Sustainability Report 2019
Lek d. d.

Contents

Sustainability Report 2019 – Lek d. d.

Published by: Lek d. d.
Text: Mojca Bernik, Lek d. d.
Editorial and Consulting: Studio Kernel d. o. o.
Design: Intesa RD d. o. o.
Photos: Tadej Bernik, Barbara Zajc, Archive Lek d. d., Shutterstock
Cover: bebsy/Shutterstock, taken in Slovenia
Our health, safety and environment policy and its active implementation is presented in Chapter 4.
Printed by: Silveco d. o. o.
Number of printed copies: 25
Year of publication: 2020

This report is printed on environmentally friendly, 100% recycled uncoated Desistar 150 paper, made from 100% post-consumer PCF (Process Chlorine Free) fibers, with EU Ecolabel (No. AT/11/002)*. The paper has been manufactured in a paper mill that holds an ISO 14001 certificate. The carbon footprint of the Lenzing papier manufacturer is 242 kg CO_2/t of paper (Bilan Carbone© methodology).

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

2019 Highlights

1,159.954 million EUR

NET SALES IN 2019, 9% MORE THAN 2018.

4,349

EMPLOYEES AT THE END OF 2019, 6% MORE THAN 2018.

53.68 hours

OF EDUCATION AND TRAINING PER EMPLOYEE, 8% MORE THAN 2018.

6.8 million EUR

SAVED THANKS TO 370 SUBMITTED AND IMPLEMENTED TH!NK NOVARTIS IDEAS IN 2019.

-1.5%

DECREASE IN TOTAL WATER USE.

3.3 million EUR

INVESTMENT IN ENVIRONMENTAL PROTECTION IN 2019.

44.4 TJ

OF ENERGY AND 3,173t CO_2 SAVED THANKS TO NUMEROUS ENVIRONMENTAL PROJECTS.

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

The past year has been very dynamic and creative, eventful and full of achievements. In order to respect our social responsibility principles; act responsibly and expand accessibility to medicines, we have paid particular attention to working with our stakeholders and sharing best practices in order to broaden our knowledge.

Robert Ljoljo

Our employees at all four of our sites in Slovenia have made great efforts to provide high-quality, innovative and safe medicines for the treatment of patients. With this goal in mind, we constantly monitor their needs and develop and adapt medicines; being in close contact with them, involving them and learning together are our priorities. The importance of involving patients in the development of digital technologies is also a key finding of the online Novartis European Patient Innovation Summit. (EPIS), which brought together patient association representatives from more than 15 countries in real time, while opening a direct discussion in our local environment. More than 10 Slovenian patient associations presented their experiences offering great support to us in finding digital tailored solutions for patients.

We also forged new achievements in 2019 with these findings. We launched 813 new products on 88 markets around the world, including the launch of innovative medicines from Slovenian sites. More than 200 development projects were underway at the end of the year. We achieved significant growth in the total volume of production, which due to more demanding products are reflected in different measuring units, not in total weight volume. We produced several products from the existing portfolio as well as new innovative biologics and biosimilars.

All of our environmental impacts remain below legally prescribed limits, moreover within Novartis' even stricter limits, even as we have expanded our capabilities to respond to the needs of patients around the world for high-quality affordable healthcare. We developed new solutions (Lendava and Mengeš) and adjusted the composition of the portfolio (Mengeš) to the strengthening the role of more demanding medicines, which affected the indicators of our environmental efficiency. As a result, the total waste produced increased by more than 6%, of which 74% was biodegradable, which are further used to generate energy. Their larger volume were influenced by the improved technological process, which has further reduced electricity consumption and thus indirectly succeeded in our overall impact on the environment. At the Prevalje and Ljubljana sites, waste was reduced by 9% and 7%, respectively. A 16% production increase at the Mengeš site contributed to the 13% increase in hazardous waste, mostly non-halogenated waste or-

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

ganic solvents. Ljubljana and Lendava sites significantly reduced the quantity of hazardous waste (by 13 and 67%, respectively).

To improve energy efficiency, we introduced several projects at all sites, which saved 44.4 TJ of energy. Thus, despite the growth of production, we managed to keep the total energy consumption to a similar level as last year. Measures to reduce water consumption were also successful, as we reduced its total usage by 2%.

As part of the Novartis family, we want to manage our environmental impact as responsibly as possible. We are therefore accelerating the preparation of implementation plans for our sites, with which we want to contribute to the realization of Novartis' ambitious sustainable strategy. By 2025, it envisages PVC-free secondary packaging and the reduction of disposed waste by half compared to 2016. Its long-term goal is to switch to the use of exclusively renewable energy and halve our total water consumption.

Concern for the safety of our employees and suppliers

We dedicate many activities to caring for the health and safety of our employees, as well as employees of contractors who are an important link in the Novartis business chain. We are systematically developing a high safety culture, which includes more and more safety walkthroughs and training, in order to minimize the risk of injuries in the workplace. In 2019, we focused on the prevention and management of major risks, where serious consequences can or could occur. To identify potentially serious and other incidents, we performed 2,586 safety walkthroughs and drew attention to potential risk areas. We also performed safety inspections at contractors and gave them recommendations for improvement. Despite this, our colleagues suffered 13 minor injuries, which mean we have to continue to work intensively, specifically on the ergonomic aspects of the workplace.

In order to respect our social responsibility principles; act responsibly and expand accessibility to medicines, we have paid particular attention to working with our stakeholders and sharing best practices in order to broaden our knowledge

Innovation and progress of the company are not something that happens automatically; we are introducing new ways of developing talent and strengthening the creativity of employees. We are building a culture that encourages curiosity and exploration. In the past year, employees received more training and actively proposed improvements to work processes, and out of 510 ideas presented, we put 370 into practice. Our employees at all four sites were joined by 496 new employees. We ended the year in all Novartis divisions in Slovenia with more than 4,400 full-time employees, of which 530 have a master's degree or a doctorate. Our employees have received numerous prestigious national and international awards for their work.

We were delighted to be recognized as the most reputable employer in the country. We are especially pleased that, in addition to experts from academia and business, we are also appreciated by students.

Due to the knowledge and creativity of our employees, we are also strengthening our trust and our role in Novartis, which has invested more than 2.5 billion euros in Slovenia since 2003. Last year, we opened new development laboratories and the first fully automated analytical laboratory at the Development Center Slovenia, and set up three new high-performance and technologically advanced packaging lines for blisters in Lendava.

In order to ensure the accessibility of treatment, we focus on disadvantaged groups, such as the elderly and young people and children from socially weaker backgrounds. For several years, we have been a proud partner of the Elderly for Elderly project and Lek's Sunshine Games, which is part of the A Wink at the Sun humanitarian program. Among us are many volunteers and some for the 15th year in a row attended the traditional Community Partnership Days and tightened relationships all the way from Lendava to Debeli rtič.

I would like to take this opportunity to thank my colleagues, users of our products, suppliers, healthcare partners and our local communities for their amazing cooperation. By working together, listening and respecting each other, we can reimagine medicine and improve people's lives around the world through innovative approaches.

Robert Ljoljo,
President of the Board
of Management of Lek and
Novartis Country President Slovenia

1. Company Profile

Lek, a Sandoz company

Company name: Lek Pharmaceuticals d. d.[2]
Abbreviated name: Lek d. d.
Registered office: Ljubljana
Business address: Verovškova 57, 1526 Ljubljana, Slovenia
Registration number: 1732811000
Standard Classificaion 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@sandoz.com
Website: http://www.lek.si

Contacts

Legal Representative
Robert Ljoljo, President of the Managing Board

Qualified person
Robert Hribar, Head of Health Safety and Environment (HSE);
robert.hribar@novartis.com

Contact person for reporting on sustainable development[3]
Mojca Bernik, Environment Safety Authority;
mojca.bernik@novartis.com

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

1.1 Key data for 2019

1.1.1 Performance in 2019

Key performance figures for 2019[4]

Indicator	Unit	31. 12. 2019	31. 12. 2018	31. 12. 2017	Index 2019/2018
Number of employees		4,349	4,084	3,889	106
- Ljubljana Site		2,310	2,152	2,079	107
- Mengeš Site		1,118	1,098	1,058	102
- Lendava Site		664	571	484	116
- Prevalje Site		248	256	261	97
- hired warehouse		9	7	7	128
Production output*	1,000t	5.01	5.12	4.92	98
Net sales	mil. EUR	1,159.954	1,061.302	951.480	109
Liabilities	mil. EUR	1,286.430	1,196.518	1,120.868	107
Capital	mil. EUR	1,002.339	889.571	773.979	112

* The annual data comparing the volume of volume production are incomparable due to very large differences in the weight of products and the composition of production between individual years. These differences arise from adapting to changes in demand and Novartis' portfolio transformation. The differences in product weight should also be taken into account when analyzing data on the efficiency per ton of product. For example, the weight of biosimilars is significantly lower compared to certain self-medication drugs, yet their manufacture requires larger quantities of water and energy resources. At the same time, the financial value of the manufactured biosimilars is higher.

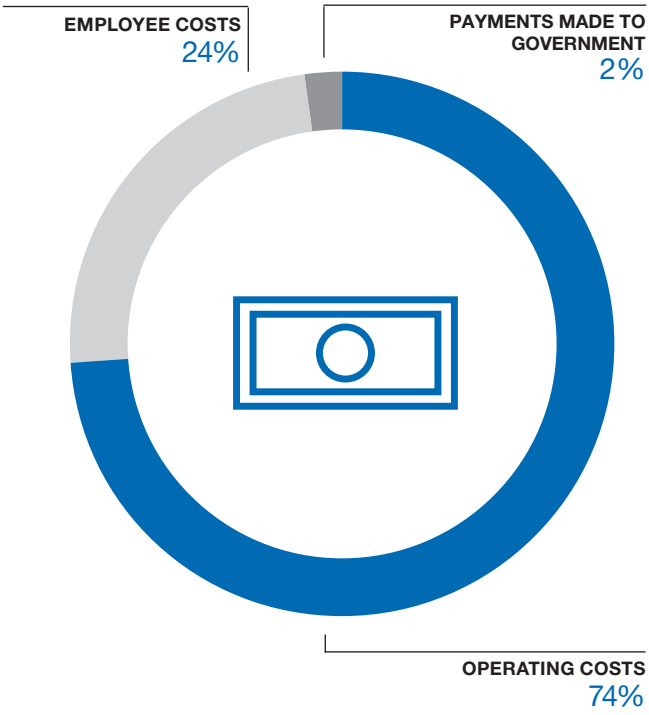
Economic performance[5]

In 2019, Lek created 1,159.954 Euros of net sales, this represents a 9% increase compared to the previous year (1,061.302). Net profit for the accounting period amounted to 115.81 million Euros.

Direct economic value reached 1,205 million Euros (1,092 in 2018), of which 82% (987 million Euros) was **economic value distributed**; the largest proportion (74%) representing Operating Costs, which reached 730 million Euros. **Employee Costs** were 236 million Euros (24%). In 2019, no **Payments to Providers of Capital** were made, and **Payments to Government** amounted to 21 million Euros (2%).

In 2019, we received public subsidies in the amount of 728,000 Euros (1.4 million in 2018). There was zero tax relief value due to investment in research activity.[6]

Structure of economic value distributed



987 million EUR

Economic value distributed, 9% increase from 2018.

[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. 2019	31. 12. 2018	31. 12. 2017	Index 2019/2018
Energy efficiency*	GJ/t	268	262	269	102
Water efficiency**	m^3/t	685	680	696	101
Amount of waste – efficiency	t waste/ t product	7.9	7.3	7.5	108
VOC emissions – efficiency	t VOC/ t product	0.018	0.014	0.013	120
LTIR*** – Lost time injury and illness rate		0.30	0.21	0.21	143
TRCR*** – Total recordable case rate		0.32	0.25	0.26	128

* In 2018, the calculation of natural gas changed from volumes (Sm^3, Nm^3) to energy units (kWh). The High Heating Value is considered as the basic energy value, and previously all calculations and reports contained energy conversions to the Low Heating Value.

** The table shows the total water efficiency at Lek (for technological and cooling purposes).

*** 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*.

1.1.2 Highlights and milestones of Lek's performance in 2019

In 2019, we reached the majority of the Novartis targets in Slovenia. Through excellent work in development, production and services, we made an important contribution to Novartis' global success, including cooperation in the production of innovative APIs for two approved key Novartis innovative drugs for breast cancer and multiple sclerosis. By further optimizing and adapting our production across Slovenia, we continued to successfully implement Novartis' strategy to focus on personalized, patient-friendly medicines in small quantities, on high value-added medicines and biosimilars.

Operation highlights 2019:

- We hired **496 new employees**. At the end of the year, Lek had 4,349 full-time employees in fact 4,422 full-time employees in all Novartis divisions in Slovenia, of which 530 have a master's degree or a doctorate. In the last eight years, more than 2,700 new employees have joined us.
- In the **Development Center Slovenia**, we completed the development and submitted 21 dossiers for drugs from the therapeutic fields of anemia, oncology, anti-rheumatics, anti-infectives, diabetes and potency disorders.
- We achieved **growth in total production**, and we market medicines worldwide through Sandoz and Novartis' extensive sales network. Some key medicines also contain our own developed and manufactured active ingredients.
- We launched **813 new products on 88 markets** around the world, including the launch of innovative medicines from Slovenian sites.
- Since 2003, **Novartis has invested more than 2.5 billion euros in Slovenia**. Of this, more than half was devoted to development and the other to modernization and expansion of production capacity. In 2019, we opened new development laboratories and the first fully automated analytical laboratory at the Development Center Slovenia, and set up three new high-performance and technologically advanced packaging lines for blisters in Lendava.
- We continued **innovative employment practices**, such as the Regional BioCamp and Novartis' Career Breakfast, and for the first time we organized Novartis' business employment event, which is intended for those who want to change their career and continue working for one of the best employers in Slovenia and in the world.
- As part of **Novartis' strategy for responsible environmental management**, we strive to prevent and reduce our impact on the environment. We achieve this by certifying environmental management in accordance with the requirements of ISO 14001: 2015 and Regulation EC122 / 2009 with amendments (EMAS). We are also constantly improving the established management system in the field of occupational health and safety according to the ISO 45001: 2018 standard.
- At Lek, we are clearly aware of the importance **of maintaining a high level of quality**, as this is the only way we can provide patients with a safe and effective medicine. In 2019, we successfully passed the most demanding assessment of the US Food and Drug Administration (FDA) at two sites (Ljubljana and Lendava).
- More than 700 Novartis employees from our Ljubljana, Mengeš, Lendava and Prevalje sites participated in more than 25 volunteering activities. **Over 15 years** Novartis employees in Slovenia have dedicated more than 41,200 working hours to **volunteering** in the local community.

[7] GRI GS 302-3.

1.1.3 Novartis' sustainable strategy

Our ambition is to be a catalyst for positive change and a leader in environmental sustainability. As part of Novartis, we will promote sustainability through our own operations and through our value chain. We have set very ambitious goals with which we want to minimize the impact on the climate, waste and water.

	Ambition for Novartis	2025 targets	2030 targets
Climate	**Carbon neutrality** Energy and climate resilient	- Use only renewable energy (carbon-neutral operations) - Environmental criteria in all supplier contracts	- Carbon footprint reduced by half
Waste	**Circular economy & plastic neutrality** Minimize waste and increase material efficiency	- Eliminate PVC in secondary and tertiary 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 achieve this by:

- 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 and Lek strive 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 utmost 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 the coordination, which is prepared by the HSE department 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 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.

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

Exercise at work station

Status of Lek's short term HSE targets for 2019

Area	Indicator	Target	Status 2019
Health and safety	Employee exposure to chemicals and other hazardous substances that exceed the (Novartis) permitted values	0	8
	LTIR (own employees + employees hired through employment agencies) with potential SIF	0	**Not reached.** 1
	Walkthrough inspections per 200,000 working hours	>15	**Reached.** >15
	Near misses and good catches per 200,000 working hours	>50	**Reached.** >50
	Serious injuries and fatalities (SIF)	0	0
	REEP (Risk-based exposure evaluation process)	≥70 %	**Reached.**
Environment	Decrease energy use	–5% in comparison to 2018	**Not reached.** Increased by 0.42%.
	Decrease water use	–5% in comparison to 2018	**Not reached.** Decreased by 1.5%.
	Decrease waste removal	–7% in comparison to 2018	**Not reached.** Increased by 6.4%.
	Number of overdue larger or critical actions (CAPA)	0	**Reached.** 0
Corrective actions	Actions implemented after inspection	100%	**Reached.** 100%

Lek's HSE targets for 2020

Area	Indicator	Target
Health and Safety	Serious injuries and fatalities (SIF)	0
	Walkthrough inspections per 200,000 working hours	>15
	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0
	REEP	100%
Environment*	Decrease Energy use	≥ 8% in comparison to 2019
	Decrease water use	≥ 8% in comparison to 2019
	Decrease waste removal	≥ 8% in comparison to 2019
Corrective actions	Actions implemented after inspection	100%
	Number of overdue larger or critical actions (CAPA)	0

* Lek pursues the ambitious goals of Novartis' sustainability strategy.

The patient should be at the forefront

Kristina Modic, co-founder and executive director of the Slovenia Lymphoma and Leukemia Patient Association and President of the Cancer patients association of Slovenia ONKO NET

Patients must be involved at all levels in the development of digital treatment technologies. This is a fundamental recommendation of EPIS, the European Innovation Forum for Patients, organized by Novartis together with European organizations advocating for patients' rights.

The "Nothing without us" principle is also the guiding principle of the Slovenian Association of Patients with Lymphoma and Leukemia L&L, which is very actively involved in it and in many other initiatives for cancer patients.

Many years ago, Kristina Modic's own experience in overcoming lymphoma led her to become an advocate for blood cancer patients. Through her public activities, she pushed boundaries and contributed a lot to changing society's attitude towards patients. Due to its programs, projects and patient advocacy, the association has become recognizable and respected in the professional public, among decision-makers and among patients and relatives of patients with whom its members are in daily contact and help them in various fields. Through its activities, it has contributed to the fact that the treatment of Slovenian patients is comparable to the treatment in the most developed European countries.

The L&L Patients Association is very successful in connecting with domestic and foreign organizations of patients in the field of oncology and others in many joint projects and in advocacy.

We are connected by the experiences we share and common goals. We want to provide patients with access to the most modern forms of disease detection and treatment, timely and quality diagnostics and treatment. We are committed to holistic treatment at all levels, quality of life and successful return to life, to the work or educational environment.

Many experts who work with us make an important contribution to our success and visibility at home and abroad.

You were among the first to share your experiences and story with others. You are also a moderator on a very popular web portal.

Since the illness, I have moderated the forum Lymphoma and Leukemia and How to Live with Cancer on the Med. Over.Net portal. Recently, the role of the chat room has been taken over by social networks and questions via our website or e-mail. It is very lively in closed groups on Facebook, where patients and relatives share their experiences and stories.

Getting support, acceptance, understanding of one's emotions is sometimes even more valuable to a patient than medical advice. When you say it, others help you bear the burden. And it's much, much easier. You also receive a lot of support and positive encouragement that you need both during treatment and on the road to recovery.

You also devoted a lot of your energy to the Put yourself on the list campaign, which also included employees of Novartis companies in Slovenia.

Unexpectedly, we quickly exceeded our main goal and expanded the register of potential hematopoietic stem cell donors so that patients with blood cancer have a better chance of survival. At the same time, we raised awareness about the role of the registry and about donation. Lek and Novartis took a hearty and organized approach to the campaign and supplemented the register with more than 300 new potential donors, which was an exceptional and record number. Due to successful public communication and campaigns led by our vice president of the association and former Lek employee, Mrs. Milena Remic, today almost every young individual knows the register, and companies and individuals continue to contact us for organized registrations.

How do modern technologies change the treatment of patients and members of your association?

Undoubtedly, modern technologies are on the rise. I believe that we have all adapted to them quickly and successfully - patients, professionals, decision-makers and supporters. We have seen that older patients are also increasingly reaching for them, although at first it seemed different. A lot of data is collected here, so it is important that they are protected from misuse. We have a lot of education ahead of us, but that is the future.

However, it should still be kept in mind that personal contact counts for a lot in patient support.

You also moderated the participation of Slovenian patient associations at the last European Patient Innovation Summit (EPIS) 2019.

I welcome the EPIS project, which is both international and local. Many more patient advocates can participate in it, get educated, exchange practices and experiences than at a classic conference. It is also a unique opportunity for patient associations to work together to find new digital solutions for patients. Empowering makes it easier and better to make patients aware of the use of digital tools.

At the last meeting, we looked for effective approaches for more active involvement of patients in the planning of digital health solutions. With our experience, we can contribute a lot to make solutions tailored to the patient. There are no digital solutions for patients without patients, so the patient should be put in the forefront.

Info day for blood cancer patients and their families (photo: www.limfom-levkemija.org).

All leaders need to be safety leaders

Gorazd Sušnik, authorised person for health and safety at Lek d. d.

At the forefront of our work for occupational health and safety are our patients, employees and the community, as well as a risk management strategy to ensure stable care. We work as a team to check and improve existing ways of working and always with safety in mind.

At Lek, Gorazd Sušnik is responsible for the compliance of the internal occupational health and safety system with legislation and the Novartis guidelines, as well as professional assistance to employees on-site. In addition to his professional tasks and external contractor management, his regular and main job is networking between Lek's sites and units for the operation of uniform systems.

He has built on his expertise not only in his primary field of occupational health and safety and fire protection, but also management and control systems and lean manufacturing and development methods. His extensive training has been both in Slovenia and abroad with renowned experts.

Lek's local goals, priorities and key programs were set in 2019 were again based on Novartis' annual goals for occupational health and safety. What interesting aspects would you highlight?

Among the general objectives, I would highlight the use of new technologies and innovative solutions to improve processes and efficiency, including in the field of health and safety. With the help of technological support, it is easier to standardize processes and simplify their management.

Most attention was paid to the prevention and reduction of major risks, systemic simplifications of their management and monitoring improvement. Regarding this, we produced GAP-analyzes, we identified opportunities for improvement, prepared implementation plans and programs.

Gorazd Sušnik (pictured right) on a operational (safety) walkthrough at Lek site.

Experts and specialist doctors play a central role in identifying risks to the health and safety of employees. However, what is the role of employees?

Expert health professionals and specialists are an important link in identifying risks, but we are not the decisive factor for the effectiveness of the system itself.

The profession is a kind of moderator who leads, collaborates, connects, researches and explains. Employees are the key, i.e. those who are preparing to perform certain activities, supervise or carry out work. Therefore, we invested the most in improving the safety culture and actively promoting a healthy lifestyle amongst employees. We brought the basic safety rules and new programs related to the system of safe work and activities with increased risk closer to our employees.

Do you also involve contractors in occupational health and safety awareness?

We pay equal attention to employees, agency workers and contractors. We value them and their health and safety and we are aware that they are also crucial for successful and smooth operations, and at the same time we expect their positive contribution to our safety culture. In addition to the daily activities, once a year we acquaint them with the specifics, measures, requirements and innovations in health, safety and the environment. At these meetings we organize, we exchange practical experiences and share good practices and answer open questions and challenges. In 2019, the purpose of the mutual meetings was to ensure safe work at height.

Which moves are you happy with and where do you see the biggest opportunities?

We have made significant progress in the safety culture of external contractors, but we are far from the target. We have prepared good programs for the management of some critical activities, such as the already mentioned work at height and work with hazardous energies, and the promotion of safety culture. Challenges await us in their effective implementation in practice and the establishment of critical monitoring over activities with increased risk. We still have many opportunities to raise awareness and promote a safety culture, to become even more proactive and to make concern for health and safety an indispensable and automatic habit.

You pay a lot of attention to risk prevention and taking corrective measures. How do you achieve the best results?

The number of corrective measures identified and implemented does not yet represent final effectiveness. We achieve the best effects through open communication, good promotion of occupational health and safety and with employees who are trained to identify risks and are open in expressing their opinions. Of particular importance are leaders who demonstrate the importance of safety through their leadership and conduct. All leaders need to be safety leaders, they need to involve employees, encourage them and also reward them. In the last year, we have significantly reduced the number of open corrective measures, which is an important indicator of the described efforts.

Approach is as important as professionalism

Igor Kalšek, Head of the HSE Compliance Program for Novartis Suppliers in Europe and the Other World regions.

Anti-corruption, animal treatment, labor rights, information security, data privacy protection, quality for good manufacturing practices and health, safety and the environment – these are the seven areas in which we implement the Third Party Risk Management program in cooperation with suppliers.

Diverse professional roles at all levels, demanding projects and rich international experience in managing the health and safety of employees and environmental protection, has greatly shaped Igor Kalšek.

The head of Novartis' supplier compliance program and global auditor in this area is consistent and willing to help.

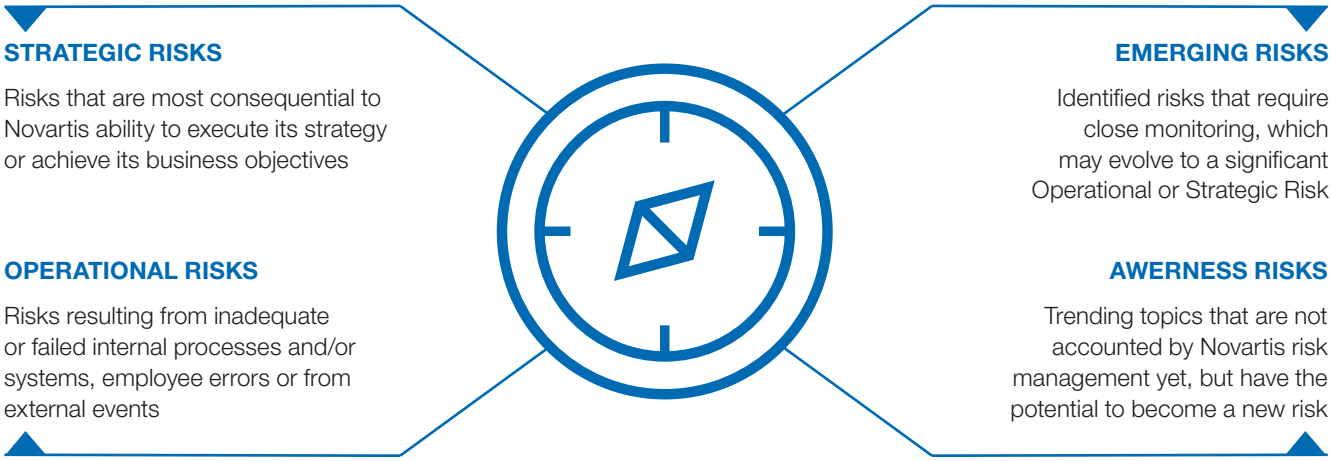
With his expert team, he also promotes the culture of employee health and safety and environmental responsibility with suppliers, and strives for their continuous progress.

Novartis also extends its commitment to health, safety and the environment to suppliers. Why are you working to improve their business?

Comprehensive care for health, safety and the environment is fundamental to the long-term success of Novartis' business. However, we cannot achieve it alone, only in cooperation with key stakeholders, among whom are definitely our suppliers.

We value them and so we also work with them on HSE. At Novartis, we systematically approached third party risk management in 2017. Our culture attaches the same importance as other business goals to protecting the health and safety of employees, neighbors and others affected by our business, as well as protecting the environment.

The Novartis Risk Compass



So are your efforts reducing the risks?

Of course, the continued success of our business depends on our ability to integrate risk management. Discussions on risk management therefore involve not only global leaders, but also in close cooperation with all units and countries. A reflection of such a process is Novartis' compass of risks with four dimensions, namely strategic, operational, emerging and awareness risks.

What role does your team of experts play in this?

Among other things, our expert team assesses the aspects of HSE at suppliers. We identify their risks and perform due diligence. For example, we also advise on concluding business agreements and introducing continuous improvements in supplier programs. We enforce the same Novartis internal standards everywhere and, of course, respect local law.

How and with whom is the verification carried out?

We check all suppliers that produce or package raw materials, active ingredients or medicines for Novartis. We plan to prepare around 150 supplier evaluations in one year in Europe and Other World regions.

We first send a detailed questionnaire to each supplier. If, after an expert analysis of the answers, the need arises, we also perform an on-site assessment. Its results and appropriate corrective measures and deadlines for their implementation are coordinated with the supplier and the responsible administrator for business cooperation on our site.

How do suppliers accept your expectations and performance?

In order to implement the principles and standards that lead to sustainable development, a common attitude towards health, safety and care for the environment is just as important as professionalism around the world. Our responsibilities therefore go beyond just professional support in ensuring these standards, as we want to create a mutual partnership with our suppliers, only then can we be successful on both sides. In addition to verification and support in ensuring compliance in the field of health and safety of employees, our goals are primarily aimed at ensuring long-term sustainable operations, which in all environments is based on responsible operations and attitude towards the environment.

What are the concrete results of your checks?

In the case of suppliers from the European Union, which are subject to rather strict legislative criteria, in most cases we only suggest improvements. For some, coordination is more extensive and we also offer help to achieve process improvements. In some cases, we terminated our cooperation because the partners failed to achieve a high level of risk management in the field of employee health and safety and environmental protection.

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. 2019, Lek had 100% ownership share in Sandoz Pharmaceuticals d.d. and 74.5% ownership share in Wastewater treatment plant Lendava d. o. o.

In 2019, 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

As part of Novartis, one of the leading pharmaceutical companies in the world, we understand social responsibility as an integral part of our business strategy and implement it holistically in conjunction with all business activities and functions and our stakeholders.

Accessible healthcare and responsible business are the foundations of our social responsibility. Through research achievements and innovation, we are creating new and more accessible treatment options for patients around the world. Responsible business practice is the common starting point of our business strategy.

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

[8] GRI GS 102-5.

1.2.1 Key customers and markets[9]

In accordance with strategic orientations, Sandoz Group and Novartis companies are the key buyers of our products and active pharmaceutical ingredients. In 2019, the leading three buyers accounted for 74%, 8% and 4%.

We sell our own products and the products of other Sandoz companies. The majority of our products in 2019, 95%, were sold to foreign markets (Western Europe, Russia and the USA), Slovenia accounted for 5%. The majority of sales (90%), came from pharmaceutical products, the remaining 10% came from APIs and biopharmaceutical products.

With all its divisions, Novartis consolidated its leading position on the Slovenian pharmaceutical market with a 14.3% market share and increased its market share by 0.2 percentage points compared to the previous year. Lek is in first place on the Slovenian market of over-the-counter medicines, second in sales of generic medicines, and the largest supplier of biosimilars.

Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 76% of sales in 2019. The total value of the Slovenian pharmaceutical market was 767 million Euros. 49.9 million Euros of sales and a 6.5% market share makes Lek the second largest pharmaceutical company. On the generic market, where the total value is 135 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 with a 23.5% share.

The market for biosimilars amounted to 7.6 million EUR, with Lek in first place with a market share of 44.9%. In the market of over-the-counter medicines (worth 58.9 million EUR), where Lek is also the leader, recorded a 4.5% growth.

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.

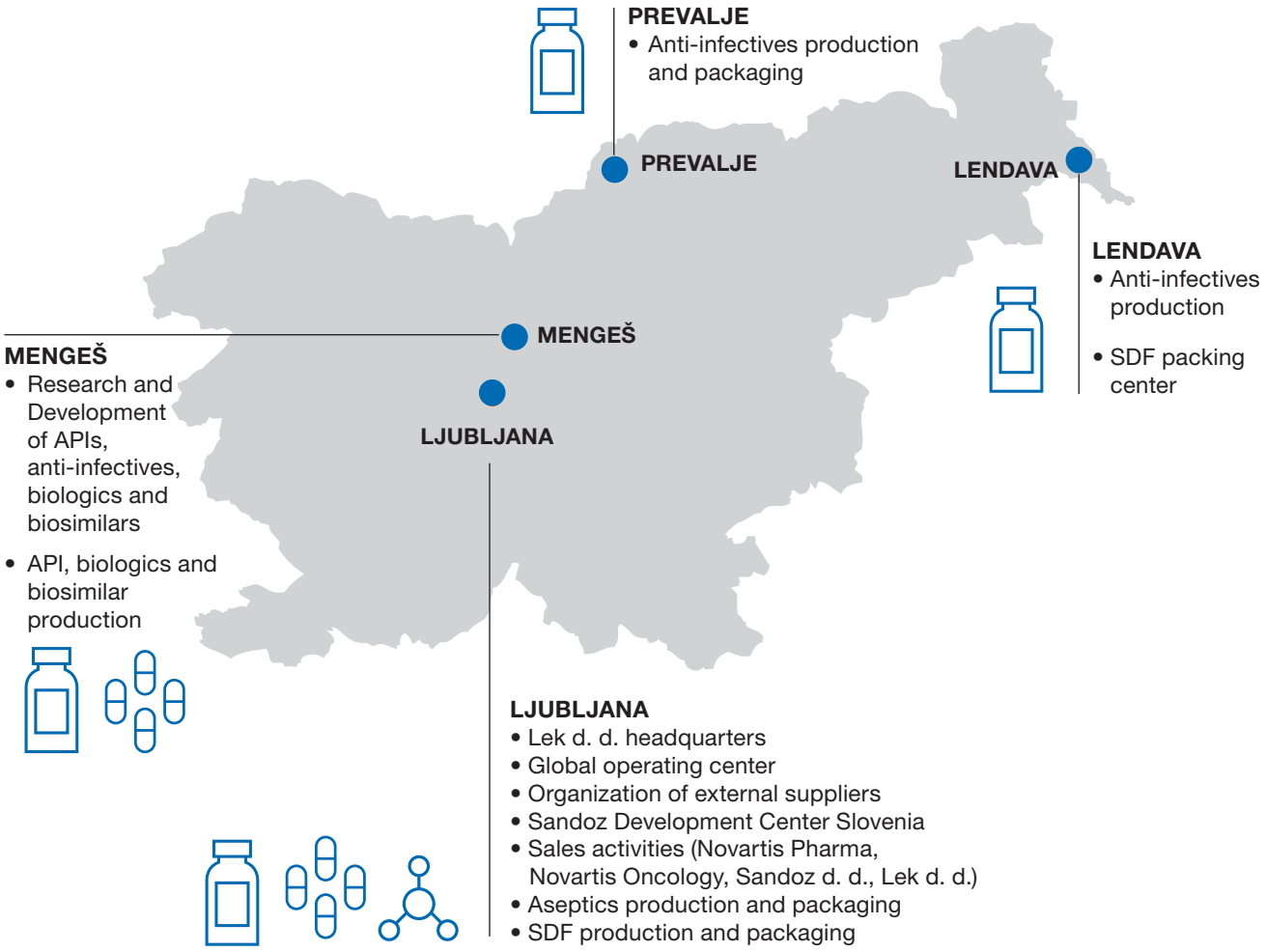
In 2019, Lek's leading prescription medicines on the Slovenian market were Iroprem (a trivalent iron drug), Coupet (rosuvastatin), Amoksiklav (amoxicillin with clavulanic acid), and Ospen (phenoxymethylpenicillin). The range of prescription drugs was supplemented with a new antibiotic for the treatment of urinary tract infections, Cisof (fosfomycin). The best-selling biosimilar was Rixathon (rituximab). In 2019, three new biosimilars, Hyrimoz (adalimumab), Ziextenzo (pegfilgrastim) and Zessly (infliximab), also became available to Slovenian patients.

Amongst the leading over-the-counter brands we achieved the highest sales with Lekadol, Linex, Lekadol plus C, Operil and Fluimukan. We launched a new drug to treat the symptoms of allergic rhinitis in adults, with a confirmed diagnosis, Mommox Rino.

[9] GRI GS 102-6.

[10] GRI GS 102-2.

1.2.3 Development sites and processes[11]



>4,400
inspired employees

48%
~48% women
in senior management positions

More than 70 years
of pharmaceutical heritage

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

Carlo Gargiulo, Head Solids Ljubljana

9.2 billion

pieces of solid pharmaceuticals and

132 tons

of granules and micropellets 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 procurement, legal affairs, supplying, corporate communication, Novartis Pharma and Novartis Oncology 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)
In the Solids unit, we produce solid dosage forms for oral use; granules, tablets, dragees, film-coated tablets, micropellets for oral suspension and capsules with granules in modified-release pellets. The finished pharmaceutical products are packaged in blisters, bottles, jars and sachets.

In 2019, the growth in production volume in the Solids unit reached a record and was among the highest in Novartis' technical operations. We produced 9.2 billion pieces of solid pharmaceuticals and 132 tons of granules and micropellets. We packaged 137 million packs with 348 million primarily packaged units. In addition to the high production volume, the utilization of our production capacities was also high. We launched 271 new products, both innovative and generic.

In the field of innovative medicines, an important highlight was the launch of a new launch drug for the treatment of breast cancer, which we carried out in record time, immediately after receiving the approval of health authorities, first in the US and then in some other markets.

The Solid Dosage Forms unit has also become one of the centers for the future launch of formulations for children such as mini tablets and powder for oral suspension in sachets.

We significantly increased our activities in the field of innovative medicines. These will be produced with existing capabilities and in some places also with new and innovative technologies, such as the recently installed equipment for particle shaping (nano-milling), which we will use in the introduction of completely new products in the coming years. The unit has also become one of the centers for the future launch of formulations for children such as mini tablets and powder for oral suspension in sachets.

Key acquisitions include the certification of the unit according to the principles of NOSSCE (Novartis Operational Standard for Supply Chain Excellence) to ensure comprehensive care for customers and patients. We also performed a number of inspections, which confirmed the quality and compliance of our production and processes, as well as the knowledge and responsibility of our employees.

Tjaša Bantan Polak, Head Aseptics Ljubljana

Matjaž Tršek, Head Development Center Slovenia

Aseptics

In the Ljubljana Aseptics Unit, the volume of production increased significantly. While the production of ampoules and liquid non-sterile products remained unchanged, we recorded a significant increase in the field of vial products. We produced 17.6 million vials, almost 50% more than in 2018. The increase is mainly due to a 35% increase in the production of the biosimilar rituximab. As a result, we also employed more than 70 new employees.

Also in 2019, we successfully introduced new products into production. We started the development of a new biosimilar, launched a new product, and completed two demanding technological transfers of new sterile products from the Development Center Slovenia.

Development Center Slovenia

Development Center Slovenia specializes in the development of technologically demanding products and is the leading development center in Sandoz. It is home to more than a quarter of all Sandoz global development projects. At the locations in Ljubljana and Mengeš, Development Center Slovenia employs more than 330 experts, mainly pharmacists and chemists, a third of whom are doctors of science.

With new investments in increasing and modernizing capacity, we have consolidated our position as a leading development center. With an investment of 7.5 million EUR, we acquired new technological laboratories, in which we can also develop demanding solid and sterile forms for the treatment of oncological diseases. We are also richer for the new fully automated analytical laboratory, which operates five robotic devices and represents an important step towards greater digitalization and automation, and brings many advantages in the development processes.

We have taken important steps in the development of competencies, knowledge and processes. We further strengthened an open and inclusive organizational culture. All of this will be an important foundation for our successful work in the years to come.

New laboratory in Development Center Slovenia

Uroš Urleb, PhD, Global Head Technical Development Biosimilars in Novartis and Head Biologics Technical Development Mengeš

Vesna Kapelj, Head Chemical Operations Mengeš

Polonca Kuhar, Head Drug Substance Bioproduction Mengeš

1.2.3.2 Mengeš Site

Chemical Operations Mengeš

In the coming years, the Chemical Operations Mengeš Unit will focus on the production of innovative and selected value-added generic active ingredients. We have successfully supported the launch of two key Novartis innovative drugs in the US to treat breast cancer and multiple sclerosis. We completed a 10 million EUR investment in one of the key parts of the production of innovative pharmaceutical products and a 3 million EUR investment to support the launch of a new generic product. With this, our location has acquired new production facilities for the production of the most technologically demanding active ingredients.

We have become a certified location according to the principles of NOSSCE standards, specifically MRP Class A, which brings additional stability and reliability to our business processes to provide comprehensive care to customers and patients. We significantly saved more than $7 million by significantly improving our production and business processes.

We also successfully passed all the assessments of domestic and international health inspections and once again proved the high level of the quality system in our company. We also successfully renewed the certification for ISO 14001 and EMAS environmental management systems and ISO 45001 health and safety management systems.

Drug Substance Bioproduction Mengeš

The year was marked by successful operations, as we produced record quantities of the active ingredient erythropoietin in the recombinant technology plant, which is used to treat anemia in chronic kidney patients and in oncology. We have successfully performed audits of domestic and international health inspections, and our unit has also become a certified NOSSCE unit, which places us among the most reliable locations in the Novartis supply chain. We completed the construction of a new production facility, where we will produce active ingredients for biological and biosimilar drugs. Drug Substance Bioproduction Mengeš have been selected as a testing center for raw materials and excipients used in the production of biological active ingredients and biological medicines.

At **Biologics Technical Development Mengeš** we have been very successful in all areas of our operations. We strengthened our capacity and completed the construction of new laboratories and office space for the development of biological medicines. We are developing a large number of projects in the field of innovative biological and biosimilar pharmaceuticals, which are in various stages of development, especially in the field of oncology and immunology. As part of Novartis' Global Drug Development - Technical Research & Development, we have consolidated our important role in the development of biological and biosimilar pharmaceuticals and strengthened our operations in the areas of innovation, data science and digitization. The culture of innovation, curiosity and cooperation has been at a very high level for many years, which is also confirmed by numerous internationally recognized projects and awards for the scientific work of our employees.

Roman Burja, Head Anti-infectives Prevalje

1.2.3.3 Prevalje Site

At Prevalje, we produce the broad-spectrum antibiotic Amoxiclav, which we sell in more than 80 of the world's most demanding markets. In 2019, we performed excellent audits, including the more demanding European regulatory bodies, and through numerous audits of our customers we confirmed that we ensure the highest quality standards and consequently the production of safe, effective and quality medicines. We also invested in new production equipment and technology to ensure product traceability, which is the latest regulatory requirement.

We continued our business optimization processes and, among other things, successfully improved the production process of tableting and packaging products. To automate the business, we introduced the first robot on the blister packaging line. We gave the top talents new tasks, more responsibilities and additional tasks.

In total, we produced 616 million tablets, a third for the U.S. market. We produced 12.2 million pieces of oral suspensions, 47.2 million packs and 295 tons of mixtures.

In October, due to the projected reduction in demand in the USA, we announced our intention to change the role of the Prevalje production site. As part of this transformation process, we plan to phase out production at Prevalje, which is expected to be completed by the third quarter of 2021, when the operation of Novartis' Global Operations Center is expected to be established in Koroška. With the company TAB d. d. we signed a letter of intent to sell our new building, which would allow for further use of the facility and the possibility of employment for some of our coworkers.

Through numerous audits of our customers we confirmed that we ensure the highest quality standards and consequently the production of safe, effective and quality medicines.

Gizela Štampar, Head Anti-infectives Lendava

Simon Rečnik, PhD, Head Solids Lendava

1.2.3.4 Lendava Site

Anti-infectives Lendava

The Anti-infectives Lendava unit produces the active ingredients gentamicin sulfate and potassium clavulanate. The latter is a key ingredient in a broad-spectrum antibiotic, one of Lek's and Sandoz's most important products. Gentamicin sulfate is sold in the most demanding world markets. The production of both products is based on classical biotechnology, which is the result of our own knowledge. Potassium clavulanate production capacity was fully occupied in 2019, while gentamicin sulphate production was slightly lower due to lower market needs. We also made some small investments to increase production in the coming years.

We are constantly improving our sustainability on site. At the end of the year, we introduced a new partially continuous fermentation process for the production of potassium clavulanate. This extended the process phase, where the production of the active substance is most intensive, whilst significantly reducing electricity consumption. We made significant savings in energy consumption with the introduction of "free cooling", where we use the power of nature to cool the water during periods of lower temperatures. In compliance with environmental regulations, we increased the capacity of incineration of solvents and solid waste of our own production, which significantly reduced the consumption of natural gas. We have reaffirmed the high level of our production and quality system. We successfully passed all inspections and audits, the most important of which were inspections by the US FDA and the Slovenian JAZMP. We achieved all the set HSE goals and successfully completed two important assessments in the field of process safety and process compliance. We paid a lot of attention to raising the safety culture and improving the safety of processes.

Solid Dosage Forms Lendava

We celebrated our tenth anniversary at Solid Dosage Forms Lendava. The year was extremely demanding, but the production site nevertheless had a number of successes. At the end of the year, we had already packed almost 6.5 billion tablets and capsules into 170 million packages.

Our priority was to successfully continue the transformation of the portfolio with a larger share of innovative medicines. We successfully performed numerous initial validations and packaged the first batches of several key Novartis innovative medicines which put Solids Lendava and Slovenia on the global map of the innovative pharmaceutical industry. At the end of the year, we acquired three new high-performance and technologically advanced blister packaging lines.

With a total of 26 packing lines, we have become Novartis' largest production site for SDF, generic and innovative portfolio packing.

At the beginning of December, we obtained the NOSSCE certificate and became certified pharmaceutical producers in Novartis with the highest level of reliability – Class A. We hired 120 new employees and achieved all key operational business objectives in terms of employees, quality, employee safety, customer care and finance.

1.3 Development and Reporting Framework

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. For the third year in a row, we are also preparing an overview of the areas in which we are contributing to the realization of the United Nations Sustainable Development Goals, which can be seen in the GRI index. Even before 2010, we prepared environmental reports and reports within the RCI.[12] The Sustainability Report was last published in July 2019.

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. 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/.

We also take into account the materiality analysis prepared by Novartis in the preparation of the report. Novartis and, consequently, Lek's essential and important areas of social responsibility are shown in Point *2.2. Stakeholder overview and inclusion.*

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.

1.3.1 Reporting characteristics for 2019[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 Standards

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

- Reporting refers to Lek d.d. and all its manufacturing sites in Slovenia. All disclosures in the present report refer to the 2019 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' 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 2019 is comparable to similar annual reports of Novartis. The changes did not affect the scope of disclosures in the report.
- In 2019, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures.
- In order to improve the accuracy of reporting, the following corrections were made for 2019 in the collection of data that affect the comparability of data with previous years.
- In the DMS data system, an error was found in the reporting of volatile organic compounds for the Ljubljana location and data on water pollutants for the Mengeš location.

[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.

1.4 Govarnance and management[16]

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

Board of Management

In 2019, the members of the Board of Management were as follows:

- **Zvonko Bogdanovski,** President – Technical Operations (until 30 April 2019)
- **Robert Ljoljo, President** (from 1 September 2019)
- **Ksenija Butenko Černe,** Member – Legal Affairs
- **Ivan Ďurovčík,** Member – Finance
- **Andrej Pardo,** Member – Commercial Operations
- **Samo Roš, Member –** Human Resources (until 30 September 2019)
- **Uroš Urleb,** Member – Research and Development (from 1 October 2019)
- **Raul Intriago Lombeida,** Member – Technical Operations (from 1 October 2019)
- **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 2019, the members of the Supervisory Board were as follows:

- **Francesco Balestrieri,** Chairman
- **Richard Francis,** Vice Chairman (until 30 June 2019)
- **Ingrid Sollerer,** Vice Chairman (from 1 July 2019)
- **Andreas Michael Brutsche,** Member
- **Knut Mager,** Member (until 8 March 2019)
- **Peter Svete,** Member – Workers' Representative
- **Fikret Bašanović,** 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.
- 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

[16] GRI GS 102-18.

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 2019, the Supervisory Board had six 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 none 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.

1.4.1 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, etc.). 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 seventeen members that represent workers' interests, form opinions and forward proposals and initiatives to management on improvements to the 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 2019, the Workers' Council was regularly informed at its meetings about the company's economic situation and its development goals. They were acquainted with organizational changes in individual units, current topics decided by the management board and other current events in the company and the trade union.

The Workers' Council regularly publishes monthly minutes of meetings on its intranet site (it also sends them by e-mail to the management, directors and secretariats, which forward them to co-workers). The intranet page of the works council also contains other current information that helps employees (information in the field of labor law, tax area, links to important laws, institutions, etc.).

There were also **10 meetings with employees** at all Lek sites, which were attended by members of the works council together with the management and the Lek trade union.

The term of office of the workers' director expired last year, so the workers' council announced the candidacy procedure and elected the workers' director. Following the procedure, he submitted a proposal to the President of the Board of Management that the Supervisory Board appoint him as the Workers' Director and a member of the Board of Management. The proposed candidate was appointed to Lek's Board of Management.

Members of the works council attended 10 regular and 1 extraordinary meeting of the workers' council. Among other things, they discussed business results, organizational changes in units, current topics and events in the union, projects and new regulations in the field of employee health and safety, development of competencies and talents of employees, the Community Partnership Days, etc.

[17] GRI GS 103-1.

1.4.2 Lek's commitment to external incentives, principles and initiatives[18]

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.[19]

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

[19] GRI GS 102-11.

2. Accessible treatment

Accessible treatment is one of 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

We actively contribute to solving global health challenges through innovative medicines based on completely new discoveries, as well as through the development and production of generic medicines. 2019 was very dynamic and creative; we exchanged best practices and built new knowledge through various collaborations. We increased our visibility in wider society as an employer who pays great attention to the professional and personal development of its employees, the development of the profession and social well-being.

2.1.1 Achievements in medicine development

In the **Biologics Technical Development Mengeš**, a large number of projects are underway in the field of innovative biological and biosimilar pharmaceuticals, which are at various development stages. In 2019, our employees also made an important contribution to the approval of the biosimilar pegfilgrastim in the US market. We are proud that as a leading provider of biosimilars, we are helping to make patients more accessible to modern therapies.

The first fully automated analytical laboratory in Lek was officially opened by Subodh Deshmukh, Head of Global Development in Sandoz, Ph.D., Tina Trdan Lušin, Head of Prototype Analytics Group 1, PhD, and Bojan Mitrović, Head of Analytical Development at the Development Center Slovenia.

At the end of the year, over 200 development projects for pharmaceutical products and active ingredients were in progress at the **Development Center Slovenia**. Oncology drugs, drugs for the treatment of cardiovascular diseases, drugs for the treatment of diabetes, allergic rhinitis, migraine, insomnia, urological and gastric diseases, as well as non-steroidal anti-inflammatory drugs predominate. We completed development and submitted 21 dossiers for medicinal products in the US, European Union, Russia, Canada, Australia, Mexico and China markets, and 1 dossier for active substances in the USA.

We successfully launched several products in the markets of the USA, the European Union, Canada, Russia and China. The U.S. Food and Drug Administration accepted and reviewed "First to file" status for anemia medication.

We are especially proud of our team that participated in the launch of the cholesterol reduction product in the Chinese market. It is the first Sandoz drug to successfully compete in a public tender to supply the drug to the Chinese market. We also received the prestigious International Generics Bulletin Award for product registration in China.

2.1.2 Facilitating mass inventive culture

Th!nk Novartis 2019

Th!nk Novartis is a system that manages the employee ideas and actively involves them in introducing changes and improving work processes. In 2019, Lek employees delivered **510 ideas, 360 ideas were approved** for implementation. In total, **370 ideas** were implemented, and the direct measurable savings of approved ideas amounted to **6.8 million Euros. 404** different promoters participated in the submission of ideas, representing **5.58 percent** of all Lek's internal and external employees. We published four online Th!nk Novartis newsletters, where we quarterly shared the results of Th!nk Novartis, good practices, and gave advice and informed employees about the awards received and events.

Week of Innovation

The seventh consecutive Week of Innovation lasted throughout the year. Every three months we devoted one day to innovation to talk about a specific topic. It was held at a different site each time; at Ljubljana we spoke about operational excellence, at Mengeš about digitalization, at Prevalje employees presented new learning models, and in Lendava we dedicated the day to the promotion of innovation and the Th!nk Novartis application. On the final, fifth day, we presented our annual achievements to the members of the Board of Management, and we also awarded prizes to the best innovators of the year; the proposer, the unit and the team.

Open innovation 2019

We work closely with faculties, research institutions and career centers. In cooperation with the Faculty of Electrical Engineering of the University of Ljubljana, in 2019 we created a virtual model of a packaging line for training after the cleaning process, and with an external partner Viar we developed the possibilities of using augmented reality (AR) in production. During the year, we also shared our knowledge, experience and good practices in the field of digitization and operational excellence with other companies.

We approached students and other young talents at career days and fairs, visits to companies and at career fairs abroad. We organized two summer schools for students and presented ourselves at the European Association of Pharmacy Students event "Summer University", this time in Portorož organized by the Student Section of the Slovenian Pharmaceutical Society.

Innovation and open innovation gained additional visibility with the appointment of Uroš Urleb, Ph.D., as the member for development and innovation on the Board of Management. We have established a new inter-functional team of experts for the co-creation and implementation of our company's development strategy, also in connection with research institutions.

Career Breakfast

For the fifth time in a row, we organized a Career Breakfast in Mengeš, intended for young Slovenian experts in natural sciences who are studying or working abroad. During informal conversations with managers and HR managers from Novartis units in Slovenia, forty participants learned about the career opportunities we offer them in our pharmaceutical company.

Career Breakfast at Mengeš

Regional BioCamp 2019

The ninth three-day Regional BioCamp, the best students meet with renowned experts and leading managers from Lek, Sandoz and Novartis. It is an excellent opportunity for young talent to gain a direct insight into the world of research and the international pharmaceutical industry environment. The overarching topic was "Neuroscience Today and Tomorrow". For the first time, in addition to science students, we also hosted economics students. 35 students learned about the opportunities and challenges of the future treatment of neurological diseases, as well as the development of new therapies for patients with neurological and other diseases.

The winning team of the Regional BioCamp 2019

Scientists Day

On the occasion of the World Science Day for Peace and Development, which is celebrated on November 10th, Novartis Slovenia, in cooperation with scientific institutions, hosted the Scientists Day event for the first time. Around 80 scientists from Slovenian academic institutions and Lek learned about the latest research achievements and discussed ways to strengthen the connection between the academic sphere and the economy. In addition to Lek researchers, experts from the Faculty of Pharmacy of the University of Ljubljana, the Faculty of Chemistry and Chemical Technology of the University of Ljubljana, the Faculty of Chemistry and Chemical Technology of the University of Maribor, the Faculty of Mechanical Engineering of the University of Maribor, the Institute of Chemistry, the Jožef Stefan Institute and Slovenian Science Foundation. The event also marked the 100th anniversary of the University of Ljubljana and the 25th anniversary of the Slovenian Science Foundation.

Address by the President of the Board of Management Robert Ljoljo at Scientists Day

Golden innovators from Lek

2.1.3 Awards for innovation

Central Eastern European Pharmaceutical Manufacturing Excelence Award

In April, our employees won the CEE Pharmaceutical Manufacturing Excellence Award at the annual conference of the international association PHARM Connect. Team members, Nemanja Aničić, Polona Smrdel, Teo Morožin, Sara Vidovič (Development Center Slovenia), Domen Kitak and Peter Usenik (Sensum d. o. o.) received the award for the innovation "Implementation of real-time particle size analysis within the processing of multilayered pellets".

Awards of the Chamber of Commerce and Industry Slovenia 2019

We received three awards from the Chamber of Commerce and Industry Slovenia, including Gold for the **Lincomplex™** innovation: **A new generation of high-quality food supplement with the best researched strain of Lactobacillus Rhamnosus GG**. The product was developed in Development Center Slovenia thanks to many years of experience and expert knowledge of products with lactic acid bacteria.

The second Gold award was given to the innovation **Continuous and connected process for cleaning biopharmaceuticals**. The innovation **Predicting the Stability of Monoclonal Antibodies in Solution** received the bronze award.

American Chamber of Commerce Award

At the American Chamber of Commerce's "Best of the Best" competition, Development Center Slovenia employees entered the **Science for Lek** project in the "integration" category. The project was presented by Biljana Janković, Ph.D., and Miha Jaklič, Ph.D., and came 2nd.

The finalist of the "Best of the Best" competition of the American Chamber of Commerce, Biljana Janković, Ph.D., and Miha Jaklič, Ph.D.

TARAS Award

We were awarded recognition from the IRT industrial forum "TARAS'' for the most successful cooperation of economy and research and development in the field of innovation, development and technologies for the project **"Artificial stomach for analysis and direction of development of complex solid pharmaceutical forms''**. Leading participants were Igor Legen, Ph.D., Janez Diaci, Ph.D., (FS UL) and assist. Helena Vrbanac (FFA UL).

The winning team with their TARAS 2019 awards 2019

TOP Th!nk Awards

Special thanks were once again given to the employees who contributed and implemented the most innovative ideas and solutions. "TOP Th!nk proposer", Saša Lukić gave the largest number of accepted ideas, the award for "TOP Th!nk team" was received by Davor Margeta and the team Packaging 1. Uroš Urleb, Ph.D., Head Biologics Technical Development Mengeš, once again took the award for the "TOP Th!nk unit".

Female Engineer of the Year

In Cankarjev dom, the 2019 award was presented for the Female Engineer. For the second year in a row, we also had a finalist, Nina Lah, Ph.D., Head of the Aseptic Particle Analysis Laboratory. Among other things, she convinced the members of the commission with her many years of academic and industrial experience and her love of identifying and solving problems.

Nina Lah, Ph.D., (pictured left), head of the Aseptic Particle Analysis Laboratory and finalist for the 2019 Female Engineer of the Year

Novartis Awards

Matej Horvat, Ph.D., received the highest Novartis scientific recognition VIVA, the Distinguished Scientist Award was received by Matej Horvat, Ph.D., Head of Predictive Analytics and Modeling from the Development of Biological Medicines Mengeš. In addition, Ivana Gazić Smilović, Ph.D., Andrej Bastarda and Damjan Šterk, Ph.D., researchers from the Development Center Slovenia, received Leading Scientist Awards.

Sandoz R&D Awards

Scientists from the Development Center Slovenia and the Development of Biological Medicines Mengeš received an incredible nine Sandoz awards for research and development. With the Scientific Excellence Award, Sandoz recognizes the best scientists each year with years of outstanding research and development achievements. In 2019, the recipients of both awards were Slovenians, Barbara Podobnik, Ph.D., from the Biologics Technical Development Mengeš and Biljana Janković, Ph.D., from the Development Center Slovenia.

2.2 Stakeholder overview and inclusion[20]

Business in the field of pharmacy and caring for patients' health requires a high level of trust, which is essential to our success. As part of the Novartis network, we strive to become the most respected and successful healthcare company in the world, so we are constantly building and maintaining the trust of our key stakeholders - the people we work with and the patients whose health we improve.

We include our stakeholders in our operations in several ways in order to understand their needs and expectations, and subsequently improve access to healthcare.

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)
- society (local communities, non-governmental organizations, scientific and educational institutions, and the media).

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

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. We use Novartis' global quarterly employee survey (Our voice) to determine employee satisfaction and attitudes. The results give us clear starting points to further build a healthy organization and opportunities for development.

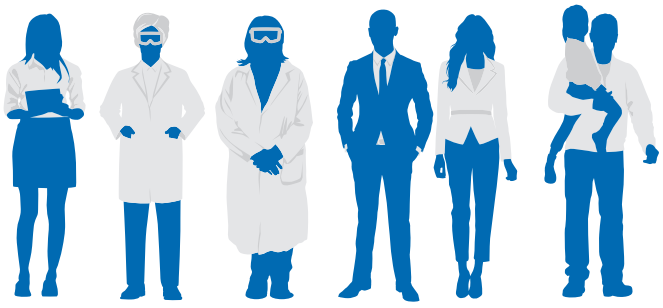
Each survey also helps us to better respond to patient needs and provide solutions for a healthier society.

We try to identify the expectations and experiences of suppliers as much as possible in joint meetings and efforts for further improvements in accordance with the Novartis Code of Conduct for third parties, which is described in section *3.2.1. Purchasing system and purchasing policy*.

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.

Lek's key stakeholder groups



SOCIETY

(local communities, NGOs, scientific and research institutuions and media)

SHAREHOLDERS

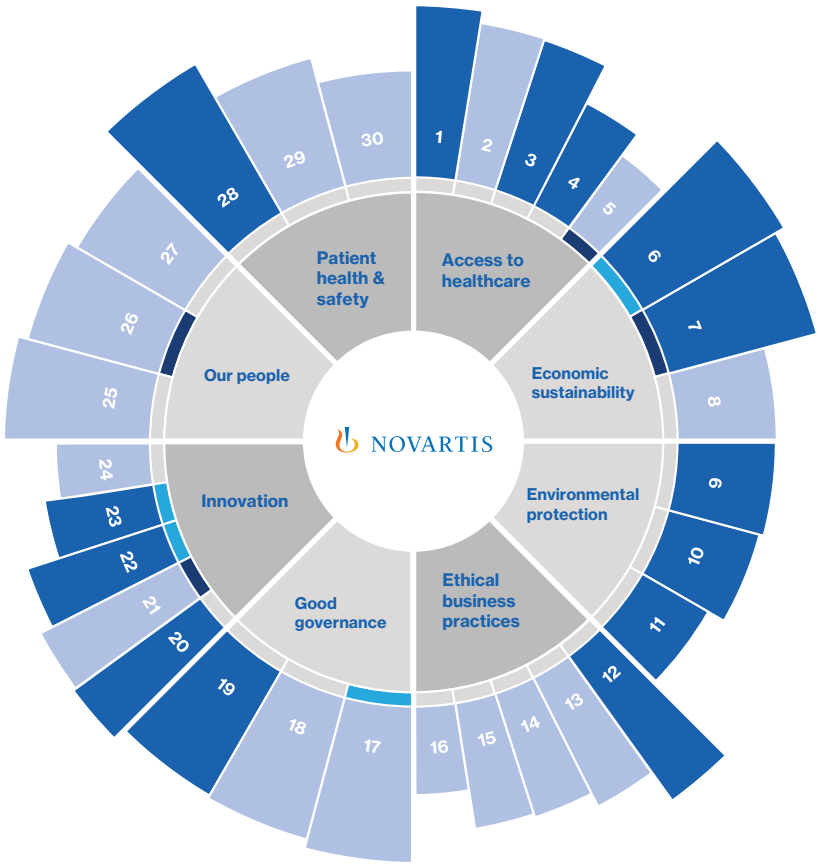
PATIENTS

EMPLOYEES

HEALTHCARE PARTNERS

(healthcare professionals, regulators, professional associations, buyers, suppliers)

Novartis' key areas of social responsibility



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 four main areas of social responsibility in the inner circle are marked with a darker background. The middle circle identifies topics with significant differences in perception between internal and external stakeholders. The outer circle represents 30 individual topics, and their relative importance is reflected by the height of the column, not the width. The classification of areas (internal circle) is based on the answers collected with separate questions and not on the basis of calculations of the importance of individual (specific) topics.

Lek's stakeholders and recognised interests:[21]

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 • Respect and understanding of patient groups • Increased accessibility to our drugs • Undertaking responsible clinical studies • Recognising the importance of transparency and reporting
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

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

2.2.1 Cooperation with the local communities

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. We establish socially responsible partnerships, organize Open Days, Community Partnership Days, organize meetings and events with groups of patients and activities to increase access to treatment.

Community Partnership Days

In 2019, we held Community Partnership Days for the 15th time, the initiative of corporate volunteering was also taken up by many other companies in Slovenia. Around 680 Novartis employees in Slovenia (Lek, Sandoz, Pharmaceutics and Oncology) dedicated their working hours between April 10th and May 29th with more than 25 different activities and projects to individuals and various organizations throughout Slovenia – from Lendava to Debeli rtič. Our employees have dedicated more than 41,200 hours to corporate volunteering over fifteen years and helped more than 60 different organizations and more than 12,000 individuals.

Globally, Novartis' corporate volunteering project takes place on six continents in 58 countries. On average, Community Partnership Days are attended by more than 20,000 Novartis employees worldwide.

At the Na Fari Prevalje retirement home we danced to some good music with the residents.

Playing Bingo with the residents of the Mengeš Home for the Elderly.

Lek Sunshine Games

Lek's Sunshine Games is part of the humanitarian program Wink at the Sun®, with which the Association of Friends of the Youth of Slovenia and Lek have been providing free holidays to children from socially disadvantaged families for 20 years. As part of the program, more than 100 children spent their holidays free of charge.

In Maribor, Lek's Sunshine Games was also joined by the traditional Funny Olympics, where children went on 42 trips around Maribor and the close and far surroundings to be creative at various art workshops. There were also 35 thematic workshops available to them. In total, in July and August, we recorded almost 6,000 children in Maribor, activities were attended by about 700 children from Maribor and neighboring areas, 230 of them were included in holiday care, which was this year's new addition to the holiday program.

Lek's Sunshine Games and Funny Olympics attracted 6,000 children this year.

Elderly for the Elderly

Among the activities with which we demonstrate our connection with the wider social environment is the multi-year partnership with the program of the Association of Pensioners' Associations of Slovenia (ZDUS) Elderly for the Elderly, which has been running for 15 years.

3,500 volunteers at home care for the elderly from the age of 69 onwards and help them in a variety of life situations according to their needs. Also this year, we supported the program with a donation.

From left: Rožca Šonc, Head of the Elderly for the Elderly program, Vera Pečnik, Vice President of ZDUS, Mojca Pavlin from Lek and Duška Zdovc Mavrin, Regional Elderly for the Elderly program coordinator for Koroško.

Patient groups

At Lek, we cooperate with many groups of patients through various meetings and other activities. Among other things, we participated again in the Novartis European Patient Innovation Summit (EPIS) 2019. Its goal was to find solutions that will help patients have an important say in the future of digital health. With the help of digital technology, the EPIS meeting brought together representatives of patient associations from more than 15 countries, and the participating representatives of Slovenian patient associations contributed their thoughts on the role of digital health.

More than 10 Slovenian associations shared their thoughts on the role of digitization of healthcare at the EPIS summit.

Mechanisms for addressing complaints[22]

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 2019, we received two questions, which we classified as public complaints. The questions and the concurrent initiatives concerned the quantity and type of packaging used in the packaging of medicines. The first case referred to the possibility of reducing the amount or the possibility of recycling packaging when packaging the product Amoxiclav, and others on the possible replacement of plastic packaging with glass.

When defining the packaging, we always consider all environmental impacts. Thus, in all Novartis companies, we have set ourselves the goal of removing all PVC packaging by 2025, which is not directly related to ensuring the product's compliance with the expiration date. We want to achieve a neutral use of plastic and ensure the reuse or recycling of the same amount of plastic as we will use. As medicines are a specific product, the choice of materials is regulated and must be proven to ensure the quality and effectiveness of the medicine and its constant properties during its shelf life. The size and type of primary contact packaging (e.g. blisters) are also determined by market requirements and technological conditions. More about materials and the sustainable approach in chapter *4.3.3 Sustainable approach to packaging management*.

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.

2.3 Product compliance[23]

We develop and manufacture high-quality products that not only meet but also exceed regulatory requirements. We ensure patient safety by timely identification, management and reporting of risks associated with products.

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

The Rules on advertising of medicines in Slovenia stipulates that the professional public consists of prescribing doctors, pharmacy masters dispensing prescription drugs and non-prescription drugs. 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 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. No infringements in the field of information and labeling of products were detected in 2019.[24]

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

[23] GRI GS 103-1, 103-2, 403-7, 417-1.

[24] GRI GS 417-2.

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.

We develop and manufacture high-quality products that not only meet but also exceed regulatory requirements.

Also in 2019, 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]

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.

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.

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.

[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. For almost two decades We have incorporated **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 in addition to the principles and ethical standards of our organization. It provides a basis for the trust of our key stakeholders. 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 continued to implement Novartis' initiative to promote open communication and report inappropriate behavior in the company.

We promote the system of anonymous reporting of inappropriate behavior with the so-called **"speak up"** culture, which also allows us to address ethical issues. We continue our awareness-raising campaign amongst our employees.

We are also guided in our operations by **Novartis' human rights guidelines** www.novartis.com/files/novartis-human-rights-guideline.pdf. In a large and diverse company with employees who represent more than 140 nationalities and speak several languages, human rights are one of the most important areas that unite us. At Lek, human rights are intertwined in the foundations of our operations, which is why in 2019 we joined ten large Slovenian companies that signed a Commitment to Respect for Human Rights in Business. It dictates that we respect them in the operation of the company, in the supply chain, and in avoiding and preventing violations.

[27] GRI GS 103-1, 103-2, 103-3, 102-16.

Novartis' global policies and our internal acts clearly define the obligations arising from the duty to disclose conflicts of interest, prevent bribery and ensure compliance with applicable laws and internal rules.

We pay a lot of attention to education in the field of ethics, integrity and compliance. We organized e-trainings for employees on the Code of Conduct, reporting of adverse events, responsible procurement, conflicts of interest and information security. On average, more than 98% of employees successfully completed them. All these areas are, among other things, part of the regular induction program for new employees. We also conducted a series of targeted training in areas such as personal data protection, prevention of bribery and cooperation with third parties, reporting and investigations of inappropriate practices, professional practices of drug advertising and interactions with the professional public and application of fair competition rules.[28]

Numerous topics in the field of compliance and ethics were also discussed in regular articles in our internal newspaper Kolektiv. Employees thus deepen their knowledge of the principles of integrity and consistent behavior, and incorporate them into their daily lives.

In 2019, more than 98% of employees successfully completed the online training on the Code of Conduct, responsible purchasing, reporting adverse events and personal data protection.

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 kinds of teams are more creative and successful in facing challenges and makes work more stimulating and interesting.

In 2019, 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]

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

Public disclosures of payments made to doctors and health organisations

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 (Medicines for Europe) 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.

The commitment to respect human rights in business was signed on behalf of Lek by Ksenija Butenko Černe, a member of the Board of Management.

3.2 Cooperation with contractors

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 within Novartis' business 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

[28] GRI GS 412-2.
[29] GRI GS 406-1.
[30] GRI GS 206-1.
[31] GRI GS 102-9, 102-10.

responsibilities are outlined. 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 2019, we further improved our partnership with service centers and continued to search for additional savings in all purchasing categories (direct and indirect).

In 2019, the purchase value increased in both direct and indirect purchasing and totaled 727 million USD (647 million Euros)[32], of which 304 million USD (270 million EUR) was indirect purchase and 423 million USD (376 million EUR) 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 for Direct Purchases were still Switzerland, Slovenia, Germany, China and India. In the field of Indirect Purchases, the largest markets were Slovenia, Germany, Italy, the USA and Austria.

647 million EUR

Total purchase value in 2019.

Supplier audit procedures[33]

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.

In 2019, the Novartis Code of Conduct for Third Parties came into force, upgrading the Novartis Supplier Code. The Code combines the risk assessment in dealing with third parties into a unified framework that enables coherence, consistency and greater transparency. It further describes the areas of quality assurance and trade sanctions and import controls, as well as an updated topic describing the area of responsible use of minerals.

At Novartis, we have set ambitious environmental goals that we want to achieve by 2030, and we expect the help and support of our third party contractors. At Lek, we encourage third parties to adhere to the social and environmental values of the United Nations Global Compact. We expect them to adhere to the standards of our Code. We also expect them to enter into agreements with their suppliers that reflect the same principles. The Code complies with the principles of the pharmaceutical industry for responsible supply chain management related to ethical values, employee rights, health and safety, environment, animal welfare, prevention of corruption and fair competition, protection of privacy and data, responsible use of minerals, quality assurance, problem reporting and appropriate management systems.

Compliance with the standards in the Code of Conduct for Third Parties is one of the evaluation criteria in the selection and evaluation procedures of Novartis for third parties. Preference is given to contractors with the same social and environmental values.

We strive for further improvements through mutually constructive cooperation with third parties. This may include reviews, monitoring of developments and progress of corrective action plans, referral of third parties to external experts and other reasonable improvement plans.

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 co-operate mainly with local suppliers.

In 2019, the share of Slovenian based suppliers amounted to 293 million USD (261 million Euros) or 40.2% of total purchasing cost. In terms of number, Slovenian suppliers represented as much as 62% of all our suppliers.

In the composition of direct purchasing by country, Slovenia accounts for a 15.6% share (66 million USD or 59 million EUR) and 74.5% share (227 million USD or 202 million EUR) in indirect purchasing.

62%

of all our suppliers are from Slovenia.

[32] Data is converted into EUR according to the reference exchange rate of the ECB from the Bank of Slovenia's website as of 31st December 2019

[33] GRI GS 103-1, 103-2, 103-3, 308-2, 414-2.

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

- 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 is a company 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 ISO 14001 standard, and ISO 45001 occupational safety and health standard, and the Responsible Care Initiative for the chemical industry, coupled with the EMAS Eco-Management Scheme.

Our key guidelines are:

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

[35] GRI GS 102-11, GS 103-1, 103-2, 103-3.

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]

SComplying 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 external contractors 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 IPPC permits also cover the release of greenhouse gases from cooling devices, whereas these types of emissions at the Ljubljana and Prevalje sites are included in permits dealing with atmospheric emissions. All Lek sites comply with the Decree on Limit Values for Atmospheric Emissions of Volatile Organic Compounds from Installations Using Organic Solvents. As a low-risk source, the Mengeš site is obligated to adhere to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences.

New legal and other requirements are promptly and efficiently transferred in our work processes and practices. Authorized persons for HSE actively monitor and identify them, 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.

We require external service providers to have at least equivalent work programs, which in practice means, in addition to meeting legal requirements, also proving the provision of measures from the established conformity assessments.

In 2019, we had 12 inspections, eight of which were environmental; two biosafety inspections, two inspections of the adequacy of usable permits for facilities, two inspections were by the Ministry of Infrastructure (Energy and Electricity), one review of fire safety and from chemical safety. None of the sites were any non-compliances found, due to which a decision would be issued with the payment of a fine, and all regulatory measures were implemented within the prescribed deadline.[38]

In 2019, we were also involved in operation and product quality control inspections (e.g. JAZMP, FDA…), namely in the field of health inspections and waste management.

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

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

[37] See glossary on page 91.

[38] GRI GS 307-1.

ways to safely store raw materials and products on-site and are thus strictly adhered to.

Environmental permits and their amendments at all 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.
- Decision amending the environmental permit for the Ljubljana site regarding emission substances into water and air, permit no. 35440-2/2019-4, dated 23 May 2019.
- 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.
- 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. 35530-29/2019 (concerning no. 35536-19/2011), and dated 12 March 2019.
- 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
- Permit for groundwater research no. 35505-69/2019, dated 24 July 2019.
- 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).

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, over which we have direct management control, as well as the effects resulting from the company's connections with third parties. All direct and indirect environmental aspects with a significant impact on the environment are covered in the register of aspects.

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.

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.

In 2019, we were not charged with any penalties or non-monetary fines for non-compliance with environmental laws.[39] Our responsible management policy of environmental impact requires us to constantly identify potential risks to the environment. 67 cases were identified however once we gave detailed responses only 7 were seen as having an actual impact on the environment. In six cases, they were seen as only short-term (half hour) breaches of the air emission parameters (about 17,520 continuous air emission measurements are carried out annually). The remaining case was for a breach in a water emission parameter. All cases were handled immediately and in accordance with environmental legislation including notifying the competent inspectorates. The latter found that no environmental damage had been caused and therefore did not prescribe additional measures. We also received two enquires and simultaneously initiatives from the public which are outlined under Chapter *2.2.1 along with the measures 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.

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. In 2019, Mengeš underwent a significant portfolio change; we eliminated several long-selling products from production, introduced new ones to existing production lines and increased production capacity for some current products by optimizing processes.

4.1.2 Environmental protection investments and achievements[40]

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 2019 is 3.3 million EUR.

[39] GRI GS 307-1.

[40] GRI GS 103-2.

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.

Major projects in the area of environmental protection in 2019 were:

Lendava

- installation of additional closed circuit cooling systems,
- installation of a cooling tower to undercool water and thus reduce the need for the operation of the free cooling unit. As a result, electricity consumption is reduced,
- change in the fermentation broth production process of fermentation broth with electricity savings (feeding),
- reduced consumption of natural gas at the incinerator due to additional solvent regeneration in production (the project was implemented in 2018, with results shown in 2019),
- introduction of additional regeneration of isopropanol, thus reducing the consumption of this solvent and anti-foaming agent at the fermentation plant (the project was implemented in 2018, with results shown in 2019).

Ljubljana

- optimization of HVAC systems,
- replacement of lighting (LED lights) in the installation floor of the production facility,
- optimization of softener devices,
- reuse of wastewater in the preparation of demineralized water in non-production facilities, reuse of wastewater in the preparation of WFI water (water for injections),
- project of returning steam condensate to Energetika Ljubljana.

Prevalje

- optimization of preheating industrial hot water,
- optimization of HVAC systems,
- optimization of ECO1 steam boiler operation - utilization of waste heat.

Mengeš

- connection of production waste streams with storage facilities for co-incineration and optimization of co-incineration of waste solvents,
- introduction of saving measures of drinking water, such as reduction of flushing water volumes on toilet bowls, replacement of aerators on water taps with low-flow ones.
- With these measures, we have further reduced the use of drinking water at the site,
- diversion of non-contact water from fermentation plant into the cooling wastewater channel.

4.1.3 Verification of established standards[41]

We constantly ensure that we comply 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 Health and Safety System ISO 45001:2018. The latter replaced OHSAS 18001. The new standard emphasizes strict compliance with legislative requirements, cooperation with employees and requires management to establish a good safety 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 2020 that data and information in the Lek d. d. Sustainability Report 2019 gives 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 2019 (JAZMP, FDA, suppliers, etc.).

4.1.4 Key projects

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 includes 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. In 2019, we received/ renewed 25 certificates for Ex equipment maintenance.

[41] GRI GS 103-2.

LOTO

As part of the LOTO – LockOut/TagOut activities, we placed even greater emphasis on training staff in the proper use of LOTO procedures in handling equipment during maintenance work and handling hazardous energies. 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 at all sites. The trained staff received a certificate of competence for work in accordance with the LockOut/TagOut standard and the internal Novartis Regulation.

NOSSCE – Novartis Operational Standards for Supply Chain Excellence

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. 2019 was a turning point in the NOSSCE project as almost all sites were certified, with some being certified at the beginning of 2020.

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. Read more in *3.2 Cooperation with contractors*.

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 *4.9.3.2 Distribution*.

We restrict transport by using more frequent teleconferences and video conferences 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 168 company cars were in use in 2019 (155 in 2018). A total traveling distance of 7,870,027 km (5,317,326 km in 2018) was recorded, with fuel consumption of 359,666 liters (244,407 in 2018). In addition to company cars, we had 17 other vehicles (fire engines, forklifts). Together all vehicles released 1,004 tons of CO_2 emissions (692 in 2018).

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]

At Lek we strive for 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.

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.

In 2019, we increased the use of raw materials by 3% with a 2% decrease in the volume of production. The largest reduction was seen at the Prevalje site (by 9% with a 5% decrease in production), followed by Ljubljana with a 7% decrease (with a 4% decrease in production). At the Mengeš location, we increased the use of raw materials by 7% (with 16% increased production), and in Lendava by 4% (with 3% lower production).

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

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

Annual mass flow of various material used* [44]

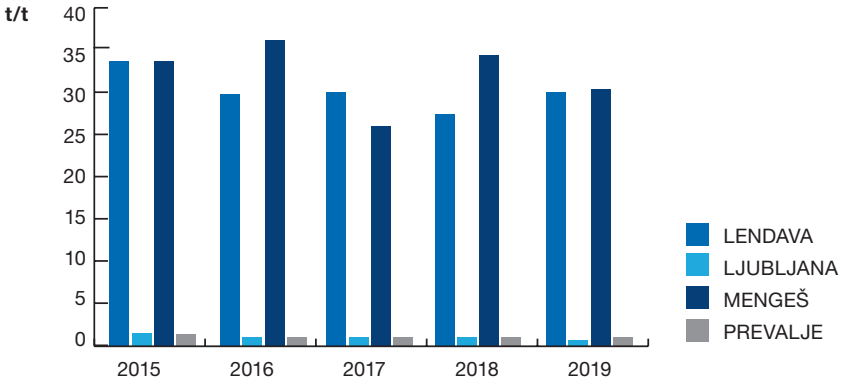
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2015	t	9,107	3,413	15,779	1,939	30,239
2016	t	8,803	3,484	15,261	1,861	29,409
2017	t	8,740	3,379	13,043	1,879	27,041
2018	t	8,549	3,324	14,253	1,998	28,125
2019	**t**	**8,910**	**3,097**	**15,225**	**1,814**	**29,046**

* 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).

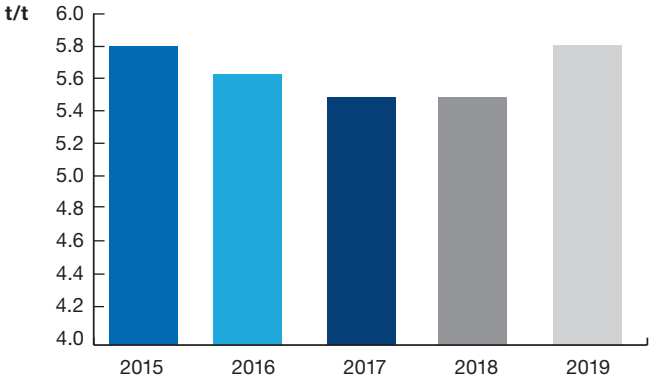
4.2.2 Efficiency of materials

The efficiency of the use of raw materials of the quantities of materials is given by the indicator of the consumption of raw materials per unit of the product. 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 2019 stayed the same as in 2015.

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

Lek's environmental sustainability efforts also include the use of packaging that must be made from as natural materials as possible and designed efficiently. It must meet relevant market criteria, meet product and consumer requirements and be affordable. It must be environmentally friendly throughout its life cycle, so it is important that it is handled correctly and responsibly even after use.

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.

In 2019, Solids Lendava began returning used 50 l barrels to the raw material supplier. The packaging, which would otherwise have become waste, was redirected for reuse by a related Lek company and used for a specific purpose.

When planning the standardization of the Euceras/Galvusmet product, Solids Lendava also managed to reduce the size of the blisters, thus indirectly reducing the consumption of materials. At the annual level, they saved 13t of plastic foil and 1.5t of aluminum cover foil. At the same time, they also saved 285 GJ of energy and 195,000 liters of water, which would be needed for the production of aluminum cover foil, and another 13.5t of CO_2 air emissions.

4.3 Energy

4.3.1 Energy consumption

In 2019, total energy consumption amounted to 1,344,882 GJ and was 0.42% higher than in the previous year. The increase is due to newly built or expanded plants and an increase in the production of more energy-intensive products. To increase energy efficiency, we prepared and implemented several projects at all sites and saved 44,434 GJ (3.3%) of energy or reduced CO_2 emissions by 3,173t.

Lendava (by 0.33%) and Prevalje (by 0.42%) decreased their total annual energy consumption, while Mengeš (by 1.66%) and Ljubljana (by 0.33%) increased their energy consumption compared with 2018.

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
2019	**GJ**	**469,189**	**442,506**	**370,440**	**62,747**	**1,344,882**

* The table covers all fuels / energy sources that entered the processes of energy use, which we corrected in the totals for previous years as well. Energy obtained from biomass in Lendava and Mengeš and waste solvents in Lendava were added. Due to the transition to the calculation with the upper calorific value, the data are shown for the last four years.

At the Mengeš site, we use waste solvents as a secondary fuel for the operation of a steam boiler that produces heat and steam for technological purposes. This reduces the consumption of natural gas by about 25% per year, which is the same as for heating used by 850 average Slovenian households. The share of renewable energy sources at the Lendava site is up to 1%, and they are obtained by burning organic waste from fermentation production (biomass).

[46] GRI GS 302-1.

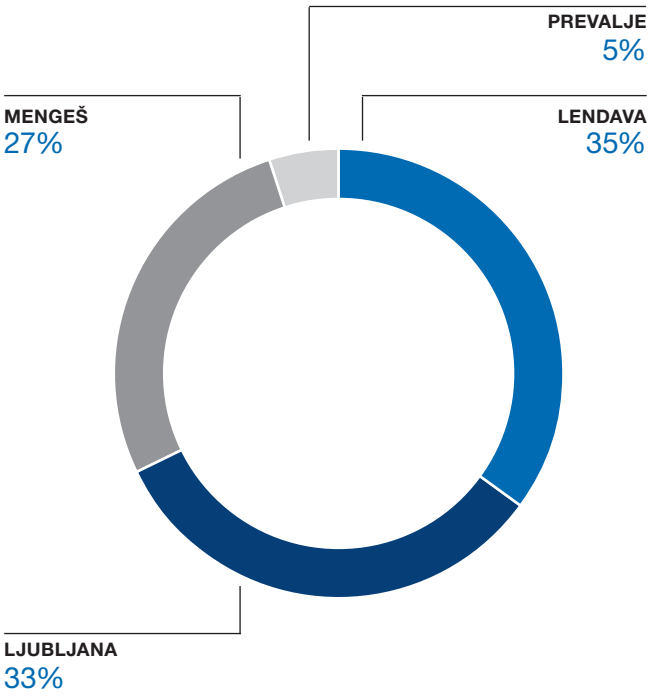
Energy used from waste solvents at Lendava and Mengeš

Year	Unit	Lendava	Mengeš	Lek (total)
2016	GJ	13,881	52,546	66,427
2017	GJ	4,658	57,082	61,740
2018	GJ	26,578	50,441	77,019
2019	**GJ**	**30,364**	**63,542**	**93,906**

Energy used from biomass at Lendava

Year	Unit	Lendava
2016	GJ	4,500
2017	GJ	4,191
2018	GJ	4,612
2019	**GJ**	**3,417**

Energy distribution by site



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

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

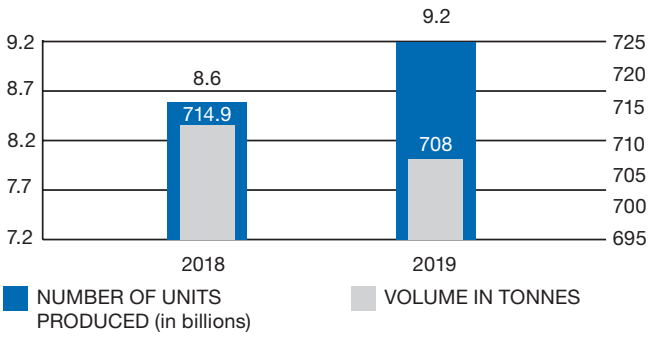
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2016	GJ/t	1,489	151	835	45	252
2017	GJ/t	1,485	169	734	45	269
2018	GJ/t	1,538	155	846	41	262
2019	**GJ/t**	**1,580**	**161**	**743**	**43**	**268**

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

The total efficiency of energy use decreased by 2.3%, but we must take into account that the company has very diverse types of production units and their product portfolios at sites, which are produced annually in different quantities. From products that are produced in a few kg per year, to those where annual quantities exceed hundreds of tons with similar or even lower energy consumption. Below are some examples of how different types of production contribute to total volumes produced and how to total energy use.

In the case of a production unit with a large number of products and also a large number of pieces, the total volume in tonnes decreased by 1%, despite a significantly higher number of units produced (by 6.8%). The energy consumption of the production unit increased due to the higher number of units produced (as did some other indicators, such as the consumption of packaging), despite the fact that the volumes were lower.

An example of production with large quantities of products with different volumes



Energy used per employee*

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2016	GJ/employee	980	235	374	271	363
2017	GJ/employee	908	217	344	253	340
2018	GJ/employee	824	205	332	246	328
2019	**GJ/employee**	**707**	**192**	**331**	**253**	**302**

* Data is recalculated according to the number of full-time employees at Lek as of 31 December and does not include contractual or external contractors.

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[48]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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
2019	**GJ**	**229,513**	**175,873**	**129,703**	**23,980**	**559,070**

Electricity consumption increased by 0.1% in comparison with the previous year.

[48] GRI GS 302-1.

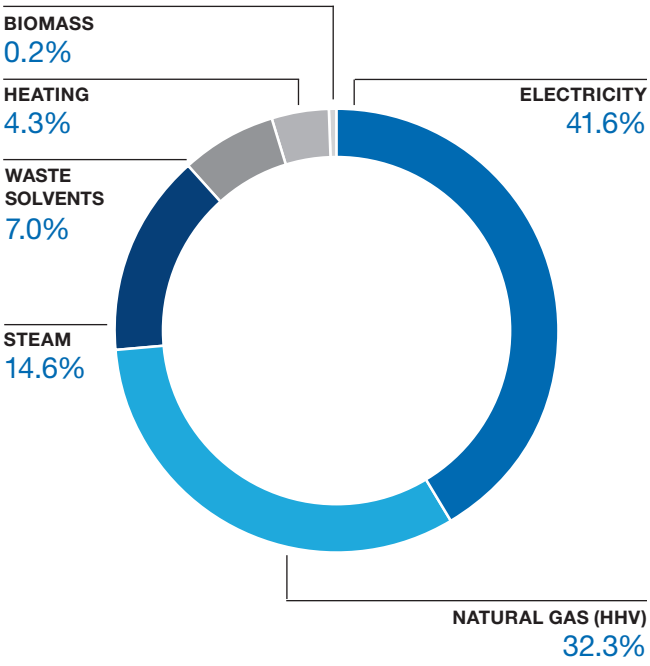
4.3.2 Distribution of energy sources

In the structure of purchased energy sources, electricity accounts for the largest share with 42%, followed by natural gas with 32%. 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 7%. We can replace more than 25% of the energy needed with waste solvents only at the Mengeš site for steam production.

The share of renewable energy sources at the Lendava site is 1%, they are obtained by burning organic waste from fermentation production.

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 2019, additional projects were carried out to improve energy efficiency, generating energy savings of 44.4 TJ, with which reduced CO_2 air emissions by 3,173 tons. In total, we thus saved 3.3% of total annual energy consumption.

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.

For the Mengeš site, we developed an environmental strategy for sustainable development until 2025, which envisages a 50% reduction of non-recycled waste and contact water and sets out measures to reduce the carbon footprint in order to achieve carbon neutrality by 2025.

With a similar approach, environmental strategies for the Ljubljana and Lendava site are being prepared.

With measures to improve energy efficiency, we saved a total of 44.4 TJ of energy, thus reducing CO_2 air emissions by 3,173 tons.

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

Energy and greenhouse gas savings by site 2019

Indicator	**Lendava**	**Ljubljana**	**Mengeš**	**Prevalje**	**Lek** (total)
Annual energy savings from energy projects (in GJ)	17,515	16,632	8,771	1,516	44,434
Annual reductions in greenhouse gases thanks to energy projects (in tCO_2)	1,024	1,542	516	91	3,173

These results were reached with the following projects:

- **Lendava:**
  - optimization of the incinerator filling process - less cooling and ventilation required,
  - use of free cooling,
  - optimization of cooling system,
  - combustion optimization - fuel optimization - ecological columns.

- **Ljubljana:**
  - comprehensive inspection and repair of compressed air distribution,
  - comprehensive inspection and repair of the steam distribution system,
  - change in the level of humidity in HVAC systems in the production of solid products,
  - more optimizations run via AcEM for power systems.

- **Mengeš:**
  - improved cascade control of steam boilers,
  - steam condensate system inspection - improved condensate return ratio,
  - seasonal adjustments/settings of humidity level and temperature in HVAC systems,
  - replacement of the refrigeration unit - better efficiency of the refrigeration station,
  - inspection and repair of leaks on the compressed air system in several buildings,
  - more optimizations run via AcEM for power systems.

- **Prevalje:**
  - preheating of technological hot water,
  - HVAC system optimization,
  - improved efficiency of the compressed air system,
  - optimization of steam boiler operation ECO1 - waste heat utilization,
  - more optimizations run via AcEM for power systems.

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. Water consumption (water for process purposes and cooling water) was reduced by almost 2% in 2019, but at the same time the efficiency of its use was reduced by less than 1%, mainly due to the already mentioned disparities in the reporting of environmental indicators.

Water use in 1,000 m³ [51]

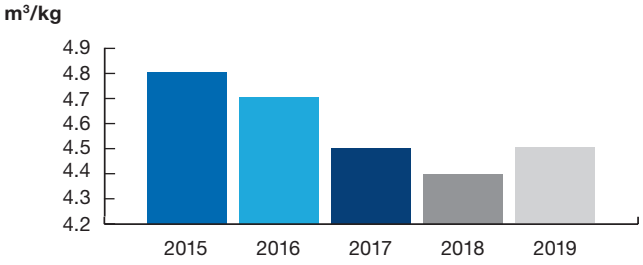
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2015	1,000 m³	1,315	569	1,627	42	3,553
2016	1,000 m³	1,304	588	1,433	36	3,361
2017	1,000 m³	1,323	574	1,488	37	3,422
2018	1,000 m³	1,347	605	1,490	37	3,479
2019	**1,000 m³**	**1,337**	**574**	**1,475**	**40**	**3,425**

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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
2019	**m³/t**	**1,135**	**209**	**614**	**27**	**251**

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

Water consumption per kg of product at the Lendava site



[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. Based on all data, we determine the angles of groundwater levels, their direction and gradient.

In Mengeš, the groundwater level in 2019 was around average or slightly below average. A smaller rise in groundwater was detected in June due to heavy rainfall at the end of May. Due to the above-average November precipitation, there was a sudden rise in levels in December. Monitoring of groundwater levels in Mengeš indicates a slow emptying of the hydrogeological basin of the Kamniška Bistrica valley and its filling with precipitation (large catchment area), which confirms the very large dynamic reserves of the Mengeš 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 15m.

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).

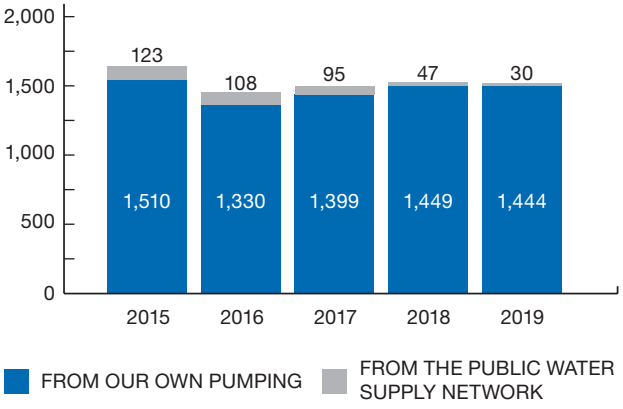
Water supply quantities and sources at the Mengeš and Lendava sites[54]

Mengeš	2015	2016	2017	2018	2019
From our own pumping station (in 1,000m³)	1,510	1,330	1,399	1,449	1,444
From the public water supply network (in 1,000m³)	123	108	95	47	30

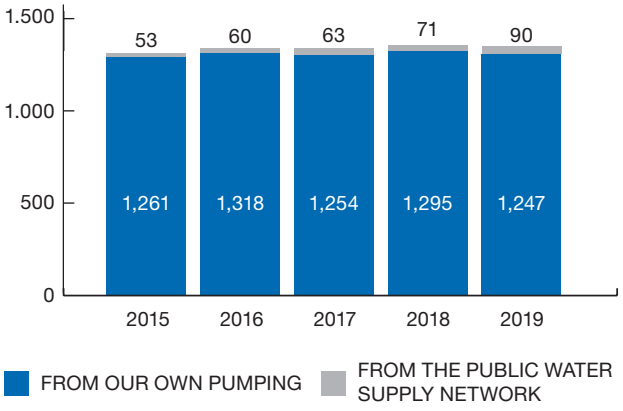
Lendava	2015	2016	2017	2018	2019
From our own pumping station (in 1,000m³)	1,261	1,318	1,254	1,295	1,247
From the public water supply network (in 1,000m³)	53	60	63	71	90

In five years, we reduced the use of water from the public water supply system by 75% and water from our own pumping station by more than 4% in five years. In Lendava, due to increased production of solid products and the introduction of a more energy-efficient fermentation production process, the use of drinking water increased by 27% compared to 2018 and the use of water from our own pumping station decreased by 4%.

Water supply quantities and sources at Mengeš in 1,000m³



Water supply quantities and sources at Lendava in 1,000m³



In compliance with the IED Regulation 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.

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

[54] GRI GS 303-3.

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 the cooling process. The share of recycled water is constantly being increased, mainly at the Mengeš site.

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

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]

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.

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, which emphasizes the prevention of waste generation. Where this is not possible, it provides preparation for reuse, recycling or processing with other processes. 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.

More than 91 % of all generated waste is recycled, and their share stays at the same level as the year before.

The quantities of mixed municipal waste were reduced at all sites, with the exception of Mengeš. In Ljubljana they were lower by 2%, in Prevalje by 12% and in Lendava by 15%, mainly due to greater control over the waste of construction contractors on site. In Mengeš, they increased by 16%.

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 biodegradable 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.

86% of all waste in Mengeš is hazardous waste, of which 94% is non-halogenated waste solvents. In 2019, in two steam boilers, we processed 28% more high-calorific waste solvents into the energy used for the preparation of technological steam. 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.

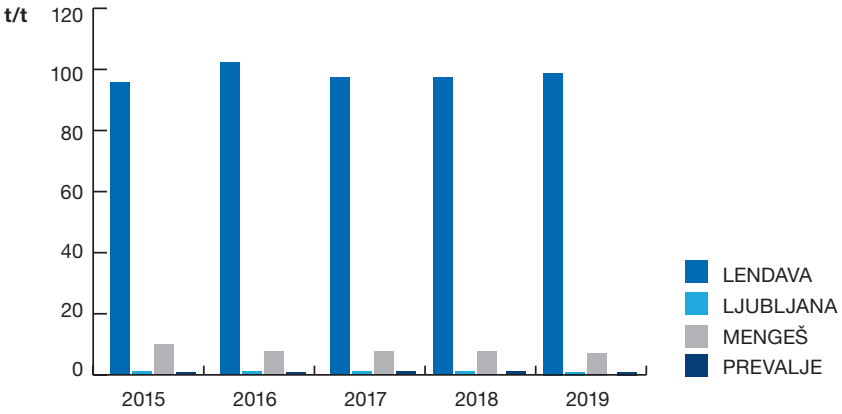
Due to the increase in production and changes in capacity compared to the product portfolio in Mengeš and due to the changed process of fermentation production in Lendava, the amount of waste produced in 2019 increased by more than 6%. The Prevalje and Ljubljana sites show a decrease in the amount of all waste; Ljubljana by 9% and Prevalje by 7%.

Volumes of waste generated

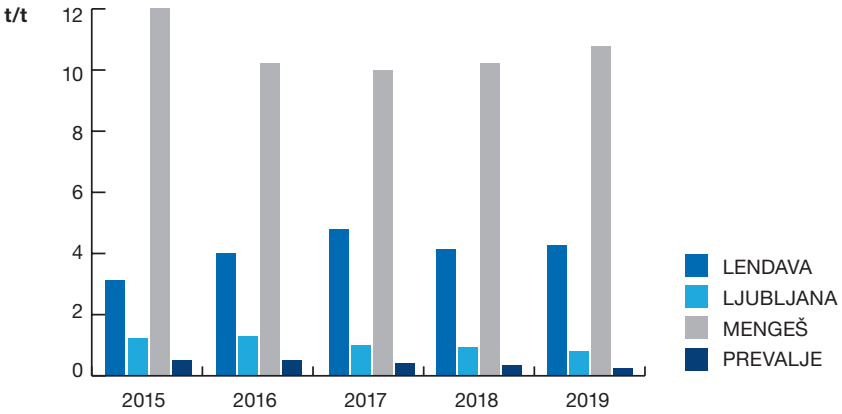
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2015	t	25,588	2,748	5,692	766	34,794
2016	t	28,862	3,010	4,597	800	37,269
2017	t	27,856	3,305	5,010	827	36,998
2018	t	28,727	3,156	4,493	784	37,160
2019	**t**	**30,407**	**2,872**	**5,524**	**731**	**39,535**

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

Volumes of waste per ton of product – efficiency



Volume of waste per ton of product – efficiency/without mycelium waste



4.5.2 Disposal of hazardous waste[56]

A large part of our environmental efforts is to prevent and reduce the generation of hazardous waste. In doing so, we also strive to continuously increase their share for recycling or energy use. Nevertheless, due to the increased volume of production in Mengeš, the amount of hazardous waste in 2019 increased by 13%. The Ljubljana and Lendava sites significantly reduced the amount of hazardous waste (by 13 and 67%), while Prevalje increased it (by 19%). This reduced the efficiency of hazardous waste management by 16%.

In the data for the Lendava site, we must take into account that with the expansion of the production of solids, the quantities of waste also increased, but their quantitative realization is not taken into account and thus is not shown in the calculations of efficiency of individual indicators.

In 2019, we processed and reused a good 86% of all organic solvents. In Lendava, the share of reused organic solvents is 97.5%, in Mengeš the share of reuse is on average 64%, and in some processes this share is more than 95%.

At the Mengeš site, high-energy waste solvents represent 94% of all hazardous waste. By co-incineration with natural gas, we removed 2,018 t of waste solvents, which is equivalent to 25% of the primary energy for steam generation to supply the processes with energy.

At the Ljubljana site, more than 70% of the total amount of waste is non-hazardous waste, among which packaging predominates. Among hazardous waste, the most important in terms of quantity are waste from production and expired products or medicines returned from the market.

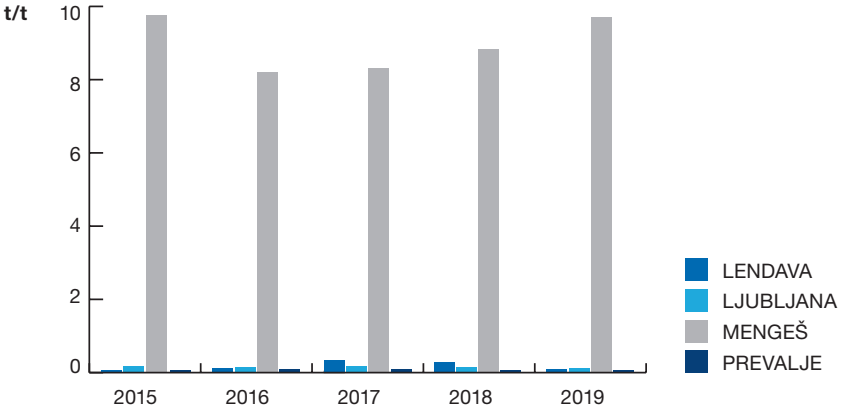
[56] POR OI 5, GRI GS 306-2.

Quantity of hazardous waste*

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (total)
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
2019	**t**	**61**	**784**	**4,777**	**229**	**5,851**

* The data shows the quantities of hazardous waste that we handed over to external authorized contractors. However, the quantities of hazardous waste that we process ourselves by incineration or co-incineration at sites are not included, but the emissions that occur are recorded. Otherwise, the consequences of their removal, which occur once, would be recorded twice. In accordance with its methodology, we report to the ARSO Agency on all generated waste, regardless of how it is disposed of and where the related emissions are generated.

Quantity 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, mostly Lendava mycelium waste and the Lendava Treatment Plant sludge. Biodegradable waste also includes waste from tea kitchens. Biodegradable waste is handed over to biogas plants, where biogas is produced from various organic substrates and waste. Electricity produced in biogas generators with a high percentage of methane is one of the renewable energy sources.

Municipal waste accounts for less than 0.5% of all waste. In 2019, their quantities were increased by 1%, mainly due to increased municipal waste at Mengeš. All the other sites recorded reduced quantities mainly due to increased control over the handling of waste by construction contractors.

Packaging accounts for 9% of waste and is recycled in sections (paper, plastic, wood, metal, glass). In 2019, we reduced this by 5%. We mainly recycle waste packaging (through the Gorenje Surovina system), and the same applies to construction waste. Other non-hazardous wastes are disposed of by authorized companies by means of incineration.

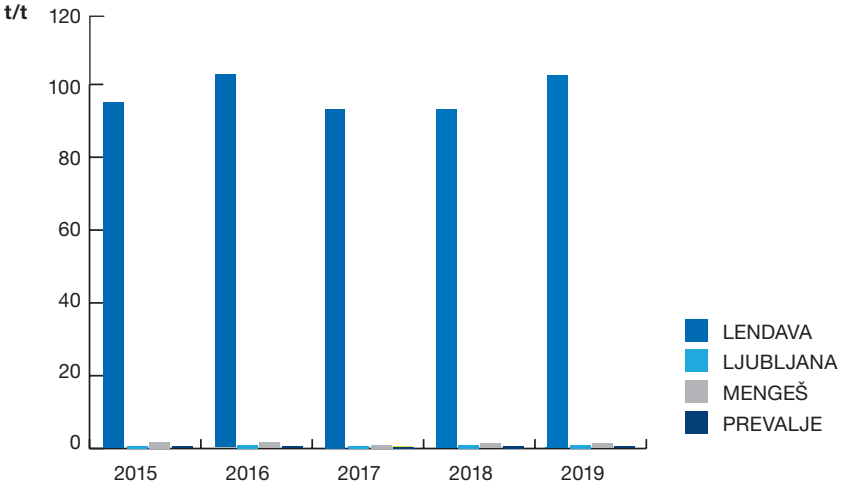
The amount of non-hazardous waste increased by 5% in 2019 due to increased quantities of mycelium waste at Lendava and consequently increased production in Mengeš. Efficiency – the amount of non-hazardous waste per tonne of product – has consequently decreased by 8%.

Quantity of non-hazardous waste by site

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (total)	**Lek** (recyclable non-hazardous waste without packaging)
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
2019	**t**	**30,346**	**2,088**	**747**	**502**	**33,684**	**29,950**

[57] GRI GS 306-2.

Quantity 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 chapter *4. Compliance with legislation and standards in the field of 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.

At Lek, we closely monitor air emissions, both organic and inorganic pollutants, as we are aware that they can lead to acid rain and smog, with a detrimental impact on human health, the natural environment and also on cultural, historical and economic values.

Inorganic air pollutants such as sulphur dioxide (SO_2) and nitrogen oxides (NO_x) contribute the most to the formation of acid rain. Air pollutants such as particulate matter, volatile organic compounds (VOCs) and NO_x, along with sunlight, are precursors to ozone generation and the formation of smog and consequent associated environmental impacts.

At Lek, we monitor greenhouse gas emissions and emissions from stationary devices separately. Among them, the emissions of volatile organic compounds (VOC) and dust are central. Measuring points for sampling for analysis and measurement of the content of substances and / or dust in the air are located on technological devices and lines, where the emission of volatile organic substances, dust particles or other substances is expected in the exhaust air.

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.

The compliance of total VOC emissions with the emission limit value, expressed as a percentage of organic solvent input, is demonstrated on the basis of the results of periodic measurements, solvent balance, assessment of diffuse emissions and other data. For new installations, the emission limit value is 5%, and for existing installations 15%, depending on the solvent input to the installation. VOC emissions in the captured waste gases shall not exceed the concentration limits of 20mg C/m^3.

We also maintain compliance with the limit value for total dust of 150 mg/m^3. For a mass flow rate of total powder exceeding 0.2kg/h, the limit value is 20mg/m^3.

In the case of thermal combustion plants, in addition to VOCs, expressed as total carbon (TOC), we also measure emissions of nitrogen oxides and carbon monoxide (MV = 100mg/m^3). The operation of these devices according to the mentioned parameters is also legally compliant.

4.6.1 Emissions from incinerators and co-incinerators

Incineration of waste is carried out in Lendava, co-incineration in 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 of energy. Emission monitoring is regularly performed at all the emission release points by external authorized institutions.

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

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 of product)
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	0.0258*	0.0062	0.0560*	0.0109*
2019	t	0.0000	0.0120	0.0000	0.0069	0.0189	0.0038

* Amendment to quantity released for Mengeš 2018.

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 and burning devices. The production of nitrooxoline in Mengeš, which was also a small source of nitrogen oxides in the past, was discontinued in 2019.

Regular emission checks are carried out at all sites. The total amount of these emissions decreased by 13% in 2019, to which the locations of Ljubljana and Mengeš contributed. NO_x levels in Lendava remain at the level of 2018, while in Prevalje they increased by 8%.

Nitrogen oxide emissions (NO_x)[60]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t NO_x/t of product)
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	16.20*	2.47	38.18*	0.008*
2019	t	17.28	1.14	12.26	2.68	33.36	0.007

* Amendment to quantity released for Mengeš 2018.

[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 emissions (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 (total)	Efficiency (Lek) (t CO_2/t product)*
GHG1	2015	tCO_2	10,591	2,737	15,429	2,109*	30,866	5.9
	2016	tCO_2	11,642	3,118	14,375	2,032	31,168	6
	2017	tCO_2	12,161	2,610***	14,146	2,097	31,015***	6.3***
	2018	tCO_2	13,213*	2,260	13,916*	1,846*	31,236*	6.1*
	2019	**tCO_2**	**13,692**	**2,569**	**14,627**	**1,944**	**32,832**	**6.6**
GHG2	2015	tCO_2	1,672	26,675	1,033	234	29,613	5.4
	2016	tCO_2	0**	26,743**	0**	0**	26,743**	6
	2017	tCO_2	0***	25,911***	0***	0***	25,911***	5.3
	2018	tCO_2	17,066	39,047	9,432	1,940	67,484	13.2
	2019	**tCO_2**	**16,961**	**39,275**	**9,585**	**1,772**	**67,593**	**13.5**

* Corrected values due to incorrect use of emission factors for natural gas (HHV/LHV energy ratio). No additional gas emissions (HFCs) were included for Mengeš.

** Purchase of green certificates for 2016 in the total value of CO_2 emissions from electricity, and CO_2 at the Ljubljana site 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.

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 kg CO_2/kWh). The ratio between lower and upper heating value (LHV/HHV) for calculations and reporting by Lek d. d. is 0.90265 kWh/kWh.

The total amount of direct greenhouse gas emissions (GHG1) is 5% higher than the previous year.

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.

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. The decision by Novartis not to purchase certificates of origin for the consumed electricity for the Lek sites for 2018 and 2019 has a significant impact on the total CO_2 emissions (GHG2). In the calculation and reporting for the period from 1 January 2018 to 31 December 2019, the value of 0.0739 tCO_2/GJ or 0.26604 kg/kWh, as determined by the Novartis guidelines for Slovenia.

[61] Indicator POR OI 10.

[62] Indicator POR OI 11.

[63] Indicator POR OI 12.

[64] Indicator POR OI 13.

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

4.6.5 Volatile organic compounds (VOC)[66]

Emissions of halogenated volatile organic compounds (VOCs) represent less than 1% of emissions of all VOCs, which was achieved by systematic replacement of halogenated organic solvents 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 2019, we increased the total emissions of volatile organic compounds by 18%, which is due to the increase in production capacity for some products that require greater use of organic non-halogenated solvents in Mengeš. In Lendava, a short shutdown of the RTO device due to the elimination of a fault on the device contributed to the increase.

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 21%.

Total emissions of volatile organic compounds

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (total)	**Efficiency (Lek)** (t HOS/t of product)
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	0.016
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
2019	**t**	**23.9**	**3.2**	**53.9**	**6.9**	**87.9**	**0,018**

4.7 Water releases[67]

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.

Wastewater is discharged into the public sewerage system via technological, cooling and municipal lines. Prior to the discharge of technological water into the sewage system, we have equalization pools at all locations. In Prevalje, technological wastewater is pre-treated before being discharged into the public wastewater system.

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

[66] POR OI 9.

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

At all sites we perform prescribed periodic monitoring of the parameters of individual wastewater flows, including the constant monitoring of the flow, pH and temperature of thewaste water. Monitoring is carried out by an authorized external contractor. The limit values are prescribed in environmental permit and can be expressed as the concentration of the substance, as the quantity of the substance per mass of the product or raw material (emission factor) or as the maximum annual permitted quantity of each discharged hazardous substance.

4.7.1 Waste waters

At Lendava and Mengeš sites 63% of the total quantity of water used is unpolluted waste water. In 2019, we reduced the use of water for cooling purposes by 5%, and the use of industrial water increased by 4%, mainly due to the Lendava location, where an energy-optimized production process was introduced.

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

Waste water volumes by discharge quality and destination[68]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
Use of cooling water – unpolluted							
	2015	1,000m³	1,137	33	1,307	9	2,486
	2016	1,000m³	1,095	34	1,050	11	2,190
	2017	1,000m³	976	4.2	1,154	11	2,145
	2018	1,000m³	1,068	36	1,159	9	2,272
	2019	1,000m³	1,000	0	1,169	0	2,169
Discharge			Into the surface water	Into sewage system cleaning at WWTP	Into the surface water course	into sewage system	
Use of industrial water – polluted							
	2015	1,000m³	177	536	320	33	1,067
	2016	1,000m³	209	554	383	25	1,172
	2017	1,000m³	347	570	334	26	1,277
	2018	1,000m³	279	569	331	28	1,207
	2019	1,000m³	337	574	306	40	1,257
Discharge			Into sewage system cleaning at WWTP	Into sewage system cleaning at WWTP	Into sewage system cleaning at WWTP	Into sewage system	

4.7.2 Phosphorus and nitrogen compounds and chemical oxygen demand

Emissions of phosphorus compounds in water are caused by residues of inorganic substances from fermentation production, most of them in Mengeš and Ljubljana. In 2019, we recorded a 28% increase in the quantities of such compounds compared to the previous year, which is still lower in absolute terms than in 2016 and 2017.

Emissions of nitrogen compounds in water also occur during fermentation production, and their largest share is at the Lendava site, followed by Mengeš and Ljubljana, while in Prevalje these emissions are negligible. The total amount of these emissions in 2019 decreased by 16%.

As the annual amounts of phosphorus and nitrogen compounds are reported after treatment in the wastewater treatment plant, they largely depend on the efficiency of the wastewater treatment. Wastewater from the Mengeš site is transferred to the Central Wastewater Treatment Plant Domžale-Kamnik, which 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, whilst at the same time presenting indicators.

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

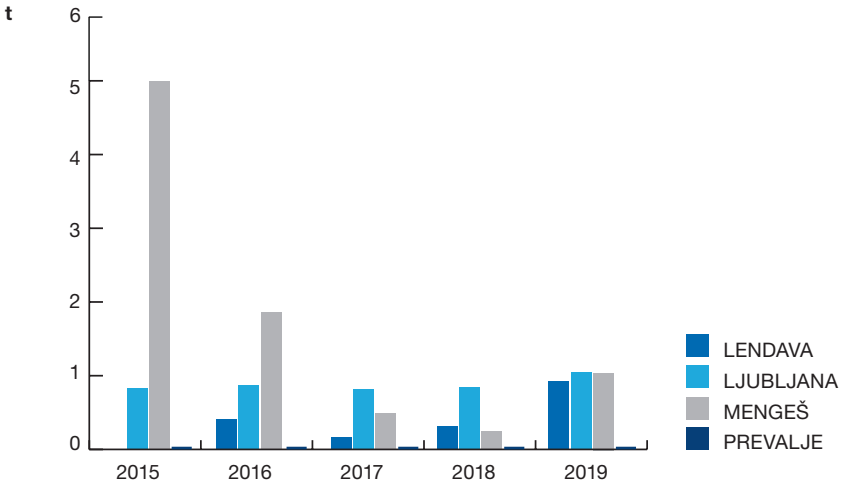
To provide an assessment of the level of pollution with organic impurities, chemical oxygen demand is an important parameter, providing the quantity of oxygen needed for chemical oxidation of organic pollution in wastewater. Chemical oxygen demand measurements are carried out at the point of discharge of waste cooling waters into the sewage system. In 2019, we recorded an increase in the chemical oxygen demand of 8%. Which is mainly due to the decrease in industrial water and therefore increase in the concentration of pollutants in the water at Mengeš.

The amount of wastewater from the production of finished products in Prevalje and Ljubljana is low, which is also reflected in the contribution of the chemical oxygen demand. The sites together contribute less than 5% of the total pollution of waste waters with organic impurities.

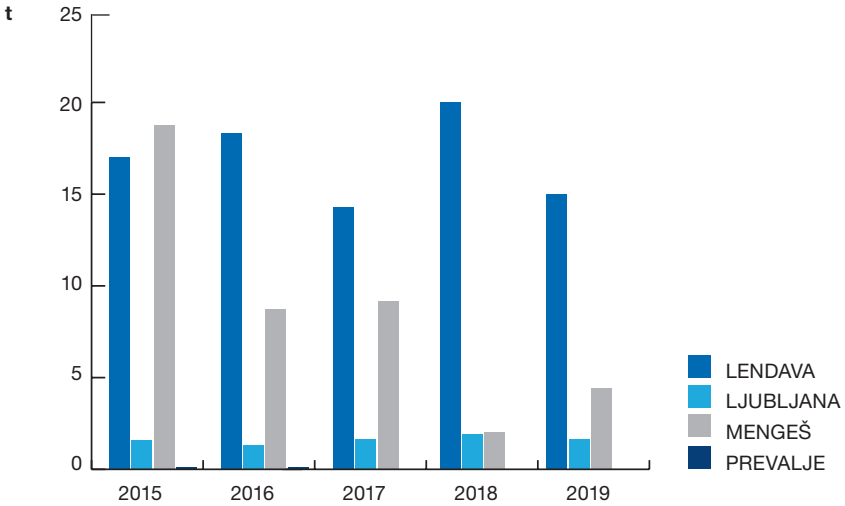
Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute parameters for the calculation of the environmental fee. The highest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds 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 twelve times a year, depending on the volumes of wastewaters at the respective site.

Emissions of phosphorous compounds in wastewater[69]

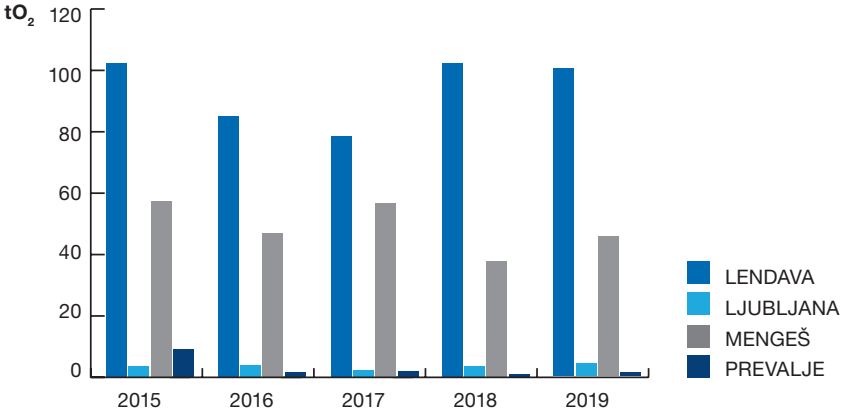


Emissions of nitrogen compounds in wastewater[70]



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

Chemical oxygen demand[71]



4.8 Other environmental impacts

4.8.1 Odor

The odor is triggered by various volatile substances, mostly of organic origin. The nature of the substance, the concentration and the time of their presence affect the perception of odor.

The area of environmental pollution with odors in Slovenia is not regulated, so there are no direct requirements in relation to odors in environmental permits. Nevertheless, we have installed biofilters in accordance with good practice in controlling the release of emissions into the environment in all places where disturbing odors could occur for people living in the immediate vicinity (e.g. above leveling pools) or gas washers (e.g. on fermenter discharges), and on devices for heat treatment of volatile organic compounds from production. At these sites, the National Laboratory for the Environment and Food (NLZOH) regularly monitors odor emissions. In addition to the aforementioned techniques, the method of waste management and the maintenance of cleanliness of the sites are of utmost importance for limiting the smell.

We did not receive any complaints regarding odor in 2019.

4.8.2 Soil

Soils are a non-renewable natural resource, so it is necessary to preserve their diversity, quality and ability to maintain ecosystems. Preventing soil pollution is crucial for sustainable soil management.

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.

Through regular safety walkthroughs, we monitor measures and influence employee behavior to prevent dangerous behaviors and conditions that could lead to incidents and soil contamination.

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

Excessive noise pollution due to device operation is prevented by careful planning of new projects and a number of preventive measures. During the preparation of the technical documentation for new projects, the authorized contractor must make an estimate of noise emissions on the basis of calculation methods using model calculations. Additional measures to reduce noise at existing sources

[71] POR OI 14.

are intended, despite the fact that the results of operational noise monitoring at all sites show that the prescribed limits have not been exceeded. Past experience has shown that noise pollution is not only affected by the intensity of the noise source and the distance of the receiver, but also by the frequency of the sound, weather conditions, sound reflection, etc.

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. Three out of four lek sites are located directly next to highways which increases the overall noise in the area.

In 2019 we received no noise complaints in Lek.

4.8.4 Biodiversity

Conserving biodiversity is extremely important for the stability of nature. Wildlife is a complex system that will probably never be fully explored, so it is important to preserve it, as we do not yet know all the consequences of reducing the diversity of animal and plant species. Important factors threatening biodiversity are pollution, intensive agriculture and the increase of urban areas. At Lek, we are aware that over-exploitation and economic activity can be a cause of biodiversity loss.

Lek's sites are located in industrial zones and not located in Natura 2000 natural value areas or in protected and other areas important for the conservation of biodiversity. We consistently meet all legal requirements, and with proactive measures in the field of environmental protection we reduce the impacts of our operations and contribute to the preservation of biodiversity in the vicinity of our sites.

Surface use by site[72]

	Mengeš	Lendava	Ljubljana	Prevalje	Lek (total)
Total site surface area with parking lots (m^2)	133,763	116,217	142,632	32,285	424,897
Of which green surfaces (m^2)	32,407	55,618	29,249	1,437	118,711

4.8.5 Light pollution

Artificial light sources raise the level of natural light in the environment, especially if light escapes uncontrollably outside the lighting targets. The consequences are glare, reduced night visibility, glowing night sky, negative impacts on the biosphere and increased energy consumption.

For companies and transport, the management of light pollution is a great challenge, mainly due to different legal provisions from different fields. The existing regulation on light pollution requires a reduced illumination of outdoor production areas and car parks, whilst minimum conditions of work standards dictates sufficient illumination.

In the past, with the help of external experts, we have conducted comprehensive light pollution control studies for Lek's sites with the aim of looking for technical solutions that enable compliance with regulations and meet the criteria and requirements for occupational health and safety. Outdoor lighting uses lighting with higher efficiency (LED), and at the same time reduces its operation during times of lower work needs. Restricting the operation of outdoor lighting and consequently reducing illumination in certain areas has forced us to strengthen the video surveillance system in certain places. We continue to use efficient LED lamps in all new projects, paying attention to the use of LED light spectra that do not harm wildlife.

The total electrical power of the lamps at any site does not exceed 50kW, 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.

4.9 Safety

4.9.1 Fire safety

We did not record any major cases at Lek's sites in 2019 in the field of fire protection. All sites regularly conduct fire drills, annual fire drills and evacuation drills.

Lek has three voluntary industrial fire brigades. PIGD Lek, which operates in Ljubljana and Mengeš, PIGD Lek Prevalje and PIGD Lek Lendava. Volunteer firefighters improved their knowledge at the Ig, Sežana and Pekre protection and rescue training centers. Our firefighters also perform intervention work in high-risk cases, such as work at height or work in confined spaces. We organized practical rescue training for them to ensure they are appropriately trained.

In 2020, we are planning at least one training for volunteer firefighters from Lek's sites at the Ig Protection and Rescue Training Center. Volunteer firefighters will also take part in training within the Fire Brigade Association of Slovenia.

We conducted regular annual evacuation drills at all sites. At the Lendava and Mengeš sites, a major rescue and firefighting drills took place according to several scenarios (NEM scenarios).

[72] EMAS Core Indicator.

In Mengeš and Lendava (pictured above) we carried out major rescue and firefighting drills.

In Lendava, we simulated a power outage and the associated power outage in the entire production, as well as a fire in a waste incinerator and the cessation of waste dosing. We also performed rescue from a height and technical rescue (traffic accident with a forklift driver).

4.9.2 Biological safety

In Lek, we work in different work processes with the biological factors of groups 1 and 2. Only group 1 organisms enter the production process, in which we use larger amounts of biological factors. 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. In most cases, effective prevention or treatment is available, and the risk of spreading to the environment is small.

The biosafety system is integrated in all levels of work and is linked to all relevant stakeholders. At the level of Novartis is recorded in an application, for the purpose of ensuring biosafety, 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.

We also strictly follow the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising out of their use. Lek does not use genetic materials that belong to the said protocol.

In 2019, a new production plant of biosimilar medicines was built at the Mengeš location, which was registered for the handling of GMOs of the 1st safety class. The plant became operational at the end of 2019 with the latest technology for the production of biosimilar drugs. We also reported to the Ministry of the Environment and Spatial Planning three expansions of closed systems for working with GMOs at the Mengeš site. One closed system was registered for work in the 2nd safety class.

Active substances in the environment
In Novartis' sustainability strategy, water quality is highlighted as the greatest asset, and special attention is paid to the handling of antibiotics. In addition to the annual risk assessment of active substances in the aquatic environment, we closely monitor discharges into water, introduce measures to reduce the release of antibiotics into water, and monitor the latest published studies.

4.9.3 Warehouse and distribution safety

4.9.3.1 Warehousing
Lek's safe storage is based on knowledge of the hazardous properties of chemicals and their compatibility. 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. In accordance with the stability conditions, we introduced the highest technical and safety measures to maintain the quality of chemicals used in production. The contractual partner, Kuehne + Nagel, has also introduced the highest standards of safe storage of chemicals, which ensure that Lek maintains the quality of raw materials, semi-finished and finished products and distributes them to pharmaceutical production and customers.

In 2019, a total of 5,512t of dangerous goods were shipped from Lek's production warehouses.

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). Lek's Safety Adviser for the Transport of Dangerous Goods is responsible for updating knowledge and constantly monitoring the implementation of requirements in the field of transport of dangerous goods at Lek. Due to their specific hazardous properties, some raw materials for the production of medicines need additional protection during transport and packaging according to the criteria set out in the agreement.

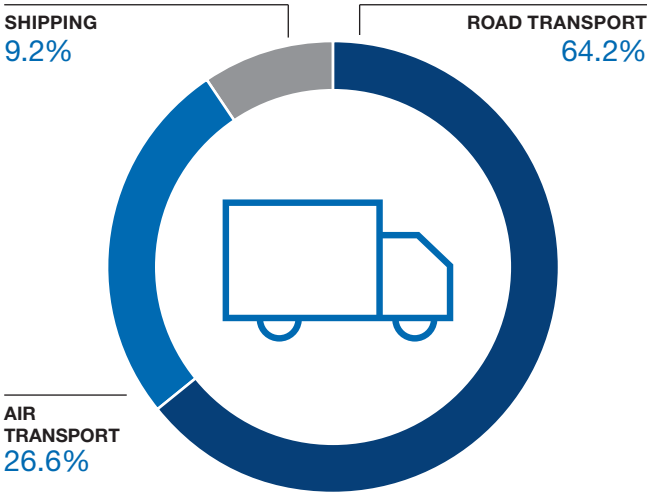
In 2019, we shipped 10,602 shipments of products from Lek's sites and warehouses to our customers (9,177 in 2018).

10,602 shipments of products

were dispatched to our customers in 2019.

We had 64.2% road, 26.6% air and 9.2% sea shipments. The ratio between shipping and air transport, measured in kg, was 1:0.5 in favor of shipping. This reduces our carbon footprint, as shipping has a lower emission factor than other modes of transport (shipping 10–40g/tkm, road 60–150 g/tkm, air transport 500g/tkm; Source: Lufthansa Air cargo).

Dispatches in regard to transportation means



4.9.4 Chemical safety

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. 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 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.

Measurements of exposure to chemicals in the work environment

In the field of chemical safety, we introduced the European standard SIST EN 689: 2018, which determines the frequency of measurements of exposure to chemicals at workplaces. In cooperation with an accredited monitoring provider and an accredited laboratory, we follow the legislative requirements for the control of technical and organizational measures and improve them if necessary.

Biological monitoring

In cooperation with a doctor, an occupational medicine specialist and the competent medical laboratory, we continue to carry out biological monitoring at workplaces where chemicals with binding limit values are used. We make employees aware of the importance of biological monitoring in work processes and maintaining health with the safe use of chemicals.

5. Labor

5.1 Human resources policy[73]

As part of Novartis, we enable unhindered talent development and creativity of our employees. We build a culture that encourages curiosity and exploring new ways of working. We offer a number of learning opportunities to our employees and external experts. We want to follow the digital revolution in healthcare and accelerate innovation in biomedical research.

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. We pay a lot of attention to finding young prospective talent.

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

From left to right: Roman Pogačar, Darja Ferčej Temeljotov, Ksenija Butenko Černe, Katarina Klemenc and Špela Bernhard

The most reputable employer

At Lek, we received the title of the most reputable employer, which is awarded by the employment portal MojeDelo.com. Reputation measurement was first carried out in collaboration with a leading European employer brand management company, the Swedish company Universum Global.

More than 19,000 respondents took part in the survey, including experts from academia and business, as well as students. In addition to the recognition of the most reputable employer in 2019, we achieved first place among reputable employers selected by students, social sciences experts, natural science experts and first place in the pharmaceutical and biotechnology and chemical industries.

In all previous surveys, we have been ranked among reputable employers, and this time we received the title of the most reputable employer for the second time since 2013.

MOST REPUTABLE EMPLOYER

- 2019 -

MojeDelo.com 15 let universum

5.2 Employment

5.2.1 Total workforce by employment and employment contract[74]

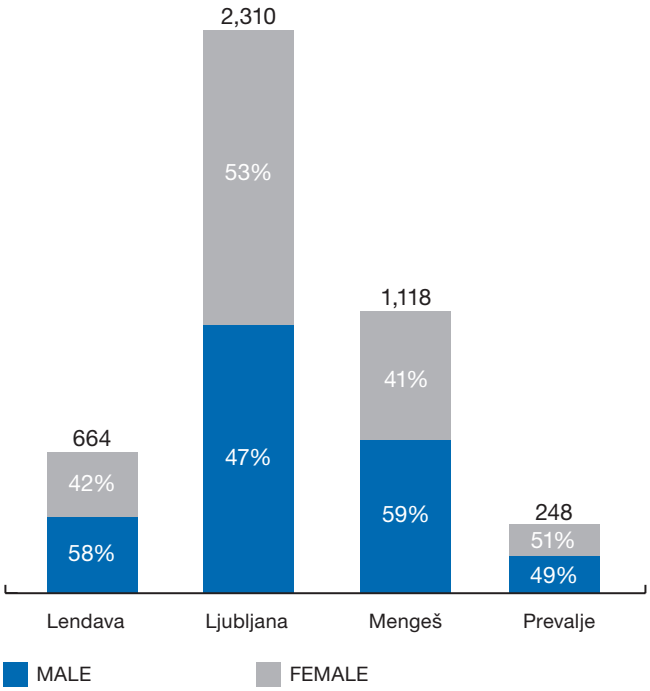
In 2019, we created 482 new jobs and finished the year with 4,349 full-time employees. At the end of the year, the proportion of women employed was 48%, 1% higher than the previous year. At year-end, 93.4% of all employees worked on a full-time permanent basis, and 6.6% were fixed-term employees and 2.1% of all employees worked on a part-time basis.

Number of full-time employees on 31 December 2019 by site and gender

Site	Male	Female	Total
Lendava	387	277	664
Ljubljana	1,084	1,226	2,310
Mengeš	659	459	1,118
Prevalje	122	126	248
Others*	9	0	9
Total	**2,261**	**2,088**	**4,349**

* Rented warehouses

Number of full-time employees by site and gender (in %)



Number of new employees in Lek in 2019

Age group	New employees in 2019
0–25	116
26–30	194
31–35	75
36–40	53
41–45	23
46–50	16
51–55	3
56–60	2
Total	**482**

5.2.2 Percentage of employees covered by collective agreements[75]

In 2019, the Collective Agreement covered 99.3% of the total workforce, a level similar to that in the previous years.

5.2.3 Liabilities from the pension plan[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

[74] GRI GS 102-7, 102-8, 401-1.
[75] GRI GS 102-41.
[76] GRI GS 201-3.

amount of 5.844% of the employee's gross salary, or an annual amount that cannot exceed 2,819 EUR. At the end of 2019, 90.94% of the workforce was included in the scheme.

5.2.4 Employment process and percentage of local employees in senior management[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 was somewhat lower (86.67%) than in 2018 (93.55%).

5.2.5 Parental leave[78]

The growth in the number of employees taking parental leave continued in 2019, the return to work rate after parental leave remains high. Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act.

479 employees

went on parental leave in 2019.

Parental leave and return to work rate

	2019	2018	2017
Number of employees having taken parental leave	**479**	**458**	**397**
• Male	230	219	191
• Female	249	**239**	206
Number and share (in %) of employees returning to work after parental leave	**478**	**458**	**394**
	(99.8%)	**(100%)**	**(99.2%)**
• Male	229	219	191
	(99.6%)	(100%)	(100%)
• Female	249	239	203
	(100%)	(100%)	(98.5%)

[77] GRI GS 103-1, 202-2.

[78] GRI GS 103-1, 401-3.

5.3 Occupational health and safety[79]

The safety of our employees and local communities is, in addition to patient safety, the foundation of our operations and risk management strategy, which ensures an uninterrupted supply of products. With the health and safety management system, we prevent work-related injuries and illnesses and ensure healthy and safe workplaces. We strive to eliminate any dangers and minimize risks through effective preventive and protective measures.

We recognize that our success depends on leadership, commitment, and collaboration at all levels and functions of the organization, including outsourcing. Ensuring and promoting continuous improvement is part of our day-to-day activities.

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.

With the health assessment, which is an integral part of the Safety Statement, we identify, eliminate and decrease all forms of risks for employees. All extended preventive measures are assessed by contractors. Due to the organizational changes that will be completed in 2020, the Safety Statements will also be revised.[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 education and training for occupational health and safety and fire protection. We continued training to acquire competencies for roles and activities with increased risk. We promoted the Novartis Life Saving Rules, a set of ten basic safety rules for high-risk activities where non-compliance can result in serious injury or death.

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

Detailed records of work-related incidents, which is one of key occupational health and safety indicators, allows us to assure the suitability of the approved measures and plan additional measures to further decrease incidents. Regarding this, we evaluate the LTIR indicator (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 (Lost Time Injury and Illness Rate) indicator

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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	0.21
2019	**0.12**	**0.24**	**0.11**	**1.24**	**0.30**

TRCR (Total Recordable Case Rate) indicator

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
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
2019	**0.12**	**0.28**	**0.11**	**1.24**	**0.32**

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

[80] GRI GS 403-2.

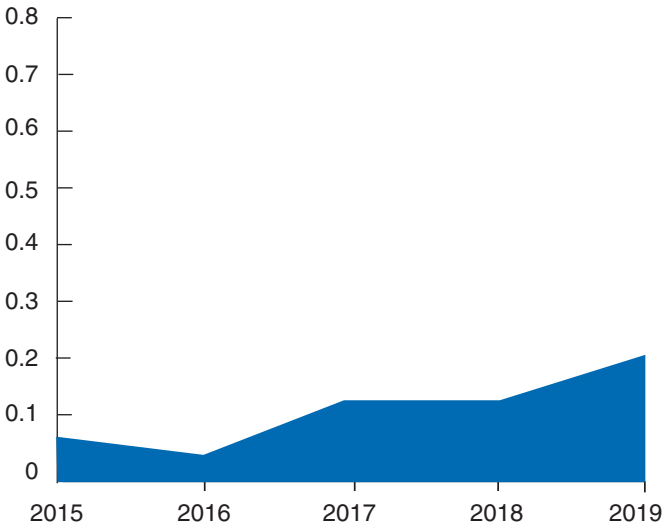
[81] GRI GS 403-1.

[82] POR OI 2, GRI GS 403-9.

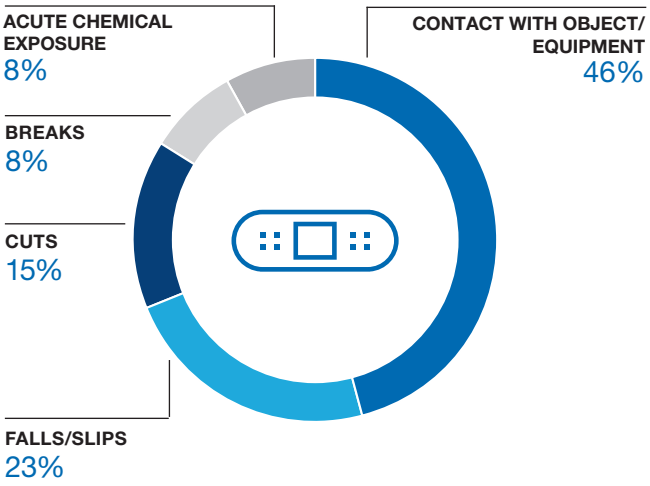
Despite extensive activities with the adoption of the new General Operating Procedures (GOP) in the field of HSE, the LTIR rate increased from 0.20 to 0.30. We recorded 13 cases where employees were on sick leave due to an injury at work. We recorded no serious work-related injuries, which would leave health consequences due to the injury. The TRCR indicator amounted to 0.32, which means 14 recorded cases.

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

Trend of LTIR injuries



Categories of accidents based on cause (LTIR and TRCR) in 2019



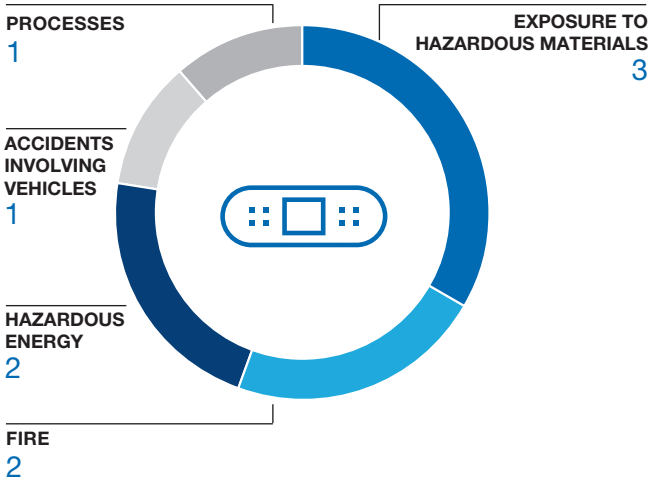
Measurements on stress in the workplace was attended by 110 employees.

HSE system

Preventive activities to prevent accidents and injuries in 2019

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. Most of the pSIF events were related to hazardous energies and exposure to hazardous substances, so we envisioned intensive training in these areas and a review of existing procedures that will continue in the coming years.

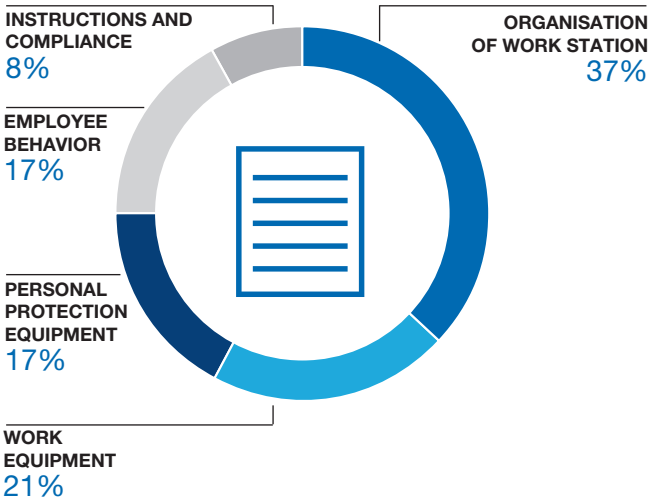
High Risk Situations in 2019



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 promoters (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.

In 2019, we carried out 2,586 safety walkthroughs.

Classification of risks noticed by area



Safe driving training

We also actively involve drivers of company vehicles in measures in the field of HSE. For all those who are entitled to drive company cars, we organize initial or refresher training in safe driving. In the introductory course (theoretical and practical), drivers learn about the technique of non-aggressive (defensive) and environmentally friendly driving, which reduces the possibility of accidents, lowers fuel consumption and greenhouse gas emissions. In 2019, we trained 390 employees.

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 2019, the proportion of sick leave was 6.45%, recording a slight decrease compared to the previous year (6.59%).

Share of sick leave

	2019	2018	2017
Women	5.07%	7.92%	4.42%
Men	10.82%	5.43%	6.11%
Total	**6.45%**	**6.59%**	**5.20%**

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

Outsourcing security management remains an integral part of day-to-day operations. We involve external contractors in various specialized activities. In many cases, these are increased or high-risk tasks, requiring a lot of training, hazard reduction and control. We have more than 80 external contractors carrying out activities with increased risk, such as work at height, work with hazardous energies, etc. There were several construction sites in Lendava, Ljubljana and Mengeš, where we provided support to group leaders, supervisors and workers in the field of HSE.

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.

There were three injuries recorded in the performance of work in 2019 amongst outsourcers, which is at the same level as in the previous year. The causes of accidents were the same as the previous year; lack of awareness of the danger and lack of control by the competent persons of the operators and inadequate work organization.

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[86]

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.

In this area, we focus primarily on the prevention and management of occupational diseases, accidents, disabilities and the elimination of factors that can be dangerous to health and safety at work. We promote a healthy and safe working environment, strengthening the physical, mental and social well-being of employees and maintaining their working ability and productivity.

In addition to compulsory periodic training in safety and health at work and fire safety, in 2019 we also carried out:

- fire extinguishers and equipment training,
- anti-explosive protection training,
- high risk activity training (work at height, small spaces etc.),
- meetings with external contractors on the topic of health and safety at work,
- acquainting external contractors with site regulations,
- safe driving training,
- occupational health and safety procedures training,
- fire drill and evacuation practice exercises.

In accordance with internal health plans, we perform regular preventive medical examinations performed by occupational physicians every year. In 2019, 2,646 of our employees from all four sites underwent examinations. The health status of employees remains similar to previous years. Most of the health problems of employees are related to the musculoskeletal system, obesity and deterioration of vision, which is mainly a consequence to the aging population.

[83] GRI 403-9.

[84] POR OI 1 and POR OI 3, GRI GS 403-9.

[85] GRI GS 403-10.

[86] GRI GS 403-3, 403-4, 403-5, 403-6.

As part of the health promotion program, our employees participated in the following activities:

Program	No. of employees included
Instructed exercise (swimming, gym, climbing, dancing, group workouts, pilates) and active breaks at work station - exercise at work station	670
Vaccination	700
Health spa recovery	60
Preventative dentist check-up	200
Measuring body composition with expert consultation, measuring blood sugar levels and cholesterol, healthy eating workshop	300
Stress level measurement	110
Activities aimed at raising awareness about mental health (lectures on stress and burnout in the workplace, basic resuscitation procedures and providing first aid with a semi-automatic defibrillator, a healthy lifestyle with articles and video presentations, Faldenkrais method)	1,080

5.4 Training and education[87]

The education and training of employees is closely intertwined with Lek's business strategy – to reimagine medicine. This 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.

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 attend an external or internal conference or a work visit abroad with other colleagues are highly desirable. We also conduct mentoring and coaching.

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.

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.

HSE education is divided into legally obligatory and expert development.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.

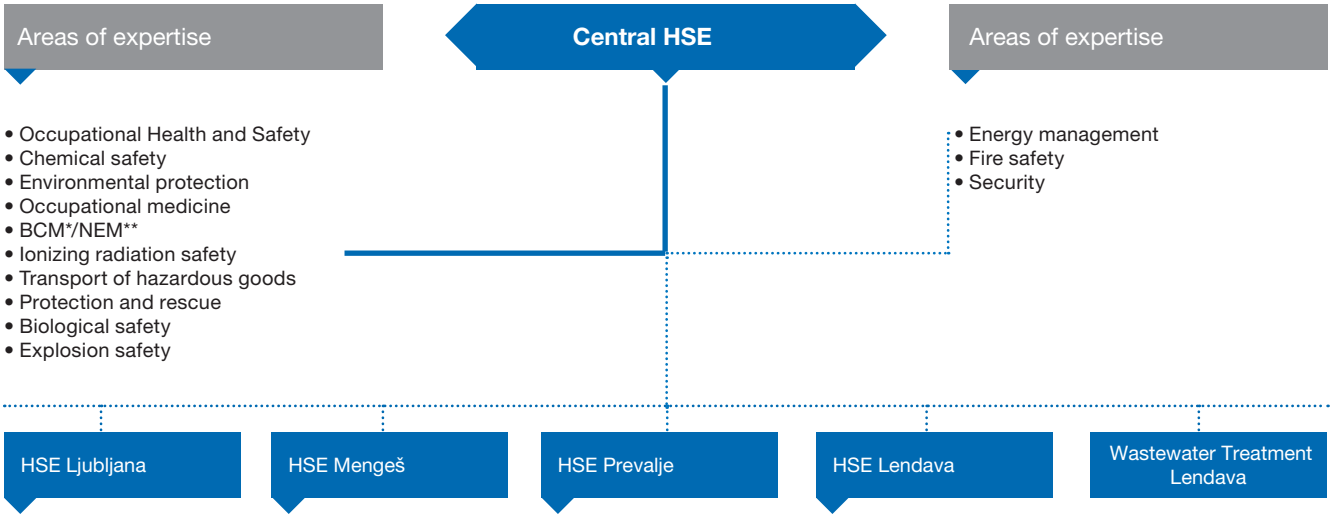
At the end of 2019, we completely switched to the training management application, Up4Growth. Entire teams have been formed at individual production sites to ensure compliance in the field of employee training and learning. We have designed curricula that ensure that employees are trained in a timely manner in relevant content so that they can perform their work efficiently and safely. Numerous e-trainings, professional and soft skills training offered by the Coursera and LinkedIn platforms are available free of charge to all Novartis employees. In 2019, we also paid special attention to the practical training of employees on basic resuscitation procedures. In cooperation with the SIM unit of Ljubljana Health Clinic, more than 500 employees took part in the training.

HSE department

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

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

HSE Organization Scheme on 31 December 2019.



* BCM: Business Continuity Management

** NEM: Novartis Emergency Management

By organizing appropriate training programs, we assure all our employees have a sufficient level of HSE qualification. In cooperation with unit heads, the HSE unit prepares a training catalogue. We promote direct involvement of employees in different roles, functions and units, exceeding the formal HSE organization.

HSE aspects and system of achievement monitoring

Pursuant to the Novartis guidelines, environmental aspects at Lek d. d. were upgraded into so-called HSE aspects, 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 lifecycle.

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 2019, external auditing of the company's compliance with ISO 14001:2015, ISO 45001:2018 was 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 ISO 45001:2018 requirements were carried out. 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, ISO 45001 and the EMAS Directive.

In 2019, we performed Novartis' thematic assessment of the transfer of production processes at the Development Center in Ljubljana and Novartis' assessment of legal compliance with an emphasis on environmental protection, occupational health and safety and chemical safety. The results of internal audits showed 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 noncompliance 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 2019, 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

The HSE Data management System; HSE DMS enables the management, reporting and communication of HSE performance in Novartis and to its stakeholders. By setting and reviewing HSE performance goals, it helps manage HSE risks and opportunities, enables the exchange of experiences and data analysis within Novartis, and provides an overview of compliance with national HSE regulations and compliance with international conventions.

Data management and procedures are established in accordance with GRI standards..

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. Sites or units within sites are responsible for collecting data and ensuring their accuracy.

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.

Measure 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 of 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 Zürich Hazard Analysis (ZHA) or the Hazard and Operability Study (HAZOP Study) in the project qualification phase,
- Facilities and production line: Zürich Hazard Analysis (ZHA) or the Process Risk Assessment (PRORA),
- Process Risk Assessment (PRORA) for new products and product lines,
- Assessment of product quality risks: priority use of FMEA.

A prerequisite for carrying out an individual risk assessment is the acquisition of sufficient information and the composition of a team that includes competent representatives in individual areas. Depending on the type of risk assessment, the persons who will participate in the risk assessment will be determined in advance:

- User (technologist, operator, technician, etc.)
- Process planner (PI technologist, project engineer, equipment or material supplier, etc.)
- HSE representative (experts in individual fields)
- Site Matter Expert (SME)
- External experts or consultants (Ex experts, ADR experts, etc.)

The set of risks serves the Novartis management as a review of 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 2019, 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.

Assuring business continuity management in 2019
The following activities have further helped to increase our resilience to unforeseen events:

- Coordination of BCM with quarterly meetings of BC coordinators,
- Updated Business Critical Position Holders,
- Updated BC plans for all sites and key support functions,
- Did BC scenarios drill for all systems at all sites,
- Held BC training for management teams at certain sites,
- Internal BCM inspection at Sandoz Ljubljana unit – Sandoz 3rd Party Sales organization Ljubljana.

Novartis emergency management activities in 2019
In 2019, we updated the NEM structure in Slovenia and adjusted it to changes in the management structure. All Novartis departments were trained according to the NEM process. NEM training was held for new members of the NEM group, including training for media relations representatives (for NEM directors) by the HSE and the corporate communication department. Teams at the sites were tested in different scenarios.

In 2019, we witnessed one case of NEM and one case of pre-NEM, which later proved to be a case with an impact on continuity of operations.

The NEM case related to a viral infection with Norovirus at the Ljubljana and Mengeš sites, where about 200 employees fell ill. The NEM team came together and acted quickly and efficiently. Another case was related to a business disruption (BC). We treated it as pre-NEM, as we faced a malfunction of the production information system MES (Werum), which affected production at several of our sites. It took us 11 days to establish a stable operational solution.

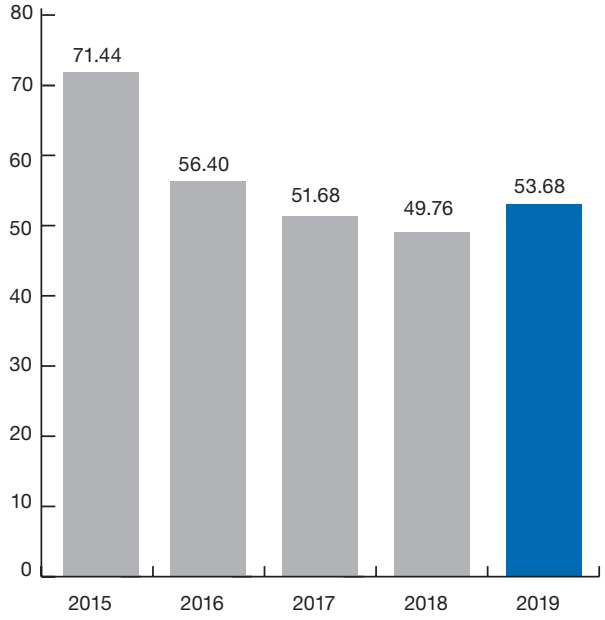
5.4.1 Average hours of training per employee[88]

The average amount of time spent for training of Lek's employee was **2.29 days**, and if adding compulsory training at the workplace (3.94 days) and training in compliance (0.48 days) it amounted to a total of **6.71 days** which is 8% more than 2018. 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.

6.71 days

Total average training time of Lek's employee in 2019.

Average training hours/employee



[88] GRI GS 404-1.

5.4.2 Training by field

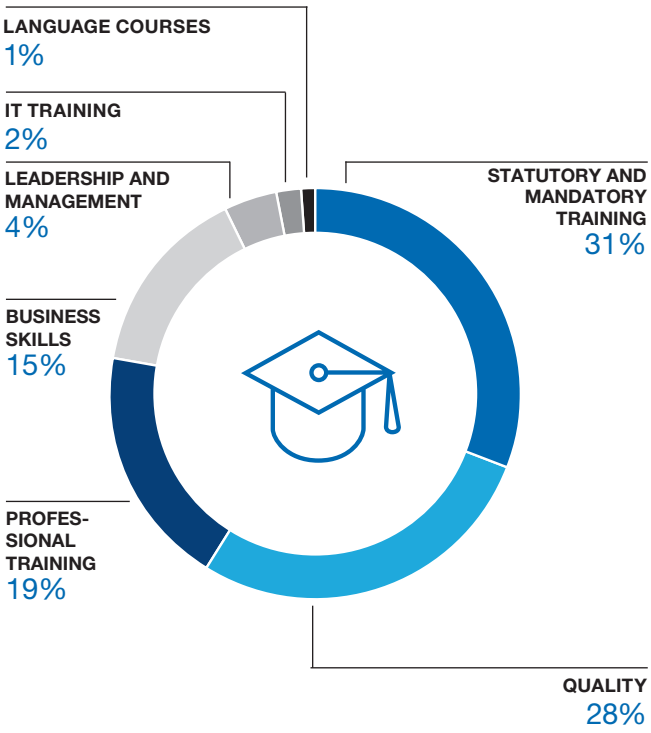
We build a learning culture, thus introducing additional non-formal forms of learning. All employees have one-hour workshops called "Are you coming?" where they have the possibility and opportunity to share their knowledge and experience in the setting of a friendly gathering, and gain new insights into 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 also offer our employees the opportunity of in-service education; in 2019, 44 employees involved in undergraduate studies, and 65 in post-graduate studies, mainly in biotechnology and biomedicine, as well as chemistry.

The highest participation rate was recorded in statutory and mandatory training (31%), quality (28%), and professional skills (19%).

Education in 2019 by field (% attendance)



6. GRI Content Index

This report has been prepared in accordance with the GRI Standards: Core option[89]

GENERAL STANDARD DISCLOSURES

GRI standard	Disclosure	Section/Page numbers	UN Sustainable Development Goals (SDG)/ EMAS Core indicators
GRI 101: Foundation 2016			
GRI 102: General Disclosures 2016			
Organizational Profile			
102-1	Name of the organization	1./6	
102-2	Activities, brands, products and services	1.2.2/19	
102-3	Location of headquarters	1./6	
102-4	Location of operations	1.2.3/20	
102-5	Location of operations	1.2/18	
102-6	Markets served	1.2.1/19	
102-7	Scale of the organization	1.1.1/7, 5.2.1/74	
102-8	Information on employees and other workers	5.2.1/74	8 12
102-9	Supply chain	3.2.1/42	
102-10	Significant changes to the organization and its supply chain	1.2.3/20, 1.3.1/26, 3.2.1/42	
102-11	Precautionary Principle or approach	1.4.2/29, 4./44	
102-12	External initiatives	1.4.2/29	
102-13	Membership of associations	1.4.2/29	
Strategy			
102-14	Statement from senior decision-maker	Letter from the President of the Board of Management Page 4	
Ethics and integrity			
102-16	Values, principles, standards and norms of behavior	3.1/41	16
Governance			
102-18	Governance structure	1.4/27	
Stakeholder engagement			
102-40	List of stakeholder groups	2.2/34, 37	
102-41	Collective bargaining agreements	5.2.2/74	8
102-42	Identifying and selecting stakeholders	2.2/34	
102-43	Approach to stakeholder engagement	2.2/34 2.3/40	
102-44	Key topics and concerns raised	2.2/34, 37, 2.3/40	

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

Reporting practice				
102-45	Entities included in the consolidated financial statements	1.3.1/26		
102-46	Defining report content and the topic Boundaries	1.3/26		
102-47	List of material topics	6/85–89		
102-48	Restatements of information	1.3.1/26		
102-49	Changes in reporting	1.3.1/26		
102-50	Reporting period	1.3.1/26		
102-51	Date of most recent report	1.3/26		
102-52	Reporting cycle	1.3/26		
102-53	Contact point for questions regarding the report	1./6		
102-54	Claims of reporting in accordance with GRI Standards	1.3.1/26		
102-55	GRI content index	6/85–89		
102-56	External assurance	1.3/26		

SPECIFIC STANDARD DISCLOSURES

Management approach disclosures	Topic-specific disclosures	Section/ Page numbers	Remarks/ Omissions	UN Sustainable Development Goals (SDG)/ EMAS Core indicators
ECONOMIC TOPICS				
GRI 201: Economic performance 2016				
103-1	Explanation of the material topic and its Boundary	Letter from the President of the Board of Management/4–5		
201-1	Direct economic value generated and distributed	1.1.1/7		
201-3	Defined benefit plan obligations and other retirement plans	5.2.3/74		
201-4	Financial assistance received from government	1.1.1/7		
GRI 202: Market presence 2016				
103-1	Explanation of the material topic and its Boundary	Letter from the President of the Board of Management/4–5		
202-2	Proportion of senior management hired from the local community	5.2.4/75		
GRI 204: Procurement practices 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	3.2.1/43		
204-1	Proportion of spending on local suppliers	3.2.1/43		
GRI 206: Anti-competitive behavior 2016				
103-1 103-2	Explanation of the material topic and its Boundary	3.1/41		
206-1	Materials used by weight or volume	3.1/42		
ENVIRONMENTAL TOPICS				
GRI 301: Materials 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4.2.1/50		
301-1	Materials used by weight or volume	4.2.1/51		EMAS Core Indicator

GRI 302: Energy 2016			
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4/45	
302-1	Energy consumption within the organization	4.3.1/52, 54	7 8 12 13
302-3	Energy intensity	1.1.1/8, 4.3.1/52	7 8 12 13 EMAS Core Indicator
302-4	Reduction of energy consumption	4.3.3/55	7 8 12 13
GRI 303: Water 2018			
103-1 103-2	Explanation of the material topic and its Boundary	4/45	
303-1	Interactions with water as a shared resource	4.4/57	6 12
303-2	Management of water discharge-related impacts	4.4/57	6 12
303-3	Water withdrawal	4.4.1/57, 4.4.2/57	6 12 EMAS Core Indicator
303-4	Water discharge	4.7.1/66	
GRI 305: Emissions 2016			
103-1 103-2	Explanation of the material topic and its Boundary	4/45, 4.6/62	EMAS Core Indicator
305-1	Direct (Scope 1) GHG emissions	4.1.5/50, 4.6.4/64	3 12 13 14 15
305-2	Energy indirect (Scope 2) GHG emissions	4.6.4/64	3 12 13 14 15
305-4	GHG emissions intensity	4.6.4/64	12 13 14 15
305-5	Reduction of GHG emissions	4.3.3/55	13 14 15
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	4.6.2/63, 4.6.3/63	3 12 14 15 EMAS Core Indicator
GRI 306: Effluents and waste 2016			
103-1 103-2	Explanation of the material topic and its Boundary	4.7/65	
306-1	Water discharge by quality and destination	4.7.1/66	3 6 12 14
306-2	Waste by type and disposal method	4.5.1/59, 4.5.2/60, 4.5.3/61	3 6 12 14 EMAS Core Indicator
GRI 307: Environmental Compliance 2016			
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4/45	3 12
307-1	Non-compliance with environmental laws and regulations	4/45, 4.1/48	
GRI 308: Supplier environmental assessment 2016			
103-1 103-2	Explanation of the material topic and its Boundary	3.2.1/43	
308-2	Negative environmental impacts in the supply chain and actions taken	3.2.1/43, 4.1.5/50	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	5.1/72		
401-1	New employee hires and employee turnover	5.2.1/74		5 8
401-3	Parental leave	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	5.3/75		
403-1	Occupational health and safety management system	5.3/76		
403-2	Hazard identification, risk assessment, and incident investigation	5.3/75		
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	2.3/39		
403-9	Work-related injuries	5.3/75, 5.3.1/76, 5.3.2/79		
403-10	Work-related ill health	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	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	3.1/41		
406-1	Incidents of discrimination and corrective actions taken	3.1/42		
GRI 412: Human rights assessment 2016				
103-1 103-2	Explanation of the material topic and its Boundary	3.1/41		
412-2	Employee training on human rights policies or procedures	3.1/42		
GRI 413: Local communities 2016				
103-1 103-2	Explanation of the material topic and its Boundary	1.4.3.1/32		
413-1	Operations with local community engagement, impact assessments, and development programs	1.4.3.1/32	The data collected for now does not allow us to calculate the share, but we report the number of activities.	

GRI 414: Supplier social assessment 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	3.2.1/43		5 8 16
414-2	Negative social impacts in the supply chain and actions taken	3.2.1/43	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	2.3/39		
417-1	Requirements for product and service information and labeling	2.3/39	We operate in a strictly regulated industry; this information is obligatory for us to have a license to operate.	
417-2	Incidents of non-compliance concerning product and service information and labeling	2.3/39		
417-3	Incidents of non-compliance concerning marketing communications	2.3/40		

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 2019 – Lek d. d., June 2020**; chapters: 1. Company profile, 2.2. Stakeholder review and involvement, 3.2 Cooperation with suppliers, 4. Environment and 5.4 Training and education " reflects 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

Validation date: 2012-04-06

Issue: 09/2020-06-05

Igor Likar:
Director of SIQ

SLOVENSKA AKREDITACIJA
SIST EN ISO/IEC 17021-1
SI-V-0001

SIQ Ljubljana, Mašera Spasičeva 10, SI-1000 Ljubljana, Slovenija,
tel.: +386 1 4778 100 • fax: +386 1 4778 444 • e-mail: info@siq.si • http://www.siq.si

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.[90]

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.[91] Modern science knows several thousand substances producing an antibiotic effect. In practice, there are several dozen molecules which have been fully established in standard medical practice. Certain bacteria produce beta-lactamase and are therefore resistant to specific forms of antibiotics. Clavulanic acid is a beta-lactamase inhibitor. In combination with potassium clavulanate which prevents bacterial resistance to amoxicillin action, the antibiotic is effective in the treatment of bacterial infection.

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

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

Biosimilars are officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following expiry of patent and exclusivity on the innovator product. They demonstrate quality, safety and efficacy identical to those of originator drugs, yet their lower price makes them more affordable for a wider patient popu-

[90] 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).

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

lation. Chemically, biosimilars are protein drugs or glycoproteins. The concept of biological similarity as defined by the European Medicinal Products Act requires a higher level of expertise in science, technology and logistics.

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

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

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

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

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

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

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

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

The Integrated Pollution Prevention and Control (IPPC) Directive on integrated pollution prevention and control of industrial pollution, has been transposed into Slovenian law by the Regulation on activities and installations with major pollution potential in 2015. The European Union has brought the IPPC Directive together with six other directives related to industrial emissions in a single Industrial Emissions Directive (IED).

a Sandoz company