

Prepared in accordance with the requirements of Section 56.3 of Financial Instruments Market Law of the Republic of Latvia, following the European Commission Guidelines on non-financial reporting.



# Content

- **✓ 3** Introduction
- **✓ 6** Business model
- ✓ 12 "Grindeks" policies and risk management
- ✓ 18 Health and safety
- **26** Environment protection
- **✓ 37** Ethics
- 40 Our highlights of 2018

# **Introduction**



For many years, operating in the healthcare area as the representative of pharmaceutical industry, the joint stock company "Grindeks" takes the leading position among pharmaceutical manufacturers in the Baltic States and makes a significant contribution to its shareholders and employees, as well as to society. "Grindeks" has a vivid history of more than 70 years during which industry's traditions have been perfected. To think and act responsibly is both our commitment and approach developed over years.

Today, corporate social responsibility is an integral element of "Grindeks" activity, becoming even more important than before. It plays a significant role in strengthening trust from our partners, patients and society as a whole.

Our mission is to care about patient health, motivation of our employees and interests of shareholders, being innovation based and environmentally friendly company.

Additionally to the annual business objectives, we have set a target to improve the company's activity in the corporate social responsibility area too. In 2018, "Grindeks" made a comprehensive performance analysis and defined three key priorities of corporate social responsibility:

- → Health and safety, comprising both our patients and employees
- Environment protection
- **Ethics**, demonstrating our ability to act fairly in the multifaceted pharmaceutical business

In order to evaluate our development in corporate social responsibility field according to the set priorities, we have identified and defined performance indicators of health and safety, and environmental protection that we find particularly important. We are constantly doing their measurements and monitoring progress, by combining data collection and testing, internal audits, equipment evaluation and management system's reviews.



#### Kirovs Lipmans, the Chairman of the Council of JSC "Grindeks"

On behalf of Shareholders' Council I welcome the company's ambition for constant growth and development, including the field of corporate social responsibility. Health and safety makes a fundamental background, as it affects both our employees and patients – everyone using our medicine. For me, acting in step with respect for the environment and doing business with clear conscience goes without saying, therefore I fully support company's initiated direction and defined priorities.



 $\it Juris\,Bundulis, the\,Chairman\,of\,the\,Board\,of\,JSC\,''Grindeks''$ 

By setting corporate social responsibility's priorities, we are pleased to admit, that it contributes to sustainable growth of the company, helps to achieve better performance indicators and financial results, as well as increases business value of "Grindeks". These priorities are the key to a strong long-term success.

**Business model** 

"Grindeks" is an international pharmaceutical company focused on research, development, manufacturing and sales of original products, generics and active pharmaceutical ingredients.

"Grindeks" specializes in the heart and cardiovascular, CNS, anti-cancer and gastroenterological medication therapeutic groups. A range of products covers a combination of original products Mildronate® (meldonium\*) and Ftorafur®, generics, food supplements and active pharmaceutical ingredients.

## Mission

We care about patients' health, the motivation of our employees and interests of shareholders. We are innovation based and environmentally friendly company.

# Branches and representative offices

Lithuania, Estonia, Belarus, Ukraine Azerbaijan, Georgia, Uzbekistan, Moldova, Kazakhstan, Armenia, Kyrgyzstan

## **Values**

- Employees
- Quality
- Innovations
- **✓** Stability

## "Grindeks" Group



JSC "Tallin Pharmaceutical Plant"



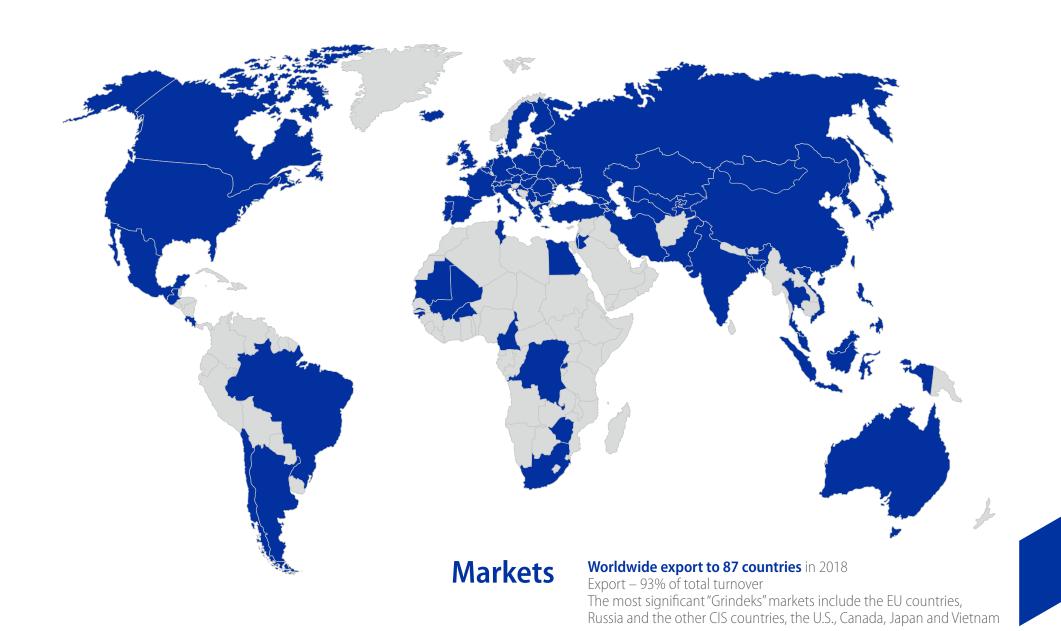
JSC "Kalceks" Latvia



"Namu apsaimniekosanas projekti" Ltd., Latvia



"HBM PHARMA" Ltd., Slovakia



# **TOP products**

#### **Final dosage forms**

**Brand produkts** 

**MILDRONĀTS**®



**FTORAFUR®** 



**Prescription medication** 









OTC produkts and food supplements









#### Most demanded active pharmaceutical ingredients

dexmedetomidine, pimobendan, oxytocin, zopiclone, medetomidine, atipamezole, detomidine and droperidol

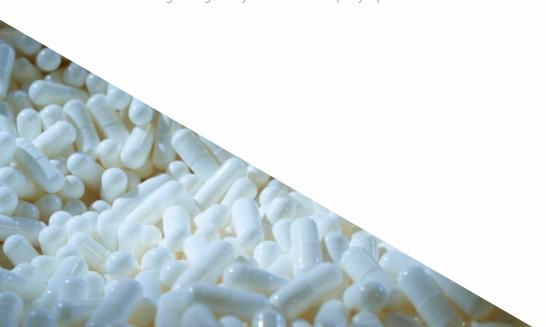


### **Business objectives for 2019**

In 2019, "Grindeks" will strategically focus on complex solutions to meet the needs of patients, will continue focusing on the new markets and it will diversify its operations thereby reducing business risks. Also in 2019, "Grindeks" will continue expanding its product range.

- Strategic markets of business development European Union and South East Asia countries
- ✓ Strengthening positions in Russia and the other CIS countries
- ✓ Business expansion of JSC "Kalceks"
- Expected increase in turnover of the Group by at least 12% in 2019
- ✓ Investments in 2019 9 million euro
- ✓ Successful maintenance of the new Medicines Verification System

Decrease in value or devaluation of national currencies in the CIS countries and changes in geopolitical situation are still the most significant business risks that might negatively affect the company's performance indicators.





# "Grindeks" policies and risk management

www.grindeks.eu/company/policies

CSR priorities

Health and Safety

Environment protection

Ethics

#### Company's policies



The Code of Ethics



Quality, Environment, Energy, Occupational Health and Safety Policy



Collective Agreement



Quality, Environment, Energy, Occupational Health and Safety Policy



The Code of Ethics



Privacy Policy

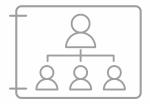


Collective Agreement

#### Risk management



Risk Management Policy



Since 2013, **the Code of Ethics of JSC "Grindeks"** is binding on all our employees, including in company's affiliates and representative offices. The Code is comprehensive and defines the Company's principles in:

- employment;
- ethics in scientific research and clinical trials;
- patient safety and pharmacovigilance;
- cooperation with healthcare professionals and institutions;
- prevention of conflict of interest;
- prevention of bribery and corruption;
- communication, information and documentation;
- disclosure of confidential information;
- fair business practice and partnerships;
- cooperation with patient organizations;
- conflicts and their prevention;

According to the Code, managers must ensure that all activities in their responsibility are performed in accordance with the requirements of the Code, as well as they are obliged to consult their employees on implementation of requirements of the Code.

In case of violation of the Code, employees are subject to disciplinary penalty – remark or reprimand, while in case of major violations of the Code, the Company is entitled to terminate the employment contract with employee.





**Quality, Environment, Energy, Occupational Health and Safety Policy** states, that Research, development, production and distribution of active pharmaceutical ingredients and final dosage forms manufactured by JSC "Grindeks" are managed in such a way to ensure product quality throughout its life cycle, to take care and to save energy resources and environment, and to encourage employee's safety and health protection at work.

#### The basic principles of the Policy

All activities are coordinated with:

- needs and expectations of shareholders and employees;
- expectations and satisfaction of customers and other involved parties of interest;
- legislative requirements of the industry and other regulatory enactments.

Implementation and continuous supervision of fulfilment of the current "Good x Practices" and "Guidance for Industry ICH Q10 Pharmaceutical Quality System" principles.

Continuous improvements within the framework of the planned resources:

- of the Quality Management System in accordance with the Standard LVS EN ISO 9001;
- of the Environmental Management System in accordance with the Standard LVS EN ISO:
- of the Energy Management System in accordance with the Standard LVS EN ISO 50001;
- of the Occupational Health and Safety Management System in accordance with the Standard LVS EN ISO 45001.

Continuous reduction of environmental impact of manufacturing process, products and services.

Continuous planning of energy purchases, energy consumption, increase of energy effectiveness and decrease of costs of energy recourses.

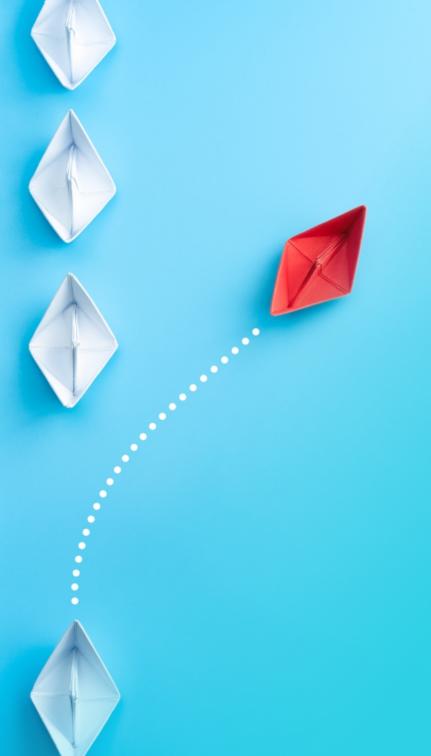
Continuous risk management and workplace risk reduction ensure safe and healthy working conditions, while preventing work-related accidents and occupational diseases and extending working life.







The Privacy Policy of JSC "Grindeks" certifies that the highest security requirements are followed regarding personal data coming at disposal of the company and privacy of data subjects is subject to maximum protection. The company invests resources and takes care of personal data in its day-to-day operations.





The Risk Management Policy of JSC "Grindeks" states, that company supports and promotes a comprehensive risk management for the benefit of our clients, owners, employees and partners. Our approach is based on grouping risk factors and linking them to respective business functions, thus department and unit managers are as equally responsible for successful implementation of Risk Management Policy, as they are responsible for an achievement of company's overall objectives. The Policy defines identification, assessment and management of risks covering all business areas of the company. For each of identified key risks, potential consequences and existing control procedures are assessed, and specific tasks for further action assigned.

The policy, as well as the company's internal procedure of risk management were both updated in 2016.

**The purpose of the Risk Management System of JSC "Grindeks"** is to ensure structured and systematic identification process of company's risks, assessment of identified risks accordingly to a value function of consequences/impact and frequency of occurrence/likelihood, and based on the assessment results, development of suitable risk prevention and minimization strategy with specific plan of activities and their performance control.

Everyone in the company is responsible for risk management.

At "Grindeks", following persons are involved in the risk management process:

- Chairman of the Board;
- Risk Manager;
- Managers of structural units (risk owners), who are risk management representatives of their unit, simultaneously;
- Chief Finance and Administrative Officer;
- Internal audit team:
- ✓ All employees of the company.

Covering all business areas of the company, there are total of 16 risk owners in the company.

**Health and Safety** 

# **Responsibility for PATIENTS**

The health and safety of our patients is one of "Grindeks" top priorities. We are fully responsible for the quality and safety of our products.

# High quality standards

We are aware of that representing pharmaceutical manufacturing means operating in one of the most responsible areas, as drug manufacturers are entrusted with patients' health and even life, and thus pharmaceutical manufacturing has to meet extensively high quality requirements.

In the drug manufacturing and quality assurance, "Grindeks" operations are licensed in accordance with:

- ➤ EU "Good Manufacturing Practice" certificates for final dosage forms and active pharmaceutical ingredients;
- ➤ EU "Good Distribution Practice" certificate for the drug wholesaler:
- Russian "Good Manufacturing Practice" certificate for final dosage forms.

In 2018, for the maintenance of "Good Manufacturing Practice" certificates the State Agency of Medicines made a successful inspection on manufacturing and quality assurance for six active pharmaceutical ingredients in the company, as well as the World Health Organization's inspection and 21 client audits on compliance with "Good Manufacturing Practice" standard requirements were held. For maintenance of "Good Manufacturing Practice" certificates for seven active pharmaceutical ingredients, an inspection by the U.S. Food and Drug Administration was held.





#### NO to counterfeit medicines!

In 2018, to comply with the requirements of the EU Falsified Medicines Directive, we introduced a new drug verification system that provides each package of medicines with an authentication code. The total cost of the project is 6 million euros.

# Safe pharmacovigilance

We continuously develop drug adverse reaction monitoring (pharmacovigilance) in all countries, where "Grindeks" medicines are available. "Grindeks" carries out pharmacovigilance in compliance with the standards of "Good Vigilance Practice" set by the European Union and with respective legislation of each country where products are distributed. In Latvia, the process is additionally regulated by the Republic of Latvia Cabinet Regulation No. 47 Adopted 22 January 2013 "Pharmacovigilance Procedures", as well as operations of company's Pharmacovigilance division are regulated by a number of company's approved internal procedures.

On a regular basis, "Grindeks" audits the quality of company's pharmacovigilance system, the State Agency of Medicines makes inspections, and additional audits are performed by our clients and partners too. "Grindeks" acquaints the competent authorities with drug safety related information. Any individual can report side effects of "Grindeks" medicines using company's webpage Grindeks.eu, by submitting a report on section Pharmacovigilance, as well as by sending an e-mail or via phone.



## Responsible clinical trials

In clinical trials, we ensure all processes of "Good Manufacturing Practice" and "Good Clinical Practice" that are related to manufacturing and logistics of investigational drugs and organization and performance of clinical trials are in accordance with following national and international guidelines and legislative acts:

in manufacturing and logistics of investigational drugs – Pharmaceutical Law, the Republic of Latvia Cabinet Regulations No. 289, No. 304, No 396, EudraLex Volume 4 of "The rules governing medicinal products in the European Union";

in organization and performance of clinical trials – the Republic of Latvia Cabinet Regulations No. 289, the quality, safety, efficacy and multidisciplinary guidelines developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), Regulation (EU) No 536/2014 of the European Parliament and of the Council, Directive 2001/20/EC of the European Parliament and of the Council and other European Commission guidelines, as well as other national legislative requirements of countries, where "Grindeks" performs clinical research.

Additionally within the company, procedure for performing clinical trials is regulated by seven SOPs (standard operating procedures) approved by "Grindeks".

In clinical trials, we partner with contract research organizations.



#### 1355 1422 Average number of employees in the Group JSC "Grindeks" in Latva Average number of employees 678 696 Employees with the university degree 61% 62% Average age of employees (years) 43.7 43.61 Average length of service (years) 10.94 10.5 Staff turnover rate 5.75% 5.27% **Proportion of females** Total number of employees 64% 63% Supervisory Council 25% 25% Board Executive team 50% 50% Management (running departments under direct supervsion of Chairman of the Board) 60% 53% **Trainings** Total hours of trainings 9409 11008 Average hours of trainings per 1 employee 13.88 15.82 **Student internships** Number of interns 93 41

2018

2017

# Responsibility for EMPLOYEES

Health, safety and wellbeing of "Grindeks" employees is constantly the company's management's top priority



Motivating work environment Being responsible employer is our obligation, and one of the ways to take care of employees' satisfaction is achieved by providing an attractive social program of Personnel policy.

#### "Grindeks" employees are ensured with:

- ✓ social guarantees and benefits;
- health and accident insurance;
- paid study leave and holidays;
- co-financed lunch;
- shuttle bus to work and back;
- sports classes and free access to sports center;



# Workplace safety comes first!

We are fully aware and strictly respect that pharmaceutical manufacturing is an industry where employees' safety has to be among management priorities constantly. The Occupational Health and Safety Management System of "Grindeks" is developed and certified in compliance with OHSAS 18001:2007 standard, whereas in 2019, to comply with the LVS EN ISO 45001 standard and to ensure continuous development, recertification of the system is planned. The company promotes a safe working culture and regularly organizes employee trainings on the occupational health and safety.

In occupational health and safety, "Grindeks" follows the STOP principle, based on risk identification and preventive actions in new product planning.

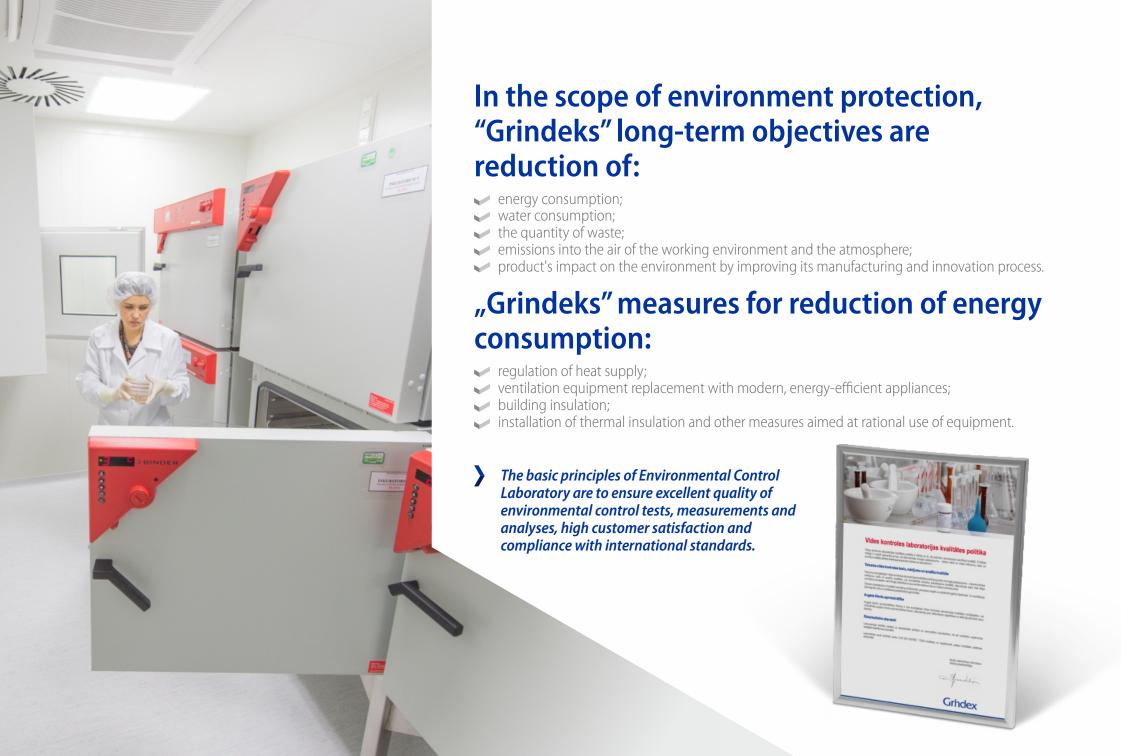
Pyramid of STOP principle



In the company, workplace accidents are list in accordance with the legislative acts of the To prevent causes of the accidents risks are i prevention measures are planned on a regul	Republic of Latvia. dentified and risk	2016	2017	2018
Indicator	Unit of measure	3	6	5
Workplace accidents (minor)	number	0	0	0
Workplace accidents (serious)	number	0	0	0
Workplace accidents (fatal)	number	69	129	117
Lost work days	number			

**Environment protection** 







# **Energy management**

#### Energy consumption of "Grindeks"



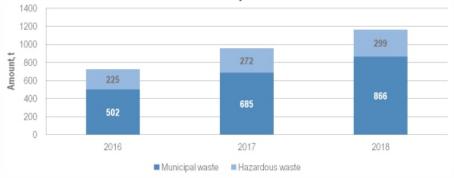
*In 2018, the total energy consumption of "Grindeks" decresed by 1.2% in comparison to 2017.* 

Energy indicator (energy consumption to output)	2016	2017	2018
Final dosage forms manufacturing	233.9	245.2	242.4
Active pharmaceutical ingredients manufacturing	80.45	44.67	42.68

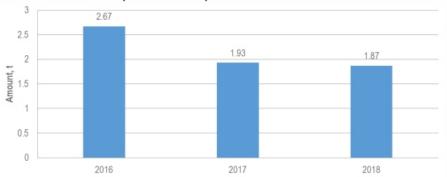


# Waste management

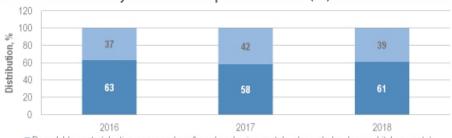
#### Distribution of hazardous and municipal waste



#### Hazardous waste (t) per tonne of production (API)



#### Distribution of recyclable and disposable waste (%)



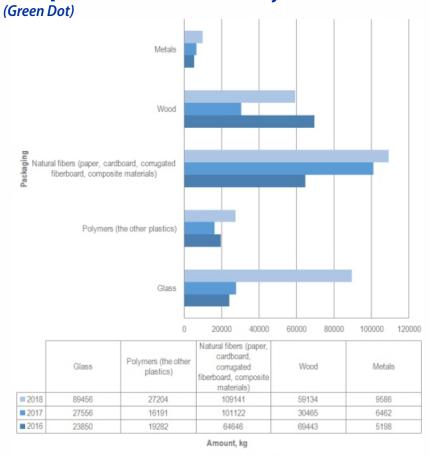
■ Recyclable waste (plastics, paper and cardboard packaging, metals, glass, sludge, leaves, kitchen waste)

■ Non Recyclable waste (unsorted municipal waste, construction and bulky waste)



In 2017, we improved our waste management system. In its framework, a number of glass, paper and plastics containers was raised and employees were educated to learn how to sort garbage already in the place of their origin. In 2018, we increased the volume of recyclable waste by 3% in comparison to 2017, and exceeded our goal by 1%.

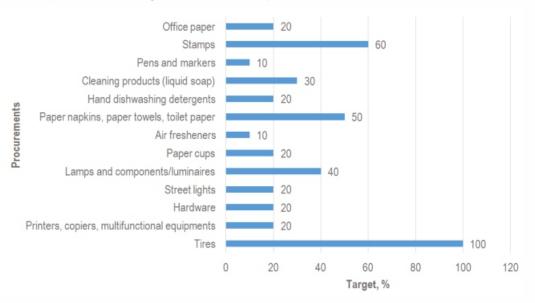
# Management of used packaging in cooperation with "Zaļais Punkts" Ltd.



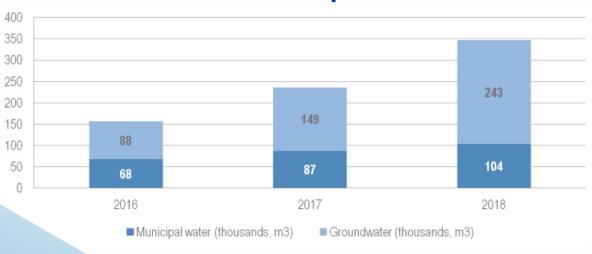
■2018 ■2017 ■2016



In 2018, we developed the principles of "green procurement" for specific purchases, while in 2019 we have set procurement targets (%) of the total procurement.



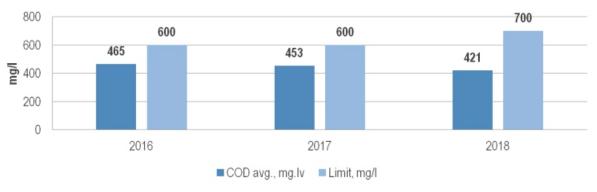
# "Grindeks" water consumption



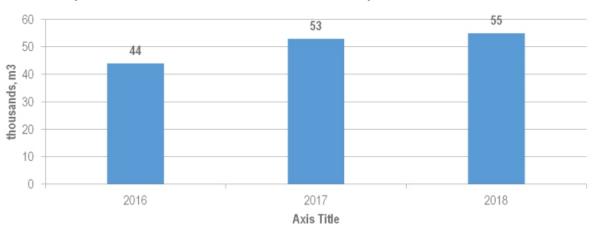


#### "Grindeks" wastewater treatment and purification

Concentrations of pollutants in wastewater discharged in centralised sewer system of Riga city, COD\*, mg/l

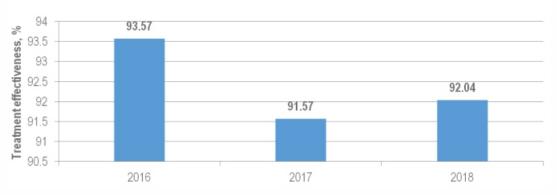


Amount of purified wastewater in wastewater treatment plant (thousands, m3)

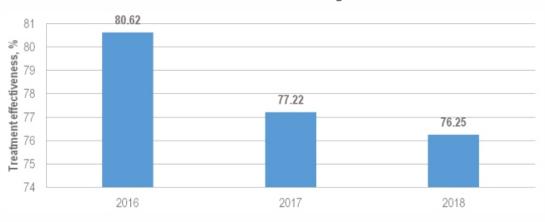




#### Industrial wastewater treatment effectiveness, COD\*/target (92)



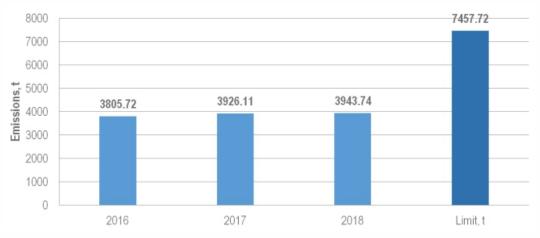
#### Industrial wastewater treatment effectiveness, N/target (75)



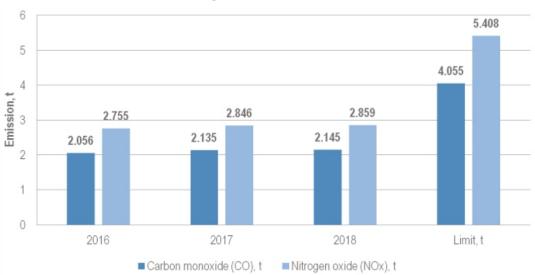
\*COD – chemical oxygen demand

# **Direct emissions**

Carbon dioxide (CO2) emissions



#### Carbon monoxide (CO) and Nitrogen oxide (NOx) emissions



# Volatile organic compounds (VOC) emissions 10 9 8 7 6 5 5 4.115 4 3 2 1 0

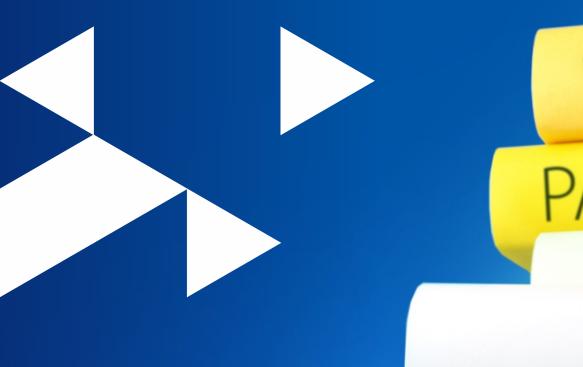
2018

Limit, t

2017

2016

## **Ethics**



PATIENT

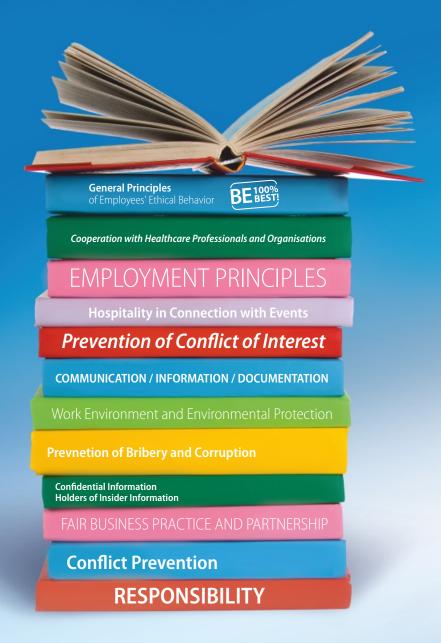
COMMUNICATION

CODE OF ETHICS

COOPERATION

OUR PEOPLE

Our ability to act fairly in the multifaceted pharmaceutical business is affected by all "Grindeks" employees, therefore, since 2013, we have our own guide – a comprehensive Code of Ethics, binding to all company's employees.



## Being ethical to society

Since 2016, when the principles of EFPIA Code (The European Federation of Pharmaceutical Industries and Associations Code) were enacted in Latvia and also incorporated in Regulations of Cabinet of Ministers of the Republic of Latvia, "Grindeks" is disclosing data on transfers of value to healthcare organizations, societies, doctors and other representatives of the industry.

"Grindeks" actively participates in the activities of public organizations in health and chemical industries (Latvian Generic Medicines Association (LPMA), Association of the Latvian Chemical and Pharmaceutical Industry (LAKIFA)) and is involved in the development and improvement of legislative acts aimed at promotion of access to medicines in the country.

In marketing communication that also includes product advertising, "Grindeks" respects respective national ethical principles and regulatory requirements by providing objective and truthful information on medication and without exaggerating their properties.

## **Effective patent protection**

To achieve effective protection of our intellectual property, we tend to handily combine the forms of protection – patent protection, trademark and design protection, as well as domain protection. "Grindeks" has developed guidelines on ensuring its intellectual property. The guidelines aim to ensure proper and correct registration and protection of the new and existing pharmaceutical preparations, medical ointments, cosmetics and nutritional supplements, patent protection of new and existing inventions, as well as use, maintenance and protection against infringements of intellectual property at "Grindeks" disposal.

## Reliable and ethical partnerships

It is of great significance to us that not only we respect ethical behavior in business, but so do our partners. The "Grindeks" "Principles of cooperation in international procurements" state that all our procurement processes are intended to provide effective cooperation principles, following good procurement practice and business ethics.

At "Grindeks", we believe that the sense of social responsibility has to be reflected in all our everyday operations and decisions we make. Together, our team's day-to-day performance creates shared achievements, initiatives, public recognitions and awards, resulting in "Grindeks" highlights of the year.

"Grindeks" highlights of 2018









"Grindeks" named 3rd best employer in the manufacturing sector in Latvia by the CV-Online Latvia survey "Top Employer 2017"































From Individual Research Projects to Strategic Long-Term Cooperation: "Grindeks" and Latvian Institute of Organic Synthesis Sign Agreement















"Grindeks" ranks 2nd in the Good Practice Competition of work safety "Golden Helmet 2018", this year dedicated to risk prevention measures related to managing dangerous substances







