Label Drugs with High Medical Needs, evaluates the medical need for the drug concerned and ascertains the validity of clinical studies required to support an application for approval and the drug's eligibility for an Application Based on Public Knowledge, thus promoting the development of such drugs by pharmaceutical manufacturers.

Sumitomo Pharma also acts on requests for the development of unapproved and off-label drugs. Thus far, we have obtained approvals for 6 such drugs, among them a partial change to the approval details for the biguanide oral hypoglycemic agent METGLUCO® in September 2022, to include the additional indications of induction of ovulation in polycystic ovary syndrome and regulated ovarian stimulation for assisted reproduction in polycystic ovary syndrome. In addition, we are working on a development request for the use of RETHIO®, an alkylating anticancer agent belonging to the ethylenimine family, in the treatment of CNS lymphomas (including primary and other lymphomas with CNS invasion).

### Sumitomo Pharma's responses on invitations/requests for development

Invitation /request for development	Product name	Indication(s)	Development status
4th round	METGLUCO®	Ovulation induction for patients with polycystic ovary syndrome	Approved on September 16, 2022
		Controlled ovarian stimulation in assisted reproductive technology for patients with polycystic ovary syndrome	
2nd round	RETHIO®	Conditioning treatment prior to autologous hematopoietic stem cell transplantation for pediatric malignant solid tumors	Approved on March 26, 2019
		Conditioning treatment prior to autologous hematopoietic stem cell transplantation for malignant lymphoma	Approved on March 25, 2020
1st round	Amlodin®	Additional indication of hypertension in pediatric patients	Approved on June 22, 2012
1st round	METGLUCO®	Additional indication of type 2 diabetes in pediatric patients	Approved on August 29, 2014

## Participation in Humanitarian Aid

In conjunction with our domestic and foreign partners, we participate in the delivery of humanitarian aid in countries and regions where access to medicines is made difficult due to disasters and conflicts.

In fiscal 2022, we have decided to donate our antiepileptic drug, EXCEGRAN® 100mg tablets (generic name: zonisamide), to Ukraine and neighboring countries. The drug was delivered to those in need in partnership with local governments and industrial associations etc.; as of June 2022, 3.5 million tablets were donated to Ukraine, and 20,000 tablets were donated to the Republic of Moldova, which is accepting many refugees from Ukraine. In relation to the donation to the Republic of Moldova, swift delivery to the Moldovan national medicines warehouse was made possible thanks to the assistance from Inabata & Co., Ltd.



Medicines donated to the Republic of Moldova

## Fight against Counterfeit Pharmaceuticals

Illegally manufactured or distributed pharmaceuticals (counterfeit pharmaceuticals) not only provide no therapeutic effects but could pose fatal risks to the patient because of their unknown side effects. The threat is expanding throughout the world in terms of both quantity and the targeted areas. The problem of counterfeit pharmaceuticals has another international dimension: their trading could be a lucrative business for organized crime and international terrorist organizations.

To ensure safety of and trust in our products, we join together with peer pharmaceuticals companies in the initiatives of industrial associations and international organizations to collect and exchange up-to-date information in the fight against counterfeit pharmaceuticals. Specific actions are detailed below.

### Initiatives to Fight against Counterfeit Pharmaceuticals

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## **Membership in PSI: Pharmaceutical Security Institute**

As a member of the Pharmaceutical Security Institute (PSI), the Company maintains close contact with other global pharmaceutical manufacturers in information gathering and promoting anti-counterfeit enforcement operations. PSI is a U.S.-based not-for-profit organization founded in 2001. It liaises between pharmaceutical companies and public health authorities and transmits information on counterfeit pharmaceuticals.

## **Working with INTERPOL to Combat Crimes Involving Counterfeit Pharmaceuticals**

Sumitomo Pharma is one of 29 global pharmaceutical companies (including eight companies in Japan) that worked together to donate to the International Criminal Police Organization (INTERPOL) a total of 4.5 million Euro over a three-year period beginning in 2013. The donation was used to fund activities to promote public awareness of counterfeit pharmaceuticals and efforts to prevent pharmaceutical crime, as well as for the training of specialist pharmaceutical crime investigators. Pharmaceutical crime is becoming more diverse, including an increase in online transactions. Sumitomo Pharma works to prevent pharmaceutical crime through close sharing of information with INTERPOL via industry group activities.