## Material Issue 15

# **Respect for Human Rights**

## Management of Priority Issues We believe that we have a responsibility to work toward the realization of a society in which people's human rights are respected through our business activities, and we are working to strengthen our human rights risk management. Reason for being We also recognize that the right to access necessary medical care and to live a healthy life is a priority issue a human rights issue. As a pharmaceutical company with problem-solving capabilities, we believe that we have a responsibility to contribute to this issue to the maximum extent possible. Human rights risk management A human rights risk management system has been established within the Ono Pharmaceutical Group to minimize the negative impact of human rights on business activities. Improving access to healthcare Vision over the medium • We are delivering innovative medicines for rare and pediatric diseases. to long term • We are contributing to local capacity-building\* in areas with immature medical infrastructures (in collaboration with NPOs and NGOs). \* Providing support for the development of medical human resources and the establishment of medical systems so that communities facing challenges can overcome them on their own. Human rights risk management (up to 2026) • Conduct human rights due diligence within the Group · Conduct human rights risk assessments for high priority suppliers **Indicators** Improving access to healthcare • Number of approved rare disease/pediatric indications Project outcome goals (new project to begin in FY2022) Human rights risk management • Conduct human rights due diligence Improving access to healthcare **Major initiatives** Develop new drugs and get additional approvals for rare diseases and pediatric indications with high unmet medical needs • Collaborate with NPOs and NGOs and support local capacity-building in areas with immature healthcare infrastructure

#### **Basic Stance on Human Rights**

In all of our business activities in and outside Japan, ONO understands and respects the human rights of each individual and the diversity of their values, personalities, and characteristics and will act accordingly. Upholding these principles, we established and administer our personnel system so that internally and externally discrimination and bullying of any type on the basis of race, nationality, ethnicity, gender, age, color, religion, or belief/philosophy, is prohibited. We also prohibit any form of harassment and conduct compliance training. Furthermore, as a signatory of the United Nations Global Compact (UNGC), we support its ten principles. In addition, we also fully respect human rights initiatives in compliance with the following international standards, the Universal Declaration of Human Rights, the International Covenant on Civil and Political

Rights, the International Convention on Economic, Social and

Declaration on Fundamental Principles and Rights at Work, and

Cultural Rights, the International Labour Organization (ILO)'s

the UN Guiding Principles on Business and Human Rights.

Web ONO PHARMACEUTICAL Human Rights Global Policy https://www.ono-pharma.com/company/policies/human\_rights.html

#### **Initiatives for Human Rights Due Diligence**

In accordance with the United Nations Guiding Principles on Business and Human Rights, we have established and continuously implement a human rights due diligence mechanism to prevent or mitigate the negative impacts of our company on human rights in society.

We use EcoVadis' CSR evaluation system to objectively and continually monitor the CSR status of important suppliers in our supply chain. With this system we can obtain reliable information on the CSR management of our business partners at least once a year, and propose appropriate corrective measures to them. In the fiscal 2021 assessment, no companies were classified as high CSR risk. In addition, we will conduct comprehensive human rights due diligence from FY2022.

#### Improving access to healthcare

Even today as we see remarkable developments in the medical field, there are many diseases against which no effective treatment exists.

Also, in low- and lower middle-income countries, there are many people who have difficulty receiving necessary medical care due to various reasons such as inadequate medical infrastructure and poverty.

Under the corporate philosophy Dedicated to the Fight against Disease and Pain, we aim to improve access to healthcare by pursuing the following goals: the development of innovative pharmaceutical products, improvement of medical infrastructure, and establishment of partnerships with outside parties. We currently sell our pharmaceutical products by ourselves in Japan, South Korea, and Taiwan; in Japan and Asia, we will make efforts for improving access to healthcare including the treatment of rare diseases. In other regions, we are providing pharmaceuticals with the help of our partner companies. We are also working on supporting medium- and long-term activities to strengthen medical systems by means such as medical education and the development of medical infrastructure through partnerships with NPOs and the Global Health Innovative Technology Fund.

#### The Direction of our Efforts

- Promotion of research and development for measures against diseases for which patients' medical needs are not yet met, rare diseases, and intractable diseases
- Local medical education, training of medical personnel, improvement of medical equipment in countries and regions where medical infrastructure is not fully developed

 Strengthening the medical system through partnerships with external parties

Web Our Policies on Intellectual Property Rights and on Patents in Countries with Limited Access to Healthcare

https://sustainability.ono-pharma.com/en/themes/102#927

#### Development of Pharmaceutical Products to Improve Access to Healthcare

We are working to develop and provide drugs for rare diseases, for which the number of patients is small and it is difficult to develop treatments, through in-house drug discovery and licensing activities. We are also aiming at improving access to medical care for pediatric patients, by working to obtain indications with the belief that drugs should be appropriately evaluated for pediatric patients.

For drug discovery research targeting intractable diseases, we are working to provide new treatment options through industry-academia collaboration. Together with Keio University, Kochi University, Iwate Medical University, the National Institutes of Biomedical Innovation, Health and Nutrition, Mitsubishi Tanabe Pharma Corporation, and Daiichi Sankyo Company, Limited, we launched the Immune-mediated Inflammatory Diseases Consortium for Drug Development in 2018 with the aim of conducting drug discovery research targeting immunoinflammatory intractable diseases. We believe that the results from this consortium will lead to the discovery of next-generation drugs with high utility for immunoinflammatory intractable diseases and provide new treatment options for patients and healthcare professionals.

## ■ Efforts Made against Rare Diseases (as of July 29, 2022)

Product name	Therapeutic indication*	Date designated as an orphan drug	Development Status
OPDIVO intravenous infusion	Malignant melanoma	June 17, 2013	Approved
	Hodgkin's lymphoma	March 16, 2016	Approved
	Malignant pleural mesothelioma	December 1, 2017	Approved
	Cancer of unknown primary	March 11, 2021	Approved
DEMSER Capsules	Improvement of catecholamine excess and various symptoms in pheochromocytoma	May 25, 2015	Approved
KYPROLIS for intravenous infusion	Relapsed or refractory multiple myeloma	August 20, 2015	Approved
ONOACT for intravenous infusion	Life-threatening refractory and emergent cardiac arrhythmias: ventricular fibrillation and hemodynamically unstable ventricular tachycardia	August 24, 2016	Approved
MEKTOVI Tablets	NRAS or BRAFV600 mutation-positive malignant melanoma	December 4, 2013	Approved
BRAFTOVI Capsules	BRAFV600 mutation-positive malignant melanoma	December 4, 2013	Approved
VELEXBRU Tablets	Primary central nervous system lymphoma	August 20, 2019	Approved
	Waldenström's macroglobulinemia, lymphoplasmacytic lymphoma	November 19, 2019	Approved

 $<sup>^{\</sup>star}$  Anticipated indications or diseases on the designation

#### ■ Efforts to Obtain Approval for Pediatric Use (as of July 29, 2022)

Product name	Therapeutic indication	
ONON Dry Syrup	Bronchial asthma, allergic rhinitis	
EMEND Capsules	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc.) (including the delayed phase)	
PROEMEND for intravenous infusion	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc.) (including the delayed phase)	
ORENCIA for intravenous infusion	Active polyarticular juvenile idiopathic arthritis	
DEMSER Capsules	Improvement of status of catecholamine excess secretion in patients with pheochromocytoma	
OPDIVO intravenous infusion	n Relapsed or refractory classical Hodgkin lymphoma	
ONOACT for intravenous infusion	Tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in patients with low cardiac function	

### **ONO SWITCH Project**

As an effort made to promote both medical system support and work style reform, we have been working on the ONO SWITCH Project since August 2018. This is an effort to make donations to NPOs and NGOs related to medical care using the money saved through the reduction of overtime work through the promotion of work style reform, aiming to further promote the embodiment of the corporate philosophy Dedicated to the Fight against Disease and Pain by contributing to the promotion of working style reform, healthcare, and people's health around the world.

The project was named SWITCH by abbreviating **S**ave the **W**orld with our work style **I**mprovemen**T** and **CH**ange (meaning saving the world through improvement and reform of our ways of working). The project name also expresses switching work methods to new ones, switching the funds obtained through working style reform to donation, and switching to the process of reexamining how to work.

In this project, we will work on improving access to healthcare products and improving medical infrastructure through partnerships with outside parties.

Web ONO SWITCH Project

https://sustainability.ono-pharma.com/en/themes/102#929

## Participation in the Global Health Innovative Technology Fund

We became a member company of the Global Health Innovative Technology Fund (GHIT Fund) in 2018. The GHIT Fund is an international, non-profit organization that invests in the development of new drugs, vaccines, and diagnostic agents against less marketable diseases such as malaria, tuberculosis and neglected tropical diseases, and is funded by the Japanese government, the Bill & Melinda Gates Foundation, the Welcome Trust, and private enterprises in Japan and overseas. In order to reduce the health disparities between developed countries and low-and middle-income countries, the therapeutic agents, vaccines, and diagnostic agents developed through the GHIT Fund's investments are priced according to the "No Gain, No Loss" principle. We understand the efforts and policy, and we contribute to the funding of the GHIT Fund. Through participation in the GHIT Fund, we will strengthen the establishment of partnerships aiming to improve access to healthcare in low- and middle-income countries.

## **■** Recipients of Support from the ONO SWITCH Project (FY2021)

Partner	pport from the ONO SWITCH Project (FY2021)  Description of efforts made		
(Regions with ONO-sponsored	FY2021 Plan	FY2021 Results	
Japan Committee, Vaccines for the World's Children (Bhutan)	Provide DPT (diphtheria/pertussis/tetanus) vaccines for 53,500 children	The DPT vaccine was given to 96% of 2 year olds. (The target vaccination rate was over 95%). We were also able to systematically conduct on-site vaccination of the children of nomads.	
	Hepatitis B vaccines for 9,000 people	The hepatitis B vaccine was given to 96% of newborns. (The target immunization coverage was 95% or higher.)	
	TD (tetanus/diphtheria) vaccines for 69,482 people	The TD vaccine was given to 96% of children and 92.8% of pregnant women. (The target immunization coverage was 95% or more) In addition, systematic mass vaccinations at schools and other locations were also done.	
	Provide 5 refrigerators for vaccines	With our support pharmacy refrigerators for vaccines were installed in 5 facilities and are in continual use.	
Japan Heart (Cambodia)	Donations of equipment for the early detection of neonatal jaundice and phototherapeutic devices for jaundice  We donated new testing equipment because the bilirubin* analyzer currently in use, which is necessary for the diagnosis of jaundice, breaks down repeatedly. In addition, we donated the latest phototherapy equipment, with high levels of safety, necessary for jaundice treatment. We also donated medical equipment necessary for managing the body temperature of newborns.  * Bilirubin: The yellow pigment that forms when the hemoglobin in old red blood cells breaks down.	The donated testing equipment was used to examine all babies admitted after delivery, and the phototherapy equipment was used for babies whose bilirubin was a concern at the public hospital we collaborate with, while admissions were suspended at the hospital due to the spread of COVID-19. Japan Heart commented, "We used the donated analyzer and confirmed the safety of the babies. We have been able to avoid unnecessary blood sampling based on the readings from the analyzer. It has also made it easier to evaluate after phototherapy has been started. We have been able to prevent elevated bilirubin. Compared to the previous analyzer, the median value and history can now be checked, making it easier to use. In addition to 53 inpatients, we were able to measure several outpatients."  The newly donated infant warmers (open incubators) take less time to warm up than those previously used and are spacious making them very easy to use and perform procedures. It is also used for neonatal care after C-sections when an obstetrician is in the hospital.	
	Training is provided so that local medical personnel can provide treatment by themselves for newborns who require breathing support and temperature control shortly after birth.	Training was conducted so that local medical personnel could provide treatment by themselves for newborns requiring breathing support and temperature control shortly after birth. Three local medical personnel are now able to do this.	

## Recipients of ONO SWITCH Project (FY2021)

Recipients of ONO SWITCH Project (FY2021)					
Partner (Regions with	Description of efforts made				
ONO-sponsored initiatives)	FY2021 Plan	FY2021 Results			
Japan Heart (Cambodia)	Support for a student who is aiming to become a healthcare professional  For a student who is good enough to enter medical or nursing school but has difficulty attending school due to family financial reasons, the program provides study support for study and, after graduation, a two-year training period at the Japan Heart Children's Medical Center. We are continuing support for the Cambodian nursing student we have been supporting since FY2018.	The Cambodian nursing student we have been supporting since FY2018 advanced to the fourth year on November 15, 2021. Currently, due to the impact of COVID-19, she is continuing to take classes online. Not only are her grades excellent, but she also actively participates in volunteer work in medical activities on days when she does not have classes. Although she is not yet a medical professional, she is growing into a very reliable person, seeking out what she can do while still a student to "bring medical care to places where it is not available."			
	Environmental upgrades at Japan Heart Children's Medical Center (making the environment more sanitary during the rainy season) The grounds around the Japan Heart Children's Medical Center were not well maintained, and every year puddles of water formed during the rainy season. Puddles that lasted a long time led to mosquito outbreaks. In addition, because the paths were muddy, patients' and accompanying family members' feet got dirty, and the floors of the hospital became dirty as well. To solve this problem, we created a channel to draw water from the areas where water tended to accumulate to the sewer system, and paved the gravel road in front of the hospital, improving the sanitation of the environment around the hospital.	With the improvement of the environment around the Japan Heart Children's Medical Center it has become easier to use a wheelchair due to reduced vibration. Previously, on sunny days, dust would fly up and enter the hospital, and when it rained, and it was dirty with mud even in the entrance, but since the area was paved, it has been kept clean. Even after it rains, the feet of patients and staff are less likely to get dirty, and the hospital is kept clean and comfortable. In addition, since a waterway has been secured, drainage has been improved, preventing water from pooling for long periods of time. The sanitation of the environment has been greatly improved.			
People's Hope Japan (Myanmar)	Skills monitoring for midwives and auxiliary midwives (2nd time) We will do a second round of skills monitoring, following up on FY2020, to see if they are applying the knowledge and skills they've learned in clinical settings, and we will measure retention and improvement. In addition, we plan to train people for a mother and child health promotion committee, according to local needs. Post-graduate training for midwives and refresher training for auxiliary midwives	Due to the difficult domestic situation in Myanmar since February 2021, the planned skills monitoring for midwives and auxiliary midwives and post-graduate training for midwives and refresher training for auxiliary midwives could not be implemented, and were postponed to the next fiscal year. In place of the original plan, we trained volunteer maternal and child healthcare promoters to serve as a bridge between local residents and health services.  In March 2022, we conducted two sessions of training for volunteers or maternal health checkups, care for newborns, and danger signs during pregnancy, and trained 60 mother and child healthcare promoters in 13 villages. The third training was held in May 2022 (25 mother and child healthcare promoters from 6 villages). Furthermore, training will continue to be conducted in villages that have been to be safe and that have the needs. The trained			
	Post-graduate training for midwives and refresher training for auxiliary midwives  The training scheduled for FY2020 will be implemented as soon as the local apprirenment is ready.	mother and child healthcare promoters provide health education and home visits to expectant and nursing mothers, while ensuring their safety.			

Mother and child health promoter's activities in a village. (Photo taken in August 2019)

The activities of Future Code (supported area: Bangladesh), which we supported in FY2020, were delayed due to strict national regulations caused by COVID-19. A new hospital that had been planned opened in December 2021, and we donated PCR machines to it. As of May 10, 2022, a total of 31 PCR tests had been conducted to diagnose COVID-19, of which 12 were positive, and the number of deaths among those who tested positive was zero. Of those tested with the PCR, 61% were poor and were treated free of charge.

environment is ready.

Note: Due to the changes in the situation in Myanmar after February 2021, the assistance may be changed to more urgent assistance.

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