Sustainability Report 2018 – Lek d. d.

lek

a Sandoz company

Contents

Sustainability Report 2018 – Lek d. d.

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

2018 key facts

1,061.3 mil. EUR

NET SALES IN 2018 OR 11.5% MORE THAN IN 2017.

4,084

EMPLOYEES AT THE END OF 2018 OR 5% MORE THAN 2017.

93.55%

SHARE OF LOCAL EMPLOYEES IN SENIOR MANAGEMENT.

6.2 mil. EUR

SAVED IN 2018 THANKS TO 370 IMPLEMENTED TH!NK NOVARTIS IDEAS SUBMITTED INTO THE SYSTEM.

+2%

IMPROVED WATER EFFINCIENCY.

4.9 mil. EUR

INVESTMENT IN ENVIRONMENTAL PROTECTION IN 2018.

+3%

IMPROVED WASTE MANAGEMENT EFFICIENCY.

The Novartis Sustainable Development Strategy has set ambitious 2025 and 2030 targets for us; responding to current and far reaching global issues by defining climate neutrality, circular economy and plastic neutrality and sustainable water use.

Ivan Ďurovčík

Letter from Management[1]

The Novartis Sustainable Development Strategy has set ambitious 2025 and 2030 targets for us; responding to current and far reaching global issues by defining climate neutrality, circular economy and plastic neutrality and sustainable water use. The path to these changes, in a relatively short period of time, will not be easy. However, we can say with certainty that their achievement will further strengthen our culture of innovation, quality, cooperation, results, courage and integrity. It is our values that will assure triumph over this high set bar.

In 2018, we started to reflect more widely on the realization of the updated Novartis Social Responsibility and Sustainable Development Strategy, especially regarding the environment.

We are proud that the Mengeš and Ljubljana sites were selected to prepare Novartis pilot projects to implement a global vision of environmental sustainability in sites around the world. Their trust is based on our sites developed internal culture, past results and professional competences.

We are proud that the Mengeš and Ljubljana sites were selected to prepare Novartis pilot projects to implement a global vision of environmental sustainability in sites around the world. Their trust is based on our sites developed internal culture, past results and professional competences.

Progress at all of our sites

At the core of our social responsibility is the expansion of access to treatment and responsible operations; with our stakeholders in Slovenia giving special importance to environmental aspects.

Results achieved in this area are encouraging; in 2018, we not only

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

expanded our operations and production, but improved our key performance indicators. Despite a 4% volume increase in production, we preserved consumption of raw materials at 2017 levels. We consumed nearly 3% less energy per unit produced, with measures saving 16.5 TJ of energy and increasing the efficiency of water use by more than 9%. Recycled waste accounts for nearly 92% of all waste generated.

It is worth highlighting some of the many achievements of our sites on which the overall results are based. In Ljubljana, the consumption of raw materials decreased by 8%, the quantity of waste produced by 5%. In Mengeš, we reduced the quantity of waste produced by a tenth, in Prevalje, by 5%. In Lendava, they were especially successful regarding water use, where they improved their efficiency, without cooling water, by more than 22%, consuming a fifth less technological water.

Expanding access to healthcare and doing business responsibly

Our role in increasing the accessibility of healthcare remains mainly in scientific discoveries and innovations; we are active in the development of demanding generic, biological and biosimilar medicines, effective registration procedures and professional achievements in the transfer of new products into production.

Our greatest contribution to more accessible treatment is the knowledge of our employees.

Our greatest contribution to more accessible treatment is the knowledge of our employees. This is demonstrated by numerous acknowledgments to our scientists and development teams, 200 development projects in progress at the Development Center Slovenia and more than 370 approved ideas contributed by our employees under the Th!Nk Novartis initiative. It is extremely important that the development of biological medicines in Mengeš is part of Novartis global development of medicines, while Ljubljana remains one of the leading Sandoz locations for the introduction of new medicines on global markets.

We are developing a culture of equal opportunities and diversity for a knowledge society and a high quality working environment; we strive for a work-life balance, we encourage preventive health programs and offer recreation opportunities. With a comprehensive employee potential development program, we commit to being a responsible and interesting employer, which is why we were delighted when we were awarded the title of reputable employer for the seventh consecutive year.

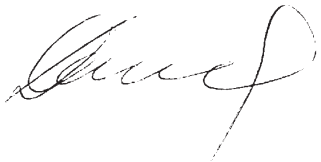
In the context of responsible operations, we remain, above all, an environmentally sustainable business, primarily committed to employee care and ethical business practice, cooperation with local communities, NGOs and playing an active role in the Novartis partnership with patient groups. How important it is to our employees to contribute to society is reflected by the 650 Lek volunteers who attended the Community Partnership Days.

Achieving global sustainable development goals

In this report, you will again find, in the conclusions, a chart for the implementation of the United Nations' sustainable goals. By doing so, we are upgrading our comprehensive public information started in the area of environmental protection in 2009, and the broader aspects of sustainable development have been clarified since 2011. In a world that is increasingly connected and co-dependent, we are determined to support common global development goals by operating responsibly in every local environment. And every local environment is the path to our knowledge in the world.

On behalf of the Board:

Ivan Ďurovčík



1. Company profile

Lek, a Sandoz company[2]

Company name: Lek Pharmaceuticals d. d.
Abbreivated 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
Telephone: + 386 1 580 2111
Fax.: + 386 1 568 3517
E-mail: info.lek@novartis.com
Website: http://www.lek.si

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Mojca Bernik, Environmental Manager;
mojca.bernik@novartis.com

[2] GRI GS 102-1, 102-3.
[3] GRI GS 102-53.

1.1 Key data for 2018

1.1.1 Operations in 2018

Key figures for 2018[4]

Indicator	Unit	31. 12. 2018	31. 12. 2017	31. 12. 2016	Index 2018/2017
Number of employees		4,084	3,889	3,599	105
- Ljubljana site		2,152	2,079	1,923	103
- Mengeš site		1,098	1,058	1,002	104
- Lendava site		571	484	423	118
- Prevalje site		256	261	246	98
- hired warehouse		7	7	5	100
Production output*	1,000 t	5.12	4.92**	5.20	104
Net sales	In mil. EUR	1,061.302	951.480	895.270	111
Liabilities	In mil. EUR	1,196.518	1,120.868	1,032.615	107
Capital	**In mil. EUR**	**889.571**	773.979	691.787	**115**

* 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.

** Correction of quantitative realization for Aseptics, which also implies a change in the volume realization for the entire Lek for 2017.

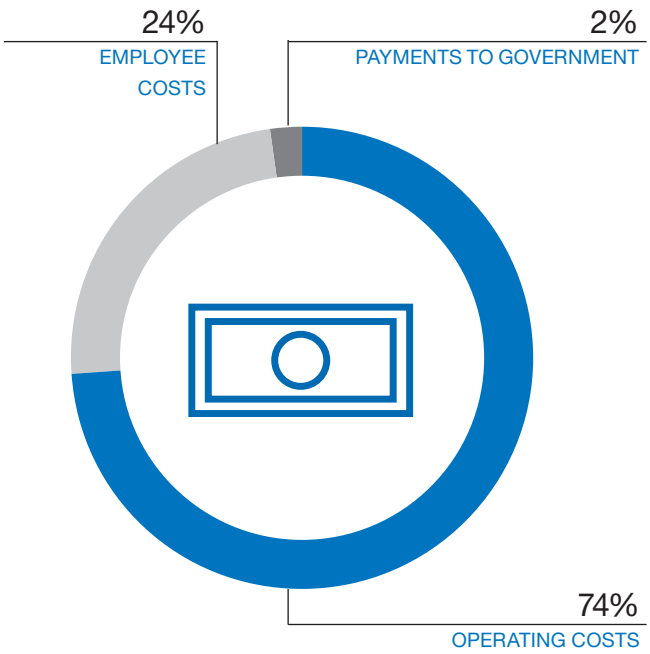
Economic performance[5]

In 2018, Lek, created 1,061.302 Euros of net sales, this represents an 11% increase compared to the previous year (951.480). Net profit for the accounting period amounted to 116.67 million Euros.

Direct economic value created reached 1,065 million Euros (965 in 2017), of which 82% (901 million Euros) was **economic value distributed**; the largest proportion (74%) representing Operating Costs, which reached 666 million Euros. **Employee Costs** were 214 million Euros (24%). In 2018, no **Payments to Providers of Capital** were made, and **Payments to Government** amounted to 21 million Euros (2%).

In 2018, we received public subsidies in the amount of 1.4 million Euros (1.05 in 2017). There was zero tax relief value due to investment in research activity.[6]

Structure of Economic Value Distributed



901 million EUR

ECONOMIC VALUE DISTRIBUTED

[4] GRI GS 102-7.
[5] GRI GS 201-1.
[6] GRI GS 201-4.

Major environmental and social impacts[7]

Indicator	Unit	31. 12. 2018	31. 12. 2017	31. 12. 2016	Index 2018/2017
Efficiency of energy resource use	GJ/t	262	269***	252	97
Water use efficiency**	m^3/t	680	696***	646	98
Waste volumes – efficiency	t waste/ t product	7.3	7.5***	7.2	97
VOC emissions – efficiency	t VOC/t product	0.014	0.013***	0.017	108
LTIR* - showing the frequency of work-related accidents and illnesses, resulting in the use of sick leave		0.20	0.21	0.05	95
TRCR* - showing the frequency of work-related accidents and illnesses, resulting in the use of sick leave, requiring more than basic first aid		0.25	0.26	0.28	96

* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 5.3.1 Frequency of absences due to injuries at work.

** 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 quantitative data for Aseptic Products Ljubljana in the DMS system and consequently in the Lek d.d. Report on Sustainable Development for the year 2017.

1.1.2 Highlights and milestones of Lek's operations in 2018

2018 was a success in respect of our operational goals. We continued to optimize and adjust our production network across Slovenia and thus successfully implementing Novartis's strategy of focusing on patient-adjusted and personalized medicines in small quantities, and high-value added medicines, biosimilars and digital therapies.

Highlights of operations in 2018:

- In the **Development Center Slovenia**, we have completed the development and filed 20 dossiers for medicines on the markets of the USA, Russia, Europe, Canada, Thailand and China, and one dossier for an active substance in the USA and Canada. We have completed the development of the high-quality innovative food supplement LincomplexTM, which is already available to Slovenian users.
- We have **launched important** anti-inflammatory drugs, drugs for cholesterol-regulation, prostate problems and the treatment of erectile dysfunction and fungal diseases. With the US Food and Drug Administration (FDA), the medicine with the active substance amantadine was the first to file a dossier and thus acquire a six-month generic exclusive right to sell in the US market.
- We **expanded the active substances manufacturing range for the production of innovative medicines**. In Mengeš, we started to produce three active ingredients for innovative medicines that will come on the market in the coming years. At other Lek sites we started to implement the final production stages of some innovative medicines.
- In Mengeš, we participated in the development of **three new Sandoz biosimilar medicines** that entered the market in 2018. We are building a new site facility for the production of APIs, which will further strengthen the role of this site as a key Novartis Center for Biotechnology; the investment value is 38 million euros.
- Since 2003, Novartis has invested more than EUR 2.3 billion in Slovenia. More than half of this was devoted to development, the second to modernization and expansion of production capacities.
- **We have recruited 370 new full-time employees.** At the end of 2018, Lek had 4,084 full-time employees, of which 495 had a M.Sc. or a Ph.D. degrees. In the last seven years, more than 2,100 employees have been recruited.
- By increasing the market share by 30.1%, we **consolidated the position of the second largest provider of generic medicines in Slovenia** and in the non-prescription pharmaceuticals sector strengthened the role of market leader. We also contributed to better patient care by organizing a number of professional events, attended by more than 2,500 health professionals from Slovenia.
- The efforts for **comprehensive prevention and reduction of the environmental impacts** of the activities continued with the re-certification of environmental management in accordance with the requirements of the ISO 14001:2015 and the ES 1221/2009 (EMAS) including changes ES 1505/2017 and ES 2026/2018 and the Occupational Health and Safety System in accordance with BS OHSAS 18001:2007 and a new upgrade of the occupational health and safety standard ISO 45001:2018.
- 650 co-workers from Novartis sites in Ljubljana, Mengeš, Lendava and Prevalje participated in **more than 25 volunteer activities**. In 14 years of volunteering, Novartis employees in Slovenia devoted more than 33,000 working hours to volunteering in the local community.

[7] GRI GS 302-3, 403-2.

1.1.3 Novartis' sustainable strategy

Our ambition is to be a catalyst for positive change and a leader in environmental sustainability. We aim to drive sustainability through our own operations, as well as those of our suppliers.

	Ambition for Novartis	2025 targets	2030 targets
Climate	**Carbon neutrality** Energy and climate resilient	- Only renewable energy used (carbon-neutral own operations): Scope 1 and 2 - Environmental criteria in all supplier contracts	- Carbon footprint reduced by half: Scope 1, 2 and 3
Waste	**Circular economy & plastic neutrality** Minimize waste and increase material efficiency	- Eliminate PVC in packaging - Waste disposal reduced by half	- Plastic neutral - All new products meet sustainable design principles
Water	**Water sustainability** Ensure sufficient and safe water, being a water steward wherever we operate	- Water consumption reduced by half in our operations - No water quality impacts from manufacturing effluents, including suppliers	- Water neutral in all areas - Enhance water quality wherever we operate

1.1.4. Health, safety and environment (HSE) objectives

Plans, objectives and programs in the area of environmental protection are carried out with the aim of continuous improvement of operations. We provide this with:

- setting measurable goals at all levels of the organization,
- drafting and documenting action plans,
- maintaining HSE strategies and long-term plans,
- integrating setting goals and action plans into the business planning process.

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.

The basis for determining the HSE objectives is:

- HSE policy,
- the objectives and requirements of Novartis,
- recognized important HSE perspectives for individual areas,
- legal and other requirements and views of interested parties,
- financial and technological capabilities,
- requirements of associations.

The HSE objectives are the result of harmonization, which is prepared by the HSE department on the basis of the aforementioned entry requirements, and is confirmed by LEK management and the head of the global HSE function. The targets are determined by site and together determine the goals of Lek. We are separate the organizational goals and the personal goals of the managers. Persons responsible are defined for individual objectives, as well as the necessary resources and deadlines. The realization of objectives is evaluated and monitored periodically at various levels of the organization, and biannually and annually in Lek's discussions.

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).

Lek's short term HSE targets for 2018

Area	Indicator	Target	Realized in 2018
Health and safety	Serious injuries and fatalities (SIF)	0	0
	LTIR (own employees + employees hired through employment agencies) with potential SIF	≤ 10	0
	Walkthrough inspections per 200,000 working hours	12–15	**Reached.** > 15
	Near misses and good catches per 200,000 working hours	35–50	**Reached.** **> 50**
	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0	0
Environment	Reduction of technological water use	≥ 3%	**Reached.** 5% reduction.
	Reduction of greenhouse gas (GHG) emissions due to energy use	≥ 5%	**Not reached.***
	Reduction of non-recyclable waste	≥ 4%	**Reached.** 12% reduction.
Corrective actions	Number of overdue corrective actions (CAPA)	0	0
	Number of overdue corrective actions on inspection	0	0
Business continuity preparedness index	Assuring uninterrupted operations	20–22 points	**Reached.** 22 points
Emergency management preparedness index	Readiness for emergency response	20–22 points	**Reached.** 22 points

* Considering that the purchase of green certificates was carried out more than a year ago, the 2018 target evaluation is irrelevant at the moment.

Lek's HSE targets for 2019

Area	Indicator	Target
Health and safety	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0
	LTIR (own employees + employees hired through employment agencies) with potential SIF	0
	Walkthrough inspections per 200,000 working hours	> 15
	Near misses and good catches per 200,000 working hours	> 50
	Serious injuries and fatalities (SIF)	0
	Risk-based exposure evaluation process of unit operations	≥ 70%
Environment	Reduction of water use	–5% in comparison to 2018
	Reduction of total non-recyclable waste	–7% in comparison to 2018
Corrective actions	Number of overdue corrective actions (CAPA)	0
	Number overdue corrective actions on inspection	100%

In July 2018, the President of the Management Board of Novartis, Vas Narasimhan, visited Development Center Slovenia, the largest and best equipped center in Sandoz.

1.2 About us[8]

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 (C21.200). On 31. 12. 2018, Lek had 100% ownership share in Sandoz Pharmaceuticals d.d. and 74.5% ownership share in Wastewater treatment plant Lendava d.o.o.

In 2018, there were no changes to the size, structure or ownership of Lek, moreover no merging activities or joint investments were made.

Novartis' key principles for social responsibility in Slovenia

In 2018, we adopted the updated Novartis strategy for social responsibility in Slovenia.

Expanding access to healthcare:

- Scientifically based innovations to address health challenges in society
- Working with patient groups to take into account their views and needs
- Promoting the development of modern technologies to increase access to treatment
- Preventive healthcare in local communities
- Expanding interest in science and access to treatment among young people
- Expand access to treatment and health promotion for socially sensitive groups
- Donations of medicine

Doing Business Responsibly

Novartis's principles of responsible business are established in Slovenia in all six areas, where we ensure continuous implementation of uniform Novartis standards:

- Ethics and compliance
- Transparency and clarity of business
- Health, safety and the environment
- Care for employees
- Responsible management of the supply chain
- Assistance in case of natural disasters

In 2018, we adopted the updated Novartis strategy for social responsibility in Slovenia.

[8] GRI GS 102-5.

1.2.1 Key customers and markets[9]

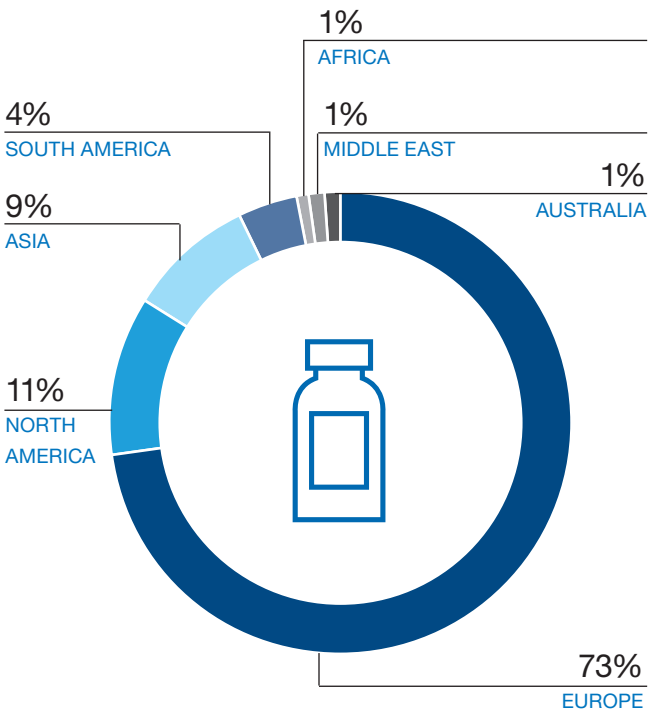
In accordance with strategic orientations, Sandoz Group companies are the key buyers of our products and active pharmaceutical ingredients. In 2018, the leading three buyers accounted for 75%, 9% and 3% of our net sales, respectively (the same as in 2017).

We sell our own products and the products of other Sandoz companies. The majority of our products in 2018, 73%, are sold to European markets, of which Slovenia accounts for 12.4%. Followed by North America with 11%, Asia 9% and other regions in the world. The majority of sales (94%), came from pharmaceutical products, the remaining 6% came from APIs and biopharmaceutical products.

Lek is the market leader in non-prescription pharmaceuticals market in Slovenia, and in second place for generic drugs sales.

Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 75% of sales in 2018.

Sales by region, recipients of goods in 2018



In 2018, the total value of the Slovenian pharmaceutical market was 663 million Euros. 49.01 million Euros of sales and a 7.4% market share makes Lek the second largest pharmaceutical company. On the generic market, where the total value is 163 million Euros, with a market share of 30.1% we are also the second largest company. On the over-the-counter market, where Lek is the market leader, sales saw 2.1% growth, despite the sale of the Persen brand.

1.2.2 Major product groups and brands[10]

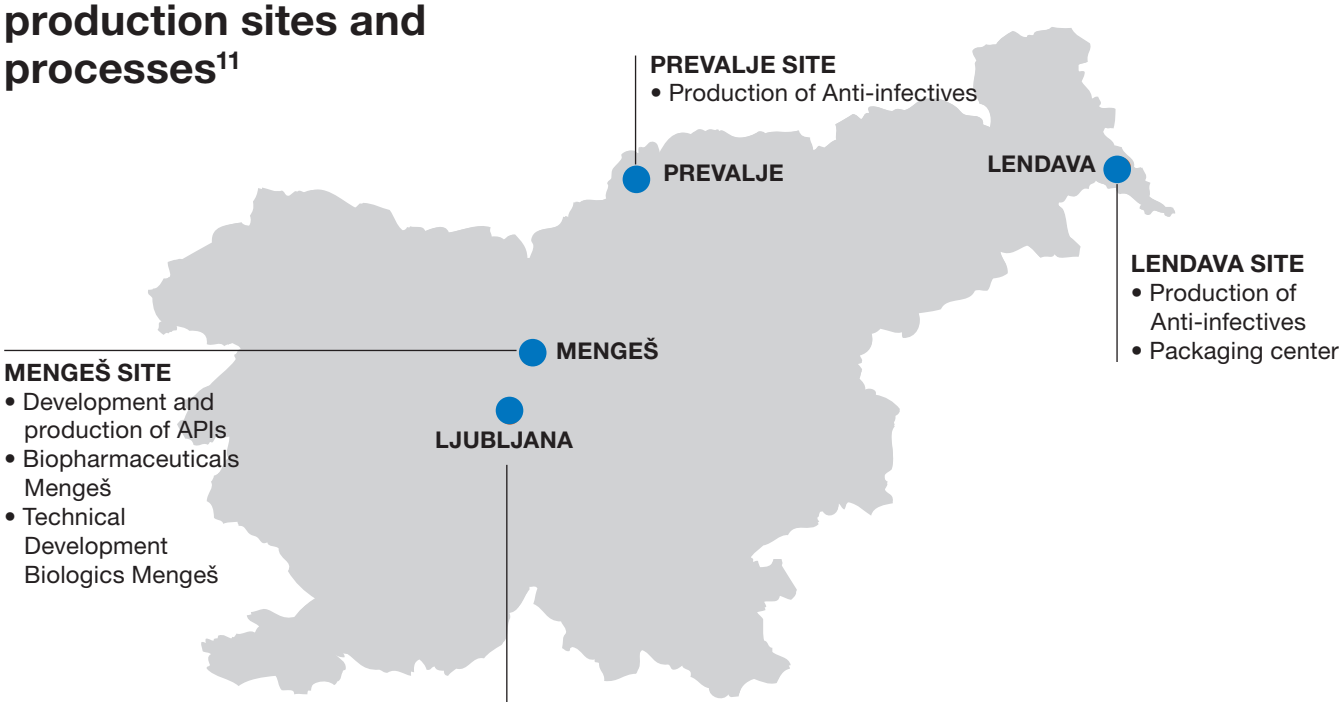
We develop, manufacture and market efficient, safe and high quality medicinal products. Our key therapeutic groups are:

- 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.

In 2018, 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 Fluimukan®. We also offered the market the new high quality dietary supplement LINCOMPLEX™.

[9] GRI GS 102-6.
[10] GRI GS 102-2.

1.2.3. Development and production sites and processes[11]



LJUBLJANA SITE
- Headquarters of Lek d. d.
- Development Center Slovenia
- Production of Solid dosage forms
- Production of Aseptics
- Quality Control Competence center
- One of leading global supply centers for Sandoz
- Sandoz d. d.
- Novartis Pharma
- Novartis Oncology
- Alcon d.o.o.

Ljubljana

Mengeš

Lendava

Prevalje

[11] GRI GS 102-4, 102-10.

Aleš Rokavec, PhD, Head of Solids Ljubljana

8.6 billion

PIECES OF SOLID DOSAGE FORMS AND 165 TONS OF GRANULES AND MICRO-PELLETS PRODUCED.

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, supplying, 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.

Solid Dosage Forms (SDF)

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; 150 different technological forms with around 80 different APIs. Our product range includes granules, tablets, film-coated tablets, pellet capsules and granulates, dragees and micro pellets for oral suspension. The final pharmaceutical products are packaged in blisters, bottles, bottles and bags that are then shipped to around 100 markets.

Production growth continued in 2018 stayed at the same level as our record 2017. We produced more than 8.6 billion pieces of solid dosage forms and 165 tons of granules and micro-pellets. We packaged 6.6 billion tablets and capsules in 148 million packages with almost 370 million primary packaging units. We launched around 240 new products. The share of innovative products in our portfolio will increase in the future due to the integration of Novartis's innovative products and technology transfers from the Sandoz Development Center in Ljubljana.

The share of innovative products in our portfolio will increase in the future due to the integration of Novartis's innovative products and technology transfers from the Sandoz Development Center in Ljubljana.

Antoine Maupu, Head of Aseptics Ljubljana

Matjaž Tršek, Head of Development Center Slovenia

Aseptics
In 2018, we continued to increase the number of employees. In addition to ensuring the smooth production and packaging of sterile and non-aseptic liquid products, many resources have been devoted to satisfying increasingly stringent regulatory requirements in the field of aseptic filling technology. We have renewed our portfolio of products with a view to the upcoming strategic placement. Nevertheless, we reliably guaranteed the supply of Rituximab, our first biosimilar product, which was marketed in 2017 in many countries.

In order to secure young, prospective co-workers, we are closely associated with the local university. We also spent a lot of time on the internal training of our employees and providing a safe working environment.

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.

In 2018, 23 employees of the Development Center Slovenia participated in the job rotation program within the framework of the Sandoz initiative "Onwards & Upwards", whereby we acquire and share new knowledge and skills. We completed the Second Leadership Academy, through which 8 out of 14 participating young talents already occupy a leadership position. As the greatest achievement in 2018 in the field of development of the organizational culture, we emphasize the introduction of flexi-work, namely the possibility of working from home, which is a major step towards the development of an open and inclusive culture.

In building the extension to Development Center 2, we have increased capacities and added new capabilities in the field of Pharmaceutical and Analytical Development. The laboratories will be fully equipped and put into service by the middle of 2019 and represent the basis for further growth of the Development Center Slovenia.

The culture of operational excellence in the Development Center was well established in 2018. We have completed 50 improvement initiatives that have resulted in a 2.1 million EUR saving in labor costs and significant time savings. We invested them in increasing the number of development projects and activities on demanding development projects.

In 2018, Development Center Slovenia consolidated its position as the leading Sandoz Development Center.

Vesna Kapelj, Head of Chemical Operations Mengeš

Polonca Kuhar, Head of Bioproduction Mengeš

Uroš Urleb, PhD, Global Head Technical Development Biosimilars

1.2.3.2 Mengeš site

Chemical Operations Mengeš

In API Mengeš, we started successfully introducing the production of three Novartis innovative ingredients from the Development Center in Basel for new, originating medicines, which will be on the market in the coming years. We successfully completed the investment for the production of the pharmaceutical intermediate Everolimus Solid Dispersion and at the end of the year we started the transfer from Basel.

We are continuing the introduction of NOSSCE (Novartis Operational Standard for Supply Chain Excellence) and as planned, we also anticipate site certification. With a number of activities to rationalize operational costs, we achieved savings of 5 million EUR and enabled the production of additional quantities of active ingredients with existing resources.

In the field of health, safety and the environment, we have achieved many successes, which are the result of good site employee awareness. We efficiently reduced the amount of waste generated. We reduced the amount of drinking water from the grid by as much as 50 percent, and energy use by 2 percent. We successfully carried out external audits and retained certification for ISO 14001 and EMAS environmental management systems, and ISO 45001 occupational safety and health management systems.

Biopharmaceuticals Mengeš

Once again, in the production plant for recombinant technology (PORT) we produced record quantities of the erythropoietin active ingredient used to treat anemia in cancer and kidney patients. Due to the increased demand for such an active ingredient on the market, in October we started up an additional production line. Meanwhile, we started a new investment project for the construction of a new API production building that will further consolidate our position as a key Novartis Center for Biotechnology Excellence.

At the Mengeš site we successfully passed all the assessments of domestic and international health inspections and the assessment of Business Continuity Management (BCM) for the established system of ensuring the smooth operation.

At **Technical Development Biosimilars Mengeš**, we create many successful stories that have a strong impact on patients around the world. The unit is undergoing various stages of development of all biosimilars and certain new biological medicines. In 2018, we established new organizational units, strengthened investments in development projects and successfully passed all the assessments of domestic and international health inspections. The year 2018 was an exceptional year also for the submission of applications, approvals and launches of biosimilar medicines. We have become part of Novartis Global Drug Development - Technical Research & Development, which has opened up many new opportunities for cooperation, creating synergies and developing breakthrough ideas.

Technical Development Biosimilars Mengeš employees also contributed significantly to the fact that at the end of 2018 the European Commission approved a Sandoz biosimilar medicine pegfilgrastim, which is used in oncology to shorten the duration of neutropenia.

Roman Burja, Head of Anti-infectives Prevalje

1.2.3.3 Prevalje site

In 2018 we again increased the production volume. Compared to the previous year, we produced 6 million tablets more, producing a total of 651 million tablets altogether. A good third of these are for the United States market (USA). The production of mixtures was approximately 10 percent higher than 2017, and finished the year with 300 tons of produced blends. Production of oral suspensions fell by around 8% compared to the previous year, with 13.5 million pieces produced. In total, we have produced 51 million packs, which is comparable to 2017. The wide-spectrum antibiotic Amoxiclav, which we produce, is sold in more than 80 of the world's most demanding markets, including the US, Europe and Russia.

We invested in new equipment in production. We performed excellently on assessments, among others we successfully completed the demanding Brazilian regulatory authorities ANVISA assessment. We are particularly proud of the reduction of recurring deviations and improvement to the series indicator without withdrawals.

Through reorganization and adjustments in almost all departments, we achieved business optimization and increased efficiency. We introduced improvements in the production process of tabletting and packaging of products and successfully completed the implementation of the study for the introduction of continuous production. In the area of automation, we carried out the first pilot project, which is the first step in digitizing production lines. We continued upgrading packing lines with T & T functionality.

In 2018 we celebrated three important anniversaries; 40 years of production, 30 years of Amoxiclav production and 20 years of production in our existing plant.

651 million

TABLETS PRODUCED.

In 2018 we celebrated three important anniversaries; 40 years of production, 30 years of Amoxiclav production and 20 years of production in our existing plant.

Gizela Štampar, Head of Anti-infectives Lendava

Simon Rečnik, PhD, Head of Solids Lendava

In 2018

PRODUCTION AGAIN REACHED A RECORD HIGH.

1.2.3.4 Lendava site

Anti-infectives

At Lendava Anti-infectives unit, we produce two active ingredients: potassium clavulanate and gentamycin 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. Gentamycin 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 also reached a record high last year. This was achieved by optimizing the use of fermentation materials and 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, whereas the production of gentamycin sulphate less due to decreased market demands.

Investments at the location were mainly focused on ensuring further growth in production. Investing in the change in the production of Clavulanic acid fermentation broth from batch into partly continuous, for example, enables us to produce larger quantities and further reduce costs.

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 are constantly increasing the safety processes and the safety culture of our employees. We have also been successful in the field of health and environmental protection, as we reached nearly all the set goals in the field of environmental protection.

Solid Dosage Forms (SDF)

At Solids Lendava we continued our dynamic growth in 2018. Within the framework of Novartis Technical activities, we have finally established ourselves as a strategic packaging plant for solid pharmaceuticals and as one of the largest Novartis suppliers of medicines for customers and patients worldwide. In 2018, we started to pack the first innovative drug - immunosuppressant that Novartis Pharmaceuticals supplies to patients around the world

Compared to 2017, we increased the production volume by 15 percent to almost 6.2 billion tablets and capsules packaged in 171 million packs of medicines. We also increased the complexity of the product portfolio, which included more than 85 different molecules packed in more than 3,200 final pharmaceutical forms. Increase in production volumes meant new jobs. Thus, we completed the year with 460 employees, which is almost a quarter more than the year before.

We paid a lot of attention to the development of professional knowledge and competences, operational excellence, organization and processes. 2018 also ended without work incidents that would result in sick leave. All operational goals and key performance indicators were achieved.

In 2019, Novartis will start shipping to Lendava the packaging of the most crucial innovative pharmaceuticals of Novartis Pharmaceuticals. We will start packing eight new innovative medicines and prepare everything to launch innovative medicines from all over Novartis in the coming years.

In 2019, Novartis will start shipping to Lendava the packaging of the most crucial innovative pharmaceuticals of Novartis Pharmaceuticals.

6.2 billion

TABLETS AND CAPSULES PACKED.

1.3. Development and reporting framework

One of the principles of Novartis's corporate social responsibility policy is transparency 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.[12] The Sustainability Report was last published in July 2018.

In the 2018 Sustainability Report, we have upgraded the previous reporting according to GRI GS standards. We have incorporated updated standards from the fields of Occupational Health and Safety (standard 403) and Water (standard 303).

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.[13] The essential aspects of sustainable business are recognized and are evident in the GRI Index in Point 6. We have not yet decided to seek external assurance for our sustainability reporting.[14] The Sustainability Report which contains the EMAS Environmental Statement is available at https://www.lek.si/en/corporate-responsibility/reporting/.

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). 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 the preparation of the report. Novartis and, consequently, Lek's material and important areas of social responsibility are shown on page 26.

[12] GRI GS 102-51, 102-52.

[13] GRI GS 102-46.

[14] GRI GS 102-56.

[15] GRI GS 102-45, 102-50, 102-10, 102-48, 102-49, 102-54.

1.3.1 2018 reporting characteristics[15]

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) including changes, disclosing the required indicators for each site separately.

Reporting in accordance with GRI Guidelines

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

- Reporting refers to Lek and all its manufacturing sites in Slovenia. All disclosures in the present report refer to the 2018 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 82.
- 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.
- The content structure of the Sustainability Report for 2018 is comparable to similar annual reports of Novartis. The changes did not affect the scope of disclosures in the report.
- In 2018, there were no changes in the size, structure and ownership of Lek. There were no merger activities or joint ventures.
- In order to improve the accuracy of reporting, the following corrections were made for 2018 in the collection of data that affect the comparability of data with previous years:
  - In the DMS, during verification an error was found in the reporting of the quantitative realization for Aseptic Products Ljubljana for 2017. The products in the primary packaging and not the net weight were taken into account. Consequently, data on quantitative realization for Lek for the year 2017 also changed.

- Due to the purchase of electricity origin (GOO) for 2017, the quantities of indirect greenhouse gas emissions for 2017 were corrected. For 2017, we purchased certificates of origin of electricity from renewable sources.
- From January 1, 2018, the calculation of natural gas from volumetric quantities (Sm^3, Nm^3) to energy quantities (kWh) was changed in Slovenia for all four Lek sites thus the High Heating Value from this date is taken into account. Previously, all the billing and reports contained energy conversion into the Low Heating Value.

1.4 Governance, commitment and inclusion

1.4.1 Governance and management[16]

Lek 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 2018, the members of the Board of Management were as follows:

- **Zvonko Bogdanovski**, President – Technical Operations,
- **Ksenija Butenko Černe**, Member – Legal Affairs,
- **Daniel Michalek**, Member – Finance,
- **Andrej Pardo**, Member – Commercial Operations,
- **Samo Roš**, Member – Human Resources,
- **Marjan Novak**, Member – Workers' Director.

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 2018, the members of the Supervisory Board were as follows:

- **Francesco Balestrieri**, Chairman,
- **Richard Francis**, Deputy Chairman,
- **Miguel Pagan Fernandez**, Member (until 19. 3. 2018),
- **Andreas Michael Brutsche**, Member (from 20. 3. 2018),
- **Knut Mager**, Member,
- **Fikret Bašanović**, Member – Workers' Representative,
- **Peter Svete**, Member – Workers' Representative.

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.

[16] GRI GS 102-18.

Novartis employees in Slovenia presented their working day to the students of the Summer School and gave them insights into the world of pharmaceutical industry.

- 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 2018, 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.

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[17]

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. 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 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

[17] GRI GS 103-1.

quality of the work environment. 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.

In 2018, 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.

The Workers' Council regularly published the session records 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.

1.4.3 Stakeholder overview and inclusion[18]

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. Each survey also helps us to better respond to patient needs and provide solutions for a healthier society. Through the years, it has become a constant on the path of realizing our mission - to discover new ways of improving and extending the lives of people.

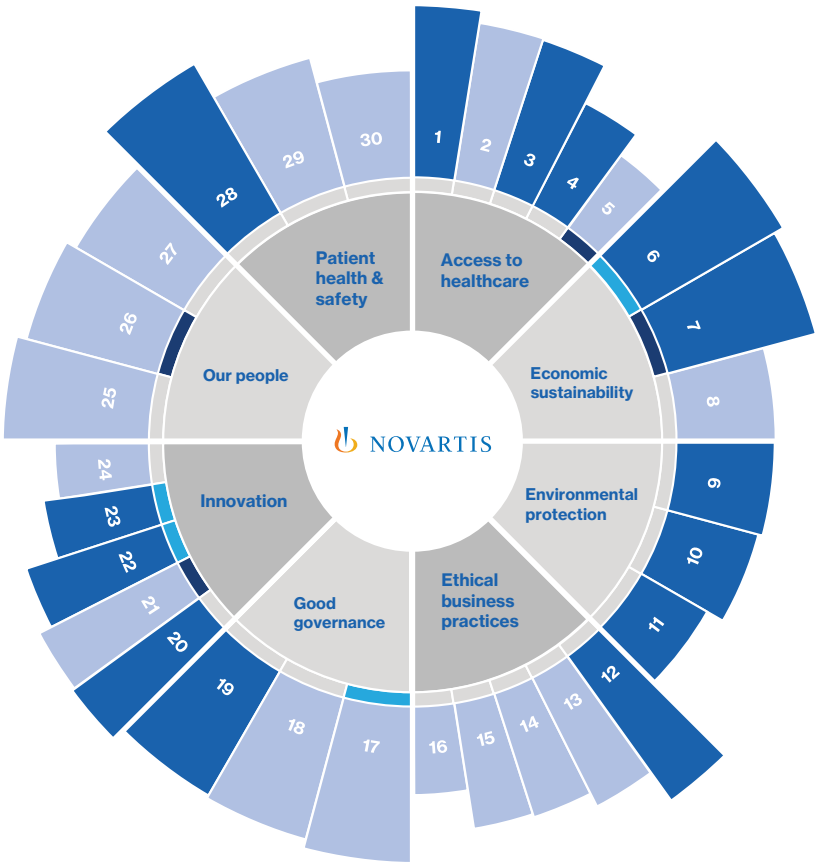
We meet with our suppliers to learn about their expectations and experience.

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.

[18] GRI GS 102-40, 102-42, 102-43.

Novartis corporate responsibility material issue cluster



Legend

Outer circle

Priority topics

Middle circle

External stakeholders perceive as more important

Internal stakeholders perceive as more important

No significant difference in perception

Inner circle

Material issue clusters

Access to healthcare

1 Pricing
2 Availability of medicines
3 Intellectual property
4 Health system strenghtening
5 Patient assistance programs

Economic sustainability

6 Financial health & performance
7 Recruitment & retention of employees
8 Fair contribution to society

Environmental protection

9 Pharmaceuticals in the environment
10 Pollution, waste & effluents
11 Sustainable use of resources

Ethical business practices

12 Ethical & compliant behavior
13 Respect of human rights
14 Responsible supply chain management
15 Responsible use of new technologies
16 Animal testing

Good governance

17 Corporate governance
18 Data privacy and security
19 Transparency

Innovations

20 Inovative technologies
21 R&D for unmet medical needs
22 Business model innovation
23 Drug resistance
24 R&D for neglected diseases

Our people

25 Health & safety
26 Fair working conditions
27 Diversity & inclusion

Patient health & safety

28 Pharmacovigilance, safety profile & quality of drugs
29 Counterfeit medicines
30 Health education & prevention

The inner circle reflects the issue clusters. The top four CR material clusters are highlighted in bold. The middle circle indicates topics with significant differences in perception between internal and external stakeholders. The outer circle represents the 30 individual topics. The relative importance of a topic is indicated by the height of the column, not its width. The cluster ranking (inner circle) is based on a separate topic cluster ranking question; it is not derived from a calculation of the individual impact rankings of topic-specific questions.

Lek's stakeholders and their recognized interests:[19]

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
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

[19] GRI GS 102-40, 102-44.

1.4.3.1 Co-operation with the local communities

Our donation supported the ZDUS program, Elderly for the Elderly. (From left to right: Janez Sušnik, President of ZDUS, Rozca Šonc, Head of the Elderly for the Elderly program, Katarina Klemenc, Director of Corporate Communications in Lek and Branislava Ogrinc, President of the Lek Pensioners' Association).

As part of the 14th Community Partnership Day, Novartis employees also helped the Ana's Star charity organization, where they prepared as many as 300 packages for families in need.

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. This is how we organize Open Days and Community Partnership Days with the local community.

Community Partnership Days
Between April 16 and May 15, Lek's employees assigned their working hours to individuals and organizations across Slovenia. By doing this, they give back to society and the environment in which they work and live. The Community Partnership Days were attended by as many as 650 employees in Novartis in Slovenia on 26 activities and projects.

Over 14 years, employees of Novartis in Slovenia spent more than 33,000 hours in organized Community Partnership Days volunteering, helping more than 60 different organizations and more than 12,000 individuals.

Lek živžav
Lek živžav is part of the humanitarian program **Wink at the Sun**, with which the Association of Friends of Youth of Slovenia (ZPMS) and Lek allow free holidays for children from socially at risk families. In 2018, 130 children were given free holidays. For the past 19 years, Lek has been supporting and co-operating from the very beginning. A number of Lek employees also participate with ZPMS every year, as volunteers and help organize their holiday homes. In 2018, more than 100 employees helped prepare the holiday homes and their surroundings in Pacug, thereby further enhancing the carefree holiday for children.

Elderly for elderly
In 2018, our donation also supported the program of the **Association of Pensioners' Associations of Slovenia** (ZDUS) **Elderly for the Elderly**, which ZDUS implemented for the 14th year. This program connects our common missions, that is, helping others and giving back to the society in which we live and work.

Mechanism for addressing complaints[20]
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 Head of HSE shall ensure that the corrective measures are taken and fulfilled. The entire procedure is documented and archived.

In 2018 we received four complaints, one from the field of health and three from the field of the environment. In Mengeš, a resident pointed out the lights being switched on on our building, which we immediately switched off. Similarly, in Mengeš, an agricultural land owner opposed the new borehole and demanded its relocation, although the borehole was in place as determined by the Farmland Fund of the Republic of Slovenia. We met with the landowner and responded accordingly. In Ljubljana, we received a complaint from a waste contractor due to inadequate separation of biodegradable waste. We have introduced regular controls in the waste separation in the kitchen. In Prevalje, the employees warned about the small number of guided exercise instructors, which is why we expanded and updated the list of providers in Lek.

[20] GRI GS 103-1, 103-2, GS 413-1.

More than 100 Lek employees participated in preparing the ZPMS holiday home and its surroundings in Pacug.

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 https://www.lek.si/en/corporate-responsibility/reporting.

1.4.4 Lek's commitment to external initiatives and principles[21]

Lek is a member of the following Slovenian societies and associations:

- American Chamber of Commerce
- Business women's society
- Maintenance company
- European patent institute
- Slovenian Chamber of Commerce
- Fire brigade of Slovenia
- Chamber of Engineers of Slovenia
- ICS, Ljubljana (Institute for Corporate Security Studies)
- Agriculture and Forestry Chamber
- Palsit d.o.o. (IT Manager Club)
- Slovenian Society for Laboratory Animals
- Slovenian Public Relations Society
- Slovenian Water Protection Society
- Slovenian Pharmaceutical Society
- Slovenian Information Exchange EGIZ
- Slovenian Institute of Auditors
- SIQ (Slovenian Institute for Quality and Metrology)
- Slovenian Advertising Chamber
- Slovenian Association of Representatives for Intellectual Property
- Slovenian Association for Quality and Excellence
- Slovenian Fire Protection Association
- Veterinary Chamber
- Occupational Safety and Health Chamber
- Association of Employers of Slovenia
- Association of Workers' Councils
- Industrial Property Protection Association
- Association of pharmaceutical manufacturers of Slovenia
- Association of Senior Citizens of Slovenia
- Association of Managers
- Association of Supervisory Board Members
- Association of Purchasers of Slovenia

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,
- 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.

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.[22]

[21] GRI GS 102-12, 102-13.

[22] GRI GS 102-11.

2. Access to Healthcare

Access to Healthcare is one of three Novartis and Lek key principles of corporate social responsibility. We achieve it with our core business, that is, by discovering, developing and marketing innovative medicines that help prevent and treat diseases and improve the quality of life of people all over the world. At the same time, we are striving to provide more and more people with the treatment they need. We facilitate greater accessibility by promoting the development of modern technologies, expanding the interest in science and accessibility of treatment among young people, as well as through donations of medicines.

2.1 Innovation

Lek, as part of Novartis, actively contributes to addressing global health challenges with innovative medicines based on brand new discoveries as well as the development and production of generic medicines.

2.1.1 Achievements in medicine development

At **Technical Development Biologics Mengeš**, we have achieved important milestones in the development of biosimilars and new biopharmaceuticals. We have developed many innovative approaches that bring faster and cost-effective solutions to their development.

Persistent work, dedication and top-level knowledge in the development of biopharmaceuticals enabled the authorization and launch of three new biosimilars in 2018 - infliximab, adalimumab and pegfilgrastim.

At end of 2018, at the **Development Center Slovenia** we completed more than 200 development projects for pharmaceuticals and active ingredients. The majority being drugs to lower cholesterol levels and high blood pressure, oncological, to treat diabetes, allergic rhinitis, migraines, insomnia, urological and gastric diseases, and also non-steroidal anti-inflammatory drugs. We finished the development and submitted 20 dossiers to for medicines on the markets of the USA, the European Union, Russia, Canada, Australia, Mexico and China, and two dossiers for active ingredients in the USA and Canada.

We successfully launched 13 new products in the USA, European Union, Canada, Mexico, Japan, Australia and Brazil, developed in the Development Center Slovenia.

The US Food and Drug Administration accepted for approval and confirmation i.e. first to file status for four dossiers for the treatment of Parkinson's disease, type 2 diabetes and idiopathic pulmonary fibrosis.

We successfully launched 13 new products in the USA, European Union, Canada, Mexico, Japan, Australia and Brazil, developed in the Development Center Slovenia.

We are particularly proud of our team, who, together with their colleagues from the USA, succeeded at the US Food and Drug Administration as the first and sole dossier for extended release capsules with the active substance amantadine. This is used in the treatment of patients with Parkinson's disease. By doing so, we have acquired an extremely important, 'exclusive first to file' status. After completing the registration process, our generic medicine with this substance has the right to a 181-day market exclusivity right on the US market.

Development Center Slovenia

The active substances can be crystallized in several polymorphic forms, which differ in terms of solubility, chemical stability and many other chemical and physical properties.

Assoc. prof. Zdenko Časar, PhD, Head of Analytics at the Sandoz Development Center Slovenia, receives the highest Novartis scientific award.

We know how to come together to find a solution

After his very first chemistry lesson, he knew that he was interested in it. He received his chemical technology PhD at the University of Maribor and his Chemistry PhD at Rennes University 1. He is driven by his ambitious attitude towards research, something that he learned during his studies in France.

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Zdenko Časar, PhD, led the development of new polymorphic forms of active substances, developed innovative synthesis of active substances and improved processes. In doing so, he created intellectual property, which have been the basis for 67 patents in the last five years. For exceptional scientific achievements, he received the highest Novartis prize "Distinguished Scientist".

How do you see the benefits of combining two scientific fields and research at Novartis?

During my doctoral study of organic molecular materials synthesis, organic chemistry and chemistry of materials kept cropping up. For a graduate of chemical engineering, it was a considerable challenge to acquire knowledge in two totally different fields. Then, through a series of happy circumstances, my research in pharmacy started at Lek. I would say that studying various fields of chemical science gave me the professional breadth and provided me with a good understanding of various areas of the pharmaceutical industry. In the Novartis development work, I am motivated by the opportunity I have to

face the most demanding projects and work with an excellent team.

Your scientific research and new discoveries, facilitates savings in development and manufacturing medicines and thus more affordable treatment. Which aspect is most important?

Development savings can be relatively small compared to subsequent ones made in production, if, of course, we have developed a good process for the preparation of the active substance or pharmaceutical product. More importantly, the innovative development of a generic drug can enable new discoveries to accelerate market entry, and hence quicker access to a newer and better medicine for a wider circle of patients.

Where do you appreciate the contribution of your colleagues the most?

In complex development work, such as the development of active substances and medicines, an individual cannot achieve anything by themselves. Each project is developed in a project team, involving 15 to 30 colleagues from different fields. All my personal achievements are also based on good teamwork. In Lek, I was always lucky, I worked with several top researchers and very good technicians, meaning we could also realize the most demanding ideas and create breakthrough solutions. In addition to the exceptional support and trust of superiors. My team is especially important to me when we are faced with difficult challenges and we can solve them together. I am proud of the great commitment to work and the overall goals of the team I run.

What kind of developments in pharmaceuticals and main opportunities in the field of treatment do you expect to see?

I assume that the current and future development of pharmacy will head in two directions. Digitization will facilitate faster progress of the pharmaceutical industry, which is restricted due to a highly regulated environment. There is a lot of possibilities for digitizing processes, development and production processes, which could enable faster development and more robust production processes. At the moment, my biggest personal challenge is the digitization of work processes in the development of medicines. Digitization also enters the segment of therapies. Sandoz has recently established itself as a pioneer and leading producer of digitized medicines, i.e. "Digital therapeutics". The approach to treatment will at the same time be more personal in the treatment of chronic diseases, for example with a personalized dose or combination therapy. In oncology it will probably be a targeted one-time therapy that will cure the patient. Such an example is Novartis's CAR-T cell therapy. The medicines will be more tailored to the individual, which will force developers to think differently, and can encourage the pharmaceutical industry and researchers to innovate.

At Development Center Slovenia, on average, you develop 20 new medicines annually, or approximately 2 monthly with a new active substance, a new pharmaceutical form or a new market. How are you doing it?

I think that the reason is in our knowledge, we have developed products that others couldn't. Our flexibility is also distinguished by the fact that when it gets tough we can come together to find solutions.

Assoc. prof. Zdenko Časar, PhD, Head of Analytics at the Sandoz Development Center Slovenia, receives the highest Novartis scientific award.

2.1.2 Facilitating mass inventive culture

Our ideas through Th!nk Novartis 2018 numbers

Th!nk Novartis is an application to support the development of an innovation culture in the company. It is accessible to all internal employees and external workers. By entering ideas into the application, promoters are actively involved in introducing changes and improving work processes. In 2018, Lek employees delivered **617 ideas**, **384 ideas were approved** for implementation. In total, **370 ideas** were implemented in 2018, and the direct measurable savings of approved ideas amounted to **6.2 million Euros. 448** different promoters participated in the submission of ideas, representing 5.8 percent of all Lek's internal and external employees. In 2018 we also recorded the jubilee **6000th idea**.

Week of innovation

In April 2018 we carried out the Sixth Week of Innovation, which we named the Digital Week of the Future. The organizational team prepared a rich set of content so each participant could find something that was of interest to them. The program included two main panel events in Ljubljana, two creative breakfasts in Ljubljana and one creative breakfast in Lendava, Mengeš and Prevalje. Both panel discussions in Ljubljana could be attended by employees who could not attend the event live via Skype. On some occasions, we also used Mentimeter, an application for getting instant results from the audience.

In 2018, the 6th Week of Innovation was titled the Digital Week of the Future.

24th Slovenian Science Festival

Between 25 and 27 September 2018, the 24th Slovenian Science Festival took place in Ljubljana, which included nearly 80 free events, including many with foreign guests. In Lek, together with the University of Ljubljana, we co-organize the festival, thus significantly strengthening our cooperation with Slovenian educational institutions. The slogan for this year's festival was "Nature, Man and Experiments", and the central part of the program was related to science and the use of experimental methods of research.

Lek's employees participated at the opening ceremony, press conferences and a workshop on innovation. We took younger visitors to see Lavicka's collection, where **Zlatko Pflaum, PhD**, Project Manager at API Mengeš, and **Janko Ignjatovič, PhD**, a research assistant in analytics, showed simply through thoughtful experiments, what we should all pay attention to when transferring the theory of innovation into practice.

Sciencetival

For the fifth consecutive year, Lek has been participating at the Sciencetival - Scientific Festival of Science and Adventures, organized by the House of Experiments. Janko Ignjatovič, PhD, a professional associate in the Development of Biopharmaceuticals Mengeš, presented chromatography in a simple and fun way. With the tests on the stand in the garden of experiments, young people were especially impressed with science.

2.1.3 Awards for innovation

Central Eastern European Pharmaceutical Manufacturing Excellence Award

Employees of the Development Center Slovenia won the "4th CEE Pharmaceutical Manufacturing Excellence Award 2018" prize with their co-workers from Lek's penicillin products manufacturing company Prevalje to develop a child-friendly form of rapidly dissolving AmoxiClav tablets. The prize was awarded to Petra Perhavec, Head of Pharmaceuticals Development Department and Mateja Šikovec, project manager from the Development Center Slovenia at the annual conference of the PHARM Connect Association.

Award of the Chamber of Commerce Slovenia

The Lek Innovation team received a bronze award from the Chamber of Commerce and Industry of Slovenia for the "Advanced Business Analytic Tool for Monitoring Strategic Indicators and Data Mining" in the Sandoz Development Organization. In the team of innovators were Uroš Klančar, Robert Kušar and Andrej Vivod from the Development Center Slovenia and Domen Petan, Tibco Spotfire Advisor. With this prototype, new opportunities have been created in optimizing and digitizing business processes in Sandoz's global development organization. The innovative tool combines and processes data from various data sources, while also shortening the time for data analysis up to 100 times.

Prometeus of Science

The Slovenian Science Foundation awarded us the "Prometheus of Science" Award for Excellence in Communication of Science.

Lek's team of innovators received a bronze award from the Chamber of Commerce and Industry of Slovenia. (From the left: Uroš Klančar, Robert Kušar, Andrej Vivod and Domen Petan).

TOP Th!nk award

We received special acknowledgment for innovative achievements of our colleagues who contributed and in practice introduced the most innovative ideas and solutions. "TOP Th!Nk Proposer", Anton Kosec delivered the greatest number of ideas, the prize for "TOP Th!Nk Team" was given to Vesna Stergar, PhD, and 23 of her colleagues from the Unit of Development Processes of Pharmaceutical Ingredients. Uroš Urleb, PhD, Director of Technical Development Biologics Mengeš, took the prize for "TOP Th!Nk Unit".

Sandoz Awards

At the Sandoz Research and Development Day (SRDD) 2018, which recognizes the best of the best scientists each year, our colleagues from the Development of Biopharmaceuticals Mengeš and the Development Center Slovenia received the most awards in the history of SRDD. They were awarded with a prize for scientific excellence for pioneering work in the field of digitization and data analysis in the development of biopharmaceuticals and in many other fields of activity.

Boštjan Petek, lead researcher from the IVIVC Group at the Development Center Slovenia, received the Sandoz Prize for Scientific Excellence. Sandoz's development awards were given to Lidija Vraničar Savanović in the category "Head of the Year", Melita Hribar in the category of "Rookie of the Year" and the Amantadine eFTF Development Team in the "Team of the Year" category. All prize winners came from the Development Center Slovenia.

At the 10th Sandoz Research and Development Days, our colleagues from the Development Center Slovenia won three awards for the best presentations with posters. We also published more than 10 scientific articles in influential scientific journals and 10 articles at international conferences.

Sandoz HACk contest

Sandoz's HACk contest focused on finding digital solutions in 2018 to improve access to health care. The second contest, an upgrade of the first is more extensive, as it seeks to find more general digital solutions to improve access to healthcare. More than 400 ideas from 80 countries, including those from Slovenia, were submitted to Sandoz's HACk. The award-winning solutions were presented on March 10, coming from Uganda, the United States and the Netherlands.

Lek's researchers, Vesna Stergar, PhD, and Dušan Teslić, PhD, received the Prometheus of Science award.

Global Sandoz HR Awards 2018

Out of more than 50 applications from different countries, Lek won two categories of the competition. Our application "Innovative Collaborations with Academia, Talent Attraction and Employee Branding" won the "Organization" category. The winning team consisted of Janko Ignjatović, Zdenko Časar, Sandra Nedog, Tea Vizjak, Darja Ferčej Temeljotov, Bojan Lauko and Igor Novak. In the Culture category, we won the application "Innovation Culture and Idea Management Program" prepared by Darja Ferčej Temeljotov, Tea Vizjak, Sara Lipovec, Bojan Lauko, Damir Lukežić, Janko Ignjatović, Roman Pogačar, Petar Kerčmar, Jure Vajs, Matej Pilat, Irma Jedlovčnik and Vesna Premović.

Novartis Awards

In 2018, two of our colleagues received Novartis's scientific awards for outstanding and lasting scientific achievements in research and development. Assoc. prof. Zdenko Časar, PhD, received the highest Novartis scientific award for a distinguished scientist and Jerneja Opara, PhD, received the leading science award.

Novartis awards global awards in the fields of health, safety and the environment (HSE) and unhindered business (BCM) and ambassadors. One of the recipients of this prize in 2018 was a colleague from Aseptics, Saša Tanasić. He received the award in the ambassadorial category for innovative technical solutions and personal contributions in the field of occupational safety.

Recipients of Novartis' scientific awards, among them assoc. prof. Zdenko Časar, PhD, and Jerneja Opara, PhD.

Bioequivalence studies are of paramount importance in the development of generic drugs as they prove that there is no significant difference in the rate and extent of absorption of the same dose of the originator and generic drug. Jerneja Opara, PhD, has developed a scientific methodology for predicting the results of bioequivalence studies.
Using state-of-the-art digital technologies, it contributes significantly to reducing the amount of laboratory experiments needed and clinical studies.

Jerneja Opara, PhD, researcher at the Sandoz Development Center Slovenia, winner of the Novartis “Leading Science” award

Changes will be faster

You are concentrating on the in vitro/in vivo correlations and by laboratory experiments predicting how a drug will behave in the human body. Have you always been familiar with the digital technologies you are using?

The in silico research method has interested me since my studies, mainly due to efficiency and relatively low costs. I began to explore the usefulness of artificial intelligence methods for predicting plasma concentrations of active pharmaceutical ingredients and focused on research using digital approaches. I was also interested in data processing and new computer approaches.

Commercial programs for pharmacy purposes were not available so I used and customized general tools. Upon my arrival at Lek, I adjusted the methodology for predicting the results of bioequivalence studies. The lack of commercially available tools for the generic pharmaceutical industry and the high demand for predictions were crucial for the development of new approaches.

You have shortened development time and risks in generic medicine development. You have significantly contributed to the fact that the success of bioequivalence studies in Sandoz is significantly higher than the average in the pharmaceutical industry.

In the last ten years, Sandoz Development Center Slovenia has strengthened modeling in the development of medicines in other areas, not only in the field of In vitro / In vivo correlations. We are extending approaches and tools everywhere and upgrading our knowledge. More and more researchers are involved in modeling. Over the years, we have built a system for evaluating and reducing the risks in the development of medicines, which we are constantly upgrading. Modeling plays an important role here.

What are the particularities of digitization in the pharmaceutical field?

Perhaps, as an industry, we are lagging behind in respect to other industries, but we have been catching up in recent years. For the pharmaceutical industry, it is important that digitalization is also accepted by regulatory authorities. Although in modeling they tend to favour mechanistic approaches, the FDA modeling group in 2018 began to mention the possibility of using artificial intelligence in supporting the registration of medicines, which is definitely progress and innovative.

What is the potential of data processing and modeling in the development of pharmacy?

In a word - big. More laboratory and clinical trials could be done in silico, thereby relieving and accelerating development. In the field of treatment, model simulations could be used to individualize therapy in a wide range of patients. On the basis of individual physiological characteristics and parallel illnesses, general practitioners could predict patient-adjusted therapy and side effects. In many areas of treatment, new knowledge acquisition approaches are introduced through data processing, applications are developed to support the patient in treatment. Changes will be constantly faster.

In the second half of her pharmacy undergraduate studies, she realized that research was the most attractive for her. After the doctorate, she was finally completely convinced. Jerneja Opara, PhD, received the Novartis 2018 VIVA leading science award for leading scientist for her outstanding scientific contribution to the modeling and simulation of generic drug development using state-of-the-art digital technologies.

However, every innovation needs time for people to accept it and begin to use it.

The greatest challenge is therefore perseverance and constant demonstration of the usefulness of new approaches and the integration of people and different knowledge. A new idea requires a lot of time and, therefore, often a lot of costs too. Since we cannot be certain of its efficiency, it is important to have highly motivated researchers. Communication and knowledge exchange with regulatory authorities and patients are also important in pharmacy. An important, yet stimulating, internationally open environment is what we have in Novartis.

The Leading Science Award was handed to Jerneja Opara, PhD, by John Tsai, Head of Global Drug Development for Novartis.

2.2 Product compliance[23]

In line with Novartis' principle we are committed to high standards of ethical business. Therefore, our 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 addition to numerous Novartis initiatives, we also contribute to expand access to healthcare with our core business - research, development and marketing of innovative medicines and innovative treatments. We offer customized solutions to our customers.

The information about our products must be transparent, non-misleading and in accordance with approved product labels.

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. 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. No infringements in the field of information and labeling of products were detected in 2018.[24]

We inform the professional public of prescription and non-prescription drugs with visits made by experts to health institutions and at professional meetings organized 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 2018, the inspection authority at JAZMP instituted no inspection procedure in the field of information and labeling of products. There were also no cases of violations of marketing communication rules, standards and non-binding codes, including those related to advertising, promotion and sponsorship.[25]

The information about our products must be transparent, non-misleading and in accordance with approved product labels.

Customer satisfaction[26]

The satisfaction of the professional public is measured by opinion surveys. By means of these surveys we determine the company's reputation with doctors and pharmacists, satisfaction with our employees and activities.

The results of the last survey which was carried out at the end of 2018 show that the professional public recognizes the integrity of our operations and highly values our ethics. They highly rated our educational activities and specifically highlighted our professionalism and appropriate approach.

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By conducting consumer research 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.

[23] GRI GS 103-1, 103-2, 417-1.
[24] GRI GS 417-2.
[25] GRI GS 417-3.
[26] GRI GS 102-43, 102-44.

3. Doing Business Responsibly

3.1 Ethics, business compliance and human rights[27]

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 and everyday activities and is the key that defines 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 also guided by **Novartis Human Rights Guideline** https://www.novartis.com/sites/www.novartis.com/files/novartis-human-rights-guideline.pdf.

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 2018, we organized online training for employees on the Code of Conduct, reporting adverse events, personal data protection as well as an e-training in the field of expert practice in working relationships with health workers and organizations.

On average, more than 99% of employees successfully completed training. All the above stated areas are also a part of the regular induction program for all new employees at Lek.[28]

[27] GRI GS 103-1, 103-2, 102-16.

[28] GRI GS 412-2.

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.

We also conducted an **awareness campaign on conflicts of interest**. We also discussed a number of issues related to compliance in regular contributions in our internal newspaper Collective. With this, the employees continuously deepen their knowledge of the principles of integrity and harmonious behavior, and integrate them into their daily lives.

Compliance standards 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"** and **"Novartis Initiative for Women's Inclusion"** are important contributors 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 2018, there were no cases of discrimination and no requests to remedy any violation in this area.[29] The company was also not involved in any antitrust procedure for any violation of antitrust regulations.[30]

Compliance standards 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.

At Lek, we reject all forms of child, forced or compulsory labor.

Payments to doctors and healthcare organizations

In accordance with its Integrity Policy and the Disclosure Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA), all Novartis companies in Slovenia disclose information on payments to doctors and health organizations. Novartis publicly publishes data on payments to doctors and health organizations each year for the past year.

Novartis also follows the disclosure rules for generic and biosimilar medicinal products and value-added medicines as required by the European Generic and Biosimilar Medicines Association and the requirements of MedTech representing healthcare equipment manufacturers.

Reports on payments to doctors and health organizations by country are publicly available on the Novartis website: https://www.novartis.com/our-company/corporate-responsibility/reporting-disclosure/transparency-disclosure/payments-healthcare-professionals.

[29] GRI GS 406-1.

[30] GRI GS 206-1.

In the management of risks, Lek is assisted by a series of control mechanisms, managed by highly multidisciplinary teams.

Luka Hojnik, Compliance Officer at Lek d. d. and South-Eastern Europe and Country Compliance Officer for Slovenia

When it comes to ethical standards, there is no room for compromise

When asked what is the biggest challenge regarding ethics and compliance in the pharmaceutical industry, Luka Hojnik responds simply and clearly: "Integrity of people."

Speak up in good time

Luka Hojnik is responsible for compliance of practices at Lek, South-Eastern Europe and Slovenia. He emphasizes that the reputation of the pharmaceutical industry when it comes to business ethics is justified by the principles it applies to combat illicit practices in relations with physicians and violations of fair competition rules. However, the field of professional practices and cooperation with health professionals is becoming increasingly complex. Ethical dilemmas cannot be avoided. It is important that we recognize them and ask ourselves questions about whether it is right, whether our decision is for the well-being of patients. Will we be proud of ourselves if we accept it? How would our family react to our decision?

At Lek, we apply prevention measures at several levels, from training and raising awareness of employees to a comprehensive identification and evaluation of risks. We have established a system of anonymous reporting of misconduct and promote the so-called "speak up" culture, which also allows us to address ethical issues. Addressing cases of compliance and compliance violations has shown that it would be better for everyone involved to speak out in a timely manner. Luka adds that with open and transparent communication, and especially with honest work and compliant behavior, we can create a positive working environment where we feel good.

I'm proud to work with colleagues who recognize their responsibilities.

Compliance specialists, an integral part of the sales and marketing team

In the management of risks, Lek has set up a series of control mechanisms, managed by highly multidisciplinary

teams. Luka, together with Vlatka Erić, Ethics and Compliance Counsel, has been a part of the Sales and Marketing Team since 2018. They are providing advice to the team in delicate fields of professional practice in working with healthcare professionals, physicians, pharmacists and healthcare organizations. Associates can be therefore confident in their relationship with healthcare partners, as they know that compliant behavior builds trust and safeguards both sides with the right choices, and in particular provides protection to the patients who use Lek products.

At the same time, Luka's scope of responsibilities is much wider, in line with Novartis's job profile of the Compliance Officer. It covers all segments of ethical operations of Lek, d. d., and all divisions operating in Slovenia.

High level of culture of integrity

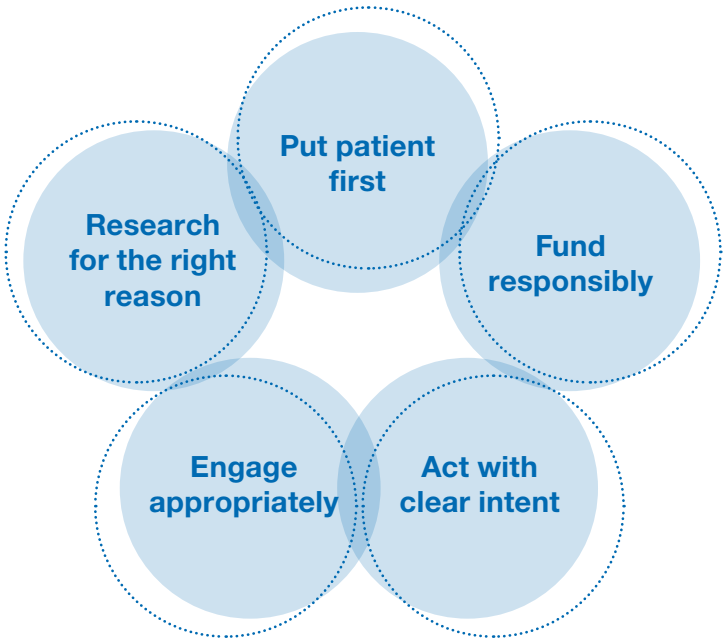
CA culture of integrity is not built overnight, he stresses. In a long-term process, leadership and leading by example are central to all levels, motivation of employees and working environment in which everyone feels good. At Lek, he sees a high level of culture of integrity, he is also pleased with the extremely high participation in compliance e-trainings. "I'm proud to work with colleagues who are aware of their responsibilities. There is no room for compromise when it comes to ethical standards."

New legal aspects related to modern technology, information technology and human rights already engaged him during his studies. He has added extensive work experience in the field of e-commerce, legal aspects of digitalization, project management and customer engagement, data privacy and compliance. He predicts that the complex technologies used by companies in their processes will dictate even more specialized knowledge that will need to be interconnected. "Processes must serve their purpose and make employees creative; they must dare to express their ideas and also point out when something is wrong", he believes.

At Lek, we are also shaping the environment outside the company by spreading best practices. We are convinced that the economy is positively impacted by compliant practices and ethical behavior. We are ambassadors of corporate integrity and recognized as a leading company in this field. In 2019, we will be one of the first Slovenian companies to accede to the Commitment on human rights in business, based on the Universal Declaration of Human Rights of the United Nations.

P3 principles

Novartis has adopted a single set of ethical principles that should be applied in daily decisionmaking by all Novartis associates by highly multidisciplinary teams.



3.2 Suppliers

3.2.1 Purchasing policy and system[31]

The purchase department is a separate organizational unit, responsible for purchase of direct and indirect material and services. 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 Purchasing is fully responsible for the implementation of and adherence to the guidelines, laws and internal procedures determining the purchasing processes.

In 2018, we moved transacted and tactical purchasing activities into service centers, which proved to be successful. With various methods of operation, especially partnership with service centers, we intensively continued to search for additional savings in all purchasing categories.

593 million EUR

TOTAL PURCHASE VALUE IN 2018.

In 2018, the **purchase value** increased in both direct and indirect purchasing and totaled 667 million USD (593 million Euros), of which 308 million USD was indirect purchase and 359 million USD direct purchase. 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 still Switzerland, Slovenia, Germany, China and India. In the field of Indirect Purchases, the largest markets were Slovenia, Germany, Italy, Canada and Austria.

Supplier audit procedures[32]
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.

[31] GRI GS 102-9, 102-10.
[32] GRI GS 103-1, 103-2, 103-3, 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.[33]

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.

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.

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.

Policy and practices for selecting local suppliers[34]

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 2018, the share of Slovenian based suppliers amounted to 282 million USD (251 million Euros) or 42.3% of total purchasing cost.

In the composition of direct purchasing by country, Slovenia accounts for a 14.8% share (53.4 million USD) and maintains the largest 73.8% share (229 million USD) in indirect purchasing. In the domestic market we mainly purchase domestic products. We mainly purchase packaging and raw materials from the Slovene chemical industry.

42.3%

TOTAL PURCHASING COST OF SLOVENIAN BASED SUPPLIERS.

[33] GRI GS 403-7.

[34] GRI GS 103-1, GS 204-1.

4. Environment

Health, safety and environment policy (HSE)[35]

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, 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 BS 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.

[35] GRI GS 102-11, GS 103-1, 103-2.

- 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.
- 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[36]

Complying with legal and other requirements is the basis of our responsible operations is the foundation of our responsible operations and we demand it of our outsourcers too. We take into account internal and also applicable international, national and local legal requirements. In case of overlap between the use of internal requirements and statutory requirements, the more stringent requirements apply.

The key environmental management regulation is the Environmental Protection Act, which 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 IED[37] (Industrial Emissions Directive) certified company, our Lendava and Mengeš sites operate in compliance with Decree on activities and installations causing large-scale environmental pollution. Both existing IED 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, keep records of all relevant legislative requirements in the HSE Registry and uninterrupted operations and other compliances, provide explanations of new requirements by analyzing the shortcomings in the HSENet application and arrange for their transfer to sites. In the case of regulatory changes requiring substantial capital and/or infrastructure changes, an action plan for HSENet shall be drawn up and documented. The register shall be updated when changes in requirements, operational changes, results of regulatory inspections and third-party regulatory compliance reviews are concluded, and/or at least twice a year. Responsibility for effective application in practice lies with the site heads/representatives of the HSE units. A review of new and expected legal requirements is carried out at least once a year as part of the management review.

In 2018, a total of 6 inspections were carried out, three in Ljubljana regarding the parking lot, one in Mengeš to confirm the registration of the extension of closed work systems with genetically modified organisms and one regular inspection in Lendava and Prevalje. In addition to environmental, three H&S inspections were carried out, two in Mengeš and one in Prevalje, where a contracted construction worker was injured. We also had two energy inspections, one in Ljubljana and Lendava and two fire safety inspections - a regular inspection in Lendava and Lek as a whole, where they were subject to the inspection of F gases in fire extinguishers and their marking. None of the sites were found to have fineable incompliances, all regulatory measures were implemented within the prescribed time.[38]

[36] GRI GS 103-1, 103-2.

[37] See the glossary on page 91.

[38] GRI GS 307-1.

In 2018, 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 and waste management as well as deratization and disinsection.

We regularly obtain environmental permits for all our projects and/or changes. By complying with the environmental protection authorizations issued by the Environmental Agency of the Republic of Slovenia and the Water Directorate of the Republic of Slovenia and additional Novartis guidelines, production in our plants is safe and does not create excessive environmental impacts. Licenses and guidelines define the emission limit values for air and water, waste management, measures to reduce light pollution and ways to safely store raw materials and products on-site and are thus strictly adhered to.

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 2016.
- 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.
- Decision amending the environmental permit for the Mengeš site, Permit no. 35406-77/2017-5, dated 15 November 2018
- 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 Ljubljana site, permit no. 35440-1/2017-6, dated 28 May 2018.
- 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 35536-19/2011), and dated 4 April 2016.
- Water use permits for direct use of water No. 35536-20/2008-4 dated 18 September 2008, 35536-45/2012-5, dated 19 February 2013 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.
- Decision on environmental tax exemption due to fuel combustion, Permit No. 35483-67/2016-3, dated 9 June 2016 (Lendava)
- Decision on environmental tax exemption due to fuel combustion, Permit No. 35483-66/2016-3, dated 9 June 2016 (Mengeš).

Modern technologies and data processing open up opportunities for new savings and employee involvement in a sustainable energy culture.

Gašper Antičevič, Head of Technical Services at Mengeš and Energy Manager at Novartis Slovenia

We are codesigning the environmental strategy of tomorrow

Gašper Antičevič monitors the processes taking place in Lek, from the point of view of managing energy and natural resources. His energy map has not only clearly identified the largest energy consumers, such as compressors, distillation columns, fermentation processes but also each and every small consumption is included too. The greatest incentive for him is an excellent team, teamwork and a diversified worker. Among many working roles, he is especially attracted by energy management, where he and his colleagues can change the field at a strategic level.

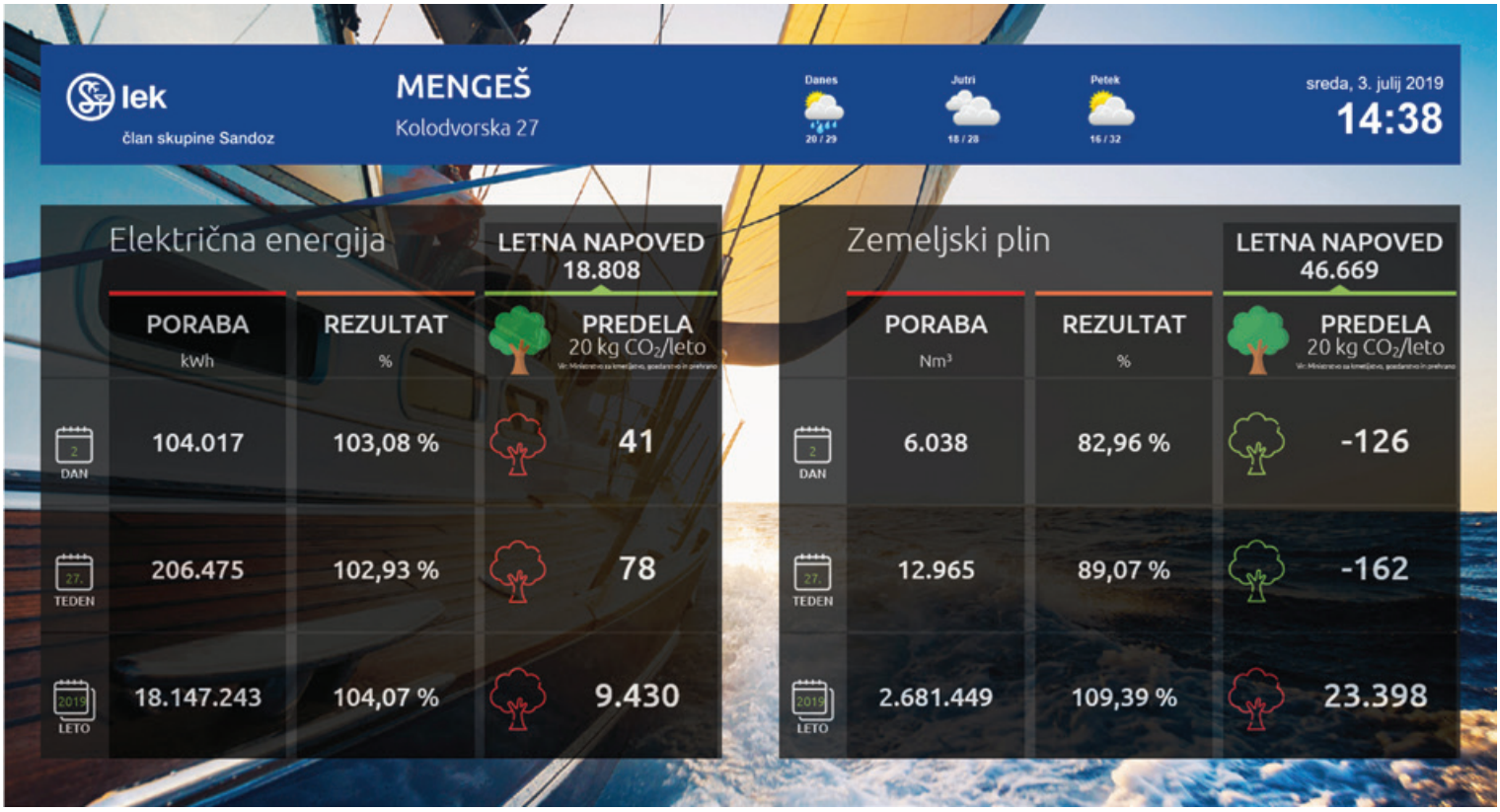
At Lek's Ljubljana and Mengeš sites, pilot projects are being implemented for the implementation of Novartis's new energy efficiency strategy.

Energy savings are another springboard for development

An active efficient energy use policy has already brought Lek good results for a decade. During this period, all sites greatly expanded their activity and some units doubled their volume of operations. However, as Gašper Antičevič explains, consumption has not followed the growth of production, the deviations are much lower. In the case of the development of the Mengeš site, it is clear how important energy efficiency is. Despite continuous business growth, energy consumption remained at about the same level. Each year, several projects and measures are implemented to improve the operations of energy infrastructure and reduce energy consumption.

Novartis pilot project on the way to carbon neutrality

The results and tradition of energy management have contributed to the fact that Mengeš and Ljubljana were selected for Novartis pilot projects.



The energy calendar, an application that displays the daily, weekly and annual consumption of electricity and natural gas, simultaneously reflects the approach to the annual and long-term Novartis goals.

Their goal is to formulate solutions for the realization of Novartis's strategy of CO_2 neutrality, reducing the use of water and the amount of waste at sites.

An active energy management project was also involved in this unique professional opportunity, which in 2018 took place in Mengeš and Ljubljana. They monitor all systems on a weekly level and try to achieve their optimum performance. As Gašper explains in the case of various devices, for each device they find the load at which it achieves optimum performance, and strive to maintain these conditions as long as possible. The results are good and the project will be extended to the Prevalje and Lendava sites in 2019.

Power consumption displays

Energy efficiency achievements are to a great extent a reflection of the culture and values of employees, which Novartis' Energy Manager Slovenia gives great importance to. With his colleagues, he is looking to the future, where he sees new solutions that will dictate and directly show the energy consumption for facilities and processes. By doing so, employees will immediately know the impact of their behavior on energy consumption. Modern technologies and data processing bring new opportunities for savings and employee involvement in a sustainable energy culture.

So far, we have been looking for savings in energy audits and employee suggestions for improvements. In the past five years, we have also been joined by an application for targeted monitoring and control of energy use, which compares processes across sites and searches for improvements. With it we build awareness to the fact that everyone can influence and contribute. Its upgrade is an energy calendar application. Gašper's team is already preparing a new function which will allow employees to directly monitor energy use indicators at their site.

Open to alternative solutions

In broad thinking, it does not stop opportunities such as the use of alternative renewable sources that can lead to energy restructuring. "We are open for innovations, but every new solution is thoroughly checked, and successful measures are quickly expanded to new facilities and sites. At the same time, we must not forget that the measures would not work without the dedicated work of colleagues who take care of regular maintenance of the systems and the correction of errors and malfunctions, "emphasizes Gašper Antičevič.

We are open for innovations, but every new solution is thoroughly checked, and successful measures are quickly expanded to new facilities and sites. At the same time, we must not forget that the measures would not work without the dedicated work of colleagues who take care of regular maintenance of the systems and the correction of errors and malfunctions.

4.1 Active environmental policy implementation

In Lek we are continuously searching for improved efficient use of raw materials and limiting the impact of our activities on the environment. HSE aspects include activities, products and services, as well as impacts in their life cycle (raw materials, development, production, transport, use, final disposal).

Environmental responsibility is a top commitment of our operations, 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. By assessing environmental impacts, we assure that the benefits of the new product, processes and technology outweigh the remaining risks. Criteria for assessing HSE aspects are summarized in the unified Novartis risk assessment proposal.

Our primary environmental aspects are **energy consumption** and the impact of GHG on **air**, **water** and **micro-pollutants** and **raw materials** and **waste**, specifically the possibilities to reuse and/or recycle it. Among the indirect environmental aspects, we mainly categorize environmental impacts on the part of suppliers/ contractors (supply) which, due to the specific nature of pharmaceutical production, we must take into account that our impact on product use and their processing at the end of their life expectancy, is limited.

In 2018, we were not charged with any penalties or non-monetary fines for non-compliance with environmental laws.

In 2018, we were not charged with any penalties or non-monetary fines for non-compliance with environmental laws.[39] However, we received five external complaints, which are described under Item 1.4.3.1, together with action taken.

4.1.1 Specifics of business operations and deviations in data collected

When preparing data for the sustainability report, we find some deviations 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.

Deviation 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. Additionally, there is a noticeable trend in portfolio change from high volumes of product to smaller volumes of high value-added products.

4.1.2 Environmental protection investments and achievements[40]

Responsible management of the environment is an essential part of Novartis' business strategy and is included in all our business decisions, while investments in advanced environmental technologies remain an integral part of our investments.

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. Environmental investments include the renovation of roofs, facades and sewage systems. The estimated value of environmental investments in 2018 is almost 4.9 million EUR.

Major projects in the area of environmental protection in 2018 were:

Lendava

- Renovation and integration of two cooling systems,
- starting the regeneration column of isopropanol.

Ljubljana

- Repair of compressed air distribution, optimization

[39] GRI GS 307-1.

[40] GRI GS 307-1.

of air compressors and installation of frequency converters to circulating pumps in cooling systems,
- inspection and repair of condensing cups on a steam divider.

Prevalje

- Installation and commissioning of a new air compressor, which will provide sufficient capacity for production,
- upgrading control of cooling compressors for optimum energy consumption.

Mengeš

- Optimization of the operation of air compressors and cooling units and the installation of free cooling in the engine room,
- connection of the facility 67 to the capture system of vapors of non-halogenated and halogenated solvents,
- redirection of cooling non-contact water from technological to cooling wastewater sewer system,
- the installation of a new tank for the collection of waste solvents and the transfer of an existing tank,
- reducing the consumption of drinking water from the water supply system by diverting water capture for technological purposes from its own wells,
- replacing the exterior lighting with environmentally-friendly energy-saving LED lamps in the parking lot.

Construction of a new facility for the production of biological agents (Biopharmaceuticals Mengeš).

Extension to the Development Center 2 building.

4.1.3 Verification of established standards[41]

In 2018, we also complied with all legal regulations and requirements of international standards in the fields of health, safety and the environment.

We voluntarily implement the Responsible Care Initiative (RCI); we again certified the environmental management system according to the ISO 14001: 2015 standard and the Occupational Safety and Health System according to BS OHSAS 18001: 2007 standard. In addition, in November 2018, we successfully defended all the requirements of the new standard ISO 45001: 2018, which will replace the BS OHSAS 18001 standard after a transitional period. The new standard emphasizes strict compliance with legislative requirements, cooperation with employees and requires management to establish a good security culture.

All four sites are included in the EMAS scheme, the European Union's environmental impact management system; as the only economic entity in all four municipalities. As an environmental verifier, the Slovenian Institute of Quality and Metrology (accreditation number SI-V-0001) also confirmed in 2019 that data and information in the Lek d.d. Annual Report on Sustainable Development for 2018 give a reliable, credible and correct picture of all organization activities to the extent indicated in the environmental statement.

The compliance of our business in the field of health, safety and the environment were confirmed by other external checks in 2018 (JAZMP, FDA, suppliers, etc.).

4.1.4 Key projects for optimizing business processes

Anti-explosive protection – ATEX

Anti-explosive protection applies to all processes with potentially explosive atmospheres and is fully compliant with the legislative and internal regulations. For all parts of production processes at all sites, Ex equipment maintenance certificates are obtained, which are regularly updated every 5 years. On the sites, there are teams of qualified Ex equipment maintenance personnel within production engineering. In case of changes in equipment or technological processes, the early phase of preparation of project documentation in the Project Engineering unit also include the requirements for the appropriate implementation of ATEX before the new Ex equipment goes into use. Employees are trained to work with Ex equipment on the basis of internal regulations and training. At all Lek's sites, we review the realization of the certifications and the competence of the Ex equipment maintenance personnel.

[41] GRI GS 103-2.

LOTO

In 2018, we continued with LOTO (LockOut / TagOut) activities, focusing on training staff, purchasing missing equipment, and developing LOTO systems on site. Training for responsible works managers and authorized contractors for high-risk work (in accordance with the LOTO procedure) was carried out with an external certified contractor. Lendava was fully completed and at Mengeš partially. The trained staff received a certificate of competence for work in accordance with the LockOut / TagOut standard and the internal Novartis Regulation. We presented the presentation of the LOTO system, its responsibilities and requirements to all employees at all sites in electronic form.

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.

4.1.5 Indirect environmental impacts[42]

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.

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 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 total of 155 company cars were in use in 2018 (186 in 2017). A total traveling distance of 5,317,326km (5,245,149 km in 2017) was recorded, with fuel consumption of 244,197 liters (223,546 in 2017) and CO_2 emissions of 692 tons (667 in 2016). In addition to company cars, we had other vehicles (fire engines, forklifts), whose emissions are also included in the data above.

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.

Suppliers for transport and waste management are also carefully selected. In accordance with legislation and internal regulations, we only select suppliers that have the necessary permits and are registered in the records of contractors at the ministry.

4.2 Raw materials and natural resources

4.2.1 Mass flow of materials[43]

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 2018, the consumption of raw materials stayed at 2017 level in spite of higher volume of production. Ljubljana reduced their use (by 8% due to lower volume of packaging) and came close to their 2014 use, followed by Lendava with a 2% decrease. Prevalje stayed at the same level as the previous year. Mengeš increased their use of raw material by 9%, but is still below the quantitate value from 2016.

[42] GRI GS 305-1, 308-2, 414-2.

[43] GRI 103-1, 103-2, 103-3.

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.

Annual mass flow of various materials used* in tons[44]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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	10,861**	13,425	5,442	38,506**
2018	t	8,588	10,033	14,600	5,444	38,664

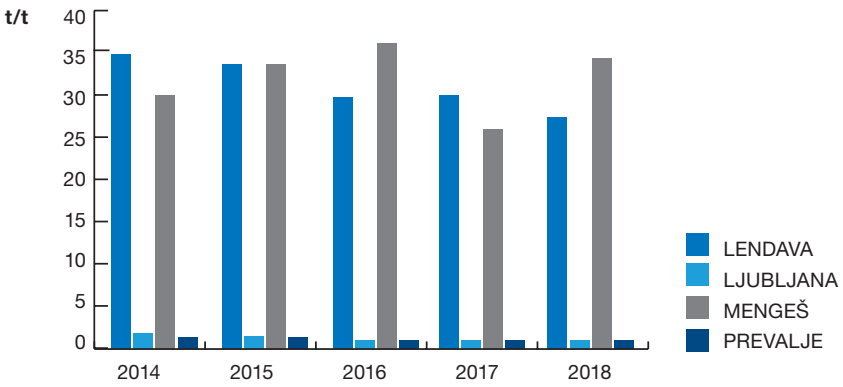
* Total quantity of materials purchased within the reporting period to ensure seamless progress of the manufacturing process to the finished product phase (including packaging but exclusive of fuels, water and manufacturing equipment).

** Change in data for 2017, location Ljubljana, due to error regarding the volume of packaging.

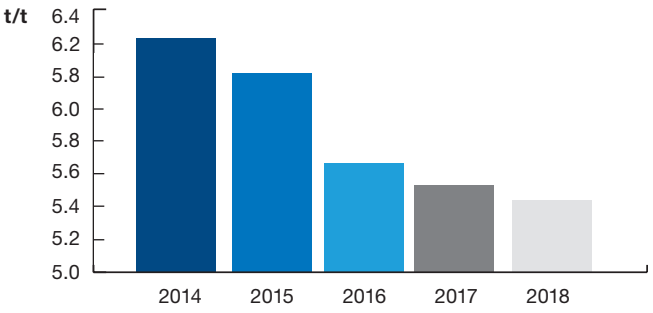
4.2.2 Efficiency of materials

A more accurate picture from the absolute values of the quantities of materials is given by the indicator of the consumption of raw materials per unit of the product and shows the efficiency of the use of raw materials. 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 ton of active substances produced in 2018 stayed the same as in 2017, however over the years we see a declination. Between 2014 and 2018, we increased the efficiency of the use of materials by more than 12%.

Efficiency of the use of raw materials per unit of product – by site[45]



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



[44] EMAS Core indicator, GRI GS 301-1.

[45] EMAS Core indicator.

4.2.3 Sustainable packaging approach

Packaging that is discarded and becomes waste can have a significant negative impact on the environment, and therefore we are making improvements in this area as well. The basic principles of packaging design and production are consistent with the Novartis policy of sustainable packaging use and defined in Sandoz's global packaging catalog. The catalog prescribes a comprehensive selection of recommended packaging materials, taking into account the binding waste hierarchy, as well as the dimensions and shape of the primary and secondary packaging. 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 63% and Prevalje with 33%. In Mengeš and Lendava, however, consumption represents less than 4% of the total packaging used in Lek.

In 2018, employees of MS & T from Solids Lendava redesigned the entire packaging for the Quetiapine product. By optimizing the packaging of blister packs for a product marketed in Slovenia under the name Kvelux, we will create savings of 300 thousand EUR each year due to the use of another type of foil. However, the size of the blister, boxes and packaging time remain unchanged.

4.3 Energy

4.3.1 Energy consumption

Overall energy consumption (HHV – High Heating Value)* [46]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2016	GJ	414,383	452,025	375,130	66,563	1,308,102
2017	GJ	439,585	451,273	364,479	66,156	1,321,493
2018	GJ	470,766	441,039	364,387	63,013	1,339,204

* The table shows data values for the last three years due to data comparability.

From 1 January 2018, the calculation of natural gas from volume (Sm^3, Nm^3) per unit of energy (kWh) was changed for all four Lek sites. Namely, the basic energy value is taken into account in the upper heating value. Prior to that, all calculations and reports contained energy conversion into the lower heating value. Consequently, in comparison with the previous reporting of the energy value (in kWh or GJ), this energy source automatically increased by 10.78%.

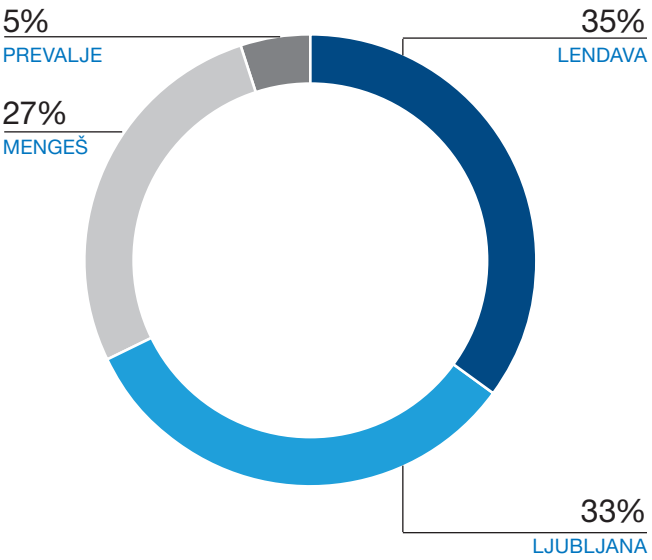
At the level of Lek, the energy use was 1.3% higher than a year before. The increased use was recorded by the Lendava site (by 7.1%), as we also included waste solvents and biomass among the energy products. Other locations recorded a decrease in energy consumption:

- **Ljubljana 2.27%,**
- **Mengeš 0.02%,**
- **Prevalje 4.75%.**

In the total energy consumption, Lendava has the highest share with 35% closely followed by Ljubljana with 33%, then by Mengeš with 27% and Prevalje with a 5% share.

[46] GRI GS 302-1.

Distribution of energy by site



2.6%

INCREASE IN EFFICIENCY OF ENERGY RESOURCE USE.

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. This reduces the consumption of natural gas by approx. 25% per year, which equivalent to heating 850 Slovenian households.

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.

Efficiency of energy resource use per unit of product[47]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2016	GJ/t	1,489	151	835	45	252
2017	GJ/t	1,485	169	734	45	269
2018	GJ/t	1,538	155	846	41	262

Electricity consumption[48]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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	221,602*	176,139	124,772*	26,431*	548,943*
2018	GJ	230,964	173,551	127,633	26,250	558,397

* Change due to correction in DMS system entry.

Electricity represents the main source of energy for starting production equipment, preparing energy means for production (compressed air, cooling agents ...), lighting and cooling of non-production facilities.

Electricity consumption increased by 1.72% in comparison with previous years.

[47] EMAS Core indicator, GRI GS 302-3.

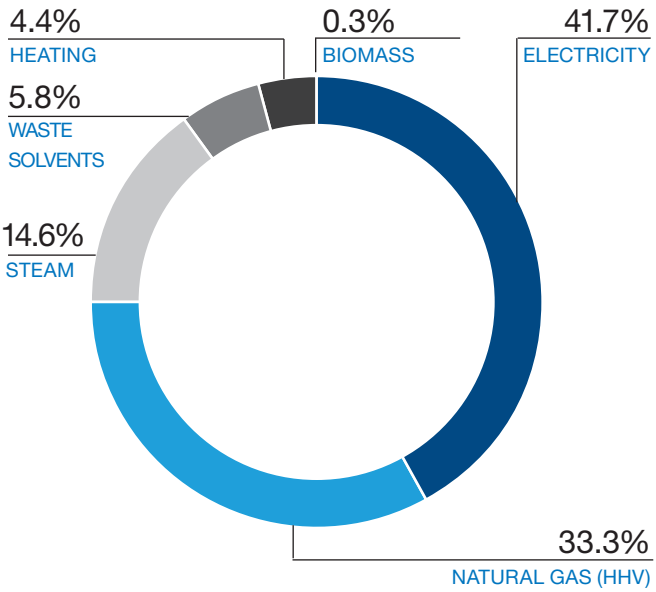
[48] GRI GS 302-1.

4.3.2 Distribution of energy by energy sources

In the structure of purchased energy sources, electricity accounts for the largest share with 42%, followed by natural gas with 33%. 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 (15%) and heating water (4%).

At Mengeš and Lendava, waste solvents from production are used in addition to natural gas for the production of steam in the co-incineration. The share of waste solvents in total energy consumption represents 6%. We can replace 20% of the energy needed with waste solvents only at the Mengeš site for steam production. In Lendava 0.3 percent of energy is produced from biomass.

Distribution of energy used by primary energy sources*



* In the case of natural gas, the high heating value (HHV) is taken into account, as it is written on the invoices of suppliers. Waste organic solvents are produced as waste in fermentation production in Mengeš and we do not buy them on the market.

4.3.3 Energy efficiency improvements[49]

In 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 2018, additional measures were taken to improve energy efficiency, generating energy savings of 16.5 TJ and reducing CO_2 emissions by 560 tons, which is equivalent to planting 28,000 new trees.

In 2018, additional measures were taken to improve energy efficiency, generating energy savings of 16.5 TJ, with which reduced CO_2 emissions by 560 tons.

These results were reached with the following projects:

- At **Mengeš**, we optimized the operation of the air compressors and cooling units and installed free cooling in the engine cooling room, thus saving 4,386 GJ of energy.
- At **Ljubljana**, we comprehensively inspected and repaired the compressed air distribution, optimized air compressors, installed frequency converters to circulating pumps in cooling systems and several projects for optimizing the operations of energy systems, thus saving 9,467 GJ of energy.
- At **Lendava**, we renovated and combined two cooling systems and optimized the removal of ash from the incineration plant, thus saving 2,620 GJ of energy.
- At **Prevalje**, we optimized the operations of energy systems, thus saving 20 GJ of energy.

We have implemented an active energy management project at all sites - actively monitoring energy systems, performance analysis and thus active energy management. We have created new tools for a quick and transparent overview of our energy systems and started with weekly analyses. Based on reviews, benchmarking and determining key performance indicators, we were able to take immediate action to improve regulation, adjust work points, display malfunctions, and choose the most efficient devices. We also identified future potential savings projects through regular monitoring of energy systems.

[49] GRI GS 302-4, 305-5.

4.4 Water[50]

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. Regular monitoring of quantities oversees the supply and consumption of water, and the monitoring of quantities and parameters of pollution of waste water.

Technological wastewater can be waste water from cleaning processes, by-product from the production of intermediates and active substances, waste water from the preparation of demineralized water or waste water from the steam preparation. Higher quantities of water are used wherever technological processes or technologies and their 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.

4.4.1 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 2018, we increased the amount of water used by 2% and increased our efficient use of water by 9%.

Water use in 1,000 m³ [51]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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
2018	1,000 m³	1,347	605	1,490	37	3,479

Efficiency of water use per unit of product* [52]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2014	m³/t	650	196	532	24	208
2015	m³/t	645	183	670	21	204
2016	m³/t	753	185	852	17	225
2017	m³/t	1,173	214**	672	18	260**
2018	m³/t	912	200	769	18	236

* The table only provides the data on water use efficiency for industrial wastewaters (cooling waters excluded).
** Amendment to production data for Aseptics Ljubljana for 2017.

Water consumption per kg of product at the Lendava site

- 2014: 5.3 m³ of water/kg of product
- 2015: 4.8 m³ of water/kg of product
- 2016: 4.7 m³ of water/kg of product
- 2017: 4.5 m³ of water/kg of product
- 2018: 4.4 m³ of water/kg of product

[50] GRI GS 303-1, 303-2.
[51] EMAS Core indicator, POR OI 21, GRI GS 303-3.
[52] EMAS Core indicator.

4.4.2 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.[53] 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.

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 15 m.

The precipitation in 2018 were average, but very unevenly distributed and time restricted (storm events). At the beginning of 2018, melting of snow cover and above-average spring precipitation led to a sudden rise in levels. A smaller rise in groundwater occurred in November as a result of more extensive precipitation at the end of October and early November. Levels of groundwater were in average in 2018.

In November 2017, three piezometers (two shallow and one deep) were installed for operational monitoring of groundwater contamination. The piezometers located to the south of the plant (outlet water), showed groundwater has better quality than in piezometers north of the plant (inlet water).

Water supply quantities and sources at the Mengeš and Lendava sites in 1,000 m³ [54]

Mengeš	2014	2015	2016	2017	2018
From our own pumping station (in 1,000 m³)	1,480	1,510	1,330	1,399	1,449
From the public water supply network (in 1,000 m³)	83	123	108	95	47

Lendava	2014	2015	2016	2017	2018
From our own pumping station (in 1,000 m³)	1,340	1,261	1,318	1,254	1,295
From the public water supply network (in 1,000 m³)	58	53	60	63	71

In Mengeš, we reduced the use of water from the public water supply by almost half due to the increased use of water from our own pumping station. In Lendava, due to increased production, the use of water from both sources increased: by 3% from its own pumping station and by 13% from the public water supply system.

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. The aim of the comparison is to determine whether the pollution of soil and groundwater has increased significantly due to the operation of the plant over a given period of time.

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 (Slovenian Environment Agency) within the prescribed deadline. The initial report for the Lendava site is still under construction, and it needs to be submitted to ARSO at the first major modification of the environmental permit.

4.4.3 Recycling and reuse

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.

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

[53] Water permit no. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8.

[54] GRI GS 303-3.

and depend on individual processes. It has been estimated that the entire cooling water volume is reused at least twice.

The investment in optimization of closed loops has reduced the consumption of fresh water for cooling systems. The use of best available techniques (BAT) is considered in all new projects regarding water use.

4.5 Waste

4.5.1 Waste management[55]

Within the environmental management system, we have a waste management plan based on the type, quantity / trends and sources of waste generation. 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.

Hazardous and non-hazardous waste is generated when operating. Most of them are produced continuously during production, and occasionally waste is generated, for example, cleaning and maintenance of technological devices and machines, cleaning of oil traps, performing construction work, replacing fluorescent tubes, replacing toners, etc.

Almost 92% of all waste generated is recycled, and their share in the year 2018 increased by 1%.

Almost 92% of all waste generated is recycled, and their share in the year 2018 increased by 1%. In accordance with the Novartis policy of hazardous waste management, these cannot be disposed of in landfills, and for many years we have devoted many activities to reducing the amount of non-hazardous waste for disposal.

At Mengeš, the volume of mixed municipal waste decreased by an additional 40% in 2018, mainly due to consistent sorting and greater control over the waste of construction contractors at the site.

Biodegradable waste accounts for almost 74% of all Lek waste. 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. This accounts for 99.8% of all biodegradeable waste.

Amongst the volume of important non-hazardous waste at Lendava, waste packaging that is produced in the packaging of final forms of medicinal products is also included and is being disposed of for recycling by authorized contractors.

84% of all waste in Mengeš is hazardous waste, of which 94% is non-halogenated waste solvents. In 2018, in two steam boilers, we processed 26% 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 often using waste as a fuel according to the R1 procedure.

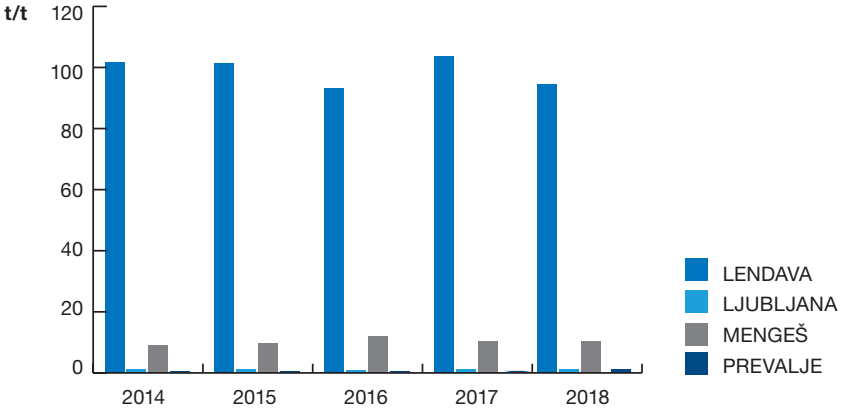
Despite the increase in production, the quantities of waste produced remained at 2017 levels in 2018. All sites, with the exception of Lendava, which increased the quantity of mycelium waste due to increased production, show a reduction in the amount of waste: Ljubljana and Prevalje by 5% and Mengeš by 10%.

Volumes of waste generated in tons

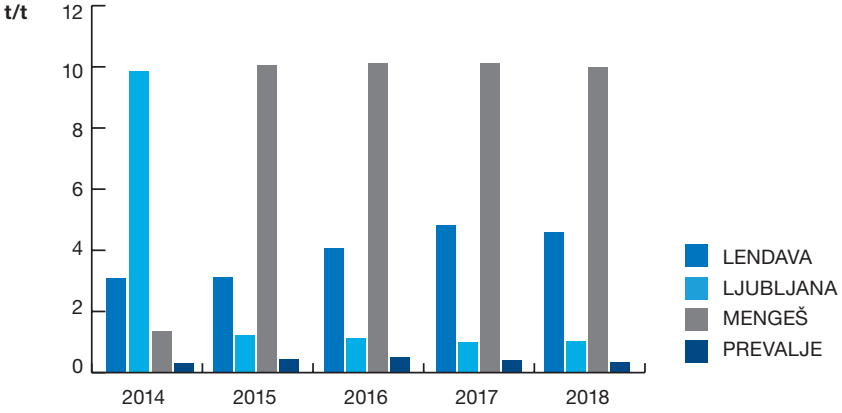
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2014	t	26,147	2,739	5,146	636	34,667
2015	t	25,588	2,748	5,692	766	34,794
2016	t	28,862	3,010	4,597	800	37,269
2017	t	27,856	3,305	5,010	827	36,998
2018	**t**	**28,727**	**3,156**	**4,493**	**784**	**37,160**

[55] EMAS Core indicator, GRI GS 306-2.

Volume of waste per ton of product – efficiency



Volume of waste per ton of product – efficiency/disregarding mycelium waste



4.5.2 Disposal of hazardous waste[56]

The amount of hazardous waste at the Lek level has decreased by just over 1%, mainly on the account of Mengeš. However, the efficiency of hazardous waste management increased by 5%.

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 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. In 2018, with processing and re-use, 88% of all organic solvents achieved an improvement of 2 percentage points compared to the previous year.

In Lendava, the share of re-used organic solvents was 97.5% and increased by more than 2 percentage points with the project of regenerating additional solvents, which ended in 2017. In Mengeš, the share of re-use is on average 64%, and for some processes it is more than 95%. The share of recycling of organic solvents in Mengeš decreased by 1 percentage point compared to 2017, due to changes in the range and volumes of products.

At the Mengeš site, high-energy waste solvents represent 94% of all hazardous waste. By co-incineration with natural gas, we removed 1,823 t of waste solvents, equivalent to 20% of primary energy for steam generation for the supply of energy processes.

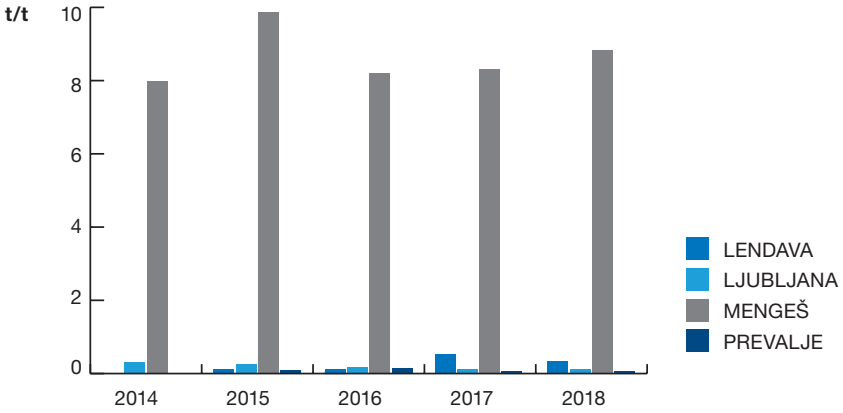
In Ljubljana, more than 70% of the total quantity of waste is non-hazardous waste, of which the packaging is predominant. In the case of hazardous waste, the quantity of waste is important from the production and products with expired shelf life, or the medicine returned from the market.

[56] POR OI 5, GRI GS 306-2.

Volume of hazardous waste in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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
2018	**t**	**183**	**902**	**3,893**	**193**	**5,171**

Volume of hazardous waste per ton of product – efficiency



4.5.3 Disposal of non-hazardous waste[57]

Non-hazardous waste accounts for 86% of all Lek waste, with 74% of all waste being biodegradable waste that is transferred to biogas plants. At Mengeš, this is mostly waste from the production of mushroom juice, whilst at Lendava mycelium waste and the Lendava Treatment Plant sludge. Biodegradable waste also includes waste from tea kitchens.

Municipal waste accounts for less than 0.5% of all waste. In 2018, their quantities were additionally reduced by 18%, mainly due to the consistent sorting of packaging and increased control over the handling of waste by construction contractors. Packaging accounts for 11% of waste and is recycled in sections (paper, plastic, wood, metal, glass). We mainly recycle waste packaging (through the Gorenje Surovina system), and the same applies to construction waste. Most other non-hazardous wastes are used by authorized companies as fuel by means of co-incineration.

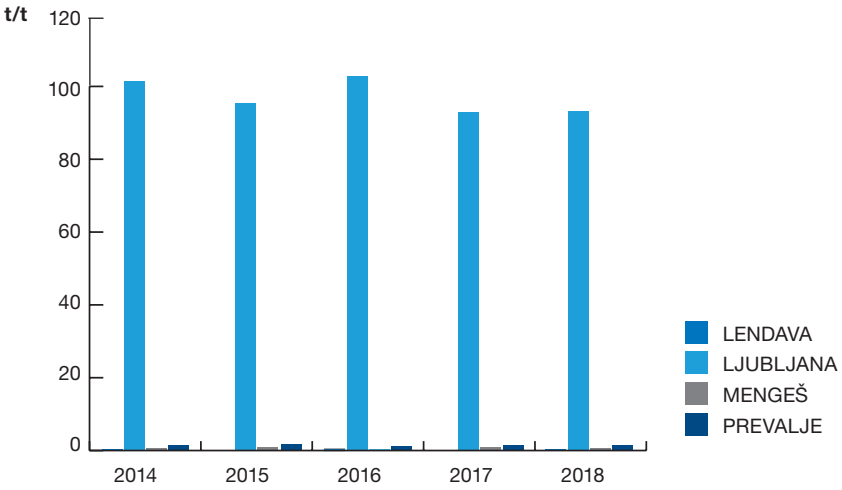
The amount of non-hazardous waste increased by slightly less than 1% in 2018 due to increased quantities of mycelium waste as a result of increased production in Lendava.

Volume of non-hazardous waste in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	**Lek** (recyclable non-hazardous waste without packaging)
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
2018	t	28,544	2,254	600	591	31,989	28,041

[57] GRI GS 306-2.

Volume of non-hazardous waste per ton of product – efficiency



4.6 Air emissions[58]

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. These targets provide for the achievement of climate neutrality by the exclusive use of renewable energy sources by 2025, and by the same year, requirements for sustainable environmental criteria into all contracts with our suppliers. The 2030 ambitious goal is also to reduce the carbon footprint by 50%, compared to the base year 2016. 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.

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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. 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.

4.6.1 Emissions from waste incinerators and co-incinerators

Incineration and co-incineration are carried out at two sites, Lendava and Mengeš. 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

[58] EMAS Core indicator, POR OI 7, POR OI 10, GRI GS 103-1, 103-2, 103-3.

of energy. Emission monitoring is regularly performed at all the emission release points by external authorized institutions. Energy from waste solvents represents more than 20% of the primary energy for steam generation at the location needed for the supply of processes.

Even in Lendava, incineration of waste is carried out solely from our own production, which enables us to effectively control and monitor the operation of the incineration plant due to the precise knowledge of the composition of the waste. The set and quantity of waste for incineration is defined in the permit issued by the Environmental Agency of the Republic of Slovenia.

Technological solutions and continuous measurements allow us to ensure our emissions are constantly controlled and within permitted limits. The set limit/alarm values prevent the waste incineration process from running outside the permissible limits.

We regularly report to the competent ministry on the quantities and types of waste disposed of. The subject of reporting and control is also all emission monitoring, both permanent and occasional measurements from co-incineration or incineration plants. With the incineration of waste and natural gas as a support fuel we obtain technical steam.

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).

4.6.2 Sulphur dioxide[59]

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. Due to small quantities, legislation does not prescribe mandatory monitoring of the SO_2 parameter from RTOs and combustion plants anymore if the equipment operator provides the combustion setting carried out by the authorized service provider of the device at least once a year. The content of Sulphur in natural gas is practically non-existent.

On the basis of prescribed monitoring from incineration and co-incineration of waste, we obtain data on the quantities of emissions that are moving at the boundary of the determination. However, due to occasional fluctuations in the combustion of waste containing Sulphur, these emissions also vary.

Sulphur dioxide emissions (SO_2)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (kg SO_2/t product)
2014	t	0.1306	0.0000	0.0040	0.0105	0.1451	0.0310
2015	t	0.0971	0.0000	0.0049	0.0064	0.1084	0.0208
2016	t	0.0008	0.0000	0.0017	0.0066	0.0091	0.0018
2017	t	0.0000	0.0000	0.0006	0.0062	0.0068	0,0014*
2018	t	0.0000	0.0240	0.0000	0.0062	0.0302	0.0059

* Amendment to volume realized for Aseptics Ljubljana for 2017.

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.

4.6.3 Nitrogen oxides

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

Regular emission checks are carried out at all sites. In 2018, nitrogen oxide emissions increased by 9% due to the Ljubljana and Mengeš sites, all other sites recorded the same level of emissions as 2017.

Nitrogen oxides emissions (NO_x)[60]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t NO_x/t product)
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	0.005
2017	t	17.97	0.05	11.34	2.46	31.83	0.006
2018	t	17.26	2.26	12.86	2.47	34.85	0.007

[59] EMAS Core indicator, POR OI 7, GRI GS 305-7.

[60] EMAS Core indicator, POR OI 8, GRI GS 305-7.

4.6.4 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),[61] data reported also includes:

- dinitrogen oxide (N_2O) in CO_2 equivalents,[62]
- fluorinated hydrocarbons (hydrofluorocarbons – HFC) in CO_2 equivalents[63] and
- other greenhouse gases (methane and others) in CO_2 equivalents.[64]

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.

Carbon dioxide and other gases contributing to the greenhouse effect[65]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiancy (Lek) (t CO_2/t product)
GHG1	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	2,610***	14,146	2,097	31,015***	6.3***
	2018	**t CO_2**	**13,199**	**2,260**	**13,104**	**1,665**	**30,228**	**5.9**
GHG2	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	0**	25,911**	0**	0**	25,911**	5.3
	2018	**t CO_2**	**17,066**	**39,047**	**9,432**	**1,940**	**67,484**	**13.2**

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

** Purchase of green certificates for 2017 in the total CO_2 emissions from electricity, and CO_2 at the Ljubljana location comes from the supply of steam and hot water. Values were corrected according to the 2017 Sustainability Report, as guarantees of origin were purchased only at the end of 2018.

*** Correction of a typographical error in the 2017 report.

In the calculation of GHG1, the natural gas consumption value for 2018 is 55.29 kg CO_2 / GJ (0.199044 kg CO_2 / kWh). It should be understood that this value takes into account the lower heating value of natural gas in kWh (LHV) and that the equivalent emission value of natural gas is converted to the higher heating value (HHV) calculated in the invoices of 49.9076 kg CO_2 / GJ 0,179667 kgCO_2 / kWh). The ratio between lower and upper heating value (LHV / HHV) for calculations and reporting by Lek is 0.90265 kWh / kWh.

The total amount of direct greenhouse gas emissions (GHG1) remains at the level of previous years.

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.

[61] Indicator POR OI 10.

[62] POR OI 11.

[63] POR OI 12.

[64] POR OI 13.

[65] GRI GS 305-1, 305-2, 305-4.

The decision by Novartis not to purchase certificates of origin for the consumed electricity for the Slovenian locations for 2018 has a significant impact on the total GHG emissions. In the calculation and reporting for the period from 1 January 2018 to 31 December 2018, the value of 0.0739 tCO_2 / GJ or 0.26604 kg / kWh, as determined by the Novartis guidelines for Slovenia, is given in the HSE & BCM Data Management WORKBOOK, on page 50 in the "Scope 2 National and Sub-national Standard Location-Based CO_2e Emission Factors" table.

4.6.5 Volatile organic compounds VOC[66]

Halogenated solvents are being systematically replaced with non-halogenated ones. Therefore, in Mengeš we terminated one of the productions which used Methylene chloride in the technological process in recent years. 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.

In 2018, the total volume of emissions of volatile organic compounds increased by 14%, mainly due to the increase at Mengeš. The research has shown that the concentration values of the captured emissions from the defined discharges are comparable with the emissions of previous years and below the prescribed limit value. The resulting difference was due to fugitive emissions. In calculating the solvent balance, because of the large quantities, the concentration of the solvent in the waste is an important factor, which makes the variation of the measurement uncertainty in the analysis of waste solvents lead to a significant increase in the display of fugitive emissions. By means of appropriate measures, such as the transfer of solvents from tankers into storage tanks with appropriate connectors for returning discharged vapors into the tank, or checking the tightness of stationary tanks, we try to reduce the effluent emissions efficiently.

Consequently, efficiency per ton of product has also decreased by 8%, which still means better efficiency than we achieved in 2016.

Total emissions of volatile organic compounds

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t HOS/t product)
2014	t	22.9	13.3	56.8	7.2	100.2	0.021
2015	t	24.6	9.3	55.6	4.7	94.2	0.018
2016	t	23.9	10.1	48.0	3.8	85.7	0.017*
2017	t	23.6	4.6	32.0	4.7	64.9	0.013*
2018	t	22.0	4.8	42.1	5.2	74.1	0.014

* Amendment to volume realized for Aseptics Ljubljana for 2017.

4.7 Water releases[67]

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 2017/2018, 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.

As early as 2016, Novartis, by signing the Davos Declaration Combating Antimicrobial Resistance, additionally committed itself on a global scale 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. 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 physio-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. Studies have shown that the proportion of pharmaceutical ingredients coming into the water from the pharmaceutical industry is low compared to the source represented by the end-users of pharmaceutical products.

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.

[66] POR OI 9.

[67] GRI GS 103-1, 103-2, 103-3.

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. Monitoring is carried out by an authorized external contractor.

4.7.1 Waste waters

In Lek, 65% of the total quantity of water used is unpolluted waste water. At the Mengeš and Lendava sites, waste cooling waters account for 98% of the total water quantity used. In 2018, their consumption increased by almost 6%, the consumption of industrial water decreased by a good 5%.

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

In Lek, 65% of the total quantity of water used is unpolluted waste water.

Volumes of wastewater by discharge quality and destination[68]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
Use of cooling water - unpolluted							
	2014	1,000 m³	1,212	75	1,278	8	2,573
	2015	1,000 m³	1.137	33	1,307	9	2,486
	2016	1,000 m³	1,095	34	1,050	11	2,190
	2017	1,000 m³	976	4,2	1,154	11	2,145
	2018	1,000 m³	1,068	36	1,159	9	2,272
Discharge			into the surface water course	into sewage system cleaning at WWTP	into the surface water course	into sewage system	
Use of cooling water - polluted							
	2014	1,000 m³	168	494	279	34	975
	2015	1,000 m³	177	536	320	33	1,067
	2016	1,000 m³	209	554	383	25	1,172
	2017	1,000 m³	347	570	334	26	1,277
	2018	1,000 m³	279	569	331	28	1,207
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

4.7.2 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 2018, we recorded a 2% increase 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 2018, the total volume stayed at a similar level as the previous year.

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

[68] EMAS Core indicator, GRI GS 306-1, 303-4.

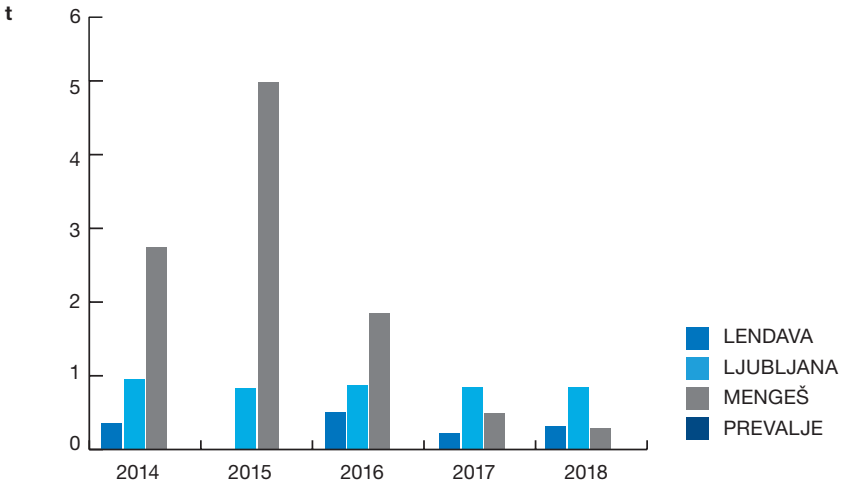
Plant Domžale-Kamnik, which had an extensive upgrade in order to increase the level of treatment of nitrogen and phosphorus by 40%. The upgrade of the treatment plant has an important impact on both the improved ecological state of Kamniška Bistrica and assuring the protection of groundwater, at the same time presenting indicators for 2018.

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 2018, we recorded an increase in the chemical oxygen demand of 6%. 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.

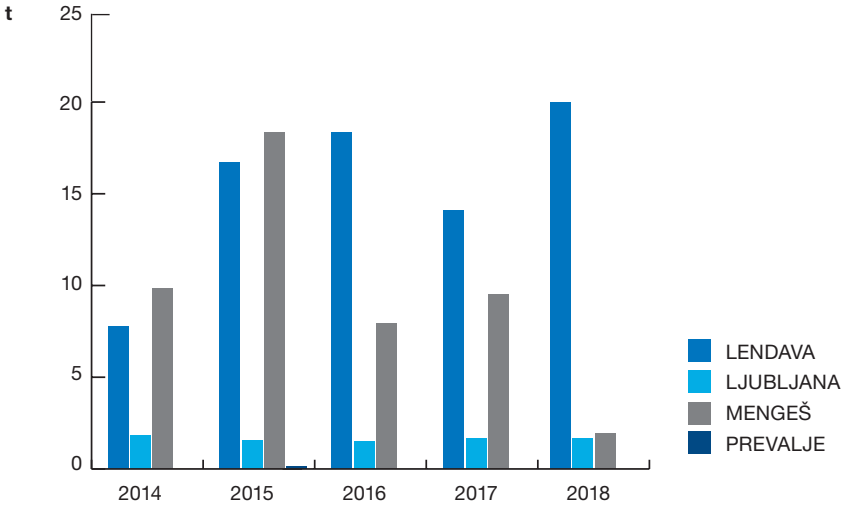
Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute parameters for the calculation of the environmental fee. The highest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds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

Emissions of phosphorus compounds in wastewater[69]

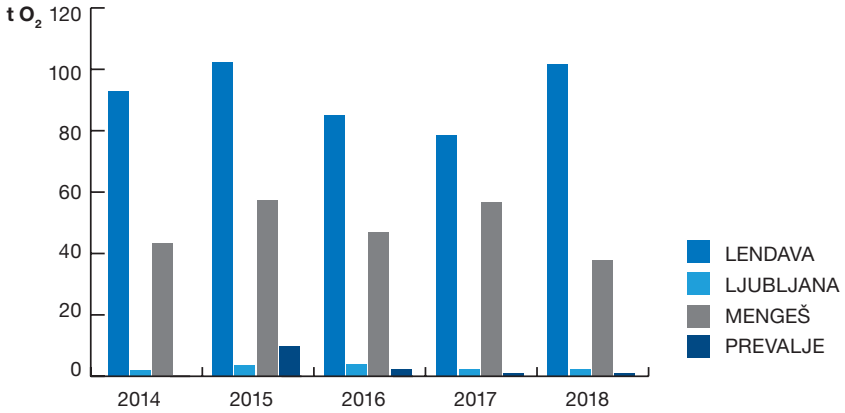


Emissions of nitrogen compounds in wastewater[70]



[69] POR OI 15.
[70] POR OI 16.

Chemical oxygen demand (in tons O_2)[71]



4.8 Other environmental impacts

4.8.1 Odor

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 and gas detergents (for example, on fermenters discharges) and devices for the thermal treatment of waste volatile organic compounds from production.

Despite the fact that the problem of odor in Europe and in Slovenia is not regulated by regulations, and consequently also in the environmental permit there are no requirements related to the odor, monitoring odor emissions is regularly carried out by the National Laboratory for Environment and Food (NLZOH). The concentration of odor is only one of the variables - weather conditions, especially the direction and strength of the wind, are crucial for the smell.

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.

4.8.2 Soil

As the environmental impact on soil pollution is usually irreversible, this area is of special concern to us.

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. Pollutants are transferred to the environment from contaminated soil by washing in water, through the food chain, floods, as well as by moving or incorrectly handling contaminated soil.

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

Pollutants are transferred to the environment from contaminated soil by washing in water, through the food chain, floods, as well as by moving or incorrectly handling contaminated soil.

Among our most important identified possible sources of soil contamination are the storage of harmful substances and their transport by location. To date, no remedial action due to soil pollution has been needed at Lek.

4.8.3 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. The assessment takes into account weather conditions that are favorable for noise dissemination, since the assessment is always based on a conservative approach, which represents the least favorable scenario.

In 2018 we received no complaints about noise in Lek.

[71] POR OI 14.

4.8.4 Biodiversity

The preservation of plant and animal species and their habitats is the identification of protected, ecologically important and special protection areas. At 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 the area of environmental protection we reduce the impacts of our activities and thus contribute to maintaining biodiversity around our sites, despite the fact that our locations are in the area of industrial zones and are not located in Natura 2000 sites of natural value or in protected areas and other areas important for the conservation of biotic diversity.

In 2018, in order to raise awareness among the employees about the importance of biodiversity in the environment, during the International Day of Biodiversity, within the framework of the "Moment for the Environment", we prepared a clear presentation accessible to employees online.

Surface use by site[72]

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
Total site surface area with parking lots	m^2	140,242	116,217	142,632	32,455	431,546
Of which green surfaces	m^2	29,332	55,618	27,609	1,437	113,996

4.8.5 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.

With the help of external experts, Lek's sites have made comprehensive studies of light pollution control, looking for technical solutions that enable compliance with regulations and meet the criteria and requirements for the health and safety of employees. Outdoor lighting was implemented using the lighting with greater efficiency (LED) and at the same time we reduced its operation during the time when labor needs are reduced. Due to reduced brightness in certain areas, while limiting the operation of external lighting, we were forced to strengthen the video surveillance system in certain places.

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. In 2018, plans were forwarded to ARSO.

4.9 Safety

4.9.1 Fire safety

We pay great attention to the safety of our employees, especially those who perform work with increased risk, such as working at altitude and entering into confined spaces. The presence of our voluntary operational on-site firefighters is very important, who in the event of an incident take the first steps at the site of the accident and as the first on scene also help potential victims. That is why our firefighters are provided with and assured quality professional training, both theoretical and practical. The training is carried out by experienced professional instructors who transfer their knowledge to our colleagues. Practical knowledge is renewed each year, with actual equipment, in actual work areas and realistic everyday situations.

We started training all our operational firefighters in accordance with the specific training program and for all the applications foreseen by the new Novartis guidelines in the field of work at altitude and entering into confined spaces with a focus on rescue.

Lendava was the first to carry out such training under the new Novartis guidelines. With this, it has laid a good foundation for the implementation of the guidelines at other Lek sites in Slovenia. In 2018, Lendava was followed by Mengeš and Ljubljana, the training for Prevalje is planned for 2019.

[72] EMAS Core indicator.

The Mengeš firefighting center was moved to the center of the site, assuring even better on-site coverage and fire safety.

4.9.2 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 factors of Group 2 are used in small quantities, especially in quality control, where we check the effectiveness of products. 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.

The biosafety system is integrated in all levels of work and is linked to all relevant stakeholders. At the level of Novartis, a global group is operating, which in 2018 redefined the biosecurity guidelines. Novartis in the application for the purpose of ensuring biosafety records all risk assessments and all biological material used in research, development, production and quality control.

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.

In the area of biosafety Novartis also emphasized the consistent application of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their use. In Lek, already in 2014, in accordance with the protocol, for the first time we checked all the genetic material we use and found that we do not use genetic materials that are part of this protocol.

4.9.3 Providing warehousing and distribution safety

4.9.3.1 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.

Storage of chemicals is carried out under the conditions defined in the legal provisions on technical and organizational measures for the storage of hazardous chemicals. We also take into account the requirements of good manufacturing practice that determine the stability conditions for maintaining the quality of raw materials and finished products - medicines.

In preparation and dispatch of raw materials and products belonging to dangerous goods, in addition to high standards that ensure lasting quality during distribution, the requirements of the European Agreement on the International Road Transport of Dangerous Goods ADR are also taken into account. Some raw materials for the manufacture of medicinal products, due to their specific hazardous properties, need additional protection with the packaging and vehicle in the course of transport, according to the criteria set out in the agreement.

A total of 5,512 tons of raw materials classified as dangerous goods were shipped from Lek in 2018. The quantity of dangerous goods transport increased by 16% compared to 2017, mainly due to higher quantities of biological materials and flammable substances.

4.9.3.2 Distribution

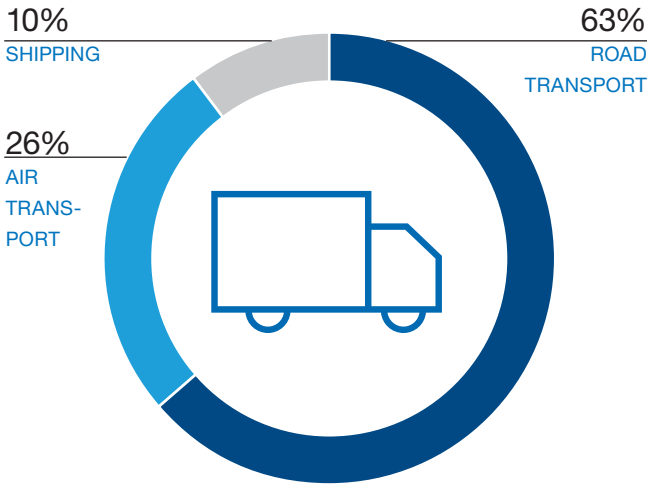
For safe transport without accidents, it is important to follow the guidelines for the requirements for the transport of dangerous goods and good distribution practices with contractors. Employees who prepare and dispatch dangerous goods, are familiar with the requirements of international agreements and are trained in the procedural measures for the transport of dangerous goods (ADR).

In 2018, 9,177 product shipments (7,915 in 2017) were dispatched from our Lek sites and warehouse to our customers.

9,177 product shipments were dispatched to our customers in 2018.

We had 26.4% of aviation, 10.3% of shipping and 63.3% of road freight. The ratio between ship and air transport, measured in kg, was 1:0.235 in favor of shipping. This reduces our carbon footprint, since shipping has a lower emission factor than other types of transport (10-40g/tkm, 60-150 g/tkm road, air transport 500 g/tkm; Source: Lufthansa Air cargo).

Dispatches in regard to transportation



4.9.4 Chemical safety

Safe handling of chemicals is ensured in all segments of their use, in particular through technical measures that prevent direct exposure and the consistent use of personal protective equipment, defined in the risk assessment for the workplace. In order to have up to date understanding of the hazardous properties and measures for safe work with chemicals, Lek employees have continuous training. The employees and Lek Chemical Consultant actively recognize the hazardous properties of chemicals and take protective measures in specific workplaces.

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.

5. Labor

5.1 Human resources policy[73]

Lek's human resources policy highlights three principles regarding this: "Cooperation. Development. Excellence." The HR policy supports the basic business orientations, aiming to achieve a high level of innovation, growth and better productivity. The priority task is to design processes, tools and systems for employment, talent development and planning succession, awarding achievements, organizational development and education.

We provide our employees with a working environment that offers professional and personal challenges and facilitates creative and dynamic work.

Considerable emphasis is given to the acquisition of prospective young talent. With this purpose, we cooperate with a wide range of educational institutions. In 2018, we organized the eighth Regional BioCamp - a three-day forum, where selected students meet with recognized experts and leading managers. It represents an excellent opportunity for young talent to get a direct insight into the world of research and the international business environment of the pharmaceutical industry.

At the Regional BioCamp 2018, 35 students took part in the study of antimicrobials and challenges to effective therapies - both in terms of science and research, and through the experience of doctors and patients. Regional BioCamp was awarded the 2nd prize by the American Chamber of Commerce at the Best of the Best Competition in the "Connecting" category.

Lek extended the full Family Friendly Enterprise Certificate.

Lek extended the full Family Friendly Enterprise Certificate.

5.2 Employment

5.2.1 Total workforce by employment type and employment contract[74]

In 2018, we created 370 new jobs and finished the year with 4,084 full-time employees. At the end of the year, the proportion of women employed was almost 47%, 1% higher than the previous year. At year-end, 93.7% of all employees worked on a full-time permanent basis, and 6.2% were fixed-term employees and 2% of all employees worked on a part-time basis.

[73] GRI 103-1, 103-2, 103-3.

[74] GRI GS 102-7, 102-8, 401-1.

Number of full-time employees on 31. 12. 2018 by site and by gender

Site	Men	Women	Total
Lendava	330	241	571
Ljubljana	1,037	1,115	2,152
Mengeš	664	434	1,098
Prevalje	126	130	256
Others*	6	1	7
Total	**2,163**	**1,921**	**4,084**

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

Numbers of new employees in Lek in 2018

Age group	New employees in 2018
0–25 years	82
26–30 years	149
31–35 years	69
36–40 years	37
41–45 years	17
46–50 years	13
51–55 years	2
56–60 years	1
Total	**370**

5.2.2 Percentage of employees covered by collective agreements[75]

In 2018, the Collective Agreement covered 99.2% of the total workforce, a level identical to that in the previous years.

5.2.3 Coverage of the organization's defined benefit plan obligations[76]

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 2018, 90.45% of the workforce was included in the scheme.

5.2.4 Procedures for local hiring and proportion of senior management hired from the local community[77]

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 diversity of our employees. The proportion of local human resources in the senior management team in 2018 was similar to the previous year i.e. 93.55%.

5.2.5 Parental leave[78]

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.

[75] GRI GS 102-41.
[76] GRI GS 201-3.
[77] GRI GS 103-1, 202-2.
[78] GRI GS 103-1, 401-3.

Level of parental leave and return to work

	2018	2017	2016
Number of employees having taken parental leave	**458**	**397**	**357**
• Men	219	191	205
• Women	239	206	152
Number and share (in %) of employees returning to work after parental leave	**458 (100%)**	**394 (99%)**	**354 (99%)**
• Men	219 (100%)	191 (100%)	205 (100%)
• Women	239 (100%)	203 (98%)	149 (98%)

458 employees have taken parental leave in 2018.

5.3 Occupational health and safety[79]

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 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.[80]

We strive for continuous improvements in the established occupational health and safety management system. The system includes both employees, other people involved in processes at our sites, including visitors.[81]

In addition to regular periodic training in health and safety at work and fire protection, in 2018, we started to carry out additional training courses in order to obtain the necessary competencies for deposits and activities related to the activities with increased risk (LOTO, Closed spaces, work at a height), which will continue in the coming years.

5.3.1 Frequency of absences due to injuries at work[82]

In 2018, we devoted much attention to proactive identification of potentially serious incidents and to preventive measures for their effective prevention.

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).

LTIR Index (Lost Time Injury and Illness Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2018	0.00	0.18	0.22	0.79	0.20

[79] GRI GS 103-1, 103-2, 103-3.
[80] GRI GS 403-2.
[81] GRI GS 403-1.
[82] GRI GS 403-9.

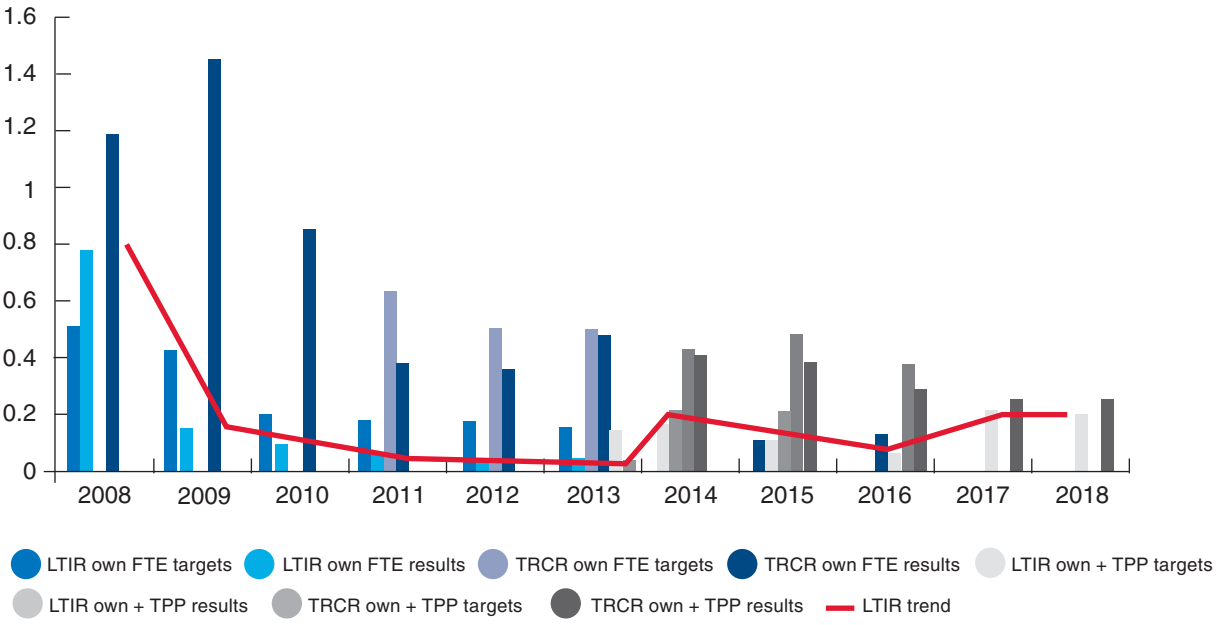
TRCR Index (Total Recordable Case Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2018	0.20	0.18	0.22	0.79	0.25

In 2018, the LTIR rate amounted to 0.20 (0.21 in 2017), 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 0.25 (0.28 in 2016), which means 10 recorded cases.

The most common causes of injuries contact with the facility or equipment, slips and falls as well as cuts.

Trend of LTIR injuries

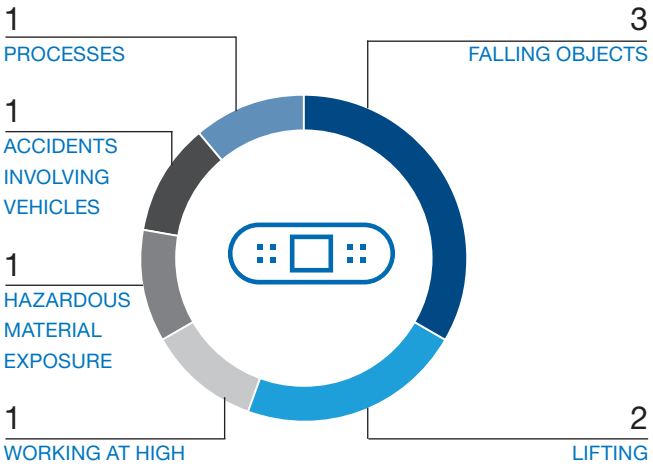


HSE system

Preventive activities to prevent accidents and injuries in 2018
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 sites where, under different circumstances, accidents with serious consequences can occur. In 2018, we recorded 9 such cases, which we investigated and prepared preventive measures for.

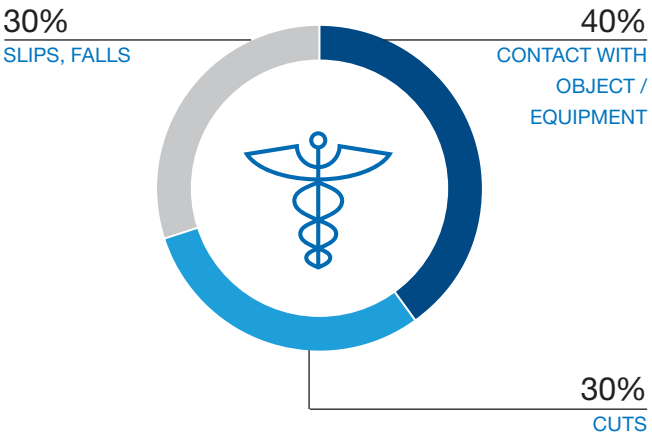
In 2018, we recorded 9 cases of potentially serious incidents.

High Risk Situations in 2018

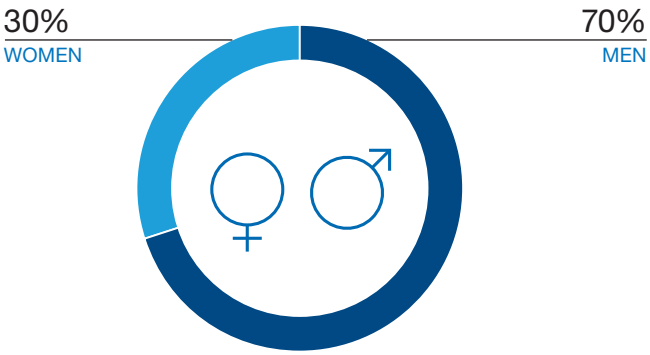


We are constantly implementing numerous preventive measures for preventing and reducing hazards and risks in the workplace. This report highlights only the most important: active role of safety promotors (meetings, walkthroughs), safety walkthroughs by site management, notifying and informing employees about work instructions, employee training, risk assessment, prevention/analysis of work accidents and almost events, prepared HSE presentations for internal meetings, provision of preventive health care and health promotion, organization of work environment inspections, and inspections and tests of work equipment.

Classification of causes of work-related incidents (LTIR and TRCR) for 2018



Classification of work-related incidents by gender



5.3.2 Absenteeism[83]

In order to determine the degree of absenteeism, the number of absent employees' working hours is divided by the working hour's fund. In 2018, the proportion of sick leave was 6.59%, recording a slight increase compared to the previous year (5.20%).

Share of sick leave

	2018	2017	2016
Women	7.92%	4.42%	5.59%
Men	5.43%	6.11%	4.12%
Total	6.59%	5.20%	4.79%

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

There were three injuries recoded in the performance of work in 2018 amongst outsourcers, which is at the same level as in the previous year. The causes of accidents were related to the lack of awareness of the danger and lack of control by the competent persons of the operators and inadequate work organization.

In order to prevent such events in the future, additional measures have been adopted. We have clearly defined and verified competencies, conducted practical workshops with the participation of contractors, works managers, construction site managers, coordinators and representatives of Lek's sites. In addition, we have newly added additional permanent operational functions on construction sites in order to proactively operate.

The contractors carrying out activities at increased risk (construction sites, workshops) at Lek's sites undergo the process of special approval and annual review by Lek in order to ensure safe operation.

5.3.4 Number of work-related fatalities[84]

No fatalities were recorded amongst our employees or external contractors.

5.3.5 Occupational disease rate[85]

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.

5.3.6 Health promotion program

Provision of preventive health care is carried out in cooperation with labor practitioners who also prepare and revise the risk assessment (health assessment), health promotion measures, counseling and participation in work environment, job and work equipment investigations and other preventive activities in the field of employee health.[86]

Considerable attention is paid to safety walkthroughs, which influence employees' behavior and prevent dangerous behavior and situations that can lead to incidents or injuries. In 2018, we carried out 2,935 safety walkthroughs and found that in 78 cases, in the work process, in other circumstances, employees could be injured or incur health problems.[87]

In addition to compulsory periodic training in safety and health at work and fire safety, in 2018 we also carried out:[88]

- fire extinguishers and equipment training,
- anti-explosive protection training,
- meetings with external providers on the topic of health and safety at work,
- acquainting external contractors with site regulations,
- safe driving training
- occupational health and safety procedures training,
- evacuation practice exercises,
- issue theme of the month for employees,
- issue moments for security.

In 2018, we once again assured the successful implementation of our health promotion programs.[89]

[83] GRI GS 403-9.
[84] POR OI 1 and POR OI 3, GRI GS 403-9.
[85] GRI GS 403-10.
[86] GRI GS 403-3.
[87] GRI GS 403-4.
[88] GRI GS 403-5.
[89] GRI GS 403-6.

Preventive programs for health promotion among employees in 2018

Program	No. of employees
Instructed exercise (swimming, gym, climbing, dancing, group workouts)	600
Vaccinations	
- against tick-borne meningoencephalitis	435
- against influenza	200
- against measles	28
Spa recovery	61
Preventative dentist check-up	192
Awareness campaign on iron deficiency	575
Measuring body composition with an expert consulting	955
Lectures (on stress and burnout, anemia, basic revitalization procedures and first-aid with a semi-automatic defibrillator)	1,000

5.4 Training and education[90]

The education and training of employees is closely intertwined with Lek's business strategy, which is crucial for the growth and progress of the company.

We are investing in the development, education and training of our employees on a permanent and planned basis. Employees can attend:

- regular training programs prescribed in the Training Catalog,
- tailored workshops according to the needs of the target group,
- formal forms of education, such as in-service studies,
- non-formal forms of education and
- volunteer workshops.

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.

Most of the courses are conducted in the company and performed by internal and external lecturers. Our employees also take part in external training courses, and above all, they participate in training 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.

The need for training 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 training are linked to the work position of a colleague.

Lek follows global guidelines and new strategies in the field of training, which include combined forms of learning, shorter implementations in the classroom, supported by the implementation of knowledge at the workplace.

We received the TOP 10 education management award for strategic and systematic investment in knowledge and employment training for the sixteenth time.

We received the TOP 10 education management award for strategic and systematic investment in knowledge and employment training for the sixteenth time.

[90] GRI GS 103-1, 103-2.

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.

Training is a key tool for developing employee competencies. In HSE, we are divided into statutory and expert developmental training. 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.

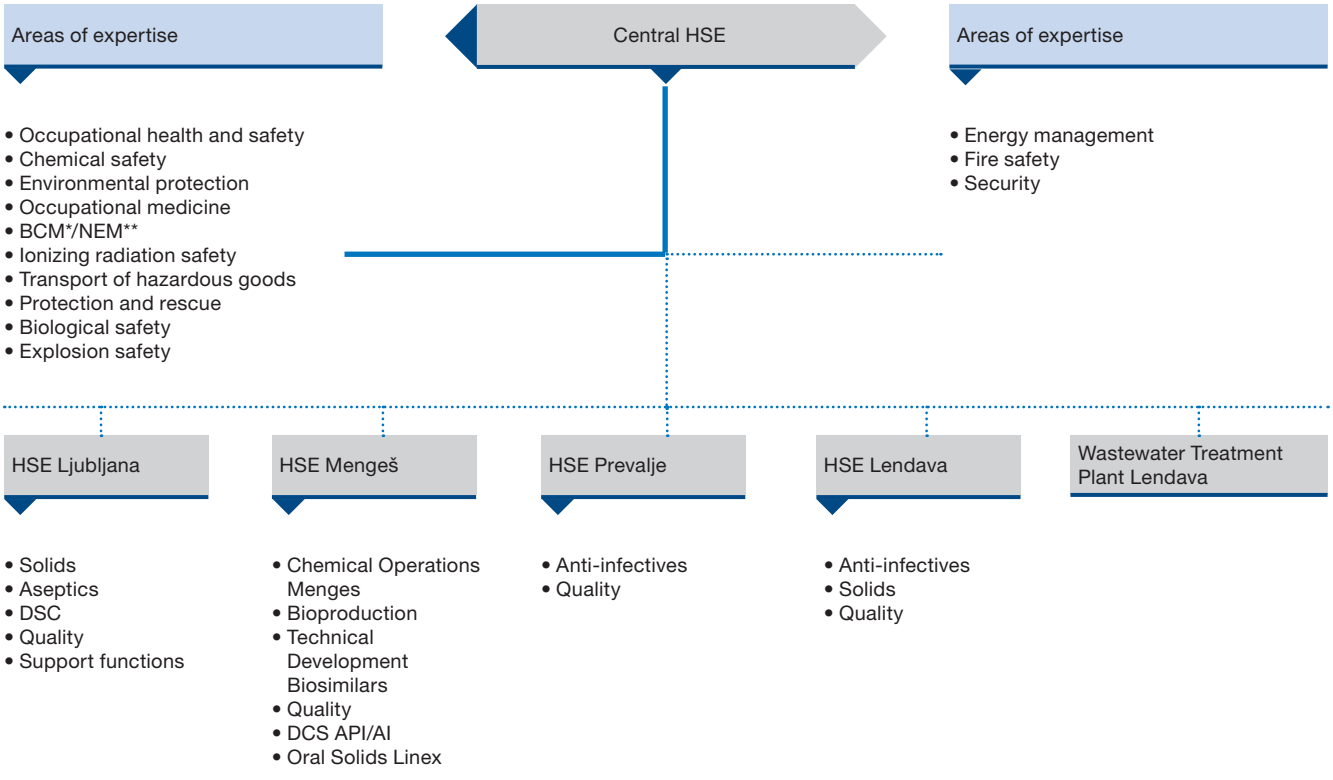
With the introduction of the Up4Growth application, Novartis manages the curriculum for each employee, and puts the quality of trainings at the forefront. In 2018, a lot of education was transferred to the e-environment, which enables better organization of the individual's time to train. We transferred the responsibility for acquiring relevant and required knowledge to the employee and at the same time enabled them to control the development of their own competences.

HSE department

The HSE system has been established at all four sites of Lek 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.

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 Organization Scheme on 31. 12. 2018.



* BCM: Business Continuity Management

** NEM: Novartis Emergency Management

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, meaning, in addition to environmental aspects, we thus also have HSE, chemical safety, fire safety, explosion safety and biological safety aspects and others.

The HSE aspects cover activities, products and services, as well as impacts in their life cycle (raw materials, development, production, transport, use, final disposal). The effects may be local, regional or global, and by their nature are direct, indirect or cumulative. Due to the specific production of pharmaceuticals, Lek has a limited influence on the use of products that it provides to others and their treatment at the end of their life.

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 2018, external auditing of the company's compliance with ISO 14001:2015, BS OHSAS 18001:2007 and ISO 45001:01 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 BS OHSAS 18001:2007 requirements were carried out and we completed H&S systems inspection under new standards ISO 45001:2018. Internal Novartis 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, BS OHSAS 18001, and the EMAS Directive. In 2018, we had a Novartis internal BCM Audit in Ljubljana. The results of internal audits performed in 2018 showed the high level of the company’s compliance with the statutory requirements as well as internal and external standards in all areas. Small deviations were efficiently resolved with corrective actions, which eliminated the cause of incompliance and prevented them from recurring. We use 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 2018, we continued with the Novartis commitment policy to continuously improve environmental performance and met the requirements of the EMAS system at all sites in order to verify compliance with the provisions of the Regulation. This time too, environmental verifiers have confirmed that we are in compliance with the applicable legal requirements in relation to the environment, and that the data and information from the environmental statement provide a reliable, credible and accurate picture of all activities at all Lek sites.

Reporting methodology

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 are ensured. The reporting methodology enables us to monitor absolute indicators and trends for individual key aspects of environmental protection and health and safety at work. The data are included in reporting on the main indicators and other existing indicators of environmental performance in this environmental statement.

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 system in accordance with ISO 14001 and ISO 45001 in addition to registration requirements in the EMAS system by the organization's top management.

Measures for risk prevention and mitigation

Likely scenarios for emergencies are identified with appropriate risk assessment methodologies for each site/business unit. In the context of risk assessment, we evaluate the potential impact and level of supervision and identify appropriate risk mitigation measures.

We take into account potential incidents in all our operations and business activities, as well as possible external resources such as weather, security, suppliers and neighborhood activities. Quarterly we update HSE's set of risks based on risk assessments performed and the current situation in the company and the environment. For each location, we create a Site Threat Assessment, which is updated periodically every 5 years, or in case of major changes that could mean changes threat to sites. Depending on the site risk assessment, a Protection and Rescue Plan is also drawn up.

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 employees 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 set of risks serves the Novartis management as a review the major risks in the area of HSE and the degree of their control at individual sites, in individual countries, business groups and the entire corporation.

Analysis of monthly/yearly trends includes measured environmental, safety and economic parameters for each site separately and together for Lek. In 2018, we carefully identified the risks in the field of HSE in carrying out its activities and processes, and performed all the required activities in the area of risk management, in accordance with the Novartis guidelines in the field of health, safety and the environment (HSE). We have implemented measures to limit the risks to the minimum, such as: avoiding potential hazards, reducing the hazard, limiting the possibility of exposure to hazards and measures to mitigate the negative consequences of a dangerous event in the event of an occurrence.

Activities assuring business continuity management (BCM) in 2018

In 2018 we carried out the following activities, which additionally helped to increase our resistance to unpredictable events:

- BCM coordination with quarterly meetings of BC coordinators,
- we have revised Business Critical Position Holders,
- we updated BC plans for all sites and key support functions,
- BCM assessments took place: Novartis internal audit of NTO Ljubljana, internal assessment of NTO Mengeš,
- we have tested scenarios for all systems and sites,
- we updated BC plans for all production units and support functions,
- training of management teams was carried out at selected sites.

Activities in Novartis emergency management (NEM) in 2018

In 2018, we updated the NEM structure in Slovenia due to changes in the management structure. All Novartis departments have been trained in accordance with the NEM process. Local scenarios were conducted at sites where our teams were confronted with possible real situations. These exercises are a good tool for creating a NEM plan for various possible scenarios in our locations. A simulation of a terrorist attack took place at Ljubljana NEM exercise. In 2018 we did not witness any real NEM case.

5.4.1 Average hours of training per employee[91]

The average amount of time spent for training of Lek's employee was 1.77 days, and if adding compulsory training at the workplace (3.19 days) and training in compliance (1.26 days) it amounted to total of 6.22 days. A good indicator of the success of our education system is the fact that in many of our inspections, our system was presented well and thus no adjustments or improvements were needed.

Average training hours/employee

Year	Number of hours/employees
2014	61.68
2015	71.44
2016	56.40
2017	51.68
2018	49.76

[91] GRI GS 404-1.

5.4.2 Training by area

We build a learning culture, thus introduce additional non-formal forms of learning. All employees have one-hour workshops called "Are you coming?" where they have the possibility and opportunity to share their knowledge and experience in the setting of a friendly gathering, and gain new insights into interesting topics that touch both their professional and private life.

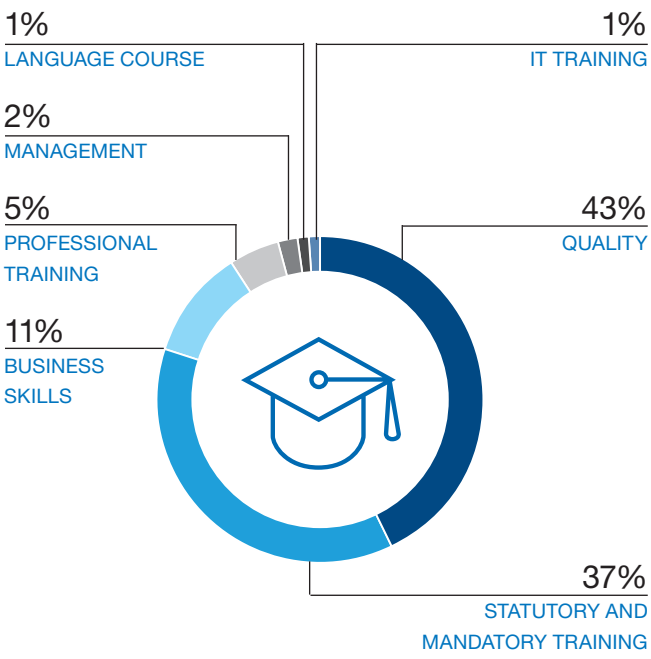
In addition to regular systematic education and leadership development, leaders have the opportunity to acquire useful, modern and effective management skills in the form of short "Leader +" workshops. By doing this, they gain effective tools for easier and more efficient management of employees and themselves, as well as a wider view of the work and mission of the leader.

We take care of promoting learning in the organization, new ways of learning and e-learning, which is supported by a global platform and covers a wide range of content.

We also offer our employees the opportunity of in-service education; in 2018, 52 employees involved in undergraduate studies, and 68 in post-graduate studies, mainly in biotechnology and biomedicine, as well as chemistry.

The highest participation rate was recorded in quality (43%), statutory and mandatory training (37%) and business skills (11%).

Training in 2018 by topic (attendance)



6. GRI content index

GRI content index GS – Core[92]

GENERAL STANDARD DISCLOSURES					
GRI-standard	**Disclosure**	**Reporting boundaries (within and outside the organization)**	**Section/ page numbers**	**Remarks/ Omissions**	**UN Sustainable Development Goals (SDG)**
GRI 101: Foundation 2016					
GRI 102: General Disclosures 2016					
Organizational Profile					
102-1	Name of the organization	Lek	1/6		
102-2	Activities, brands, products and services	Lek and all Lek sites	1.2.2/14		
102-3	Location of headquarters	Lek	1/6		
102-4	Location of operations	Lek	1.2.3/15		
102-5	Ownership and legal form	Lek	1.2/13		
102-6	Markets served	Lek	1.2.1/14		
102-7	Scale of the organization	All Lek sites	1.1.1/7, 5.2.1/74		
102-8	Information on employees and other workers	Lek	5.2.1/74		8 12
102-9	Supply chain	Lek	3.2.1/44		
102-10	Significant changes to the organization and its supply chain	Lek	1.2.3/15, 1.3.1/22, 3.2.1/44		
102-11	Precautionary Principle or approach.	Lek, local communities, patients and customers	1.4.4/29, 4/46		
102-12	External initiatives	Lek, Lek stakeholders	1.4.4/29		
102-13	Membership of associations	Lek	1.4.4/29		
Strategy					
102-14	Statement from senior decision-maker	Lek	Letter from Management /4		
Ethics and integrity					
102-16	Values, principles, standards and norms of behavior	Lek	3.1/40		16
Governance					
102-18	Governance structure	Lek	1.4.1/23		
Stakeholder engagement					
102-40	List of stakeholder groups	Lek	1.4.3/25, 1.4.3/27		
102-41	Collective bargaining agreements	Lek	5.2.2/75		8
102-42	Identifying and selecting stakeholders	Lek, Lek stakeholders	1.4.3/25		
102-43	Approach to stakeholder engagement	Lek, Lek stakeholders	1.4.3/25 2.2/38		
102-44	Key topics and concerns raised	Lek, Lek stakeholders	1.4.3/27, 2.2/38		

[92] GRI GS 102-47, 102-55.

Reporting practice			
102-45	Entities included in the consolidated financial statements.	Lek	1.3.1/22
102-46	Defining report content and the topic Boundaries	Lek	1.3/22
102-47	List of material topics	Lek	6/85
102-48	Restatements of information	Lek	1.3.1/22
102-49	Changes in reporting	Lek	1.3.1/22
102-50	Reporting period	Lek and all Lek sites	1.3.1/22
102-51	Date of most recent report	Lek and all Lek sites	1.3/22
102-52	Reporting cycle	Lek and all Lek sites	1.3/22
102-53	Contact point for questions regarding the report	Lek	1/6
102-54	Claims of reporting in accordance with GRI Standards	Lek	1.3.1/22
102-55	GRI content index	Lek	6/85
102-56	External assurance	Lek	1.3/22

SPECIFIC STANDARD DISCLOSURES

Management approach disclosures	Topic-specific disclosures	Reporting bounderies	Section/ Page numbers	Remarks / omissions	UN Sustainable Development Goals (SDG)
ECONOMIC TOPICS					
GRI 201: Economic performance 2016					
103-1	Explanation of the material topic and its Boundary	Lek, local communities	Letter 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	5.2.3/75		
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, local communities	Letter of Management/4		
202-2	Proportion of senior management hired from the local community	All Lek sites, local communities	5.2.4/75		
GRI 204: Procurement practices 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	Lek, suppliers	3.2.1/44		
204-1	Proportion of spending on local suppliers	All Lek sites, local communities, suppliers	3.2.1/45		
GRI 206: Anti-competitive behavior 2016					
103-1 103-2	Explanation of the material topic and its Boundary		3.1/40		
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Lek, local communities	3.1/41		

ENVIRONMENTAL TOPICS				
GRI 301: Materials 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		4.2.1/54	
301-1	Materials used by weight or volume	All Lek sites	4.2.1/55	
GRI 302: Energy 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		4/47	
302-1	Energy consumption within the organization	All Lek sites	4.3.1/56, 4.3.2/57	7 8 12 13
302-3	Energy intensity	All lek sites	1.1.1/8, 4.3.1/57	7 8 12 13
302-4	Reduction of energy consumption	All Lek sites	4.3.2/58	7 8 12 13
GRI 303: Water 2018				
103-1 103-2	Explanation of the material topic and its Boundary		4/47	
303-1	Interactions with water as a shared resource		4.4/59	
303-2	Management of water discharge-related impacts		4.4/59	
303-3	Water withdrawal		4.4.1/59 4.4.2/60	
303-4	Water discharge		4.7.1/68	
GRI 305: Emissions 2016				
103-1 103-2	Explanation of the material topic and its Boundary		4/47, 4.6/64	
305-1	Direct (Scope 1) GHG emissions	All Lek sites, local communities	4.1.5/54, 4.6.4/66	3 12 13 14 15
305-2	Energy indirect (Scope 2) GHG emissions	All Lek sites, local communities	4.6.4/66	3 12 13 14 15
305-4	GHG emissions intensity	All Lek sites, local communities	4.6.4/66	13 14 15
305-5	Reduction of GHG emissions	All Lek sites, local communities	4.3.2/58	13 14 15
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	All Lek sites, local communities	4.6.3/65, 4.6.4/65	3 12 14 15
GRI 306: Effluents and waste 2016				
103-1 103-2	Explanation of the material topic and its Boundary		4.7/67	
306-1	Water discharge by quality and destination	All Lek sites, local communities	4.7.1/68	3 6 12 14
306-2	Waste by type and disposal method	All Lek sites, local communities	4.5.1/61, 4.5.2/62, 4.5.3/63	
GRI 307: Environmental Compliance 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		4/47	3 12
307-1	Non-compliance with environmental laws and regulations	All Lek sites	4/47, 4.1/52, 4.1.2/52	
GRI 308: Supplier environmental assessment 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	All Lek sites	3.2.1/44	

308-2	Negative environmental impacts in the supply chain and actions taken	Lek, suppliers	3.2.1/44, 4.1.5/54	The environmental responsibility of suppliers is one of the important criteria in the process of procurement and choosing suppliers.	
SOCIAL TOPICS					
GRI 401: Employment 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary		5.1/74		
401-1	New employee hires and employee turnover	All Lek sites, employees	5.2.1/74		5 8
401-3	Parental leave	Lek, d. d., employees	5.2.5/75		
GRI 403: Occupational Health and Safety 2018					
103-1 103-2 103-3	Explanation of the material topic and its Boundary		5.3/76		
403-1	Occupational health and safety management system		5.3/76		
403-2	Hazard identification, risk assessment, and incident investigation		5.3/76, 1.1.1/8		
403-3	Occupational health services		5.3.6/79		
403-4	Worker participation, consultation, and communication on occupational health and safety		5.3.6/79		
403-5	Worker training on occupational health and safety		5.3.6/79		
403-6	Promotion of worker health		5.3.6/79		
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships		3.2.1/45		
403-9	Work-related injuries	All Lek sites, employees	5.3.1/76, 5.3.2/79, 5.3.4/79		
403-10	Work-related ill health	Lek, employees	5.3.5/79		
GRI 404: Training and education 2016					
103-1 103-2	Explanation of the material topic and its Boundary		5.4/80		
404-1	Average hours of training per year per employee	Lek, employees	5.4.1/83	We do not yet record education by gender and by employee category.	4 5 8
GRI 406: Non-discrimination 2016					
103-1 103-2	Explanation of the material topic and its Boundary		3.1/40		
406-1	Incidents of discrimination and corrective actions taken	Lek, employees	3.1/41		
GRI 408: Child labor 2016					
103-1 103-2	Explanation of the material topic and its Boundary		3.2.1/44		
408-1	Operations and suppliers at significant risk for incidents of child labor	Lek, suppliers	3.2.1/44		
GRI 409: Forced or compulsory labor 2016					
103-1 103-2	Explanation of the material topic and its Boundary		3.2.1/44		

409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	Lek, suppliers	3.2.1/44		
GRI 414: Human rights assessment 2016					
103-1 103-2	Explanation of the material topic and its Boundary		3.1/40		
412-2	Employee training on human rights policies or procedures	Lek, employees, local communities	3.1/40		
GRI 413: Local communities 2016					
103-1 103-2	Explanation of the material topic and its Boundary		1.4.3.1/28		
413-1	Operations with local community engagement, impact assessments, and development programs	All Lek sites, local communities	1.4.3.1/28	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		3.2.1/44		4 5 8
414-2	Negative social impacts in the supply chain and actions taken	Lek, suppliers	4.1.5/54	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		2.2/38		
417-1	Requirements for product and service information and labeling	Lek, regulators	2.2/38		
417-2	Incidents of non-compliance concerning product and service information and labeling	Lek, regulators, patients, healthcare workers and healthcare service providers, buyers	2.2/38		
417-3	Incidents of non-compliance concerning marketing communications	Lek, regulators, patients, healthcare workers and healthcare service providers, buyers	2.2/38		

7. Declaration of environmental verification

Environmental Verifier's Declaration on verification and validation activities
No O-006

Slovenian Institute of Quality and Metrology,
with EMAS environmental verifier registration number SI-V-0001,
accredited for the scope (NACE: 21.20),

declares to have verified that the organization at sites:

Lek Pharmaceuticals d.d.
Ljubljana, Verovškova 57; Mengeš, Kolodvorska 27;
Prevalje, Perzonali 47 and Lendava, Trimlini 2 D, Slovenia

with registration number Reg.No. SI-00006,

meet all requirements of the Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organizations in a Community eco-management and audit scheme (EMAS).

By signing this document, we declare that:
- the verification and validation have been carried out in full compliance with the requirements of Regulation (EC) No. 1221/2009, (EU) No. 2017/1505 and (EU) No. 2018/2026;
- the outcome of the verification and validation confirms that there is no evidence of non-compliance with the applicable legal requirements relating to the environment;
- the data and information in the environmental statement "**Sustainability Report 2018 – Lek d. d., July 2019**" reflect a reliable, credible, and correct image of all organisations activities, within the scope specified in the Environmental Statement.

This document is not equivalent to EMAS registration. EMAS registration can only be granted by a Competent Body under Regulation (EC) No. 1221/2009. This document shall not be used as a stand-alone piece of public communication.

EMAS

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8. 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.[93]

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.[94] 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 itscharacterization 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

[93] 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).

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

European Medicinal Products Act requires a higher level of expertise in science, technology and logistics. 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.

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 exactlydefined 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.

Industrial Emissions Directive (IED) 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 EU Ecolabel or EU Flower  reflects the manufacturer’s commitment to continual environment management improvements.