lek

a Sandoz company

Growing with a sustainability culture

Sustainability Report 2020
Lek d.d.

Contents

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2020 Highlights

EUR 1,184.431 million

NET SALES IN 2020, 2% MORE THAN 2019.

4,823

EMPLOYEES AT THE END OF 2020, 11% MORE THAN 2019.

68.9 hours

OF EDUCATION AND TRAINING PER EMPLOYEE IN 2020, 28% MORE THAN 2019.

EUR 3.9 million

SAVED THANKS TO 337 SUBMITTED AND IMPLEMENTED TH!NK NOVARTIS IDEAS IN 2020.

-14%

DECREASE IN TOTAL WATER USE.

EUR 3.7 million

INVESTMENT IN ENVIRONMENTAL PROTECTION IN 2020.

45.1 TJ

OF ENERGY AND 3,617t CO_2 SAVED THANKS TO NUMEROUS ENVIRONMENTAL PROJECTS.

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

2020 was the year COVID-19 affected our everyday lives and activities. At Novartis, our top priority was focusing on the health and safety of our employees and ensuring the uninterrupted supply of vital medicines to patients around the world. The measures we took successfully prevented the spreading of infections among employees and met all the needs of the pharmaceutical market.

Robert Ljoljo

Despite the extenuating circumstances, our values and culture of sustainability pushed our development forward. At Novartis, we updated our environmental sustainability strategy in the second half of 2020 where we set even more ambitious goals; we will strive to achieve carbon neutrality throughout the entire value chain and plastic and water neutrality by 2030.

Novartis Slovenia has also taken progress in these areas seriously and implemented several small projects to increase energy efficiency and reduce water and waste. We are also planning major, developmentally groundbreaking projects which we want to contribute to the realization of these goals. Our diligent employees will continue to be decisive in their realization; this is one of the reasons why the awards "Top Employer" and "Most reputable employer'' mean a lot to us.

I am proud of our intergenerational cooperation, the circulation of knowledge and the many initiatives that grow within our internal culture. Therefore, I am happy that a group of young and hard-working employees has set up a Youth Advisory Board, where they can exchange views, information and suggestions about the company with members of the Board of Management. In Mengeš, a group of volunteers founded the first Green Team in Slovenia, which is modeled on other Novartis teams abroad and, in addition to its regular work, is looking for new fresh ideas to reduce environmental impacts. Such efforts will be further enhanced in 2021. Associates contributed as many as 455 different ideas to the Th!nk Novartis idea submission system. 337 were approved for implementation, which resulted in savings of EUR 3.9 million.

The development potential and ability of Slovenian experts have been well recognized in Novartis and thus we are intensively continuing to invest in strengthening development and production capacities. This facilitates our strategy to transform from a generic to a more innovative pharmaceutical company. In 2020, we invested EUR 204 million, over the past 17 years we have invested more than EUR 2.7 billion in Slovenia. We produced and packaged a total of 27 innovative medicines last year.

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

Solids Ljubljana started packaging and finished investment in production for one of the most important Novartis innovative products for the treatment of heart failure for the American market. In the Development Center Slovenia more than 200 development projects for pharmaceutical products and active ingredients were underway. We completed development and submitted 22 dossiers for medicines from various therapeutic areas.

The development potential and ability of Slovenian experts have been well recognized in Novartis and thus we are intensively continuing to invest in strengthening development and production capacities. This facilitates our strategy to transform from a generic to a more innovative pharmaceutical company.

In Mengeš, we produced, among other things, the first clinical series of two original biological drugs and began to expand production capacity in the new plant and launched the eighth biosimilar drug. By strengthening our operations in the areas of innovation, data science, digitization and automation, we have strengthened the development of innovative biopharmaceuticals and strengthened our role as Novartis' Biopharmaceticals development center.

In Lendava, we carried out all registration series for the production of potassium clavulanate mixtures, which will contribute to the growth of the unit in the future, and we also focused on investing in a new automated high-tech line for integrated blistering, bagging and packaging. Our colleagues have also received numerous international and national awards for their knowledge, including the Chamber of Commerce of Slovenia Award for Innovation, which we received for a prolonged-release capsule with the active substance tacrolimus, intended for immunosuppressive treatment of patients with organ transplants.

We place great emphasis on reducing our environmental impacts and implementing Novartis' environmental sustainability strategy. We have directly invested EUR 3.7 million in environmental protection, and we are also striving for it in all our investments and operations. At all four sites, we carried out projects to increase energy efficiency, which saved 45.1 TJ of energy and thus prevented 3,617 t of CO_2 being released into the atmosphere. We reduced total energy consumption by 1.23%, and improved energy efficiency per employee by 9%. Due to changes in the portfolio, where we replaced some large-tonnage products with more complex, more energy-demanding production processes, the energy efficiency indicator per tonne of product decreased by more than 5%. Through various measures, we reduced water consumption by 14% and improved its efficiency by 9%. The total amount of waste increased by 6%, mainly due to the increased amount of waste mycelium, which is a non-hazardous and biodegradable waste with a 95% water content, from Lendava production. Significantly, we reduced the amount of hazardous waste by almost 18%, and the indicator of the efficiency of hazardous waste management, measured in tonnes of waste per tonne of product, also shows a high 12% improvement. We continue to be an important and inclusive employer in Slovenia, striving to unleash the best potential among employees. We accepted 649 new employees and ended the year with 4,823 full-time employees at Lek, and Novartis Slovenia with more than 4,890 employees. In the first quarter of 2021, the number of employees has already exceeded 5,000. Despite the stringent measures due to the COVID-19 pandemic, we further strengthened employee training. On average, a Lek employee received 68.9 hours of training or 8.6 days, which is 28% more than in 2019. In support of Pride Month, we hung rainbow flags at our sites in keeping with the initiative of diversity and inclusion.

An important part of our emergency response was to support the wider community. At the beginning of the pandemic, our colleagues on their own initiative organized the production of a disinfectant, which we donated to 106 health centers, hospitals, homes for the elderly and local communities throughout Slovenia. In total, we contributed more than 27,000 liters of disinfectant. We donated $500,000 from the Novartis Global Fund to Slovenia to help manage the pandemic. The funds were donated to the Red Cross of Slovenia and the Association of Friends of the Youth of Slovenia. Due to restrictions, we held our Community Partnership Days in a slightly different way; together with members of the Lek Pensioners' Association, we tried to make time pass quicker for the elderly by telephone conversations. We helped the youngest from socially vulnerable families by donating 182 computers with all the software they needed to distance learn.

It is at this point, I thank my colleagues for the sacrifice and responsibility we show together to our communities, and congratulate them on all their accomplishments. I am convinced that we are ready for the future and it is precisely because of our culture of sustainability that we will continue to grow.

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

1. Company Profile

Lek, a Sandoz company[2]

Company name: Lek Pharmaceuticals d.d.
Abbreviated name: Lek d.d.
Registered office: Ljubljana
Business address: Verovškova ulica 57, 1526 Ljubljana, Slovenia
Registration number: 1732811000
Standard Classification of Economic Activities in the European Community (NACE):
21.200 Manufacturing pharmaceutical preparations
Registered at: District Court in Ljubljana under entry number: 1/36542/00
Telephone: + 386 1 580 2111
Fax: + 386 1 568 3517
E-mail: info.lek@novartis.com
Website: http://www.lek.si/en

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

1.1 Key Data for 2020

1.1.1 Performance in 2020

Key performance figures for 2020[4]

Indicator	Unit	31. 12. 2020	31. 12. 2019	31. 12. 2018	Index 2020/2019
Number of employees		4,823	4,349	4,084	111
- Ljubljana site		2,755	2,310	2,152	119
- Mengeš site		1,134	1,118	1,098	101
- Lendava site		699	664	571	105
- Prevalje site		226	248	256	91
- hired warehouse		9	9	7	100
Production output*	1.000 t	4.70	5.01	5.12	94
Net sales	mil. EUR	1,184.431	1,159.954	1,061.302	102
Liabilities	mil. EUR	1,231.563	1,286.430	1,196.518	96
Capital	mil. EUR	940.771	1,002.339	889.571	94

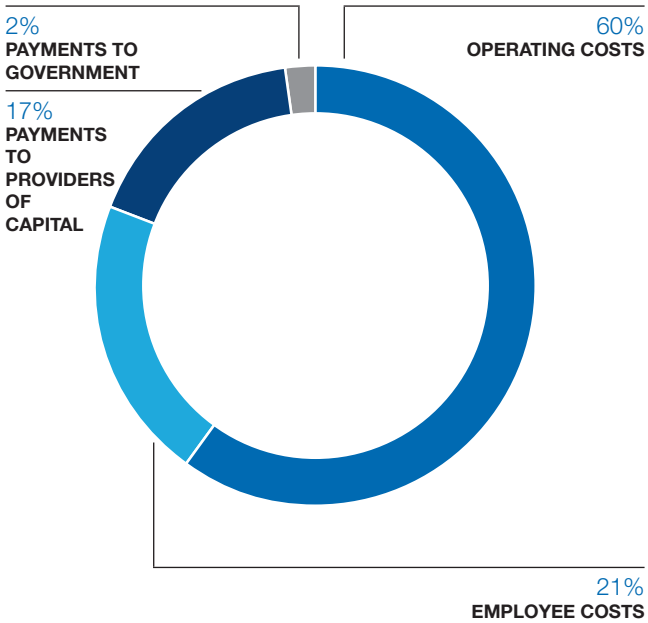
* The annual data comparing the volume production are incomparable due to very large differences in the weight of products and the composition of production between individual years. These differences arise from adapting to changes in demand and Novartis 'portfolio transformation. The differences in 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 biosimilar is higher.

Economic performance[5]

In 2020, Lek created 1,184.431 Euros of net sales, this represents a 2% increase compared to the previous year (1,061.302). Net profit for the accounting period amounted to 140.31 million Euros.

Direct economic value reached 1,223 million Euros (1,205 in 2019), of which 98% (1.204 million Euros) was **economic value distributed**; the largest proportion (60%) representing Operating Costs, which reached 726 million Euros. **Employee Costs** were 256 million Euros (21%). In 2020, 200 million Euros (17%) of **Payments to Providers of Capital** were made, and **Payments to Government** amounted to 22 million Euros (2%). We received 990,000 Euros worth of subsidies directly from the state (728,000 in 2019).[6]

Structure of economic value distributed



EUR 1,204 million

economic value distributed, 22% increase from 2019

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

Major environmental and social impacts[7]

Indicator	Unit	31.12.2020	31.12.2019	31.12.2018	Index 2020/2019
Energy efficiency*	GJ/t	283	268	262	106
Water efficiency**	m^3/t	626	684	680	92
Amount of waste – efficiency	t waste/t product	8.9	7,9	7.3	113
VOC emissions – efficiency	t VOC/t product	0.022	0.024	0.022	92
LTIR – Lost time injury and illness rate***		0.34	0.30	0.21	113
TRCR – Total recordable case rate***		0.34	0.32	0.25	106

* The table shows the total water efficiency at Lek (for technological and cooling purposes).
** The data shown for the Lendava site emissions has been amended. The previous Sustainability report showed the estimated amount, this report shows the final data.
*** 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 2020

Despite COVID-19 and the challenges it presented, we achieved our ambitious goals in 2020 by through excellent work and innovative solutions and made an important contribution to the realization of Novartis' strategy to become the world's leading pharmaceutical company.

Our key performance highlights and milestones in 2020:

- We provided full-time employment to **649 associates**. At the end of the year, Lek had 4,823 full-time employees, while Novartis in Slovenia had more than 4,890 employees, of which more than 550 have a master's degree or a doctorate.
- With € 204 million, Novartis continued **to invest in strengthening development and production capacity** in Slovenia, more than € 2.7 billion in 17 years. With these investments, Novartis in Slovenia continues the transformation from a generic to a more innovative pharmaceutical company. We have already produced and packaged 27 innovative medicines at production sites in Slovenia.
- Novartis in Slovenia, with all its divisions with **a 13.9-name market share, maintains its leading position on the Slovenian pharmaceutical market**. With a 29.3% market share, Lek is the second largest company in the market for generic medicines and second largest providers of prescription medicines, as well as a leading provider of over-the-counter medicines.
- Novartis Oncology provided 30 Slovenian patients with **free access to state-of-the-art therapies** under managed access programs, among which the first two patients in Slovenia received the renewed Novartis full therapy CAR-T (Kymriah) for the treatment of severe blood cancers.
- Novartis' ambitious 2025 and 2030 goals in its **strategy for environmentally responsible operations** were implemented at all Novartis locations in Slovenia and good environmental practices were disseminated. We consistently supervised and carried out our operations in accordance with the requirements of the ISO 14001:2015 standard, RCI and ES122/2009 with amendments (EMAS), which we voluntarily commit to as one of the companies in Slovenia. We implemented continuous improvements in the establishment of an occupational health and safety management system according to the ISO 45001:2018 standard.

[7] GRI GS 302-3

1.1.3 Novartis' environmental sustainability strategy

Environmental responsibility is at the core of our business and is in line with Novartis' vision to reimagine medicine to improve and extend people's lives. Our ambition is to be a catalyst for positive change and a leader in environmental sustainability. As part of Novartis, we promote sustainable operations through our own activities and through our value chain, setting ambitious goals to reduce our impact on climate, waste and water.

Novartis' commitments

People

We will encourage associates across our operations to adopt an environmental sustainability mindset.

Patients

We will work to understand how a changing climate will impact people's health.
We will deliver environmentally sustainable medicines to people that need them.

Innovation

We will use data and technology-based tools to boost our agility to respond to future challenges.
All new products will meet sustainable design principles.

Planet

We will minimize the impact of our actions on the planet and invest in environmental solutions that also protect biodiversity.
Through our value chain, we will benefit ecosystems and planetary health in general.

Climate

Water

Circular Economy

	Climate	Water	Circular Economy
	Be energy and climate resilient	**Ensure sufficient and safe water by being a water steward wherever we operate**	**Minimize waste and increase material efficiency**
2025	- All Novartis sites to be carbon neutral (GHG Scope 1 and 2) - Environmental criteria in all supplier contracts	- All Novartis sites to reduce the amount of water consumed by half - No water quality impacts from the manufacturing of our products	- Reduce the amount of waste sent for disposal by half - Eliminate PVC from secondary and tertiary packaging
2030	- Be fully carbon neutral across the value chain (GHG Scope 1, 2 and 3)	- Be water neutral in all areas - Enhance water quality wherever we operate	- Become plastic neutral

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, reducing the climate change and environmental impacts of its activities and products throughout the life cycle, therefore setting the appropriate goals in the area of environmental protection is of the utmost importance. Specific goals are defined with clear 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 goals are confirmed by the Head of Site Development NTO, Site Heads, Head of HSE and HSE site representatives. 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, where they are the persons responsible, individual objectives, as well as the necessary resources and deadlines are defined. 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 Green Team operations, 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).

Status of Lek's short term HSE targets for 2020

Area	Indicator	Target	Status 2020
Health and Safety	Serious injuries and fatalities (SIF)	0	0
	Walkthrough inspections per 200,000 working hours	>15	Reached. >27
	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0	Not reached. 2
	REEP (Risk-based exposure evaluation process)	100%	Reached. 100%
Environment	Decrease energy use	≥8% than 2019	Not reached. Reduced by 1.23%
	Decrease water use	≥8% than 2019	Reached. Reduced by 14%
	Decrease waste removal	≥8% than 2019	Not reached. Increased by 6%
Corrective Actions	Actions implemented after inspection	100%	Reached. 100%
	Number of overdue larger or critical actions (CAPA)	0	Reached. 0

Lek's HSE targets for 2021

Area	Indicator	Target
Health and Safety	Serious injuries and fatalities (SIF)	0
	Management walkthrough inspections per 200,000 working hours	>15
	Rate of near miss/good catches reports	>70 NTO >10 GDD
	Increase in reporting of events with SIF potential (pSIF cases)	>50%
Environment	Decrease energy use	Mengeš ≥4% than 2020 Prevalje ≥1% than 2020 Lendava ≥2% than 2020 Aseptics Ljubljana ≥1% than 2020 Solids Ljubljana ≥5% than 2020
	Decrease water use	Mengeš ≥4% than 2020 Prevalje ≥1% than 2020 Lendava ≥2% than 2020 Aseptics Ljubljana ≥1% than 2020 Solids Ljubljana ≥5% than 2020
	Decrease waste removal	Mengeš ≥4% than 2020 Prevalje ≥1% than 2020 Lendava ≥2% than 2020 Aseptics Ljubljana ≥1% than 2020 Solids Ljubljana ≥ 5% than 2020
	Number of serious environmental non-compliance events	0

1.1.5 Response to COVID-19 pandemic

Supporting associates' wellbeing

- In the face of the pandemic, we adapted our work processes to protect associates in both production and laboratories and took measures to prevent the spread of infections. Our remaining office-based employees also began working remotely. We paid special attention to the psychophysical well-being of employees, as well as working parents, by adjusting schedules, chilcare and additional working days of paid leave.
- We offered free vaccination against seasonal flu to more than 1,000 employees and their family members.
- We helped employees with advice and recommendations on ergonomics, computer equipment and office furniture in arranging a more comfortable and flexible work space. We provided additional laptops and monitors.

Supporting the community

- At the beginning of the pandemic, we donated funds in the amount of 500,000 US dollars from the Novartis Global Fund to help manage the pandemic with the Slovenian Red Cross and the Association of Friends of the Youth of Slovenia.
- We donated 182 computers with all the necessary software needed for distance learning to primary schools in Lendava, Mengeš, Ljubljana, Domžale, Prevalje, Naklo, Kranj, Koper and Trebnje for children from socially vulnerable families.
- Associates, on their own initiative, produced much needed disinfectant. We donated a total of 27,000 liters to 106 health centers, hospitals, homes for the elderly and local communities throughout Slovenia.

Constant care and access to medicines

- For the smooth production of vital medicines for patients in Slovenia and around the world, we launched the Business Continuity Assurance System (BCM) and the Novartis Emergency Management System (NEM).
- Novartis manufactures 15 medicines that treat the key symptoms of COVID-19 and are available to low- and middle-income countries at non-profit prices. Sandoz also maintains stable baskets of essential medicines that could help treat COVID-19.
- We offered Slovenian doctors and pharmacists the first Lek mobile application **MedLex** with recommendations, guidelines, algorithms and dosing schemes that they often need in their work. A digital collection of medical professional information allows them to have key information quickly to hand when seeing and treating patients.

Working together with partners

We work with several external stakeholders, including the COVID-19 Therapeutics Accelerator and the COVID-19 Innovative Medicines Initiative.

Young talents in direct dialog with management

The YAB initiative received a 2020 Gold Practice Award, rewarded for innovative and efficient HR practices in Slovenia.

The Young Advisory Board is based on creativity that knows no hierarchy. It also directly reflects Novartis' culture of empowerment, inclusion and diversity, and the formation of agile teams.

Luka Ilić has always been involved in topics related to leadership and sustainable development, both environmental and social. The young expert, who is otherwise dedicated to the financial operations of the plant in Switzerland, is motivated to achieve change with innovative solutions that challenge the "status quo" and have a positive impact on the company and society. Together with like-minded people, he established the initiative Young Advisory Board (YAB). It connects young and ambitious associates with the most experienced and leading associates and is the first of its kind at Novartis.

What is the YAB initiative and what facilitated the idea?

YAB represents an advanced mindset and a new concept of co-creating a company for the future. It contributes to the strategic decisions of the company and builds trust between young talents and the company's management. Through conversation with management, young people are involved early on in the topics faced by top leaders, in decision-making and in learning about leadership. The idea for the YAB initiative came to us in a relaxed conversation between members of the Novartis delegation at one of the Slovenian business conferences,

Luka Ilić, BPA business partner, founder of the YAB initiative.

where we met young, aspiring employees and more experienced associates. In the conversation, we found that everyone would gain a lot from a more structured exchange of views. My role was to conceptually lead and coordinate the initiative, which would not have been successful without the openness of the leaders and collaborators. Currently, the initiative takes place through meetings with Amit Nastik, a member of Lek's Supervisory Board, and Robert Ljoljo, President of the Board of Management.

Do you also share experiences with colleagues at Novartis? How can the initiative contribute to business success and intergenerational cooperation?

I am very happy to share my experiences with colleagues inside and outside Novartis, as good practices need to be shared and learned from each other.

YAB represents an excellent intergenerational co-creation of the future, combining experience and ambition with youth and wisdom.

On the one hand, there are young leaders of the future, eager for challenges and full of ideas. On the other hand, there is an opportunity for experienced managers to obtain first-hand information about what is happening within the company and to find out directly how their decisions affect employees in different jobs. At the same time, they learn about "out of the box" ideas, which enables fast and efficient innovation. All participants find that mutual cooperation and learning are the key to successful decision-making and the future of the company.

How do you use the experience you have gained from YAB?

At the meetings, members get to know each other, which create synergies in the regular work process. It helps everyone involved to get to know other departments and units with a broader understanding of the company's strategic outlook. In our regular work, this benefits us because we better understand the impact of decisions on the area we cover.

What have been the positive steps, achievements of the initiative so far? What does the future hold for YAB?

We addressed a wide variety of topics, from current ones, such as the company's response to COVID-19 and new forms of work, to strategic ones, i.e. to the acquisition of talent, long-term development of competencies and the company's activities.

A wide range of ideas is currently being implemented, but we have certainly made a big step with the "Energized for Life" initiative and on topics related to pandemic resilience.

The responses of the associates so far are very good, as through the members of the group they can highlight burning topics and at the same time obtain first-hand information about the company. I want YAB to be involved in our human resource development and to enable all employees to be involved in it. For the initiative itself, I want it to experience sustainable progress in Slovenia and then expand to other Novartis countries.

The Green Team for green solutions

The Green Team at the Mengeš site, in coordination with a local food service provider, prepared a menu based on a healthy planetary diet.

A volunteer group of associates at the Mengeš site have joined the Novartis Green Team initiative.

Petra Zalokar has encountered taking care of nature or the environment for many years now. She is an associate scientist and her field of work mainly includes work in the analytical laboratory. However, as she is an engineer of nature protection by education, she is constantly looking for ways to bring the topic of environmental sustainability closer to her associates and pass on at least a part of her love for nature. She joined Novartis' global group for sustainable development and set up a Green Team volunteer group in Mengeš.

What does sustainable development and caring for the environment mean to you?

I believe that caring for the environment and sustainable operation is the first step in being aware of the adverse effects of today's society on nature. Our current way of life exceeds the regenerative capacity of our planet, so drastic measures are needed to reduce our ecological footprint. Not tomorrow, not the day after tomorrow, we must act today! Otherwise, in a few years we will be able to observe and use only the pale shade of nature as we know it today. Healthy nature is a prerequisite for

Petra Zalokar, associate scientist at Mengeš technical development.

our health, so caring for it is my leading guide in everyday decisions.

Novartis wants to be a pioneer in environmental sustainability. How does the Green Team project contribute to Novartis' environmental focus?

Green Team is a group of volunteers at the Mengeš site, which currently has just over 10 active members. It was established in early 2020 on the model of good practices of some other Novartis sites. The role of our team is primarily to connect people from all branches of the organization, who in their work and in everyday life in environmental sustainability recognize the opportunities for progress and change and demand to see them made. Our tasks also include raising the awareness of our employees about the human impact on the environment and reminding them that something drastic needs to change in the lifestyle of society.

The Green Team mainly helps to involve associates in Novartis initiatives and proposes new and fresh ideas.

It is also important that, as a group, it allows each associate to have their voice heard and have more weight in a large company like Novartis.

What is the role of Green Team?

Our task is to identify opportunities for greater environmental orientation of our organization and find ways to achieve them. We work closely with the Department of Health, Safety and the Environment. All our initiatives are based primarily on changing the operation and culture of the company and are in line with Novartis guidelines and principles. We could say that in the Green Team we encourage the company to set higher goals of environmental sustainability.

Which projects has the Green Team already implemented and what are you planning next? How are they received by your associates?

We are currently focusing on recognizing and promoting the team and encouraging employees to join. Among major successes we can count our participation in the project of green certification of laboratories. This global project brings together 24 Novartis laboratories from eleven countries around the globe. We also successfully carried out the Earth Day project, when we prepared menus based on a healthy planetary diet for our associates at the Mengeš site in cooperation with a local food service provider. We were pleasantly surprised by the positive response of employees to the menus served, which gave us the motivation to undertake similar campaigns more often. In 2021, we have several plans: from encouraging employees to use sustainable mobility to replacing lighting with more efficient LED lighting technology in two buildings at the site. At the same time, we would like to increase the number of volunteers in the group, which will contribute to the diversity and amount of great ideas. It is also our wish that Green Teams be established in other Slovenian sites and thus creating a network of well-connected teams that encourage each other and help each other achieve their goals.

An innovative project for the circular economy

Steam condensate storage tank from Novartis Solids and Aseptics production. The condensate is returned to the district heating system of Energetika Ljubljana using distribution pumps.

We monitor Novartis' efforts for energy and climate resilience with new solutions for resource efficiency and the circular economy. For this purpose, together with our partner, we designed and successfully carried out the return of excess steam condensate generated at the Ljubljana site to Energetika Ljubljana.

Associates at the Technical Services Ljubljana, led by Jordan Mržljak, take care of the preparation and distribution of primary energy sources, such as steam, thermal energy, electricity, gas and water. In their work, they are committed to improvements to reduce energy and water consumption and, consequently, greenhouse gases.

How are Novartis' orientations towards energy efficiency and carbon neutrality reflected in your work, how do they influence the selection of projects and the implementation of improvements at the Ljubljana site?

Efficient energy use is the responsibility and focus of everyone in our team, and our basic task is the uninterrupted supply of energy to production. All energy consumption savings are measured and analyzed in the ENIS (energy monitoring information system). In the last three years, when production was increasing, we reduced energy consumption at the location by about

Jordan Mržljak, Site Head of Technical Services Ljubljana.

3.5% and water by 15%. Initiatives and project ideas are generated by all team members who are in daily contact with our energy preparation and distribution systems. Project proposals are first evaluated in terms of costs and in terms of energy or water savings, and we select the ones that have the most favorable impact on energy consumption and the environment. In doing so, we pay attention to the financial sustainability of the project and the shortest possible return period.

How did you and your associates recognize the opportunity for savings in the excess heat generation at the Ljubljana site?

Excess heat or steam condensate was used for heating water on the site in the past, but it was not use in full, we discarded part of this heat, and we wanted to improve this.

We identified a public hot water system as the best option in finding solutions for the utilization of waste heat.

We got in touch with Energetika Ljubljana, our on-site heat supplier, and started talks on the implementation of the excess heat recovery project, connecting experts from both companies.

What kind solutions were needed? When will the project be profitable and what kind of savings will be made?

The solution is relatively simple and the profitability of the project is also favorable, we will achieve it in the short term. The project will pay off in just over a year. Of course, we initially performed chemical analyzes of the condensate itself and determined its suitability for reuse, and agreed on our entire project with our partner. The condensate is basically collected in a storage tank and pumped into the Energetika hot water system. The return of condensate started in March 2020 and since then we have returned 2.8 GWh of thermal energy to the heating system meaning we reduced annual CO_2 emissions by approximately 1,000 tons due to fuel savings. With such an amount of heat, Energetika Ljubljana can heat or prepare sanitary hot water for about 300 apartments, and the water we saved would fill a good 20 Olympic pools.

Where do you see the biggest challenges and opportunities in your future work? What role will digitization play?

The challenges remain unchanged in the future - our goal is to reduce energy consumption and the carbon footprint by introducing new innovative energy projects that will ensure our transition to carbon neutrality. We are already planning a complete renovation of our main heating and steam station, the implementation of a new energy-efficient air intake for air conditioning systems in the field of production and the installation of solar collectors for electricity production on the roof of production facilities.

The digitization of our processes is of great importance in this, as it brings us new opportunities in finding solutions for energy savings. Above all, the analysis of implemented environmental projects and achieved savings are key to the implementation of our environmental sustainability strategy.

Shorten distance, use space and reduce emissions

First electrical delivery vehicle in the cold chain in Slovenia for distributing samples between the Mengeš and Ljubljana sites.

We have delivered medicines to more than 120 countries on all continents by road, ship and air. To improve efficiency, we are constantly introducing changes and new forms of distribution in the field of logistics and connecting with suppliers.

In 2020, Miha Egart, Site Strategy & PMO BP, headed the Logistics Department, which, within the Supply Chain unit, is responsible for warehousing, distribution and transport of finished products from Slovenia around the world. Together with his colleagues, they actively looked for solutions to reduce the environmental impact of distribution. Thus, the first electric delivery truck in the cold chain in Slovenia was introduced in the distribution of samples between the Ljubljana and Mengeš sites.

Logistics services for Novartis Slovenia are provided by suppliers. Does the focus on reducing indirect greenhouse gas emissions affect their selection and cooperation?

Definitely. Due to our policy of reducing emissions, we require the use of trucks that meet the latest environmental standards in terms of greenhouse gas emissions in all tenders for road

Miha Egart, Site Strategy & PMO BP

transport services. In sea as well as air transport, for example, we look for the shortest route together with suppliers with as few intermediate stops as possible, as each stop significantly increases fuel consumption. We also cooperate with each other in the introduction of new distribution models through hubs, which in certain cases allow shorter transport distances and above all, better capacity utilization.

But how do you work directly to reduce the environmental impact of transport?

In the distribution of overseas shipments, we are trying to increase the ratio between air and sea transport in favor of sea shipment, which has a lower emission factor than other modes of transport. Thus, the share of shipping increased from 76% in 2019 to 81% in 2020.

For efficient distribution, it is very important how well we use the available space in vehicles. We reflect this with so called load factor indicator, which measures the number of pallets shipped by a single container or truck.

We achieve 90% utilization, which is an extremely good result and can be largely attributed to the knowledge and commitment of our associates in Logistics.

You also introduced the first electric van in the cold chain in Slovenia. Why did you decide to do this and how satisfied are you with the addition?

Already at the beginning of 2020, Supply Chain, under the leadership of the then director Jela Zdolšek, dealt with the idea of how Novartis Slovenia, as a responsible, sustainable company, can break new ground in this area. We started talks with suppliers about how they, as our technology partners, can help us with this. At the same time, a similar initiative was launched at the level of Novartis Global Logistics. Numerous consents had to be obtained for the introduction of the electric van. The key factor, however, was that our supplier, Prigo d.o.o., was able to offer us a vehicle in a very short time.

I would like to point out that all those involved in Novartis, including the president of Novartis Slovenia, Robert Ljoljo, have shown their support for the initiative and their commitment to its implementation.

After obtaining the approvals, we were able to introduce the electric delivery van in a very short time. For now, we are very happy with it.

It has replaced a fossil-powered vehicle and will save eight tons of carbon dioxide emissions a year, equivalent to 400 newly planted trees.

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 31.12.2020, Lek had 100% ownership share in Sandoz Pharmaceuticals d.d. and 74.5% ownership share in Wastewater treatment plant Lendava d.o.o. In 2020, there were no changes to the size, structure or ownership of Lek, moreover no merging activities or joint investments were made.

Purpose

Reimagining medicine to improve and extend people's lives.

Vision

Our vision is to become the most valued and trusted medicines company in the world.

Values

Inspiring
Curious
Unbossed
Integrity

[8] GRI GS 102-5

Our values and behavior

Novartis' social responsibility strategy

Social responsibility is an integral part of our business strategy and we implement it holistically in connection with all business activities and functions and our stakeholders. As part of Novartis, we follow its four key pillars of the social responsibility strategy, which was updated in 2020. It encompasses high ethical standards, pricing and access to treatment, addressing global health challenges and responsible citizenship, which includes caring for associates and the environment.

High ethical standards

Building solid long-term trust from customers, patients, associates and society is the foundation of our long-term success. Stakeholders not only expect us to meet the legal requirements, but they also expect us to act to high ethical standards wherever we operate, moreover our responsibility to people and the environment. Our goal is to promote personal responsibility for associate behavior. In addition, we are strongly committed to respecting human rights and managing risks, including in our supply chain.

Pricing and expand access to treatment

Improving the availability of treatment remains one of the greatest health needs worldwide. Through our core business - the discovery, development and marketing of innovative medicines - we contribute to the prevention and treatment of disease and the improvement of the quality of life of people around the world. Novartis' principles of accessibility focus on three areas: addressing patients' research and development needs, providing affordable medicines, and supporting quality patient care in close collaboration with governmental and non-governmental organizations and other healthcare partners.

Tackling global health challenges

With our expertise and organizational skills, we contribute to tackling the core unresolved global health challenges. Novartis has taken a comprehensive approach to eliminating or managing certain diseases for which there is no

market interest and little investment in research and development. It also aims to reach more patients and increase access to the entire portfolio of medicines, especially in the underserved population and lower income countries.

Responsible citizenship

We are committed to a positive and constructive role in society and focus on building a company that our patients, customers, associates, shareholders and partners can be proud of.

- **Health and safety of our patients:** In discovering and developing breakthrough treatments, our main concern is to protect the safety and well-being of all who use our medicines.
- **Employees:** we create an organization where our employees are empowered and can make full use of their talent and energy and take care of their health and safety.
- **Volunteering:** we encourage employees to participate and get involved in voluntary activities, including through the annual global initiative Day of Cooperation with the Local Community.
- **Environmental sustainability:** our ambition is to be a leader in environmental sustainability and to be a catalyst for positive change through our business as well as the business of our suppliers.

1.2.1 Key customers and markets[9]

In accordance with organizational and strategic orientations, Sandoz Group and Novartis companies are the key buyers of our products and active pharmaceutical ingredients. In 2020, the leading three buyers accounted for 71%, 9% and 5%.
We sell our own products and the products of other Sandoz and Novartis companies. The majority of our products in 2020, 96%, were sold to foreign markets (Western Europe, Russia, Canada and the USA), Slovenia accounted for 4%. The majority of sales (83%, somewhat less than the previous year), came from pharmaceutical products, the remaining 17% came from APIs and biopharmaceutical products.

In the Slovenian pharmaceutical market, Novartis, with all its divisions, remains the leading provider of medicines with a 12.5% market share.

Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 74% of sales in 2020. Lek is in first place on the market of over-the-counter medicines, second in the sale of generic medicines and the largest provider in the sale of similar biological medicines.

The total value of the Slovenian pharmaceutical market was 837 million Euros, and a 6% market share makes Lek the third largest pharmaceutical company. On the generic market, where the total value is 182 million Euros, with a market share of 27.6%.

The biosimilar market for amounted to 11.7 million EUR, with Lek having a market share of 42.4%. In the market of over-the-counter medicines (worth 101 million EUR), Lek recorded 3.1% 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.

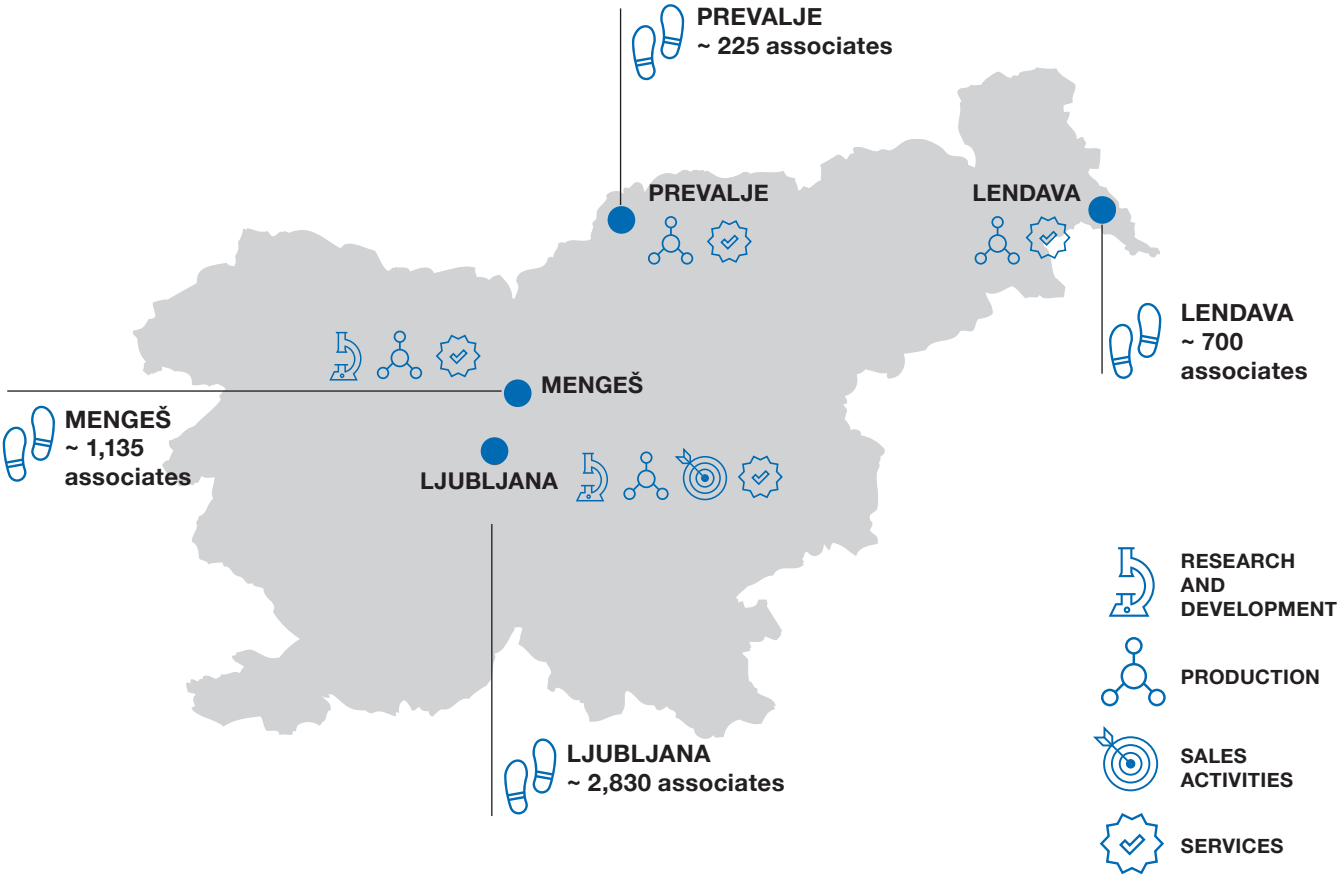
In 2020, Lek's leading prescription medicines on the Slovenian market were Amoksiklav® (amoxicillin with clavulanic acid), Iroprem® (a trivalent iron drug) and Coupet® (rosuvastatin). The best-selling biosimilar was Rixathon (rituximab), the new biosimilar Erelzi (etanercept) is also available to patients in Slovenia.

Amongst the leading over-the-counter brands we achieved the highest sales with Lekadol plus C®, Linex®, Operil® and Fluimukan®. We also offered a new painkiller Lekofusin.

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

1.2.3 Development and production sites[11]

Novartis – the largest medication provider to Slovenian patients



Novartis Slovenia – operations

RESEARCH AND DEVELOPMENT

- Global technical development of biological and bio-similar medication
- Sandoz development center (small molecules)

~ 715 associates

PRODUCTION

- Sandoz technical operations
- Small molecules
- Large molecules

~ 3,010 associates

SALES ACTIVITIES

- Sale of generics Slovenia
- Sale of innovative medicine Slovenia

~ 165 associates
(Sandoz d.d. ~ 900 associates abroad)

SERVICES

- **Global Operative Center** (GOC)
  · Logistics center
  · Service center for quality
  · Cell and gene testing
- **Novartis Business Services (NBS)**
- **Center of Excellence**

~ 1,000 associates

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

Site Development and Engineering NTO Slovenia

The global involvement and role of our expert teams are even greater.

Site Development and Engineering NTO is a local organizational structure that oversees the efficient implementation of engineering and HSE activities for our production units. In addition to operational tasks, it is responsible for the implementation of development plans for individual sites as well as for their strategic development for the upcoming years.

The site development NTO brings together all units of **Production Engineering** and the following:

- **Central functional units:**
  - Project Management: manages investment projects, major upgrades, conversions, upgrades of equipment and systems.
  - Automatization: takes care of digitization and automation of systems and parts in production.
  - Technical Services: ensures the operation of production equipment. She is in charge of infrastructure and energy media for the production of pharmaceutical products.
  - Maintenance: plans to maintain production equipment at the umbrella level, thus ensuring its reliability and high standards of operation.
- **HSE Unit:** expert team who take care of all areas of health, safety and environment.

"With the recent organizational changes in Novartis and the establishment of the Global Operations Center for Technical Operations in Slovenia, the role of our experts has greatly increased, as teams in Slovenia have gained a much more important role in formulating strategies. Excellent associates and a culture of openness, support and opportunities for development and proving key to our success. We are a young organization and we are aware that investing in our associates and promoting their curiosity and proactivity is our priority. As such we are simultaneously realizing all technical goals."
Matej Ambrož,
Head of Site Development and Engineering NTO Slovenia.

"One of the priorities in the engineering activities, which belong to the Development of NTO locations, is the realization of environmental sustainability. We have prepared several groundbreaking development projects, for which we are obtaining internal approvals. These projects will enable us to meet Novartis' goals set to achieve water and carbon neutrality. At the same time, we are very active in energy management and invest heavily in the energy efficiency of production equipment. We have an excellent team, knowledge and ideas, and we also work with top innovative Slovenian companies in this field."
Robert Hribar,
Head of Engineering Slovenia

"In 2020, we focused most of our activities on safety and other measures, with which we successfully managed the epidemic and at the same time ensured the compliance of operations with our professional teams for health, safety and the environment. In 2021, we will focus on further improving the safety culture and managing high risk activities. In the field of the environment, in cooperation with Technical Services, we will support the introduction of programs that implement Novartis' sustainability strategy. In an unified approach and the introduction of new technological solutions, we see many opportunities for more simplified and standardized process management in all areas of the HSE."
Eva Podgoršek,
Head of HSE Slovenia

1.2.3.1 Ljubljana site

The Ljubljana site is home to our headquarters and Lek's business center from which we lead operations and corporate functions for the wider region of central and eastern Europe. These fields are regulatory affairs, procurement, legal affairs, 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.

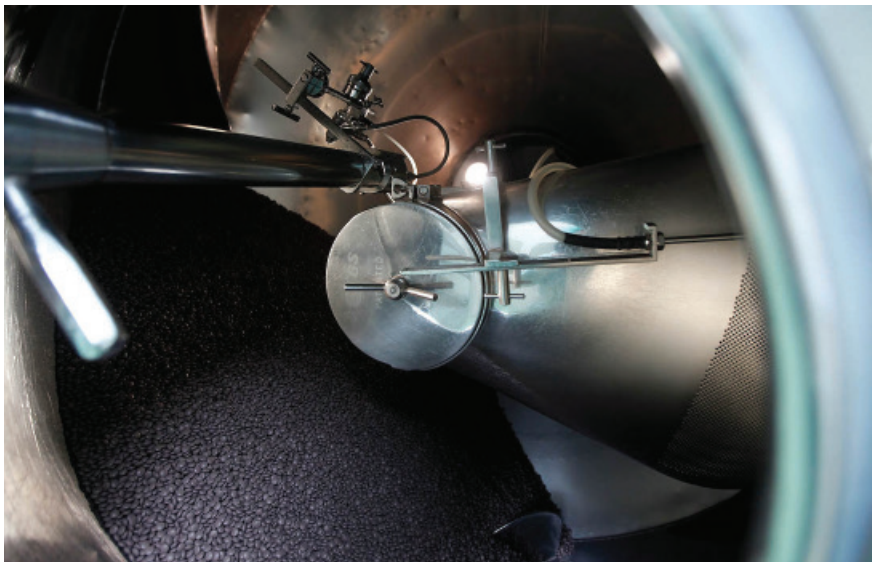
Solids Ljubljana

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 2020, despite demanding conditions, we provided uninterrupted care to customers and patients and again produced record quantities. We produced 9.7 billion pieces of solid pharmaceuticals and 124 tons of granules and 11 tons of micropellets. We packaged 125 million finish products with 331 million primarily packaged units (blisters, bottles, jars and sachets).

Daniela Zaccara, Head Solids Ljubljana

With the reorganization of technical activities, we have become an important location in the Small Molecule platform. We have successfully implemented the strategy of transforming the location from the production of predominantly generic medicines to the production of innovative medicines. Thus, we increased the number of packaged products of innovative medicines by as much as 36% compared to 2019. Among the important milestones is the launch of one of Novartis' most important innovative heart failure treatment products for the U.S. market.



Tablet film coating in Solids Ljubljana

In the future, we will increase the amount of packaged products, so we plan to increase the capacity of bottling and establish a line for packaging products for the Japanese market. We have started the introduction of many new innovative products in production and packaging. Although the portfolio of innovative medicines is growing, generic medicines remain an important part of our production. Several important new product launches have also taken place in the field of generic medicines.

The year was also a record year in terms of investment in new equipment. We completed an investment to produce one of Novartis' most important products for the treatment of heart failure. The investment in melt extrusion technology and in the first line for continuous production in technical operations for the production of powder tablets with a high degree of automation and process control and environmentally advanced solutions also stands out in terms of importance.

Just before the announcement of the first wave of the epidemic, we successfully passed the JAZMP inspection. Several customer reviews were successfully conducted remotely. We re-certified the NOSSCE standard (Novartis Operational Standard for Supply Chain Excellence) and further improved customer service.

Tjaša Bantan Polak, Head Aseptics Ljubljana

Matjaž Tršek, Head Development Center Slovenia

Vesna Kapelj, Head Chemical Operations Mengeš

Aseptics Ljubljana

At Aseptics Ljubljana, we implemented numerous projects to improve our supply chain and achieved excellent results in supplying customers with process optimization and stable production of all pharmaceutical forms.

In the production of vial products in all segments, we exceeded the quantities produced in 2019 by as much as 50%. With innovative solutions, we once again improved productivity and met all market needs, thus enabling access to medicines to all our patients worldwide. The volume of ampoule production decreased slightly, while the production of nasal sprays remained at a similar level as in 2019.

We also successfully introduced production of new products, focusing on the development of new biological drugs and demanding generic sterile products. We have completed the demanding technological transfer of a new sterile product from the Ljubljana Development Center and numerous optimization projects in the existing product portfolio.

We have successfully completed inspections and audits, thus reaffirming the high level of quality system and teamwork. We have reorganized some departments to improve efficiency and operations.

Development Center Slovenia

Development Center Slovenia specializes in the development of tech Center Slovenia employs 360 experts, technologically demanding products and is home to half of all Sandoz global development projects. At the Ljubljana and Mengeš sites, Development Center Slovenia employs 360 experts, mainly pharmacists and chemists and around a third are doctors of science.

More than 200 development projects for pharmaceuticals and active ingredients took place in 2020. We achieved 25% growth in the development portfolio through the constant development of knowledge, the introduction of new technologies and technological platforms, digitization and an agile work approach. We invested more than seven million US dollars in three key pillars; laboratories and laboratory equipment, digitization, and human resources and knowledge development. We completed more than 20 initiatives in the areas of operational excellence and digitization with estimated savings of more than $ 3 million.

The COVID-19 pandemic affected our way of working. We paid a lot of attention to our associates, maintaining and promoting teamwork, connectivity and distance learning. We conducted more than 90 hours of virtual training. We co-created various events, internal and external, which contributed to strengthening the innovation culture, the visibility of our company and the well-being of our employees.

Aseptics Ljubljana

Polonca Kuhar, Head Drug Substance Bioproduction Mengeš

Špela Jalen, Head Techical Development Biologics Mengeš

1.2.3.2 Mengeš

Chemical Operations Mengeš

In Chemical Operations Mengeš, we produce high-quality and technologically demanding active ingredients for various therapeutic areas. They are used in the treatment of secondary progressive multiple sclerosis, COPD (chronic obstructive pulmonary disease), breast cancer, Cushing's disease, in the prevention of organ rejection after transplantation, in oncology, in the treatment of anemia due to iron deficiency, in the treatment of acute mania, depression and bipolar disorder. to lower blood cholesterol levels and prevent heart attacks and strokes. They are also used to treat high blood pressure, angina pectoris and heart failure, reduce the risk of heart attack and treat dermatitis.

Our goal is to become the leading site for the launch of new innovative active ingredients in 2021, and at the same time a competitive supplier of innovative and complex generic active ingredients. By transferring new active ingredients to the site, we improve the occupancy and cost-effectiveness of our facilities.

Drug Substance Bioproduction Mengeš

We are an industrial center for modern biotechnology, where we produce active ingredients for biological and biosimilar medicines. In 2020, the active substances erythropoietin and pegfilgrastim were successfully transferred to commercial production, and the transfer and validation campaign of denosumab were completed in accordance with the plans.

Drug Substance Bioproduction Mengeš

We also produced the first clinical series of two originator biological drugs and began to implement additional expansion of production capacity in the new plant, which will bring us a doubling of capacity.

In 2020, we launched the Manufacturing Execution System (MES) project, which will enable us to further automate production and move to electronic production reports. We have successfully completed NOSSCE re-certification, which is a confirmation of our excellence in process management. In September 2020, we completed the regular JAZMP inspection and certification of the new plant with excellent results. Another important acquisition is the new office building, which is built in line with Novartis' efforts to continuously improve the working environment, which offers employees modern working conditions.

Techical Development Biologics Mengeš

Despite the changes to our work, in 2020 we were very successful in all areas of our operations. With new, state-of-the-art laboratories and the strengthening of innovation, data science, digitization and automation, we increased our development capacity and strengthened our role as Novartis' development center for the development of innovative biological and biosimilar medicines.

With new laboratories, even more environmentally and user-friendly and more energy-efficient, we are introducing many advantages into development processes, following modern trends, shorter development timelines and quality assurance. The state-of-the-art knowledge, which is a reflection of our innovation culture, curiosity and cooperation, is at a very high level, which has been reaffirmed by internationally recognized projects and awards for the scientific achievements of our employees.

Roman Burja, Head Anti-infectives Prevalje

Gizela Štampar, Head Anti-infectives Lendava

Dr. Simon Rečnik, Head Solids Lendava

1.2.3.3 Prevalje site

In Prevalje, where we produce the broad-spectrum antibiotic Amoxiclav and sell it in more than 75 of the world's most demanding markets, we attached great importance to ensuring the uninterrupted supply of patients with quality, effective, safe and affordable medicines.

We coordinated the production volume with the movement of demand and ensured the implementation of increased orders from Russia through additional changes. In total, we produced 504 million tablets, of which about 40% were for the Russian market, and 9.4 million pieces of oral suspensions, 47.2 million packs of our products and 318 tons of mixtures.

Numerous assessments of our customers have confirmed that we ensure the highest quality standards and the production of safe, effective and high-quality medicines. We can be especially proud that we are reducing the share of recurring deviations and improving the indicator of the share of batches without deviations.

As part of the transformation of Novartis' technical operations, we plan to phase out production at the Prevalje location, which is expected to be completed by the end of the first quarter of 2022. As part of the transformation, we participated in the transfer of our products to Lendava and Kundl. More than 60 transfers of employees to the Global Operations Center or to other locations in Slovenia were also successfully carried out.

1.2.3.4 Lendava site

Anti-infectives Lendava

In Anti-infectives Lendava, we continued the production of two active ingredients, potassium clavulanate - the leading product of the site - and gentamicin sulfate, which we produce in smaller quantities. Both production processes are based on classic biotechnology, which is the fruit of our own knowledge. The year was demanding, as under changed conditions, the production of our main product of potassium clavulanate was at full capacity. The biggest achievement was the implementation of all registration batches for the production of potassium clavulanate mixtures, which will be introduced in 2021 and represents a new product that is

Prevalje site

expected to contribute to the growth of the unit in the future.

We implemented a sustainable business orientation and improved the results of the semi-continuous fermentation process, which, while increasing production capacity, enables material and energy savings. We have successfully launched a new line for drying and packaging of the intermediate product, DIPEDA-clavulanate, for production under strictly controlled conditions.

We started to introduce the process of isolation of potassium clavulanate without drying and packaging of the intermediate product, which will improve the production time, reduce safety risk and save materials. During the regular annual overhaul, we successfully upgraded the incinerator during the overhaul works and carried out some smaller projects.

We reaffirmed the high level of quality and good practices, as we achieved or exceeded the expected targets for all indicators. Due to the epidemic, most inspections and audits were carried out virtually, which was even more demanding. We also achieved the set goals in the field of health and environmental protection, increased the safety of processes and the safety culture of employees.

Solids Lendava

In the Lendava Solid Products unit, which became part of the NTO Small Molecule platform, we responded agilely to the challenges of the COVID-19 pandemic and fully achieved the set goals and even a few record months in a row. The location is crucial for the NTO as it is the largest solid pharmaceutical packaging plant with more than 4,000 finished product codes. In 2020, we packaged nearly 7 billion tablets or capsules for patients worldwide.

The production site started or was already implementing several important innovation initiatives for automation, digitization and innovative packaging, which will meet the increased expectations regarding our competitiveness and operational excellence in the coming years. We focused on investing in a new automated high-tech line for integrated blistering, wrapping and packaging, which will significantly increase the competitiveness of one of the key drugs after organ transplantation.

Automated packaging projects are also underway, multipacks and the replacement of booklets with 3 pre-folded instructions. Other innovation highlights include innovative 3D-printed half-shaped respirators that have been designed and tested as feasible prototypes during a crisis in the supply of personal protective equipment. 3D printing brought great savings in maintenance costs and numerous benefits.

As the largest packaging center in the NTO and a supplier of medicines, we in Lendava have made a significant contribution to reducing the shortage of stocks of finished products. We contributed more than half of the overall stock improvement at solid product sites across the NTO. We also improved several other indicators of customer service quality.

With 26 packaging lines, the production site is one of the key suppliers of Novartis' innovative pharmaceuticals in solid pharmaceutical forms, and has also left a strong mark in Sandoz's portfolio. At the end of 2020, we re-certified the NOSSCE Class A certificate and maintained our position in the group of the most reliable drug suppliers in Novartis.

Anti-infectives Lendava

Solids Lendava

1.3 Development and Reporting Framework

Ever since 2010, we have compiled an annual 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 Standards.

We also prepare 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 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 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*.

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

Comprehensive reporting is also carried out within Novartis, which in turn performs regular 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 2020[15]

Reporting in accordance with RCI requirements

Lek's reporting has been based on the ACIS for years, it now reports within RCI (Responsible Care Initiative) requirements, the present report being an upgrade of the previous reporting model.

Reporting in accordance with EMA

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

Reporting in accordance with GRI Standards

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

- Reporting refers to Lek and all its manufacturing sites in Slovenia. All disclosures in the present report refer to the 2020 calendar year.
- Employee data, key data on financial operations, and economic impacts on operations were acquired in the financial reporting process for the purpose of compiling the company's annual report in accordance with International Accounting Standards (IFRS) and Slovenian legislation.
- The objective of Lek's HSE reporting is compliant with Novartis' and Sandoz' objectives to provide a fair and well-balanced picture in the field of HSE. The system of monitoring HSE achievements and the reporting methodology are described on page 98.
- Sustainable development reports are compiled annually and also include the amended (at any major change) EMAS. The reports contain the key data for all Lek sites in Slovenia.
- The content structure of the Sustainability Report 2020 is comparable to similar annual reports of Novartis. The changes did not affect the scope of disclosures in the report.
- In 2020, 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:
  - The previous Sustainability report showed the estimated amount of volatile organic compounds at the Lendava site, this report shows the final data.

[12] GRI GS 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 Governance 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 2020, the members of the Board of Management were as follows:

- **Robert Ljoljo**, President
- **Ksenija Butenko Černe**, Member – Legal Affairs
- **Ivan Ďurovčík**, Member – Finance
- **Andrej Pardo**, Member – Commercial Operations
- **Uroš Urleb**, Member – Research and Development
- **Raul Intriago Lombeida**, Member – Technical Operations
- **Marjan Novak**, Workers' Director

The Board of Management runs the company, independently and on its own responsibility. In their function, board members act to the benefit of the company and with due diligence, bound by an obligation of confidentiality. All members of the board avoid any conflict of interest and 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 2020, the members of the Supervisory Board were as follows:

- **Rebekka Guntern Flückiger**, Chairman (from 18. 3. 2020)
- **Francesco Balestrieri**, Chairman (to 17. 3. 2020)
- **Ingrid Sollerer**, Vice Chairman
- **Nastik Amit Kumar**, Member (from 18. 3. 2020)
- **Andreas Michael Brutsche**, Member (to 17. 3. 2020)
- **Peter Svete**, Member – Workers' Representative
- **Fikret Bašanović**, Member – Workers' Representative

The management of company operations is overseen by the Supervisory Board, in accordance with its mandates and responsibilities, through regular reports from the Management Board, which are forwarded to the them, in accordance with legislation and internal regulations, and other notifications which they deem important. This allows the Board to perform comprehensive control of the company's environmental, social and corporate governance (ESG) impacts. These impacts are also communicated within the competence of 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.

[16] GRI GS 102-18

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

In 2020, the Supervisory Board had five 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 2020, the Workers' Council was regularly informed at its meetings about the company's economic situation and its development goals. 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. 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. We also conducted consultations related to the transfer of employees, transformation, new models of rewarding work performance, etc.

The Works 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.).

In 2020, the Workers' Council successfully organized and conducted elections for a member of the Supervisory Board, a workers' representative, on the Lek Supervisory Board. Members of the Workers' Council regularly attended meetings with employees in the units they represent. Due to the epidemic, most of the activities were carried out virtually using MS Teams.

The more important activities of the Workers' Council in 2020:

- weekly meetings of the Workers' Council members and the Workers' Director, at which we discussed the events by units and locations and were updated on the situation in the company,
- weekly meetings with HR representatives, at which we discussed current topics in the field of human resources,
- participation in the NEM group, where we were informed on the situation in the company and the planned measures related to containing the epidemic,
- participation in the preparation of measures relating to employees (allowance, use of special leave, transport to work, childcare ...) during an epidemic.

[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 Association
- 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 Information Exchange EGIZ
- Slovenian Institute of Auditors
- Slovenian Advertising Chamber
- Slovenian Association of Representatives for Intellectual Property
- Slovenian Association for Quality and Excellence
- Slovenian Fire Protection Association
- Veterinary Chamber
- Occupational Health and Safety Chamber
- Association of Employers of Slovenia
- Association of Workers' Councils
- Association for industrial property protection
- Association of pharmaceutical manufacturers of Slovenia
- Association of Senior Citizens of Slovenia
- 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. Access to Healthcare

Access to healthcare is one of Novartis' key strategic areas. We established the principle of the strategy in 2017 and it is directly integrated into our core business – 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 access by promoting the development of modern technologies and innovative solutions. Moreover, with affordable access, expand the interest in science and access to healthcare among young people, as well as through donations of medicines. In cooperation with governmental and non-governmental organizations and other partners, we are looking for opportunities to reduce local barriers to improving health care and quality patient care.

2.1 Innovativeness

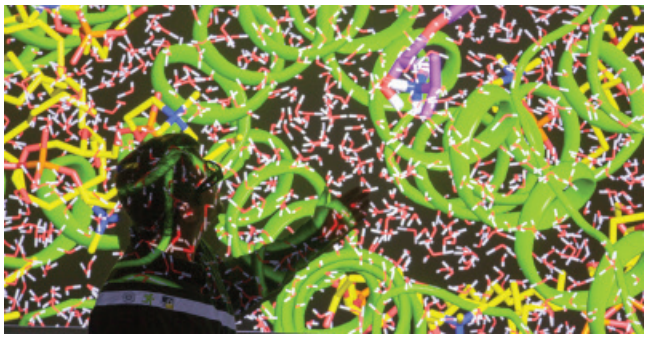
We actively contribute to solving global health challenges through innovative medicines based on completely new discoveries, as well as through the development and production of generic medicines. At the same time, we constantly pay great attention to innovation and innovative culture, professional and personal development of employees, development of the profession and social well-being.

The year 2020 was quite different from previous years, as we had to move almost all the planned activities to the virtual world. Nevertheless, the year was full of various creative and dynamic events and achievements, both internally and at the national and international level. We exchanged best practices and built new knowledge through various collaborations.

2.1.1 Achievements in medicine development

A large number of projects in the field of innovative biological medicines and biosimilars are underway in the **Biopharmaceutical Development Center Mengeš**. In 2020, we launched the eighth biosimilar (Erelzi) and remained the leading provider of similar biological medicines in Slovenia.

With the support state-of-the-art laboratories and strengthening innovation, data science, digitization and automation, we have strengthened the development of innovative biological and biosimilars and further established our role as the Novartis Development Center.



At the end of the year, more than 200 development projects for pharmaceutical products and active pharmaceutical ingredients took place 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 the development and submitted 22 dossiers for drugs from the therapeutic areas of blood pressure management, anticoagulation, anemia, oncology and diabetes, as well as anti-inflammatory and antiviral drugs, drugs for the treatment of pulmonary fibrosis and for the treatment of gastric diseases. The dossiers were filed in the markets of Japan, Europe, the USA, China, Mexico, Canada and Brazil. Sandoz has successfully launched several products developed at the Development Center Slovenia, namely in the field of blood pressure control in China and Europe, a probiotic product in Russia, a drug for the treatment of fungal diseases in Canada and Australia, a drug for rheumatoid arthritis in Japan and a drug for treatment of gastric diseases in the United States.

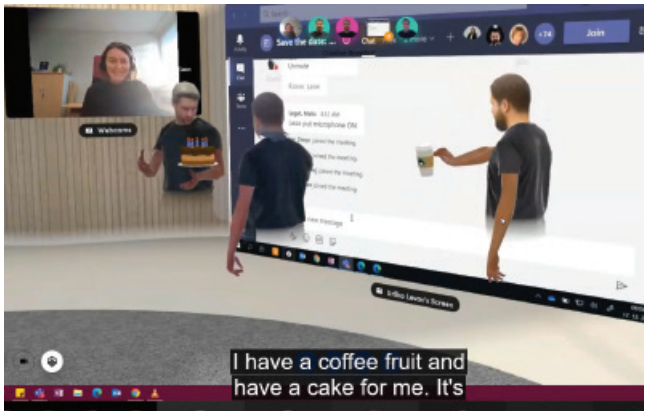
2.1.2 Facilitating mass inventive culture

Th!nk Novartis 2020

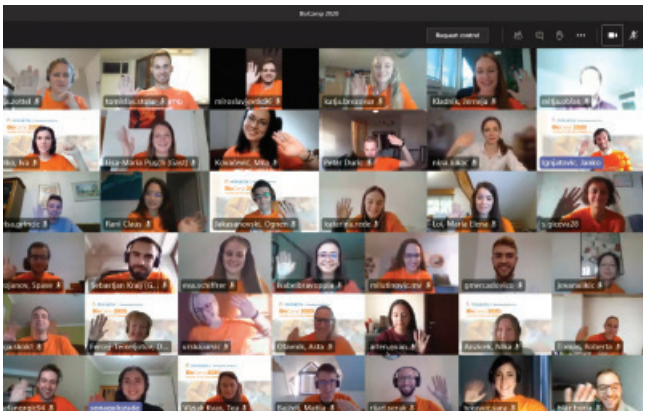
The Th!nk Novartis app enables online idea management, allowing employees to actively participate in introducing changes and improving work processes. In 2020, **342** Lek employees submitted **455** ideas, of which **337 were approved** for implementation. Directly measurable savings of approved ideas amounted to **3.9 million EUR**. Special recognition was given to employees who contributed and put into practice the most innovative ideas and solutions. We published four internal Th!Nk Novartis newsletters, where we gave the results of Th!Nk Novartis on a quarterly basis, shared good practices, advice and informed employees about the awards received and events. Since 2012, we have already invested 7,196 ideas and implemented 3,620, which brought a total of **59.9 million EUR in benefits**.

Week of innovation

The eighth Week of Innovation was held virtually for the first time. The events took place in three sets throughout the year. The first Innovation Day in June was dedicated to cooperation between universities and industry. We presented useful solutions created in collaboration with students on their various study projects, and discussed the importance of our collaboration with professors from the University of Maribor and the University of Ljubljana. The second day of innovation, held as part of the month of learning in September, brought a new milestone, as the events (virtual agile creative breakfast, round table, virtual workshop, and presentations) attended by more than 300 collaborators. In December, we organized the third day of innovation on the topic of mixed reality.



The third day of innovation took place in December on the theme mixed reality.



Participants from the two-day BioCamp got to know new business models in the pharmaceutical industry.

Open innovation

We work closely with faculties, research institutions and career centers. We established new academic partnerships with the Biotechnical Education Center Ljubljana, the Biotechnical Center Naklo, the School Center Celje, the School Center Ljubljana, the Secondary School Ravne na Koroškem, the Vocational School of Economics Murska Sobota and the Faculty of Engineering Belgrade. Our new partners are Axiologo, the VTIS association, the Ljubljana University Incubator - LUI, the European Institute of Innovation and Technology - EIT, the Office for the Transfer of Health and Knowledge (University of Ljubljana).

In cooperation with LUI, we organized the Novartis hackathon and were part of two hackathons organized by students of the Faculty of Pharmacy and the Faculty of Economics (“Business Hive” and “Innovation Incubator”). We approached students and other young talents at career days and fairs, visits to companies and at career fairs abroad. We were part of two summer schools for young students and talents, namely the EIT Digital summer school and the school organized by the UL and Mediade Career Center.

Career Breakfast

For the sixth time in a row, we organized Novartis’ Career Breakfast, intended for young Slovenian natural science experts who are studying or working abroad. This time, held as an online event, a record 300 science and other experts attended. Representatives of Novartis’ units in Slovenia offered them an insight into the operation of the pharmaceutical industry on 12 thematic platforms and highlighted the available career opportunities in one of the leading pharmaceutical companies in the world.

BioCamp 2020

At the tenth BioCamp, over two days, the best students met with renowned experts and leading managers from Lek, Sandoz and Novartis. It brought excellent opportunities for young talent to gain a direct insight into the world of research and the international business environment of the pharmaceutical industry. The event was held virtually under the central theme New Business Models in the Pharmaceutical Industry. A record number of students applied, 191 from 24 countries, of which 42 participants took part in the event.

Day of Research and Technology Breakfast

In November, we organized the second Day for Researchers. It took place within the UNI.MINDS online festival in cooperation with the universities of Ljubljana and Maribor on current topics such as time machine stability, machine learning and data mining in bioprocesses using the Orange program, modeling and simulation of the lyophilization process, polysorbates in biology and development of cell lines for biology. At the beginning of February, we also participated in the first Technology Breakfast - on the way to Industry 4.0, where technological content or good practices on the topic of the factory of the future, technology and career opportunities were presented.

We participated in the first Technology Breakfast – on the way to Industry 4.0.

Young Advisory Board

In the autumn 2020, we launched a new initiative, the Youth Advisory Board (YAB). The project is in a pilot six-month phase. As part of it, a group of 12 young talents from all over the company is discussing important topics with the President of the Management Board, Robert Ljoljo, such as previous issues: talent search, COVID-19 and Energized for life.

Talent Cloud

We participated in a talent exchange project - Talent Cloud, organized by AmCham as part of the Partnership for Change project. The project connects different companies with their own challenges with consultants from other companies who already have solutions to their challenges. In solving the challenge "How to (successfully) introduce agile teams in production units?", We worked with consultants from Danfoss throughout the year and also helped with the challenges of two other companies.

2.1.3 Awards for Innovation

Central Eastern European Pharmaceutical Manufacturing Excellence Award

At the annual conference of the international association PHARM Connect, our employees once again won the main recognition "CEE Pharmaceutical Manufacturing Excellence Award". The team from the Development Center Slovenia received the award for the introduction of data science in the development of generic medicines.

Awards of the Chamber of Commerce and Industry Slovenia 2020

The awards for the best innovations at the national level are the highest recognition for the innovative achievements of Slovenian companies. As one of the best innovations at the national and regional level, they recognized the innovation from Lek, namely the **prolonged-release capsule with the active substance tacrolimus**, which is intended for immunosuppressive treatment of patients with organ transplants. Patients with transplanted organs must take appropriate medication throughout their lives so that the body does not reject the new organ.

Lek associates received one national and three regional awards for innovation from the Chamber of Commerce Slovenia.

The silver award at the regional level was won by colleagues from the Biopharmaceuticals Development Center Mengeš for **biosensor analysis of biosimilar medicines**. Advanced systems of biosensor analytical methods are characterized by significantly improved time and cost efficiency compared to conventional ones.

The Chamber of Commerce and Industry of Central Slovenia awarded the bronze award to the project **modeling and simulation of the lyophilization process for biological active ingredients**. The project enables higher quality in the initial design of the lyophilization process and is based on an in-depth understanding of the process and the reduction of costs and errors in the transfer of technology to a larger scale. The project was conceived by Biopharmaceuticals Development Center Mengeš in cooperation with the Faculty of Mechanical Engineering of the University of Maribor and the Faculty of Mechanical Engineering of the University of Ljubljana.

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 Dr. Biljana Janković and Dr. Miha Jaklič and came 2nd.

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 Dr. Igor Legen, Ph.D. Dr. Janez Diaci (FS UL) and assist. Helena Vrbanac (FFA UL).

TOP Th!nk Awards

Associates who contributed and implemented the most innovative ideas and solutions were awarded for their work. The "TOP Th!nk proposer" award was given to Damir Čajić. The "TOP Th!nk team" was given to Nina Malešič and the team at the Linex unit, the "TOP Th!nk unit" award was given to Darijan Mlakar and associates at Solids Ljubljana. The »TOP Th!nk special achievement« award was given to Saša Lukić.

2020 Novartis Award winners from Slovenia

Novartis Awards

Novartis, with its scientific awards, which it has been awarding for more than 20 years, recognizes individuals and teams that are paving new paths in the field of pharmacy. In 2020, the Leading Scientist Award was awarded to dr. Biljana Janković, head of the IVIVC group from the Development Center Slovenia, and dr. Drago Kuzman, Head of Innovation of Development Processes in the Biologics Technical Development Mengeš. The award for leading scientists was also given to dr. Rok Grahek, Ph.D. Andrej Kocijan and mag. Nejc Golob, members of the Analytical Research Department at the Development Center Slovenia.

Sandoz R&D Awards

Sandoz, Novartis' division and the world's leading company in the field of generic and biosimilars, rewards outstanding achievements in research and development. Among the winners were Slovenian researchers from the Development Center Slovenia and the Biologics Technical Development Mengeš. They received 17 Sandoz scientific awards. With the Scientific Excellence Award, Sandoz recognizes the best researchers each year with years of outstanding research and development achievements. The recipients of both awards were again from Slovenia, namely Dejan Krajcar from the Development Center of Slovenia and Matjaž Brinc from the Biologics Technical Development Mengeš.

Star Awards

The Star awards thank individuals and groups every year for their achievements and actions, which stood out in the past year. Awarded individuals and teams and their achievements were presented in video format. In the category of values and behaviors, we awarded twelve individuals and nine teams for outstanding achievements.

2.2 Stakeholder Overview and Inclusion[20]

We are aware that our activities have impacts that go beyond mere financial operations. For long-term successful operation, we therefore integrate into the social environment and look for ways to coordinate our operations and their positive and negative impacts with the expectations of shareholders, stakeholders and society in general.

Taking care of patients' health and improving access to healthcare requires a high level of trust, which we are constantly building with our key stakeholders. In doing so, we try to understand as much as possible the environmental, social and governance topics (ESG) that are most important to them.

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).

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).

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 are described in section *3.2.1. Purchasing system and purchasing policy*.

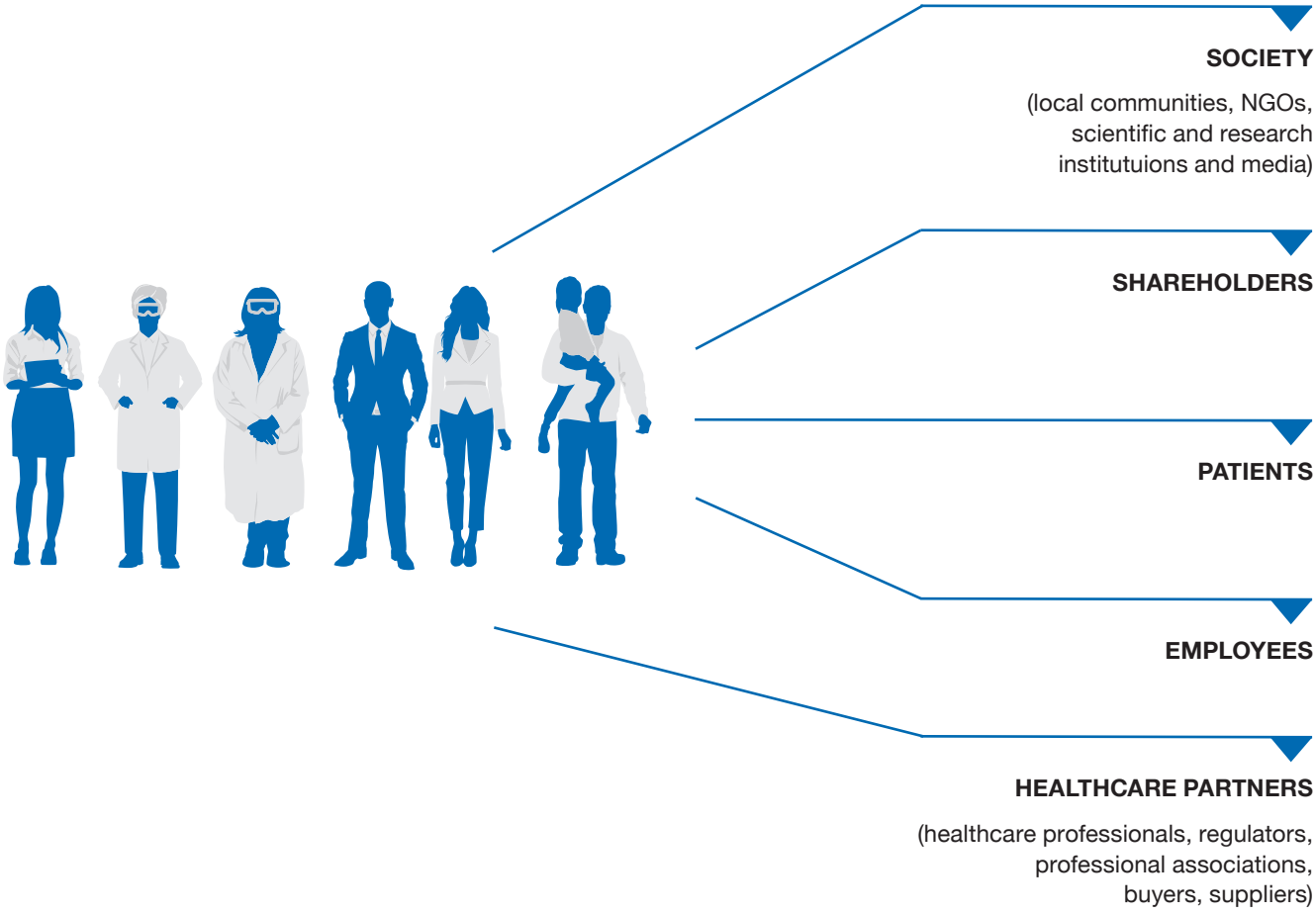
We involve patients, doctors, pharmacists, wholesalers and retailers through the use of new technologies and information channels. We provide balanced, accurate and easy-to-understand scientific information on diseases, treatments and treatment policies that concern patients. We pursue an interest in 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 comment handling.

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.

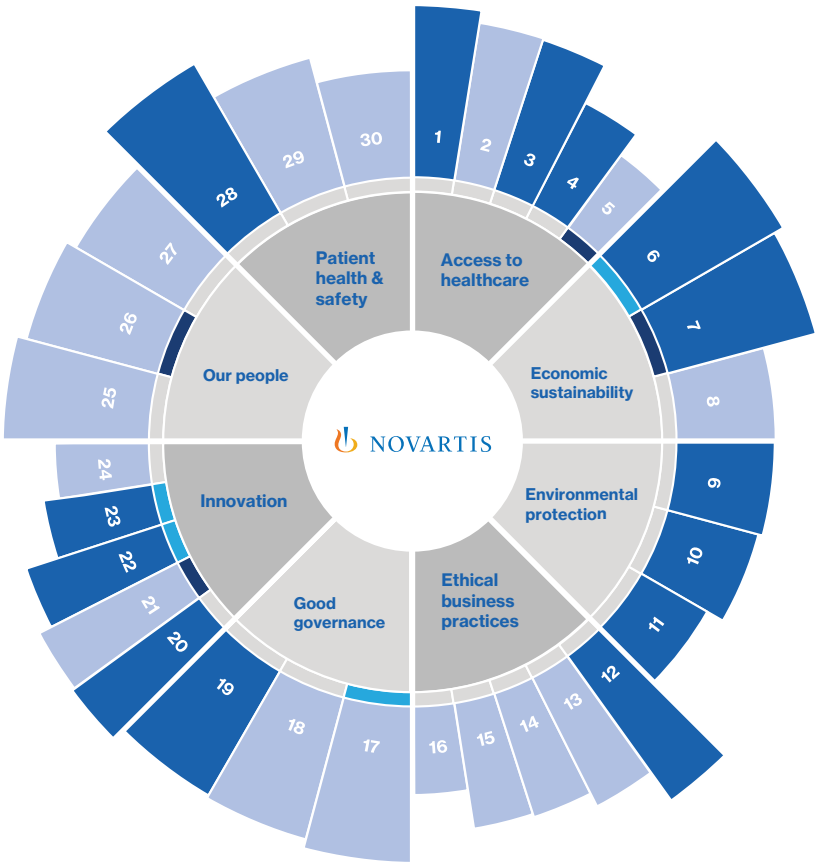
[20] GRI GS 102-40, 102-42, 102-43

Lek's key stakeholder groups



To understand and identify key environmental, social and governance issues (ESGs), Novartis conducts a global materiality analysis at four-year intervals, the last of which took place in 2017. 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 (inner circle) is based on the answers collected with separate questions and not on the basis of calculations of the importance of individual (specific) topics.

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

Lek's stakeholders and recognized interests[21]

Stakeholders	Stakeholders interests
Employees	• Continuous care for a healthy and safe work environment • Improving knowledge and skills • Equal opportunities for career development • Employment safety • Work-life balance • 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 medicines • Affordable medicines • Development of new and efficient medicines • Functional packaging of medicines with low environmental impact • Responsible handling and disposal of medicines • Cooperation with patient groups • Respect and understanding of patient groups • Increased access to our medicines • Carrying out responsible clinical studies • Recognizing 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 medicines • Accountable business practices • Providing information on new medicines • Providing information on proper medicine use • Proper product labeling • Responsible handling and disposal of medicines
Customers	• Safe, efficient and high-quality medicines • Affordable medicines • Proper product labeling and information clarity • Responsible handling and disposal of medicines
Regulators	• Safe, efficient and high-quality medicines • 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 in the environmental aspects in 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 local community life • 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 data access related to environmental and social impact in public interest
Non-government organizations	• Support and cooperation on projects • Good social responsibility practices • Data access 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 more than 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 patient groups and activities to increase access to healthcare.

Corporate volunteering

Novartis Slovenia associates fulfilled their need to help others in a year when changes and restrictions were set by the pandemic. This prevented us from having our Community Partnership Days as we have held them in the past, we joined the **ČvekiFON project - a chat room for the elderly**. Employees from all sites and members of the Lek Pensioners' Association shortened the time for the elderly and exchanged experiences through telephone conversations.

Our associates are always ready to share their knowledge with others, so during the pandemic, many joined the **database of volunteer distance instructors** and helped students across Slovenia to better understand their learning materials.

An important part of our work in 2020 was to support the wider community. At the beginning of the pandemic, Novartis donated $ 500,000 to Slovenia from the **global fund** to help manage the pandemic. The funds were donated to Red Cross Slovenia and the Association of Friends of the Youth of Slovenia.

We donated computers with all the necessary software to youngsters from socially vulnerable families. Pictured from left to right: Director of Anti-infectives Prevalje Roman Burja, Head teacher of Fran Golob Elementary School in Prevalje Mira Hacman and the Mayor of Prevalje Matija Tasič.

We also helped the youngsters from socially vulnerable families by **donating computers** with all the **necessary software** to families in Lendava, Ljubljana, Domžale and Prevalje. Our employees organized the **production of a disinfectant** on their own initiative, which we donated to 106 health centers, hospitals, homes for the elderly and local communities throughout Slovenia. The project was the result of a quick response and excellent cooperation between the teams of various Novartis units in Slovenia, which established production in an extremely short time, provided appropriate packaging and took care of filling and distribution of disinfectants.

We nurture long-term partnerships. We have supported the **Seniors for Seniors** program, implemented by the Association of Pensioners' Slovenia, for 16 years. More than 3,500 volunteers assist the elderly from age 69 onwards at care homes in a variety of life situations according to their needs. With the donation, we also supported the **Materina dušica safe house**.

Mechanisms for addressing complaints[22]

A safe and environmentally friendly environment is important to the residents who live in the area of our sites as well as our employees. By effectively addressing complaints from the field of HSE and by implementing the appropriate corrective measures. 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 entire procedure is documented and archived.

In 2020, we received two complaints. The first concerned waste masks on a fence outside Lek's site. Even though the research did not show the origin of the waste by Lek, we carried out a cleaning campaign in our immediate vicinity. The second complaint was filed by a citizen who was sprayed with "unknown" liquid while walking on the sidewalk in a public area outside Lek's site. We investigated the complaint and found that under specific conditions of temperature and wind, the cause of condensation from Lek's air conditioners could be the cause. We answered the citizens in writing.

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.

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

2.3 Product Compliance[23]

In line with Novartis' principle we are committed to high standards of ethical business. Therefore, our patients/users of our products always come first.

We develop and manufacture high-quality, safe, tested and efficient products meet but regulatory requirements. We ensure patient safety by timely identification, management and reporting of risks associated with products.

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 dispensing prescription drugs and Masters of Pharmacy, dispensing prescription drugs and non-prescription drugs. Pharmaceutical technicians only dispense and recommend over-the-counter medications.

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 also inform the professional public about diseases and their treatment through various professional publications, websites and other digital media (e.g. with the help of the MedLex application developed for this purpose) and at professional meetings, which in 2020 were mostly held at a distance.

We also provide the general public with access to a range of useful information related to our medicines and medical conditions, in the form of various publications, online articles and information at events and in the media.

No infringements in the field of information and labeling of products were detected in 2020.[24]

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.

Once again in 2020, JAZMP inspection authority did not carry out any 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 in 2020 show that the professional public recognizes Lek as among the most reputable pharmaceutical companies in Slovenia. In particular, our partners are pleased with our associates and the way we communicate, which has changed a lot during the COVID-19 situation, with the strengthening of digital communication channels.

The partners are also satisfied with the professional approach of our employees, the wide range of medicines and ethical operation.

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

[23] GRI GS 103-1, 103-2, 403-7, 417-1
[24] GRI GS 417-2
[25] GRI GS 417-3
[26] GRI GS 102-43, 102-44

3. Doing Business Responsibly

3.1 Ethics, Business Compliance and Human Rights[27]

Our business operations are guided by Novartis' values which are founded on a strong commitment to business integrity and ethical business in all areas of our organization.

In 2020 we adopted the new Novartis' **Code of Ethics** which was formed by more than 1000 associates. The Code defines who we are, what we believe in, and sets out the areas for which we are responsible. It is based on ethical principles that provide a framework to support associates in making the right decisions, and identifies 22 commitments in key areas of our operations. The Code reflects our commitment and guides us in decision-making in unclear and complex situations. It is designed to encourage important discussions about ethics.

We believe that in addition to business success, the way we achieve our results is important, so we have zero tolerance for any form of inappropriate behavior. To this end, we continued Novartis' initiative to promote open communication and reporting of misconduct.

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

We have an established system of anonymous reporting of inappropriate behavior and we are spreading the "speak up" culture, which also enables the addressing of ethical issues. We are also constantly raising the awareness of our employees. We are also guided in our operations by Novartis' human rights guidelines https://www.novartis.com/sites/www.novartis.com/files/novartis-human-rights-guideline.pdf.

Human rights are built into the very foundations of our work. Lek is a signatory to the **Commitment to Respect for Human Rights in Business**, which dictates that they be respected in the operation of the company, its supply chain and the avoidance and prevention of any violations.

Numerous activities within the **Diversity and Inclusion** initiative also make an important contribution to creating a pleasant and, above all, inclusive work environment. At Novartis, we encourage the diversity and individuality of our associates, as we firmly believe that we must provide an environment in which everyone can develop personally and professionally. We support the participation of people who differ from each other, as such teams are more creative and successful in tackling challenges and work is more stimulating and interesting.

In the company, we have zero tolerance for all forms of discrimination against employees based on personality traits, such as gender, age, nationality, religion, sexual orientation, disability, etc. We expect employees to treat each other with respect. This is the only way we can continue to build an inclusive work environment. The **"Novartis Women's Inclusion Initiative"** also makes an important contribution to this.

We pay a lot of attention to education on ethics, risks and compliance. In 2020, we organized e-training for employees on the code of ethics, personal data protection, professional practices in cooperation with healthcare professionals, reporting adverse events, information management and preparation for fulfilling commitments (prevention of bribery, antitrust rules and fair competition, trading on the basis of internal information, risk management in cooperation with third parties). Almost 100% of all associates successfully completed the training, and they continue to be topics in training new Lek employees.[28]

Content in the field of ethics and compliance was also addressed in articles in our internal newspaper Kolektiv, and one issue was entirely devoted to this field as part of the **"Ethics through my eyes"** campaign. We asked our associates, ambassadors of ethics, about the moments when it is not the easiest thing to do. Their stories reflected the ethical principles of the code (let's be open-minded, honest, responsible and bold) and illustrated the importance of acting in all areas of our operations, from access to medicines, respect for human rights, animal welfare, diversity and inclusion to financial integrity and ensuring compliance.

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 also enforce compliance standards with our business partners through the Third Party Management Guidelines.

Based on the guidelines, we establish and maintain business relationships with our business partners, who are obliged to follow the same principles as apply to our employees. We have improved the process of risk assessment in cooperation with third parties (TPRM).

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

In 2020, 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]

Public disclosures of payments made to doctors and health organizations

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

[28] GRI GS 412-2
[29] GRI GS 406-1
[30] GRI GS 206-1

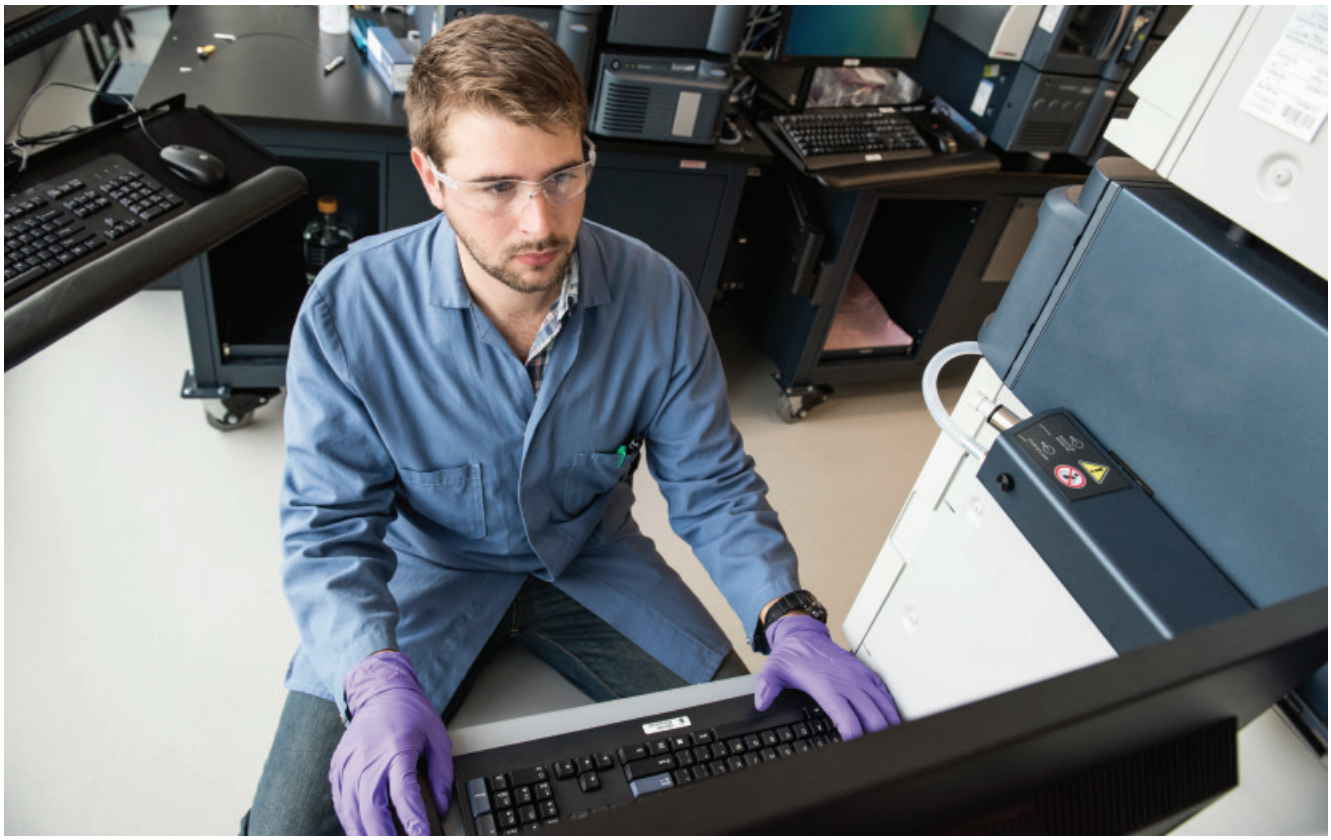
Pride month was welcomed by the raising of the rainbow flag

As a sign of support for Pride Month we raised the rainbow flag at all four sites in Slovenia.

Novartis strives to ensure that every associate, regardless of gender, gender identity or orientation, is true to themselves without fear of discrimination. That is why in Novartis Slovenia, we hung a rainbow flag at all four of our sites in June in support of Pride Month. At the global level in 2018, Novartis also approached the signing of Conduct Standards in support of the business community in combating discrimination against LGBTI+ community.

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 responsibilities are clearly 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 2020, we further improved our partnership with service centers and optimized expenditures in all procurement categories (direct and indirect). Lek's Purchasing Department introduced two additional tools for digitization and increasing the efficiency of procurement procedures, as well as the Ariba platform for further rationalization and greater transparency of the procurement process.

In 2020, the purchase value somewhat decreased and totaled 715 million USD (727 million in 2019), of which 289 million USD (270 million EUR) was indirect purchase. The COVID-19 pandemic has had a major impact on the global pharmaceutical supply chains. Our largest direct purchasing markets remain Slovenia, Germany, China, Switzerland and India. In indirect purchases, the largest markets were Slovenia, Germany, Austria, Switzerland and Canada.

In 2020, Novartis' new global purchasing policy came into force. Among its key principles is green procurement, in line with a sustainable strategy based on three pillars: climate, waste, water.

Supplier audit procedure[32]

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

[31] GRI GS 102-9, 102-10
[32] GRI GS 103-1, 103-2, 103-3, 308-2, 414-2

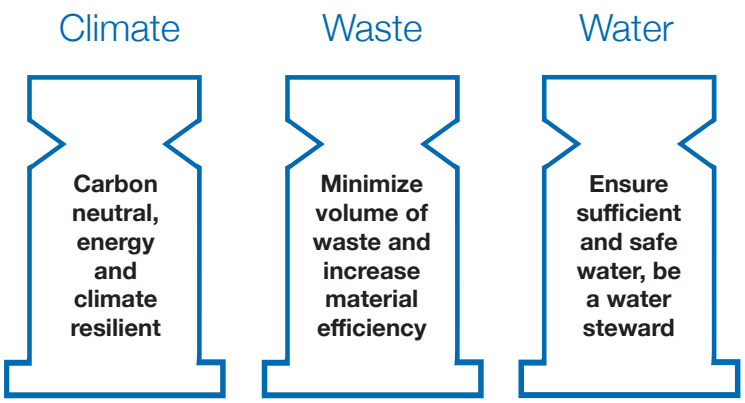
Novartis is committed to working with partners who work in accordance with our principles, values and standards. To meet this commitment, we updated our risk management framework in 2020 to better identify third party exposure and effectively protect ourselves and our stakeholders from negative impacts on the company's reputation and prevent potential financial damage.

We also implemented a new third-party risk management guideline (TPRM) and a revised version of the code of conduct for third parties. It combines risk assessments in dealing with third parties into a single framework designed to ensure consistency, coherence and greater transparency. The revised version of the Code updated the areas of human rights and business continuity, employees' rights, prevention of bribery, and health, safety and the environment.

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.

Pillars of the sustainable strategy



715 million USD

Total purchase value in 2020

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 monitor suppliers, thus evaluating and monitoring their performance and identifying areas (credit rating, costs, quality, supply and customer support) of necessary improvements.

Policy and practices for selecting local suppliers[33]

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 2020, the share of Slovenian based suppliers amounted to 281 million USD or 39.2% of total purchasing value. In terms of number, Slovenian suppliers represented as much as 57% of all our suppliers.

In direct purchasing by country, Slovenia accounts for a 15.1% share (64 million USD) and 74.8% share (216 million USD) in indirect purchasing.

[33] GRI GS 103-1, 103-2, 103-3, 204-1

Off gas treatment device in Lendava

4. Environment

Health, safety and environment policy (HSE)[34]

At the beginning of 2021, the renewed Health, Safety and Environment (HSE) policy further emphasized the connection with the business strategy; its key focuses, summarized below, are integrated into all our activities and are at the center of our decisions.

The HSE policy defines the fundamental principles and management rules in this area and describes approaches to reducing risks and impacts in the field of health, safety and the environment. It contains a basic expectation for all employees and is the foundation on which we establish the internal HSE guidelines.

Impacts on health, safety and the environment are taken into account throughout the entire work process, from the start of development, production and distribution to the use and disposal of our final products. We also reduce the risks related to health, safety and environmental impacts by consistently implementing our Code of Ethics. Through the Third Party Risk Management Policy, we also transfer our standards in the field of HSE to our suppliers and contractual partners.

We implement the system of health, safety and environmental protection according to clear guidelines, which we incorporate into our operations. Compliance with legal regulations and corporate policies is the basis of our health, safety and environmental risk management system. In addition, we are voluntarily committed to complying with the requirements of the ISO 14001 environmental management system, the ISO 45001 occupational health and safety management system, the Responsible Care initiative for the chemical industry and the Community Environmental Management and Audit Scheme (EMAS).

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

We are committed to:

- **environmental sustainability** by reducing the environmental impacts of our activities and products throughout their life cycle; and
- **health and safety,** protecting and promoting the safety and health of co-workers, suppliers, visitors, patients and the local communities in which we operate.

Principles of the HSE Policy

Health, safety and environmental protection are the fundamental responsibilities of all employees and they are expected to respond to HSE-related content with the same care as other business objectives. All employees must perform their tasks with due regard for social responsibility and environmental sustainability.

We take care of the health and safety of our employees
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. We regularly make our employees aware of our HSE policies and constantly train them for their implementation. Employees are encouraged to warn each other of potential risks or hazardous behaviors. If necessary, we propose and implement preventive and corrective measures to achieve the set plans and goals in risk management.

We are constantly integrating improvements
By continuously improving business and production processes, we improve efficiency in the field of HSE and reduce our impact on the environment. By introducing the best available, efficient and economical technologies, we want to rank among the leading companies in environmental protection. We strive for continuous progress in the use of raw materials and energy resources and the reduction of environmental impacts, which we verify through regular measurements and monitoring of data. We have systems and measures in place to prevent environmental pollution, which we regularly check and upgrade. We are also guided in our search for continuous improvement by the recommendations of independent auditors of international environmental standards.

We operate in accordance with the strictest standards
We regularly check the compliance of our operations with legislation, regulations and guidelines. We are committed to complying with all legal and other regulations for pharmaceutical production and Novartis standards relating to HSE. In doing so, we always consider the more stringent requirements. We document and update the HSE policy and its implementation, informing and raising the awareness of our employees. We consistently achieve the set goals.

We achieve the environmental sustainability principles
We use natural resources wisely and monitor and reduce the impact of our business on the environment. We want to become a carrier of positive change and a leader in environmental sustainability. To improve efficiency and accountability, we set long-term and annual measurable goals, which we monitor through measurements, research and verification of impacts. The set goals are comprehensively managed within the Novartis Environmental Management System (EMS). Objectives are defined by sites, taking into account their specifics. Together, they form Lek and Novartis goals. We implement Novartis' strategy of environmental sustainability, with which we build trust in the company. We have set ambitious goals with which we intend to achieve carbon, plastic and water neutrality by 2030. We encourage employees to reduce their impact on the environment in their daily work.

We build partnerships
We cannot achieve long-term business success alone, but rather in cooperation with key stakeholders. Our suppliers and contractual partners also play an important role in achieving environmental goals. We also transfer our HSE standards to them through a third-party risk management policy. Together we build a network of responsible business partnerships.

We report publicly and comprehensively
We report on the HSE results comprehensively, transparently and publicly. We disclose our environmental, social and economic impacts in our annual Sustainable Development Report, which is publicly published and available on our website. We use internationally recognized guidelines and standards in our reporting. The veracity of the information provided in the report relating to environmental impacts shall also be verified by an external verifier.

Information on the sustainable aspects of our operations can be found at www.lek.si/en.

Compliance with HSE laws and standards[35]

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.

The amendment to the law in 2020 regulates three substantive areas: the system of trading in greenhouse gas emission rights in the EU, the system of extended producer responsibility and the requirements for the implementation of operational monitoring.

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.

[35] GRI GS 103-1, 103-2

Being an IED (Directive of industrial emissions)[36] certified company, our Lendava and Mengeš sites operate in compliance with Decree on activities and installations causing large-scale environmental pollution. Both existing IED permits also cover the release of greenhouse gases from cooling devices, whereas these types of emissions at the Ljubljana and Prevalje sites are included in permits dealing with atmospheric emissions. All Lek sites comply with the Decree on Limit Values for Atmospheric Emissions of Volatile Organic Compounds from Installations Using Organic Solvents. As a low-risk source, the Mengeš site is obligated to adhere to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences.

New legal and other requirements are promptly and efficiently transferred in our work processes and practices. Authorized persons for HSE actively monitor and identify them, keep records of all relevant legislative requirements in the HSE Registry and uninterrupted operations and other compliances, provide explanations of new requirements by analyzing the shortcomings in the HSENet application and arrange for their transfer to sites. In the case of regulatory changes requiring substantial capital and/or infrastructure changes, an action plan for HSENet shall be drawn up and documented. The register shall be updated when changes in requirements, operational changes, results of regulatory inspections and third-party regulatory compliance reviews are concluded, and/or at twice a year. HSE representatives are responsible for the efficient transfer into practice. Once a year new and expected legislation is reviewed as a part of the management review.

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 2020, we had 3 inspections, one of which was for environmental, fire and chemical safety. No non-compliances were found during the inspections. In 2020, we were also included in inspections of operation quality control and products in the field of health inspections and waste management.[37]

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

Environmental permits and their amendments at all sites:

- Environmental permit for operation of a device with a high pollution potential (IED) 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.
- Decision amending the environmental permit for the Lendava site, No. 35406-1/2021-7 dated 19 February 2021.
- Decision amending the environmental permit for the Lendava site, No. 35406-42/2019-12 dated 30 March 2021.
- Environmental permit for operation of a device with a high pollution potential (IED) for the Mengeš site, Permit 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.
- Partial decision on the amendment to environmental permit for Mengeš site, Permit No. 35406-21/2019-9, dated 23 December 2019.
- Decision amending environmental permit for risk facilities (SEVESO risks) for the Mengeš site, Permit No. 35492-4/2018-18 dated 25 February 2021.
- Environmental permit with regard emissions into water and air for the Ljubljana site, permit No. 35431-6/2016-9, dated 22 November 2016.

[36] See glossary on page 109.
[37] GRI GS 307-1

- 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.
- Decision amending environmental permit for emissions into water and air for the Ljubljana site, Permit no. 35440-25/2020-5 dated 20 August 2020.
- 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.
- Greenhouse gas emission permit for Lendava site, Permit No. 35485-56/2020, dated 18 December 2020.
- Greenhouse gas emissions permit for Mengeš site, Permit No. 35485-57/2020, dated 18. December 2020.
- Decisions on environmental tax exemption due to fuel combustion, No. 35483-52/2020 dated 21. December 2020 (Lendava).
- Decisions on environmental tax exemption due to fuel combustion, No. 35483-53/2020 dated 21 December 2020 (Mengeš).

4.1 Active Environmental Policy Implementation

Environmental responsibility is a top commitment of our operations, which 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.

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**. Among the indirect environmental aspects, we mainly categorize environmental impacts on the part of suppliers/contractors (supply) which, due to the specific nature of pharmaceutical production, we must take into account that our impact on product use and their processing at the end of their life expectancy is limited.

In 2019, we were not charged with any penalties or non-monetary fines for non-compliance with environmental laws.[38] However, we received two complaints from the public, which are outlined in chapter *2.2.1. along with the measures taken.*

4.1.1 Specifics of business operations and deviations in data collected

Environmental indicators are difficult to compare due to disparities in data collection. Disparities arise in the weight of certain pharmaceutical products and active substances, especially in biological medicinal products, where production is complex and is measured in kilograms. on the other hand you have self-medication drugs which are measured in more than ten tons.

Disparities also occur due to differences in the portfolio of individual sites, especially where this portfolio is large

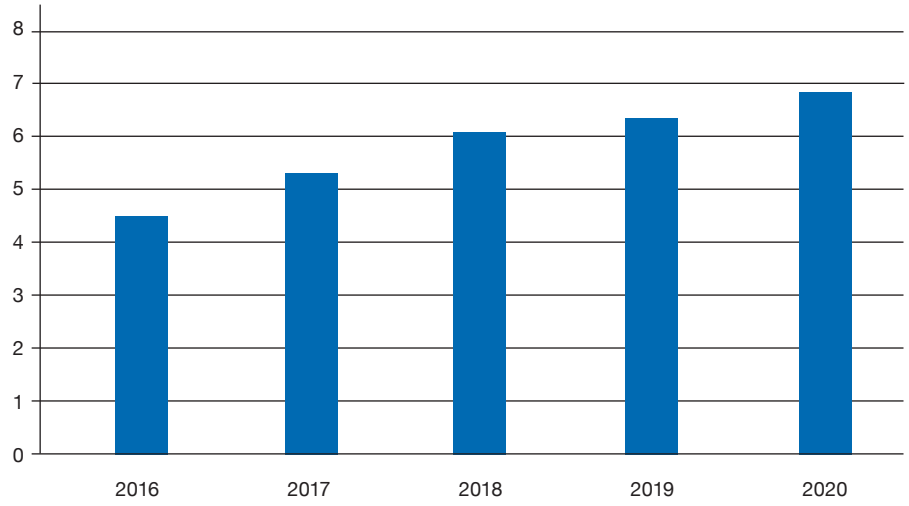
[38] GRI GS 307-1

(Mengeš, Ljubljana). Additionally, there is a noticeable trend related to changes in the portfolio (production structure) from large-tonnage products to products of smaller quantities with high added value. In Mengeš, we eliminated several long-selling products in 2020, introduced new ones to existing production lines and increased production capacities for some current products by optimizing processes.

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.

Disparities are especially noticeable at the Lendava site, where the production growth at Solids Lendava increases the use of raw materials (energy, water), the amount of generated waste, and to a lesser extent also water and air emissions. As the plant carries out the activity of packaging various pharmaceutical forms produced by other Novartis sites, their quantitative realization is not taken into account and therefore is not shown in the calculations of the efficiency of individual indicators for the entire Lendava site. In the event that the packaging plant in the Novartis data system (DMS) also shows the annual realization, there would be a duplication of quantities.

Solids Lendava Production Growth (number of tablets packaged in billion)



4.1.2 Environmental protection and achievements[39]

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. Environmental investments include the renovation of roofs, facades and sewage systems. The estimated value of environmental investments in 2020 is 3.7 million EUR. More about major environmental protection projects in 2020 are reported in *4.3.3 Energy efficiency improvements* and *4.4.1 Water use efficiency*.

4.1.3 Verification of established standards[40]

We constantly ensure that we comply with all legal regulations and requirements of international standards in the fields of HSE.

We voluntarily implement the Responsible Care Initiative (RCI). Recertification of the environmental management system according to the ISO 14001:2015 standard and the Occupational Health and Safety System ISO 45001:2018 was, due to the COVID-19 circumstances, postponed to 2021. Additionally, all four sites are included within the EMAS scheme, the European Union environmental impact management system.

The Slovenian Institute of Quality and Metrology (accreditation number SI-V-0001) also confirmed in 2021 that data and information in the Lek d.d. Sustainability Report 2020

[39] GRI GS 103-2
[40] GRI GS 103-2

gives a reliable, credible and accurate picture of all organizational 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 2020 (JAZMP, FDA, suppliers, etc.).

4.1.4 Key projects

Anti-explosive protection – ATEX

All stages of production processes at all sites are included in the Lek anti-explosive protection system. 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 2020, despite the beginning of the COVID-19 pandemic, we successfully carried out all planned explosion protection trainings - initial and advanced seminars with certification and all planned recertification of Ex equipment at our sites.

LOTO – LockOut/TagOut

Together with an external certified contractor, we successfully carried out one set of seminars for responsible works managers and authorized contractors. Among the qualified persons are also nine newly trained trainers for the internal training of our employees for responsible work managers and authorized contractors. As part of the LOTO activities, we also focused on walks and inspections of LOTO processes. We checked the prepared documentation for individual machines, such as LOTO procedures, brief instructions for implementation and the availability of LOTO equipment for locking technical equipment in case of maintenance interventions.

NOSSCE – Novartis Operational Standards for Supply Chain Excellence

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. 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.

4.1.5 Indirect environmental impacts[41]

Indirect environmental impacts mainly include impacts from suppliers; therefore 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. We expect our suppliers to respect the principles of the Novartis environmental sustainability strategy.

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*.

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.

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 175 company cars were in use in 2020 (168 in 2019). A total traveling distance of 4,284,362km (7,870,027 km in 2019) was recorded, with fuel consumption of 199,917 liters (359,666 liters in 2019). In addition to company cars, we had 17 other vehicles (fire engines, forklifts). Together all vehicles released 570 tons of CO_2 emissions (1,004t in 2019).

[41] GRI GS 305-1, 308-2

4.2 Raw Materials and Natural Resources

4.2.1 Mass flow of materials[42]

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. In 2020, we improved the efficient use of raw materials by 9% with a 6% decrease in production volume.

Due to the change in the composition and the volume of pharmaceutical active ingredients, there are some annual fluctuations in the mass flows of materials. Due to the change in the composition and production volume of active pharmaceutical ingredients, annual fluctuations in the mass flows of materials occur. The largest fluctuation was in Mengeš, where with the abolition of some large-scale production processes, their production decreased by 37%, and consequently the use of raw materials decreased by 26%. In Lendava, the process of fermentation production with supplementary feeding changed, which resulted in a 13% increase in the use of raw materials with less than 1% increased production (see more in section *4.5.1*).

Annual mass flows of different materials used* [43]

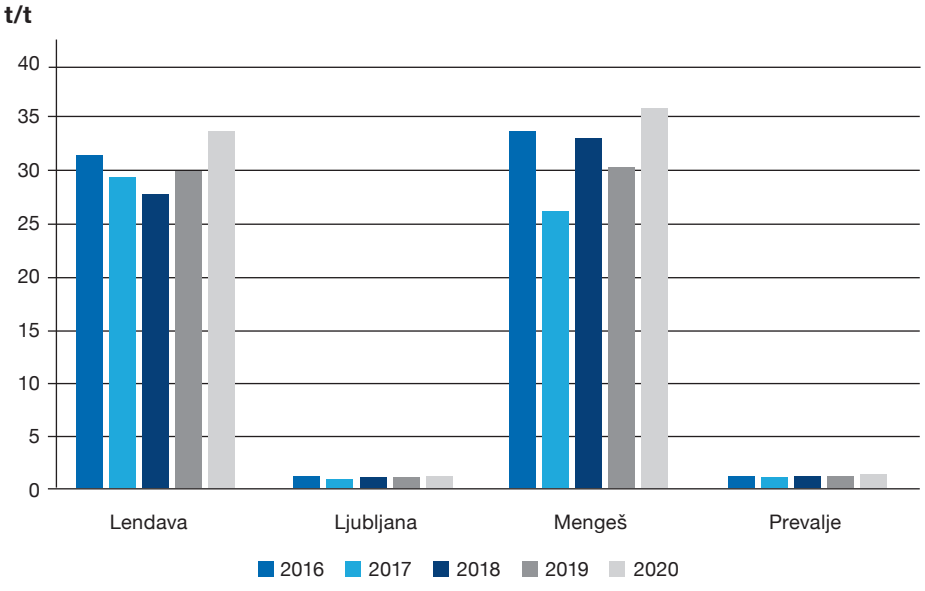
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2016	t	8,803	3,484	15,261	1,861	29,409
2017	t	8,740	3,379	13,043	1,879	27,041
2018	t	8,549	3,324	14,253	1,998	28,125
2019	t	8,910	3,097	15,225	1,814	29,046
2020	t	10,044	3,378	11,227	1,925	26,574

* 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

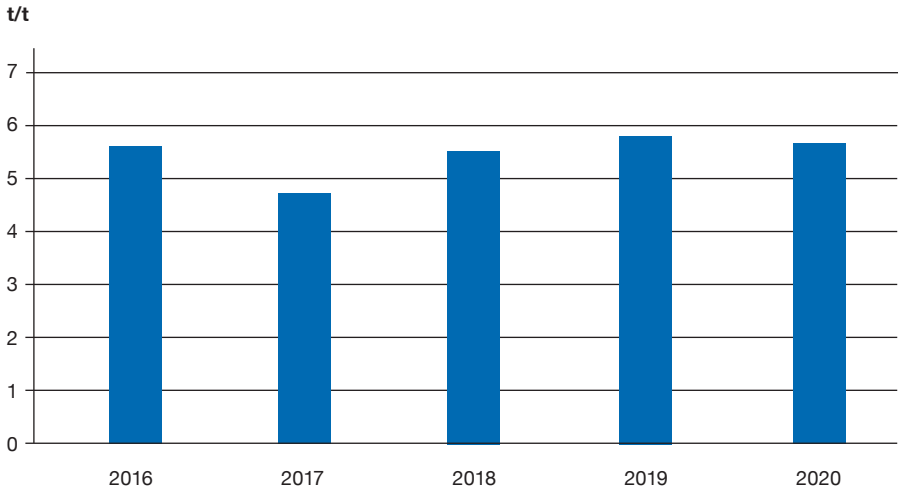
The efficiency of the use of raw materials of the quantities of materials is given by the indicator of the consumption of raw materials per unit of the product. From the graphic presentation of the efficiency of the use of all raw materials, it is evident that the amount of raw materials consumed per ton of active substances produced in 2020 stayed the same as in 2016.

Efficiency of the use of raw materials per unit of product - by site[44]



[42] GRI GS 103-1, 103-2, 103-3
[43] EMAS – Core Indicator, GRI GS 301-1
[44] EMAS – Core Indicator

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



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.

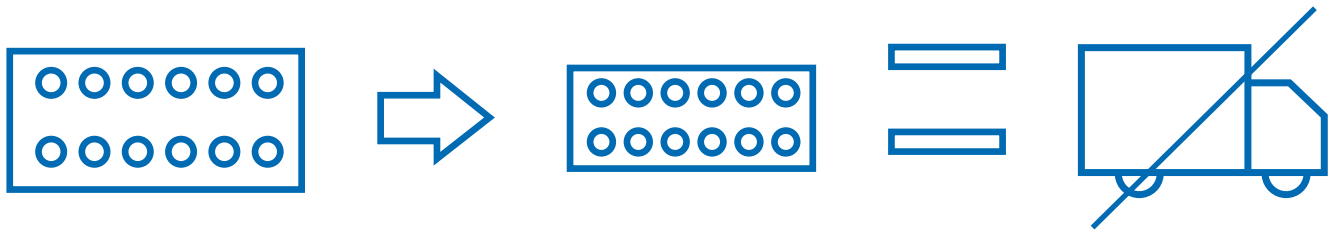
The basic principles of packaging design and production are consistent with the Novartis policy of sustainable packaging use and defined in Sandoz's global packaging catalog. The catalog prescribes a comprehensive selection of recommended packaging materials, taking into account the binding waste hierarchy, 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 the case of packaging waste, in accordance with the established hierarchy of waste management, we are additionally looking for opportunities to reuse packaging in the circular economy system. In 2020, Solids Lendava continued to return used 50-liter barrels to the raw material supplier. With this, we redirected the packaging, which would otherwise become waste, to reuse.

In the Lendava dining room, we replaced disposable plastic glasses with compact reusable ones, which save more than 70,000 plastic glasses annually. We also replaced disposable plastic glasses with glass ones in one of Ljubljana's dining rooms - in the other dining room, glass glasses were in use from the very beginning.

Savings in reduction of the size of PVC blisters for GalvusMet

At Solids Lendava, we introduced the use of smaller blisters in the packaging of GalvusMet (euacreas). The change reduced the size of the blister by 13% and the consumption of plastic by 0.6g per blister. By using smaller blisters, we saved 27 pallets of material or 1 truck per year and increase productivity, reduce waste and save on costs.



1 truck per year less

Savings with replacement of plastic barrels with barrels made of recycled material

In Aseptics Ljubljana, we reduced the amount of waste plastic by 16 tons annually by replacing barrels for packaging waste vials and ampoules. The new barrels are made of recycled material and mean less waste, and are also easier to handle due to their lower weight.

-16t

of waste plastic annually

4.3 Energy

4.3.1 Energy consumption

In 2020, total energy consumption decreased by 1.23% or 16,532 GJ in comparison with the previous year. At all four sites, we implemented numerous projects to increase energy efficiency, which saved 45,102GJ (3.4%) of energy and thus prevented 3,617t of CO_2e in the atmosphere. As we introduce more energy-intensive products at sites, the final savings in energy use compared to 2019 are otherwise lower than the savings achieved with implemented projects.

Compared to 2019, the total energy consumption was reduced at the locations of Prevalje (by 8.77%), Ljubljana (by 3.16%) and Mengeš (by 1.20%), while in Lendava it increased (by 1.58%), where we also recorded higher production volumes.

Total energy consumption* [45]

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
2020	GJ	476,617	428,502	365,986	57,245	1,328,350

* The table covers all fuels / energy sources that entered the processes of energy use, respecting the HHV – High Heating Value.

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
2020	GJ	26,963	83,739	110,702

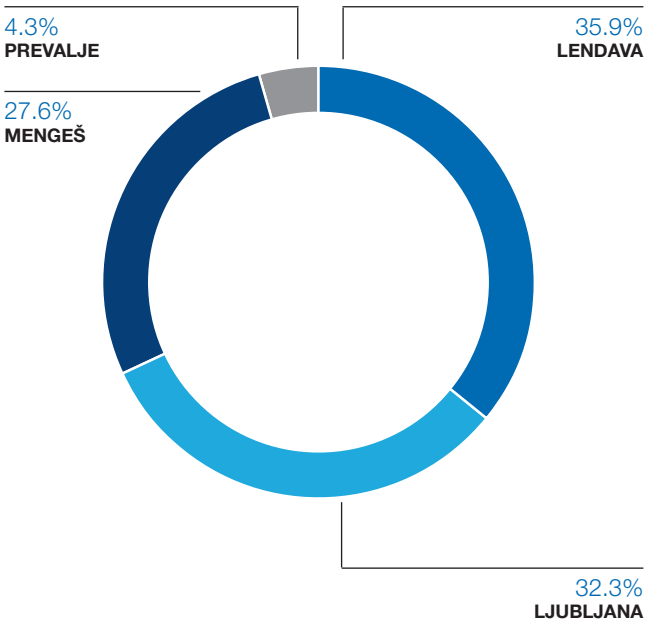
Energy used from biomass at Lendava

Year	Unit	Lendava
2016	GJ	4,500
2017	GJ	4,191
2018	GJ	4,612
2019	GJ	3,417
2020	GJ	5,086

Lendava has the highest share in total energy consumption with 35.9%, followed by Ljubljana with 32.3%, Mengeš with 27.6% and Prevalje with 4.3%.

[45] GRI GS 302-1

Energy distribution by site[46]



Efficiency of energy resource use per unit of product[46]

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
2020	GJ/t	1,595	153	1,170	44	283

The total efficiency of energy use decreased by 5%, 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. In Mengeš, we have significantly reduced energy efficiency for the site by eliminating some large-capacity and introducing more complex products with more energy-intensive production processes.

A more appropriate comparison of our efforts to improve efficiency is shown by the energy efficiency indicator per employee, which shows the increasingly complex production of products, which also requires more employees. Our energy efficiency has thus improved by 9% compared to 2019.

[46] EMAS – Core Indicator, GRI GS 302-3

Energy efficiency 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
2020	GJ/employee	682	156	323	253	275

* 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.

The overall efficiency of energy use decreased by 2.4% in comparison with the previous year. 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[47]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2020	GJ	225,772	173,497	123,232	22,913	545,415

4.3.2 Distribution of energy resources

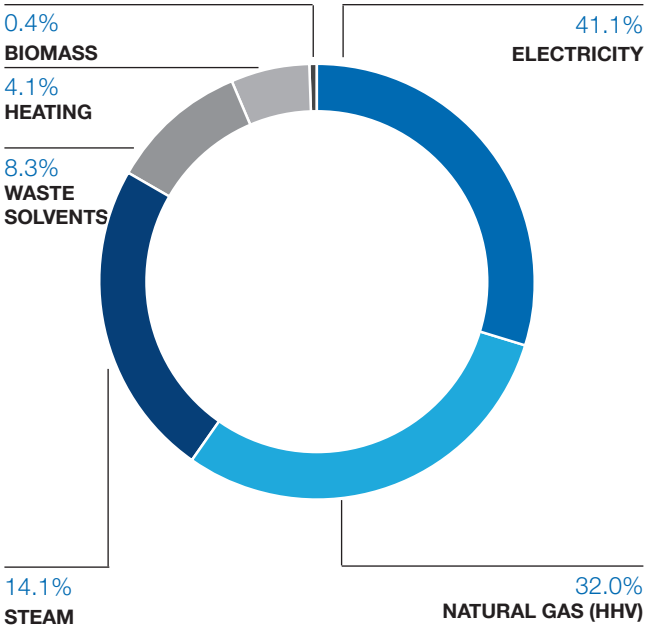
In the structure of purchased energy sources, electricity accounts for the largest share with 41%, followed by natural gas with 32%. These two energy sources are the primary source for three sites. At the Ljubljana site – in addition to these energy sources, we also purchase industrial steam (14%) and 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 8%. We can replace more than 35% of the energy needed with waste solvents only at the Mengeš site for steam production.

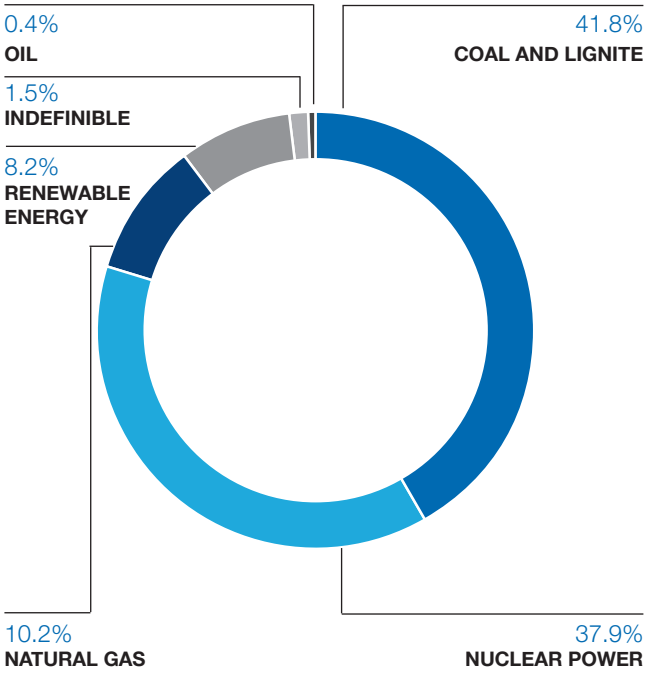
The share of renewable energy sources at the Lendava site is 0.4%; they are obtained by burning organic waste from fermentation production.

[47] GRI GS 302-1

Distribution of energy used by primary energy sources



Sources of purchased electrical energy*



* Data on the composition of primary sources for electricity production, which we received from the electricity provider, are for 2019. At the time of compiling the report, data for 2020 were not yet available.

4.3.3 Energy efficiency improvements[48]

In 2020, we implemented several energy efficiency improvement projects, which together generated 45.1 TJ of energy savings and consequently reduced CO_2 emissions into the atmosphere by 3,617 tons. The total savings of the estimated projects represent 3.4% of the savings of the total annual energy consumption.

We continued with active energy management (AcEM) - active monitoring of energy systems, performance analysis and thus active energy management. Based on weekly reviews, comparative analyzes and the determination of key performance indicators, we took immediate measures to improve regulation, adjust operating points, display malfunctions and select the most efficient devices. By regularly monitoring energy systems, we also identified future potential savings projects.

Energy and greenhouse gas savings by site in 2020

	Lendava	**Ljubljana**	**Mengeš**	**Prevalje**	**Lek** (Total)
Annual energy savings from energy projects (in GJ)	3,538	29,312	6,712	5,540	45,102
Annual reductions in greenhouse gases thanks to energy projects (in tCO_2)	216	2,645	406	350	3,617

These results were reached with the following projects:

Lendava:
- optimization of lighting in production premises and installation of timer switches,
- installation of meters on the cooling water system and optimization of operation,
- installation of measures on the cooling system and operation optimization,
- replacement of the cooling unit with a more efficient one,
- upgrade of the waste dozing system,
- optimization of the fermentation process.

Ljubljana:
- organization of the technical condensate steam system in production premises,
- expansion of moisture limit in solids production,
- optimization of cooling system in production premises,
- HVAC system operation optimization in production premises,
- returning condensate to Energetiko Ljubljana.

Mengeš:
- HVAC system operation optimization,
- replacing pneumatic pipes, reducing loss of air pressure,
- review and repair leaks in air pressure system on several buildings.

Prevalje:
- increasing conductivity of boiler water – decreasing the use of fresh and heated feed water,
- regulation of the operation of the hot bypass damper on the RTO device, optimization of the combustion temperatures and the on and off mode,
- optimization of HVAC systems - inspections and resetting of control valves and optimization of heating/cooling parameters,
- shortening the operating time of the refrigeration machine after the appropriate cold water temperature has been reached.

[48] GRI GS 302-4, 305-5

4.4 Water[49]

Access to fresh high quality water is of great importance for pharmaceutical production. 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.

In Novartis’ environmental 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.

4.4.1 Water use efficiency

We pay a lot of attention to improving water efficiency. Thus, water consumption was reduced by 14% in 2020 through various projects, despite the changed range of products and increased production intensity, and the efficiency of water use was improved by 9%. The consumption of technological and drinking water was optimized with the following measures:

- optimization of cooling water flows,
- water reuse (cooling systems, condensate),
- optimization of water consumption in energy systems and pharmaceutical water treatment systems,
- timely replacement of used equipment,
- connection of technological consumers to well water,
- active monitoring of consumption - timely action and elimination of leaks,
- reduction of maximum faucet flows in toilets and kitchens,
- reduction of flushing volumes in toilet bowls,
- raising employee awareness of water saving.

Water use in 1,000 m³ [50]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2020	1,000 m³	1,260	523	1,123	36	2,943

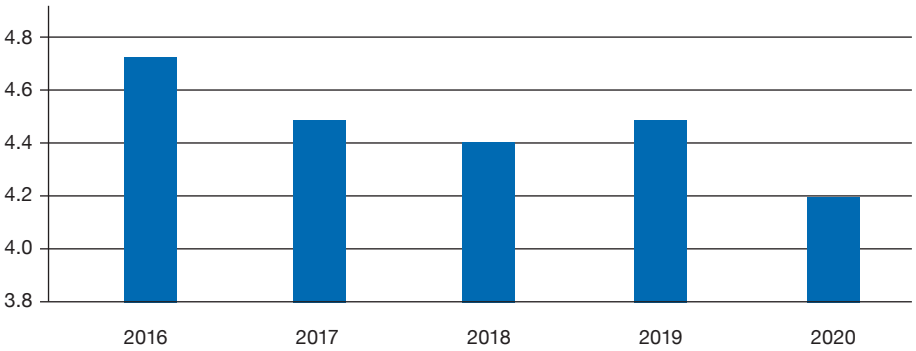
Water use efficiency per product unit* [51]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2020	m³/t	1,051	187	683	28	231

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

[49] GRI GS 303-1, 303-2
[50] EMAS – Core Indicator, RCI OI 21, GRI GS 303-3
[51] EMAS – Core Indicator

Water consumption per kg of product at the Lendava site



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.[52] 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 2020 was slightly below average. Precipitation was average in quantity, but uneven and limited in time (due to storm events). A smaller rise in groundwater was detected in November, due to heavy rainfall in late September and October.

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 Mengeš site shows fluctuations in groundwater levels of Mengeško Polje are extensive and amount to 15m.

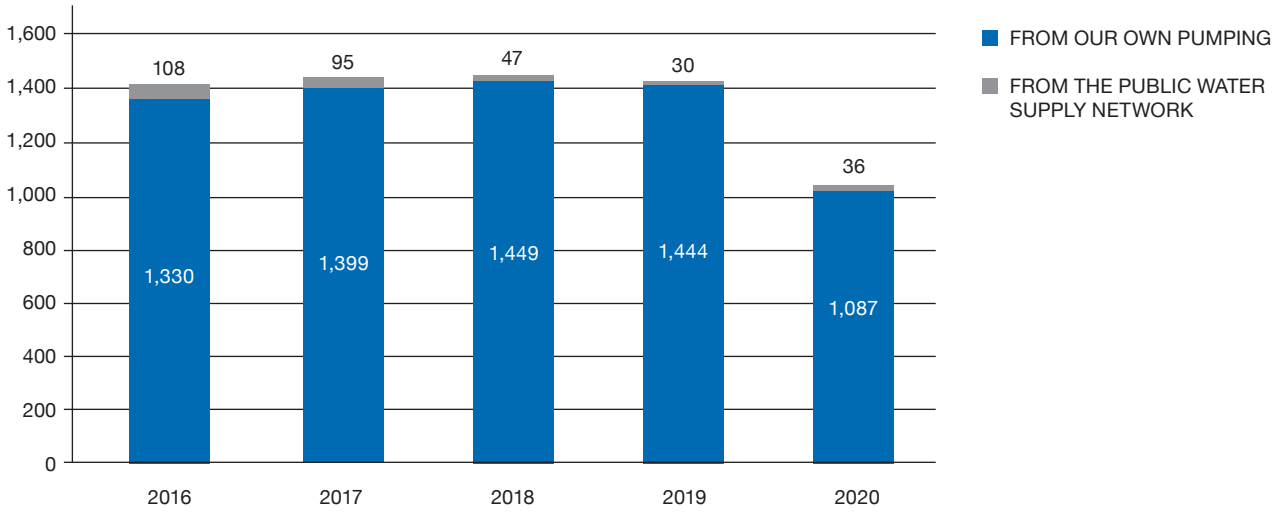
Based on the monitoring, we found that the groundwater level in the area of our location was 2 m higher in the high water period than in the low water period.

We have drilled piezometers for operational monitoring of groundwater pollution. The piezometers located to the south of the site (outlet water), showed groundwater has better quality than in piezometers north of the site (inlet water).

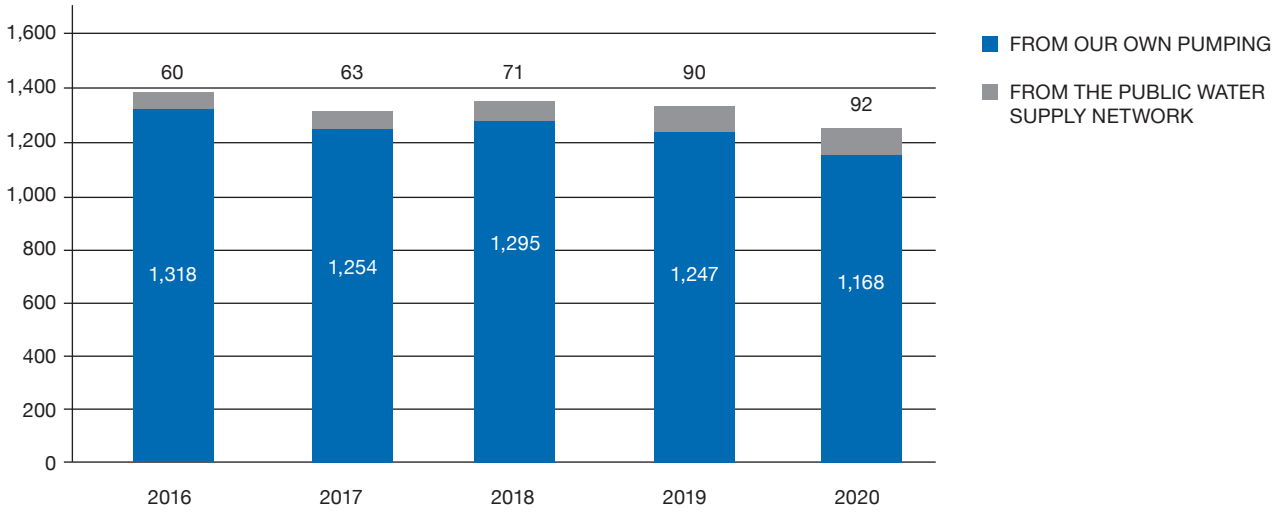
In Mengeš, the use of water from the public water supply system was reduced by more than 66% in five years, while in the last year the use of this water was higher by 20%. We significantly reduced the use of water from our own pumping station by 25%. In Lendava, due to increased production of solids and the introduction of a more energy-efficient fermentation production process, we increased the use of drinking water by 2% and reduced the use of water from our own pumping station by more than 6%.

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

Water supply quantities and sources at the Lendava site in 1,000 m³ [53]



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



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. It has been estimated that the entire cooling water volume is reused at least twice.

[53] GRI GS 303-3
[54] GRI GS 303-3

4.5 Waste

4.5.1 Waste management[55]

Separate waste collection and sorting are important activities on the way to waste recycling and the basis for an increasingly topical circular economy. In waste management, we follow the prescribed hierarchy of waste management, paying particular attention to the possibilities of reducing waste at source, reuse and recycling, and the use of waste for fuel. We dispose of only a small proportion of non-hazardous, municipal waste.

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. Hazardous waste, in accordance with the Novartis policies, is not disposed of in landfills, and we strive to reduce the amount of non-hazardous waste for disposal.

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.

The total amount of waste increased by 6% in 2020, mainly due to the increased amount of waste mycelium from Lendava production. The increase in mycelium, which is a non-hazardous and biodegradable waste with a water content of 95%, is due to a change from the technological bioprocess to feeding culture due to energy optimization.

In the data for the Lendava site, we must take into account that the expansion of the production of solids also increases the amount of waste, but their quantitative realization in accordance with Novartis instructions is not taken into account and thus not shown in the calculations of efficiency of individual indicators. (Read more in *4.1.1*)

As can be seen from the table below, more than 92% of all generated waste is recycled or. reused, their share increased by 1% in 2020. Biodegradable waste accounts for 77% of all Lek waste. In addition to the Lendava mycelium, which is sent for processing to the biogas plant, the entire amount of waste sludge from the Lendava Wastewater Treatment Plant is added to biodegradable waste. Together, waste represents almost 100% (99.99%) of all biodegradable waste.

Composition of generated waste in 2020 in t

	Generated waste	Waste directed to recycling and prepped for reuse	Waste directed for incineration, co-incineration or landfill*
Hazardous waste	4,826	2,132	2,694
Non-hazardous waste	37,221	36,882	339
Total	**42,047**	**39,014**	**3,033**

* We only put non-hazardous waste to landfill.

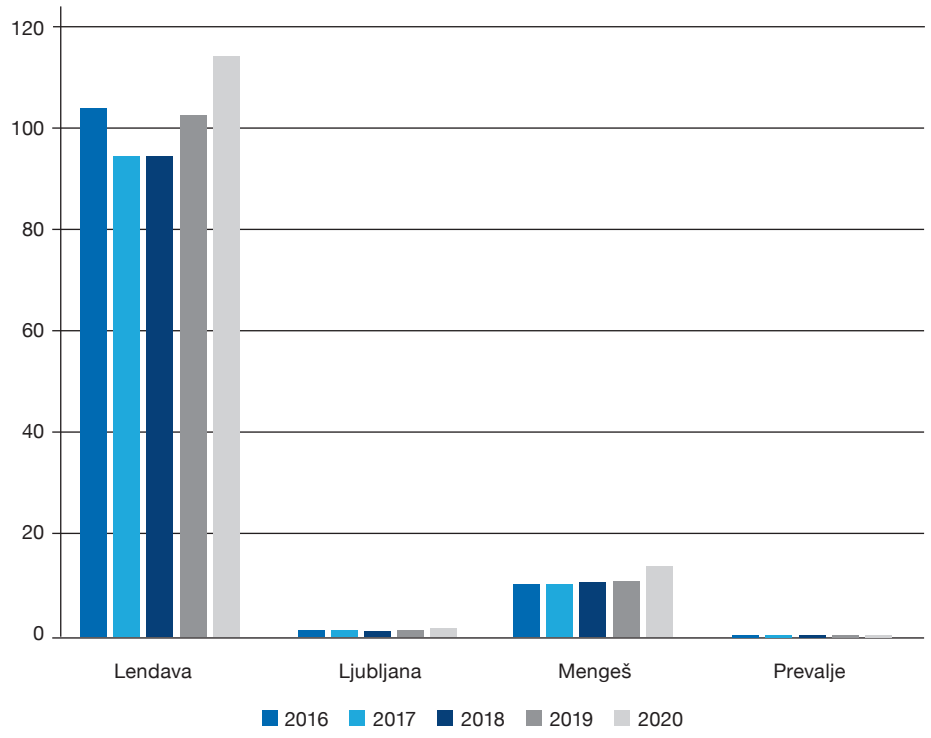
[55] EMAS – Core Indicator, GRI GS 306-1, 306-2, 306-3, 306-4, 306-5

Composition of generated waste, in t by site

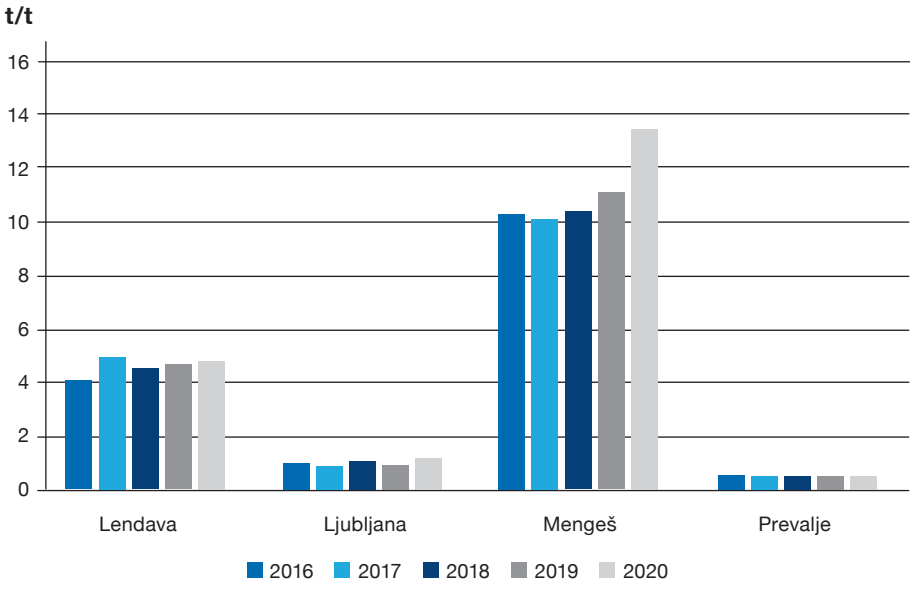
	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Hazardous					
2016	38	673	3,691	191	4,593
2017	182	654	4,208	186	5,230
2018	183	902	3,893	193	5,171
2019	61	784	4,777	229	5,851
2020	79	1,109	3,451	186	4,826
Non-hazardous					
2016	28,824	2,337	906	610	32,677
2017	27,674	2,651	802	642	31,768
2018	28,544	2,254	600	591	31,989
2019	30,346	2,088	747	502	33,684
2020	33,851	2,181	730	459	37,221

Volume of waste per ton of product – efficiency

t/t



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



4.5.2 Hazardous waste disposal[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, which is outlined in our annual targets.

We reduced the amount of hazardous waste by almost 18% in 2020, and part of this reduction must also be attributed to 6% lower production. The more appropriate situation is shown by the indicator of the efficiency of hazardous waste management (t of waste/t of product), which shows a 12% improvement compared to 2019. The change in the product portfolio and greater use of waste for energy purposes at our sites significantly contributed to improved efficiency.

We processed and reused a good 82% of all organic solvents; in Lendava this share was as high as 96%. The total amount of waste solvents generated in Mengeš was 12% lower, and the share of reuse was on average 58%, and in some processes this share is more than 95%.

At the Mengeš site, high-energy waste solvents represent 92% of all hazardous waste. By co-incineration with natural gas, we removed 2,521 t of waste solvents, which is equivalent to 35% of the primary energy for steam generation to supply the processes with energy. By processing waste solvents, we reduce energy consumption for steam preparation, transport of waste solvents and consequently CO_2 emissions. The rest of the waste solvents are handed over to authorized companies that dispose of waste in an environmentally friendly manner, most often using waste as fuel according to the R1 procedure.

At the Ljubljana site, hazardous waste represents just fewer than 34% of the total amount of waste produced at the site. Among them, discards from production and expired products or medicines returned from the market are important in terms of quantity. The amount of the latter increased by 80% in 2020. At the Prevalje site, hazardous waste represents 29% of all waste at the site and has decreased by almost 19% compared to the previous year.

[56] RCI OI 5, GRI GS 306-1, 306-2, 306-3, 306-4, 306-5

Hazardous waste directed to recycling and prepped for reuse in t*

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2016	t	2	21	1,150	0	1,173
2017	t	0	273	2,048	0	2,321
2018	t	0	574	1,860	33	2,467
2019	t	1	650	2,073	61	2,785
2020	t	0	832	1,233	67	2,132

* The data shows the quantities of hazardous waste that we handed over to external authorized contractors.

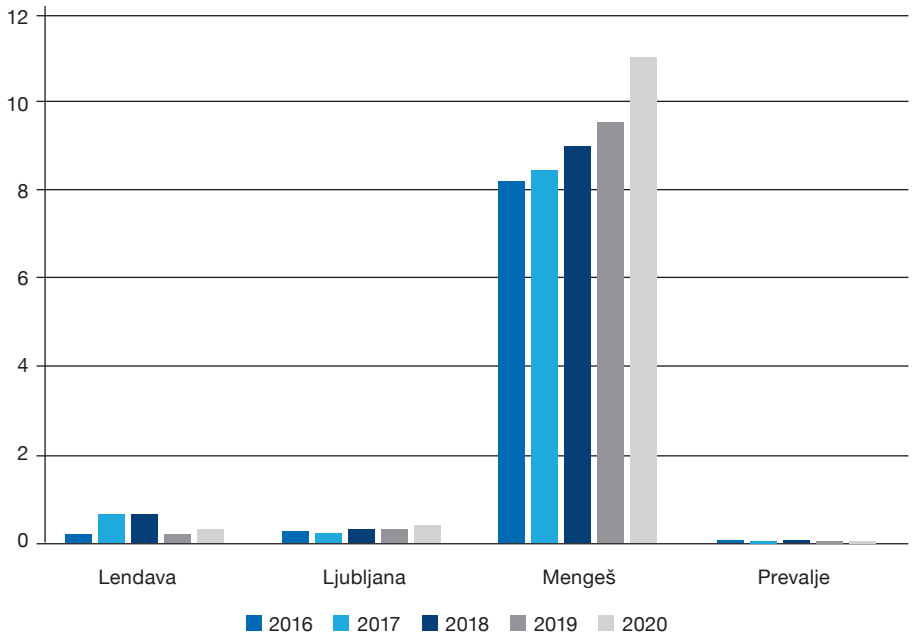
Hazardous waste directed to incineration and co-incineration in t*

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2016	t	38	652	2,541	191	3,419
2017	t	182	380	2,161	186	2,908
2018	t	183	328	2,034	160	2,704
2019	t	60	134	2,704	168	3,066
2020	t	79	277	2,218	120	2,694

* The data shows the quantities of hazardous waste that we handed over to external authorized contractors.

Volume of hazardous waste per ton of product – efficiency

t/t



4.5.3 Disposal of non-hazardous waste[57]

Non-hazardous waste accounts for 88% of all Lek waste. The amount of non-hazardous waste increased by a good 10% in 2020 due to increased quantities of mycelium waste at Lendava.

77% of all biodegradable waste was mostly Lendava mycelium waste and the Lendava Wastewater 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 0.5% of all non-hazardous waste, of which only 13% is put to landfill. Packaging accounts for a good 10% of non-hazardous waste and is recycled in sections (paper, plastic, wood, metal, and glass) and in comparison with 2019, increased by 3%. We mainly recycle waste packaging, and the same applies to construction waste. Other non-hazardous wastes are disposed of by authorized companies by means of incineration.

Volume of all non-hazardous waste by site in t

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)	**Lek** (non-hazardous waste without recycled packaging)
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
2020	t	33,851	2,181	730	459	37,221	33,378

Non-hazardous waste directed to recycling and prepped for reuse in t

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
2016	t	28,407	2,134	780	554	31,876
2017	t	27,337	2,593	714	588	31,232
2018	t	28,409	2,247	557	535	31,748
2019	t	30,088	2,083	682	461	33,314
2020	t	33,656	2,151	657	419	36,882

Non-hazardous waste directed to incineration and co-incineration in t

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
2016	t	292	72	97	41	502
2017	t	240	55	83	37	414
2018	t	1	3	40	41	85
2019	t	0	1	62	28	91
2020	t	1	28	68	28	124

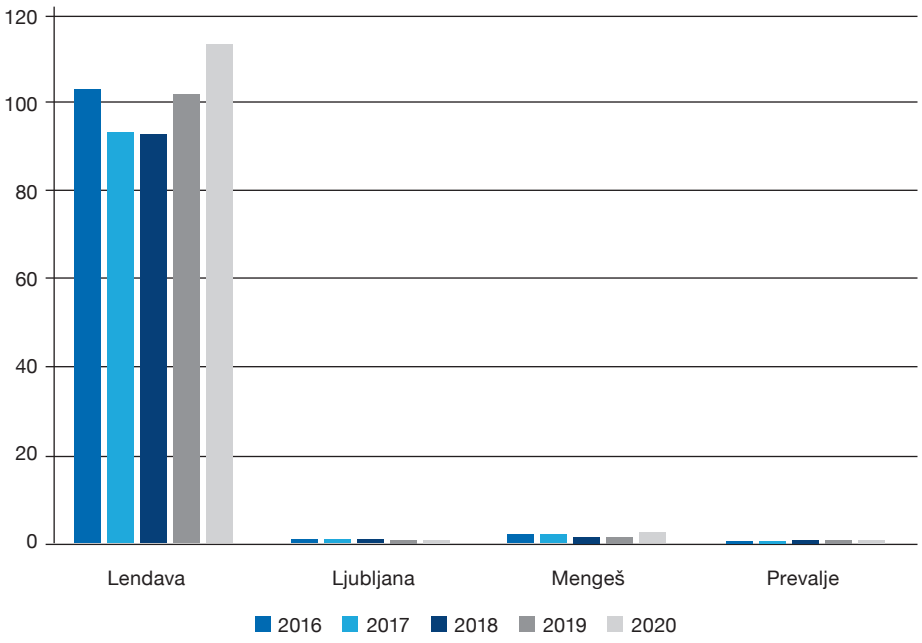
[57] GRI GS 306-1, 306-2, 306-3, 306-4, 306-5

Non-hazardous waste directed to landfilling in t

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
2016	t	125	131	29	14	299
2017	t	97	4	5	17	123
2018	t	134	4	3	15	156
2019	t	258	3	4	13	278
2020	t	195	3	5	13	215

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

t/t



4.6 Air Emissions[58]

Novartis' environmental sustainability strategy focuses on limiting emissions into the atmosphere. The objectives of the strategy envisage achieving carbon neutrality in all its activities (direct and energy-indirect greenhouse gas emissions) by 2025, and by the same year to include their requirements for sustainable environmental criteria in all contracts with our suppliers. It is also Novartis and our ambition to achieve carbon neutrality throughout the value chain by 2030, including our supply chain.

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. 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, biofilters 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 20 mgC/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 0.2 kg/h, the limit value is 20 mg/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 is carried out in Lendava and co-incineration at 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.

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

Technological solutions and continuous measurements allow us to ensure our emissions are constantly controlled and within permitted limits. The set limit 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 disposed waste. The subject of reporting and control is also all emission monitoring, both permanent and occasional measurements from co-incineration or incineration plants.

The sites, as operators of industrial complexes performing single or multiple activities, are covered by Regulation (EC) No. 166/2006, and are obligated to report 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, incineration,

[58] EMAS – Core Indicator, RCI OI 7, RCI OI 10, GRI GS 103-1, 103-2, 103-3
[59] EMAS – Core Indicator, RCI OI 7, GRI GS 305-7

co-incineration and operation of combustion plants. 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. As stated by our supplier, natural gas does not contain sulphur.

On the basis of prescribed monitoring from incineration and co-incineration of waste, we obtain data on the volumes 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, but they are always within the prescribed limits.

Sulphur Dioxide emissions (SO_2)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) (kg SO_2/t product)
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
2020	t	0.4778	0.0160	0.0000	0.0580	0.5518	0.1174

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

4.6.3 Nitrogen Oxides

Nitrogen oxide emissions arise mainly from incinerators and co-incinerators and combustion devices. Regular emission checks are carried out at all sites. The total amount of emissions stayed at the same level as 2019.

Nitrogen Oxide emissions (NO_x)[60]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t NO_x/t product)
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
2020	t	11.35	1.50	14.98	5.20	33.03	0.007

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.

[60] EMAS – Core Indicator, RCI OI 8, GRI GS 305-7
[61] RCI OI 10
[62] RCI OI 11
[63] RCI OI 12
[64] RCI OI 13

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

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (Lek) (t CO_2/t product)
GHG1	2016	t CO_2	11,642	3,118	14,375	2,032	31,167	6.0
	2017	t CO_2	12,161	2,610	14,146	2,097	31,014	6.3
	2018	t CO_2	13,213	2,261	13,916	1,846	31,236	6.1
	2019	t CO_2	13,692	2,569	14,627	1,944	32,832	6.6
	2020	t CO_2	14,133	2,675	14,551	1,719	33,078	7.0
GHG2	2016	t CO_2	0	26,743	0	0	26,743	6
	2017	t CO_2	0	25,911	0	0	25,911	5.3
	2018	t CO_2	17,066	39,047	9,432	1,940	67,484	13.2
	2019	t CO_2	16,961	39,275	9,585	1,772	67,593	13.5
	2020	t CO_2	16,685	37,816	9,107	1,695	65,302	13.9

In the calculation of GHG1, the natural gas consumption value for 2018 is 55.29 kgCO_2/GJ (0.199044 kgCO_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) which amounts to 49.9076 kgCO_2/GJ 0,179667 kgCO_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 at the same level as the past five years. It is influenced by new highly complex products which are more demanding on energy but are produced in smaller volumes. 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 onwards has a significant impact on the increase of 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.

4.6.5 Volatile organic compounds (VOC)[66]

The total amount of emissions of volatile organic compounds (VOCs) was reduced by 16% in 2020 and thus improved efficiency by 8%, mainly due to the reduction of the use of organic non-halogenated solvents in Mengeš and the smooth operation of the Lendava RTO device.

Emissions of halogenated volatile organic compounds (VOCs) represent less than 0.5% of emissions of all VOCs, which was achieved by systematic replacement of halogenated organic solvents with non-halogenated ones. In Prevalje, the use of halogenated solvents was already abolished years ago with the final replacement of methylene chloride with ethanol. 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.

[65] GRI GS 305-1, 305-2, 305-4
[66] RCI OI 9

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. The variation of the measurement uncertainty in the analysis of waste solvents leads 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.

Total VOC emissions*

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) (t HOS/t product)
2016	t	73.3	10.1	48.0	3.8	135.2	0.026
2017	t	70.6	4.6	32.0	4.7	111.9	0.020
2018	t	59.3	4.8	42.1	5.2	111.4	0.022
2019	t	58.7	3.2	53.9	6.9	122.7	0.024
2020	t	45.6	3.9	50.3	3.0	102.8	0.022

* Data for Lendava and consequently for Lek as a whole were presented in previous years according to the estimate, and in the present report according to actual/final emissions.

4.7 Water Releases[67]

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.

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 the waste water. Monitoring is carried out by an authorized external contractor. The limit values are prescribed in the 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.

We have been monitoring the effects of pharmaceutical substances on the aquatic environment for several years; resistance to antibiotics is a serious problem. Novartis, by signing the Davos Declaration Combating Antimicrobial Resistance additionally proactively committed itself to prevent the emergence of bacterial resistance to antibiotics.

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.

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

4.7.1 Waste water

With 14% lower water use, which we achieved through a number of measures, the quantities of cooling and technological wastewater also decreased by the same percentage. Unpolluted waste cooling water in Lendava and Mengeš represents more than 63% of the total amount of water used.

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

Waste water by quality and outlet location[68]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Use of cooling water – unpolluted							
	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
	2020	1,000m³	946	0	910	0	1,856
Discharge			Into the surface water	Into sewage system cleaning at WWTP	Into the surface water	Into sewage system	
Use of industrial water – polluted							
	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
	2020	1,000m³	314	523	214	36	1,087
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

In 2020, we significantly reduced emissions of phosphorus and nitrogen compounds and the chemical oxygen demand, as a result of the smaller volume of fermentation production in Mengeš.

Emissions of phosphorus compounds in water are caused by residues of inorganic substances from fermentation production, most of them in Mengeš and Ljubljana. We recorded a 24% decrease in the quantities of such compounds compared to the previous year.

Emissions of nitrogen compounds in water also occur during fermentation production, and their largest share is at the Lendava site, followed by Ljubljana and Mengeš, while in Prevalje these emissions are negligible. The total amount of these emissions in 2020 decreased by 15%.

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.

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 2020, we recorded a decrease in the chemical oxygen demand of 20%.

[68] EMAS – Core Indicator, GRI GS 303-4

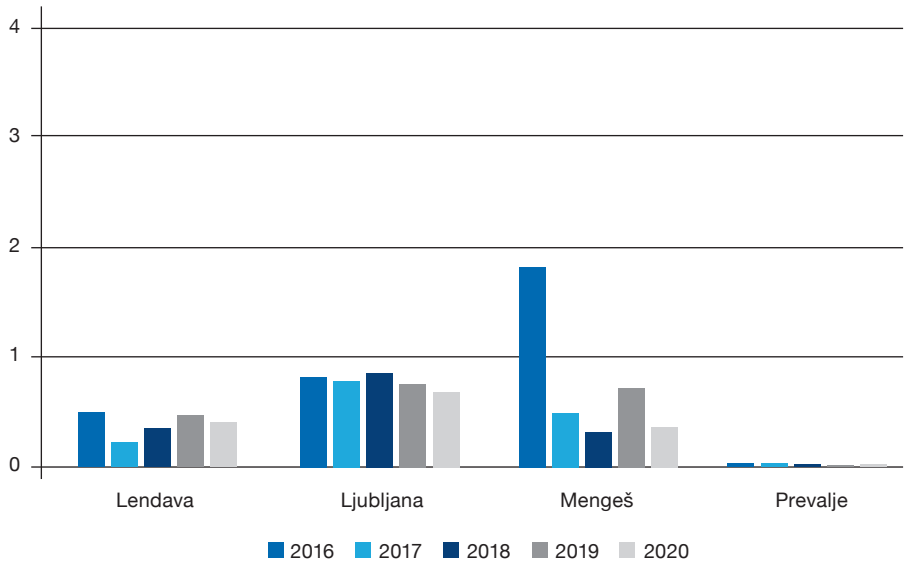
The amount of wastewater from the production of finished products in Prevalje and Ljubljana is low, which is also reflected in the contribution of the chemical oxygen demand. The sites together contribute less than 4% of the total pollution of waste waters with organic impurities.

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.

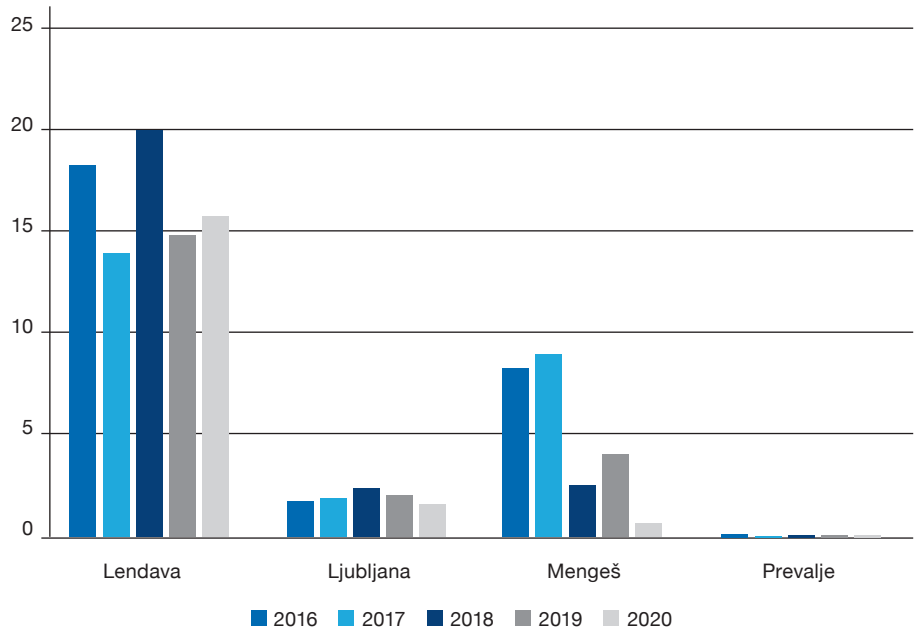
Wastewaters and the content of all the three parameters are constantly monitored by the authorized monitoring authorities. Monitoring is carried out three to twelve times a year, depending on the volumes of wastewaters at the respective site.

Emissions of phosphorous compounds in wastewater (in t)[69]

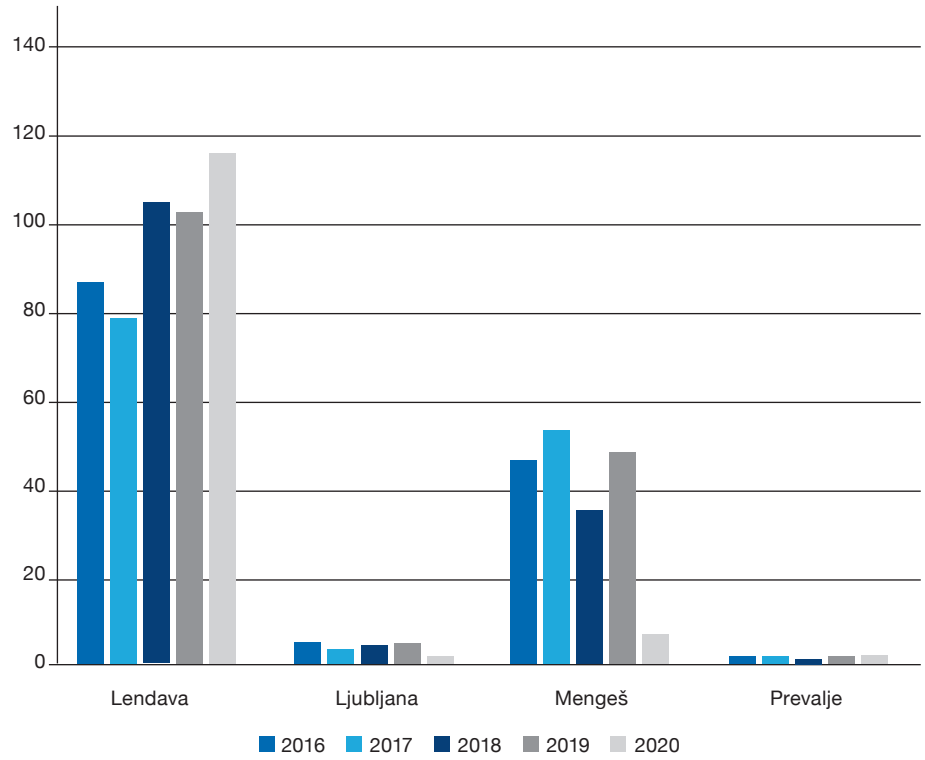


[69] RCI OI 15

Emissions of nitrogen compounds in wastewater (in t)[70]



Chemical oxygen demand (in tO_2)[71]



[70] RCI OI 16
[71] RCI OI 14

4.8 Other Environmental Impacts

4.8.1 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. The odor is triggered by various volatile substances, mostly of organic origin.

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.

4.8.2 Soil

Soils are a non-renewable natural resource, threatened by natural degradation processes such as soil erosion due to wind or water action, and anthropogenic processes such as soil pollution. These processes reduce biodiversity, which also has a wide impact on the development potential of the company. 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, and acid rain), traffic, intensive agricultural production and unregulated waste dumps.

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.

In the event of a spill, all surfaces, both internal and external, are secured with catch basins to prevent the spillage of hazardous substances. 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.

At these two sites, the networks of cooling and meteoric wastewater are equipped with a safety damper (collection volume > 2,000m^3), and in addition to risk management, there are also balancing pools with a holding volume of 800m^3 in Mengeš and 400m^3 in Ljubljana.

Dangerous behaviors and conditions that could lead to incidents and soil pollution are also prevented by regular security patrols.

Among our most important identified possible sources of soil contamination are the storage of harmful substances and their transport around the site.

To date, no remedial action due to soil pollution has been needed at Lek. In 2020, in accordance with the legislation, we made a record of the zero soil condition for the Mengeš site. The analyzes results showed that the soil is not loaded with hazardous substances.

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.

Although results have found that prescribed limits have not been exceeded at any site, additional measures to reduce noise at existing sources are being made at the source of the noise and at the points where the sound is spread.

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, time and place (e.g. noise at night is more disturbing) and how each individual experiences sound.

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 2020 we received no noise complaints in Lek.

4.8.4 Biodiversity

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]

	Lendava	Ljubljana	Mengeš	Prevalje	Lek
Total site surface area with parking lots (m^2)	116,217	142,632	133,763	32,285	424,897
Of which green surfaces (m^2)	56,114	27,609	34,228	1,437	119,388

4.8.5 Light pollution

The management of light pollution is a great challenge for companies, 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.

Lek is not obliged to ensure the operational monitoring of light pollution, as the electrical power of the lamps at no location exceeds 50 kW. 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), so it does not shine horizontally and at the same time reduces its operation during times of lower work needs.

In the past, with the help of external experts, 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.

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[72] EMAS – Core Indicator

4.9 Safety

4.9.1 Fire safety

We did not record any major cases at Lek's sites in 2020 in the field of fire protection. All sites regularly conduct fire drills in accordance with COVID regulations to prevent spreading of the virus. Annual fire drills and evacuation drills had to be moved to 2021.

Lek has three voluntary industrial fire brigades. PIGD Lek, which operates in Ljubljana and Mengeš, PIGD Lek Prevalje and PIGD Lek Lendava. Volunteer firefighters upgraded their knowledge of recommendations to prevent the spreading of COVID at the Administration for Civil Protection and Disaster Relief training centers in Ig, Sežana and Pekre.

Our firefighters also perform intervention work in high-risk cases, such as work at height or work in confined spaces. For appropriate training, we organized practical rescue trainings for them. In 2021, we are planning at least one training session for volunteer firefighters from Lek's sites in the Ig Civil Protection and Disaster Relief Training Center. Volunteer firefighters will also take part in training within the Fire Brigade Association of Slovenia.

In Lendava, we also conducted practical training for extinguishing initial fires with a simulator for extinguishing initial fires and presented to employees the full range of fire extinguishers used in production. We also showed our employees which fire extinguishers are also suitable for use at home and on the road in the car.

Practical training for putting out an initial fire in Lendava.

4.9.2 Biological safety

In Lek, we work with Group 1 and 2 biological agents in different work processes. Most biological agents, including genetically modified organisms (GMOs), are classified in Hazard Group 1, where the likelihood of causing disease in humans is minimal and the risk of spreading to the environment is negligible.

At Lek, biological agents and GMOs from Hazard Group 1 are used in the development, production and quality control departments. Biological agents classified in Hazard Group 2 are used in small quantities in the development and quality control departments, where we test the effectiveness of products. Biological agents from Hazard Group 2 can cause disease in humans, but in most cases effective prevention or treatment is available and the risk of the organisms spreading to the environment is low.

In all departments where employees handle biological agents, we have introduced strict containment measures that prevent as much as possible, direct contact of employees with biological agents and GMOs and the spread of organisms in the environment.

The biosafety system is integrated in all levels of work and is linked to all relevant Lek stakeholders. It 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. In any closed system where we deal with biological factors, we have a specific project manager for work, a caregiver for an action plan in the case of an irregular incident. 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 2020, we obtained a permit from the Ministry of the Environment and Spatial Planning for two expansions of closed systems at the Ljubljana location and two expansions of closed systems at the Mengeš location.

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. In August, the Office of the Republic of Slovenia for Chemicals carried out an inspection at Lek's production site in Ljubljana and found that Lek met all legal requirements for the storage of hazardous chemicals.

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 2020, a total of 5,078t of goods were shipped from Lek's production warehouses as part of the transport of hazardous goods. At the same time, we did not record any events or accidents that would have resulted from the loading, transport and unloading of hazardous goods.

4.9.3.2 Distribution

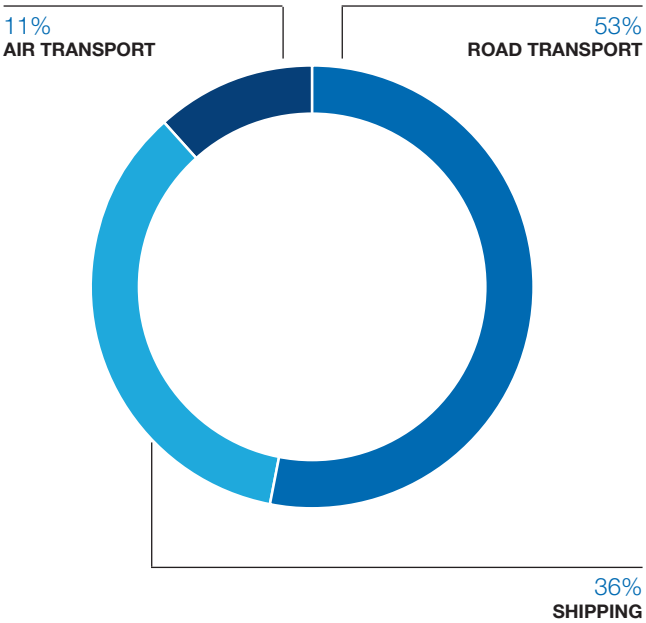
For safe transport it is important to follow the guideline requirements and good distribution practices with contractors. Employees who prepare and dispatch dangerous goods, are familiar with the requirements of international agreements and are trained in the procedural measures for the transport of 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 2020, we shipped 9,803 shipments of products from Lek's sites and warehouses to our customers, which is 7.6% less than 2019 (10,602).

In gross weight, we had 52.7% road, 11.6% air and 35.6% sea shipments. In comparison to last year, we increased the ratio of shipments in favor of sea transport (2019: 9.2%). This reduces our carbon footprint, as shipping has a lower emission factor than other modes of transport (sea 10-40g/tkm, road 60-150 g/tkm, air transport 500 g/tkm; Source: Lufthansa Air cargo).

Shipments by type of transport



4.9.4 Chemical safety

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

In the production of pharmaceuticals, we prevent direct exposure to chemicals with modern technologies. Descriptions of measures to protect employees and the environment in API production are also the key content of REACH (Registration, Evaluation and Authorization and Restriction of Chemicals) registration of strategic chemicals at the European Chemicals Agency (ECHA). The registrations provide Lek with continuous imports and isolation of raw materials in API production. In November 2020, the international consulting company ERM conducted a three-day compliance assessment with the requirements of the REACH regulation for all Novartis companies in Slovenia and in the Lendava Wastewater Treatment Plant, which is co-owned by us. No critical deviations have been recorded and the findings and recommendations will be included in the monitoring of the implementation of REACH.

When the epidemic was declared in March 2020, due to the lack of disinfectants in Slovenia, we donated a larger amount of disinfectants to protect against the COVID-19. Employees from the Mengeš and Ljubljana sites prepared recipes for production, procured appropriate packaging and the necessary documents in the field of chemical safety. The Office of the Republic of Slovenia for Chemicals issued an extraordinary permit for the donation of disinfectants in an extremely short time. Until the expiration of the permit in September, we donated 24 tons of disinfectants to hospitals, health centers, public institutions and civil protection.

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 Resource Policy[73]

At Lek, which is part of Novartis, we are building a culture that encourages curiosity and exploring new ways of working. It provides a work environment where leaders set clear goals, remove barriers, and help co-workers achieve their personal goals.

Lek's human resource policy emphasizes the principles of cooperation, development and excellence. It supports fundamental business orientations aimed at a high level of innovation, growth and improved productivity.

The priority is to design processes, tools and systems for recruitment, talent development and succession planning, achievement rewards, organizational development and education. In doing so, we are fulfilling our purpose – to reimagine medicine – and to improve and extend the lives of people around the world.

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

Novartis Slovenia receives Top Employer award

We were rewarded best personnel practice – honorable mention for Regional Biocamp.

Motivation and efficiency of employees, innovative staffing practices and development programs were also awarded by the independent institution Top Employers Institute. As the first pharmaceutical company in Slovenia, Novartis Slovenia received the prestigious international “Top Employer” award for the best employer. We received the award based on the results of a survey covering six human resources areas, consisting of 20 topics such as human resource management strategy, work environment, talent acquisition, learning, well-being, and diversity and inclusion.

In 2020, at the 39th International Conference on the Development of Organizational Sciences for the BioCamp project, we also received the award for best personnel practice 2020 - an honorable mention. For the initiative of the Young Advisory Board (YAB), we received the Golden Practice Award, which is awarded by the Dnevnik newspaper for innovative and efficient personnel practice. The recognition was earned by the initiative, which involves regular meetings of young employees with the company’s management, which are intended for the exchange of opinions, experiences and ideas.

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5.2 Employment

5.2.1 Total workforce by employment and employment contract[74]

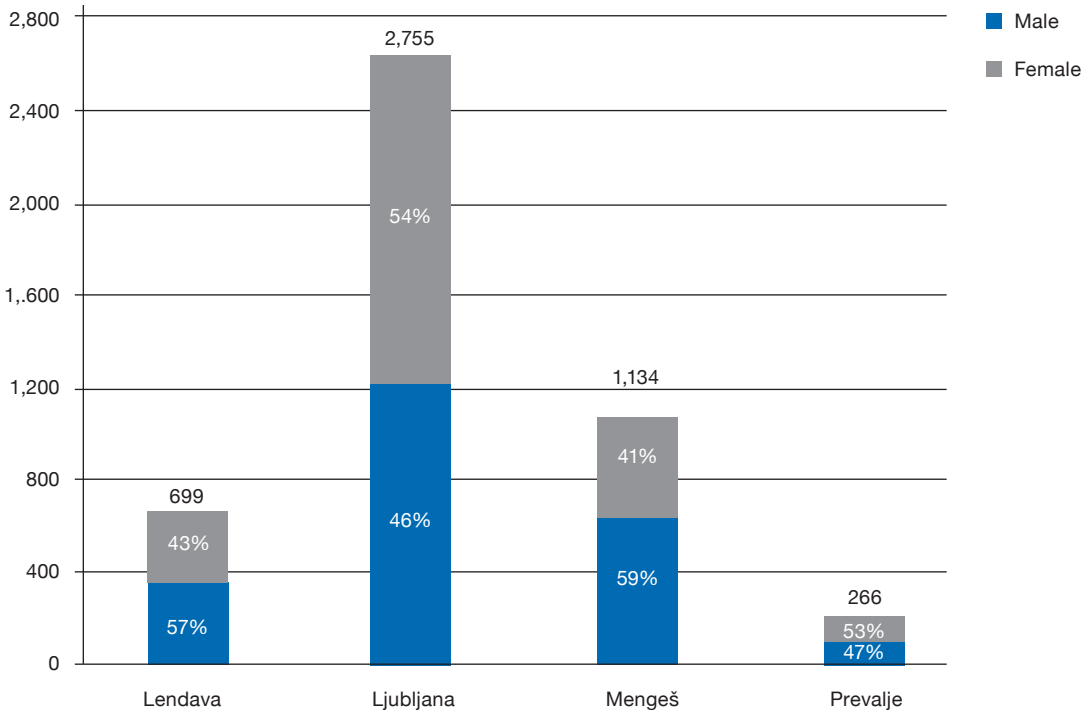
In 2020, we created 645 new jobs (34% more than 2019) and finished the year with 4,823 full-time employees (11% more than 2019). At the end of the year, the proportion of women employed was 489%, 1% higher than the previous year. At year-end, 94.6% of all employees worked on a full-time permanent basis, and 5.4% were fixed-term employees and 1.7% of all employees worked on a part-time basis.

Number of full-time employees on 31. 12. 2020 by site and gender

Site	Male	Female	Total
Lendava	397	302	699
Ljubljana	1,278	1,477	2,755
Mengeš	674	460	1,134
Prevalje	107	119	226
Other*	9	0	9
Total	**2,465**	**2,358**	**4,823**

* Leased warehouses

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

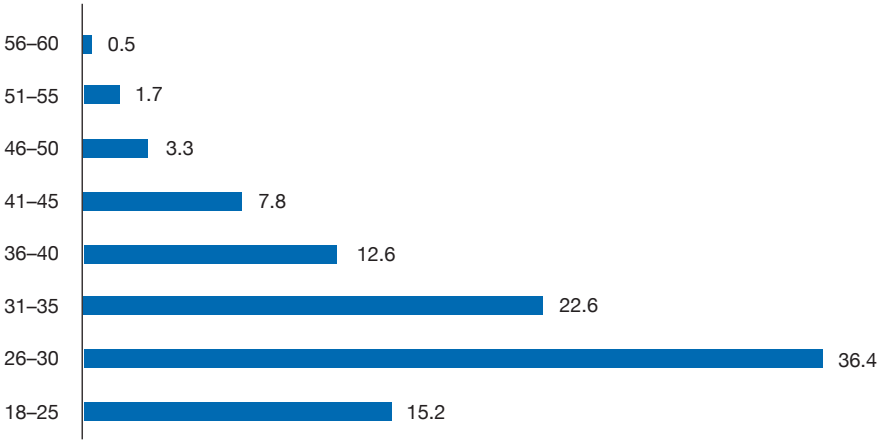


[74] GRI GS 102-7, 102-8, 401-1

Number of new employees in 2020 by age

Age group	Number of new employees	%
18–25	98	15.2
26–30	235	36.4
31–35	146	22.6
36–40	81	12.6
41–45	50	7.8
46–50	21	3.3
51–55	11	1.7
56–60	3	0.5
Total	**645**	**100**

New employees in 2020 by age (in %)



5.2.2 Percentage of employees covered by collective agreements[75]

The Collective Agreement covers 99.34% 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 amount of 5.844% of the employee's gross salary, or an an nual amount that cannot exceed EUR 2,819. At the end of 2020, 93.07% 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 higher (87.10%) than in 2019 (86.67%).

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

5.2.5 Parental leave[78]

Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act. The growth in the number of employees taking parental leave continued in 2020, the return to work rate after parental leave remains high.

Parental leave and return to work rate

	2020	2019	2018
Number of employees having taken parental leave	506	479	458
- Male	219	230	219
- Female	287	249	239
Number and share (in %) of employees returning to work after parental leave	503 (99.4%)	478 (99.8%)	458 (100%)
- Male	219 (100%)	229 (99.6%)	219 (100%)
- Female	284 (98.9%)	249 (100%)	239 (100%)

5.3 Occupational Health and Safety[79]

Efforts to increase occupational health and safety are 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 a healthy and safe workplace. Our goal is to create a safety culture as a fundamental value of all employees. We strive to eliminate any dangers and minimize risks through effective preventive and protective measures. 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 external contractors.

With the health assessment, which is an integral part of the safety statement, we identify, eliminate and reduce all forms of risk for employees. All adopted preventive measures in risk assessments are regularly implemented.

In addition to the regular and planned review of the risk assessment, we also performed an additional risk assessment at all workplaces due to the declared COVID-19 epidemic. We constantly monitored and included measures recommended by the National Institute of Public Health of Slovenia (NIJZ) and Novartis. We adapted to the situation, audited and implemented preventive measures, communicated with colleagues and the external public, supervised the implementation of measures, carried out an assessment of the measures of key contractors, etc. Due to the organizational changes that will be completed in 2021, the safety statement will also be revised.

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

[79] GRI GS 103-1, 103-2, 103-3, 403-1, 403-2

The 5 golden rules we must follow

Protect the health of others and yourself.

1.

Always wear a surgical mask in both closed areas and outside. **Respect a safety distance of at least 2m.**

2.

Regularly wash your hands with soap and water.

3.

Cover your mouth and nose when you cough. This will intercept the drops which could contain the virus.

4.

Cleanliness is key to preserving health. **Contribute** by protecting everything around you.

5.

Stay at home if you do not feel well or have flu or cold symptoms. Call your doctor.

In 2020, we largely focused on the successful prevention and control of COVID-19 infections and implemented more than 300 preventive measures in all workplaces. At the same time, we continued with activities to prevent accidents, fires and other events that would cause damage.

5.3.1 Frequency of absences due to injuries at work[80]

Detailed records of work-related incidents, which are one of key occupational health and safety indicators, allow 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).

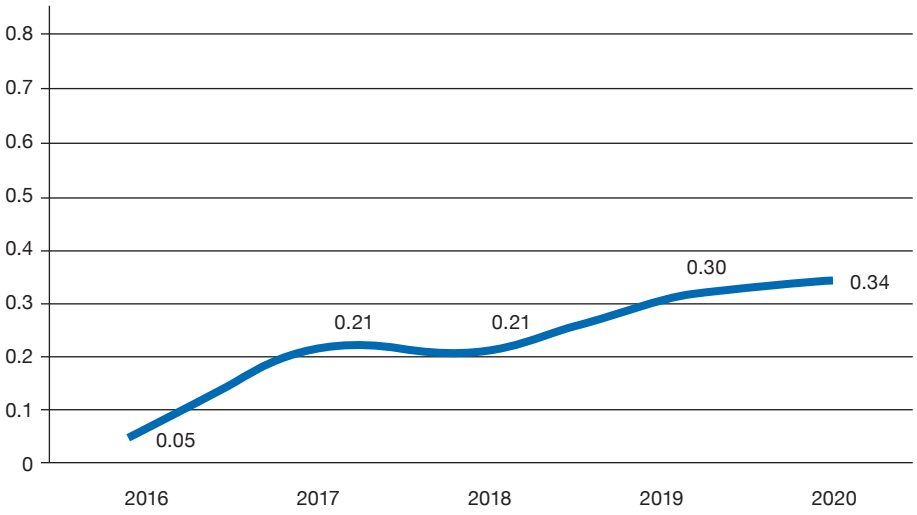
Lost Time Injury and Illness Rate

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2020	0.39	0.11	0.29	2.54	0.34

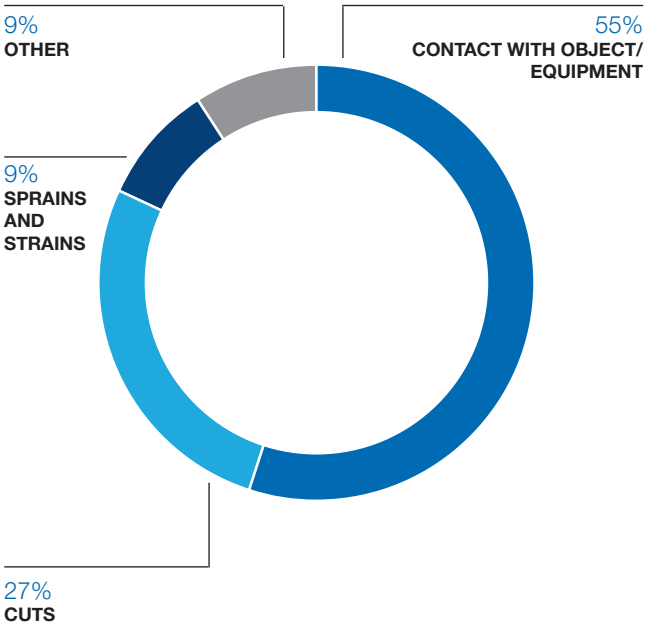
In 2020, we did not record any serious injuries at work or illnesses that would have lasting consequences for the health of our employees. We recorded 11 cases where co-workers were on sick leave due to an injury at work. The LTIR indicator increased from 0.30 to 0.34, an increase of 13% compared to 2019. The TRCR indicator also increased slightly and stood at 0.34 (0.32 in 2019).

[80] RCI OI 2, GRI GS 403-9

Trend of LTIR injuries



Categories of accidents based on cause (LTIR and TRCR)



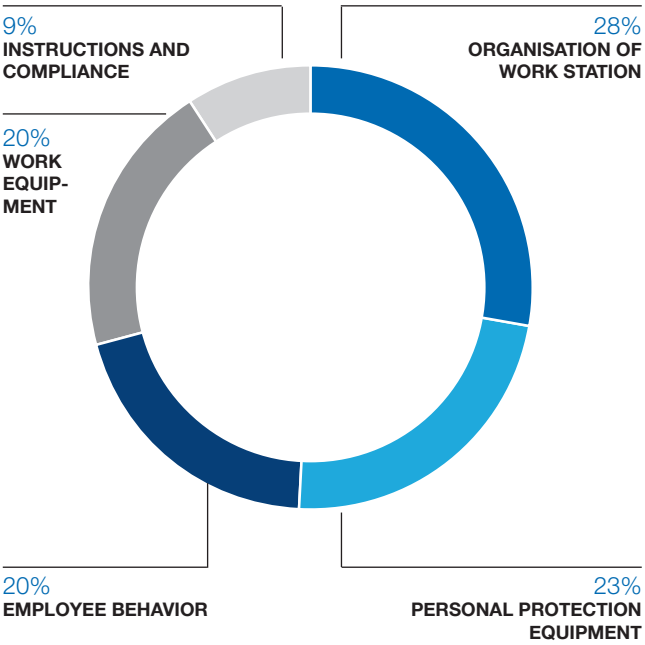
HSE system

Preventive activities to prevent accidents and injuries in 2020

We pay 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 2020, we recorded 5 such cases, which we investigated and prepared preventive measures to avoid a repeat in the future. In 2018, we recorded 5 such cases, which we investigated and prepared preventive measures for. Most of the pSIF events were related to exposure to hazardous substances, work at height, falling objects and hazardous energies. Three of these pSIF cases were connected to external contractors.

When incidents occur, it is important to understand the causes, share insights, and take corrective action to prevent them from recurring. Events that could result in serious injury or death (SIF - Serious Injury or Fatality) receive special treatment and detailed improvement plans. Safety performance is associated with a well-developed safety culture at all levels, where employees are empowered to speak up and stop a potentially dangerous activity. In 2020, we continued with safety walkthroughs, which encourage employees to speak up, create an environment of trust and information exchange, and, most importantly, show the high commitment and visible leadership. We conducted more than 2,600 safety walkthroughs, 27% of which were performed by managers.

Classification of risks noticed by area



5.3.2 Absenteeism[81]

In order to determine the degree of absenteeism, the number of absent employees' working hours is divided by the working hour's fund. The share includes sick leave of up to 30 days, over 30 days and care. In 2020, the proportion of sick leave was 4.87%, recording a slight decrease compared to the previous year (6%).

Share of sick leave*

	2020	2019
Women	5.91%	7.41%
Men	3.88%	4.67%
Total	**4.87%**	**6.00%**

* The share includes sick leave of up to 30 days, over 30 days and care. Due to changes in data included, only shares for 2020 and 2019 are shown.

[81] GRI GS 403-9

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

Outsourcing safety management remains a key element of our SIF and HSE prevention program. We involve external contractors in various specialized activities, such as servicing equipment, annual maintenance and construction work. In many cases, these are increased or high-risk tasks, requiring a lot of training, hazard reduction and control. Due to COVID-19, the activities of external contractors were reduced to a level that enabled safe work, in accordance with the preventive and protective measures taken.

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.

In 2020, more than 250 external contractors were involved at our sites. In addition to our daily activities in the field of HSE, we also performed the following:

- safety training for all external contractors (via MS Teams),
- web application for Onboarding Orientation,
- make additional recommendations due to the requirements of COVID-19,
- prepare new HSE requirements for external contractors and forward them to contractors and other internal stakeholders,
- constantly connected with external contractors and thus determined and implemented best practices regarding COVID-19.

Our work has focused on safety measures related to COVID-19 and raising awareness and meeting local and Novartis requirements. In 2020, we introduced more than 1,600 onboarding orientation.

Although we are working hard for sustainable outsourcing, in 2020 we recorded three out of five cases of pSIF that were directly related to outsourcing activities. As a result, we will review our internal program of external contractors management next year, based on best practices, lessons learned and new global outsourcing procedures.

Examples of best practice which were implemented at the construction site.

5.3.4 Number of work-related fatalities[82]

No fatalities were recorded amongst our employees or external contractors.

5.3.5 Occupational disease rate[83]

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[84]

Provision of preventive health care is carried out in cooperation with occupational doctors 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.

Due to government restrictions, all medical examinations, including preventive medical examinations, were restricted. In order to ensure business continuity due to the lack of new employees, we were able to obtain special approval from the competent authorities to continue preventive medical examinations provided by contractors (occupational physicians). Medical examinations were performed in accordance with internal plans.
The health status of employees remains similar to previous years, despite the epidemiological situation. Most of the identified health problems of our employees stem from problems with the musculoskeletal system, obesity and impaired vision, mainly due to the aging population.

We prepared guidelines and online training for working from home, with an emphasis on providing and organizing appropriate equipment, organizing the work environment and, in particular, on measures to maintain the mental health of employees. Ensuring and maintaining mental health in times of limited contact, closure of social life, social distance and other measures are challenges we must prepare for in the future.

In order to maintain the physical and mental health of our employees, we carried out the following activities within the health promotion program, taking into account the protection measures due to the pandemic:

- exercise workshops (remote),
- exercise outside the workplace,
- active wrists,
- active breaks at work,
- body composition measurements,
- workshops on healthy eating,
- raising awareness of a healthy lifestyle,
- TRE-exercises to release trauma, tension and stress,
- preventive dental examinations,
- vaccinations against seasonal flu and tickborne meningoencephalitis; and
- lectures in the field of occupational medicine.

Active breaks at work.

[82] RCI OI 1 in RCI OI 3, GRI GS 403-9
[83] GRI GS 403-10
[84] GRI GS 403-3, 403-4, 403-5, 403-6

5.4 Training and Education[85]

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 non-formal training 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. 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.

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.

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.

Due to the COVID-19 pandemic 2020 was also a special year for education. We had to respond appropriately in unexpected and unpredictable situations. Thus, all training that previously took place in classrooms was moved to a virtual form, which also required the adaptation of the content and implementation of training.

HSE organization, human resources and training

In 2020, there was a reorganization of support functions at sites. HSE is now part of the Site Development NTO, which will implement and offer optimal infrastructure, energy and professional services to production sites as well as to organizations located at Lek's sites. Production activities retained their HSE representative, who is directly responsible to the head of the production unit for certain HSE tasks, while the remaining HSE personnel joined forces as HSE support for sites as part of the Site Development NTO.

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.

Training documentation (general procedures, work instructions, etc.) is managed in Novartis' Up4Growth application. At production sites, teams have been formed to ensure compliance in the field of employee training and learning. Curricula have been developed to ensure that employees are trained in a timely manner in appropriate content to perform their work effectively and safely. Specific education and training is intended for employees who perform specific tasks, such as high-risk work, and requires Novartis to provide additional training. Training is planned and conducted in the application Corrective measures – Training and is led by HSE NTO development sites. Numerous e-trainings, professional training and soft skills training offered by the Coursera, LinkedIn, U4G platforms, etc. are also available free of charge to all Novartis employees.

In 2020, providing training was a major challenge due to the pandemic. All training that did not involve high risks and could be carried out at a distance (e-learning) was conducted through available e-applications (MS-Teams, UP4G, etc.). Thus, we managed to carry out periodic and pre-employment training for new employees in occupational health and safety and fire protection, and 1,650 external employees completed basic training before performing work at Lek's sites (safety rules, safe performance of work). Certain specific training was also carried out, such as fork-

[85] GRI GS 103-1, 103-2, 103-3

lift drivers, explosion protection (basic and regular training), first aid, work with lifting baskets, demonstrations of extinguishing and evacuation from facilities, training for Walkie Jack pole operator, training for management of mobile lifting baskets/platforms, LOTO training…

All education that was canceled due to the pandemic will be postponed to 2021, depending on capabilities.

HSE aspects and system of achievement monitoring

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. 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 2020, due to the COVID-19 epidemic, external audits of compliance with ISO 14001: 2015 and ISO 45001: 2018 were postponed to 2021, and we performed a partial audit under the EMAS regulation. Once again, the verifiers confirmed that we are operating in accordance with the applicable environmental legislative requirements and that the data and information from the environmental statement provide a reliable, credible and correct picture of all activities at all Lek locations.

Due to the epidemic, internal HSE audits, which are otherwise planned on an annual basis, were not carried out in full. An internal Novartis thematic assessment of the management of waste pharmaceuticals was carried out, which covered all sites as well as our contractors in wastewater treatment. The results showed the compliance of our operations with the requirements of legislation and internal and external standards. We have prepared effective corrective measures for minor deviations.

Novartis' internal audits are more extensive and cover all areas of HSE at the site and in all areas of operation: environmental protection, occupational health and safety, chemical safety, fire protection, biosafety, anti-explosion protection and crisis management (BCM and NEM). The frequency of assessments depends on the nature of the production. Assessments at active substance production sites are carried out every two or three years and at pharmaceutical production sites every three or four years. These assessments also include the requirements of ISO 14001 and ISO 45001 and EMAS.

We use Novartis' HSE Net application to record corrective actions/action plans for audits, inspections and safety walkthroughs.

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 2020, 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.

BCM activities in 2020

The business continuity assurance system enables the management of business processes in the event of major negative impacts on key products or key business processes. BCM and NEM were crucial to our successful response during the COVID-19 pandemic, which began in Slovenia on 13 March 2020. The key risk to our business processes was the potential "loss of people". In the case of a large number of ill co-workers, they would no longer be able to run their processes normally. The response from the entire organization has been amazing. Everyone wanted and also contributed to the successful fight against the pandemic. In the first wave (March to May 2020), only a few co-workers were infected with COVID-19. The main activities in the first wave were focused on job creation and the protection of employees, who must be physically present at our sites, such as production and laboratories. Timely communication and action (five golden rules) were crucial to keep the infection from spreading.

NEM activities in 2020

In 2020, we updated the NEM structure in Slovenia with some new members due to changes in the management structure, but the existing structures at the site level did not change. All Novartis departments were trained according to the NEM process.

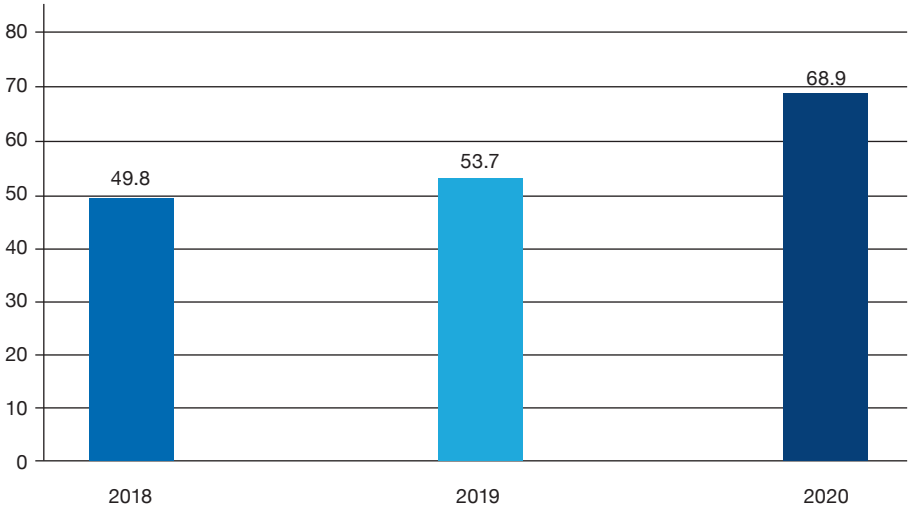
NEM training was held for new members of the NEM group and for those who did not attend previous training. Teams at the sites did not train for additional scenarios as we faced a NEM situation throughout the year due to the COVID-19 pandemic.

In 2020, we witnessed another case of NEM in Prevalje, where chlorine leaked into the atmosphere. We immediately carried out an evacuation, notified nearby neighbors, and provided assistance to our employees. Employees who were potentially exposed to chlorine were referred to the hospital, from where they were discharged the same day.

5.4.1 Average hours of training per employee[86]

In 2020, we paid even more attention to employee education than in previous years. On average, a Lek employee received **68.9** hours of training or *8.6* days, which is 28% more than in 2019.

Average hours of training per employee



[86] GRI GS 404-1

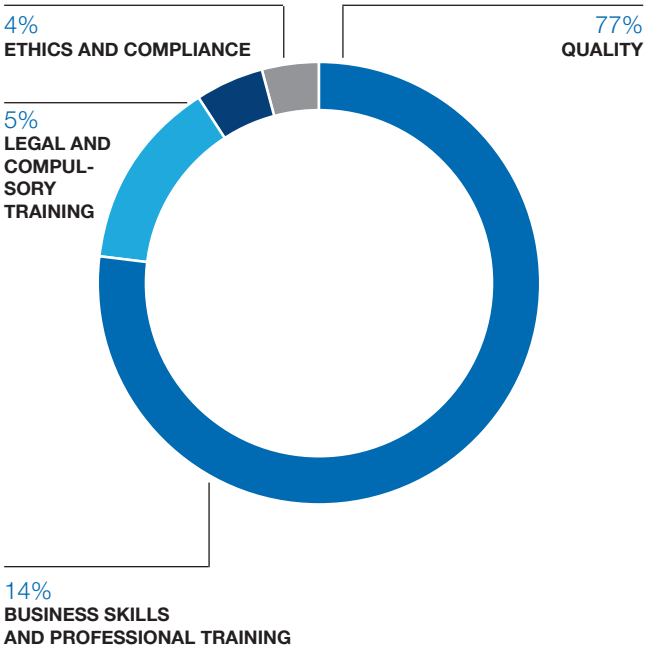
5.4.2 Training by area

We constantly take care of the promotion of learning, new ways of learning and e-learning. In 2020, we organized a month of curiosity, in which we offered employees the opportunity to participate virtually in various trainings, which is supported by a global platform and covers a wide range of content.

At Lek, we also enable our employees to study part-time. In 2020, we had 46 associates in undergraduate education and 66 in postgraduate education, most of them in the fields of biotechnology and biomedicine and chemistry.

In terms of the number of training hours, we received the most training in the following three areas: quality (77%), business skills and professional training (14%) and legal and compulsory training (5%).

Training by area in 2020



6. GRI Content Index

This report has been prepared in accordance with the GRI Global Standards: Core[87]

GENERAL STANDARD DISCLOSURES

GRI-standard	Disclosure	Section/Page numbers	UN Sustainable Development Goals (SDG)/ EMAS Core indicators	UNGC principles
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.	1.2.2/24		
102-3	Location of headquarters	1/6		
102-4	Location of operations	1.2.3/25		
102-5	Ownership and legal form	1.2/22		
102-6	Markets served	1.2.1/24		
102-7	Scale of the organization	1.1.1/7, 5.2.1/89		
102-8	Information on employees and other workers	5.2.1/89	8 12	6
102-9	Supply chain	3.2.1/50		3, 4, 5, 6, 8, 10
102-10	Significant changes to the organization and its supply chain.	1.2.3/25, 1.3.1/32, 3.2.1/50		
102-11	Precautionary Principle or approach	1.4.4/35, 4/52		7
102-12	External initiatives	1.4.4/35		
102-13	Membership of associations.	1.4.4/35		1, 8
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	3.1/47	16	1, 2, 3, 4, 5, 6, 8, 10
Governance				
102-18	Governance structure	1.4.1/33		
Stakeholder engagement				
102-40	List of stakeholder groups	1.4.3/41, 1.4.3/44		
102-41	Collective bargaining agreements	5.2.2/90	8	3
102-42	Identifying and selecting stakeholders	1.4.3/41		
102-43	Approach to stakeholder engagement	1.4.3/41 2.2/46		
102-44	Key topics and concerns raised	1.4.3/44, 2.2/46		

[87] GRI GS 102-47, 102-55

Reporting practice		
102-45	Entities included in the consolidated financial statements.	1.3.1/32
102-46	Defining report content and the topic Boundaries	1.3/32
102-47	List of material topics	6/102
102-48	Restatements of information	1.3.1/32
102-49	Changes in reporting	1.3.1/32
102-50	Reporting period	1.3.1/32
102-51	Date of most recent report	July 2020
102-52	Reporting cycle	1.3/32
102-53	Contact point for questions regarding the report	1/6
102-54	Claims of reporting in accordance with GRI Standards	1.3.1/32
102-55	GRI content index	6/102
102-56	External assurance	1.3/32

SPECIFIC STANDARD DISCLOSURES

Management approach disclosures	Topic-specific disclosures	Section/Page numbers	Remarks/ Omissions	UN Sustainable Development Goals (SDG)/ EMAS Core indicators	UNGC principles
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			
201-1	Direct economic value generated and distributed	1.1.1/7			
201-3	Defined benefit plan obligations and other retirement plans	5.2.3/90			
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			
202-2	Proportion of senior management hired from the local community	5.2.4/90			
GRI 204: Procurement practices 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	3.2.1/51			
204-1	Materials used by weight or volume	3.2.1/51			
GRI 206: Anti-competitive behavior 2016					
103-1 103-2	Explanation of the material topic and its Boundary	3.1/47			
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	3.1/48			

ENVIRONMENTAL TOPICS				
GRI 301: Materials 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4.2.1/58		
301-1	Materials used by weight or volume	4.2.1/58	EMAS Core Indicator	
GRI 201: Energy 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4/52		
302-1	Energy consumption within the organization	4.3.1/61, 4.3.2/63	7 8 12 13	7, 8,9
302-3	Energy intensity	1.1.1/8, 4.3.1/62	7 8 12 13 EMAS Core indicator	8
302-4	Reduction of energy consumption	4.3.2/65	7 8 12 13	7, 8, 9
GRI 303: Water and effluents 2018				
103-1 103-2	Explanation of the material topic and its Boundary	4/52		
303-1	Interactions with water as a shared resource	4.4/66		7, 8
303-2	Management of water discharge-related impacts	4.4/66		7, 8, 9
303-3	Water withdrawal	4.4.1/66, 4.4.2/68	6 12 EMAS Core Indicator	7, 8, 9
303-4	Water discharge	4.7.1/79	6 12 EMAS Core Indicator	7, 8, 9
GRI 305: Emissions 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4/52, 4.6/75	EMAS Core Indicator	
305-1	Direct (Scope 1) GHG emissions	4.1.5/57, 4.6.4/77	3 12 13 14 15	7, 8
305-2	Energy indirect (Scope 2) GHG emissions	4.6.4/77	3 12 13 14 15	7, 8
305-4	GHG emissions intensity	4.6.4/77	13 14 15	8
305-5	Reduction of GHG emissions	4.3.2/65	13 14 15	7, 8, 9
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	4.6.3/75, 4.6.4/76	3 12 14 15 EMAS Core Indicator	7, 8, 9
GRI 306: Waste 2020				
103-1 103-2	Explanation of the material topic and its Boundary	4.5.1/69		
306-1	Waste generation and significant waste-related impacts	4.5.1/69, 4.5.2/71, 4.5.3/73	3 6 12 EMAS Core Indicator	7, 8
306-2	Management of significant waste-related impacts	4.5.1/69, 4.5.2/71, 4.5.3/73	3 6 12 EMAS Core Indicator	7, 8

306-3	Waste generated	4.5.1/69, 4.5.2/71, 4.5.3/73		3 6 12 EMAS Core Indicator	7, 8
306-4	Waste diverted from disposal	4.5.1/69, 4.5.2/71, 4.5.3/73		3 6 12 EMAS Core indicator	7, 8
306-5	Waste directed to disposal	4.5.1/69, 4.5.2/71, 4.5.3/73		3 6 12 EMAS Core indicator	7, 8
GRI 307: Environmental Compliance 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	4/52		3 12	
307-1	Non-compliance with environmental laws and regulations	4/54, 4.1/55			
GRI 308: Supplier environmental assessment 2016					
103-1 103-2	Explanation of the material topic and its Boundary	3.2.1/50			
308-2	Negative environmental impacts in the supply chain and actions taken	3.2.1/50, 4.1.5/57	The environ-mental 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	5.1/87			
401-1	New employee hires and employee turnover	5.2.1/89		5 8	6
401-3	Parental leave	5.2.5/91			
GRI 403: Occupational Health and Safety 2018					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	5.3/91			
403-1	Occupational health and safety management system	5.3/91			
403-2	Hazard identification, risk assessment, and incident investigation	5.3/91			
403-3	Occupational health services	5.3.6/96			
403-4	Worker participation, consultation, and communication on occupational health and safety	5.3.6/96			
403-5	Worker training on occupational health and safety	5.3.6/96			
403-6	Promotion of worker health	5.3.6/96			

403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	2.3/46			
403-9	Work-related injuries	5.3.1/92, 5.3.2/94, 5.3.4/96			
403-10	Work-related ill health	5.3.5/96			
GRI 404: Training and education 2016					
103-1 103-2	Explanation of the material topic and its Boundary	5.4/97			
404-1	Average hours of training per year per employee	5.4.1/100	We do not yet record education by gender and by employee category.	4 5 8	6
GRI 406: Non-discrimination 2016					
103-1 103-2	Explanation of the material topic and its Boundary	3.1/47			
406-1	Incidents of discrimination and corrective actions taken	3.1/48			
GRI 412: Human rights assessment 2016					
103-1 103-2	Explanation of the material topic and its Boundary	3.1/47			
412-2	Employee training on human rights policies or procedures	3.1/48			1
GRI 413: Local communities 2016					
103-1 103-2	Explanation of the material topic and its Boundary	2.2.1/45			
413-1	Operations with local community engagement, impact assessments, and development programs	2.2.1/45	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	3.2.1/50		5 8 16	
414-2	Negative social impacts in the supply chain and actions taken	3.2.1/50	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	2.3/46	
417-1	Requirements for product and service information and labeling	2.3/46	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	2.3/46	
417-3	Incidents of non-compliance concerning marketing communications	2.3/46	

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 2020 – Lek d. d., June 2021;** 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: 10/2021-06-21

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

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8. Glossary of Key Terms

EMAS (ECO – Management and Audit Scheme)

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

GRI (Global Reporting Initiative)

GRI Standards 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 Standards 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.[88]

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

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

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

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

[88] 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).
[89] Source: Humar M., Šmid-Korbar J., Obreza A. Pharmaceutical terminology dictionary. Ljubljana 2011.

price makes them more affordable for a wider patient population. Chemically, biosimilars are protein drugs or glycoproteins. The concept of biological similarity as defined by the European Medicinal Products Act requires a higher level of expertise in science, technology and logistics.

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 Industrial Emissions Directive (IED) on the comprehensive prevention and control of industrial pollution has been transposed into Slovenian law by the Regulation on activities and installations that can cause large-scale environmental pollution. The Single IED Directive was created in 2010 after the merger of the IPPC Directive (Integrated Pollution Prevention and Control) with six others, which regulated this area, and was adopted into the Slovenian legal order in 2015.

a Sandoz company