

# Sustainability Report 2017

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A sustainable business platform is essential for maintaining business credibility and Orexo shall be a company with sustainable values that acts responsibly and is accountable for its actions. To support and enforce this statement, Orexo joined the United Nations Global Compact in 2017, an initiative that has now gathered over 9,500 companies in pursuit of a sustainable future.

This is Orexo's first Sustainability Report in accordance with the new Swedish Annual Accounts Act and also our first Communication on Progress according to the reporting guidelines of the Global Compact. I am pleased to reaffirm Orexo's support of the Ten Principles in the areas of Human Rights, Labor, Environment and Anti-Corruption.

Yours sincerely  
Nikolaj Sørensen  
President and CEO

This sustainability report includes the parent company Orexo AB and its subsidiaries.

# Sustainability at Orexo

“Orexo wants to be recognized for the value our pharmaceutical products bring to the patients and to be trusted for the way we work and operate in delivering benefits to patients, society, partners and other stakeholders.”

Orexo Quality Policy.



Orexo's efforts to create added value for patients and other stakeholders and to ensure access to quality pharmaceutical products has a positive impact on several sustainability aspects. In general the historic importance of adherence to local and global legislation and standards with regards to good practices within pharmaceutical development and international business conduct, has pushed the Company towards a more sustainable business. The threshold for being classified as a sustainable company is constantly increasing and Orexo is committed to continuously addressing its footprint on environmental and social aspects.

In April 2017, Orexo signed a letter of commitment to support the ten principles in the areas of Anti-Corruption, Human Rights, Environment and Labor and thus participate in the United Nations Global Compact. The participation facilitates Orexo's commitment to sustainable development by adopting globally recognized frameworks and initiatives in order to achieve the global sustainable goals.

## Orexo's sustainability agenda

In order to define corporate sustainability priorities for the fiscal year Orexo drafted an activity plan early in 2017 based on an internal stakeholder dialogue. The plan was endorsed by Orexo's Board of Directors in the spring of 2017 and it sets out Orexo's ambitions and targets within the following four areas:

- Anti-corruption, see page 33.
- Human rights, see page 33.
- Environment, see page 34.
- Labor, see page 34.

# Sustainability management and policies

To demonstrate and implement Orexo's commitment to sustainable development and to raise knowledge internally about the subject, Orexo established a Sustainability Group at the beginning of the year. The group reports on an as-needed basis to the Board of Directors and includes relevant corporate functions that can influence corporate policies and strategies. The group is led by Orexo's Chief Financial Officer and is convened by Orexo's Sustainability Manager.

The Swedish organization comprises Research and Development and Corporate Headquarters, and is responsible for maintaining policies on a corporate level and enforcing global and local policies mainly in Sweden. The majority of Orexo's commercial activities are managed by Orexo US, Inc., which utilizes and enforces a Comprehensive Compliance Policy Program adapted for federal and state-level law and expectations.

## Business Compliance and Ethics Code

Supplier Code of Conduct

US Comprehensive Compliance Policies

Safety, Health and Environment Policies

Human Resources Policies

### Business Compliance and Ethics Code

Orexo's Business Compliance and Ethics Code acts as an umbrella policy for all other policies and is based on legislation, corporate values and recognized international standards, such as the International Bill of Human Rights, the Declaration of Helsinki<sup>1)</sup> and the UN Global Compact, and applies to all directors, officers, employees, consultants and temporary staff at Orexo AB and its subsidiaries. The code also exhorts individuals to raise questions and report suspected violation of ethical business conduct, without retaliation or any threat of retaliation.

#### Supplier Code of Conduct

As a company with most of its activities outsourced, Orexo's main sustainability impacts and risks are within the supply of goods and services. Orexo's supplier management is based on the company's Supplier Code of Conduct, which describes Orexo's expectations for suppliers in a variety of sustainability aspects.

In order to enforce the Supplier Code of Conduct, Orexo utilizes processes and procedures to ensure that patient safety, occupational safety and health, product quality and other applicable business compliance and ethics aspects of suppliers are acceptable. The processes and the procedures also ensure that applicable commercial aspects like supplier

reliability, financial stability and future commercial implications for the supply chain are adequately considered.

#### US Comprehensive Compliance Policies

Orexo US, Inc. adheres to rules and regulations set out on a federal and state level by enforcing a comprehensive policy program that addresses the approach to marketing and promotion of pharmaceutical products, including, but not limited to, aspects as expense and aggregate spend reporting and interaction with governments and healthcare professionals.

#### Safety, Health and Environment Policies

The Safety, Health and Environment policies and guidelines support managers and employees in their pursuit of a workplace free of injuries and illnesses and support the company's precautionary approach to environmental challenges.

#### Human Resources Policies

The policies describe the relationship between the employer and the employees and their respective obligations and rights. They cover matters such as recruitment, equal opportunities, discrimination, conflict of interest and health insurance and other employment benefits.

<sup>1)</sup> A recognized statement of ethical principles for medical research involving human subjects developed by the World Medical Association (WMA)



## #OPIOIDCRISIS

Substance use and substance-use disorders have created a significant public health burden. In 2008, the number of deaths in the United States involving prescription opioids exceeded the aggregated number of deaths from heroin and cocaine. In 2016 more than 64,000 deaths in the US were related to drug overdose and the economic cost of the opioid epidemic in 2015 is estimated to \$504.0 billion. The statistics leave no doubt, but they do not capture the full extent of the problem. Information indicates that tens of millions of Americans abuse prescription opioids, sedatives and stimulants and globally around 75 per cent of the burden of disease caused by drug-use disorders is associated with opioids. Meanwhile, the availability and access to scientific evidence-based treatment remains limited in many countries and only about 1 in 6 people worldwide suffering from drug-use disorders receives treatment.<sup>2) 3) 4) 5)</sup>

Orexo's key therapeutic area is within treatment of opioid dependence and ever since Zubsolv® was launched in the US, one of Orexo's main objectives has been to make treatment available for more people. Multiple initiatives have been launched and are still maintained; *RISE* allows patients to choose from a selection of online tools and resources and build the plan they feel is most helpful to their recovery and the purpose of the *REZOLV* study is to inform physicians, payers and patients about factors that may have a

positive effect on the treatment outcome. Furthermore, Orexo's *Out the Monster* campaign counters stigmatization associated with opioid dependence and the *Patients Savings Program* helps patients afford medication through lower out-of-pocket costs.

Through *The National Alliance of Advocates for Buprenorphine Treatment* Orexo also contributed to the increase in the number of patients that certified physicians are allowed to treat concurrently. As a result of the signing of the *Comprehensive Addiction and Recovery Act* into law in 2016 certified nurse practitioners and physician assistants are now also allowed to prescribe medication for opioid dependence treatment.<sup>6)</sup>

During 2017 the main target was to further improve Orexo's chain of supply, in order to maintain an affordable choice for payers and patients. In addition to the Patients Savings Program, the market access agreements in the US for 2018 will give patients in the commercial segment greater access to treatment with Zubsolv, which means most patients can obtain treatment under their commercial insurance plans. The approval of Zubsolv in the EU in November 2017 also gives the prescribers in the EU increased ability to treat the estimated 1.3 million high-risk opioid users in Europe.<sup>7)</sup>

<sup>2)</sup> Progress towards the Sustainable Development Goals E/2016/75

<sup>3)</sup> Centers for Disease Control and Prevention, Annual Surveillance Report of Drug-Related Risks and Outcomes – United States, 2017.

<sup>4)</sup> United Nations Office on Drugs and Crime, World Drug Report 2017

<sup>5)</sup> The Council of Economic Advisers, The Underestimated Cost of the Opioid Crisis

<sup>6)</sup> The National Alliance of Advocates for Buprenorphine Treatment (NAABT)

<sup>7)</sup> European Drug Report 2017: Trends and Developments

## Sustainable Development Goal #3 – Good Health and Well-being



The 2030 Agenda for Sustainable Development and the 17 Sustainable Development Goals were adopted by the United Nations in 2015. The goals and their specific targets together aim at ending poverty, protecting the planet and ensuring prosperity for all.

Sustainable Development Goal number 3 and its target 3.5 is of especial importance to Orexo. The goal seeks to ensure health and well-being for all, at every stage of life and addresses all major health priorities, including universal health coverage and access for all to safe, effective, quality and affordable medicines. The target is intended to strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.

## ANTI-CORRUPTION

A recognized risk for businesses within the healthcare sector is ethics and compliance violations in interactions with Healthcare Professionals (HCP), Healthcare Organizations and Government Officials. The legislation in this area is comprehensive in the US with the Physician Payments Sunshine Act as an example where transparent disclosure of expenses in relations with HCPs is required. In order to complement the legislation and to communicate internally and externally what values should permeate Orexo's business conduct, Orexo formed the global and local policy program that was described earlier in the report.

Commitment	Target 2017	Progress
We are recognised as a reliable and professional partner with high integrity	Initiate, approve and implement new Corporate Code of Conduct	Target met on-time in-full

During 2017, Orexo revised its Business Compliance and Ethics Code to further integrate the Ten Principles of the UN Global Compact. The Code was endorsed by Orexo's Board of Directors in June 2017 and implementation was conducted continuously during the fall of 2017, peaking with a celebration of the UN Human Rights and Anti-Corruption days in December. Through this and previous implementation sessions 89 percent of the organization have participated in training on compliance and ethics within business conduct.

For the future, Orexo aims to strengthen its efforts within this area and perform a more comprehensive implementation for employees that are at higher risk of being exposed to certain situations related to anti-corruption and other sustainability issue areas.

Orexo US, Inc. adheres to rules and regulations set out on a federal and state level by enforcing a comprehensive policy program that addresses the approach to marketing and sales of products, including, but not limited to, aspects such as expense and aggregate spend reporting and interaction with governments and healthcare professionals.

At the end of 2017 Orexo US, Inc. also deployed an updated ethics compliance hotline with the ability to file confidential, anonymous reports via either the telephone or the Internet and the possibility for reporters to anonymously track the progress of their reports.

Performance indicators	2017 (year-end data)	
	Parent company	Group
Implementation of Code of Conduct (of employees)	81%	89%

## HUMAN RIGHTS

Through the Business Compliance and Ethics Code Orexo supports the International Bill of Human Rights and the ILO Declaration on Fundamental Principles and Rights at Work. The company's highest risks of violation of these rights are, however, in the Supply Chain, beyond the direct control of the company. Hence, in the Human Rights issue area the company works with enhancing external performance and the commitment is enforced through the Supplier Code of Conduct and the Supplier Management Principles.

All suppliers are categorized in segments based on their complexity and criticality (Tier A-D; A highest, D lowest) and initial and continual assessments are performed accordingly. The sustainability assessments currently focus

on a handful of strategic suppliers and depending on the nature of the business and location of the assessed partner different sustainability aspects are evaluated and audited.

Orexo's main target for 2017 was to further integrate sustainability assessments into the Supplier Management Processes and the activity is still ongoing. Although the Company aims to strengthen its efforts within this area, it is important to emphasize that sustainability aspects are separately assessed when handling new and existing suppliers. The next step is to standardize and integrate these assessments into the established Supplier Management Principles, not the least to improve the efficiency of the processes.

In the end of 2016 all existing tier A suppliers had been

Commitment	Target 2017	Progress
We train our employees and assess our partners to reduce risks	Full integration of applicable Safety, Health and Environment issues in Orexo's tiered Corporate Social Responsibility due diligence process  Approved Tier A and new suppliers assessed according to integrated process	Process remains to be fully integrated

off-site audited with regard to all four sustainability issue areas (Environment, Human Rights, Labor and Anti-Corruption), with some minor remarks that are being monitored. New partnerships are assessed continuously and will be disclosed as applicable through primary channels of communication.

The partnership with Orexo's Swedish Facility Services supplier (a Tier B supplier) was updated with a separate Supplier Account Plan where Orexo's sustainability ambitions in the collaboration are more visible. The supplier is also a signee of the UN Global Compact.

## Performance of Orexo's Supplier Management Process with regards to sustainability

Performance indicators	Number of approved Suppliers			Sustainability Assessments performed		Number of approved Suppliers with open Sustainability issues		
	1-6	7-14	15-	Result	Target 2017	Major	Moderate	Minor
Tier A	•	–	–	100 %	100 %	NONE	NONE	3
Tier B	–	•	–	0 %	0 %	Not available		
Tier C	–	•	–	0 %	0 %			
Tier D	–	–	•	0 %	0 %			

## ENVIRONMENT

Orexo focuses its efforts within the Environmental Management to where the greatest risks of adverse environmental impact are found. This risk-based approach points out the supply of goods, product development and the handling of chemicals. Within these areas, the company is committed to monitoring and improving energy efficiency, consumption of materials and waste management and keeping emissions of pharmaceutical substances at low levels. The parent company has an Environmental Management System based upon ISO 14001 (not certified).

In 2016 the organization finalized an Environmental Aspect Assessment (EAA) that pointed out areas where Orexo has the highest potential environmental impact and is able to get the most return on invested efforts. The analysis is an effective tool to see where 'violation' of a sustainability aspect is more likely to occur and also to address

potential legislative compliance issues. The tool is at present not fully utilized in order to identify improvements beyond legislation.

During 2017 the main target was to use the information from the EAA as a base, and complement it with a higher degree of detail and find certain areas where Orexo could advance a greater environmental responsibility. In parallel, measures were taken to enhance the Corporate Risk Management Procedures and the activity remains to be finalized. Accordingly, the environmental risk and benefit analysis is yet to be finalized.

In order to realize Orexo's strategies of expanding the development pipeline, the R&D site in Sweden has intensified its research activities. In 2017 the number of produced R&D-units was increased by 208% compared to 2016 and the parent company's waste generation decreased by 18%.

Commitment	Target 2017	Progress
We are aware of our operational footprint and we continuously assess and minimize our environmental impact	Initiate and finish a risk benefit analysis to assess Orexo's current Environmental footprint and thus find improvement opportunities	Environmental risk and benefit analysis ongoing, but not finalized
	Environmental issues to be further integrated in Orexo's supplier due diligence activities	For Supplier due diligence, see Human Rights section

### Performance indicators

	2016	2017
Energy intensity <sup>1)</sup> in R&D facility [MWh/SEK million turnover]	3,9	3,9
Combustible waste [kg/employee at parent company]	69,8	53,8

<sup>1)</sup> Includes heating, cooling and electricity

## LABOR

Through the Business Compliance and Ethics Code Orexo supports the International Labour Organization's Fundamental Principles and Rights at Work. Since the impacts of Orexo's outsourced business conduct are managed within the Human Rights issue area this section comprises information on the performance within the Orexo Group.

Orexo has a workforce of approximately one hundred people evenly distributed between Sweden and the United States. As a company with its roots in Sweden and a subsidiary in another developed country, fundamental labor rights standards such as the abolition of child labor, maintaining freedom of association and elimination of forced and compulsory labor are generally both ethically and legislatively well developed. Orexo, however, recognizes the local and global challenges of inequality in respect of employment and occupationally inflicted health issues.

zation maintains an equal opportunities plan which is updated every three years and will be updated again in 2018. Data such as differences in sick leave, remuneration, recruitment, work load and parental leave/absence due to care of children are analyzed and actions are described in the plan if significant discrepancies are found.

In September and October 2017 a revised Safety & Health Risk Management Report and a new incident reporting procedure were launched in Sweden. Through the Risk Management Report Orexo identified nine areas where the risk profiles were not acceptable to the Occupational Safety and Health Committee and mitigation activities are still ongoing. The new incident reporting tool raised the number of near misses reported from zero (2016) to three (2017).

Incentive	Target 2017	Status
Our work on safety and health engages all employees	Enhancement of incident and accident reporting tool to foster a proactive safety culture	New reporting process implemented on time, in full
	Safety & Health Risk Management Report to be reviewed and further utilized to drive activities within prioritized areas	S&H risk management file updated and multiple improvement activities initiated

Through the Business Compliance and Ethics Code Orexo condemns any form of harassment or discrimination including such characteristics protected by applicable laws and regulations. To enforce the policy the Swedish organi-

zation maintains an equal opportunities plan which is updated every three years and will be updated again in 2018. Data such as differences in sick leave, remuneration, recruitment, work load and parental leave/absence due to care of children are analyzed and actions are described in the plan if significant discrepancies are found.

### Performance indicators

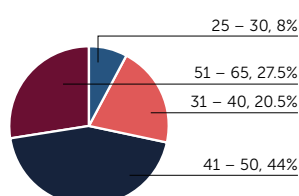
	2016 (year-end data)		2017 (year-end data)	
	Parent company	Group	Parent company	Group
<b>Employment<sup>1)</sup></b>				
Number of employees	55	102	53	90
- employees with a permanent contract	95%	97%	98%	99%
- employees with a temporary contract	5%	3%	2%	1%
Temporary workers	4%	24%	10%	32%
<b>Gender equality</b>				
Female employees	44%	57%	51%	56%
- women in management positions	50%	28%	44%	47%
- women in executive management team	-	0%	-	0%
Women in board of directors	-	29%	-	29%
<b>Other data</b>				
Employee satisfaction index <sup>2)</sup>	82	Not available	80	Not available
Employee absence due to illness <sup>3)</sup>	4%	Not available	2%	1%

<sup>1)</sup> Employees include workers with employment at the parent company Orexo AB and the subsidiary Orexo US, Inc., Temporary workers are excluded

<sup>2)</sup> Springlife – A score of 70 and above is classified as a high score and indicates that the conditions for employees carrying out their work are very good

<sup>3)</sup> Includes employees only

### OREXO GROUP AGE RANGES



# orexo



This is our **Communication on Progress** in implementing the principles of the **United Nations Global Compact** and supporting broader UN goals.

We welcome feedback on its contents.

## Read more on our websites

Our corporate website, [www.orexo.com](http://www.orexo.com), is our foremost communication channel. For more information about Zubsolv and opioid dependence in the US, see the websites targeting insurance companies, healthcare professionals and patients, [www.rise-us.com](http://www.rise-us.com) and [www.zubsolv.com](http://www.zubsolv.com).

Other channels that are updated continuously with information regarding our business or our environment are:

