lek

a Sandoz company

Sustainability Report 2017 – Lek d. d.

Contents

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* The EU Ecolabel or EU Flower reflects the manufacturer's commitment to continual environment management improvements.

2017 Key facts

951 mil. EUR

NET SALES IN 2017 OR 6.2% MORE THAN IN 2016.

2 bil. EUR

NOVARTIS' INVESTMENTS IN SLOVENIA OVER THE LAST 15 YEARS, OF WHICH 170 MIL. EUR WAS MADE IN 2017.

+8%

EMPLOYEES AT THE END OF 2017.

93%

SHARE OF LOCAL EMPLOYEES IN SENIOR MANAGEMENT.

34 mil. EUR

SAVED OVER THE PAST FIVE YEARS THANKS TO MORE THAN 5,500 IDEAS SUBMITTED TO TH!NK NOVARTIS.

–24%

REDUCED EMISSIONS OF VOLATILE ORGANIC COMPOUNDS.

+7%

IMPROVED WATER EFFIENCY.

5 mil. EUR

INVESTMENT IN ENVIRONMENTAL PROTECTION.

Letter from the President of the Board of Management[1]

Dear colleagues, partners and stakeholder,

Access to healthcare is the core principle of Novartis and our shared social responsibility. With numerous projects, in 2017 we strengthened the culture of quality and innovation, which is a prerequisite for bringing treatment closer to patients around the world. While the high quality of our processes has been proven and validated by the results of various internal and external assessments, **innovation has been strengthened as a movement at all our sites**, and that is why it has been specifically emphasized in this year's report.

Innovation is the ticket to a sustainable future; reducing the consumption of materials and energy, minimizing our impact on the environment and optimizing the work of our employees. Over 5,500 ideas for improvements proposed by employees through our internal application Th!Nk Sandoz, shows that innovation is truly at home in Lek; we contributed a third of the proposals. It celebrated its 5th anniversary as the global tool Th!Nk Novartis, available to employees in all Novartis companies in Slovenia. In Lek alone, we created savings of around 34 million Euros during this period by adopting the proposals.

Improvements in processes and procedures can in no way be limited to one tool; most were re-created directly in operations and production. Continuous improvements are an integral part of our everyday thinking and operations as well as in our investment activities where we decide on the best available technology at the time of investment.

In 2017 Novartis invested almost 170 million Euros in Slovenia, since 2003, it has already invested more than 2 billion Euros. We preserved our role as one of the leading Sandoz locations for the introduction of new medicines onto global markets; we launched more than 15 new molecules, more than 975 new medicines onto 90 markets worldwide. We have consolidated our position as the second largest provider of generic medicines in Slovenia and together with other Novartis divisions have retained the position as the leading provider of medicines on the Slovenian market.

This kind of development is simply not possible without high quality personnel; we invest a lot in finding the best colleagues. We are also innovative in this field, using approaches such as the Novartis Career Breakfast, which has been awarded as the best practice in the field of employee development, and the seventh Regional BioCamp. For the fifteenth consecutive time, we received the Top 10 Education Management Award for the full management of employee education and ranked among the most prominent employers in Slovenia. We employed 410 new employees and completed the year with

[1] GRI GS disclosures 102-14, 103-1

more than 3,880 full-time employees, including more than 480 Masters and Doctors of Science.

We pay great attention to the health and safety; this year, we recorded eight cases where employees were on sick leave due to injuries at work, the LTIR indicator was 0.21, which is more than the previous year (0.05). We did not record any serious injuries at work that would have any permanent health consequences. In order to prevent and reduce employee injuries, we focused on preventing potentially serious incidents and preparing preventive measures. We carried out nearly 2,800 safety walkthroughs to prevent dangerous behavior and conditions that could lead to incidents or injuries.

Employees contribute to the social environment through various socially engaged campaigns. More than 300 employees from all sites in Slovenia joined the campaign "Join the List", organized by the Slovenian Association of Patients with Lymphoma and Leukemia, thus enrolling in the national register of potential donors of the bloodstream stem cells. For the 13th consecutive year, 600 employees participated in voluntary activities where they helped people in cooperation with the local community. We also developed our work with local communities and neighbors through gatherings, visits and familiarization with our sites and new forms of cooperation.

With our activity, we try to minimize our impact on the natural environment as much as possible, which is achieved through improvements in production processes, taking into account environmental aspects in the research and development phases, recycling and installing environmentally advanced technologies. We invested 5 million Euros in environment protection in 2017.

Among other things, we optimized the process in Mengeš, which uses methylene chloride in its production and almost halved its consumption, and we switched additional emissions from production to the RTO. In Lendava, the optimization of closed-loop water reduced the consumption of fresh water and increased cooling efficiency. In Ljubljana, we further reduced noise levels by installing a silencer, while in Prevalje we prepared a study and prepared all the necessary steps to optimize the pre-treatment of waste water. It should be said that the demands of Novartis standards in certain HSE indicators, such as content of active pharmaceutical ingredients in wastewater, exceeds the requirements of the applicable national and EU legislation.

Our joint efforts reduced the total emissions of volatile organic compounds into the atmosphere by 24%, and improved the efficiency of water use by 7%. In spite of increased production, the quantity of waste produced fell by just under 1% and the quantity of waste per ton of product by 10%. The use of energy was higher by 0.4%, while the efficiency of energy use improved by 9%.

In Lek, we have certified the environmental management system in accordance with the requirements of the ISO 14001: 2015 standard, with the EU Regulation 1221/2009 (EMAS) and the Occupational Health and Safety System according to BS OHSAS 18001: 2007 standard. In November, we successfully defended the new requirements of the EMAS Regulation following the issue of the 14001: 2015 standards in emphasizing environmental impacts throughout the life cycle of the product. We also fulfilled all the requirements for re-certification under the Program of Responsible Care for the Chemical Industry.

All of this was a prerequisite for increasing our role within the Novartis group, including the transfer of the production of originators to our sites. In April, we laid the foundation stone for the new production plant for the wide-spectrum antibiotic Amoxiclav in Prevalje. At Aseptics Ljubljana, we successfully introduced the first formulations of a biosimilar with the active substance rituximab (Rixathon) onto the EU market.

In Lendava, we installed a technologically demanding packaging line for blister packets, thus enabling the transfer of the first Novartis Pharmaceuticals pharmaceutical packing to Slovenia; it is a medicine used for transplantation, and will be provided by Novartis from Lendava to patients worldwide. The further development of the unit will enable the decision to continue transferring packing of several key innovative pharmaceuticals of Novartis Pharmaceuticals and supplying markets from Lendava.

In Mengeš, we produced record quantities of the active ingredient used to treat anemia in cancer and kidney patients. Due to increased demand, we started to build an additional production line. At the end of the year, we also started a new investment project in Mengeš, which will bring the production of high-value active ingredients to the site and further consolidate our position as a key Novartis Center for Biotechnology Excellence.

I would like to thank all my colleagues for continued work in reaching our HSE goals and improved cooperation with our social environment.

Zvonko Bogdanovski,
President of the Board of Management

1. Company profile

Company name: Lek Pharmaceuticals d. d.[2]
Abbreviated name: Lek d. d.
Registered Office: Ljubljana
Business address: Verovškova 57,
1526 Ljubljana, Slovenia
Registration number: 1732811000
Standard Classification of Economic Activities in the European Community (NACE):
21.200 Manufacturing pharmaceutical preparations
Registered at: District Court in Ljubljana
under entry number: 1/36542/00

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[2] GRI GS disclosures 102-1, 102-3
[3] GRI GS disclosure 102-53

1.1 Key data for 2017

1.1.1 Operations in 2017

Table 1: Key figures for 2017

Indicator	Unit	31. 12. 2017	31. 12. 2016	31. 12. 2015	Index 2017/2016
Number of employees		3,889	3,599	3,361	108
- Ljubljana site		2,079	1,923	1,877	108
- Mengeš site		1,058	1,002	904	106
- Lendava site		484	423	355	114
- Prevalje site		261	246	225	106
- hired warehouse		7	5		140
Production output*	1,000 t	5.72	5.20	5.22	110
Net sales	In mil. EUR	951.480	895.270	849.413	106
Liabilities	In mil. EUR	1,120.868	1,032.615	988.717	109
Capital	**In mil. EUR**	**773.979**	691.787	616.658	**112**

* Due to extremely large differences in the weight of various types of products and the manufacturing structure resulting from changes in demand, the annual data is difficult to compare. The comparison of production outputs between the years is therefore not entirely relevant. The differences in product weight should also be taken into account when reading data on the efficiency per ton of product. For example, the weight of biosimilars is significantly lower compared to certain self-medication drugs, yet their manufacture requires larger quantities of water and energy resources. At the same time, the financial value of the manufactured biosimilars is higher.

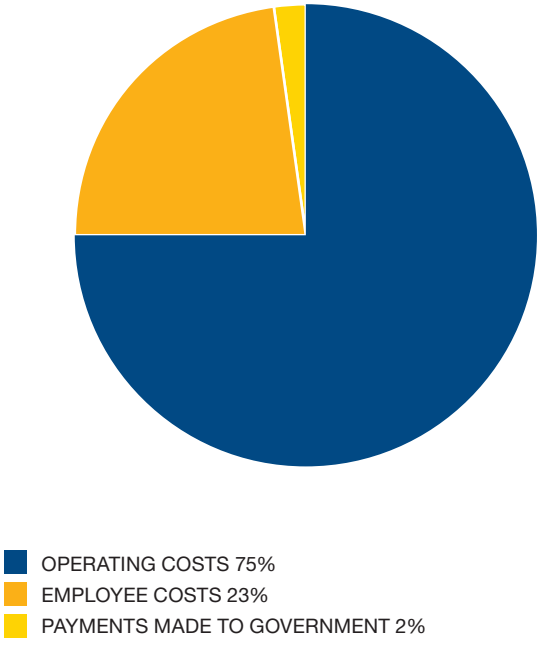
Economic performance[4]

In 2017, Lek, created 951.480 million Euros of net sales, this represents a 6.2% increase compared to the previous year. Net profit for the accounting period amounted to 83.18 million Euros.

Direct economic value created reached 965 million Euros (901 in 2016), of which 84% (810 million Euros) was **economic value distributed**; the largest proportion (75%) representing **Operating Costs**, which reached 605 million Euros. **Employee Costs** were 191 million Euros (23%). In 2017, no **Payments to Providers of Capital were made, and Payments to Government** amounted to 14 million Euros (2%).

The tax relief value due to investment in research activity amounted to 6.267 million Euros (3.191 in 2016) and public subsidies in the amount of 1.050 million Euros (543,000 in 2016).[5]

Chart 1: Structure of Economic Value Distributed



[4] GRI GS disclosure 201-1

[5] GRI GS disclosure 201-4

Table 2: Major environmental and social impacts[6]

Indicator	Unit	31. 12. 2017	31. 12. 2016	31. 12. 2015	Index 2017/2016
Efficiency of energy resource use	GJ/t	225	247	236	91
Water use efficiency**	m^3/t	598	646	680	93
Waste volumes – efficiency	t waste/t product	6,5	7,2	6,7	90
VOC emissions – efficiency	t VOC/t product	0.011	0.016***	0.018	69****
LTIR* – showing the frequency of work-related accidents and illnesses, resulting in the use of sick leave		**0.21**	0.05	0.12	420
TRCR* – showing the frequency of work-related accidents and illnesses, resulting in the use of sick leave, requiring more than basic first aid		**0.26**	**0.28**	**0.39**	93

* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 3.3.1 Monitoring of work-related injuries.
** The table shows the efficiency of use for all waters at Lek (for technological and cooling purposes).
*** The change arises from the error in entering the data into the DMS system and consequently in the Lek d. d. Report on Sustainable Development for 2016.
****Rounded to three decimal places.

More than 300 employees from all Novartis sites across Slovenia were enrolled in the National Register of Potential Blood Donor Stem Cells (SC).

1.1.2 Highlights and milestones of Lek's operations in 2017

In 2017, we continued to successfully operate and implement our mission – to discover new ways of improving and extending people's lives – by paving the way for new approaches that enable people around the world to access quality health care.

Highlights of operations in 2017:

- Positive employment trend: in 2017, we employed **410 new colleagues**. We ended the year **with more than 3,880 full-time employees; 47%** of employees **hold a university degree**, of which **more than 480 hold masters and doctoral degrees**. In the last six years, we have created **more than 1,800 jobs**.

[6] GRI GS disclosures 302-3, 403-2

- **Continued innovative human resource initiatives**: among which were the seventh Regional Bio Camp and the second Novartis Career Breakfast. The latter represents a successful and innovative human resource initiative to encourage Slovenian experts who work and study abroad to return to Slovenia.

- **Changes at the top**: In August, **Vojmir Urlep** was succeeded by **Zvonko Bogdanovski** as President of the Board of Management of Lek and President of Novartis in Slovenia. The Supervisory Board also appointed a new Management Board for a period of five years: Daniel Michalek, Finance Director, Samo Roš, Director of Human Resources, Ksenija Butenko Černe, Director of Legal Affairs, Andrej Pardo, Commercial Activities, and mag. Marjan Novak, Worker's Director.

- **High dynamic of development activities**: in the Development Center Slovenia we completed the development and filed **17 dossiers for medicines** and **three dossiers for active ingredients** on the world's most demanding markets. Sandoz successfully launched 18 medicines, developed in the Development Center Slovenia in the USA, European Union, Canada, Mexico, Japan, Australia and Brazil.

- Maintain our role as one of the **leading Sandoz sites for introducing new medicines** to the global market: we launched more than 15 new molecules, meaning more than 975 new medicines on 90 markets worldwide.

- **Maintain our highly dynamic investment activities**: Novartis allocated almost **170 million Euros** to invest in Slovenia in 2017, meaning that since 2003 they have invested **more than 2 billion Euros**. More than 1.1 billion Euros was invested in development, with the rest being invested in upgrading and broadening production capacity. In April, the foundations were laid for the new plant for the production of the wide-spectrum antibiotic Amoxiclav.

- **Increase total production capacity growth:** we reached our total production capacity growth. Medicines we manufacture in Slovenia are marketed around the world via the broad Sandoz and Novartis sales network. Certain key medicines also contain active ingredients which are the result of our own development and production.

- **Maintain our position as the leading supplier of medical products in the Slovenian market**: we have consolidated our position as the second largest supplier of generic medicines in Slovenia. With the growth of our market share to **27.8%**, we have consolidated our leading position in over-the-counter medicines. Together with other Novartis divisions, **we retained our position as the leading supplier of medical products in the Slovenian market.**

- **Quality maintenance at a high level**: through various activities and training, we continued to develop a culture of quality. We follow new requirements, such as the area of data compliance, and integrate them into the company's quality system. The high level of quality in Lek confirms the successful completion of numerous inspections and Novartis audits. We are particularly proud of the excellent outcome of the three inspections carried out by the US Food and Drug Administration (FDA) in Ljubljana, Mengeš and Prevalje.

- **Continue to protect the environment**: we are constantly working to reduce the environmental impact of our activities, and therefore we have certified the environmental management system in accordance with the required ISO 14001:2015 standards, ES 1221/2009 regulations **(EMAS)** and the health and safety systems in accordance with OHSAS 18001:2007 standards. In November 2017, we successfully met the new requirements of EMAS (2017 version), which followed the changes following the issue of **ISO 14001:2015** standards, emphasizing the environmental impacts throughout the life cycle of medicinal products. We also met all requirements to extend our certification in accordance with **Responsible Care initiative**.

- **High level of social responsibility:**
  - In an exceptionally successful campaign entitled "Get on the list" organized by the Slovenian Association of Patients with Lymphoma and Leukemia, **more than 300 employees** from all Novartis locations across Slovenia enrolled in the National Register of Potential Blood Donor Stem Cells (SC) thus contributing to the Slovenian register exceeding the incredible limit of 20,000 donors.

  - By signing the **Charter of Diversity Slovenia** has joined more than 7,600 organizations in Europe that understand the positive effects of diversity management.

  - About 600 employees from Novartis sites in Ljubljana, Mengeš, Lendava and Prevalje participated in more than 20 volunteer activities. They spent their time helping and socializing with more than 700 people. In 13 years of volunteering, Novartis employees in Slovenia devoted **more than 28,000 working hours to working with the local community and helped more than 12,000 people.**

1.1.3 Awards and acknowledgements

In 2017, Lek and its employees received a number of awards and acknowledgements:

- Lek received **a Golden National Innovation Award**, from the Slovenian Chamber of Commerce, and a Silver award from the Slovenian Chamber of Commerce of the central Slovenian region. Lek's experts received the golden award for innovation for a more child-friendly antibiotic in the form of a fast-purifying tablet.

- Amongst **the most reputable employers** in Slovenia according to a survey carried out by recruitment portal MojeDelo.com for the sixth time in a row.

Former President of the Board of Management of Lek and Novartis in Slovenia, Vojmir Urlep, received the Minařik's award.

Špela Bernhard and Samo Roš received the award for best practice in the field employee development among large companies for the Novartis's Career Breakfast.

- Lek Biopharmaceuticals was awarded a **certificate** of long-term fruitful cooperation in the field of research and expertise by the **Biotechnical Faculty**.
- Former President of the Board of Management of Lek and Novartis in Slovenia, Vojmir Urlep, received the **Minařik's award** from the Slovenian Pharmaceutical Society for outstanding contribution to the development of the pharmaceutical profession.
- Novartis's Career Breakfast was among the best employers of the Golden Thread, a project run by the newspaper Dnevnik, awarded with the **Gold Practice Award for 2016**, at the HR & M Conference hosted by Planet GV, as well as **an award for best practice in the field employee development** among large companies.
- We received our 15th **TOP 10 Education Management Award**.
- The Sandoz award in the category of *Working with Integrity* for successfully completing the demanding development of prolonged release tablets for the US market was awarded to the team of the Development Center Slovenia.
- A researcher from the Development Center Slovenia received the Sandoz award for development in the category of **Newcomers of the Year**, and the development team of bioequivalence was awarded the Sandoz Award for development in the *Team of the Year* category.

Lek received a Golden National Innovation Award from the Slovenian Chamber of Commerce.

1.1.4 Health, safety and environment (HSE) objectives

At Lek, we are committed to responsible business operations and good practice in the field of HSE. Novartis strives for the efficient use of natural resources and for reducing the environmental impacts of its activities and products throughout the life cycle, therefore setting the right goals in the area of environmental protection is of the upmost importance. Specific goals are defined with clearly defined responsibilities based on legal regulations and corporate guidelines, as well as our commitment to integrity and ethical principles.

In the field of HSE, we follow Novartis long-term plans, whilst realizing our annual short-term goals. We consider the HSE Policies when defining and realizing our targets. These policies are supplemented and amended with the revision of HSE Regulations.

We monitor targets for each individual site as well as on a corporate level. Data for reporting requirements is collected and confirmed in the Novartis Data Management System (DMS). We are constantly improving the efficiency of our environmental management by including all employees in the environmental care system, open communication with internal and external public and regular assessment of the system performance.

Production processes for pharmaceuticals at the Ljubljana, Prevalje and partly at the Lendava sites are grinding, granulating, pelleting, packing, etc.; physical processes that differ considerably from biological and chemical processes in the production of active ingredients. Consequently, their impacts also vary, particularly those pertaining to the environment (waste, atmospheric emissions, and others).

By indicating impact management we present our annual objectives for 2017 and the realization of our long-term 2020 objectives.

Lek's short term HSE targets for 2017

Area	Indicator	Target	Realised in 2017 (for all of Lek)
Health	Employee exposure to hazards that exceed the permitted values	0	0
Safety	Identifying risks of injury	12–15* walkthrough inspections/200,000 working hours. Near misses 35–50*/200,000 working hours.	**Reached.** 2,796 walkthrough inspections and 1,455 near misses detected.
	Serious injures and fatalities	0	0
	Injuries with medical assistance, with the possibility of serious injury	0	**Not reached.** 3
Environment	Reduction of pollutant emissions to water	100% assessment of Eco toxicity of APIs with risk assessment.	**Reached.**
	Reduction of greenhouse gas (GHG) emissions	4%	**Not reached in its absolute entire value. Improved efficiency of 3%.**
	Reduction of non-recyclable waste per ton of product	Project to increase the proportion of recyclable waste by 2–4*%.	**Reached. The share of recyclable waste was increased by 2%.**
Corrective measures	Implementation of corrective measures	Implementation without overdues.	**Not reached.** On average 26 overdues per month.
BCM index	Assuring Business Continuity	20–22*points	**Reached.** 23.7 points
NEM index	Readiness for emergency response	20–22*points	**Reached.** 22 points

* Values vary depending on site location.

Novartis' long-term HSE targets for 2020

Area	Indicator	Target	Status 2017
Health	Exposure of employees to dangers exceeding permissible limits	0	0
	Reducing the rate of abseentism	–10% vs. 2010	–6%
Safety	Serious injures and fatalities (SIF)	0	0
Environment	Reduction of greenhouse gas (GHG) emissions	–30% vs. 2010	–35% 2010: 94,758 t 2017: 61,688 t
	Reduction of pollutant emissions to water	10-times below PNEC*	Established monitoring system to check the status of emissions and risk to the environment for 2017.
	Reducting of non-recycable waste per ton of product	– 30% vs. 2010	–67% 2010: 2.48 t/t of product 2017: 0.61 t/t of product

* Concentration of a substance below which no adverse effects on the environment are expected.

Lek HSE targets for 2018

Area	Indicator	Target
Safety	Serious injures and fatalities (SIF)	0
	LTIR (own employees + employees hired through employment agencies) with potential SIF	0
	Walkthrough inspections per 200,000 working hours	12–15
	Almost incidents and good catches per 200,000 working hours	35–50
Health	Exposure of employees to dangers exceeding permissible limits	0
Environment	Reduction of pollutant emissions to water	3%
	Reduction of greenhouse gas (GHG) emissions due to energy use	≥ 5%
	Reduction of total non-recyclable waste	≥ 4%
Corrective measures	Number of overdue measures (CAPA)	0
	Number of overdue measures on inspection	**0**
BCM-index	Assuring Business Continuity	20–22 points
NEM-index	Readiness for emergency response	20–22 points

1.2 About us

Lek Pharmaceuticals d. d. (hereinafter; Lek) is a joint-stock company, 100% owned by Novartis Pharma AG. Its core business activity is manufacturing pharmaceutical preparations. On 31. 12. 2017, Lek had 100% ownership share in Sandoz Pharmaceuticals d. d. and 74.5% ownership share in Wastewater treatment plant Lendava d.o.o.

In 2017, there were no changes to the size, structure or ownership of Lek, moreover no merging activities or joint investments were made.

600 Novartis employees from across Slovenia took part in more than 20 volunteering activities within the Community Partnership Day.

Key principles of our corporate responsibility

Accessible treatment

We believe all patients deserve quality treatment. Our sites in Slovenia are thus development and production centers seeking ways to innovative and affordable pharmaceutical products.

Responsible operations

Trust of patients and customers is based on the quality of our products, ethical management of the company and ethical behavior of the employees.

Reporting

Lek, a Sandoz company, regularly monitors and measures sustainability indicators of its operations. Each year, it publicly presents economic and environmental impacts and social aspects of its operations, and strives for transparency and comparability of information.

Our people and community

We strive to provide our employees with a stimulating work environment as well as safe and healthy jobs. We are actively involved in local communities, mostly through employees' volunteer work and our philanthropic activities.

Environmentally sustainable operations

The active environmental policy is implemented through a number of activities to protect the environment which often goes beyond mere fulfillment of statutory provisions. Business decisions are made in consideration of direct and indirect environmental impacts. We use natural resources with deliberation and increase the efficiency of their consumption.

We are developing a society of talent, knowledge and co-operation

Dr. Darja Ferčej Temeljotov

Dr. Darja Ferčej Temeljotov, Head of Strategic Programs at Lek, encourages the search for new solutions also in connecting the academia and the pharmaceutical industry. In 2017, she was awarded a certificate for successful cooperation by the Faculty of Pharmacy at the University of Ljubljana.

What is the purpose of the many programs for the development of innovations, talents and cooperation with the academic sphere?
Most importantly, we encourage open thinking, cooperation and passion for professional and personal growth. Of course, no culture can be built overnight. Lek's culture of innovation has a tradition of ten years.

By means of a planned and systematic approach, we succeeded in launching an innovation movement that has passed through the entire organization. Its messengers are innovators, who in all units and at all Lek sites promote and connect employees to open, critical and constructive thinking and action. We try to be the best in innovation, curiosity and learning, in the implementation of new ways of operating and exceeding our goals.

How would you summarize the key points of Lek's wide innovation movement?
We build on five priority pillars, all of which contribute to shaping the organization for the future. It is of fundamental importance that we want to enable our employees to fully develop their potential. The second and third pillars promote innovative solutions and develop new ways of working and operational excellence. All columns are constantly growing and being renewed. In the fourth, we learn to master large amounts of data and digital technology, and in the fifth, in cooperation with the research sphere, we develop a wider society, its talents and knowledge.

Where is the greatest opportunity for improvement?
Opportunities for improvement are hidden and discovered in all business functions. The most technical and "lean" improvements are in production, in Biopharmaceuticals, the Development Center, Quality and Supply, they are engaged in advanced data use and simplification of processes. A friendly working environment is important for all, including the arrangement of rooms, the installation of small items and accessories, and good interconnection and knowledge of neighboring units.

Have you innovated in an innovative way?
Mass innovation in today's sense of the word was undertaken systematically six years ago. We are striving for fresh approaches, they are of course crucial. At that time, as a pilot project, in Slovenia, the first within Sandoz, we created an online application, a simple and accessible to all employees that is now called Th!nk Novartis and is being implemented throughout Novartis.

The five pillars of our innovation culture

Development of employee potential	Encouraging innovative solutions	Development of new work methods and operational excellence	Masterig large amounts of data and digital technology	Development of the wider society, talent and knowledge in co-operation with the research sphere

The winning team of 2017 Regional BioCamp.

We talked a lot about the importance of improvements, synergies between different existing initiatives, and encouraged colleagues to submit all their suggestions through a web application, which started to become our library of ideas and good practice. Once a year, the Week of Innovation full of various events takes place at all sites.

What are the results of collecting ideas?

In five years, we have recorded more than 5,500 ideas in Slovenia, which have brought more than 34 million euros of financial benefits. At least, if not even bigger, the importance of improvements in the development of organizational culture, mutual cooperation and the identification of further opportunities for improvement, building new skills and working methods.

Altogether, it certainly contributes significantly to raising the competitiveness of the company, as well as to the motivation and sense of belonging of its employees. We are aware of the importance of interdisciplinary integration inward and outward, how curiosity and knowledge sharing are important. For this reason, throughout the year, we prepare a range of events that connect internal and external talents and enthusiasts, and open the door to new knowledge and innovative thinking for the future.

How much contact do you have with young people and students?

In promoting young talents we work with secondary schools and faculties of natural sciences, for which we prepare meetings, both in Slovenia, in laboratories and in production, as well as at career fairs and faculties.

We often open our doors production of solid and sterile products, biopharmaceuticals and development center to our students, and listen to their questions and wishes. We offer students the possibility to do their practical training with us, undergraduate thesis, master's thesis, doctoral thesis work and regular employment.

We start the year with Novartis' career breakfast for young talent who study or work abroad. We developed it in Lek with the hope that they would visit us and recognize the opportunities for work and development in our country. In 2017, we became an active partner of the project We will be engineers, intended for students. A special form of integration with young people is the Regional BioCamp. This is a unique event in Slovenia, which presents an excellent opportunity for students - top young talents - to meet with experts and managers from the world of pharmaceuticals as well as from medical practice and various fields of academic research. At the same time, they have the opportunity to show their own knowledge and potential, thus opening the door to starting a career. In addition to external students, Lek's talents also participate in the event. The purpose of BioCamp is to permanently integrate the economic and academic sphere. More than 30 participants of the past BioCamps are already employed in various fields in Lek and Novartis.

1.2.1 Key customers and markets[7]

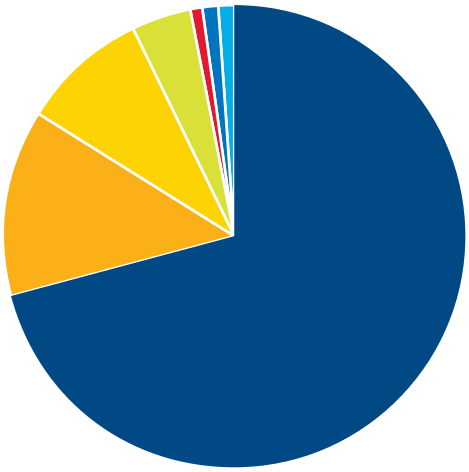
In accordance with strategic orientations, Sandoz Group companies are the key buyers of Lek products and active pharmaceutical ingredients. In 2017, the leading three buyers accounted for 75%, 9% and 3% of our net sales, respectively.

We sell our own products and the products of other Sandoz companies. The majority of our products, 95%, are sold directly to foreign markets (the USA, Russia and Western Europe), and the remaining 5% to Slovenia. The majority of sales (89%), came from pharmaceutical products, the remaining 11% came from APIs and biopharmaceutical products.

Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 74% of sales.

In 2017, the total value of the Slovenian pharmaceutical market was 621 million Euros. 47.6 million Euros of sales and a 7.7% market share makes Lek the second largest pharmaceutical company. On the generic market, where the total value is 160 million Euros, with a market share of 29.3% we are also the second largest company in Slovenia. The entire over-the-counter market reached sales of 54 million Euros, where with a 27.7% market share we have been the market leader for some years now.

Graph 2: Sales by region, recipients of goods in 2017



EUROPE 71%
NORTH AMERICA 13%
ASIA 9%
SOUTH AMERICA 4%
MIDDLE EAST 1%
AUSTRALIA 1%
AFRICA 1%

The leading markets for Lek in 2017 were the European markets (71%), followed by North America, Asia and other regions of the world.

1.2.2 Major product groups and brands[8]

We develop, manufacture and market efficient, safe and high quality medicinal products. Our key therapeutic groups are:

- cardiovascular drugs,
- anti-infectives,
- gastrointestinal drugs,
- biosimilars for the treatment of growth disorders, neutropenia and anemia, related to chronic kidney failure,
- medicines for the treatment and prevention of iron deficiency and anemia treatment,
- oncologics,
- other prescription drugs dispensed in pharmacies and covering a broad spectrum of therapeutic groups of drugs for the treatment of various diseases, and
- self-medication drugs.

Lek's leading prescription medicines on the Slovenian market are Coupet® (rosuvastatin), Amoksiklav® (amoxicillin with clavulanic acid), Iroprem® (a trivalent iron drug) and Ospen® (phenoxymethylpenicillin). Amongst the leading over-the-counter brands we achieved the highest sales with Lekadol®, Linex®, Lekadol plus C®, Operil® and Persen®.

[7] GRI GS disclosure 102-6
[8] GRI GS disclosure 102-2

1.2.3 Development and production sites and processes[9]

PREVALJE SITE
- Production of anti-infectives

MENGEŠ SITE
- Development and production of active pharmaceutical ingredients
- Development and production of biologic and biosimilar medicines
- Development of anti-infectives

LENDAVA SITE
- Production of anti-infectives
- Packaging center for solid dosage forms

LJUBLJANA SITE
- Headquarters of Lek d.d.
- Development Center Slovenia
- Production of finished dosage forms (solids and aseptics)
- Competence Center for quality control
- One of the leading global supply centers for Sandoz
- Sandoz d.d.
- Novartis Pharma
- Novartis Oncology
- Alcon

[9] GRI GS disclosures 102-4, 102-10

Heads of Lek sites in Slovenia

Matjaž Tršek, Head of the Development Center Slovenia

Dr. Aleš Rokavec, Site Head Solids Ljubljana

Antoine Maupu, Site Head Aseptics Ljubljana

Dr. Uroš Urleb, Global Head Technical Development Biosimilars at Novartis and Head Technical Development Biologics Mengeš

Vesna Kapelj, Site Head Chemical Operations Mengeš

Mario Riesner, Site Head Drug Substance BioProduction

Roman Burja, Site Head Anti-infectives Prevalje

Gizela Štampar, Site Head Anti-infectives Lendava

Dr. Simon Rečnik, Site Head Solids Lendava

Development Center Slovenia

1.2.3.1 Ljubljana site

The Ljubljana site is home to our headquarters and Lek's business center from which we lead operations and corporate functions for the wider region of central and eastern Europe. These fields are regulatory affairs, procurement, legal affairs, suply chain, corporate communication and others. It is also home to the leading and largest Sandoz development center and one of the largest Novartis production sites. Production is organized in two organizational units – Solid Dosage Forms and Aseptics.

Development Center Slovenia

We are consolidating our position as **the leading Sandoz Development Center**, in which we are responsible for managing technologically demanding development projects. Every fourth Sandoz development project comes from Slovenia. At the sites in Ljubljana and Mengeš, more than 300 experts, mainly pharmacists and chemists, are employed at the Development Center Slovenia, of which a third are doctors of science. At the end of 2017, **more than 200 development projects** for pharmaceuticals and active ingredients were carried out at our center. These include medicines to lower cholesterol levels and high blood pressure, to treat diabetes, allergic rhinitis, migraines, insomnia, urological and gastric diseases, and also non-steroidal anti-inflammatory drugs. We completed the development and submitted 17 applications to the regulatory authorities for marketing authorization for medicines on the markets of the USA, the European Union, Russia, Canada, Australia, Mexico and China, and three applications for active ingredients in the USA and Canada. We successfully launched 18 new products in the USA, European Union, Canada, Mexico, Japan, Australia and Brazil. Among them the active ingredients ezetimibe and olmesartan.

The US Food and Drug Administration accepted for approval and confirmation i.e. first to file status for six dossiers for the treatment of cardiovascular diseases, type 2 diabetes, HIV/AIDS and oncology medicines. We also filed patent applications to protect innovative approaches to the development of finished pharmaceutical products.

We made major investments in development equipment. We completed the investment in GMP-analytical laboratories for active ingredients, thus obtaining a device that enables us to provide a new type of isolation and drying of active ingredients. We have added to the equipment for analysis of active ingredients and the manufacture and analysis of pharmaceutical products. By doing this, we have expanded the capacities, which provide us with faster and more optimal implementation of development projects.

In 2017, we started a very important investment in the extension of the Development Center 2 building worth 8.6 million Euros. With new development laboratories, we will provide new capacities, greater flexibility and improved conditions for the development of final pharmaceutical forms with active ingredients of all categories.

2017 also saw Development Center Slovenia employees receiving numerous awards and published more than 10 scientific articles in influential scientific journals and 10 articles at international conferences.

Solids Ljubljana

Solids

The Solids Unit is in physical scope, product portfolio and number of employees currently the largest Novartis production site. A large range of products are made here; 160 different technological forms with around 100 different APIs. Our product range includes granules, tablets, film-coated tablets, pellet capsules and granulates, dragees and micro pellets for oral suspension. Due to the varying sizes of series and sources of APIs, we have more than 530 solid pharmaceutical forms, which we package into more than 3,000 finished pharmaceutical products for around 100 markets worldwide.

We carried out numerous investments in new production equipment and infrastructure updates, which further increased our production capacities and quality.

Production growth continued in 2017. We produced more than 8.8 billion pieces of solid dosage forms and 230 tons of granules and micro-pellets. We saw an increase in the amount of complex products, particularly tablets with a functional lining and modified-release pellets. We packaged 6.8 billion tablets and capsules in 157 million packages with almost 400 million primary packaging units – blisters, glass bottles, plastic bottles and sachets. The strongest growth was seen in plastic bottle packaging. We launched around 300 new products, which is similar to the previous year.

Aseptics Ljubljana

Aseptics

At the end of 2017, the Steriles Unit was renamed Aseptics. Here we produce sterile dosage forms which are filled into ampoules and vials. We also produce solutions, nasal sprays and syrups. We are a Novartis center of excellence for ampoules and a Sandoz center of excellence for the production of lyophilized powders stored in vials.

In 2017, we successfully introduced the first formulation of the biosimilar rituximab (Rixathon) on the EU market, manufactured and packaged at the plant in Ljubljana. In 2018, we will focus on the successful launch of the biosimilar in the USA and thus make it accessible to patients worldwide.

In order to optimize processes and increase productivity, the plant started with a thorough cultural transformation. With the introduction of NOSSCE (Novartis Operational Standard for Supply Chain Excellence), we strengthened planning and stabilized the reliability of operational performance, and through TOP (TechOps Performance) we prepared a 5-year plan to achieve greater competitiveness in key areas (quality and safety, level of customer service, costs).

The alignment of Novartis aseptic processes (NAP-CIP) and data integrity initiatives and the thorough preparation of the teams involved have contributed to the success of Good Manufacturing Practice (GMP) checks at the site this year.

Technical Development Biologics Mengeš

1.2.3.2 Mengeš site

Chemical operations Mengeš

By the end of the year, we successfully transfered the innovative drug substunce production to the site, for which launching quantitites were produced in Mengeš as well. We are particularly proud of this, as we want to become the main Novartis chemical operations center for the launch of new products. The most important active ingredients produced at Mengeš include everolimus, tacrolimus, pimecrolimus, atorvastatin, rosuvastatin, amlodipine, esomeprazole mg and mycophenolate mofetil.

Our smooth running production and customer care means we realize our vision and successfully respond to all needs in an extremely dynamic environment. At the beginning of December, we opened the new laboratory department of Manufacturing Science and Technology (MS&T), which represents an important contribution to a better and safer working environment. At the end of December we celebrated the 50th anniversary of the active ingredient production used to treat inflammation of the kidneys, urinary tract and bladder.

We also successfully passed domestic and international health inspections, which again proved the high level of the quality system at our site. Concern for safety and the environment is our constant, in 2017 we started training and improvements in the field of process safety, we renewed the certificates of standards, such as ISO 14001 and OHSAS 18001, as well as the EMAS assessment. We also had inspections in terms of fire safety and the environment, and no legal discrepancies were found in any inspections.

Biopharmaceuticals Mengeš

The year 2017 was marked with successful business operations and organizational changes. In September, the management of the unit took over Mario Riesner, and in October there was an organizational change of the unit and the establishment of two organizational units, namely Technical Development Biologics Mengeš, led by Dr. Uroš Urleb, Head Global Technical Development Biosimilars in Novartis, and Drug Substance Bioproduction Mengeš, led by Mario Riesner.

Year 2017 was an exceptionally successful year in terms of submissions, fillings, approvals and launches of biosimilar medicines. A very important part in this are playing teams of Technical Development Biologics Mengeš. At the beginning of the summer, a new biosimilar with the active substance rituximab was successfully launched in several important world markets, the development of which began in Mengeš.

Teams from Technical Development Biologics Mengeš also contributed significantly to the development of Sandoz biosimilar etanercept, which received European Commission's approval in June for use in Europe to treat multiple inflammatory diseases. They also contributed to submissions for Sandoz biosimilars pegfilgrastim and adalimumab for Europe and rituximab for US market.

In spring, we opened a new pilot laboratory for Drug Product and Process Development, which is dedicated to supporting technology transfer and as a dedicated area for the production

of the preclinical samples, reference standards and a large number of samples for stability studies. In all development areas, we have achieved all key goals and milestones for 2017 and continued with the development of biopharmaceutical drug substances and drug products.

At the end of June, Sandoz's biosimilar erythropoietin, which is used to treat anemia, especially in renal and cancer patients, celebrated its 10th anniversary of its presence on the EU market. At the PORT production plant for recombinant technology, we produced record quantities of erythropoietin drug substance and ensured an undisturbed supply of drug substance throughout the year. Due to growing market demands, in July we began to build an additional line to produce this drug substance, which aims to increase the volume of production.

New investments and growth of the site also bring new opportunities for employment in the field of biotechnology, process development and improvement of operational excellence. In 2017, 52 new employees were recruited from these fields. We are investing a lot of effort into recruiting the best talents and experts, and for the second consecutive year we organized a Novartis career Breakfast for highly educated experts in natural sciences who are studying and working abroad. This is an effective initiative in which we try to respond to modern migration trends among the highly educated workforce and to create a stimulating working environment for top Slovenian experts.

Anti-infectives Prevalje

1.2.3.3 Prevalje site

The broad-spectrum antibiotic Amoxiclav, produced at the Prevalje site, is sold on more than 70 of the world's most demanding markets, including the USA, Europe and Russia. In 2017, we started building a new production site, successfully passed various assessments, invested in new production equipment and tackled new projects.

We continued the high growth in production volumes. Compared to 2016, tablet production increased by 5.5%, meaning 645 million tablets, of which a good third were for the US market. We produced 14.7 million pieces of oral suspension and 270 tons of mixtures, which is at the same level as last year. In total we produced 51.4 million packs.

We have devoted much of our activity to ensuring safety for patients and employees. In the field of safety, we have achieved or exceeded all the indicators, with the exception of three minor injuries at work, which resulted in sick leave. The assessment by the US Food and Drugs Administration (FDA) was successfully concluded; we have not received any comments from the agency for the fifth consecutive time. Likewise, many of our customers' assessments have confirmed that we are guaranteeing the highest quality standards that enable the production of safe, effective and high quality medicines.

In 2017, we successfully installed and launched a new line for oral suspension (POS), which will provide us with sufficient capacity for the needs of the US market. We installed a new dishwasher for cleaning equipment and continued upgrading packing lines with T & T functionality. Among the most important investments is the new factory for the production of Amoxiclav, where we laid the foundation stone in April.

We also continued to employ staff with expert knowledge in the field of technical sciences, especially those with high added value, with an emphasis on recruiting staff from the local environment.

Anti-infectives Lendava

1.2.3.4 Lendava site

Anti-infectives

At Lendava Anti-infectives unit, we produce two active ingredients: potassium clavulanate and gentamicin sulphate. Potassium clavulanate is our main product in terms of production volume and is a key ingredient of a broad spectrum antibiotic, one of Lek's and Sandoz's most important products. Gentamicin sulphate is sold on the most demanding global markets. The production of both products is done through the use of classical biotechnology, which is the result of our own knowledge. In this process, special microorganisms synthesize the API, which is purified in the subsequent isolation phases to an acceptable level for the pharmaceutical industry.

The production of potassium clavulanate was also high last year and was 8% higher than in 2016. This was achieved by reducing the fermentation process, optimizing the technological process and eliminating the bottleneck at microfiltration. With many minor improvements, we further reduced production costs and thus maintained a high level of competitiveness on the global markets. Our capacities were fully occupied, as the production of gentamicin sulphate was also increased by as much as 35% as a result of increased market demands.

In 2017, we also generated significant savings in the energy sector, especially in the use of gas and electricity. In the annual overhaul we carried out a large number of smaller projects and modernized the solvent regeneration process, thus further reducing the consumption of fresh solvents. We also carried out an investment in modern environmental technology - a device for regenerative thermal oxidation (RTO) of production emissions.

In the field of quality and good practices, we once again confirmed the high level of quality of our production and quality system. We successfully completed all inspections and audits. We have also been successful in the field of health and environmental protection, as we reached all the set goals in the field of environmental protection and have been constantly increasing the safety processes and the safety culture of our employees.

Solids Lendava

Solids

Solids Lendava (formerly, Packaging Center Lendava) continued to dynamically grow and develop in 2017 and confirmed itself as a strategic packaging plant for solid forms of pharmaceuticals within Novartis Technical Operations. Growth continued with the installation of a technologically demanding packing line for blister packs. This enabled the transfer of the packaging of the first Novartis' innovative medicine to Slovenia, the Neoral Sandimun transplant medicine, which will be provided by Novartis from Lendava for patients worldwide.

A high, almost 20% growth in production volumes continued to 5.4 billion tablets or capsules in 149 million packs. The complexity of the drug portfolio has also grown to more than 85 molecules and more than 2,800 final products. This was followed by employment, at the end of the year the number of employees exceeded 370.

The strategic development of the unit will be paved in the coming years by the decision of the management of Novartis Technical Operations to continue the transfer of packaging and supply of markets from Lendava to several key innovative medicines of Novartis Pharmaceuticals.

In 2017, we paid great attention to the development of skills and competencies, operational excellence, organization and employees. The year ended without any injuries that would result in sick leave. Corporate assessments in the field of HSE were completed successfully whilst we also successfully completed the ATEX certification, introduced the system of supervision of the safe work of external contractors and concluded with the introduction of the LO/TO program.

1.3 Development and reporting framework

In accordance with the Novartis Corporate Responsibility Policy, we strive for transparent and comparable public reporting. Every year since 2010, we have compiled a comprehensive report on sustainable development, at the same time reporting in compliance with the requirements of the Responsible Care Initiative (RCI), EMAS Scheme and GRI Guidelines. Even before 2010, we prepared environmental reports and reports within the RCI.[10] The Sustainability Report was last published in August 2017.

In 2017, we added an overview of the United Nations' Sustainable Development Goals (SDG) which can be seen from the GRI Index. The competent departments co-operated in the process of determining the content of the report, which stems from the key features of Lek's activities and position. We also identified aspects that were exposed in different ways by our stakeholders: through questions raised on Community Partnership Days, interaction with the professional public at expert meetings, questions raised by employees (Workers' Council, Workers' Assembly and their representatives in the company's management bodies), contact with regulators (Agency for Medicinal Products and Medical Devices) and through media questions.[11] The material aspects of sustainable business are recognized and are evident in the GRI Index in Point 7. We have not yet decided to seek external assurance for our sustainability reporting.[12]

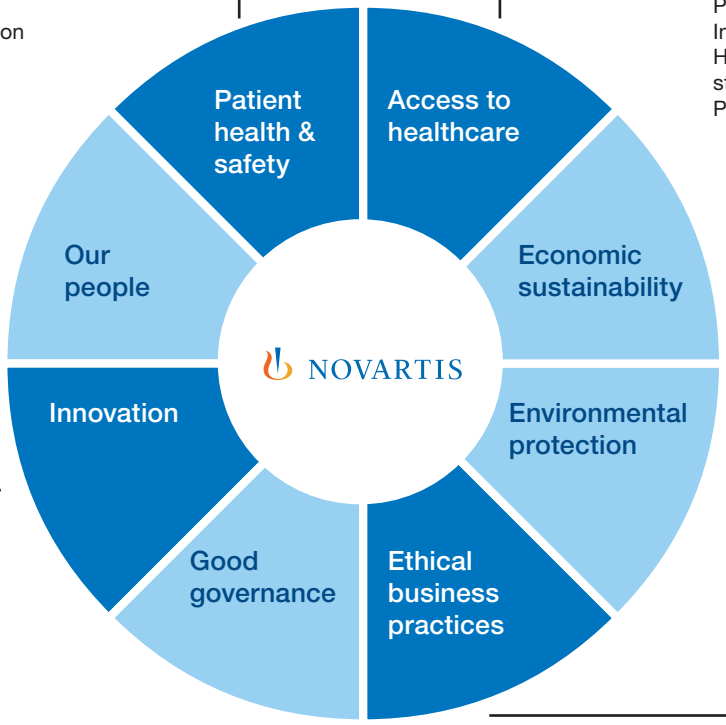
The Sustainability Report which contains the EMAS Environmental Statement is available at http://www.lek.si/sl/o-nas/druzbena-odgovornost/porocanje/.

Comprehensive reporting is also carried out within Novartis, which in turn performs internal controls and assesses the conformity of the reporting indicators. Furthermore, Lek's data for a broad set of indicators is included in Novartis' indicators (available at: www.novartis.com, www.novartisfoundation.org and www.corporatecitizenship.novartis.com). Their collection is performed in compliance with the improvement guidelines provided by Novartis internal HSE audits.

We also take into account the Materiality Analysis prepared by Novartis in preparing this report. The picture below shows Novartis, and thus Lek's material (marked with dark blue) and important (with light blue) areas of social responsibility.

Patient health and safety
Pharmacovigilance, safety profile and quality drugs
Health education and prevention
Counterfeit medicines

Access to healthcare
Availability of medicines
Pricing
Intellectual property
Healthcare system strengthening
Patient assistance programs



Innovation
R&D for unmet medical needs
R&D for neglected diseases
Drug resistance
Business model innovation
Innovative technologies

Ethical business practices
Ethical and compliant behaviour
Responsible supply chain management
Respect for human rights
Responsible use of new technologies
animal testing

[10] GRI GS disclosures 102-51, 102-52
[11] GRI GS disclosure 102-46
[12] GRI GS disclosure 102-56

1.3.1 2017 reporting characteristics[13]

Reporting in accordance with RCI requirements

Lek's reporting has been based on the RCI for several years now, the present report being an upgrade of the previous reporting model.

Reporting in accordance with EMAS

The Report meets the requirements of Appendix IV to the Regulation (EC) No. 1221/2009 (EMAS), disclosing the required indicators for each site separately.

Reporting in accordance with GRI Guidlines

Lek d. d. reports in compliance with the GRI GS (Global Standards), achieving the core level.

- Reporting refers to Lek d. d. and all its manufacturing sites in Slovenia. All disclosures in the present report refer to the 2017 calendar year.
- Employee data, key data on financial operations, and economic impacts of business operations were acquired in the financial reporting process for the purpose of compiling the company's annual report in accordance with International Accounting Standards (MRSP) and Slovenian legislation.
- The objective of Lek's HSE reporting is compliant with Novartis' and Sandoz' objectives to provide a fair and well-balanced picture in the field of HSE. The system of monitoring HSE achievements and the reporting methodology are described on page 75.
- Sustainable development reports are compiled annually and also include the Environmental Statement (EMAS) amended and upgraded at every major change. The reports contain the key data for all sites of Lek in Slovenia.
- Lek d. d. holds a 100% ownership stake in the following subsidiaries (as 31. 12. 2017) Sandoz d. d. and a 74.5% ownership stake in Wastewater treatment plant Lendava d.o.o..
- In 2017, there were no changes in the size, structure and ownership of Lek d. d. There were no merger activities or joint ventures.
- To improve reporting accuracy, the following adjustments in the data collection were made for 2017, also impacting the comparability of data with previous years:
  - due to the purchase of electricity sources (GOO) for 2016, the quantities of indirect greenhouse gas emissions for the year 2016 were corrected. In 2017, we purchased CER certificates for energy investments in the third world. The definitive greenhouse gas emissions for 2017 will be known after obtaining the supplier's data on the electricity source.
  - Data on emissions of volatile organic compounds at the Prevalje site for 2016 are corrected due to an error in the DMS registration.

[13] GRI GS disclosures 102-45, 102-50, 102-10, 102-48, 102-49, 102-54

[14] GRI GS disclosure 102-18

1.4 Governance, commitment and inclusion

1.4.1 Governance and management[14]

Lek d. d. has a two-tier board system. The management function is performed by the company's Board of Management which is controlled by the company's Supervisory Board. The mandate of a member of the board of management is five years, the mandate of a member of the supervisory board is four years.

Board of Management

In 2017, the members of the Board of Management were as follows:

- **Vojmir Urlep**, President of the Board of Management (until 1. 8. 2017)
- **Zvonko Bogdanovski**, Member of the Board of Management (until 1. 8. 2017) and President of the Board of Management (from 2. 8. 2017) – Technical Operations
- **Ksenija Butenko Černe**, Member of the Board of Management – Legal Affairs
- **Daniel Michalek**, Member of the Board of Management – Finance
- **Marjan Novak**, Member of the Board of Management – Workers' Director
- **Andrej Pardo**, Member of the Board of Management (from 2. 8. 2017) – Commercial Operations
- **Aleš Rokavec**, Member of the Board of Management (until 1. 8. 2017) – Technical Operations
- **Samo Roš**, Member of the Board of Management – Human Resources

The Board of Management runs the company, independently and on its own responsibility. In their function, Supervisory Board members act to the benefit of the company and with due diligence, bound by an obligation of confidentiality. All members of the Supervisory Board avoid any conflict of interest. Upon their appointment, they have to sign a statement pursuant to Article 255 of the Companies Act (ZGD-1), an obligation set for all Novartis Group employees in the Novartis internal Conflict of Interest Policy (the same applies to the supervisory board).

The individual members of the Board of Management are obligated to provide the President of the Board of Management with complete, comprehensive, accurate and ongoing information about any major event and development of individual transactions in the areas of their responsibility. Provision of information to the Supervisory Board and the General Assembly is the responsibility of the President of the Board of Management who reports to the Supervisory Board Chairman on:

- Profitability of the company, particularly its return on equity.
- Draft business policy and other fundamental business issues.
- Transactions that can significantly impact the company's profitability and financial solvency.
- Development of transactions under way, in particular the company's turnover and financial standing.
- Issues regarding the business operations of the parent company and its associated companies.
- Other matters in compliance with the law and according to the requirements of the Supervisory Board.

Supervisory Board

In 2017, the members of the Supervisory Board were as follows:

- **Francesco Balestrieri**, Chairman
- **Richard Francis**, Deputy Chairman
- **Miguel Pagan Fernandez**, Member
- **Knut Mager**, Member
- **Peter Svete**, Member – Workers' Representative
- **Vesna Premovič**, Member – Workers' Representative (until 17. 12. 2017)
- **Fikret Bašanović**, Member – Workers' Representative (from 20. 12. 2017)

The management of the company business is overseen by the Supervisory Board, in accordance with its mandates and responsibilities. The Board can perform reviews and verification of the company's books and documentation, its treasury, securities and goods in stock, as well as other matters. The Supervisory Board can request the Board of Management to provide any information needed for the Board to perform its supervisory role. This allows the Board to perform comprehensive control of the company's economic, environmental and social impacts, and receives this information as part of its competency of approving the company's annual report, which also encompasses all relevant information related to environmental protection.

The main responsibilities of the Supervisory Board include the following:

- Supervision of company management.
- Verification and approval of annual reports.
- Checking and proposing to the General Assembly the use of distributable net profit, together with the Board of Management.
- Providing the General Assembly with a written report on the verification of the annual report and of the management of the company during the business year.
- Reviewing reports by the Board of Management.
- Reviewing and verifying the company's books and documentation.
- Appointment and recall of Board of Management members.
- Granting the right to and setting criteria for buying stock options.
- Signing contracts with Board of Management members.
- Other competencies in accordance with the law.

The members of the Supervisory Board do not receive any payment or other rewards for their work, their duties as Supervisory Board members form part of their job-related obligations as they are also employed in Lek or other companies of the Novartis Group. Appointment of the members of the Supervisory Board is confirmed by the Executive Committee of Novartis, the highest governance body, based on the knowledge and competencies of its members, with the aim of providing the best people, to cover all the company's functions, and to ensure their operational autonomy.

In 2017, the Supervisory Board had four correspondence sessions, where they conducted a regular operations review of Lek and its subsidiaries, checked company targets and risks, which the companies highlighted to them. Due to the President of the Board of Management Vojmir Urlep and existing Members of the Board of Management finishing their mandates, the Supervisory Board at their June meeting confirmed the proposed new President of the Board of Management Zvonko Bogdanovski and the new Board of Management. The members stepped down from their five year mandate on August 2nd 2017.

Diversity in management and supervisory bodies

Lek respects the diversity of employees, patients and other stakeholders, and strives for their equal inclusion in our operations. The company encourages diversity in the gender of representatives in both management and supervisory bodies, which is written in the annual targets of the Diversity and Inclusion Initiative. The company has no independently adopted policies that would further regulate the diversity of representation in these bodies in the light of the other personal circumstances of members of these bodies.

1.4.2 Employee participation in company management[15]

Employee participation in company management is carried out in accordance with the Worker Participation in Management Act (e.g. ZDR-1, ZVZD-1). They exercise their duties and rights individually and collectively through the Workers' Council, Workers' Assembly and their representatives in the company's management bodies.

The Workers' Council serves as a form of collective and indirect participation of employees in the management of the company. It has fifteen members that represent workers' interests, form opinions and forward proposals and initiatives to management on improvements to the quality of the work environment. Two representatives of the employees are the Supervisory Board members, while the Workers' Director is also a member of the Board of Management and represents workers interest in human resources and social area for a five-year term.

The President of the Board of Management, the Workers' Director and the HR Director attend the Workers' Council meetings and respond to questions and initiatives of the employees and the Workers' Council.

[15] GRI GS disclosure 103-1

In 2017, the Workers' Council was regularly informed at its meetings about the economic situation of the company and its development objectives, organizational changes in individual units, topical issues which were subject to management decisions, and other topical events in the company and in the syndicate. It also took note of various reports (annual report, report on innovation, report on the annual assessment of performance, on the operations of the Pokojninska družba A, etc.).

The Workers' Council regularly published the minutes of their monthly meetings and other relevant information useful for employees (information on labor legislation, tax, links to more important laws, institutions…) on their intranet page. Another important channel for notification was the monthly email sent to employees after each meeting of the Workers' Council.

1.4.3 Stakeholder overview and inclusion[16]

We include our stakeholders in our operations in several ways in order to understand their needs and expectations, and subsequently improve access to healthcare. We constantly strive to improve their inclusion, and consequently understand our operations more easily, make strategic adjustments to our business practice and build trust between stakeholders.

In accordance with Novartis corporate responsibility policies, are focused on five key groups of stakeholders:

- patients,
- employees,
- shareholders,
- healthcare partners (healthcare professionals, regulators, professional associations, buyers, suppliers) and
- society (local communities, non-governmental organizations, scientific and educational institutions, and the media).

We try to understand patients' needs through focus groups and cooperation with patient groups organized in associations and initiatives. At scientific conferences, we cooperate with academia and the scientific community, with professional organizations, educational institutions, research institutions and researchers in the field of chemistry, biology and healthcare. In order to learn about the satisfaction and views of our employees, we used a Novartis global survey carried out among the employees in 2017; 69% of all Novartis employees took part and it gave a clear overview of important aspects of building health organization and opportunities for development.

We meet with our suppliers to learn about their expectations and experience.

We involve patients, doctors, pharmacists, wholesalers and retailers through the use of new technologies and information channels. We provide balanced, accurate and easy-to-understand scientific information on diseases, treatments and treatment policies that concern patients. We pursue an interest in providing information to the public through building open and proactive relations with the media.

An open dialogue is established with our key stakeholders including prompt responses to the questions received, and by means of a responsive policy and practice of complaint handling.

We will be engineers!

We have joined the project "We will be engineers", which is being held at Slovenian grammar schools. Young people are excited and encouraged by engineering, technical and natural professions and innovation, new skills and competences of the 21st century.

The initiative combines renowned engineers, top managers and managers, researchers, ambitious students of technical and natural science faculties, representatives of start-up companies and various perceptive and creative individuals. They share their experiences with young people, they represent career opportunities in science and technical professions and encourage the upgrading of engineering knowledge with business.

Professional day at Ravne na Koroškem Grammar School, on February 1, 2018, where they also talked about new professions that the future is still creating.

[16] GRI GS disclosures 102-40, 102-42, 102-43

Lek's stakeholders and their recognized interests: [17]

Stakeholders	Stakeholders' interests
Employees	• Continuous care for healthy and safe work environment • Improving knowledge and skills • Equal opportunities for career development • Employment safety • Balance between professional and private life • Awareness on responsible treatment of the environment • Diversity and inclusion • Participation in company development and management • Awareness and participation in decision-making regarding the policies and measures for health and safety at work, and environmental protection
Patients	• Safe, efficient and high-quality medicinal products • Affordable medicinal products • Development of new and efficient medicinal products • Functional packaging of medicinal products with low environmental impact • Responsible handling of medicinal products and waste medicines • Cooperation with patient groups
Owners	• Accountable business practices • Successful business results • Company's high developmental capacity • Patient trust • Employee satisfaction, • Compliance with the regulations and Novartis' health, safety and environmental standards • Efficiency in consumption of natural resources • Company's reputation
Healthcare professionals and healthcare providers	• Safe, efficient and high-quality medicinal products • Accountable business practices • Providing information on new medicinal products • Providing information on proper medicine use • Proper product labeling • Responsible handling of medicinal products and waste medicines
Customers	• Safe, efficient and high-quality medicinal products • Affordable medicinal products • Proper product labeling and information clarity • Responsible handling of medicinal products and waste medicines
Regulators	• Safe, efficient and high-quality medicinal products • Adherence with legislative requirements regarding pharmaceutics, health, work safety, protection of the environment, marketing, and product advertising, etc. • Proper product labeling • Varna, učinkovita in kakovostna zdravila • Spoštovanje zakonskih zahtev na farmacevtskem področju, področju zdravja in varnosti pri delu ter varovanja okolja, trženja in oglaševanja izdelkov idr. • Ustrezno označevanje izdelkov
Academia and scientific community	• Participation in development and research projects • Knowledge and practice exchange • Inclusion of environmental aspects into the development of new products
Professional and industry associations	• Exchange of opinions and promotion of good HSE practices in industry and professional associations • Industry reputation
Suppliers	• Good business relations • Awareness of risk factors in work environment • Adherence to legislative and Novartis' standards in protection of the environment • On-time deliveries, adequate prices for goods and services
Local communities	• Employment of workers from the local area • Successful management of environmental impacts and adherence to safety and environmental legislation • Efficiency in consumption of natural resources • Development and expansion of sites • Involvement in life of the local community • Support for cultural, sports and humanitarian organizations • Cooperation with institutions and vendors from local area
Media	• Providing information on business and events in the company • Open dialogue and accessibility of data related to environmental and social impact in public interest
Non-governmental institutions	• Support and cooperation on projects • Good social accountability practices • Accessibility of data related to environmental and social impact in public interest

[17] GRI GS disclosures 102-40, 102-44

1.4.3.1 Co-operation with the local communities

Open day at Prevalje

In order to create and maintain long-term positive relationships with residents in the local community we need to assure open dialogue. Since we began our operations 70 years ago, we have had regular and transparent relations with our local communities. Good knowledge of operations and the orderliness of our sites and HSE information are very important for the residents in neighboring towns and villages. Our open days are more active and structured than a decade ago, and are now regularly organized at all our locations across Slovenia. The feedback that we receive during or after the event itself is very valuable to us, as they show us the path to improvement and tell us in which direction we should move forward. In 2017, we organized an open day at Prevalje. There was a lot of interest, it attracted around 150 residents from the surrounding areas; they looked at the production and organization of work more closely, and received a presentation on the site development which has been particularly intense in recent times, as well as the latest investment for the construction of a new factory. Visitors were also acquainted with new employment opportunities and career paths.

We prepared adverts featuring our employees from Prevalje.

Mechanism for addressing complaints[18]

By effectively addressing complaints from the field of HSE and by implementing the appropriate corrective measures, we ensure a safe and an environmentally friendly work environment, reduce environmental risks in carrying out business activities and contribute to the creation of a good company name. Complaints are solved according to internal procedures, which require the responsible person to open an enquiry within 24 hours. Depending on the completion of the enquiry and the eligibility of the complaint, the Site HSE head shall ensure that the corrective measures are taken and fulfilled. The entire procedure is documented and archived.

In 2017, we received five HSE related complaints from residents in the area. We received two complaints at the Ljubljana site, one noise complaint was made again, which was also dealt with in the complaints between 2011 and 2016. In the past years, we have already installed dampers at the outlets on the site, as well as at the points of entry of air into production and this reduces sound level well below the limit. Detailed measurements of environmental noise in the years 2015 and 2016 have shown that our company is not a source of noise that disturbs the countryside. In 2017, we re-examined the appeal of the resident, who allegedly detected the noise caused by the fan's operation in the roof of production in Ljubljana. In the measurements, we placed a special emphasis on the analysis of the medium frequency tonal component 661 Hz during night hours, which is the cause of complaint for the resident. From the analyzes carried out, it is evident that the level of noise, in the most favorable weather conditions (western wind) and in the absence of traffic, in front of the resident's house is 33 dBA and is far below the prescribed legal limits.

The second complaint in Ljubljana was received from a contractor for the removal of waste due to the presence of containers with unknown liquid, which were mixed with plastic packaging. The containers were immediately disposed of by the Hazardous Waste Disposal Operator at Lek's cost.

At Mengeš, we received an appeal from the local people because of the unpleasant smell that apparently came from our site. After an investigation, it was found that the cause of the smell was the farmers manure spreading on agricultural surfaces around our site.

In Prevalje, the Log communal services company complained that the transport of lorries on a local gravel road, while removing the soil for the construction of new Lek facilities, significantly increased dust. The contractor for removing the soil, in cases of larger number of transports, wetted the surface of the road in order to reduce dust, while on individual transport trucks, trucks reduced the speed near residential buildings. In addition to our contractors, Koratur's buses also run along the same road. In Prevalje, Lek's contractor also filed a complaint for improper waste separation. The contractor requires specific separation in "wet" and "dry" municipal waste, where the border between them is sometimes difficult to determine. We have retrained our employees and called for strict separation of waste.

Information on the impact of our operations is published in The Sustainability Report – Lek d. d. for each individual year, the latest report can be found on our website http://www.lek.si/en/corporate-responsibility/.

1.4.4 Lek's commitment to external initiatives and principles[19]

As a Sandoz company and as a part of the Novartis Group, Lek has committed to implementing a number of initiatives, including the following:

- UN Universal Declaration of Human Rights,
- ILO Declaration on Fundamental Principles and Rights at Work,
- Rio Declaration on Environment and Development,
- UN Convention against Corruption,
- Slovenian Diversity Charter
- OECD Guidelines for Multinational Enterprises,
- OECD Convention on Combating Bribery of Foreign Public Officials, and
- voluntary commitment to reduce greenhouse gas emissions in accordance with the Kyoto Protocol.

In addition, Novartis is a member of the Workplace Wellness Alliance of the World Economic Forum (WEF) (http://www.weforum.org/issues/workplace-wellness-alliance). Their guidelines were also embraced by Lek.

When developing and manufacturing pharmaceuticals, we use the Precautionary Principle; we strictly comply with Pharmacopoeia requirements, WHO and OECD standards; requirements of the FDA and the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), and the Good Laboratory Practice recommendations. The development of medicinal products, APIs and manufacturing procedures is based on precautionary measures such as gradual approach, inclusion of independent scientists, as well as open and transparent consideration of strengths and weaknesses.[20]

[18] GRI GS disclosures 103-1, 103-2, GS 413-1

[19] GRI GS disclosures 102-12, 102-13

[20] GRI GS disclosure 102-11

2. Environment

Health, safety and environment policy (HSE)[21]

All our considerations and operations are aimed at contributing to the sustainable development of the company.

Priority is given to the following:

- the health and safety of our employees and all those affected by our operations, and
- environmental protection.

We implement Novartis' and Sandoz' HSE Policy and Guidelines, and meet the respective health, safety and environmental legislation requirements. Our operations are based on the pillars of Novartis Corporate Citizenship policy focusing on the improved access to treatment, responsible operations, transparent reporting on our impacts, employees and the community, and environmental protection.

We are raising public awareness of health and safety at work, without any excessive impact on the environment. In order to improve HSE efficacy and accountability, we set measurable long-term and annual goals.

We make rational use of natural resources and verify and reduce the impact of our operations on the environment. The goals we set reflect our environmental impacts, which are comprehensively managed within the Novartis Environmental management System, EMS.

Lek, a Sandoz company, is open to the public. We actively cooperate with local communities, responding to their initiatives and seeking common solutions for further improvements.

HSE Policy guidelines

We implement the HSE system on the basis of clear guidelines integrated into our operations. Fulfillment of legal requirements and corporate orientations constitutes a platform for our HSE risk management system. We adhere to the ISO 14001 standard, the international OHSAS 18001 occupational safety and health standard, and the Responsible Care Initiative for the chemical industry, coupled with the EMAS Eco-Management Scheme.

Our key guidelines are:

- Health, safety and protection of the environment constitute the basic responsibility of all our employees.
- We play a proactive role in protecting health, providing safety, and protecting the environment.
- We regularly check conformity of our operations with the relevant acts, regulations and guidelines. We are committed to observing all legal regulations and other pharmaceutical industry regulations as well as Novartis standards relating to any relevant aspect of health, safety and environment.

[21] GRI GS disclosures 102-11, GS 103-1, 103-2

- We raise awareness among our employees regarding HSE policies and provide them with continuous training enabling them to implement the policies. This is how we ensure they work safely and understand the risks involved.
- By introducing the best performing and cost-effective technologies available, we strive to become one of the leading environmentally-committed companies.
- Through continuous improvement of business and production processes, we improve HSE efficiency and reduce environmental impacts.
- We have systems and measures in place to prevent environmental pollution, which are regularly verified and upgraded.
- The HSE policy and its implementation is recorded, the set guidelines are updated and consistently realized, and keep informing our employees thereof.
- We strive to make continuous progress in our use of raw materials and energy resources, and in the reduction of environmental impacts, which is constantly monitored through regular measurements and data follow-up.
- At our production sites, we regularly identify, monitor, manage and document HSE risks.
- To achieve risk management goals, we propose and implement preventive and corrective measures whenever necessary.

We provide our stakeholders with well-balanced information on our corporate responsibility, which forms a solid basis for dialogue and formation of views and decisions. Information on the sustainability aspect of our operations is publicly available on our website www.lek.si/en/.

Compliance with HSE laws and standards[22]

Complying with legal and other requirements is the basis of our responsible operations. The key environmental management regulation is the Environmental Protection Act, which in 2016 underwent a significant change. It dictates the contents of other implementing regulations in the field of water, noise, waste, packaging materials, atmospheric emissions, light pollution, storage of hazardous liquids, and other areas related to environmental protection.

Requirements relating to waters are met according to the Decree on the Emission of Substances and Heat in the Discharge of Wastewater from Installations for the Production of Pharmaceutical Products and Active Substances, which particularly applies to the pharmaceutical industry.

Being an IPPC (Directive of industrial emissions)[23] certified company, our Lendava and Mengeš sites operate in compliance with Decree on activities and installations causing large-scale environmental pollution. Both existing IPPC permits also cover the release of greenhouse gases from cooling devices, whereas these types of emissions at the Ljubljana and Prevalje sites are included in permits dealing with atmospheric emissions. All Lek sites comply with the Decree on Limit Values for Atmospheric Emissions of Volatile Organic Compounds from Installations Using Organic Solvents. As a low-risk source, the Mengeš site is obligated to adhere to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences.

New legal and other requirements are promptly and efficiently transferred in our work processes and practices. Authorized persons for HSE actively monitor and identify them, ensuring appropriate internal publication after a gap analysis in the Corrective measures application, making them promptly available to persons responsible for HSE at all sites and other interested employees. Responsibility for effective application in practice lies with the site heads/representatives of the HSE units.

In 2017, we had 3 inspections from the area of environmental protection, two of them in Prevalje and one in Mengeš. In addition, 3 fire inspections were also conducted, two in Lendava and one in Mengeš, and one inspection from the field of energy in Prevalje. None of the sites were found to have fineable incompliances. All regulatory measures were carried out within the prescribed time limit.[24]

In 2017, we were involved in inspections covering the quality of operational processes and products (e.g. JAZMP, FDA, etc.) related to the area of health checks, waste management, deratisation and disinsection.

Environmental permits are the result of complying with all stipulated legal requirements for all projects or changes at all our sites. By respecting the provisions of the environmental permits issued by the Slovenian Environment Agency and Slovenian Water Agency and specify the limit values for all atmospheric and water emissions, waste management, measures to reduce light pollution, methods for safe storage of raw materials and products for the company's sites. Our adherence to these values results in the safe operation of our production plants without excessive impact on the environment.

[22] GRI GS disclosures 103-1, 103-2

[23] See the glossary on page 89

[24] GRI GS disclosure 307-1

Environmental permits and their changes at all our sites:

- Environmental permit for operation of a device with a high pollution potential (IPPC) for the Lendava site, Permit No. 35407-172/2006, dated 15 April 2010.
- Decision amending the environmental permit for the Lendava site, No. 35407-37/2011-33, dated 12 July 2012.
- Decision amending the environmental permit for the Lendava site, No. 35406-33/2012-4, dated 15 March 2013.
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2014-8, dated 23 January 2015.
- Decision amending the environmental permit for the Lendava site, No. 35406-39/2015-10, dated 27 January 2016.
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2016-7, dated 8 June 2017.
- Environmental permit for operation of a facility with a high pollution potential (IPPC), for the Mengeš site, Permit No. 35407-171/2006, dated 14 May 2010.
- Decision amending the environmental permit for the Mengeš site, No. 35407-22/2010, dated 28 December 2010.
- Decision amending the environmental permit for the Mengeš site, No. 35407-54/2011, dated 16 May 2012.
- Decision amending the environmental permit for the Mengeš site, No. 35406-24/2012-3, dated 23 August 2012.
- Decision amending the environmental permit for the Mengeš site, No. 35406-25/2013-6, dated 11 November 2013.
- Decision amending the environmental permit for the Mengeš site, No. 35406-42/2014-4, dated 10 September 2014.
- Decision amending the environmental permit for the Mengeš site, No. 35406-7/2015-7, dated 20 April 2015.
- Decision amending the environmental permit for the Mengeš site, No. 35406-33/2015-20, dated 9 February 2016.
- Environmental permit for risk facilities (SEVESO risks) for the Mengeš site, Permit No. 35415-26/2006-9, dated 25 May 2015.
- Decision amending the environmental permit for the Mengeš site, Permit no. 35406-43/2016-8 dated 30 March 2017.
- Environmental permit with regard emissions into water and air for the Ljubljana site, permit no. 35431-6/2016-9, dated 22 November 2016.
- Environmental permit with regard emissions into water and air for the Prevalje site, permit no. 35444-36/2016-12, dated 21 March 2017
- Partial water use permit for direct use of water for industrial purposes from the public water supply network, for Lek d. d. (all sites), Permit No. 35536-19/2011, and dated 15 July 2011.
- Decision amending the partial water use permit for direct use of water for industrial purposes from the public water supply network for Lek d. d. (all sites), Permit No. 35536-17/2013-2 (concerning 35536-19/2011) dated 17 April 2013.
- Decision amending the partial water use permit for direct use of water for industrial purposes from the public water supply network for Lek d. d. (all sites), Permit No. 35536-90/2014-2 (concerning 35536-17/2013-2 and 35536-19/2011), and dated 13 January 2015.
- Decision amending the partial water use permit for direct use of water for industrial purposes from the public water supply network for Lek d. d. (all sites), Permit No. 35536-18/2016-2 (concerning 35536-90/2014-2, 35536-17/2013-2 and 35536-19/2011), and dated 4 April 2016.
- Water use permits for direct use of water No. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8, dated 29 September 2013.
- Permit for groundwater research no. 35505-74/2017-3, dated 13 September 2017.
- Permits for the release of greenhouse gases No. 35485-53/2014, dated 22 October 2014, and No. 35485-54/2014, dated 15 December 2014.

2.1 Active environmental policy implementation

The combined impact of an increased population, increased consumption of natural assets and climate change for us means both challenges and opportunities. Environmental responsibility is a top priority of our operations, along with the continuous search for improved efficient use of raw materials and limiting the impact of our activities on the environment. Direct and indirect environmental impacts are taken into account when adopting business decisions. In the area of innovation and development of new products, we carefully consider the opportunities to improve environmental aspects as well as risks in a scientific and transparent manner. In doing so, we carry out numerous

environmental protection activities which often exceed the legal requirements. By assessing environmental impacts, we assure that the benefits of the new product, processes and technology outweigh the remaining risks.

Our primary environmental aspects are energy consumption and impact on air/climate, water and micro-pollutants and raw materials and waste. Among the indirect environmental aspects, we mainly categorize environmental impacts on the part of suppliers/contractors (supply).

In 2017, we were not charged with any penalties for non-compliance with environmental laws; however, we received five external complaints, which are described under Item 1.4.3.1, together with action taken.[25]

2.1.1 Specifics of business operations and disparities in data collected

When preparing data for the sustainability report, we find some disparities which when assessing and interpreting our environmental impacts, need to be taken into account.

Namely, there are considerable differences in product and API weight. On the one hand you have biosimilars, where the production is complex and is measured in kilograms, on the other hand you have self-medication drugs which are in more than ten tons. Disparity is also seen due to the versatile product portfolio of each site, especially where there is an extensive portfolio (Mengeš, Ljubljana). Moreover, our operations are also characterized by year-to-year adjustments of the production program.

Indicators, which refer to the efficiency of the use of raw materials, energy resources, water, waste, atmospheric emissions and wastewater per ton of product, are difficult to compare between the years and also the weight between the individual production sites.

With the growth of the production of Solids Lendava, the use of raw materials (energy, water), the amount of waste generated, and, to a lesser extent, water and air emissions are increasing for that site as a whole. At the same time, their quantitative realization is not taken into account and, therefore, does not appear in the calculations of the performance of individual indicators.

2.1.2 Environmental protection investments and achievements[26]

When investing in production facilities we always take into account the aspect of ensuring environmental compliance in emissions and the energy-saving technical implementation of technological systems. We also embed the best available technologies – into existing and new production. The estimated value of environmental investments in 2017 is almost € 5 million. The most important investments were in the Unit of Pharmaceutical Ingredients in Mengeš and Anti-infectives in Lendava. Environmental investments include the renovation of roofs, façades and sewage systems.

Major projects in the area of environmental protection in 2017 were:

Lendava:

- optimization of the operation of closed water loops and thus reducing the consumption of fresh water for cooling and increasing the efficiency of cooling,
- optimization of solvent regeneration to increase the recovery by changing the temperature profiles of the columns,
- the purchase of four additional 30m3 press containers for collecting and more consistent waste separation, as well as reducing the number of waste collections (less CO_2).

Ljubljana:

- lowering the level of noise by installing an additional silencer.

Prevalje:

- the production of a study to optimize the existing degradation of penicillin in wastewater and prepare for the implementation of optimization of pre-treatment of waste water,
- preparation and production of project documentation for the construction of own treatment plant, if the municipal wastewater treatment plant is not operational at the time of commencement of the extended production operation.

Mengeš:

- optimization of waste streams, which results in a greater possibility of own co-incineration of waste solvents,
- optimization of the process used in production by methylene chloride – its consumption has decreased by almost 50%,
- connecting additional emissions from production to RTO,
- replacement of the aerator in the leveling pool.

[25] GRI GS disclosure 307-1

[26] GRI GS disclosure 103-2

2.1.3 Verification of established standards[27]

All four sites are the only companies in their respective municipalities to be included in the EMAS scheme, the EU Eco-Management Audit System. In 2018, the environmental verifier (the Slovenian Institute of Quality and Metrology – Accreditation Number SI-V-0001) confirmed that the Sustainability Report of Lek d. d. for the year 2017 reflects a reliable, credible and correct image of all the organizations/ sites activities, within the scope mentioned in the environmental statement.

We successfully certified the environmental management system in accordance with the required ISO 14001:2015 standards, and Environmental Management Systems Certification in accordance with BS OHSAS 18001:2007 standards. We met all requirements to extend our certification in accordance with Responsible Care initiative.

The compliance of our business in the field of health, safety and the environment was confirmed by other external checks in 2017 (JAZMP, FDA, suppliers, etc.).

The compliance of our business in the field of health, safety and the environment was confirmed by other external checks in 2017 (JAZMP, FDA, suppliers, etc.).

[27] GRI GS disclosure 103-2

An important role of Manufacturing Science and Technology

The MS&T teams – Manufacturing Science & Technology – play an important role in developing and maintaining the competitiveness of our company. Their general tasks are to master and develop knowledge of products and production processes. At the same time, they transfer products from development to production, ensure constant validation and control of processes, manage changes and optimizations in production, and provide professional support for production.

Janez Goričanec, Head of MS&T at Solids Ljubljana

Dr. Tjaša Bantan Polak, Head of MS&T at Aseptics Ljubljana

Dr. Uroš Uršič, Head of MS&T at Chemical Operations Mengeš

Borut Bernik, Head of MS&T at Biopharmaceuticals Mengeš

Bojan Lauko, Head of MS&T at Anti-infectives Prevalje

Marko Hauptman, Head of MS&T at Solids Lendava

Robert Mencigar, Head of MS&T at Anti-infectives Lendava

"In our unit, we were very active in the field of product transfer from Sandoz development centers in 2017, and we also intensively worked with the Novartis Development Center in Basel to transfer the first original products to our production. This cooperation will definitely be the key to our future, and we are happy to welcome new opportunities and challenges in this field. The first transfer of the product from the Novartis production site in Stein was carried out very successfully and proved to be a site that can be entrusted to more demanding projects.

At the same time, we were very successful in solving the demanding technological problem with Tamsulosin and Pantoprazol products, which are among our most important products, thus confirming the understanding of our products and processes and the desire for continuous improvements.

As part of a number of improvements in 2017, we can certainly count on the successful product validation processes, such as the Ketonal duo, Ezetimibe, Rosuvastatin, on the increased size of the series, which significantly affects the cost-effectiveness of our products and more flexible production," said **Janez Goričanec**, Head of MS&T at Solids Ljubljana.

Decreasing waste and the efficient use of energy

MS&T team at Solids Lendava

The MS&T team of Solids Lendava, led by Marko Hauptman, is constantly looking for improvements in packaging design, as this can have great positive impacts on the environment as well as financial effects. Their team closely monitors innovations and improvements in the field of technological equipment and materials.

There is great emphasis on innovation at MS&T in Solids Lendava too ...

We are a Novartis strategic site for primary and secondary packaging of solid products. We have already supplied over 100 markets, of which Western Europe has the largest share. Every year, we receive about 10 thousand orders, volumes grow each year and the portfolio already covers more than 80 molecules.

Our department plays an important role in all the products we pack in our factory. Starting with the transfers from other production sites, by designing blisters, defining the secondary packaging and ensuring the consistency and efficiency of our products packaged. We must not forget the area of change management, which is also in our department. These are changes that occur during the lifetime of the product on the BULK, packaging, process or technology itself. Of course, I also include monitoring of the necessary licenses obtained or, approval and implementation of country-by-country changes. In our department, we also deal intensively with optimizations that contribute to a better price in our packaged products, thereby strengthening our competitiveness. We are aware that the experience, connections and knowledge we have gained throughout the years is as important as the equipment that we use to pack our products.

The MS&T team, their innovations, winning mentality and of course the great flexibility and commitment in finding sustainable, efficient and feasible solutions have contributed significantly to the fact that our site has become the largest and more importantly the most complex Novartis packaging plant.

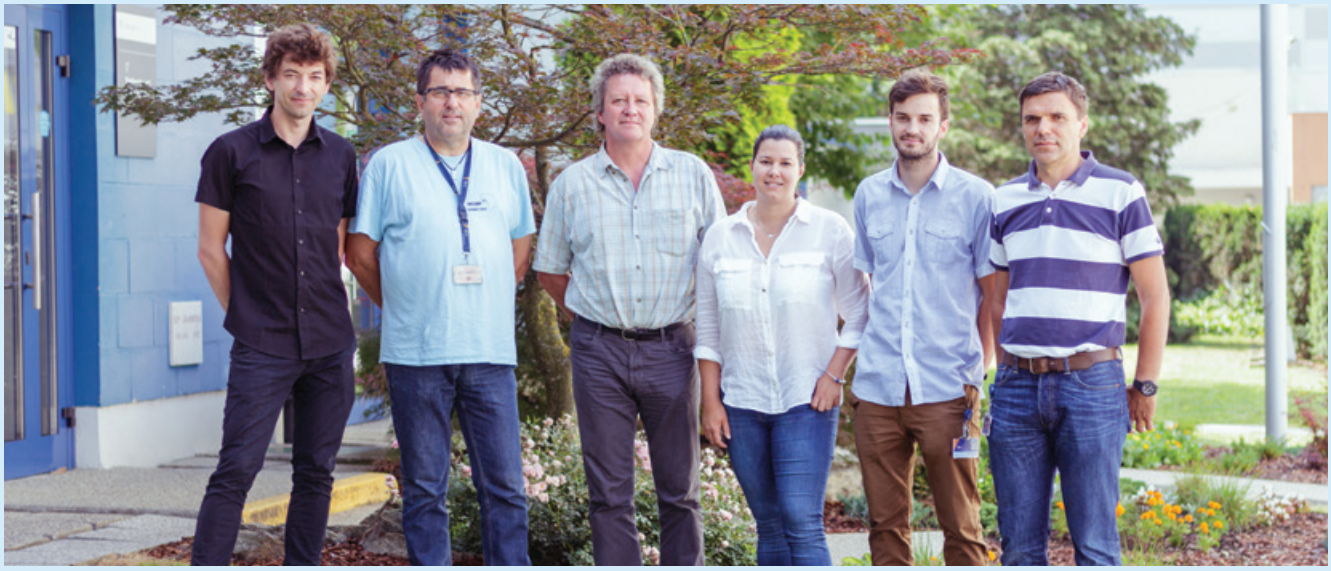
What challenges do you face?

As a strategic site for packaging of solid products, we intensively monitor innovations and improvements in the field of technological equipment and materials. Given our complexity and the breadth of our markets, we must, of course, continue to adapt to the specific requirements of individual countries, which is why managing this complexity while preserving our flexibility is a challenge we are devoting a lot of time to, and for the time being, very successful. In our work, of course, the breadth of knowledge is very important, both in packaging technology, processes, products and their specifications, as well as in the control of primary materials - films for their packaging and other materials in general.

Packaging is also essential for the efficient use of raw materials and then for waste reduction at the end consumer.

When handling packaging, we are building a sustainable approach, and the improvements are certainly also influenced by the responses of our patients. Our basic guideline for packaging production is that, in addition to meeting all regulatory requirements, the packaging must produce as little waste as possible and the energy consumption should be as low as possible for its production. In doing so, we are constantly looking for improvements, alternative packaging and their manufacturers, since any improvement can have a large environmental and, of course, a financial impact.

Only a team can accomplish optimization



The MS&T team at Anti-infectives Lendava

Head of MS&T at Anti-infectives Lendava, Robert Mencigar on the role of innovation in their department, and the importance of teamwork and collaboration with other units in optimizing processes.

The MS&T department is one of the newest functions. What is their role in Anti-infectives Lendava?
We support production and products and represent the bridge between production, quality and development. Thus we monitor the stability of processes, we participate in the introduction of new technologies and work methods, we provide support for validations. On the one hand, we monitor processes by statistical processing of process data, monitoring the movement of process and quality parameters, and on the other, we validate the transfer or introduce new processes and changes.

How is promotion of improvements and innovations going? Which examples would you highlight in 2017?
Improvements play an important role, whether they are larger, that is, process improvements, or smaller, such as improved workflow steps, process simplifications, and reduction in the number of recurring steps. All of this, of course, contributes to more efficient use of raw materials, energy and natural resources.

There were several improvements in 2017. Among other things, we started transferring the process of isolating potassium clavulanate without drying the intermediate.

I would specifically mention the development department in Mengeš, which is part of our MS&T unit, where "incredible" innovation is happening and is expected. With innovative techniques and approaches, they change the properties of microorganisms to abandon the production of unwanted metabolites and increase the ability to produce the desired active ingredient, or to achieve the ability to add certain functional groups to the biosynthesis. This reduces the number of steps required in part from the modification of the active ingredient or molecules to the final desired form.

Who do you work with the most?
We are connected to most departments in our unit on a daily basis, wherever our support is needed. We also participate in major projects at the site, in the introduction of innovations and tests, and on-line analyzes, with which we contribute to the optimization of processes and product quality. These methods offer a direct and therefore quicker insight into the developments in the process. With our work we are involved in increasing the efficiency and progress of processes and reducing the scope of manual work by automating or introducing more innovative methods for process control.

How do you transfer your knowledge to others and assure continuous process optimization? What is particularly important in this regard?
Above all, it is always a team and never an individual. Enhancing the improvement is possible if everyone works together and contributes to the ultimate goal, with everyone at the site in mind. Usually, the best ideas for improvements are born when solving problems or in a relaxed discussion, you just need to recognize them and take time to introduce them. A lot of ideas can be obtained for optimization in production, where the processes live 24 hours. Of course, Think Novartis is also a useful too here.

I believe that knowledge transfer is most effective if a new employee grows out of the process, begins their career path in production, realizes all of its practical aspects, and then moves to the office. These are invaluable experiences. Later, knowledge is transmitted through discussion, consultation, guidance, but each of the employee learns something, therefore knowledge transfer is never one-way.

The star award winners 2017

2.1.4 Key projects for optimizing business processes

Anti-explosive protection – ATEX

Currently, we have 77 facilities at all our sites, for which corresponding ATEX certifications need to be obtained. All facilities are maintained under the Rules of Anti-Explosive Protection, which means that an explosion hazard elaborate is prepared for each facility with a risk assessment. The maintenance of Ex-equipment on each Lek site is ensured by a team of internal maintenance technicians, trained and certified for this, as well as external personnel. The Ex-Equipment Maintenance Certification process is a continuous process. Certificates have to be renewed every five years, or with major upgrades of the Ex-facility.

LOTO

We continued with the introduction of the Lockout-tag out (LOTO) system at all of our sites. Also, preparation of detailed instructions for the use of the system and training of personnel in charge of using the system during intervention in production equipment were also carried out. In 2017, Novartis issued a new general procedure for Working with Hazardous Energies (Lock/Tag), which brought some innovations into our system. We immediately started coordinating the existing system with the new process, where there is more emphasis on the role of individuals in dealing with hazardous energies and related responsibilities. We prepared a weakness analysis and an action plan to align with the new procedure.

NOSSCE – For the excellence of each member in the supply chain

Each of our products has to travel a long and demanding path to the end user: from development, production, quality control to packaging and distribution. The coordination of all those involved in this process is therefore crucial to achieving outstanding results. NOSSCE (Novartis Operational Standards for Supply Chain Excellence) provides a simple, transparent and smooth operation of this chain. The key objective of the project is to establish a reliable, understandable and transparent process that brings high quality, safe and efficient products to the market. It consists of a set of principles, organizational processes, tools and metrics that ensure the structured and coherent planning of all members of the supply chain and the harmonization of customers' needs with the timely delivery of our products on the market. All of this proves to be more effective in the operation and a sustainable increase in service quality for customers and patients.

Idea management program Th!nk Novartis

The development of innovation and ingenuity is promoted through online management of ideas and numerous events for the exchange of good practices and opportunities. Our employees entered 966 ideas into Th!nk Novartis in 2017, of which 567 were accepted. The improvements were suggested by 569 different employees. There were quite a few ideas from the field of health, safety and environment, such as forwarding emergency calls to all employees at all sites, inclusion in guided exercise sessions, spatial organisation of the production line and other improvements that contribute to safer and more environmentally friendly work. In 2018, the initiative celebrates its sixth year of existence. Up until now, all implemented ideas have already helped to save more than 38 million euros.

2.1.5 Indirect environmental impacts[28]

Indirect environmental impacts mainly include impacts from suppliers, therefore we expect our suppliers to observe the principles of the Novartis Corporate Citizenship policy. The environmental responsibility of a contractor is one of the key criteria for their selection/approval. Novartis assesses the whole supply chain of raw materials and products on the basis of HSE-influences and their wider social responsibility before signing a contractual arrangement. The agreement constitutes the supplier's guarantee to comply with all applicable HSE laws and regulations, fair work practices and unlawful discrimination. Non-compliance with these standards is considered to be a material breach of the contract, which gives us the right to withdraw from the contract.

In compliance with legislation and internal regulations for waste management, we only select suppliers that have all the required authorizations, and only those suppliers that are recorded as contracting providers with the respective Ministry.

Transport is also a significant indirect environmental impact of our operations. In the urban environment, transport is recognized as the key source of air pollution, mostly due to solid particles (PM particles). We limit the environmental impacts of distribution of goods by replacing aviation by sea transport, which is reported in chapter 2.9.3.2 Distribution.

We restrict transport by using more frequently teleconferences and videoconferences instead of long business trips. We regularly monitor fuel consumption, mileage and CO_2 emissions for all the fleet cars. This data is reported quarterly into the Novartis database.

A 186 company cars were in use in 2017 (106 in 2016), however in 2017 the vehicles from the Slovenian subsidiary of Novartis Pharme Services Inc. were added. In addition to company cars, we had 17 other vehicles (fire engines, forklifts). A total traveling distance of 5,245,149km (3,643,293 in 2016) was recorded, with fuel consumption of 223,546 liters (216,279 in 2016) and CO_2 emissions of 667 tons (448 tons in 2016).

The indirect impact of transport is also taken into account in the process of selecting suppliers in categories such as placing orders for packaging materials.

2.2 Raw materials and natural resources[29]

2.2.1 Mass flow of materials

In production, two of our main guides are the most effective use of raw materials and the production of medicines in the way that preserves the natural resources to the greatest possible extent. Waste management is based on reduction, reuse, recycling and use as fuel, against incineration and disposal.

In 2017, the consumption of raw materials increased by almost 3% due to the higher volume of production in Ljubljana. Mengeš and Lendava reduced raw material consumption by almost 1% and 14%, despite increased production. In Prevalje, the consumption of raw materials was also lower, mainly due to the slightly smaller volume of production.

Due to the change in the composition and the volume of pharmaceutical active ingredients, there are some years of fluctuations in the mass flows of materials. At Lendava and Prevalje production plants, fluctuations are minimal, as only one or two products are produced there, while increasing the production volume of APIs also means increased use of raw materials.

Table 3: Annual mass flow of various materials used* in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	t	8,594	8,177	14,497	4,285	35,552
2014	t	8,891	9,901	15,646	5,063	39,501
2015	t	9,152	10,188	16,091	5,698	41,130
2016	t	8,844	10,396	15,557	5,629	40,426
2017	t	8,778	13,907	13,425	5,442	41,552

*Total quantity of materials purchased within the reporting period to ensure seamless progress of the manufacturing process to the finished product phase (including packaging but exclusive of fuels, water and manufacturing equipment).

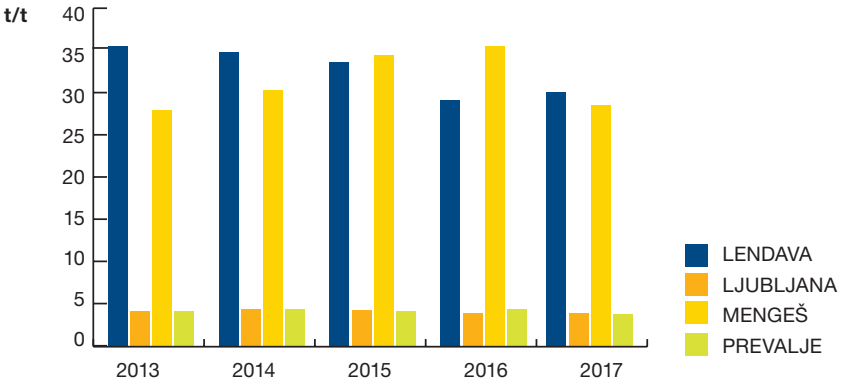
[28] GRI GS disclosures 305-1, 308-2, 414-2

[29] EMAS Core indicator, GRI GS disclosures 103-1, 103-2, 103-3, 301-1

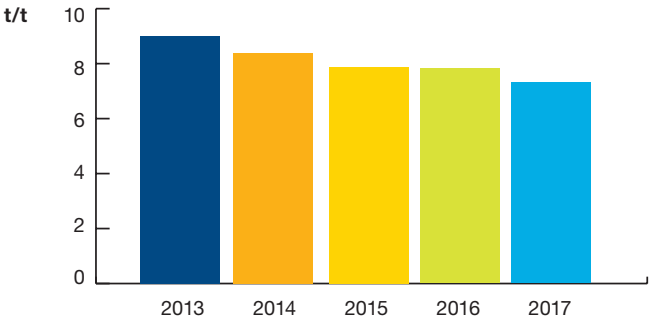
2.2.2 Efficiency of materials

In order to minimize environmental impact, we are constantly working to reduce the consumption of raw materials per unit. From the graphic presentation of the efficiency of the use of all raw materials, it is evident that the amount of raw materials consumed per tonne of produced active substances or products has been declining for many years. In 2017, we increased the efficiency of the use of materials by more than 6% compared to the previous year, and by more than 20% between 2013 and 2017.

Chart 3: Efficiency of the use of raw materials per unit of product[30] – by site and overall efficiency of the use of raw materials per unit produced



Efficiency of the use of raw materials per unit of product – Lek total



[30] EMAS Core indicator

2.2.3 Sustainable packaging approach

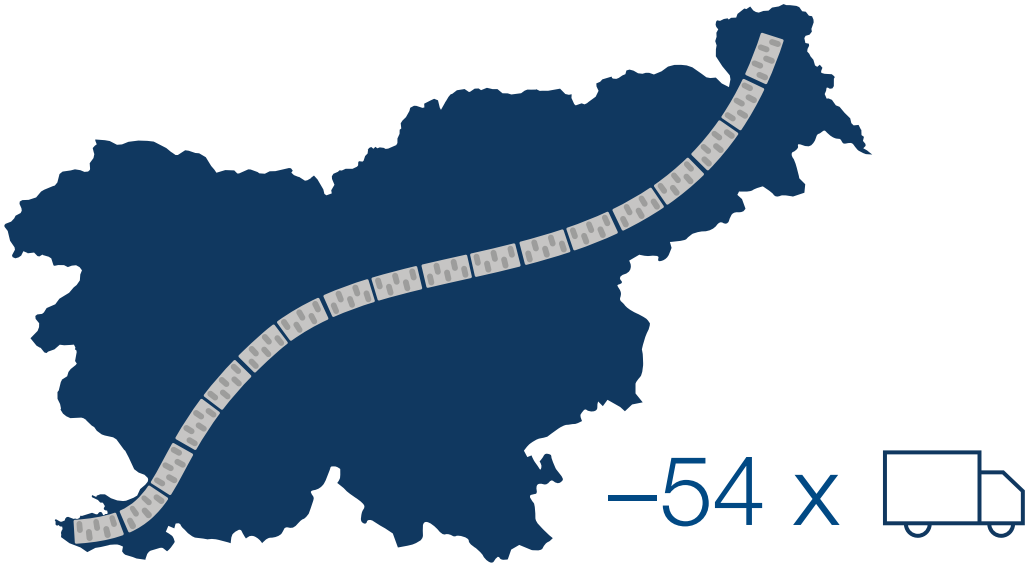
Packaging can have a large negative impact on the environment, and we therefore strive for improvements in this area as well. Lek defined the basic principles of packaging design and production in accordance with the Novartis policy of sustainable use of the packaging and the binding waste management hierarchy.

A comprehensive selection of recommended materials for the packaging, dimensions and types of primary and secondary packaging is written in the **Sandoz global packaging catalogue**. The basic principle of the guidelines is that the packaging material must, in addition to meeting all regulatory requirements, generate minimum waste and use minimum amount of energy in production.

The largest consumption of packaging is observed at the sites with the production of finished products: Ljubljana site with almost 72.6% and Prevalje with 24.6%. In Mengeš and Lendava, however, consumption represents less than 3% of the total packaging used in Lek.

In 2017, MS&T from Solids Lendava in the Omeprazole product for the UK market reclassified the entire packaging. By changing the size of the blister and, consequently, the leaflets, they achieved the optimal amount of product on the pallet, while at the same time significantly reducing the consumption of the design and cover foil. The redesign of the packaging optimized the occupancy of the pallet by 39.2%, which at the annual level reduced the occupancy of 54 cargo vehicles. This also means lower material consumption, manipulation and lower environmental impacts due to transport and distribution.

Optimization of packaging elements in the Omeprazole product



With reduced blister size, a smaller product leaflet and optimized stacking on the pallet, we reduced the occupancy of 3,516 pallet sites and 54 trucks less. The foil saved could be laid down in the length from Goričko to Piran and back. Savings were also created elsewhere.

2.3 Energy

2.3.1 Energy cosumption

Table 4: Overall energy consumption[31]

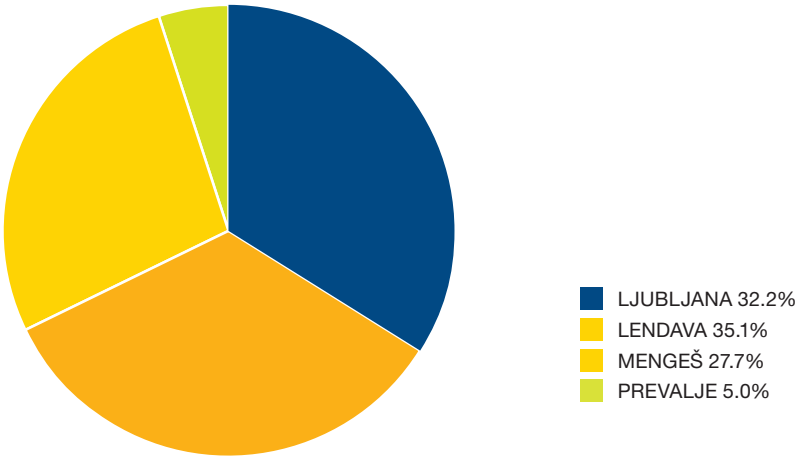
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	GJ	382,122	387,740	334,561	62,691	1,167,114
2014	GJ	387,500	412,023	330,623	64,043	1,194,189
2015	GJ	382,018	428,121	355,886	66,147	1,232,172
2016	GJ	412,721	450,709	355,584	64,432	1,283,446
2017	GJ	440,300	440,732	345,339	62,285	1,288,657

The overall annual energy consumption was a good 0.4% higher than in the previous year. The largest increase was recorded at the Lendava site (by 6.7%), where due to technological procedures, production volume was increased. Other sites reduced their energy consumption; Prevalje 3.3%, Mengeš 2.9% and Ljubljana 2.2%.

In the total energy consumption, Ljubljana and Lendava have the highest share with 34%, followed by Mengeš with 27% and Prevalje with 5%.

[31] GRI GS disclosure 302-1

Chart 4: Distribution of energy by site



At the Mengeš site, waste solvents are utilized as secondary fuel for the operation of the steam boiler that generates heat and steam for technological purposes. At the Lendava site, the share of renewable energy amounts up to 1%. It is obtained from the incineration of organic waste generated in fermentation production.

Table 5: Efficiency of energy resource use per unit of product[32]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	GJ/t	1,577	191	645	56	299
2014	GJ/t	1,501	164	632	46	255
2015	GJ/t	1,389	146	744	43	236
2016	GJ/t	1,483	151	791	44	247
2017	GJ/t	1,487	127	696	43	225

Table 6: Electricity consumption[33]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	GJ	189,032	155,394	116,498	25,686	486,610
2014	GJ	198,955	169,269	117,140	26,601	511,965
2015	GJ	201,421	173,523	124,413	28,139	527,496
2016	GJ	213,819	178,554	126,025	27,810	546,208
2017	GJ	222,317	176,139	124,764	26,474	549,694

In 2017, we used 0.6% more electricity than in the previous year, due to increased production volumes.

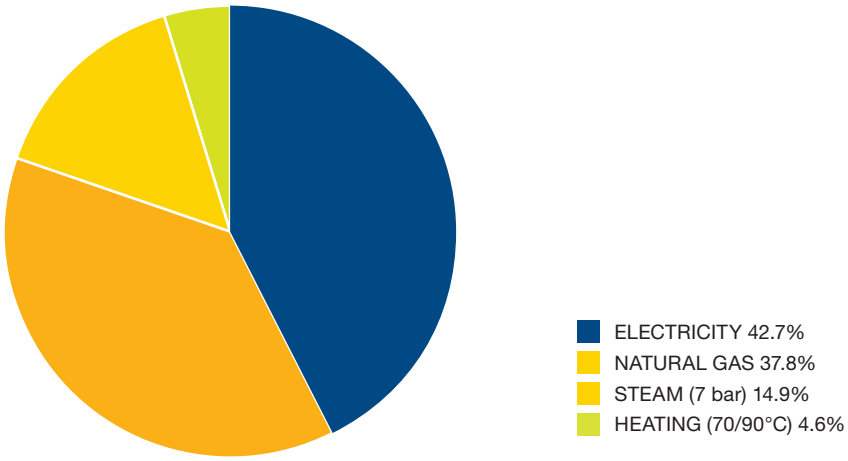
[32] EMAS Core indicator, disclosure GRI GS 302-3

[33] GRI GS disclosure 302-1

2.3.2 Distribution of energy by energy sources

In the structure of purchased energy sources, electricity accounts for the largest share with 42.7%, followed by natural gas with 37.8%. These two energy sources are the primary source for three sites. At the Ljubljana site – in addition to these energy sources, we also purchase industrial steam (14.9%) and heating water (4.6%).

Chart 5: Distribution of energy used by primary energy sources



2.3.3 Energy efficiency improvements[34]

In 2017 and 2018, we carried out energy audits with a special emphasis on the energy efficiency of processes and entirety of technological facilities at all Lek locations. We identified and evaluated measures at all locations, which will be the basis for the implementation of energy-efficient projects in the current mid-term period.

In 2017, additional measures were taken to improve energy efficiency, generating energy savings of 19.3 TJ. These results were reached with the following projects:

- At the **Mengeš** site, we optimized the distribution of energy and upgraded the pump, thus saving 1,740 GJ of energy.
- At the **Ljubljana** site, we saved 15,000 GJ of heat energy with the installation of heat recovery and recuperation on the air intake system.
- At the **Lendava** site, several projects of optimization of technological processes and replacement of the compressor station saved 1,587 GJ of energy.
- At the **Prevalje** site, 920 GJ of energy was saved through optimization of cooling systems and investments in the energy efficiency of buildings.

[34] GRI GS disclosures 302-4, 305-5

2.4 Water

Pharmaceutical production, compared with some other industries, is not a water-intensive activity. However, access to fresh water of good quality is of great importance because it is used in chemical synthesis, the production of medicines and intermediates, and the cleaning of equipment and products.

Regular monitoring of quantities oversees the supply and consumption of water, and the monitoring of quantities and parameters of pollution of waste water. Higher quantities of water are used wherever technological processes or spaces need to be cooled. In these cases, this is "non-contact" water, where the parameters are the quantity and temperature of the water, but not the quality of the water. Otherwise, water is used in the technological process, where the requirements for additional water treatment before use also occur.

2.4.1 Water use efficiency

In Lek, we pay a lot of attention to improving the efficiency of water use, which is one of the most important natural assets. In 2017, we increased the amount of water used by 2% and increased our efficient use of water by 1%.

Table 7: Water use in 1,000 m³ [35]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	1,000 m³	1,316	477	1,452	39	3,284
2014	1,000 m³	1,380	570	1,557	42	3,548
2015	1,000 m³	1,315	569	1,627	42	3,553
2016	1,000 m³	1,304	588	1,433	36	3,361
2017	1,000 m³	1,323	574	1,488	37	3,422

[35] EMAS Core indicator, POR OI 21, GRI GS disclosure 303-1

Table 8: Efficiency of water use per unit of product* [36]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	m^3/t	772	218	570	31	246
2014	m^3/t	650	196	532	24	208
2015	m^3/t	645	183	670	21	204
2016	m^3/t	753	185	852	17	225
2017	m^3/t	1,173	165	672	18	223

* Table 8 only provides the data on water use efficiency for industrial wastewaters (cooling waters excluded).

Water consumption per kg of product at the Lendava site

- 2013: 5.4 m^3 of water/kg of product
- 2014: 5.3 m^3 of water/kg of product
- 2015: 4.8 m^3 of water/kg of product
- 2016: 4.7 m^3 of water/kg of product
- 2017: 4.5 m^3 of water/kg of product

2.4.2 Water supply sources

Water from our own wells is used for technological purposes at the Lendava and Mengeš sites, for which we have obtained appropriate permits from the Ministry of Environment and Spatial Planning.[37] We regularly monitor groundwater levels, with pressure sensors every hour on a continuous basis all year around, and report the results to the respective ministry.

At the Mengeš site, the impact of the well on the level and direction of groundwater is also monitored simultaneously with this annual monitoring. Monitoring of groundwater levels clearly showed that the dynamic groundwater supplies of Mengeško Polje. A longer time interval in monitoring the groundwater levels in the area of the Lek Mengeš facility shows fluctuations in groundwater levels of Mengeško Polje are extensive and amount to over 15m (high water level in 2010 and low water level in 2012). The precipitation in 2016 were average, but very unevenly distributed and time restricted (storm events).

Table 9: Water supply quantities and sources at the Mengeš and Lendava sites in 1,000 m^3 [38]

Mengeš	2013	2014	2015	2016	2017
From our own pumping station (in 1,000 m^3)	1,376	1,480	1,510	1,330	1,399
From the public water supply network (in 1,000 m^3)	81	83	123	108	95

Lendava	2013	2014	2015	2016	2017
From our own pumping station (in 1,000 m^3)	1,297	1,340	1,261	1,318	1,254
From the public water supply network (in 1,000 m^3)	58	58	53	60	63

In compliance with the IED Regulation, adopted in August 2015, we carried out groundwater parameter measurements at the Mengeš and Lendava sites, enabling a quantitative comparison between the situation in the IED plant area and its situation after the definitive termination of the activity. Thus it can be determined whether the soil or groundwater pollution has increased significantly.

The condition of soil and groundwater pollution for the Mengeš site was analyzed by the National Laboratory for Environment and Food, and the initial report was sent to ARSO within the prescribed deadline. The initial report for the Lendava site needs to be submitted to ARSO at the first major modification of the environmental permit.

[36] EMAS Core indicator

[37] Water permits No. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8

[38] GRI GS disclosure 303-1

2.4.3 Recycling and reuse[39]

The water we use is, to the largest possible extent, recycled and reused in production. The condition for this is a consistent separation of unpolluted wastewater from other streams that require purification. Recycled water is most often used for process cooling. The share of recycled water is constantly being increased, mainly at the Mengeš site.

At the Mengeš site, a three-level cooling water system operating at different temperature regimes enables the water from one system to be fed into a higher-temperature system, while a portion of water (spill) is discharged into the sewage system. The quantities of reused water vary greatly and depend on individual processes. It has been estimated that the entire cooling water volume is reused at least twice.

2.5 Waste

2.5.1 Waste management[40]

At the Lendava site, the use of best available techniques (BAT) is considered in all new projects regarding water use. The investment in optimization of closed loops in 2017 thus reduced the consumption of fresh water for cooling systems by almost 11%, while the efficiency of cooling increased.

Regular waste management is also ensured through monitoring.

Within the framework of the environmental management system, we have a waste management plan in Lek. This, in accordance with the statutory waste management hierarchy, emphasizes the prevention of waste generation. Where this is not possible, it provides preparation for reuse, recycling or processing with other processes.

[39] GRI GS disclosure 303-3

[40] EMAS Core indicator, GRI GS disclosure 306-2

We recycle more than 90% of all generated waste and only a small part of the waste is emitted to incineration. In accordance with the Novartis policy of hazardous waste management, these are not allowed to be disposed of in landfills, and large efforts are also invested in reducing the amount of non-hazardous waste for disposal (including municipal ones).

Almost 72% of all Lek waste is biodegradable waste, among which are mycelium, waste echinacea, waste fennel, waste from the tea room, etc. Of this, the mycelia waste from Lendava fermentation production has the majority.

In addition to the mycelium, the predominant part of which is water and it is sent for processing to the biogas plant, the entire amount of waste sludge from the Lendava Cleaning Plant is added to the biodegradable waste in Lendava.

Among the volume important non-hazardous waste in Lendava belongs also waste packaging that is produced in the packaging of final forms of medicinal products and is being disposed of for recycling to authorized contractors.

84% of all waste in Mengeš is hazardous waste, of which 93% is non-halogenated waste solvents. In 2017, in two steam boilers, we processed 11% more high-calorific waste solvents into the energy used for the preparation of technological steam than in 2016. By processing waste solvents at the site, we reduce the transport of waste solvents and consequently the CO_2 emission. The remaining waste solvents are given to authorized companies that remove waste in an environmentally acceptable manner, most commonly with incineration. The incineration of waste solvents with a calorific value below 22 MJ/kg is not considered to be recyclable according to Novartis criteria.

Despite the increase in production, the quantities of waste produced decreased by just under 1% in 2017, mainly due to a greater decrease in the Lendava location.

Table 10: Volumes of waste generated in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	t	24,624	2,230	4,670	698	32,222
2014	t	26,147	2,739	5,146	636	34,667
2015	t	25,588	2,748	5,692	766	34,794
2016	t	28,862	3,010	4,597	800	37,269
2017	t	27,856	3,305	5,010	827	36,998

Chart 6: Volume of waste per ton of product – efficiency

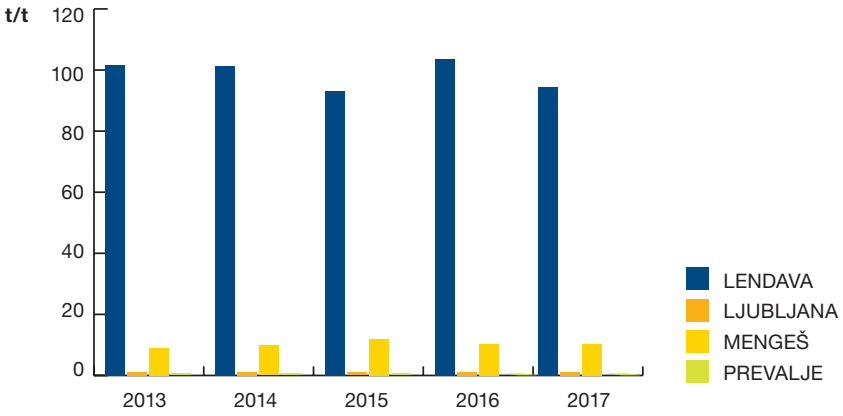
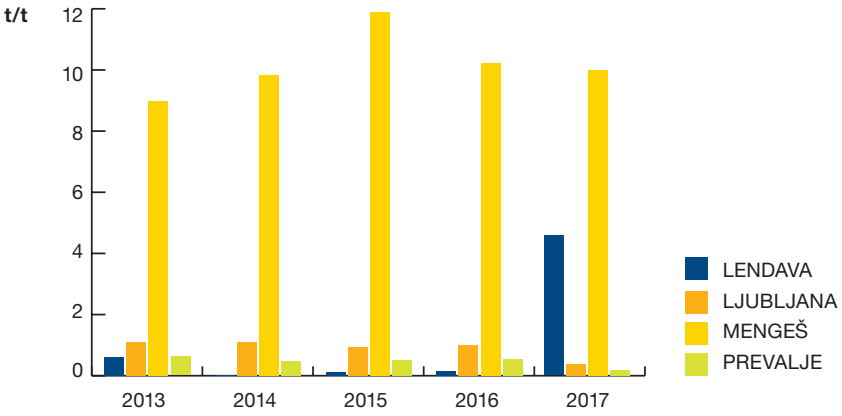


Chart 7: Volume of waste per ton of product – efficiency/disregarding mycelium waste



2.5.2 Disposal of hazardous waste[41]

The amount of hazardous waste at the Lek level increased by 13%, while the amount of hazardous waste was recorded at the location of Ljubljana and Prevalje. Absolute increase in quantities is mainly due to the locations of Lendava and Mengeš.

The expansion of Lendava Solids' products also increases the amount of waste, but their quantitative realization is not taken into account and therefore does not appear in the calculations of the performance of individual indicators. In Mengeš, the increase in waste quantities is the result of changes in the product portfolio. Waste streams for new products are not always immediately optimal and therefore more waste is generated in the initial period of production than later.

In the management of hazardous waste, our guide, in addition to preventing and reducing waste generation, is also a constant increase in their share of recycling or energy use. We processed and reused almost 86% of all organic solvents, which is 1% more than in 2016.

In Lendava, the share of reused organic solvents is more than 95% and remains at the level of previous years, and the completed project of regeneration of additional solvent in 2017 will further increase the share of solvent regeneration at Lendava. In Mengeš, the share of reuse is on average 65%, and for some processes it is more than 95%. The cause of the slightly lower percentage of recycling of organic solvents in Mengeš compared to 2016 is in the change in the range and product volumes.

Non-halogenated waste solvents, which are extremely clean and high-energy, represent 93% of all hazardous waste at the Mengeš site, while the proportion of halogenated is just over 1%. With the abolition of the production process using the halogenated solvent methylene chloride in the technological process, the amount of halogenated waste solvents decreased by 38% compared to 2016. The downward trend in halogenated waste solvents is therefore continuing.

With co-incineration with natural gas we removed 1,823 tons of waste solvents (1,644 t in 2016), equivalent to 15% of the primary energy for steam generation for the supply of energy to processes.

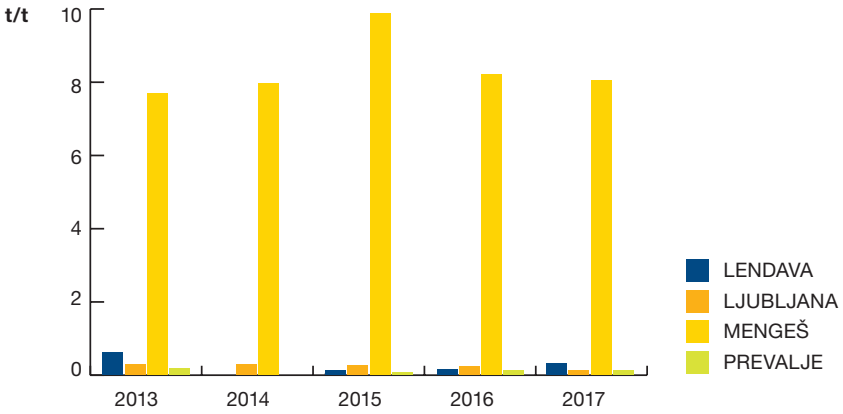
A large amount of hazardous waste at the Ljubljana site represent written-off medicines, but it cannot be reduced due to the inventory management method. Since 2011, however, we have performed intensive segregation of the waste packaging of hazardous substances (also in case a hazardous substance is only present in traces), which we release for incineration with energy recovery.

Table 11: Volume of hazardous waste in t

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	t	148	575	3,855	215	4,793
2014	t	6	747	4,136	89	4,978
2015	t	30	744	4,646	129	5,549
2016	t	38	673	3,691	191	4,593
2017	**t**	**182**	**654**	**4,208**	**186**	**5,230**

[41] POR OI 5, GRI GS disclosure 306-2

Chart 8: Volume of hazardous waste per ton of product – efficiency



2.5.3 Disposal of non-hazardous waste[42]

86% of total Lek waste volume is non-hazardous waste. In 2017, biodegradable industrial waste, sent to a certified biogas plant, accounted for 72% of total waste. At the Mengeš site, this is largely biologically degradable waste generated by the manufacture of fennel and Echinacea juices, at the Lendava site mycelium waste. Biodegradable waste also includes waste from tea kitchens.

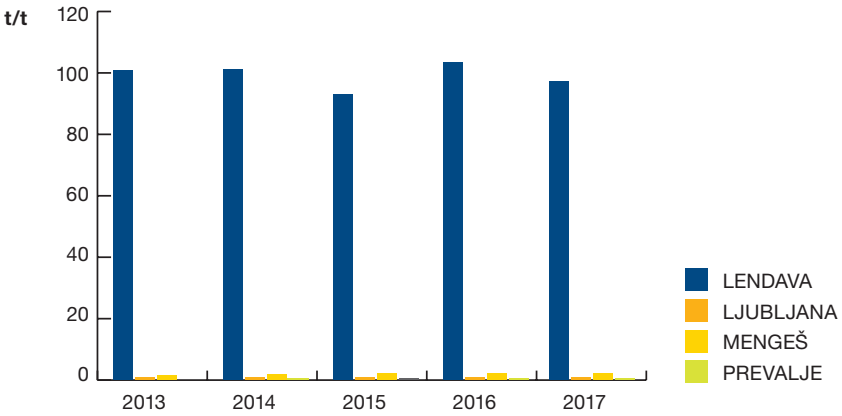
Municipal waste accounted for a mere 0.6% of all waste. In 2017, we additionally decreased it by 24% thanks to sorting packaging and installing separation containers for external (construction) contractors and increased the amount of recycling. Waste packaging, collected separately by fractions (paper, plastic, wood, metal, glass) represents 11% of all waste. We mainly recycle waste packaging (through the Gorenje Surovina system), and the same applies to construction waste. Other non-hazardous wastes are disposed of by authorized companies by means of incineration.

Table 12: Non-hazardous waste volumes by site in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Lek (recyclable non-hazardous waste without packaging)
2013	t	24,476	1,655	815	483	27,430	25,493
2014	t	26,141	1,991	1,010	547	29,689	27,411
2015	t	25,558	2,005	1,046	637	29,245	26,742
2016	t	28,824	2,337	906	610	32,677	29,787
2017	t	27,674	2,651	802	642	31,768	27,622

[42] GRI GS disclosure 306-2

Chart 9: Volume of non-hazardous waste per ton of product – efficiency



2.6 Air emissions[43]

RTO device in Ljubljana for regenerative thermal oxidation of volatile organic compounds emissions.

We implement Novartis' corporate social responsibility policy and strive to minimize our impacts on the environment. It is also one of the important long-term Novartis goals. By 2020, the total emissions should be reduced by 30% and by 50% by 2030, compared to the base year 2010. In doing so, we are also committed to respecting Slovenian and European legislation, which is described in detail in point 2. *Compliance with legislation and standards in the field of Environmental Protection act (HSE).*

Primarily, we reduce emissions at the expense of the use of energy products, thus improving energy efficiency, with emphasis on the use of renewable energy sources. In Lek separately we monitor greenhouse emissions and emissions from stationary installations.

Among them, the emissions of volatile organic compounds (VOC) and dust are central. Measuring points are installed on technological devices and lines where VOC emissions, dust particles or other substances are expected in the outlet air.

[43] EMAS core indicator, POR OI 7, POR OI 10, GRI GS disclosures 103-1, 103-2

They measure the content of the substance and/or dust in the air and capture samples for analysis. For all measured outlets, the prescribed emission and/or dust emissions estimates have been made. In addition, we focus on preventing dispersed VOC emissions and collecting them at source for the purpose of cleaning, as far as reasonably possible.

Various devices are used to reduce emissions of organic matter: for thermal combustion of gases, absorbers, gas detergents and others.

Based on the results of periodic measurements, balance of solvents used, assessment of emission dispersion, and other data, we prove the conformity of total VOC emission values with the emission limit value expressed as a percentage of organic solvent input. For new devices this value amounts to less than 5%, for existing devices it is below 15%, whereas VOC emissions in captured waste gases do not exceed the limit concentrations (20 mg C/m^3).

We also maintain our compliance with the limit value for total dust, amounting to 150 mg/m^3 and with the limit value for the mass flow of total gas in excess of 0.2 kg/h, which amounts to 20 mg/m^3.

When using devices for thermal oxidation, we not only measure VOCs quantified as total organic carbon (TOC), but also the emissions of nitrogen oxides and carbon monoxide (LV = 100 mg/m^3). According to the stated parameters, these devices comply with statutory requirements as well.

2.6.1 Emissions from waste incinerators and co-incinerators

Incineration and co-incineration are carried out at two sites, Lendava and Mengeš. As operators of industrial complexes performing single or multiple activities covered by Regulation (EC) No. 166/2006, the Lendava and Mengeš sites have the obligation of reporting the volume of releases to the European Pollutant Release and Transfer Register (E-PRTR).

The Lendava site carries out mainly the incineration of waste generated at the site. The incineration process is controlled via a control system and flue gas parameters are regularly measured. The set limit/alarm values prevent the waste incineration process from running outside the permissible limits. By incineration of waste and natural gas as supporting fuel, process steam is obtained.

At the Mengeš site, thermal oxidation of industrial fumes is carried out in two of the four combustion plants using natural gas as a primary source of energy. By co-incineration of natural gas and non-halogenated solvents of high purity and calorific potential, process steam is obtained. Emission monitoring is regularly performed at all the emission release points. Permanent emission measurements were provided on the waste solvent co-incinerator for the parameters prescribed in the environmental permit.

2.6.2 Sulphur dioxide[44]

The volumes of SO_2 emissions at our sites have always been low, and were mainly generated by the devices for the thermal treatment of volatile organic compounds. In 2017, we recorded a 33% decrease in these emissions as a result of occasional fluctuations in incineration of waste containing sulphur. The content of sulphur in natural gas is practically non-existent.

Table 13: Sulphur dioxide emissions (SO_2)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (kg SO_2/t product)
2013	t	0.00	0.0004	0.0029	0.006	0.009	0.002
2014	t	0.13	0.00	0.004	0.0105	0.145	0.031
2015	t	0.10	0.00	0.005	0.0064	0.108	0.021
2016	t	0.0008	0.00	0.0017	0.0066	0.0091	0.0018
2017	t	0	0	0.0006	0.0062	0.0068	0.0012

The values of SO_2 emission volumes by year are based on the data on their concentration at individual measuring points and on the time of device operation.

[44] EMAS Core indicator, POR OI 7, GRI GS disclosure 305-7

2.6.3 Nitrogen oxides[45]

Nitrogen oxide emissions arise mainly from incinerators and co-incinerators, burning devices and to a lesser extent the manufacture of nitrooxine at the Mengeš site.

Regular emission checks are carried out at all sites. In 2017, nitrogen oxide emissions increased by 3.7% due to the Lendava site, all other sites recorded lower emissions than 2016.

Table 14: Emissions of nitrogen oxides (NO_x)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t NOx/t product)
2013	t	10.57	1.04	9.35	1.43	22.39	0.006
2014	t	14.48	0.86	16.36	1.45	33.15	0.007
2015	t	13.55	0.11	15.79	1.47	30.92	0.006
2016	t	13.58	0.08	11.80	2.55	28.01	0.0054
2017	t	17.97	0.052	11.34	2.46	31.83	0.0056

2.6.4 CO_2 and other greenhouse gases

The sources of direct CO_2 emissions (GHG1) at our sites remain as follows: burning of fuels and the incineration/treatment of flammable organic substances, production processes (e.g. fermentation) and the use of company cars. Direct emission (GHG1),[46] data reported also includes:

- dinitrogen oxide (N_2O) in equivalents CO_2,[47]
- fluorinated hydrocarbons (hydrofluorocarbons – HFC) in CO_2 equivalents CO_2[48] and
- other greenhouse gases (methane and others) in CO_2 equivalents.[49]

The group of direct CO_2 emission sources also includes some other gases used in or arising from our processes.

CO_2 is considered an indirect greenhouse gas (GHG2) when it is generated as an equivalent to the purchased electricity, heat and steam at the site where they are produced.

Table 15: Carbon dioxide and other gases contributing to the greenhouse effect[50]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t CO_2/t product)*
GHG1	2013	t CO_2	10,774	2,792	13,966	2,053	29,585	7.6
	2014	t CO_2	10,691	3,273	14,139	2,068	30,171	6.4
	2015	t CO_2	10,591	2,737	15,429	2,109*	30,866	5.9
	2016	t CO_2	11,642	3,118	14,375	2,032	31,168	6.0
	2017	**t CO_2**	**12,161**	**2,810**	**14,146**	**2,097**	**31,215**	**5.5**
GHG2								
	2013	t CO_2	1,575	24,242	970	214	27,001	6.9
	2014	t CO_2	9,351	31,976	5,506	1,250	48,083	10.3
	2015	t CO_2	1,672	26,675	1,033	234	29,613	5.4
	2016	t CO_2	0*	26,743*	0*	0*	26,743*	6.0
	2017	**t CO_2**	**1,845**	**27,373**	**1,036**	**220**	**30,473**	**5.3**

* The purchase of green certificates for 2016 in the total CO_2 emissions from electricity, and CO_2 at the Ljubljana location comes from the supply of steam and hot water.

[45] EMAS Core indicator, POR OI 8, GRI GS disclosure 305-7
[46] POR OI 10
[47] POR OI 11
[48] POR OI 12
[49] POR OI 13
[50] GRI GS disclosures 305-1, 305-2, 305-4

The total volume of direct greenhouse gas emissions (GHG1) stayed at the same level as in 2016. The efficiency, expressed as a ton of CO_2 emissions per 1 ton of product, improved by 9%.

The increasing GHG1 emission volumes were also due to new highly complex products. Consequently, emission abatement is our top-priority task. It is mainly achieved through systematic energy management, process changes, implementation of new technological solutions in the phase of product development/transfer, and installation of energy- and environmentally efficient devices.

At the Mengeš site, the main source of direct CO_2 emissions (GHG1) is natural gas combustion in the burning devices and co-incineration of waste solvents (>90%).

The Lendava and Mengeš sites participate in trading with CO_2 emission vouchers. According to the law, we have an obligation to report the emission to the Ministry of the Environment and Spatial Planning, and to pay an environmental fee.

2.6.5 Volatile organic compounds VOC[51]

Novartis' recommendations on the use of alternative solvents in production are implemented through a systematic introduction of innovations in technological manufacture processes, where halogenated solvents are replaced with non-halogenated ones. Therefore, in Mengeš in 2016 and 2017 we terminated one of the productions which used Methylene chloride in the technological process. At the site, there is also a halogenated solvents extraction device for outlet air, with the state-of-the-art cryogenic condensation technology. In Prevalje, the use of halogenated solvents was already abolished years ago with the final replacement of methylene chloride with ethanol.

Special attention is paid to streaming of volatile organic compounds from tankers into storage tanks on site. Pipes must be equipped with such connections so that when filling the reservoirs, the displaced fumes are returned to the tank, and in accordance with the legal requirements all stationary tanks at the site are periodically tested for sealability.

In 2017, the total volume of emissions of volatile organic compounds decreased by an additional 24% and from 2012 by as much as 60%. We improved the efficiency per ton of product by 35%, which can not be attributed only to improvements, but also to changes in technological processes due to changes in the portfolio set.

Table 16: Total emissions of volatile organic compounds

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t VOC/t product)
2013	t	24	28	68	5.8	126	0.032
2014	t	23	13	57	7.2	100	0.021
2015	t	25	9	56	4,7*	93**	0.018*
2016	t	24	10	48	3,8*	85**	0.016*
2017	t	24	5	32	4.7	65	0.011

*The change arises from the error in entering the data into the DMS system and consequently in the Lek d. d. Report on Sustainable Development for 2016.
**The actual data is published, which due to rounding up does not equal the final sum in the table.

2.7 Water releases[52]

Waste water is discharged into public sewage system in technological, cooling and public utility lines. Before releasing into the sewage system, all sites have an equalization pool for technological waters. In Prevalje, technological waste water is pre-treated before releasing it into the public sewage system. With additional studies of degradation of penicillin waste waters in 2017, which we carried out together with the Faculty of Pharmacy, we detected the possibility of improving the process.

We have been monitoring the effects of pharmaceutical substances on the aquatic environment for several years, even before the requirements of Slovenian legislation and European directives were set. By 2020, we have set the goal that the active ingredients in our waste water discharges are 10 times below the concentration, which is determined to have no impact on aquatic organisms.

As early as 2016, Novartis, by signing the Davos Declaration Combating Antimicrobial Resistance, additionally committed itself to preventing the emergence of resistance to antibiotics in all possible ways. The substances from our industry can pass through to waste waters, and from there, through the treatment plants to surface waters. It was found that the proportion of pharmaceutical substances in water only to a lesser extent comes from pharmaceutical production and predominantly from end-users of pharmaceutical products.

[51] POR OI 9

[52] GRI GS disclosures 103-1, 103-2

Some of the substances decay rapidly in the aquatic environment, and some are actively removed from the water by microorganisms. The assessment of environmental risks is determined based on experimental and modeled data on pharmaceutical substances, such as physico-chemical data, data on fate and behavior of substances in the environment and data on toxicity in the aquatic environment. We regularly review and evaluate the ecotoxicological data of the substances and take measures accordingly. We raise awareness amongst employees and users of our medicines on the importance of removing unused medicines or medicines with expired deadlines in accordance with legal regulations.

Only non-contact cooling water is released into the cooling sewage system. Unpolluted cooling water is discharged directly into a surface water course whenever possible. Roof precipitation wastewater is discharged into surface water courses directly or indirectly.

At all sites we perform prescribed periodic monitoring of the parameters of individual waste water flows, including the constant monitoring of the flow, pH and temperature of the waste water. Reports on the Monitoring of Industrial Wastewaters Discharge for 2017 show that no excessive pollution was identified at any of the sites.

2.7.1 Waste waters

In Lek, 63% of the total quantity of water used is unpolluted waste water. At the Mengeš and Lendava sites, waste cooling waters account for 99% of the total water quantity used. In 2017, their consumption decreased by a good 2% or by almost 45,000 m^3, which was contributed to by Lendava. The consumption of industrial water increased by 9%.

After use, unpolluted waste cooling waters are discharged into the surface water course, a procedure for which environmental permits have been obtained.

Table 17: Wastewater volumes by discharge quality and destination[53]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
Use of cooling water - unpolluted							
	2013	1,000 m^3	1,129	35	1,156	5	2,325
	2014	1,000 m^3	1,212	75	1,278	8	2,573
	2015	1,000 m^3	1,137	33	1,307	9	2,486
	2016	1,000 m^3	1,095	34	1,050	11	2,190
	2017	1,000 m^3	976	42	1,154	11	2,145
Discharge			into the surface water course	into sewage system cleaning at WWTP	into the surface water course	into sewage system	
Use of industrial water - polluted							
	2013	1,000 m^3	187	442	296	34	959
	2014	1,000 m^3	168	494	279	34	975
	2015	1,000 m^3	177	536	320	33	1,067
	2016	1,000 m^3	209	554	383	25	1,172
	2017	1,000 m^3	347	570	334	26	1,277
Discharge			into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system	into sewage system cleaning at WWTP

[53] EMAS Core indicator, GRI GS disclosure 306-1

2.7.2 Phosphorus and nitrogen compounds, chemical oxygen demand

Phosphorous compounds also result from residual inorganic substances from the fermentation production, the Mengeš site is also the major generator. In 2017, we recorded a significant 51% decrease in the amount of such compounds in comparison with the previous year.

Nitrogen compound emissions mostly result from the fermentation production. The Lendava site accounts for the largest share of these emissions, followed by Mengeš, also at the expense of the 5-NOK production. In third place in nitrogen compound emissions in water is Ljubljana, and, at a negligible level, the Prevalje site. In 2017, the total volume decreased by almost 12%, mostly due to the reductions at Lendava and Mengeš.

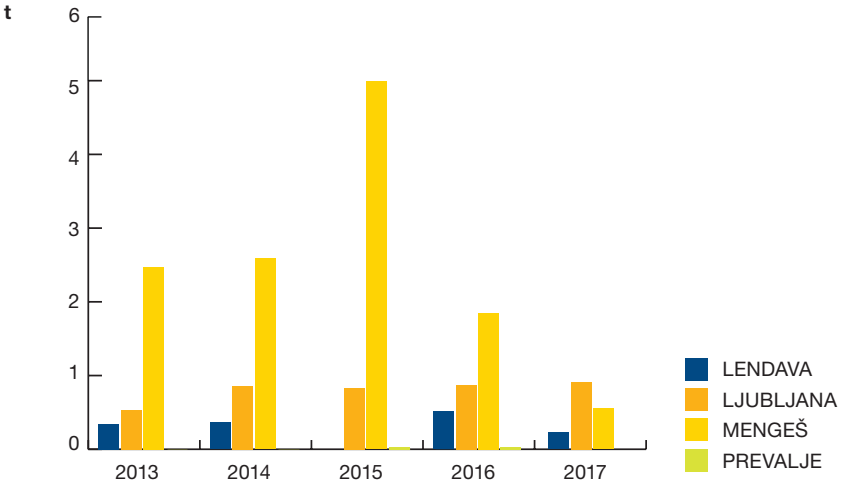
As the annual amounts of phosphorus and nitrogen compounds are reported after treatment in the wastewater treatment plant, they largely depend on the efficiency of the wastewater treatment. Wastewater from the Mengeš site is transferred to the Central Wastewater Treatment Plant Domžale-Kamnik, which in 2016 finished an extensive upgrade of the existing aerobic treatment stage, in order to increase the level of treatment of nitrogen and phosphorus by 40%. The upgrade of the treatment plant has an important impact on both the improved ecological state of Kamniška Bistrica and assuring the protection of groundwater, at the same time presenting indicators for 2017.

To provide an assessment of the level of pollution with organic impurities, chemical oxygen demand is an important parameter, providing the quantity of oxygen needed for chemical oxidation of organic pollution in wastewater. Chemical oxygen demand measurements are carried out at the point of discharge of waste cooling waters into the sewage system. In 2017, we recorded a decrease in the chemical oxygen demand of 2%. Wastewater from the production of finished products in Prevalje and Ljubljana is low in volume, which is also reflected in the contribution of the chemical oxygen demand - less than 5% of the total pollution of waste waters with organic impurities contributes to the location.

Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute parameters for the calculation of the environmental fee. The highest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds each represent about 10% of the pollution.

Wastewaters and the content of all the three parameters are constantly monitored by the authorized monitoring authorities. Monitoring is carried out three to six times a year, depending on the volumes of wastewaters at the respective site.

Chart 10: Emissions of phosphorus compounds in wastewater[54]



[54] POR OI 15

Chart 11: Emissions of nitrogen compounds in wastewater[55]

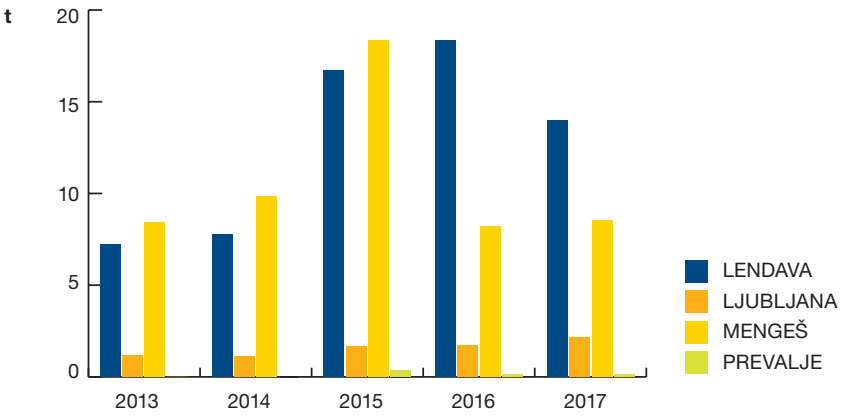
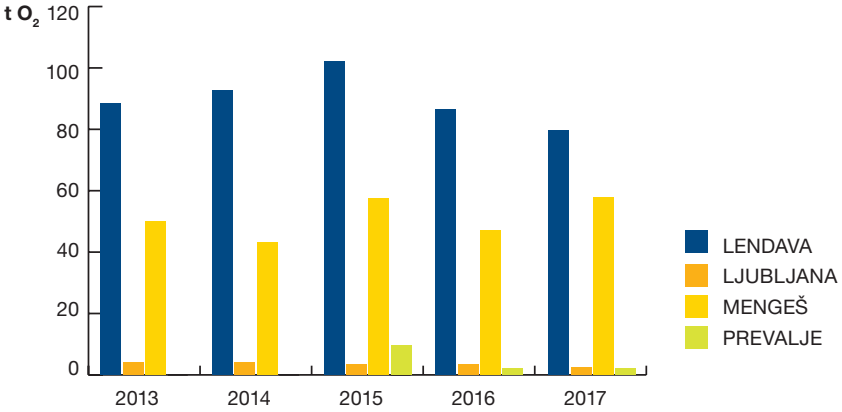


Chart 12: Chemical oxygen demand (in tons O_2)[56]



2.8 Other environmental impacts

2.8.1 Odor

Europe and Slovenia's environmental regulations do not cover environmental odor pollution, and are not planned for the future. However, in accordance with good practice of environmental emissions management, we have installed biofilters wherever odor from industrial processes is expected, thus preventing it from affecting the local population, for example, above wastewater equalization ponds. Monitoring of odor emissions is regularly carried out by the National Laboratory for Environment and Food (NLZOH). We also perform thermal treatment of waste gases from production. In addition to the aforementioned techniques, the method of waste management and the maintenance of cleanliness of the sites are of upmost importance for limiting the smell, which is already taken care of due to the fundamentals of the pharmaceutical activities.

2.8.2 Soil

The ground is the balance between living and non-living nature. Soil is the primary resource for food and biomass production, and is therefore of key importance in water treatment processes, organic mass cycle, and carbon binding. The main sources of soil contamination are polluted air from industry and household furnaces (smoke, soot, acid rain), traffic, intensive agricultural production and wild waste dumps. As the environmental impact on soil pollution is usually irreversible, this area is of special concern to us.

In Lek, we perform periodic inspections of technical measures, and thus enable seamless and reliable operation of devices.

[55] POR OI 16
[56] POR OI 14

Systematic consideration of all technical and organizational measures, both in the design, construction and operation, and maintenance of devices, is proved by the reports of external authorized contractors and internal documentation. Additionally, at all times, documentation on maintenance activities, device overviews and safety walkthroughs can be checked on site.

We consistently fulfill the requirements with regard to hazardous substance storage and transport, which are the major soil pollutants. We regularly check the leak-proof status of sewage systems, particularly those carrying industrial wastewater. This is of particular importance at the Mengeš and Ljubljana sites which are situated in a water protection area. A comprehensive overview of soil conditions is also taken into account for the composition of the soil and the soil load that has been exposed to the soil in the past.

To date, no remedial action due to soil pollution has been needed at Lek.

2.8.3 Noise

At Lek, the main identified source of noise is manufacturing activity, particularly the operation of fermenters, compressor stations, as well as ventilation and cooling devices. This is why it is important that already in the phase of project planning, we take into account possible excessive burden on the environment with noise when searching for solutions. For new projects, we often use mathematical modeling of existing and predicted noise, which is carried out for us by an authorized company.

In 2017, we re-examined the resident's complaint, which allegedly detected the noise caused by the fan's operation in the roof of production in Ljubljana. Measurements have shown that the level of noise is far below the prescribed legal limits. The noise complaint is also described in Chapter 1.4.3.1.

2.8.4 Biodiversity

In Slovenia, one of the most important mechanisms for the preservation of plant and animal species and their habitats is the identification of protected, ecologically important and special protection areas. Our sites are not located in areas of natural values, Natura 2000 areas, protected areas or other areas of importance for the conservation of biodiversity. Our facilities are located within industrial zones where there are no major environmentally critical habitat types or protected vegetation.

In Lek, we are aware that over-exploitation and economic activity can be a cause of biodiversity loss. By consistent adherence to statutory requirements and proactive measurements in handling waste and industrial water management requirements we strive to mitigate any impact on the quality of the environment and consequently contribute to preservation of the biodiversity in the areas surrounding our production sites.

2.8.5 Light pollution

The legislative regulation makes the light pollution management a great challenge for Lek. The existing legislative regulation on light pollution requires the reduction of external illumination of production and parking areas, while on the other hand meeting minimum standards for working conditions dictates sufficient illumination. Also, studies show that people exposed to warmer color shades of outdoor lighting feel better.

With the help of experts, we elaborated comprehensive studies on light pollution management for our locations. The outdoor lighting was arranged using the lighting with greater efficiency (LED) and at the same time we reduced its operation during the time when labor needs are reduced. In 2017, we repaired a billboard in the office building at Ljubljana, and reduced its electrical connection power 10 times over, and lighting pollution was also reduced by switching off the panel during certain night hours.

The total electrical power of the lamps at any location does not exceed 50 kW, therefore Lek is not obliged to provide the performance of operational monitoring. However, all locations, according to legislation, have an elaborated lighting plan with basic information on the light source.

2.9. Safety

2.9.1 Fire safety

Proper fire safety in Lek is ensured by voluntary industrial firefighting units at individual sites in cooperation with contractual occupational units.

2017 was an anniversary year for the Lek Voluntary Industrial Firefighter Association, celebrating its 70th year. The Lek unit was founded in 1947, under the name Jugolek. Throughout the years, the unit has developed, combining the firefighters of all Lek locations: Ljubljana, Mengeš, Prevalje, Lendava and Kranjska Gora. Today, they cover the Ljubljana and Mengeš sites. We celebrated the anniversary with a formal academy at the Mengeš Cultural Center.

As part of the celebration and the municipal exercise "Domžale 2018", a firefighting exercise took place at the Mengeš site, where more than 120 firefighters, first responders, members of the emergency medical services and other members of the civil defense participated.

In April 2017, the Lek Prevalje Voluntary Industrial Firefighter Association was established. The advantage of establishing our own Voluntary Industrial Firefighter Association is the inclusion in education and training at the level of the Fire Brigade of Ravne na Koroškem and the Chamber of Commerce and Industry.

Lek Voluntary Industrial Firefighter Association celebrated its 70th year.

Three voluntary industrial firefighting associations now cover the needs of Lek; Lek Voluntary Industrial Firefighter Association at Ljubljana and Mengeš site, Lek Prevalje Voluntary Industrial Firefighter Association and Lek Lendava Voluntary Industrial Firefighter Association.

There were no major fire safety interventions in 2017 at any site. All four sites regularly carry out fire fighting exercises and evacuation exercises. The operational firefighters also perfected their knowledge at the Educational Protection and Rescue Center Ig.

2.9.2 Biological safety

In Lek, we work in different work processes with the biological factors of groups 1 and 2 (cell lines of mammals, bacteria and fungi), which are negligible or present a low risk of spreading into the surrounding area. For biological factors in Group 1, the likelihood of causing disease in humans is minimal, the risk of spreading to the environment is negligible. Biological agents from Group 2 can cause disease in humans and can be hazardous to workers, but the risk of spreading to the environment is negligible.[57] We have larger quantities of biological factors in the production process, where only organisms of Group 1 enter. Biological factors of Group 2 are used in small quantities, especially in quality control, where we check the effectiveness of products.

The biosafety system is integrated in all levels of work and is linked to all relevant stakeholders. At the level of Novartis we have prescribed guidelines for safe work, we regularly report on compliance to the responsible person for biosafety. At the company level, we have a biosecurity officer, and biosecurity officials are also appointed at individual sites. Lek also has a biosecurity committee, which expertly reviews new risk assessments for biological agents of Group 2 and genetically modified organisms.

In any closed system where we deal with biological factors, we have a specific project manager for work, a caregiver for a contingency plan or an accident plan and, where we deal with genetically modified organisms (GMOs), also the person responsible for supervision and safety at work with GMOs. The basic task of all these persons is to ensure safety for human health and the environment and to ensure compliance with Slovenian legislation and Novartis guidelines. The effectiveness of the system is assessed through a number of internal audits at different levels; Novartis audits, internal audits of closed systems by the authorized person and HSE walkthroughs.

2.9.3 Providing warehousing and distribution safety

2.9.3.1 Warehousing

The chemicals we use are classified into the appropriate hazard category according to their physical properties and health and environmental hazards. They are stored in technically organized warehouse zones, in accordance with Slovenian legislation and Novartis guidelines.

Employees handling hazardous substances are practically and theoretically appropriately trained. Appropriate instructions for safe work have been drawn up which describe all the hazards, safety measures and methods of safe operation. We carry out regular monitoring and verification of organizational measures, staff qualifications and compliance with the instructions.

[57] For more explanations on biological factors, see Glossary of Important Terms.

2.9.3.2 Distribution

Following a good distribution practice (GDP) and guidelines for the transport of dangerous goods, we provide for safe transport and distribution without accidents. Employees who prepare and dispatch dangerous goods, are familiar with the requirements of international agreements and are trained in the procedural measures for the transport of dangerous goods.

We continuously carry out the qualification of transport routes for road, air and sea transport in critical winter and summer time and on transport routes selected on the basis of risk analysis.

In 2017, 7,915 shipments of products (7,296 in 2016) were dispatched from Lek sites and contracted distribution warehouses in the total amount of 26,043 tons. Lek production sites and contractual distribution warehouses shipped 4,732 tons of chemicals classified as dangerous goods.

In 2017, we had 62.5% of road shipments, 25.5% of air cargo and 12.0% of sea shipments. The ratio between ship and air transport (measured in kg) was 70/30 in 2017 in favor of the sea transport.

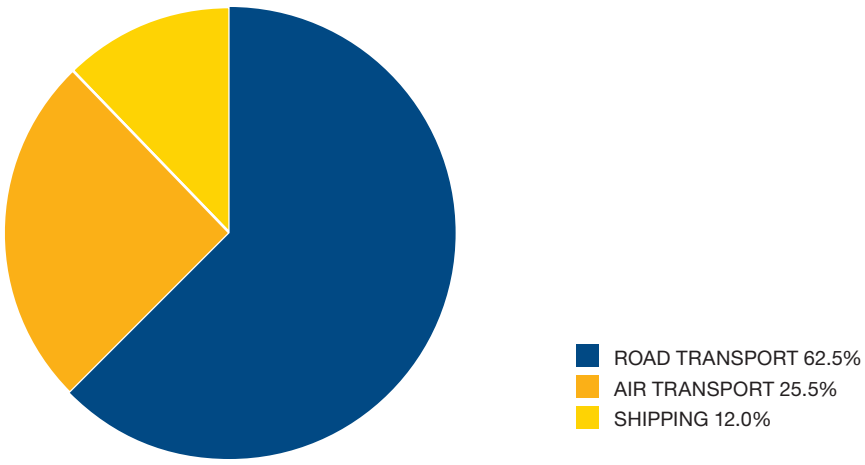
This reduces our carbon footprint, as shipping has a lower emission factor than other types of transport (shipping 10–40 g/tkm, 60–150 g/tkm road, air transport 500 g/tkm Source: Lufthansa Air cargo).

2.9.4 Chemical safety

A high level of protection of the health of employees and the environment is ensured by the safe use of chemicals in production and in laboratory work. Employees are familiar with the measures of safe work with chemicals prescribed in internal procedures.

In the production of pharmaceuticals, we prevent direct exposure to chemicals with modern technologies. Descriptions of measures to protect employees and the environment in API production are also the key content of REACH (Registration, Evaluation and Authorization and Restriction of Chemicals) registration of strategic chemicals at the European Chemicals Agency (ECHA). The registrations provide Lek with continuous imports and isolation of raw materials in API production.

Chart 13: Consignments by means of transport



3. Labor

3.1 Human resources policy[58]

Gifted, talented and responsible people are key to achieving the strategic objectives of the company, which is why people are at the heart of the entire business operation – ”It’s all about people”. Human resources policy highlights three principles regarding this: "Cooperation. Development. Excellence." The priority task is to design processes, tools and systems in the field of human resource management.

Considerable emphasis is placed on talent development, succession planning, compensation of achievements, appropriate organizational development and training. The HR policy supports the basic business orientations, aiming to achieve a high level of innovation, growth and better productivity.

We offer our employees a unique opportunity in Slovenia to work in an international research and development team in the pharmaceutical field.

3.2 Employment

3.2.1 Total workforce by employment type and employment contract[59]

In 2017, we created 410 new jobs and finished the year with 3,889 full-time employees. At the end of the year, the proportion of women employed was almost 46%, the same share as the previous year. At year-end, 93.5% of all employees worked on a full time permanent basis, and 6% were fixed-term employees and 2% of all employees worked on a part-time basis.

Table 18: Number of full-time employees on 31. 12. 2017 by site

Site	Number of full-time employees
Ljubljana	2,079
Mengeš	1,058
Lendava	484
Prevalje	261
Other*	7

* Rented warehouses: Logatec, Kranj, Šentjanž pri Dravogradu.

[58] GRI GS disclosures 103-1, 103-2

[59] GRI GS dislcosures 102-7, 102-8, 401-1

Novartis Career Breakfast, an innovative human resource practice

An experience I recommend

Dr. Rok Brišar, expert, who took part in the Novartis Career Breakfast and then bacame a part of the Lek team.

At the beginning of 2017, Rok Brisar attended the Novartis Career Breakfast in Mengeš, and by the end of December he was employed there. He immediately joined the team of experts responsible for the production of a biological active ingredients after completing his doctorate at the Leibniz Institute for Catalysis in Rostock, Germany, where he devoted himself to polymeric, organic and catalytic chemistry.

What is your area of work?
We work with our colleagues for the production of a biological active ingredient, which is produced in Mengeš. This is biotechnological production for the preparation of biological medicines. As a production technologist, I have the task of assuring work is undertaken in accordance with the prescribed procedures and timetables, and I also define new procedures for expanding production. I also take care of the validation of the technological equipment cleaning process, and currently, along with my colleagues, I am also starting a new line for biological ingredient production.

How did you find the Novartis Career Breakfast experience?
I recommend this experience to all students and jobseekers. It is a great opportunity to get to know the leading staff in Lek and make contacts that help you in your future career.

What made you decide to return to Slovenia?
There were two reasons; I want to do what makes me happy and to learn as much as possible. Lek allows this. I have seen many opportunities for working in various fields, to progress and to learn. These options are extremely wide, as we are a stable and growing company, connected to the Novartis international network, which I especially like. The conditions for professional and personal growth are good, and the more favorable balance between professional and private life contributes to motivation for work. At the same time, I believe that Lek's biopharmaceuticals belong in terms of economic development among the most promising in the country and possibly also in Europe.

3.2.2 Percentage of employees covered by collective agreements[60]

In 2017, the Collective Agreement covered 99.2% of the total workforce, a level identical to that in the previous years.

3.2.3 Coverage of the organization's defined benefit plan obligations[61]

In addition to all the obligations defined in the labor legislation, we allowed our employees to participate in a collective additional pension scheme, enabling them to receive an additional pension after their retirement. The company pays a monthly premium equal to the statutory percentage in the amount of 5.844% of the employee's gross salary, or an annual amount that cannot exceed 2,819 EUR. At the end of 2017, 88.12% of the workforce was included in the scheme.

3.2.4 Procedures for local hiring and proportion of senior management hired from the local community[62]

The employment process is based on determining the competencies required to perform the job position. In line with Novartis' strategy of diversity and inclusion, we respect and promote the cultural, ethnic and sexual

[60] GRI GS disclosure 102-41
[61] GRI GS disclosure 201-3
[62] GRI GS disclosures 103-1, 202-2

diversity of our employees. The proportion of local human resources in the senior management team in 2017 is 93%, the same as the previous year (93% in 2016).

3.2.5 Parental leave[63]

Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act. In recent years, we have seen growth in the number of employees taking parental leave, the return to work rate after parental leave remains high (around 99%).

Table 19: Level of parental leave and return to work

	2017	2016	2015	2014
Number of employees having taken parental leave	**397**	**357**	**241**	**225**
• Men	191	205	118	110
• Women	206	152	123	115
Number and share (in %) of employees returning to work after parental leave	**394 (99%)**	**354 (99%)**	**238 (99%)**	**221 (98%)**
• Men	191 (100%)	205 (100%)	118 (100%)	110 (100%)
• Women	203 (98%)	149 (98%)	120 (98%)	111 (96%)

3.3 Occupational health and safety[64]

By ensuring health and safety at work and by preventive actions and maintaining our health, we implement Lek's policy of HSE. To assure the smooth implementation of health and safety, we are properly organized and provide the necessary material and human resources. In doing so, we are constantly striving for improvements in the management systems of this area.

The risk assessment of workplace with a health assessment is an integral part of the Safety Statement, which recognizes, eliminates and/or diminishes all forms of risks for employees. All specified preventive measures from risk assessments are carried out regularly.

Obligatory training for safe and environmentally friendly driving

In Lek we have actively involved drivers of company vehicles in the realization of our HSE goals.

For all those who are entitled to drive a company car, we organize training to learn the techniques of non-emergency (defensive) and environmentally friendly driving. This mode of driving reduces fuel consumption and greenhouse gas emissions and reduces the likelihood of accidents.

After successfully completing the initial course, which consists of a theoretical and practical part, the drivers are recommended to refresh the course in 3 to 5 years. If individuals were subject to repeated violations of road traffic regulations, then they would have been included in them before.

Drivers of company vehicles must also perform i.e. commented on driving with an authorized instructor. It is intended to reveal potentially dangerous or inappropriate traffic behavior and improve driving habits.

Infringements of traffic regulations, accidents and accidents involving official vehicles, as well as CO_2 emissions are monitored at the HSE unit.

[63] GRI GS disclosures 103-1, 401-3

[64] GRI GS disclosures 103-1, 103-2

3.3.1 Frequency of absences due to injuries at work[65]

Detailed records of work-related incidents involving our employees have been kept for several years by means of the LTIR (lost time injury and illness rate: number of work-related injuries resulting in absence from work or the use of sick leave per 200,000 hours worked) index and TRCR (total recordable case rate: number of all major and minor work-related injuries per 200,000 hours worked).

Table 20: LTIR Index (Lost Time Injury and Illness Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	0.00	0.00	0.17	0.00	0.04
2014	0.00	0.22	0.26	0.49	0.22
2015	0.31	0.10	0.00	0.43	0.12
2016	0.00	0.00	0.00	0.82	0.05
2017	0.00	0.10	0.32	0.79	0.21

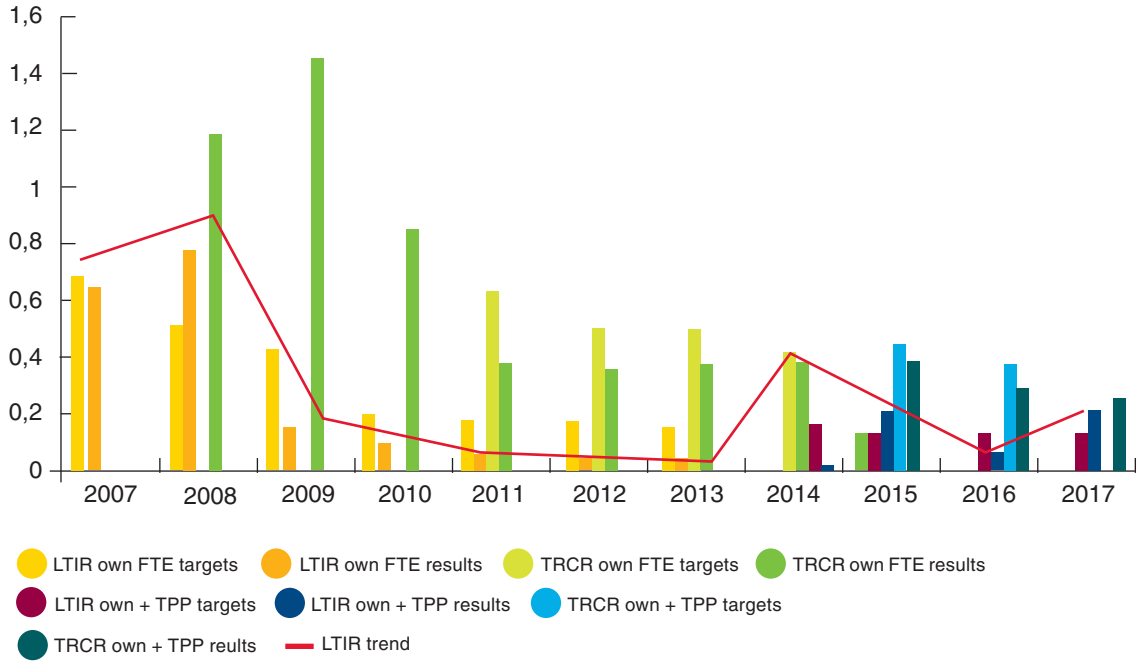
Table 21: TRCR Index (Total Recordable Case Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2013	0.00	0.42	0.52	0.00	0.38
2014	0.69	0.43	0.26	0.49	0.42
2015	0.61	0.31	0.36	0.87	0.39
2016	0.00	0.34	0.11	0.82	0.28
2017	0.20	0.05	0.43	1.18	0.26

In 2017, the LTIR rate amounted to 0.21 (0.05 in 2016), meaning that we recorded 8 cases of workplace accidents requiring sick leave. We recorded no serious work-related injuries, which would leave health consequences due to the injury. The TRCR indicator amounted to 0.26 (0.28 in 2016), which means 10 recorded cases.

The most common causes of injuries were slips and falls, contact with an object, exposure to corrosive chemicals and cuts.

Chart 13: Trend of injuries LTIR



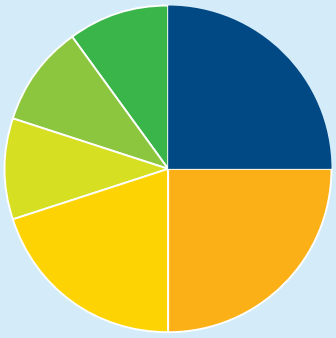
[65] POR OI 2, GRI GS disclosure 403-2

HSE system

Preventive activities to prevent accidents and injuries in 2017

We paid a lot of attention to potentially serious incidents (pSIF - Potential Serious Injuries and Fatalities) and preventive measures to prevent similar incidents. Namely, we find that we have activities in our locations where, under different circumstances, accidents with serious consequences can occur. In 2017, we recorded 11 such cases, which we investigated and prepared preventive measures for.

High Risk Situations in 2017



- HAZARDOUS MATERIAL EXPOSURE
- FALLING OBJECT
- HAZARDOUS ENERGY
- PROCESS
- ASPHYXIANTS
- WORKING AT HIGH

Causes for High Risk Situations

Working at high (insufficient trained operators / skills / competency, without risk assessment)

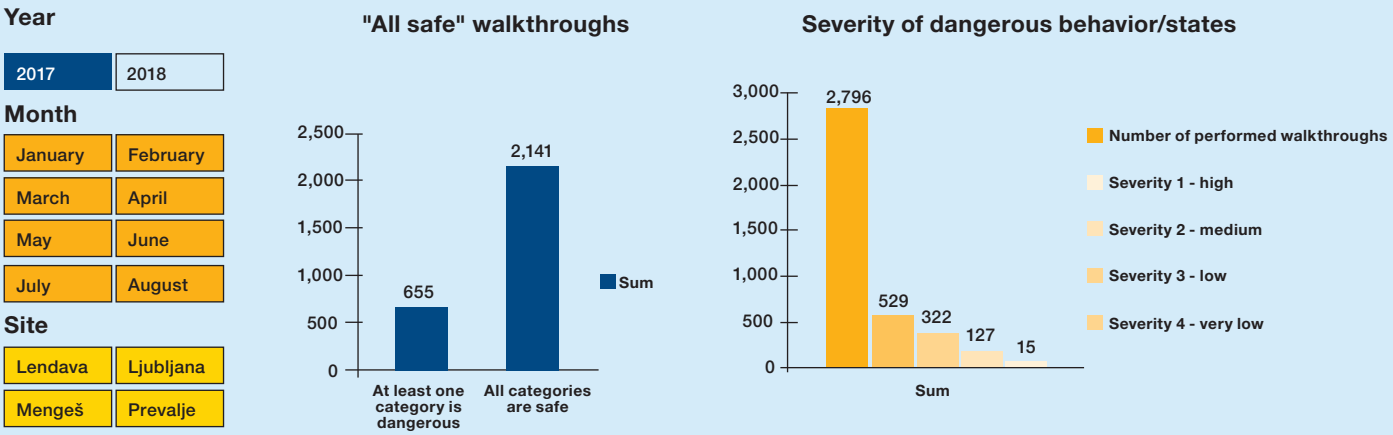
Hazardous Energy (insufficient trained operators / skills / competency, insufficent safety walkthroughs)

Hazardous material Exposure
(Steam, Corosive chemicals)
- not using proper PPE
- without risk assessments
- inefficient safety walkthroughs

Falling Object (without / poor risk assessment, inefficient safety walkthroughs, poor housekeeping)

In addition to all conventional preventive activities, we put a lot of effort into safety walkthroughs. By performing safety walkthroughs, we influence the behavior of our employees, thus preventing dangerous behavior and situations that can lead to incidents or injuries. In 2017, 2,796 safety walkthroughs were carried out, where it was found that in 142 cases in the work process, in different circumstances, there could be injuries or health problems due to various dangerous situations or inadequate behavior of employees.

By performing safety walkthroughs, we influence the behavior of our employees, thus preventing dangerous behavior and situations that can lead to incidents or injuries.



Monitoring safety walkthroughs via an online survey

We also implemented other preventive measures for preventing and reducing the risks at work, such as: active role of safety promotors (meetings, walkthroughs), safety walkthroughs by site management, notifying and informing employees about work instructions, employee training, risk assessment, prevention/analysis of work accidents and almost events, assistance in internal meetings - a moment for security (prepared presentations for internal meetings), provision of preventive health care and health promotion, organization of work environment inspections, and inspections and tests of work equipment, as well as the implementation of legislative requirements, by-laws and internal standards of occupational health and safety.

Chart 14: Classification of causes of work-related incidents (LTIR and TRCR) for 2017

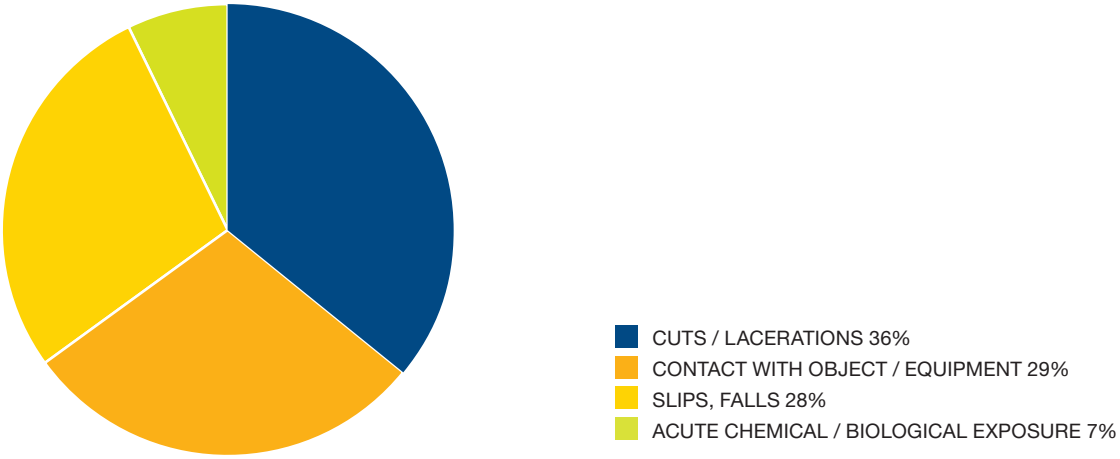
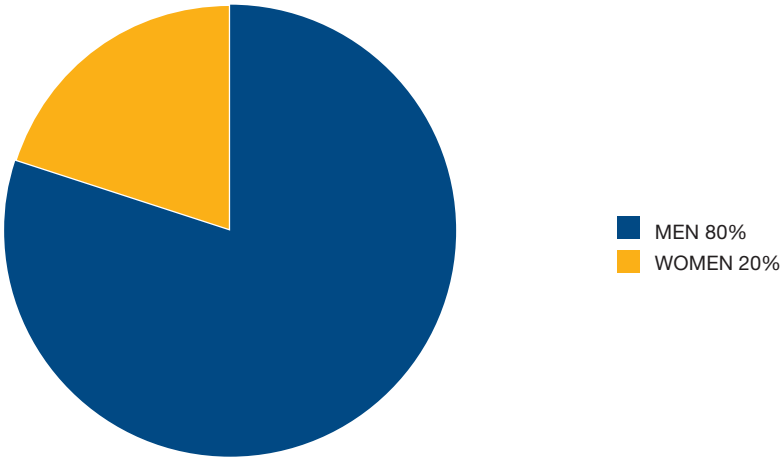


Chart 16: Classification of work-related incidents by gender



3.3.2 Absenteeism[66]

In order to determine the degree of absenteeism, the number of absent employees' working hours is divided by the working hour's fund. In 2017, the proportion of sick leave was 5.20%, recording a slight increase compared to the previous year (4.79% in 2016).

Table 22: Share of sick leave

	2017	2016	2015	2014
Women	4.42 %	5.59%	5.38%	4.65%
Men	6.11 %	4.12%	3.47%	2.96%
Total	**5.20 %**	**4.79%**	**4.33%**	**3.80%**

3.3.3 Frequency of absences of external contractors due to injuries at work

There were four injuries recoded in the performance of work in 2017 amongst outsourcers, which is at the same level as in the previous year. The causes of accidents were related to the unconsciousness of the danger and lack of control by the competent persons of the operators. In order to prevent such events, additional measures have been adopted and introduced which foresee the contractor to pre-evaluate the risk for the planned activity. The assessment with safety measures is made by the contractor (head of contractors) together with Lek at the site of the planned works.

This document is the basis for obtaining a work permit and for determining the appropriate measures, including the requirement of direct supervision of work by a person to assure the health and safety of the contractor.

3.3.4 Number of work-related fatalities[67]

No fatalities were recorded amongst our employees or external contractors.

3.3.5 Occupational disease rate[68]

Until now, Lek has not recognized and confirmed any occupational diseases as defined by the Pension and Disability Insurance Act (ZPIZ-2) and the Rules on the List of Occupational Diseases.

3.3.6 Health promotion program

Again, we successfully implemented a program of education and training for employees in the field of prevention and preservation of health at work. Participation in the programs is voluntary, and the interest of employees to be included in various programs is growing from year to year.

[66] GRI GS disclosure 403-2

[67] POR OI 1 and POR OI 3, GRI GS disclosure 403-2

[68] GRI GS disclosure 403-3

Preventive programs for health promotion among employees in 2017:

Program	No. of employees included
Measurement of health indicators	891
Guided exercise	500
Vaccinations	1,515 against tick-borne meningoencephalitis, 133 against influenza
Convalescence program	61
GCC (Global Corporate Challenge)	637
Preventative dentist check-up	108
Lectures on: - Healthy nutrition - Ergonomics of sleep - Diet of recreational sportspeople	400
Promotion of physical activity with Petra Majdič	700

Promoting physical activity with Petra Majdič.

By investing in preventative care of employee health, we want to promote healthy lifestyles (health, balanced nutrition, physical activity, stress management, etc.). Consequently, we can expect:

- less absenteeism,
- greater resilience of employees (employees retain and strengthen their health),
- employee satisfaction,
- reducing and alleviating the negative effects of stress,
- reduction of risk factors such as high blood pressure, elevated blood sugar and cholesterol leading to increased cardiovascular disease, obesity, diabetes,
- increasing the quality of products and services, and thus enhancing the reputation of the organization.

3.4 Training and education[69]

We are constantly and intentionally investing in the development, education and training of our employees, and last year, we received the TOP 10 education management award for strategic and systematic investment in knowledge and employment education for a fifth time.

Our employees can attend regular educational programs prescribed in the Education Catalog, tailored workshops according to the needs of the target group, formal forms of education such as in-service courses, and informal forms of education and workshops, where participation is voluntary. We also conduct mentoring and the so-called coaching. Both formal and nonformal education also take place in the job positions themselves.

Meetings where co-workers transfer their know-how as knowledge holders or attended an external or internal conference or a work visit abroad with other colleagues are highly desirable. In many units, especially development ones, these are regular meetings.

Most of the courses are conducted in the company and performed by internal and external lecturers. Our employees also take part in external education courses, and above all, they participate in education provided by Novartis. More and more programs are conducted in electronic form, as an independent e-learning or e-learning under the guidance of a mentor.

Being relaxed and having fun brings new ideas

Employees were impressed by the mysterious crate game, where teams competed in good spirit.

"Give a high five for innovation and excellence!" was the slogan of the 2017 Innovation Week. It is a time when employees learn new ways of thinking and finding solutions through various and relaxed events at all four locations. This time, more than a thousand employees participated, which is the most we have had to date.

The Innovation Week is a real festival of creative thinking and encourages us to step out of our comfort zone and look at our work from a different perspective; a thought that is promoted throughout the year at all sites. The current slogan was also linked to the fifth anniversary of the Th!Nk Sandoz application and with the expectation of the 5000th entry into the application.

Events are prepared in a relaxed and fun way, so that employees are more open to new knowledge and thinking about ideas. The main event at the Innovation Week was attended by more than a thousand employees at all four sites, where at the thematic stands they let themselves think openly. Innovation promoters spoke about why innovation is such an important value at Lek.

In Ljubljana, we had stalls in front of the dining room and the production, and this is where we wanted to generate interest. Our employees who work in shifts were happy that we had prepared events for them in the afternoon and night time. We get huge ideas for improvements from production, so it's right that we get as close to them as possible. The central event of Innovation Week was exceptionally well received at other sites, where we emphasized the promotion of the Th!Nk Sandoz application. This allowed us to additionally present such projects to our newcomers who are not yet familiar with them.

[69] GRI GS disclosures 103-1, 103-2

The need for education stems from individual needs linked to the individual's development plan and business needs related to the business strategy of the organization. Different tools are used to determine the developmental needs of individuals, for example, 360-degree feedback, performance assessment and talks with management. The requirements for compulsory education are linked to the work position of a colleague.

Lek follows global guidelines and new strategies in the field of education, which include combined forms of learning, shorter implementations in the classroom, supported by the implementation of knowledge at the workplace, and above all the increased use of e-learning.

A determined teams leads to improvement

The team of Anti-infectives Prevalje, which improved the control of tightness of seals on packaging; Mitja Gleščič, Urška Lednik, Jerneja Krajnc and Marko Štolcer.

Promoting innovation in production is a complex process that involves many factors to make it a perfectly safe and high quality product. Nevertheless, a significant improvement was introduced at the production of Anti-infectives Prevalje, presented by dr. Alen Miuc, Head of Production Unit.

What improvements are at the forefront in your unit?
Mostly product, process and organizational improvements. In 2017, I would like to emphasize the improved control of seals on the thread of packaging. This is thanks to Mitja Gleščič, Urška Lednik, Marko Štolcer and Jernej Krajnc who developed and achieved a higher quality and reliability of the control system, which was perceived as a critical error for our product. Although the requirement to operate the system at first glance was simple, development required a lot of time, tests and simulations to achieve the desired effect.

How did the process from identification of the issue to implementation go?
We guarantee a 100% safe and high-quality product, and the appearance of the core on the thread seal did not provide the appropriate tightness and stability of the finished product. In the past, as part of the resolution of deviations, the whole series was examined. Because we were not satisfied with the existing thread quality, we sought a solution and introduced it in the context of purchasing a new filling line for the US market. Thanks to the perseverance of the team that took part in the introduction of the line, the manufacturer developed a special program for the extraction of extremely small moonliners.

What did you achieve with the innovation?
During the control of the liners, the detection and elimination of inadequate threads of bottles containing moonliners or stains are carried out. The device now detects the wrong shape. The camera captures each thread individually and automatically excludes it if it is inadequate.

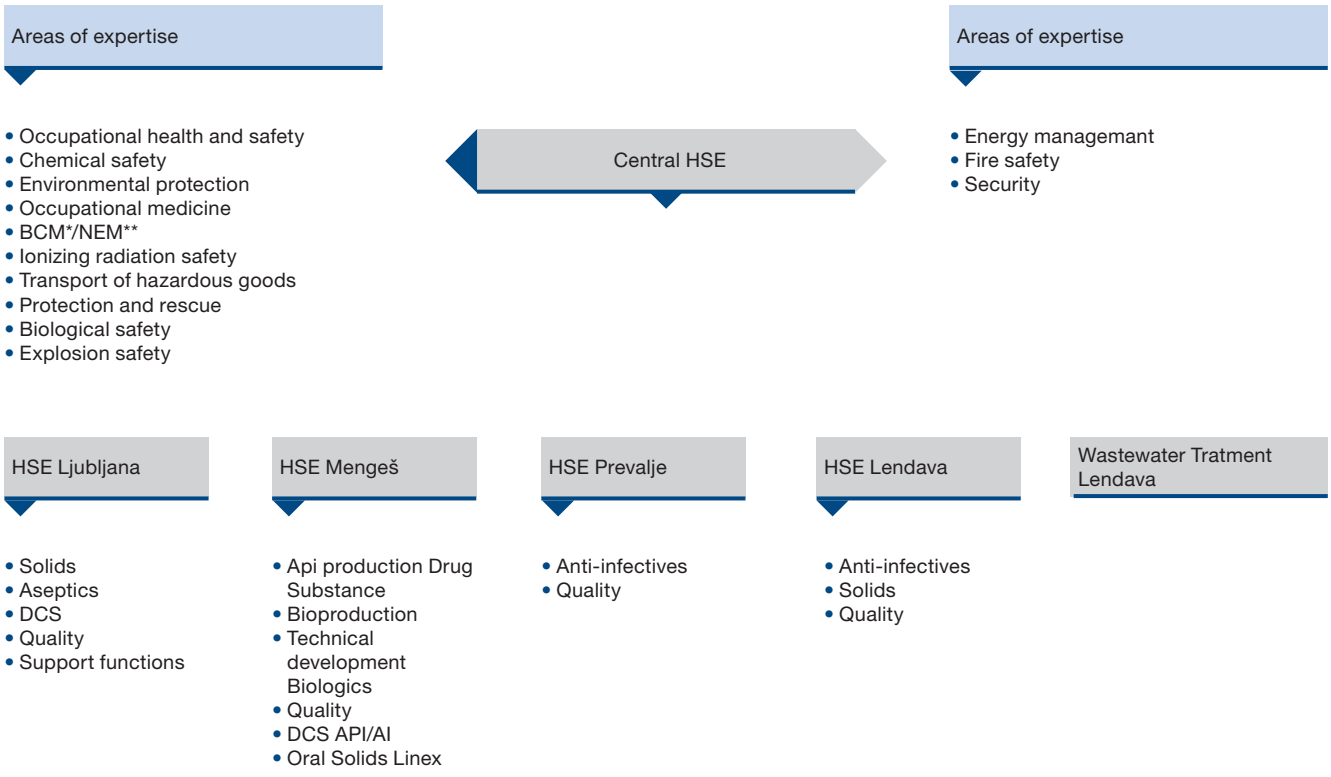
HSE organization, human resources and training

The HSE departments is made up of a management's representative for HSE (Director) and persons responsible for individual fields of expertise. By the authority of the Board of Management, they are responsible for the compliance of areas of expertise with Slovenian laws and Novartis'/Sandoz' standards, for representation of Lek in the area of expertise conducting inspections, conducting periodic internal audits, and monitoring the implementation of corrective measures, consulting and professional assistance in the implementation of preventive measures at sites as well as communication of identified risks to the management team. Education is a key tool for developing employee competencies. In HSE, we are divided into statutory and expert developmental education. Legally mandatory education and certification are the basis for work, and the development of expert knowledge is the basis for ensuring high quality of work of persons responsible and experts. Since 2017, Novartis has emphasized the importance of quality training, and with the introduction of the new application Up4Growth manages the curricula for each employee.

HSE department

The HSE system has been established at all four sites of Lek d. d. in Slovenia. HSE roles, responsibilities and authorities are determined on the basis of the organizational structure and functional organization. At multi-unit sites, activities are performed following the Host-Guest principle, whereby uniformity of HSE standards is ensured within each individual location. The same principle applies to our contract partners. The largest unit having a suitable HSE organization in place is the Host. The Host sets internal standards for individual sites that also apply to the Guests.

HSE Organization Scheme on 31. 12. 2017.



* BCM: Business Continuity Management
** NEM: Novartis Emergency Management

By organizing appropriate training programs, we assure all our employees with a level of HSE qualification sufficient for them to manage HSE aspects of their work. In cooperation with unit heads, the HSE unit prepares a training catalogue in three sections: induction, continuing education, and training for promotion. We promote direct involvement of employees in different roles, functions and units, exceeding the formal HSE organization.

HSE aspects and system of achievement monitoring

Pursuant to the Novartis guidelines, environmental aspects at Lek d. d. were upgraded into so-called HSE aspects. For a specific area of expertise, they are created at the proposal of the authorized person for each site separately. In addition to environmental aspects, we thus also have HSE, chemical safety, fire safety, explosion safety and biological safety aspects and others.

A standard selection of aspects for individual areas of expertise is determined by the head of the respective area at Lek d. d. The site's HSE responsible person makes an assessment based on the results of the Gap Analysis, audits (internal, Novartis'), inspections, complaints, and in consideration of hazardous occurrences (near-misses). The aspects are evaluated in consideration of the criteria of legal compliance, profitability and the company's reputation, using the risk assessment methodology. The criteria for assessing the importance of the HSE aspects are defined.

Based on the findings in the Registry of HSE aspects, corrective measures as well as business objectives and programs are defined. Revisions of the Registry of HSE aspects are carried out at least once a year or in the case of major change to the internal or external environment. It serves as a basis for the preparation of the Risk Portfolio, business and activity plans and programs, and for the setting of personal goals for responsible persons.

In our operations, our compliance with legal and other requirements is reflected in the successfully completed internal and external audits, inspections, water, air and noise monitoring, and with applicable environmental permits.

In 2017, external auditing of the company's compliance with ISO 14001:2015, BS OHSAS 18001:2007 were carried out and an audit according to the EMAS Directive.

Internal audits of the HSE service planned on an annual basis were performed. Concurrently, internal audits of the company’s compliance with ISO 14001:2015 and OHSAS 18001:2007 requirements were carried out. Internal Novartis and Sandoz audits are more extensive, covering all areas of HSE on the part of the site being audited: environmental protection, occupational health and safety, chemical safety, fire safety, biological safety, explosion safety and conduct in case of an accident (BCM and NEM). The frequency of audits depends on the nature of production at API production sites. They take place every two to three years, whereas at pharmaceuticals production locations they are performed every three to four years. These audits also assess compliance with ISO 14001, OHSAS 18001, and the EMAS Directive. In 2017, we had a Novartis HSE & BCM Audit and uninterrupted operations at Lendava and Mengeš. The results of internal audits performed in 2017 showed the high level of the company’s compliance with the statutory requirements as well as internal and external standards in all areas. Corrective action was taken on an ongoing basis. In 2017, we used Novartis’ application HSE Net for recording all corrective measures following assessments, inspections and safety walkthroughs.

Environmental performance assessment with regard to our general and individual objectives is an integral part of the management review procedure and regular monthly and quarterly reporting to Lek and Novartis management.

In 2017, we met the basic EMAS requirement for verification of compliance with the provisions of the EMAS Directive at all sites. From the environmental verifier we obtained a statement that we operate in compliance with applicable legal requirements with regard to the environment and furthermore, that the data and information from the environmental statement provide a reliable, credible and true picture of the organization’s operations at all Lek sites. In line with Novartis and Sandoz policy, Lek is committed to continuous improvement of environmental performance in compliance with local and national programs.

Reporting methodology

The reporting methodology used at Lek, enables monitoring of absolute indicators and trends for individual critical HSE aspects. The data is included in the main indicators and other current indicators of environmental success in future environmental statements.

HSE data is collected, recorded, verified and confirmed within a uniform Novartis reporting system in the Data Management System (DMS), whereby their transparency and comparability is ensured. Reporting frequency depends on the relevance of the reported data (monthly, quarterly or annually). Collected data serves as a basis for statutory reporting to ministries and other interested stakeholders, whereas once a year it is subject to review within the environmental management review performed by the organization's top management according to the EN ISO 14001:2015.

Measures for risk prevention and mitigation

Risk assessment is carried out using various methods. The choice of an appropriate method depends on its suitability for the area subject to assessment and on the qualification level of the associates involved.

Risk assessment is made for the following:

- Risk Portfolio,
- Workplace Health Risk Assessment – WHRA,
- Capital expenditure projects: with priority use of the Zurich Hazard Analysis (ZHA) or the Hazard and Operability Study (HAZOP Study) in the project qualification phase,
- Facilities and production lines: the Zurich Hazard Analysis (ZHA) or the Process Risk Assessment (PRORA),

- Process Risk Assessment (PRORA) for new products and production lines,
- Assessment of product quality risks: priority use of the FMEA method.

The Risk Portfolio provides the management team with an overview of major HSE risks and levels of risk management by individual site, country, business group, and in the corporation as a whole.

The Risk Portfolio development and compilation are carried out in three steps:

- Risk assessment and preparation of a Risk Portfolio for individual sites,
- Preparation of a Risk Portfolio for Lek d. d. (Slovenia) and Sandoz,
- Annual review of the Risk Portfolio for business groups at the corporate level.

In 2017, we performed all the risk management activities required in accordance with the Novartis HSE guidelines. Special care was given to identifying HSE risks in our operations and processes. On this basis, we implemented the measures to minimize risks, such as avoiding potential risks, limiting the risk of exposure to hazards, and taking action to mitigate the negative impacts of any hazardous occurrence if they actually took place.

3.4.1 Average hours of training per employee[70]

The average amount of time spent for training of Lek's employee was **2.76 days**, and if adding compulsory training at the workplace (3.50 days) and training in compliance (0.20 days) it amounted to total of **6.46 days**. We also offer our employees the opportunity of in-service education; in 2017, 56 employees involved in undergraduate studies, and 63 in post-graduate studies, mainly in biotechnology and biomedicine, as well as chemistry.

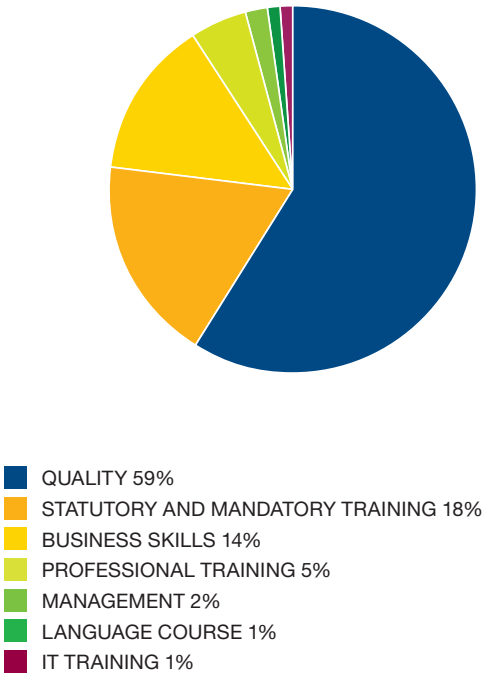
Table 23: Average training hours/employee

Year	Number of hours/employee
2013	56.36
2014	61.68
2015	71.44
2016	56.40
2017	51.68

3.4.2 Training by area

The highest participation rate was recorded in quality (59%), statutory and mandatory training (18%) and business skills (14%).

Training in 2017 by topic (attendance)



[70] GRI GS disclosures GS 404-1

4. Products[71]

In line with Novartis' vision - **To be a trusted leader in changing the practice of medicine** - we are committed to high standards of ethical business. Therefore, our employees must follow the Novartis Professional Practice Policy, which provides that patients/users of our products always come first. All contact with them should have the ultimate goal of improving the level of health care and awareness of diseases and their treatment. In doing so, the information about our products must be transparent, non-misleading and in accordance with approved product labels.

The Rules on advertising of medicines in Slovenia stipulates that the professional public consists of prescribing doctors, pharmacy masters dispensing prescription drugs and non-prescription drugs. Pharmaceutical technicians may only dispense and recommend non-prescription drugs. The latest professional information on prescription drugs and non-prescription drugs, their performance and properties are brought to clinics and pharmacies by qualified professionals. We additionally inform the professional public about disease conditions and their treatment also through various publications, websites and organized professional meetings.

We inform the professional public of prescription and non-prescription drugs with visits made by experts to health institutions and at professional meetings organised by professional associations of Lek. In accordance with the above-mentioned Rules on prescription drugs, we do not advertise these to end-users, i.e. to the lay public or patients. Non-prescription drugs are advertised in the media directly to end users in line with advertising rules for the lay public.

Also in 2017, the inspection authority at JAZMP instituted no inspection procedure in the field of information and labeling of products.[72] There were also no cases of violations of marketing communication rules, standards and non-binding codes, including those related to advertising, promotion and sponsorship.[73]

Customer satisfaction[74]

The satisfaction of the professional public is measured by opinion surveys. By means of these surveys we determine the company's reputation, satisfaction with our employees and activities. The results of the last survey in the professional public which was carried out at the end of 2016 show that Lek is among the most reputable companies in Slovenia with the best professional employees.

By conducting consumer researches we establish their satisfaction with individual brands. In addition to customer satisfaction and their knowledge of specific brands, the research results tell us in which areas we can further improve our communication to better understand the use of branded self-treatment products.

[71] GRI GS disclosures 103-1, 103-2, 417-1

[72] GRI GS disclosure 417-2

[73] GRI GS disclosure 417-3

[74] GRI GS disclosures 102-43, 102-44

We signed the Charter of Diversity Slovenia and thus formally joined the community of companies that understand the importance and positive economic impact of diversity management.

5. Human rights and antitrust compliance[75]

Our business operations are based on a strong commitment to business integrity and ethical business in all areas of our business. We have incorporated the **Novartis' Code of Conduct** into the internal regulations as early as 2003 and has been updated in 2018. It is the key act defining the principles of our ethical and accountable decision-making.

The Code of Conduct regulates our corporate and environmental responsibility and our compliance with the regulations and Good Business Practice. It provides a basis for the trust of our key stakeholders: patients, employees, shareholders, health partners and society. This strengthens our conviction that in addition to business success, the way in which we achieve success is extremely important. In doing so, we have zero tolerance to any inappropriate behavior.

We are aware that our employees represent the foundation of our success, therefore, we constantly provide for their development. We continue to pay great attention to the regular and continuous training of our employees in the field of integrity and compliance. In 2017, we organized online training for employees on the Code of Conduct, reporting side effects of medicines, reporting Inappropriate behaviour and protection of fair competition. On average, more than 97% of employees successfully completed training. We have also conducted a number of targeted trainings in the fields of personal data protection, All the above stated areas are also a part of the regular induction program for all new employees at Lek.[76]

We have also conducted a number of targeted trainings in the fields of personal data protection, prevention of bribery and cooperation with third parties, reporting and investigating inappropriate behavior, professional practices in advertising of medicines and relations with the professional public, as well as in the field of fair competition. This assures that our employees are constantly looking at themselves and are aware of their integrity principles and compliance behavior and include it in their everyday.

[75] GRI GS disclosures 103-1, 103-2, 102-16

[76] GRI GS disclosure 412-2

In order to prevent conflict of interests, corruption and to ensure compliance with the law and our internal rules, we follow Novartis' global policy regulating this area, and our internal regulations. Compliance standards which apply for Novartis' employees and their companies are implemented also in relations with third parties. On the basis of these guidelines for third parties, we establish and maintain business relations with business partners who are obliged to respect the same principles as our employees.

The Code of Conduct explicitly prohibits any form of employee discrimination in respect of personal employee characteristics such as citizenship, gender, age, nationality, religion, sexual orientation or disability. We expect our employees to treat others equally, with integrity and respect, thereby creating an inclusive working environment.

Our initiative **Diversity and Inclusion** is important contributor to this policy. We thus support inclusion of various people with differences in the way they think and lead, sex, race, religion, sexuality, age, experience etc..These kind of teams are more creative and successful in facing challenges and makes work more stimulating and interesting. In 2017, we signed the Charter of Diversity Slovenia and thus formally joined the community of companies that understand the importance and positive economic impact of diversity management.

At Lek, we reject all forms of child, forced or compulsory labor. In 2017, there were no cases of discrimination and no requests to remedy any violation in this area.[77] The company was also not involved in any antitrust procedure for any violation of antitrust regulations.[78]

[77] GRI GS disclosure 406-1

[78] GRI GS disclosure 206-1

6. Suppliers

6.1 Purchasing policy and system[79]

The purchase department is a separate organizational unit, responsible for purchase of direct and indirect material and services. In 2017 the field of purchasing continued the transformation of our activities in order to provide quality services to all our users in line with the efforts of Novartis business services. Our **business partnership model** was completed and transferred all tactical purchasing activities to service centers.

At all purchase stages, employees are committed to following the purchasing procedures laid down by the Novartis guidelines, international agreements and local regulations. Roles and responsibilities within purchasing activities (customer need identification, supplier selection, conclusion of agreements, and purchase orders) are clearly defined. The Head of Purchase is fully responsible for the implementation of and adherence to the guidelines, laws and internal procedures determining the purchasing processes.

In 2017, the **purchase value** totaled 589 million USD, of which 262 million USD was indirect purchase and (267 in 2016) and 323 million USD direct purchase (274 in 2016). We achieved a substantial growth in the value of purchases, which is due to the increased business volume of production units Unpredictable developments in commodity markets and the raising of industrial standards tightened the delivery conditions of the pharmaceutical industry this year as well.

Our biggest markets in field of Direct Purchases were Switzerland, Slovenia, Germany, China and India.

In the field of Indirect purchases, the largest markets were Slovenia, Germany, Italy, Canada and Austria.

6.2 Supplier audit procedures[80]

Supplier audits are based on the Novartis quality standards and guidelines. Selection criteria include prices, quality, delivery deadlines, reliability, compliance with regulatory requirements and Novartis guidelines, as well as suppliers' corporate responsibility policies. The selection process and criteria are documented appropriately.

[79] GRI GS disclosures 102-9, 102-10

[80] GRI GS disclosures 103-1, 103-2, GS 308-2, 408-1, 409-1

Novartis promotes the social and environmental values of the suppliers with whom it cooperates, and expects them to comply with the laws and business ethical principles established by the Novartis Code. The supplier is obliged to provide all information on work, health, safety, environmental and animal protection, corruption prevention and fair competition and the protection of personal data. The data allow the Novartis' authorized persons to monitor and verify compliance of actions. In case of established discrepancies, the supplier must eliminate them and report on the progress of their elimination.

In selection processes, priority is given to third parties who share our societal and environmental values. They must implement the supply agreement in strict compliance with all applicable HSE laws and regulations as well as the fair labor practice and unlawful discrimination policy. Priority is given to contractors who respect human rights including freedom of association and collective rights, rejection of forced and child labor.

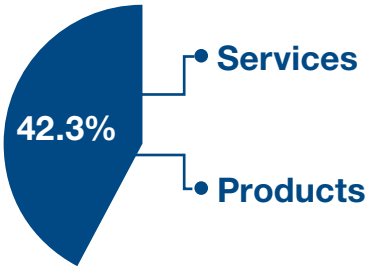
In purchasing, we continually measure the performance of suppliers, thus evaluating and monitoring the performance of suppliers, and identifying areas (credit rating, costs, quality, supply and customer support) of necessary improvements.

6.3 Policy and practices for selecting local suppliers[81]

The criteria for selecting suppliers are predetermined and equal for all. In this process, priority is given to suppliers offering the best quality, price and service. In certain categories of items where the delivery date is a key competitive advantage, along with appropriate price and quality, we build close relations and cooperate mainly with local suppliers.

In 2017, the level of deliveries from the Slovenian market amounted to 249 million USD or 42.3% of total purchasing cost. In the domestic market we mainly purchase domestic products. We mainly purchase packaging and raw materials from the Slovene chemical industry.

249 mio. USD
level of deliveries from the Slovenian market



The volume of supplies from the Slovenian market amounted to 45.6 million USD or 13.9%. Also in the indirect purchasing structure among individual countries, Slovenia maintains the largest share with 77.3% (203 million USD).

[81] GRI GS disclosures 103-1, GS 204-1

7. GRI content index

GRI content index GS – Core[82]

GENERAL STANDARD DISCLOSURES				
GRI-standard	**Disclosure**	**Reporting boundaries (within and outside the organization)**	**Section/Page numbers**	**Remarks/Omissions**
GRI 101: Foundation 2016				
GRI 102: General Disclosures 2016				
Organizational Profile				
102-1	Name of the organization	Lek d. d.	1/6	
102-2	Activities, brands, products and services.	Lek d. d. and all Lek sites	1.2.2/16	
102-3	Location of headquarters	Lek d. d.	1/6	
102-4	Location of operations	Lek d. d.	1.2.3/17	
102-5	Ownership and legal form	Lek d. d.	1.2/13	
102-6	Markets served	Lek d. d.	1.2.1/16	
102-7	Scale of the organization	All Lek sites	1.1.1/7, 3.2.1/64	
102-8	Information on employees and other workers	Lek d. d.	3.2.1/64	SDG: 8, 12
102-9	Supply chain.	Lek d. d.	6.1/80	
102-10	Significant changes to the organization and its supply chain.	Lek d. d.	1.2.3/17, 1.3.1/27, 6.1/80	
102-11	Precautionary Principle or approach.	Lek d. d., local communities, patients and customers	1.4.4/32, 2/33	
102-12	External initiatives	Lek d. d., Lek stakeholders	1.4.4/32	
102-13	Membership of associations.	Lek d. d.	1.4.4/32	
Strategy				
102-14	Statement from senior decision-maker	Lek d. d.	Page 4	
Ethics and integrity				
102-16	Values, principles, standards and norms of behavior	Lek d. d.	5/78	SDG: 16
Governance				
102-18	Governance structure	Lek d. d.	1.4.1/27	
Stakeholder engagement				
102-40	List of stakeholder groups	Lek d. d.	1.4.3/29, 1.4.3/30	
102-41	Collective bargaining agreements	Lek d. d.	3.2.2/65	SDG: 8
102-42	Identifying and selecting stakeholders	Lek d. d., Lek stakeholders	1.4.3/29	

[82] GRI GS disclosures 102-47, 102-55

102-43	Approach to stakeholder engagement	Lek d. d., Lek stakeholders	1.4.3/29, 4/77	
102-44	Key topics and concerns raised	Lek d. d., Lek stakeholders	1.4.3/30, 4/77	
Reporting practice				
102-45	Entities included in the consolidated financial statements.	Lek d. d.	1.3.1/27	
102-46	Defining report content and the topic Boundaries	Lek d. d.	1.3/26	
102-47	List of material topics	Lek d. d.	7/82-86	
102-48	Restatements of information	Lek d. d.	1.3.1/27	
102-49	Changes in reporting	Lek d. d.	1.3.1/27	
102-50	Reporting period	Lek d. d. and all Lek sites	1.3.1/27	
102-51	Date of most recent report	Lek d. d. and all Lek sites	1.3/26	
102-52	Reporting cycle	Lek d. d. and all Lek sites	1.3/26	
102-53	Contact point for questions regarding the report	Lek d. d.	1/6	
102-54	Claims of reporting in accordance with GRI Standards	Lek d. d.	1.3.1/27	
102-55	GRI content index.	Lek d. d.	7/82-86	
102-56	External assurance	Lek d. d.	1.3/26	

SPECIFIC STANDARD DISCLOSURES

Management approach disclosures	Topic-specific disclosures	Reporting boundaries	Section/Page numbers	Remarks/Omissions
ECONOMIC TOPICS				
GRI 201: Economic performance 2016				
103-1	Explanation of the material topic and its Boundary	Lek d. d., local communities	Letter from the President of the Board of Management/4	
201-1	Direct economic value generated and distributed	All Lek sites, owners, employees	1.1.1/7	
201-3	Defined benefit plan obligations and other retirement plans	All Lek sites, employees	3.2.3/65	
201-4	Financial assistance received from government	All Lek sites	1.1.1/7	
GRI 202: Market presence 2016				
103-1	Explanation of the material topic and its Boundary	Lek d. d., local communities	Letter from the President of the Board of Management/4	
202-2	Proportion of senior management hired from the local community	All Lek sites, local communities	3.2.4/65	
GRI 204: Procurement practices 2016				
103-1	Explanation of the material topic and its Boundary	Lek d. d., suppliers	6.2/80	
204-1	Proportion of spending on local suppliers	All Lek sites, local communities, suppliers	6.3/81	
GRI 206: Anti-competitive behavior 2016				
103-1 103-2	Explanation of the material topic and its Boundary		5/78	
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Lek d. d., local communities	5/79	

ENVIRONMENTAL TOPICS				
GRI 301: Materials 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	All Lek sites	2.2/42	
301-1	Materials used by weight or volume	All Lek sites	2.2/42	SDG: 8, 12
GRI 302: Energy				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		2/33	
302-1	Energy consumption within the organization	All Lek sites	2.3.1/45, 2.3.1/46	SDG: 7, 8, 12, 13
302-3	Energy intensity	All Lek sites	1.1.1/8, 2.3.1/46	SDG: 7, 8, 12, 13
302-4	Reduction of energy consumption	All Lek sites	2.3.3/47	SDG: 7, 8, 12, 13
GRI 303: Water 2016				
103-1 103-2	Explanation of the material topic and its Boundary		2/33	
303-1	Water withdrawal by source	All Lek sites, local communities	2.4.1/48, 2.4.2/49	
303-3	Water recycled and reused	All Lek sites, local communities	2.4.3/50	SDG: 6, 12
GRI 305: Emissions				
103-1 103-2	Explanation of the material topic and its Boundary		2/33, 2.6/54	
305-1	Direct (Scope 1) GHG emissions	All Lek sites, local communities	2.1.5/42, 2.6.4/56, 2.6.4/56	SDG: 3, 12, 13, 1, 15
305-2	Energy indirect (Scope 2) GHG emissions	All Lek sites, local communities	2.6.4/56	SDG: 3, 12, 13, 14, 15
305-4	GHG emissions intensity	All Lek sites, local communities	2.6.4/56	SDG: 13, 14, 15
305-5	Reduction of GHG emissions	All Lek sites, local communities	2.3.3/47	SDG: 13, 14, 15
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	All Lek sites, local communities	2.6.2/55, 2.6.3/56	SDG: 3, 12, 14, 15
GRI 306: Effluents and waste 2016				
103-1 103-2	Explanation of the material topic and its Boundary		2.7/57	
306-1	Water discharge by quality and destination	All Lek sites, local communities	2.7.1/58	SDG: 3, 6, 12, 14
306-2	Waste by type and disposal method	All Lek sites, local communities	2.5.1/50, 2.5.2/52, 2.5.3/53	
GRI 307: Environmental Compliance 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		2/33	SDG: 3, 12
307-1	Non-compliance with environmental laws and regulations	All Lek sites	2/34, 2.1/36	
GRI 308: Supplier environmental assessment 2016				
103-1 103-2	Explanation of the material topic and its Boundary		6.2/80	
308-2	Negative environmental impacts in the supply chain and actions taken	Lek d. d., suppliers	2.1.5/42, 6.2/80	The environmental responsibility of suppliers is one of the important criteria in the process of procurement and choosing suppliers.

SOCIAL TOPICS				
GRI 401: Employment				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		3.1/64	
401-1	New employee hires and employee turnover	All Lek sites, employees	3.2.1/64	SDG: 5, 8
401-3	Parental leave	Lek d. d., employees	3.2.5/66	
GRI 403: Occupational Health and Safety 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		3.3/66	
403-2	Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	All Lek sites, employees	1.1.1/8, 3.3.1/67, 3.3.2/70, 3.3.4/70	SDG: 3, 8
403-3	Workers with high incidence or high risk of diseases related to their occupation	Lek d. d., employees	3.3.5/70	SDG: 3, 8
GRI 404: Training and education 2016				
103-1 103-2	Explanation of the material topic and its Boundary		3.4/72	
404-1	Average hours of training per year per employee	Lek d. d., employees	3.4.1/76	We do not yet record education by gender and by employee category. SDG: 4, 5, 8
GRI 406: Non-discrimination 2016				
103-1 103-2	Explanation of the material topic and its Boundary		5/78	
406-1	Incidents of discrimination and corrective actions taken	Lek d. d., employees	5/79	
GRI 408: Child labor 2016				
103-1 103-2	Explanation of the material topic and its Boundary		6.2/80	
408-1	Operations and suppliers at significant risk for incidents of child labor	Lek d. d., suppliers	6.2/80	
GRI 409: Forced or compulsory labor 2016				
103-1 103-2	Explanation of the material topic and its Boundary		6.2/80	
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	Lek d. d., suppliers	6.2/80	
GRI 412: Human rights assessment 2016				
103-1 103-2	Explanation of the material topic and its Boundary		5/78	
412-2	Employee training on human rights policies or procedures	Lek d. d., employees, local communities	5/78	
GRI 413: Local communities 2016				
103-1 103-2	Explanation of the material topic and its Boundary		1.4.3.1/32	
413-1	Operations with local community engagement, impact assessments, and development programs	All Lek sites, local communities	1.4.3.1/32	The data collected for now does not allow us to calculate the share, but we report the number of activities.

GRI 414: Supplier social assessment 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		6.2/80	SDG: 5, 8, 16
414-2	Negative social impacts in the supply chain and actions taken	Lek d. d., suppliers	2.1.5/42	By signing a contractual agreement, the supplier undertakes to comply with all applicable laws and regulations related to fair working practice.
GRI 417: Marketing and labeling 2016				
103-1 103-2	Explanation of the material topic and its Boundary		4/77	
417-1	Requirements for product and service information and labeling	Lek d. d., regulators	4/77	
417-2	Incidents of non-compliance concerning product and service information and labeling	Lek d. d., regulators, patients, healthcare workers and healthcare service providers, buyers	4/77	
417-3	Incidents of non-compliance concerning marketing communications	Lek d. d., regulators, patients, healthcare workers and healthcare service providers, buyers	4/77	

8. Declaration of environmental verification

Izjava okoljskega preveritelja o dejavnostih preverjanja in potrjevanja št. O-006

Slovenski institut za kakovost in merosloviе,
z registracijsko številko okoljskega preveritelja SI-V-0001,
akreditirani za preverjano dejavnost organizacije (NACE: 21.20),

izjavlja, da smo preverili, ali organizacja na lokacijah:

Lek farmacevtska družba d.d.
Ljubljana, Verovškova 57; Mengeš, Kolodvorska 27;
Prevalje, Perzonali 47 in Lendava, Trimlini 2 D

z registracijsko številko Reg.No. SI-00006

izpolnjuje vse zahteve Uredbe (ES) št. 1221/2009 Evropskega parlamenta in Sveta z dne 25. novembra 2009 o prostovoljnem sodelovanju organizacij v Sistemu Skupnosti za okoljsko ravnanje in presojo (EMAS).

S podpisom tega dokumenta izjavljamo, da:
- sta bila preverjanje in potrjevanje izpeljana popolnoma v skladu z zahtevami Uredbe (ES) št. 1221/2009 in Uredbe (ES) 2017/1505;
- rezultati preverjanja potrjujejo, da ni dokaza o neskladnosti z veljavnimi zakonskimi zahtevami v zvezi z okoljem;
- podatki in informacije iz okoljske izjave **»Poročilu o trajnostnem razvoju družbe Lek d.d. za leto 2017, junij 2018«** podajajo zanesljivo, verodostojno in pravilno sliko o vseh dejavnostih organizacije v obsegu, navedenem v okoljski izjavi

Ta dokument ni enakovreden registraciji EMAS. Registracijo EMAS lahko podeli le pristojni organ na podlagi Uredbe (ES) št. 1221/2009. Ta dokument se pri sporočanju javnosti ne uporablja samostojno.

EMAS

Datum validacije: 2012-04-06

Izdaja: 07/2018-06-22

Velja do: 2020-12-31

Igor Likar:
Direktor SIQ

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9. Glossary of key terms

EMAS (ECO – Management and Audit Scheme)

The EMAS Scheme was designed for enterprises to improve their environmental performance and to inform the public of the environmental impacts of their operations. It is based on the ISO 14001 standard, upgraded with additional requirements for a more open communication, credibility and periodic publishing of verified environmental information. The environmental statement is the core method of publicly communicating the results of continuous improvement of the organization's environmental performance, and an opportunity to enhance the company's reputation with customers, suppliers, contractors, community and employees.

GRI (Global Reporting Initiative)

GRI Guidelines represent one of the world's most prevalent standards for corporate responsibility and sustainable development reporting. They require planning and reporting according to the measurable indicators of the economic, social and environmental impact of an organization. Depending on the scope of disclosures and measurable indicators, reports are classified into two application levels, core and apprehensive. GRI Guidelines provide a high degree of comparability, transparency and consistency of non-financial corporate reports, increasing stakeholder trust in corporate responsibility and sustainable development reports.

RCI (Responsible Care Initiative)

Launched in 1981 in Canada, the initiative was adopted globally by the chemical industry represented by the ICCA (International Council of Chemical Associations). The initiative promotes responsible treatment of employees and the environment in its broadest sense: the implementation of Good Practices, usually through management systems, particularly in the fields of occupational health and safety, environmental protection, and cautious and safe handling of chemical industry products. The initiative aims to provide constant and measurable improvement of operations in the aforementioned fields, which is measured by means of 16 indicators. Three indicators reflect occupational safety and health achievements, while the remaining indicators are concerned with environmental management, including energy efficiency.

Generics are successors to pharmaceutical products whose patent protection has expired. A generic drug is a drug product that is comparable to a reference listed drug product in quality and quantity composition, active ingredient and dosage form, its bioequivalence being proven by means of respective bioavailability studies.[83]

Active ingredient is a carrier substance exerting the pharmacological action.

Antibiotics are either natural products of microorganisms or semi-synthetic derivatives of natural products, destroying other microorganisms or inhibiting their growth. They are used in the treatment of bacterial infections.[84] Modern science knows several thousand substances producing an antibiotic effect. In practice, there are several dozen molecules which have been fully established in standard medical practice. Certain bacteria produce beta-lactamase and are therefore resistant to specific forms of antibiotics. Clavulanic acid is a beta-lactamase inhibitor. In combination with potassium clavulanate which prevents bacterial resistance to amoxicillin action, the antibiotic is effective in the treatment of bacterial infection.

Biological medicinal product is a medicine, the active ingredient of which is a biological substance or a substance obtained by a process which includes biological systems. A biological substance is a substance that is produced by or extracted from a biological source and that requires for its characterization and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control. For example, these are medicines produced by a biological or biotechnological procedure, including cell cultures and similar.

In the human organism, they try to repair the processes causing the disease. They are used for treatment of hitherto incurable diseases, and improve the quality of patients' lives. They provide a more efficient therapeutic approach to cancer, AIDS, anemia, rheumatic, cardiovascular and some other types of diseases. Over the past years, biologics have saved lives, prolonged survival and improved the quality of life for patients with severe and often chronic diseases.

Biosimilars are officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following expiry of patent and exclusivity on the innovator product. They demonstrate quality, safety and efficacy identical to those of originator drugs, yet their lower price makes them more affordable for a wider patient population. Chemically, biosimilars are protein drugs or glycoproteins. The concept of biological similarity as defined by the European Medicinal Products Act requires a higher level of expertise in science, technology and logistics.

[83] Source: Medicinal Products Act – ZZdr-1 (Official Gazette RS no. 31/06 dated 24. 3. 2006) and Act Amending the Medicinal Products Act – ZZdr-1A (Official Gazette RS no. 45/08 dated 9. 5. 2008).

[84] Source: Humar M., Šmid-Korbar J., Obreza A. Pharmaceutical terminology dictionary. Ljubljana 2011.

Biotechnology combines all the technological applications using biological systems, living organisms or their derivatives with the purpose of creating or adjusting products and processes for a specific use. In the technological use of biological cultures, it combines microbiology, biochemistry and engineering.

Recombinant DNA technology The information needed for the synthesis of a specific protein in the human organism (the desired protein-encoding sequence, or the gene) is transferred from the human organism into another organism, most frequently into a bacteria, isolated mammalian cells or yeasts. Based on the information received, these new cells produce larger quantities of proteins or glycoproteins.

Biological agents are microorganisms, cell culture and human endoparasites which may cause infection, allergy or intoxication.

- Class 1 biological agent/genetically modified organism poses minimum risk to human health and the risk of being spread into the environment is negligible;

- Class 2 biological agent/genetically modified organism of this class may cause human disease and may be hazardous for workers; the risk of being spread into the environment is minimal, in the majority of cases and effective prevention or treatment is available.

GMO (genetically modified organism) is an organism whose genetic material has been altered using methods of modern biotechnology. In such an organism a defined gene of an exactly defined characteristic from another organism has been inserted. GSOs include microorganisms (bacteria, fungi, viruses), plants and animals.

Biopharmaceutics is the latest and the fastest growing branch of pharmaceutical science. The biologics market is growing twice as fast as the entire drug market. Due to highly complex research and development, biological drugs are extremely costly. Biosimilars are however, more cost effective and therefore accessible for a larger group of patients.

Lek started its own genetic technology development as early as the 1980's, creating a solid foundation for the manufacture of recombinant proteins and/or biopharmaceuticals for human use.

The Integrated Pollution Prevention and Control (IPPC) Directive on integrated pollution prevention and control of industrial pollution, has been transposed into Slovenian law by the Regulation on activities and installations with major pollution potential. The European Union has brought the IPPC Directive together with six other directives related to industrial emissions in a single **Industrial Emissions Directive (IED)**.

a Sandoz company

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