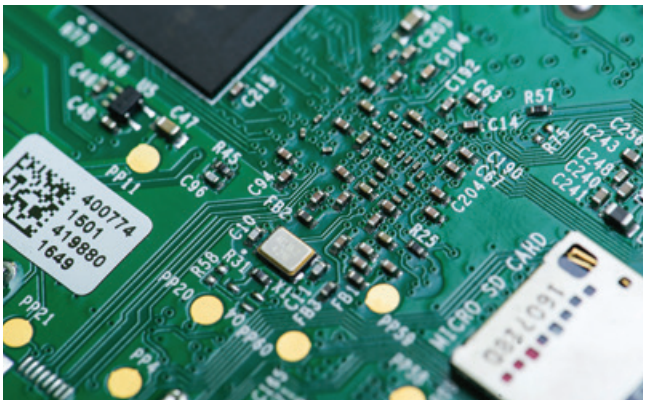
Living innovation

Sustainability Report 2021
Lek d.d.

lek

a Sandoz company

Contents



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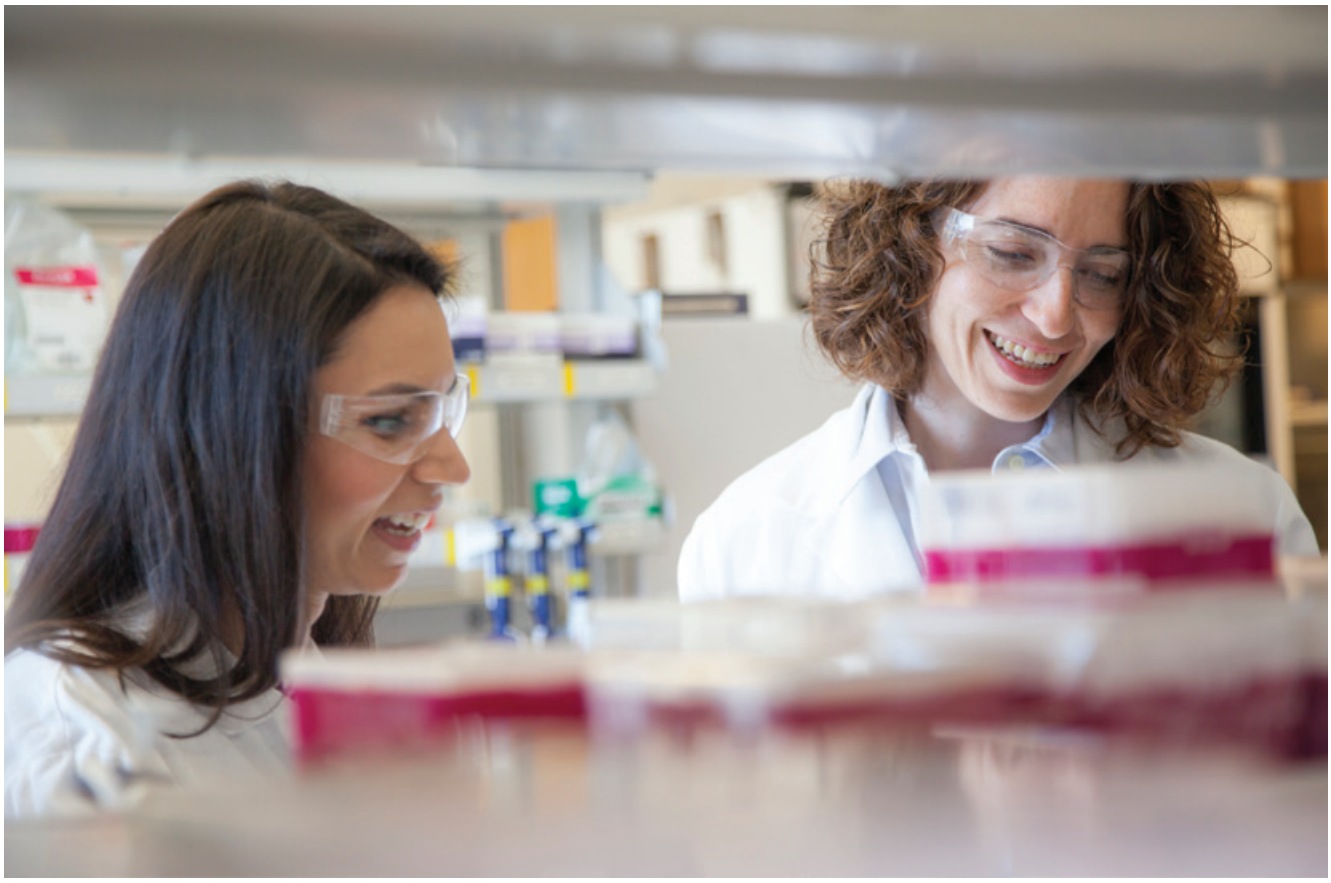
* The EU Ecolabel or EU Flower the manufacturer's commitment to continual environment management improvements.



2021 Highlights

1,270 mil. EUR

net sales income in 2021 or 7% more than 2020.

– 2.2%

less waste in 2021.

5397

employees at the year end 2021 or 12% more than 2020.

40.7 TJ

energy and 3,456 t CO_2, saved with implemented environmental projects in 2021.

83.6 hours

education per employee in 2021 or 21% more than 2020.

8 mil. EUR

investments in environmental protection in 2021.

3.87 mil. EUR

savings due to 314 implemented ideas submitted in the Th!nk Novartis system in 2021.

– 8%

less greenhouse gas emissions in 2021.

We drew the development direction from Novartis' strategic focus on technological transformation. We took this excellent possibility to utilize and implement new opportunities in digitization and science.

Robert Ljoljo

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

The health conditions due to the continuation of the COVID-19 pandemic continued to affect the operation of the pharmaceutical industry and the supply chain around the world in 2021. The experience and knowledge gained in the first year of the pandemic, and the internal systems implemented, meant we were well prepared.
We drew the development direction from Novartis' strategic focus on technological transformation; we took this excellent possibility to utilize and implement new opportunities in digitization and science. We also made progress in the sustainable development of our business.

Innovation and curiosity, the fundamental building blocks of our culture, helped us overcome challenges in 2021. The mixed reality Vision platform, developed by associates in Slovenia, has become Novartis' standard solution for work assistance and solving various problems remotely, visualizing processes and transferring knowledge. The most modern technology, such as virtual reality, was introduced in development and production. We earmarked 289 million euros for investments, the majority of which is for strengthening development and production capacities through digitization and automation.

Due to the good results in the field of sustainable business, a record number of investment projects worth more than 60 million euros were approved in Drug Substance Bioproduction Mengeš, which bring us new development perspectives. In Solids Ljubljana, we established a production line for the first continuous pharmaceutical production in Novartis and a production line for melt extrusion. In Lendava, we successfully launched an alternative method of isolating potassium clavulanate, which improved the production flow time, reduced the

Our associates have received several prestigious Slovenian and international awards for innovation, knowledge and breakthrough solutions.

1 GRI GS 102-14, 103-1

safety risk and created additional savings in materials. Our associates have received several prestigious Slovenian and international awards for innovation, knowledge and breakthrough solutions. Among them was the national recognition from the Chamber of Commerce for innovation for the project of automating analytical processes in the development of biosimilar drugs, the Minařik recognition for merits in the development of the pharmaceutical profession, and the Sandoz and Novartis awards for outstanding scientific achievements.

We successfully fulfilled our mission - we reimagined medicine to improve and extend people's lives. In Slovenia, we produced and packaged 37 innovative medicines and launched 778 new products in more than 80 countries. We introduced a new drug for advanced breast cancer to Slovenian patients and provided the first patient with a breakthrough gene therapy for spinal muscular atrophy. Three new innovative medicines from Novartis, a medicine for the treatment of the wet form of age-related macular degeneration and two for multiple sclerosis, were included in the list of publicly funded medicines.

The successes of the past year were made possible by the high sustainability culture of our colleagues. We achieved the improvement of most of our environmental indicators through numerous projects to optimize operations, reduce the consumption of natural resources and invest in environmental protection, for which we allocated 8 million euros. We thus reduced the total energy consumption by almost one percent. Energy projects saved 40,752 GJ (3.1%) of energy and prevented 3,456 t of CO_{2e} from entering the atmosphere. The newspaper Finance awarded us the energy-efficient company 2021 award.

Our achievements in energy management included the reduction in total greenhouse gas emissions by nearly 8%, also thanks to the larger purchase of green energy at the Ljubljana site. The reduction of generated waste by a good 2%; most notably, we reduced the amount of hazardous waste by as much as 34%, which was influenced by changes in the portfolio and the development of products with high added value that require less solvents, as well as improved energy utilization of waste. The changed portfolio of new products is more energy and water intensive, which is the main reason for the 0.5% higher water consumption. Concern for the efficient use of resources was also at the forefront at the other sites, which reduced water consumption and improved the indicator of the efficiency of its use per ton of product.

Our commitment to good sustainable business practices is long-term.

Our commitment to good sustainable business practices is long-term. We proved it for the fourteenth time in a row by renewing the Responsible Care and the EMAS environmental management system certificates. We once again met the requirements of the environmental standard ISO 14001:2015 and the occupational health and safety management system ISO 45001:2018.

Our efforts for an inclusive and safe working environment as well as the education and well-being of our employees were also confirmed in professional circles, as for the second year in a row we received the prestigious international »Top Employer« certificate for the best employer and were declared the most reputable employer for the third time. We added to these titles with the awards LGBT-friendly company and MEGA inspiration for good practice of intergenerational cooperation in the work environment. Among the important indicators, I should point out that our employees received an average of 83.6 hours of training per year. We improved the LTIR indicator, which indicates the number of injuries with temporary absence from work, by 6%. We attracted 573 new employees to our ranks and ended the year with 5397 employees in Lek and almost 5500 in Novartis in Slovenia.

2021 was also special because of three milestone anniversaries - we celebrated 75 years of Lek, 25 years of Novartis and 15 years of biosimilar drugs. We shared our gratitude for the long-term good cooperation with our partners, local communities, partners in science and patient associations. We financially supported new research projects of Slovenian universities, preventive activities against cancer and improving the health of oncology patients.

I would like to take this opportunity to sincerely thank all my colleagues for all their efforts and the previously mentioned achievements. Together, we will continue to build our shared culture – with innovation, courage, integrity and respect for diversity and inclusion.

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

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

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Website: https://www.lek.si

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

2021 Key data

2021 performance

Key performance figures[4]

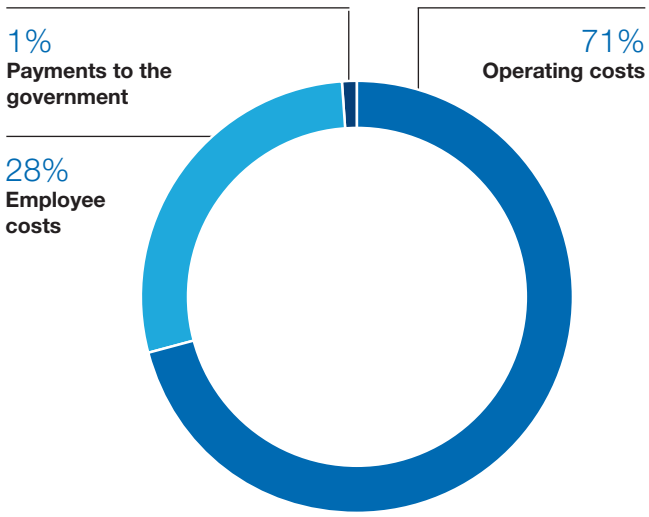
Indicator	Unit	31. 12. 2021	31. 12. 2020	31. 12. 2019	Index 2021/2020
No. of employees		**5,397**	4,823	4,349	112
Ljubljana site		**3,189**	2,755	2,310	116
Mengeš site		**1,268**	1,134	1,118	112
Lendava site		**712**	699	664	102
Prevalje site		**218**	226	248	96
hired warehouses		**10**	9	9	111
Net sales revenue	mil. EUR	**1,270.235**	1,184.431	1,159.954	107
Liabilities to resources	mil. EUR	**1,470.291**	1,231.563	1,286.430	119
Capital	mil. EUR	**1,086.285**	940,771	1,002.339	115

Economic performance[5]

In 2021, Lek created 1,270.235 Euros of net sales revenue, this represents a 7% increase compared to the previous year (1,184.431). Net profit for the accounting period amounted to 147.01 million Euros.

Direct economic value reached 1,229 million Euros (1,223 in 2020), of which 83% (1,078 million Euros) was **economic value distributed**; the largest proportion (71%) representing **Operating Costs**, which reached 761 million Euros. **Employee Costs** were 306 million Euros (28%). **Payments to the Government** amounted to 11 million Euros (1%). **Payments to Providers of Capital** were not made in 2021. We received 35,000 Euros worth of subsidies directly from the state (990,000 in 2020).[6]

Structure of economic value distributed



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5 GRI GS 201-1
6 GRI GS 201-4

Major environmental and social impacts[7]

Indicator	Unit	2021	2020	2019	Index 2021/2020
Energy efficiency*	GJ/mil. EUR	**1,039**	1,122	1,159	93
Water efficiency**	m^3/t	**659**	626	684	105
Amount of waste – efficiency	t waste/ t product	**9.1**	8.9	7.9	102
VOC emissions – efficiency	t VOC/t product	**0.016**	0.022	0.024	70
LTIR- Lost time injury and illness rate***		**0.2**	0.34	0.30	94
TRCR - Total recordable case rate***		**0.32**	0.34	0.32	94

* In previous reports, we showed the indicator of the efficiency of energy use per ton of product, but due to the very diverse product portfolio at the sites, the indicator does not show an adequate comparison between years. In this report, we therefore show the efficiency of the use of energy products in relation to net revenues.

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

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

Performance milestones and highlights in 2021

In Lek, we achieved ambitious goals in 2021, despite the still aggravated situation due to the COVID-19 pandemic. We took important steps in the development and production of medicines and active ingredients, continued digitization and automation of plants, and introduced predictive analytics and virtual technology. At the same time, we continued the transformation towards more developmentally demanding products with higher added value and the establishment of the Novartis Global Operations Center.

Key performance highlights in 2021:

- At production sites in Slovenia, we produced and packaged **37 innovative medicines** and launched **778 new products** in more than 80 countries. Among other things, we presented Slovenian patients with a new drug for advanced breast cancer.
- **Novartis allocated 289 million euros for investments in Slovenia in 2021.** Most of the investments were aimed at strengthening development and production capacities in the direction of greater digitization and automation. At the same time, a record number of investment projects worth more than 60 million euros were approved in Mengeš Biologics. In Solids Ljubljana, we established a production line for the first continuous pharmaceutical production in Novartis and a production line for melt extrusion.
- In Ljubljana we are planning a new investment, supported by state incentives, in the production capacity of aseptics in vials and syringes.
- **We increased the number of employees by 573.** At the end of the year, there were 5,396 full-time employees in Lek and almost 5,500 in Novartis in Slovenia.
- For the second year in a row, we received the **prestigious international Top Employer certificate**, and for the second time in a row and for the third time in total, we received the title of **Most Reputable Employer**. We complemented our efforts in the field of diversity and inclusion with the title **LGBT-friendly** company and the **MEGA inspiration** award for good practice of intergenerational cooperation in the work environment.
- As part of the commemoration of three anniversaries - 75 years of the Lek company, 25 years of Novartis and 15 years of biosimilar drugs - we supported **new research projects of Slovenian universities with funds in the amount of 75,000 euros and allocated an additional 25,000 euros for cancer prevention and improving the health of oncology patients**.
- We introduced and enabled Slovenian patients to be treated with some new and breakthrough medicines:
  - we introduced a new drug for the treatment of advanced breast cancer (Piqray),
  - two more patients in Slovenia received Novartis' breakthrough CAR-T cell therapy for the treatment of severe forms of blood cancer (Kymriah),
  - we sensed a common interest with the AAA company in helping to introduce breakthrough radioligand therapy for patients in Slovenia,
  - the first patient in Slovenia received breakthrough gene therapy for spinal muscular atrophy,
  - three new innovative medicines were added to the list of publicly funded medicines: a medicine for the treatment of the wet form of age-related macular degeneration (Beovu) and two medicines for multiple sclerosis (Mayzent and Kesimpta).
- For the fourteenth time in a row, we renewed the requirements of the **RCI** certificate, regulation EC122/2009 with amendments – **EMAS** environmental management system. We once again met the requirements of the environmental standard **ISO 14001:2015** and the occupational health and safety management system **ISO 45001:2018**.

7 GRI GS 302-3

Novartis' and Lek's 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.

As part of Novartis, we promote sustainable operations through our own activities and through our value chain.

In the area of environmental sustainability, we have adopted a strategy and linked activities in four pillars: planet, patients, people and policies. Lek's management and four environmental sustainability teams are responsible for their planning, implementation and monitoring, i.e. for each individual column.

Areas and environmental sustainability at Lek and Novartis

1 Planet

Our ambition is to be a catalyst for positive change and to play a leading role in environmental sustainability.

Carbon neutrality in our own operations

- Efficient energy use
- Transfer to renewable energy sources
- Sustainable mobility (e-transport)
- Environmental sustainability principles in all contracts with suppliers

Waste and waste water reduction

- Process and recycle waste
- Introduction of new materials and technoligies
- Plastic neutrality

Water use efficency

- Conservation of water supply sources
- Reuse of water

2 Patients

We take care of our patients by providing sustainable products.

- Assess product lifecycles from source to end of life management
- Sustainable developent and production solutions of medicines
- Reduction of use of hazardous substances (green chemistry)
- Sustainable packaging
- Green logistics/ distribution
- Correct sorting of our products' waste

3 People

We live and spread a sustainable culture, which os integrated in our operations.

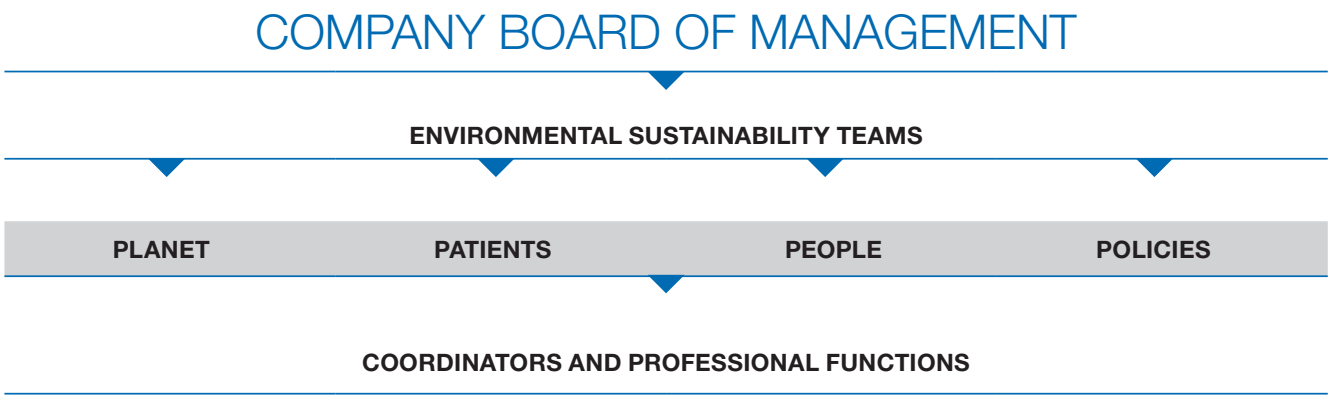
- Training and education of employees
- Internal exchange of good practice (Energy management teams, Green Teams, etc.)
- Encouraging innovations
- Certifications (»My Green Lab«)

4 Policies

We influence the sustainability policies by strenghtening Novartis' voice.

- Inclusion in initiatives and associations both locally and nationally
- Communication (both internally and externally)
- Compliance with environmental laws and international standards
- Reporting (internally and externally)

Environmental sustainability governance at Lek



Novartis Environmental Sustainability targets, 2025 and 2030

		2025	2030
Climate	**CARBON NEUTRALITY**	• Carbon neutral own operations • Environmental criteria in all supplier contracts	• Total carbon footprint neutrality
Waste	**CIRCULAR ECONOMY & PLASTIC NEUTRALITY**	• Eliminate PVC in packaging • Waste disposal reduced by half	• Plastic neutral • All new products meet sustainable design principles
Water	**WATER SUSTAINABILITY**	• Water consumption reduced by half in our operations • No water quality impacts from manufacturing effluents	• Water neutral in all areas • Enhance water quality wherever we operate

Health, safety and environment (HSE) objectives

HSE plans, objectives and programs 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.

We 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.

Common and specific HSE targets are determined by site. The goals are confirmed by the Development Directors of NO-sites, Site Directors, Head of HSE and HSE site representatives. 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 2021 HSE short term targets

Area	Indicator	Target	Status 2021
Health and Safety	Serious injuries and fatalities (SIF)	0	0
	Walkthrough inspections per 200,000 working hours	> 15	41.7
	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0	0
	REEP (Risk-based exposure evaluation process)	100%	100%
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	Mengeš: +0.4% Prevalje: –1.6% Lendava: –0.8% Aseptics Ljubljana: +0.6% Solids Ljubljana: –4%
	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	Mengeš: +3.3% Prevalje: –8.3% Lendava: –0.2% Aseptics Ljubljana: +16% Solids Ljubljana: –9.2%
	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	Mengeš: –38% Prevalje: –17% Lendava: +3% Aseptics Ljubljana: –13% Solids Ljubljana: +4%
Corrective measures	Actions implemented after inspection	100%	100%
	Number of overdue larger or critical actions (CAPA)	0	0

Lek's HSE 2022 targets

Area	Indicator	Target
Health and Safety	Serious injuries and fatalities (SIF)	0
	Walkthrough inspections per 200,000 working hours	>15
	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0
Environment	Decrease energy use	Mengeš ≥4% than 2021 Prevalje ≥2% than 2021 Lendava ≥3% than 2021 Aseptics Ljubljana ≥4% than 2021 Solids Ljubljana ≥4% than 2021
	Decrease water use	Mengeš ≥4% than 2021 Prevalje ≥2% than 2021 Lendava ≥3% than 2021 Aseptics Ljubljana ≥4% than 2021 Solids ≥4% than 2021
	Decrease waste removal	Mengeš ≥4% than 2021 Prevalje ≥2% than 2021 Lendava ≥3% than 2021 Aseptics Ljubljana ≥4% than 2021 Solids Ljubljana ≥4% than 2021
Corrective measures	Actions implemented after inspection	100%
	Number of overdue larger or critical actions (CAPA)	0

Less mistakes, fewer repetitions and lower consumption of natural resources

Jure Vajs, PhD, led the implementation of mixed reality technology at Novartis in Slovenia. In April 2022, he became Head of Strategic Programs, before that he was Alliance Manager at Technical R&D Biologics and Cell & Gene Therapies at Novartis.

Mixed reality technology has become a standard Novartis solution for remote work and remote problem solving, process visualization and knowledge transfer. An important breakthrough in this field is the Vision software, a platform developed in Slovenia that brings the aforementioned technology closer to the user and offers Novartis associates a wide range of usage options.

Simple solutions of complex problems is what fascinates and motivates Jure Vajs, PhD. This motivation combined with the innovative freedom of associates was the driving force behind his team's success story that has transcended the boundaries of Novartis in Slovenia.

You led the implementation of mixed reality technology project into business processes and development of the Vision platform with your colleagues and local external partners. Where did the idea come from?

Innovation in industry must address the current challenges faced by companies. In our case, it was definitely the COVID-19 pandemic. With the implementation of mixed reality technology, we wanted to enable colleagues to collaborate, communicate and work normally in the so-called new realities. We wanted to find a high quality platform that could be quickly integrated into our existing systems and easily upgradable. At the same time, the solution had to be accessible and user friendly, as the implementation of the new technology was difficult due to the need for social distance. Although many solutions based on virtual, augmented or mixed reality technologies were available in the past, they were rarely used due to hardware and software limitations. We identified a solution on the market that could be the basis for the successful use of mixed reality technology in industry. We seized the opportunity, followed our vision and started development.

I definitely want to emphasize that its implementation was a great example of teamwork and proof that with a clear vision and motivation we can achieve our objectives together.

Did you have the support of colleagues and superiors when developing and putting solutions into practice? What was their reaction to your idea?

Novartis creates an environment where experimentation is safe and encouraged; good ideas are supported, financed and finally implemented. As with other successful innovation stories, management played a key role in this case as well.

The use of the technology itself does not require special introduction, associates on average master it in just a few minutes. Its management is intuitive, virtual glasses quickly become the user's additional sense. Associates are using it with great enthusiasm, as they see its wide applicability and potential after the first use.

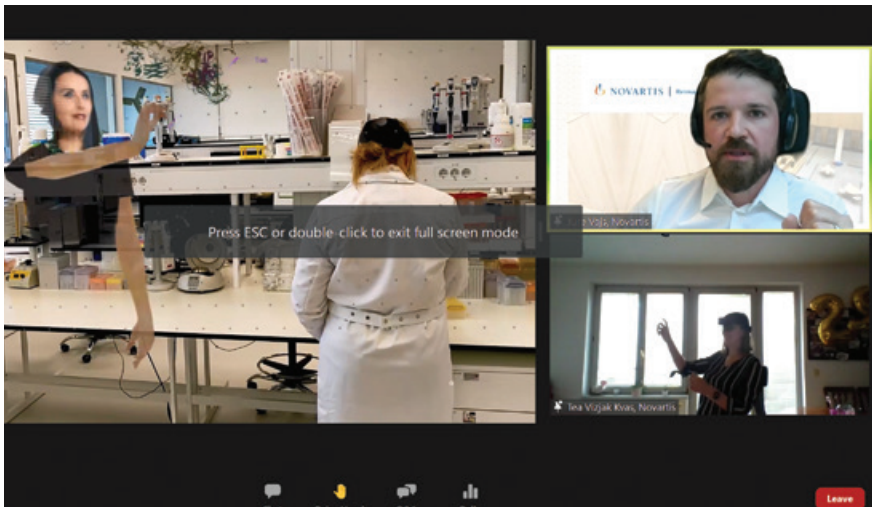
How is mixed reality technology used at Novartis in Slovenia? Is it maybe used somewhere else in Novartis?

Virtual glasses have become part of Novartis' standard solutions and we are proud to have contributed to this. This technology brings many possibilities of use, most of which have not even been explored yet. We are currently using it for remote assistance, problem solving at different sites, and for visualization of processes and complex chemical structures. It is useful for the implementation of various processes, for the dissemination and transfer of knowledge, training of new associates and work processes, where the number of personnel in the room is limited. We use it for internal and external audits, site presentations, supervision of clinical studies... In the future, it will be used at all functions and business segments, from performing tasks in laboratories and at production sites, everyday communication to wider use in HRM and marketing functions.

What opportunities does digital transformation bring to the pharmaceutical industry and sustainable business transformation?

There are certainly many opportunities associated with it. It contributes to the faster and better development and production of medicines that we supply to millions of patients around the world. This improves quality and extends their lives.

Digitization widely opens the door to sustainable business, as we have easily abolished certain processes and successfully moved them to the digital world. At the same time, this means less mistakes, fewer repetitions and, consequently, lower consumption of natural resources. Associates therefore gained time for tasks that bring greater added value. Due to instant connectivity with the entire world, the need for business trips has significantly decreased. Digital transformation also widely opened the possibilities for flexible and remote ways of working, which has a positive effect on our well-being.



The Vision project won the Best of the Best 2021 competition in the Innovation category, organized by AmCham Slovenia. In the photo, Jure Vajs, PhD and his colleague Tea Vizjak Kvas from the Strategic Programs unit.

We need to know when to set boundaries

Nika Anžiček, PhD, project manager in the development of biosimilars drugs in Mengeš and coordinator of the employee well-being program – Energized for Life - at Novartis in Slovenia.

The well-being of Novartis employees in Slovenia is ensured by the Energized for Life initiative, which has gained even more importance due to the physical distance of colleagues during the pandemic.

While studying organic chemistry abroad, Nika Anžiček started looking for ways to work and organize her day more efficiently. What she learned, she is now happy to share with others, including as the coordinator of the employee well-being program – Energized for Life.

What is the Energized for Life initiative and what is your role as coordinator of the initiative?

The initiative includes care for mental, physical and social well-being. It intertwines three areas and thus is a holistic approach to well-being. Activities that we carry out regularly and that the employees are also well aware of are, for example, vaccination against tick-borne meningoencephalitis and influenza, first aid courses, and resuscitation procedures. We prepare active breaks at workplaces, mindfulness exercises and lectures. We offer our employees guided fitness activities and subsidized workouts with external sports providers. This goes hand in hand with the monitoring of general physical fitness, e.g. body composition and stress measurements.

As a coordinator, I make sure that global guidelines are introduced in Slovenia as well. I am the link between the global team at Novartis and the employees who implement the initiative here. On the other hand, I receive feedback on what the employees would like, so that we can adapt the programs as much as possible to their needs.

How did your personal experiences contribute to the decision to participate in the Energized for Life initiative?

During my studies, I had many interests which I didn't seem to have enough time for, so I started looking for ways to work and organize my day more efficiently. I was also happy to read about the topic of health care, which was key to maintaining energy for all activities. I now like to share what I learned by trying it on my own skin with others, because it has

really improved the quality of my life. Novartis' Energized for Life initiative addresses just that, and I joined it for purely personal motivation to increase program awareness and engagement.

What were the biggest challenges of the Energized for Life initiative during the pandemic and what is its direction now in the post-pandemic era?

The biggest challenge of the initiative was the restrictions on the presence of employees in the company's premises, as a large part of the program in the past consisted of live activities. The physical distance between colleagues also brought mental health challenges and the feeling of a weaker connection among employees, who to a large extent only worked from home. By using digital tools, we managed to successfully replace and upgrade some elements of the program, especially in the area of mental well-being. Online activities can have a greater reach, allow viewing of contents in the archive, and we expect that they will be maintained in the future.

In any case, based on the feedback, we are now striving to approach people face to face again, as this approach is also more effective.

With accelerated digitization during the pandemic, new work models have developed, e.g. A responsible choice. Will these models be maintained and what will the role of the Energized for Life initiative be?

I believe that the work models that have proven successful during the pandemic will persist, but perhaps not in exactly the same form. I believe that many people did not feel sufficiently equipped with information and awareness of their own needs, how to recreate an efficient, but still healthy working environment outside the premises of the company, with enough space for rest. It is important that people know how to set boundaries, e.g. when they are reachable and when they are not. This needs to be discussed, also because something that suits me may not suit someone else. And there is absolutely nothing wrong with that.

Over the past two years, we have thoroughly explored these boundaries, and companies can now use feedback to adjust models and guidelines to serve as a long-term competitive advantage and employee satisfaction. With the initiative, we will continue to work so that employees internalize small activities during the day that help introduce movement, mental breaks, help to cope with changes and take care of energy levels. In the company's premises, all this happens already when walking around the site, taking a snack break, chatting with colleagues, almost unconsciously.

Among the five finalists at the award ceremony for the best HR practices 2022 were also two Novartis Slovenia, namely the From Offer to Contract and the Energized for Life initiative. Pictured from left to right: Boris Vukovič, Tina Kogoj and Nika Anžiček.

Breakthrough achievements lead by cooperation and trust

Luka Peternel, PhD, Head of Pharmaceutical Development at Sandoz Development Center Slovenia.

By introducing the cutting-edge technologies in development and production, we bring our patients quicker access to affordable medicines. The breakthrough project, which is based on the production of pharmaceutical forms in a closed isolator mode, was implemented in Development Center Slovenia by Dr. Luka Peternel. For excellence in pharmaceutical production, the project was awarded at the PHARM Connect congress, the largest business meeting of pharmaceutical and biotechnology companies from Central and Eastern Europe.

Your team received a prestigious award for the project »Products for the treatment of oncological diseases – from vision to reality«. What kind of solution is it and what does it bring to Novartis?

The project was extremely demanding from an engineering and technological point of view, but it is entirely the result of Slovenian know-how. When designing new laboratories in which we deal with highly potent substances, we used the most modern technology for the production of pharmaceutical form. The equipment and operation of the technological processes were previously simulated in a 3D environment, thereby ensuring more

efficient installation of the equipment. We have additionally implemented laboratories for automated dissolution and sample preparation, which ensures a higher level of safety in handling active substances and also faster processing times. We entered the development of generic oncology drugs, thereby strengthening our market presence and increasing the availability of drugs to patients worldwide.

Conceptually, the project was created when I took the position of Head of Pharmaceutical Development, so I would like to take this opportunity to once again thank everyone who contributed.

What is the role of the introduction of cutting-edge technologies in the development and production of medicines today and how do you see it in the future?

We can move a lot if we are able to transfer solutions and technologies from other industries to our work environment. With this, we can achieve multiplicative effects. The development and production of generic drugs require a lot of professional skills, pharmaceutical, chemical and technological. Scientific and technical excellence are a basis that can be built on with the help of other skills. A good example is the various approaches of data science, where the key is to build on sound foundations, from capturing to structuring and analyzing data. In Lek, we have several examples of good practices that have contributed to development and optimization breakthroughs.

How do you help or enable your colleagues to develop their potential?

By developing new generic drugs, we provide access to affordable products whose quality and effectiveness are comparable to those of the originator. The entire development process offers employees extraordinary opportunities to acquire new professional knowledge and business skills. This applies precisely to everyone involved in it. It is the duty of managers to help colleagues open doors, enable their professional and personal growth, and at the same time reward success. The key elements as Head of Pharmaceutical Development are both the development of colleagues and the development of new generic products. Of course, no role is isolated, but is embedded in a wider process and connected to the team. At the same time, this means that in the development and production of products many different roles are interconnected and each one contributes its share. I believe that the key to success is excellent mutual cooperation and trust. A prerequisite for this is, of course, an inclusive work environment that offers opportunities to those with different opinions. With this, we create space for new ideas, solutions and improvements.

The award at the PHARM Connect congress was accepted by the Head of Pharmaceutical Development, Luka Peternel, PhD (in the photo in the middle).

The priority is in the prevention of waste

Mojca Potočnik, person responsible for the environment in Lek and David Holobar, Expert for occupational health and safety.

Waste represents a major environmental problem on a global level; Novartis Slovenia tackles this issue systematically. We have set bold goals to reduce our impacts. Mojca Potočnik and David Holobar from the Health, Safety and Environment Department explained how we approach waste management and what we do in this area.

What are the priorities for waste management? Have they changed in recent years?

First and foremost we are taking into account Novartis' environmental strategy to achieve plastic neutrality by 2030, Slovenian legislation and good global practices. Priorities for managing waste have not changed. The most important are waste prevention, reuse, recycling, energy or second processing and as a last option, disposal. In recent years, we have put a lot of effort into preventing the generation of waste and its reuse. At the same time, we divert waste from independent incineration into energy processing, which produces electricity, steam and hot water. This

is how we reduce the use of natural resources, natural gas and others.

What measures are you putting in place to achieve Novartis' bold goals? How do you promote circular economy projects among employees?

We would once again emphasize the first step, which is of fundamental importance, i.e. the prevention of waste generation from the very development of medicines. After that, we try to reuse the raw materials, whenever possible. A good example, which is also presented in more detail in this report, is the reuse of plastic and metal barrels. With this process, we simultaneously prevent the creation of waste and reduce purchasing costs. We are also constantly increasing the regeneration of waste solvents, returning packaging to suppliers for their reuse and thereby promoting a circular economy.

As much as 81% of our waste is biodegradable, most of which is waste mycelia. Our colleagues in Austria process it into organic fertilizer. We are studying the possibility of reducing the amount of this waste, especially by using it as an energy substrate.

Many suggestions for improvements and reduction of waste are contributed by our colleagues. So-called »Green Teams« are established at the sites, in which environmental volunteers meet and pass on various proposals. We also get these through the Th!nk Novartis initiative, aimed at suggesting improvements to colleagues.

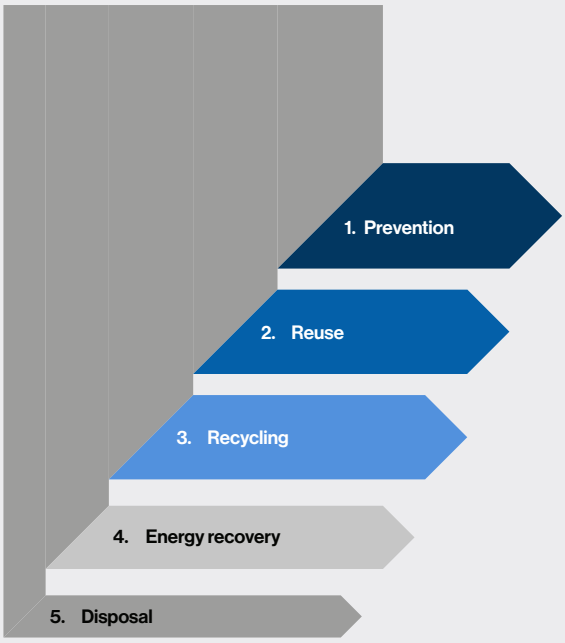
A regulation defining the manufacturer's extended responsibility for packaging came into force. In this system, what is Lek obliged to do when dealing with packaging and waste packaging?

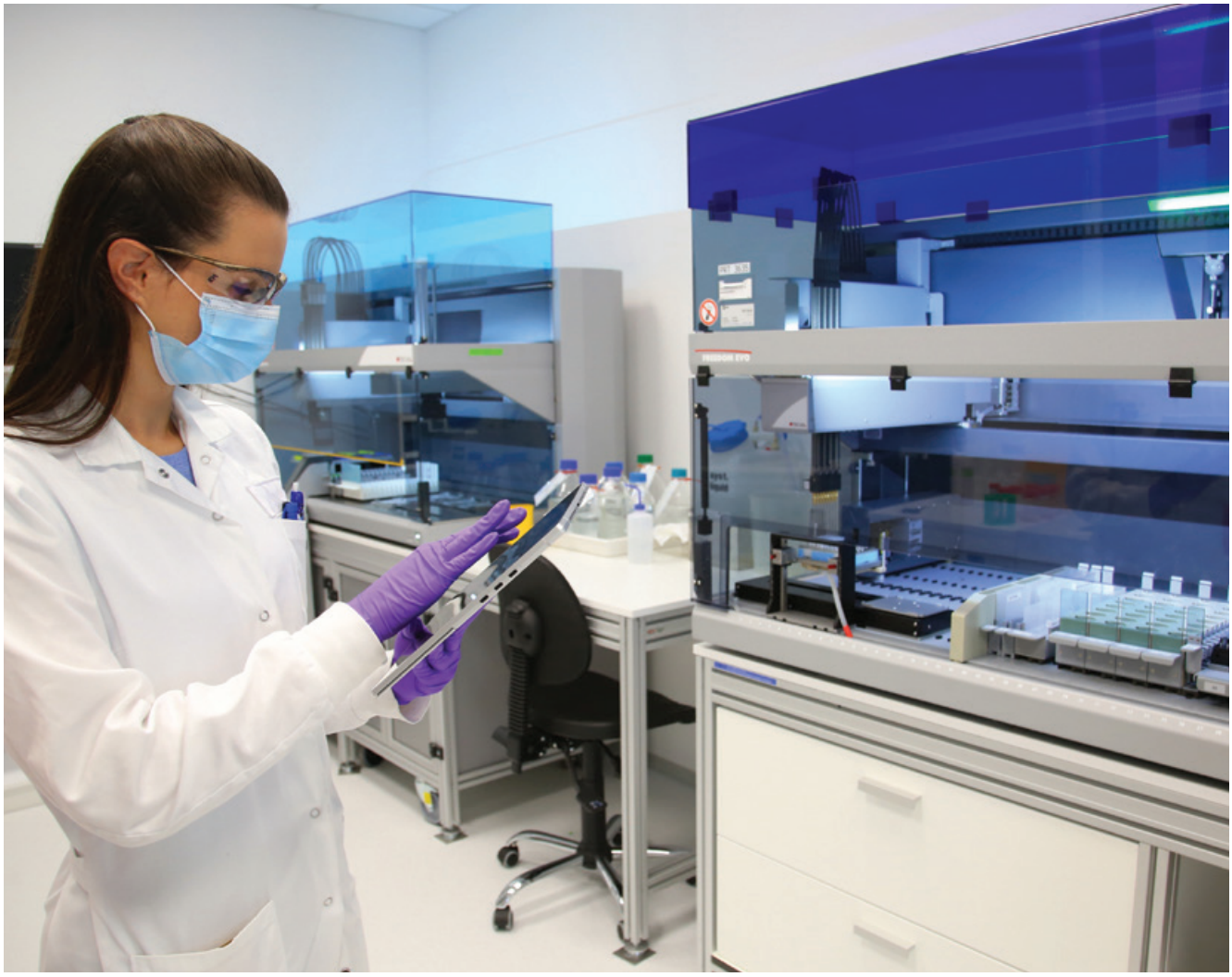
The central purpose of the concept, which is also called PRO, is to relieve the environment of waste. As a manufacturer that puts a product on the market, we are responsible for its collection and processing when it becomes waste. Therefore, when the user throws away the packaging of our product, we bear the cost of its recycling or disposal. We ensure this through a scheme that we finance; we collect and process packaging and waste medicines, document the fulfillment of these obligations, and their organization and control.

You are also introducing digital solutions in controlling waste management. What are the solutions and how do they contribute?

We track waste according to Novartis' internal requirements and ensure its proper disposal. In 2021, we started developing an internal application for waste management, which will replace thousands of documents that we fill out in paper form every year. This will save a lot of time, increase the transparency of documentation and reduce the consumption of office paper.

Waste management hierarchy





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. 2021, Lek had 100% ownership share in Sandoz Pharmaceuticals d.d. and 74.5% ownership share in Wastewater treatment plant Lendava d.o.o. In 2021, there were no changes to the size, structure or ownership of Lek, moreover no merging activities or joint investments were made.

8 GRI GS 102-5

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 and behavior

Our values and behaviors support culture and enable us to achieve our mission. We encourage all employees to be inspiring, curious and empowered while acting ethically.

Build trust with society – Novartis' social responsibility strategy

Building trust with society is a key pillar of the Novartis corporate strategy and is critical to delivering on our purpose of reimagining medicine to improve and extend people's lives. It defines our approach to managing our key environmental, social and governance (ESG) topics and risks: being part of the solution on pricing and access, addressing global health challenges, being a responsible citizen, and holding ourselves to high ethical standards. Our ESG efforts are fully integrated across the company and are key to driving long-term value for our stakeholders.

A leader in access to medicines and global health

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.

High ethical standards

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.

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.

Key customers and markets[9]

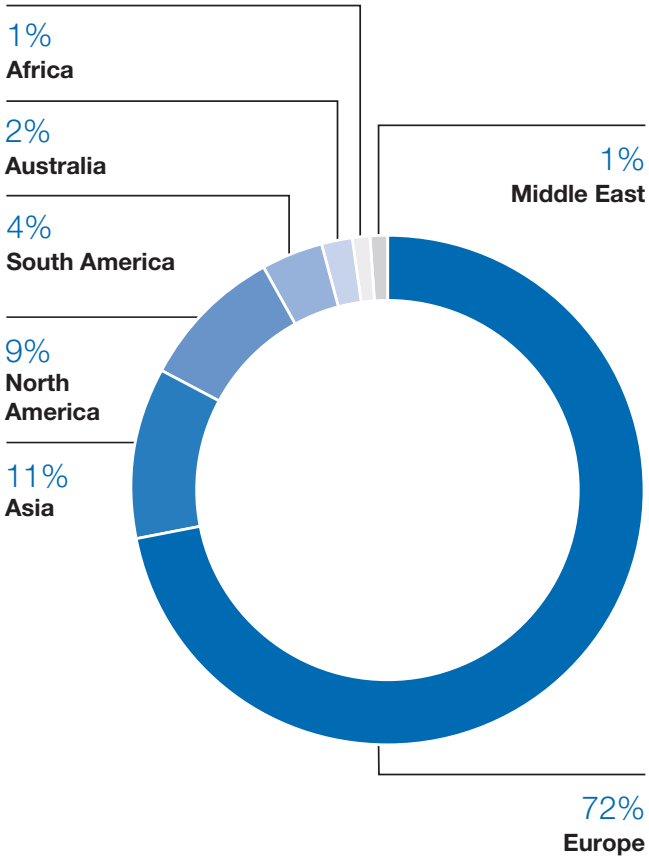
In accordance with organizational and strategic orientations, Sandoz Group and Novartis companies are the key buyers of our products and active pharmaceutical ingredients. In addition to our own products we also sell Sandow and Novartis products.

The majority of our products in 2021, 88.5%, were sold to foreign markets (Europe 72%, Asia 11%, North America 9%, South America 4%, Africa 1% and the Middle East 1%), Slovenia accounted for 11.5%. The majority of sales, 88.5%, came from pharmaceutical products, the remaining 11.5% came from APIs and biopharmaceutical products.

In the Slovenian pharmaceutical market, Novartis, with all its divisions, remains the leading provider of medicines with a 12.4% market share. Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 74% of sales. Lek is in first place on the market of over-the-counter medicines, second in the sale of generic medicines.

In 2021, the total value of the Slovenian pharmaceutical market was 907 million EUR, and a 5.9% market share makes Lek the third largest pharmaceutical company. On the generic market, where the total value is 187 million Euros, Lek has a 28.4% market share. The biosimilar market amounted to 13.5 million EUR, with Lek having a market share of 44.4%. In the market of over-the-counter medicines (worth 104 million EUR), Lek recorded 3.2% growth.

Lek product markets by geographical region



Major product groups and brands[10]

Our key therapeutic groups are:

- cardiovascular drugs,
- anti-infectives,
- gastrointestinal drugs,
- drugs for the treatment of the urogenital tract,
- 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,
- oncological,
- 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.

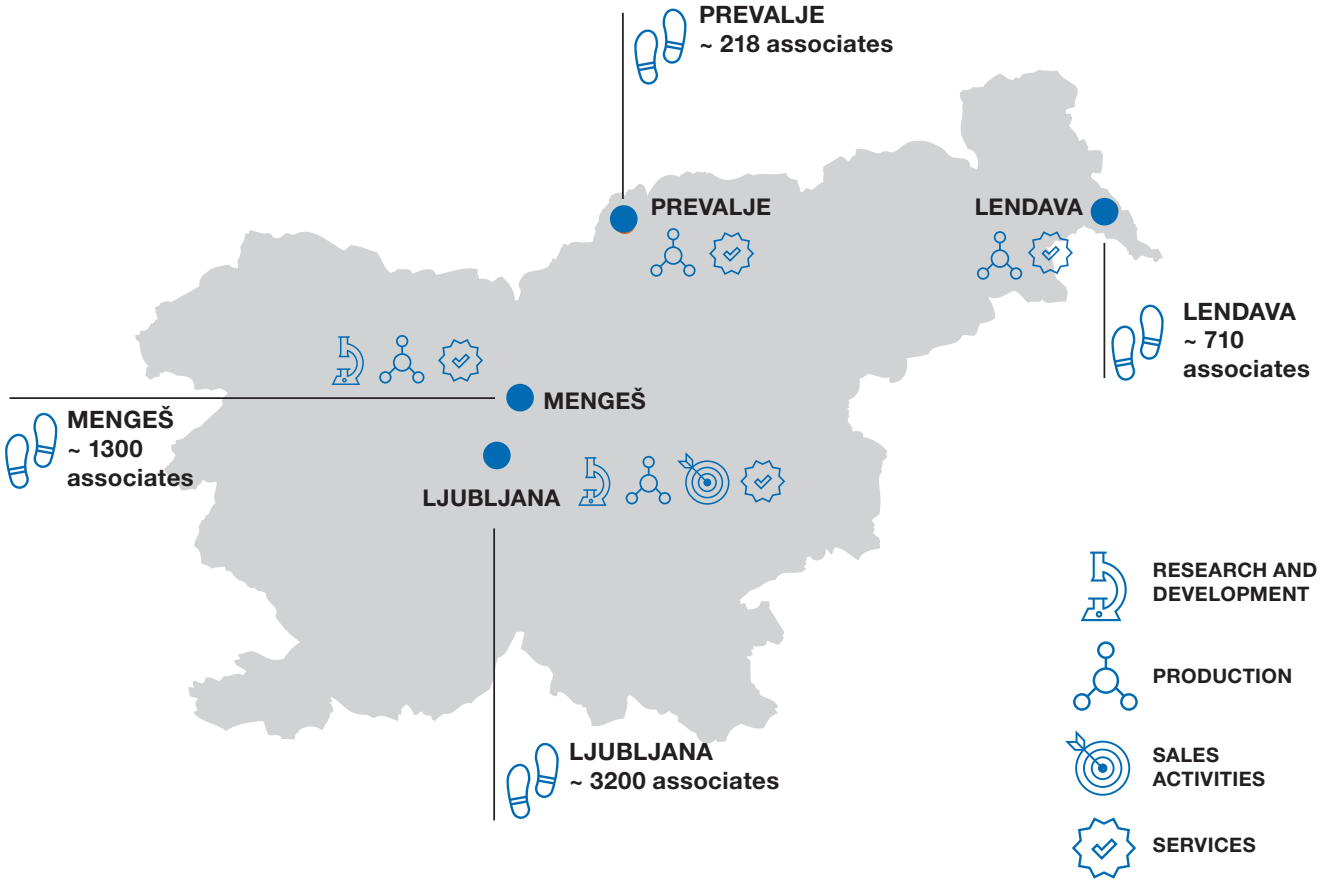
In 2021, Lek's leading prescription medicines on the Slovenian market were Amoksiklav® (amoxicillin with clavulanic acid), Iroprem® (a trivalent iron drug) and Coupet® (rosuvastatin). The best-selling biosimilar was Rixathon (rituximab).

Amongst the leading over-the-counter brands we achieved the highest sales with Lekadol, Linex, Lekadol plus C , Linex , Operil and Exoderil. We also offered a new antibacterial medicine Exoter.

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

Development and production sites and processes[11]

Novartis – the largest medication provider to Slovenian patients and healthcare



Novartis in Slovenia – operations

Research and development

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

Production

- Sandoz technical operations
- Small molecules
- Large molecules

Sales activities

- Sale of generics Slovenia
- Sale of innovative medicine Slovenia

Services

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

11 GRI GS 102-4, 102-10

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, communication and external engagement, 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.

Daniela Zaccara,
Head Solids Ljubljana

Tjaša Bantan Polak,
Head Aseptics Ljubljana

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.

2021 was still strongly marked by the pandemic, but we nevertheless continued to transform our product portfolio, introduce new and innovative approaches, ensure uninterrupted care for our patients and again reach record values in production.

We started full commercial production of two innovative drugs, Galvus and Entresto, which also includes innovative analytical approaches such as NIR to measure the uniformity of the composition of Entresto. At the same time, with the introduction of the packaging of many new oncological innovative medicines, the volume of packaging of innovative medicines increased dramatically (27% increase in orders compared to 2020). Generic medicines also remain an important part of our production, where we introduced several new generic products in previous years.

Production and packaging growth was also followed by record investments in new equipment and technology. Thus, we introduced a number of improvements to increase the capacity of bottle packaging lines, introduced sophisticated innovative technology with an automated product defect detection process, and continued to invest in melting extrusion technology.

The year was also successful in the field of compliance and high quality assurance, as we completed all inspections and other inspections positively and received the NOSSCE Class A certificate for the second time.

Aseptics Ljubljana

Aseptics Ljubljana also enjoyed record production in 2021. In the production of vial products, we exceeded the 2020 quantities. Due to the pandemic, the production of nasal products decreased in the first half of the year, and in the second half of the year it again reached full capacity. For ampoules, we ensured stable production, which was comparable in size to the previous year. The highest growth was achieved in products intended for the American market, where Pantoprazole stood out.

We successfully introduced new products into production and focused on the development of two new biological drugs and a demanding generic sterile product. We launched two new, very complex products on the market, which we developed in cooperation with the Development Center Slovenia. In the middle of the year, we launched Ferumoxytol on the American market, and Sugamadex on the Croatian market.

We started introducing a new nasal product, and with the transfer of vial packaging from the Swiss Stein plant to Ljubljana, we started investing in a new line for vial packaging. In the coming years, we will also start packing innovative medicines in vials in Ljubljana. The first one was transferred to the Aseptic Products packaging plant at the end of 2021.

We successfully conducted internal audits and audits of regulatory authorities and potential customers. Improvements were also made throughout the supply chain, where we obtained the NOSSCE Class A certificate.

Matjaž Tršek,
Head Development Center Slovenia

Roman Pogačar,
Head Chemical Operations Mengeš

Polonca Kuhar, Head Drug
Substance Bioproduction Mengeš

Development center Slovenia

The Development Center Slovenia develops technologically demanding products and is the leading development service center in Sandoz for generic medicines. At the end of 2021, half of all global Sandoz development projects took place here; oncology drugs, drugs for the treatment of cardiovascular diseases, drugs for the treatment of diabetes, allergic rhinitis, migraines, insomnia, anemia, urological and gastric diseases, as well as non-steroidal anti-inflammatory drugs predominate.

In 2021, we achieved a 25% increase in the number of dossiers filed, which is a reflection of the constant investment in digitization, operational excellence, staff and new know-how. We have successfully implemented projects for the transformation of cooperation with key external partners, the introduction *in silico* of development methods and data science, the automation of laboratory work and the modernization of key digital platforms. Initiatives in the areas of operational excellence and digitalisation have contributed to cost reductions and added value of 3 million euros. We also paid a lot of attention to the personal and professional development of our employees, about a third of whom are doctors of science.

Our scientists, who are involved in international development teams and work closely with the Slovenian academic sphere, have once again received a number of awards for outstanding scientific achievements.

Mengeš site

Chemical Operations Mengeš

We successfully completed 2021 at Chemical Operations Mengeš, where we produce high-quality and technologically demanding active ingredients for various therapeutic areas. Although the pandemic affected the supply of materials and the presence of employees, we ensured uninterrupted operation of our lines and produced all the planned quantities. We produced more than 2,500 series or more than 200 tonnes of active pharmaceutical ingredients. With the preparation of the complex generic active ingredient ferumoxytol, we supported the key Sandoz launch in the USA, and in the second half of the year we started to transfer the complex active ingredient FCM.

We increased the production of innovative and selected complex generic active ingredients and started the transfer of new innovative active ingredients for various therapeutic groups. In the coming years, we will continue such transfers, which will further increase the occupancy of our production lines, ensure the long-term competitiveness of Novartis products and support the further development of the site. We also supported the introduction of new products with several investment projects.

Successfully completed operational excellence projects also made an important contribution to the good results. In the autumn, we received the NOSSCE Class A certification for the second time, which is reflected in the excellent care of our customers, who received the ordered products in full and within the agreed deadlines.

Drug Substance Bioproduction Mengeš

In Drug Substance bioproduction Mengeš we produce active ingredients for biological and biosimilar medicines. In 2021, we celebrated the 15th anniversary of biosimilar drugs and produced the 200th jubilee batch of erythropoietin (Binocrit). The production and yields of our other biosimilar agent,

Špela Jalen, Head Biologics Technical Development Mengeš

Saša Sankovič, Head Anti-infectives Prevalje and Lendava

Simon Rečnik, PhD, Head Solids Lendava

pegylated filgrastim (Ziextenzo), were also record-breaking.

We expanded our production capacity in our new high-tech plant, which produces a number of innovative biological active ingredients and biosimilar active ingredients developed in Mengeš and Basel. We transferred seven new molecules from Biologics Technical Development Mengeš and successfully produced eleven series of innovative biological active ingredients for clinical studies intended for the treatment of various forms of cancer, diabetes, lung diseases and dermatitis.

We obtained a record number of approved new projects worth more than 60 million euros. Thus, we will build a plant for the production of viral vectors, expand the capacity of the plant for the production of new biological drugs, increase the capacity of the plant for the production of erythropoietin and build new laboratories for Production Science and Technology. Here we will develop, study and improve new technologies and processes before transfer to production. At the same time, we are digitizing and automating all our plants, and introducing PAT (Process Analytical Technology) and virtual technologies. We concluded 2021 with the extremely successful Novartis General Assessment of Good Manufacturing Practice (GMP).

Biologics Technical Development Mengeš

Last year, the Biologics Technical Development Mengeš site carried out work in various development phases of similar (biosimilars) and innovative biological medicines. We completed the internal transformation at a global level, which brought us significant advantages in portfolio management and synergies and competitive advantage brought by the agile global development organization.

We continued to optimize processes through automation and digitization, which significantly contributes to shorter timelines for the development of similar and innovative biologics. In addition to the growth in the volume of work, the number of employees also grew, which increased by 10% compared to the previous year. In doing so, we are constantly developing and strengthening the culture of diversity and inclusion and innovation, introducing new ways of working, improving mutual cooperation and taking care of the well-being of our employees through various initiatives and activities.

Prevalje site

At the Prevalje site, where we produce the broad-spectrum antibiotic Amoxiclav, we operated smoothly and provided a regular supply of medicines to patients at home and around the world. In accordance with Novartis' strategic guidelines, we continued to transform the role of the site, which is expected to become part of the newly established GOC in Slovenia from the production site by the third quarter of 2023. We conducted training for our employees, as well as the transfer of more than 80 employees to GOC or other sites in Slovenia.

We adjusted the production volume to the dynamics of demand and thus produced more than 450 million tablets, more than 7 million packages of suspensions, 340 tons of mixtures and 150,000 packages of veterinary powder. We have dedicated a large part of our activities to ensuring safety for patients and employees. Through numerous audits, we have reaffirmed that we ensure the highest quality standards that enable us to produce safe, effective and quality medicines.

Lendava site

Anti-infectives Lendava

We produce two active ingredients at the site: potassium clavulanate and gentamicin sulfate. The production of the first, which is also the site's leading product, was 3% higher than planned, and the volume realization was the highest in our history. The results exceeded expectations both in terms of the productivity of microorganisms and the yields in the purification phases of the active substance.

In 2021, we introduced the production of mixtures of potassium clavulanate with the inert substance Avicel or Syloid, which we expect additional growth in the coming years.
We successfully launched and optimized an alternative method of potassium clavulanate isolation by eliminating three stages, which improved production throughput time, reduced safety risk, and created additional material savings.

The production of gentamicin sulfate, which is also produced in smaller quantities, took place on a smaller scale, as the global demand for this product was reduced due to COVID-19.

In the protection of health and the environment, as well as in the field of quality and good practices, we confirmed a high level and achieved or exceeded the set goals in all indicators.

Solids Lendava

At Solids Lendava, we have taken important steps in increasing efficiency, automation, digitization and innovation. This will ensure higher competitiveness and operational excellence of the plant in the coming years, and take on even greater responsibilities and a key role within the NO. Namely, we are the largest plant for packaging solid pharmaceutical products with more than 4,000 finished product codes and one of the key suppliers of Sandoz's portfolio.

In 2021, we supplied patients in more than 150 markets worldwide with 160 million packages on 25 packaging lines, of which as many as 11 million packages were new products. We achieved growth in the packaging of innovative medicines and supplied the markets with more than 20 million packages or 1.2 billion tablets and capsules in 660 finished products.

We reduced the flow time from the start of packaging to the release of the drug on the market by more than 30% and reduced the occupancy of the externally rented warehouse with finished products by more than 70%. Major projects included the introduction of a new automated and fully integrated Tacrolimus packaging line in blisters and sachets. We also achieved breakthrough results in the security of supply of medicines, which was reflected in several indicators of customer supply and with 45% shorter delivery times for innovative medicines.

Solids Lendava, together with other organizational units that directly support us, employs more than 550 employees. At the end of last year, we renewed the NOSSCE Class A certification, thus confirming our position in the group as the most reliable drug suppliers in Novartis.

Development and Reporting Framework

The sustainability report shows the progress of our company in relation to the set strategy and the impacts we have in the economic, environmental and social fields. 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 Guidelines. At the same time, we show in which areas we contribute to the realization Sustainable Development Goals and the Global Compact of the United Nations, which is evident in the GRI index.[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.

Reporting characteristics for 2021[15]

For Lek's reporting we use the GRI international sustainability reporting standards (Global Standards), achieving the basic level (Core). Within the framework of the Chemical Industry Association, we report according to Responsible Care Initiative (RCI) requirements. At the same time, we follow the requirements of Annex IV of Regulation (EC) no. 1221/2009 with amendments (EMAS), where the prescribed indicators are disclosed at the level of Lek and for all four locations.

- Reporting refers to Lek and all its manufacturing sites in Slovenia and is prepared annually. All disclosures in the present report refer to the 2021 calendar year. It also includes the EMAS environmental statement, which we are supplementing with significant changes.
- 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 (MRSP), Slovenian legislation and is published in the Slovenian Business Register.
- The objective of Lek's HSE reporting is compliant with Novartis' and Sandoz' objectives to provide a fair and well-balanced picture of HSE. The system of monitoring HSE achievements and the reporting methodology are described on page 89.
- The content structure of the Sustainability Report is comparable to similar annual reports of Novartis.
- In 2021, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures.

Sustainability Reporting Framework at Lek

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

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 2021, the members of the Board of Management were as follows:

- **Robert Ljoljo**, President
- **Ksenija Butenko Černe**, Member – Legal Affairs
- **Andreja Bucik Primožič**, Member - Finance (from 1. 12. 2021)
- **Ivan Ďurovčík**, Member – Finance (until 31. 8. 2021)
- **Andrej Pardo**, Member – Commercial Operations
- **Uroš Urleb**, Member – Research and Development
- **Raul Intriago Lombeida**, Member – Technical Operations
- **Marjan Novak**, Member – Workers' Director

The Board of Management runs the company, independently, on its own responsibility and manages the statutes of the company and Lek management handbook. 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). In 2021, the Board of Management discussed topics within its competences at 13 regular and 19 correspondence sessions.

The individual members of the Board of Management are obligated to provide the President 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 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 2021, the members of the Supervisory Board were as follows:

- **Rebekka Guntern Flückiger**, Chairman (until 12. 6. 2021)
- **Matthias Weber**, Chairman (from 12. 6. 2021)
- **Ingrid Sollerer**, Vice Chairman
- **Nastik Amit Kumar**, Member
- **Peter Svete**, Member – Workers' Representative
- **Fikret Bašanović**, Member – Workers' Representative (until 21. 12. 2021)
- **Manda Firm**, Member - Workers' Representative (from 21. 12. 2021)

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 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.

Supervisory Board members form part of their job-related obligations as they are also employed in Lek or other companies of the Novartis Group. The members of the Supervisory Board do not receive any payment or other rewards for their work. Appointment of the members of

16 GRI GS 102-18

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 2021, the Supervisory Board held 1 regular and 3 correspondence sessions.

Diversity in management and supervisory bodies
We create an inspiring, curious and empowered culture in the company, based on integrity and the creation of a diverse, safe and inclusive work environment. We respect the diversity of employees, patients and other stakeholders. The company encourages diversity in the gender of representatives in both management and supervisory bodies, which is written in the annual targets of the Diversity and Inclusion Initiative. The company has no independently adopted policies that would further regulate the diversity of representation in these bodies in the light of the other personal circumstances of members of these bodies.

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 Works 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 Works 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 Works Council meetings and respond to questions and initiatives of the employees and the Works Council.

In 2021, the Works 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 Works Council. 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 participated in changes to the regulation on the reimbursement of work-related expenses (reimbursement of food expenses, transportation expenses and remote work expenses), the rules of procedure on the organization of Lek d.d., the regulations on working hours and the Responsible choice work model. They carried out a change of the manual on the work of the Lek d.d. Works Council, which made it possible to hold electronic elections. They also harmonized the number of members of the Works Council by constituency. The number of members of the Council is determined by law based on the number of employees. The new Works Council is composed of 21 members.

In 2021, the Works Council successfully organized and conducted first electronic elections for the members of Works Council. Due to the epidemic, most of the activities were carried out virtually.

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.).

The more important activities of the Works Council in 2021:

- weekly meetings of the Works 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 related to the transformation of the Lek Prevalje location
- preparation of an application for conducting electronic elections for members of the Works Council.

17 GRI GS 103-1

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 Employers of Slovenia
- 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 Pharmacopeia 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

Access to medicines

Improving access to medicines remains one of the world's greatest health challenges. Affordable treatment is therefore one of Novartis' key strategic areas, which we directly include in our core business - the discovery, development and marketing of innovative medicines. In doing so, we contribute to Novartis' vision.

2021 Highlights

≥ 10

projects for the development of biosimilar medicines were supported by us in 2021. We also successfully transferred knowledge and capabilities to a new field in cell and gene therapies.

29

dossiers for generic drugs. We completed development and filed 29 generic drug dossiers in key markets and launched 13 generic drugs.

478

ideas for introducing changes and optimizing processes were submitted by employees, of which 314 were approved for implementation. The approved ideas resulted in 3.78 million euros in directly calculated savings.

300

experts from natural sciences and other fields attended the 6th Novartis career breakfast, and in six years already more than 550 experts.

Innovativeness

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.

Through innovative medicines and the development and production of generic medicines, we strive to find new ways to treat diseases, earlier intervention in chronic diseases and improve the quality of life of patients. Our research and development (R&D) programs help millions of people around the world living with cancer, heart disease, neurological conditions, immune system disorders, and a host of other diseases. 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. We strive to develop new know-how in cooperation with external and academic partners (open innovation).

Achievements in drug development

2021 was extremely successful for **Biologics Technical Development Mengeš**, as we implemented and confirmed in practice the advantages of the new development paradigm for the parallel development of several biosimilar medicines. Thus, we completed the first part of the development for three biosimilar molecules simultaneously, and in total we supported more than ten projects for the development of biosimilar drugs. We also obtained projects of the early stage of development of innovative biological drugs and the first project has already been transferred to the production scale for the first clinical studies

In addition, we successfully transferred know-how and capabilities to a completely new field, cell and gene therapies, where state-of-the-art technology supported associates from the cell and gene therapy development unit in Austria.

Development Center Slovenia specializes in the development of technologically demanding products and is the leading development service center in Sandoz for generic medicines. At the end of 2021, half of all Sandoz global development projects took place here. Oncological drugs, drugs for the treatment of cardiovascular diseases, drugs for the treatment of diabetes, allergic rhinitis, migraines, insomnia, anemia, urological and gastric diseases, as well as non-steroidal anti-inflammatory drugs predominated.

Continuous investment in digitization, operational excellence, human resources and new know-how has contributed to a more than 25% increase in the number of dossiers filed in 2021 compared to the previous year. We completed the development and filed 29 dossiers for generic drugs in key US, European, Russian, Japanese, Brazilian, Australian, Mexican, and Thai markets, and launched 13 generic drugs to treat anemia, cancer, cardiovascular disease, fungal disease, and pulmonary fibrosis.

We also made an important contribution to two Sandoz launches; the first generic company to launch a complex non-biological drug for the treatment of anemia, Ferumoxytol, entered the US market. It was also the first generic company to launch the Sugammadex solution for injection on the European market, which is used to eliminate the effects of muscle relaxants after surgery.

Facilitating mass inventive culture

TH!NK Novartis 2021

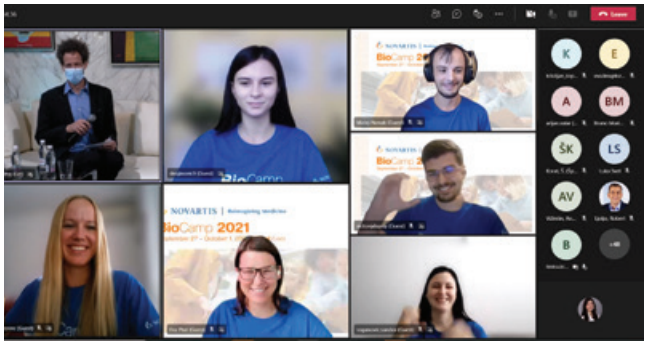
We support mass innovations with the **Th!Nk Novartis** web application, through which employees actively participate in introducing changes and improving work processes. In 2021, our employees submitted **478 ideas**, of which **314 were approved for implementation**; ideas were submitted by 271 different promoters. The approved ideas brought a total of 378 million euros in directly calculated savings. From the introduction of the application in 2012 to 2021, employees have contributed a total of 7,673 ideas, 3,937 of which were implemented, which resulted in a total saving of 60.9 million euros. Special awards were given to employees who contributed and introduced the most innovative ideas and solutions in practice: **TOP Th!Nk Unit, TOP Th!Nk Team** and **TOP Th!nk submitter**.

Pharma Data Science Hack

In cooperation with Axiologo, we successfully implemented the first **Pharma Data Science Hack**. At the competition, experienced data scientists solved various data challenges that we face at Novartis in Slovenia. Five data scientists competed, and the winning team consisted of Guillaume Azarias from France and Parag Mehta from India, who successfully solved the challenge from the production of solids. Such collaborations stem from Novartis' focus on development and innovation and networking with talented professionals from a variety of fields.

Novartis' career breakfast

The **6th Novartis Career Breakfast**, this time held as an online event, attracted 300 experts from the natural sciences and other fields. Representatives of Novartis units in Slovenia offered them an insight into the operations of



Winning team from 11th BioCamp

the pharmaceutical industry on twelve thematic stages and presented the available career opportunities in one of the leading pharmaceutical companies in the world. Novartis' career breakfast, an innovative approach to finding top staff, has so far successfully attracted 21 Slovenian experts, and in six years, more than 550 experts have attended Novartis' career breakfast.

11th BioCamp

The **11th BioCamp** took place, which encouraged promising students of natural sciences, economics and engineering from the region to connect with renowned experts and leading managers and offer them a unique insight into the pharmaceutical industry. The event was attended by 36 students from ten countries. The central topic of the forum was the impact of data and artificial intelligence on the pharmaceutical industry.

Novartis' Researchers Day

Once again, with **Novartis Researchers' Day**, we participated in the UNI.MINDS event, organized by the Knowledge Transfer Office of the University of Ljubljana. The event featured six interesting presentations on data and digital and automation and biology. We exchanged experiences on how collaboration with academia is transforming drug development. Based on the presented collaborations with various faculties, we are excited about the future, where many interesting projects await us in both industry and academia.

Open Innovation 2021

Throughout the year, we prepared various events, such as the **Digital Summer School with the EIT** (European Institute of Innovation and Technology), where we offered two challenges for which students from different faculties sought solutions. The first was related to the mixed reality that is changing the way the industry operates. In the second challenge, students explored what will define successful work in the future and what will be the retraining and overqualification of the workforce. We also organized a hackathon on the topic of **Augmented/ Mixed Reality in Healthcare**, where 32 competitors, divided into ten groups, looked for solutions on how and where mixed reality could be used in healthcare.

Awards for Innovations

Silver from Chamber of Commerce and Industry of Slovenia for Innovation

At the Innovation Day, organized by the Chamber of Commerce and Industry of Slovenia, Lek, which is part of Novartis, received a silver national award for innovation, namely for the project of automation of analytical processes in the development of biosimilar drugs. The award-winning innovation introduces new technologies and artificial intelligence into the development of biosimilars and enables the analysis of a larger number of samples in a shorter time. The award is a recognition of our efforts in the innovation ecosystem, culture of innovation and continuous learning, thus creating breakthrough solutions, increasing the availability of medicines and improving people's lives.

Tilen Vidmar, PhD, accepted the silver award for innovation on behalf of the team.

AmCham

The project of introducing mixed reality technology at the **Vision** Novartis workplace in Slovenia won in the Innovation category and was one of the super finalists of the Best of the Best 2021 project. The award is given by AmCham Slovenia and addresses the best business practices that bring innovation, motivation and connection with growth and progress in the Slovenian business community.

Prometheus of Science

We received the **Prometheus of Science Award** for excellence in communication science for the first virtual Novartis hackathon in Slovenia, which was prepared under the auspices of the European Institute of Innovation and Technology (EIT Health) together with the Ljubljana University Incubator. The awarded interdisciplinary team consisted of three Novartis associates in Slovenia, **Miha Homar**, PhD, research expert, **Leon Rižner**, researcher, and **Iva Pilko**, human resources specialist, as well as **Jakob Gajšek**, director of the Ljubljana University Incubator. At the hackathon, we brought together more than 40 experts from different faculties, who trained and demonstrated their know-how in two different professional topics. Participating experts from various fields of science participated in two challenges, namely in predicting the bioavailability of the active ingredient and its structure of physicochemical

properties and in the challenge of augmented reality and data visualization in pharmaceutical technology.

Minařik award 2021

Research expert from the Development Center of Slovenia Miha Homar, PhD, received the **Minařik Award 2021**, awarded by the Slovenian Pharmaceutical Society. He has earned recognition for his long and outstanding merits in the development of pharmacy, for his dedicated development work, connection and transfer of knowledge between industry and the university, and for all-round active cooperation with the association.

Miha Homar, PhD,
recipient of the 2021 Minařik Award.

Institute of Chemistry awards

Lek received an award from the Institute of Chemistry for good cooperation in research work. The award is given to the external partners of the Institute of Chemistry, who have excelled in joint projects in the field of research, education, acquisition of research equipment, promotion of the Institute of Chemistry and the transfer of research results to industry.

Novartis' Science Awards

Slovenian employees of the Development Center Slovenia received three awards, including the highest Novartis award for a distinguished scientist. Novartis Science Awards recognize those individuals and teams who have excelled in their work and made an important contribution to R&D in the company. The highest recognition for a distinguished scientist was received by **Igor Legen**, PhD, Head of Clinical Development, the awards for eminent scientists were also received by **Marija Bošković Ribarski**, PhD, leading researcher in Clinical Development, and **Dušan Teslić**, PhD, Head of Particle Design and Synthesis.

Recipients of the 2021 Novartis Science Awards.
From left to right: Dušan Teslić, PhD, Marija Bošković Ribarski, PhD, and Igor Legen, PhD.

Sandoz science awards

Scientists from Development Center Slovenia and the Biologics Technical Development Mengeš received eight Sandoz scientific awards, including awards for **scientific excellence**. Every year, Sandoz awards the best researchers with many years of outstanding achievements in research and development. This time, both awards for scientific excellence were received by our colleagues, namely **Matjaž Bončina** from the Biologics Technical Development Mengeš and **Katja Berginc** from the Development Center Slovenia. Researchers and research teams of the Development Center Slovenia and the Biologics Technical Development Mengeš also received awards for innovative breakthroughs in analytics and technology, for digital achievements, for a demanding application for marketing authorization, for an outstanding clinical study and for a young promising researcher.

Star awards

Every year, the Star awards are given to outstanding individuals and teams who reflect our fundamental values and who stood out with their work, attitude and behavior in the previous year. In the renewed concept of awards, the winners were directly selected for the first time by their colleagues via online voting. The theme of this selection was Resilience in uncertain times. Despite the uncertainty and adaptation to the new reality, Novartis employees in Slovenia worked well and successfully, especially in the spirit of cooperation and connection.

Stakeholder overview and inclusion[20]

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 and other stakeholders.

Achieving our strategic orientations – caring for patients' health and improving access to healthcare – requires a high level of trust, which we are constantly building with our key stakeholders. In accordance with Novartis corporate responsibility policies, are focused on five key groups of stakeholders:

- patients
- employees,
- shareholders,
- healthcare partners (healthcare professionals, regulators, professional associations, buyers, suppliers)
- 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) to assure satisfaction and understanding of employees' positions.

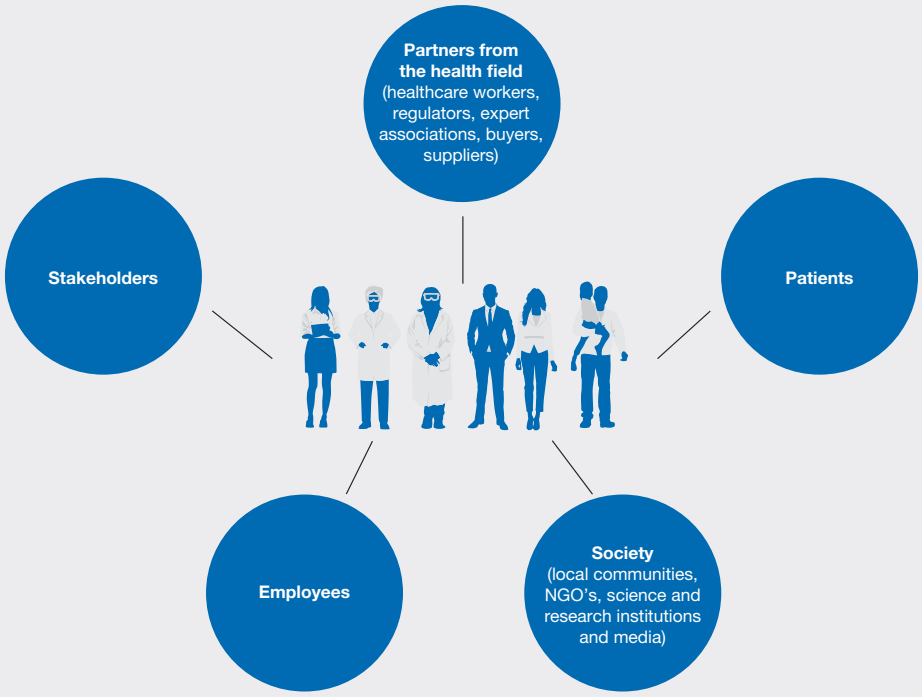
We identify the expectations and experiences of suppliers as much as possible in joint meetings and efforts for further improvements in accordance with the Novartis Code of Conduct for third parties, which are described in section *Purchasing system and purchasing policy*.

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.

Lek's key stakeholders

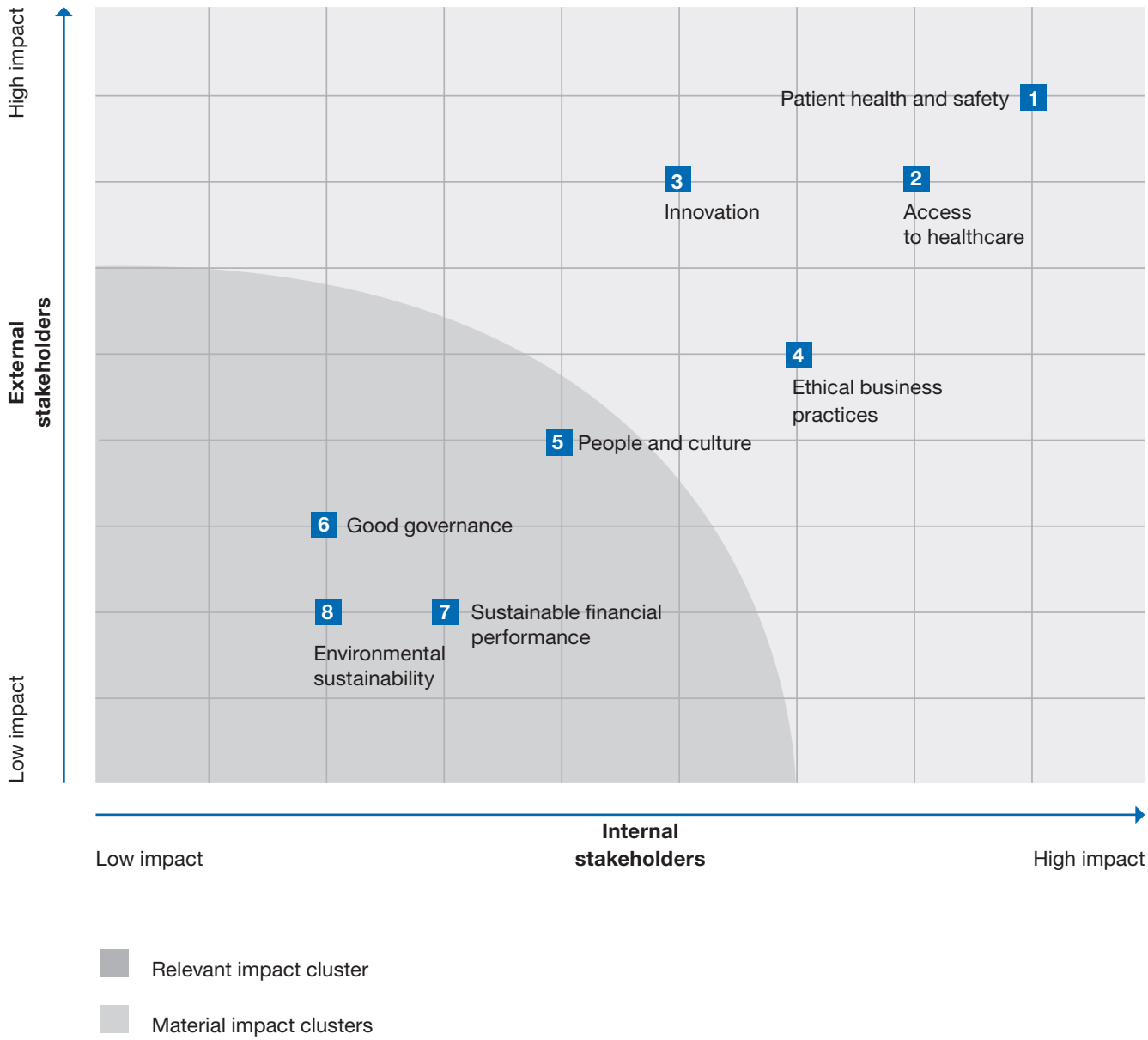


20 GRI GS 102-40, 102-42, 102-43

Novartis' key areas of social responsibility

Every four years, Novartis conducts a detailed assessment of the materiality of the identified topics that are most relevant to stakeholders and most relevant to creating value for them. The materiality analysis guides Novartis' and Lek's strategy and the scope of reporting on ESG topics. The last evaluation was conducted in 2021 and was based on a survey with more than 500 external stakeholders and 12,000 internal stakeholders and 140 interviews. Stakeholders were asked to classify Novartis' influence into eight groups. The results can be seen from the graph below. Patient Safety, Accessibility of Treatment, Innovation and Ethical Business Practices were again ranked high. Although environmental sustainability has been ranked lower than other strands, it remains an essential part of Novartis 'strategy and business model.

Ranking of impact clusters



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

Cooperation with local communities

Returning to society and supporting the community are important values that we place in our business through various projects and philanthropic activities. Through constructive and constant dialogue, we create and maintain long-term positive relationships with the population in local communities, which we have nurtured for more than seven decades. Knowledge of the activities and arrangement of our sites and information in the field of health, safety and the environment are of central importance for the trust of the inhabitants of neighboring settlements, so we organize open days, which were not held this time due to the situation with COVID-19. We establish socially responsible partnerships, organize Open Days, Community Partnership Days, organize meetings and events with patient groups.

Cooperation with academia

To increase the accessibility of treatment, we cooperate with the Slovenian academic environment and successfully transfer findings into the production of quality, safe and effective pharmaceutical products. In celebration of the 75th anniversary of Lek, in 2021 we allocated 75,000 euros to the University of Ljubljana, the University of Maribor and the University of Primorska for the development and implementation of new research projects created in cooperation with interdisciplinary teams of Novartis experts and scientists.

Cooperation with patient groups

With the Commitment to Patients and Carers, which we signed in 2018, we are committed to taking into account the views and needs of patients for more effective treatment and earlier detection of diseases. Thus, in 2021, we further strengthened partnerships with groups of patients and, through joint activities, contributed to raising public awareness of the knowledge and prevention of individual diseases and the development of modern technologies. We contributed to this with expert advice on our websites, cooperation with patient groups and free information materials in pharmacies and healthcare institutions.

Corporate volunteering

Our corporate volunteering work was again focused primarily on mitigating the effects of COVID-19. We came to the aid of socially vulnerable families from 16 primary schools from Mengeš, Prevalje, Lendava, Ljubljana, Domžale, Naklo, Kranj, Koper and Trebnje and donated 142 computers with all the necessary software. With our help, more than 40 children from socially disadvantaged families spent a carefree ten-day holiday by the sea as part of the Wink at the Sun program. Also, 60 blind and partially sighted people tasted the beauty of our mountains within the Mountaineering Association of Slovenia, more than 11,000 seniors received help within the project Seniors for Seniors. Therapeutic dogs Tačke

On the picture from left: Borut Pahor, President of the Republic of Slovenia, Robert Ljoljo, President of the Management Board of Lek and Novartis Country President, Prof. Zdravko Kačič, PhD, Rector of the University of Maribor, Prof. Klavdija Kutnar, PhD, Rector of the University of Primorska and Prof. Gregor Majdič, PhD, Rector of the University of Ljubljana.

pomagačke and their guides, with our help, performed more than 1,500 volunteer hours, dedicated to the helpless and in need of therapy, and many children and families found a safe haven in the Small House in Pilštanj.

Mechanisms for resolving 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 2021, we received only one warning from our waste disposal contractor. In one of the plastic packaging waste receptacles in Ljubljana, there was garbage that belongs in mixed municipal waste. We will therefore continue to inform employees about the correct separation of waste.

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

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 that meet regulatory requirements. We ensure patient safety by timely identification, management and reporting of risks associated with products.

All contact with employees and patients 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 2021 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 2021.[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 2021, 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 2021 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 of branded self-treatment products.

22 GRI GS 103-1, 103-2, 103-3, GS 413-1
23 GRI GS 103-1, 103-2, 103-3, 403-7, 417-1
24 GRI GS 417-2
25 GRI GS 417-3
26 GRI GS 102-43, 102-44

Responsible business

Our values are based on a culture of business integrity and ethical behavior in all parts of our organization. The Code of Ethics provides a framework to support colleagues in making the right decisions. It defines who we are and what we believe in, and defines the key areas of our operations for which we are responsible.

2021 Highlights

≈ 100%

all employees successfully completed e-training on ethics, risks and compliance in 2021.

23

commitments define the Code of Ethics and thus regulates the key areas of our responsible operation.

719

mil. USD total procurement value in 2021. Of this, 396 million USD was direct and 323 million USD was indirect procurement.

40.7%

share of the total purchase value of Slovenian suppliers. By amount, Slovenian suppliers represented 55% of all our suppliers.

Ethics, business compliance and human rights[27]

In addition to business success, the way we achieve our results is important, so we have zero tolerance to any form of inappropriate behavior. The **Code of Ethics** defines who we are, what we believe in, and sets out the areas for which we are responsible. 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 continued Novartis' initiative to promote open communication and reporting of misconduct. We have an established system of anonymous reporting of inappropriate behavior and we are spreading the so-called »speak up« culture, which also enables the addressing of ethical issues. We are also constantly raising the awareness of our employees. In our operations, we are guided by **Novartis' human rights guidelines** https://www.novartis.com/sites/novartis_com/files/novartis-human-rights-commitment-statement.pdf.

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.

As part of the **Diversity and Inclusion** initiative, we promote the diversity and individuality of our employees, as we firmly believe that we must provide everyone with such an environment in which they 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.

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. Only in this way can we continue to build an inclusive work environment. The **»Novartis Women's Inclusion Initiative«** also makes an important contribution to this.

A diverse and inclusive work environment

We create a culture based on integrity and a diverse, safe and inclusive work environment in which all employees feel accepted.

The area of diversity and inclusion, for which we received the Novartis Global Drug Development Culture Award, covers four pillars – Disabilities, LGBTQI+ Community, Intergenerational Collaboration and Diverse Talents. We organized Enable training for our colleagues, where they learned about **disability**. We have inspected all our buildings and gathered information on how they are accessible for people with disabilities.

We received the LGBT-friendly certificate awarded by the Municipality of Ljubljana, which confirms our work in the field of **LGBTQI+**. During Pride month, we raised a rainbow flag at all four locations as a sign of support.

In 2021, we tackled **intergenerational cooperation** strategically and comprehensively. We held a round table with older and younger colleagues and prepared several intergenerational collaboration workshops and a motivational video with the experiences of employees of different ages and from all locations.

During Pride Month, we raised rainbow flags at all four locations in Slovenia.

27 GS 103-1, 103-2, 102-16

We pay a lot of attention to education on ethics, risks and compliance. We organize 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 in 2021, and they continue to be topics in training new Lek employees.[28]

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 2021, 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

Cooperation with external contractors

Purchasing system and policy[31]

Lek Purchasing, which is a separate organizational unit within Novartis operations (NO), is responsible for the procurement of direct and indirect materials and services. Employees are committed to the procedures defined in Novartis guidelines, international agreements and local regulations at all stages of the procurement process. We have precisely defined roles and responsibilities. The Procurement Director is fully responsible for implementing and following guidelines, legislation and internal procedures for procurement processes. Among the key principles of Novartis' global purchasing policy is green procurement, which is consistent with the sustainability strategy and is based on the three pillars: climate, waste, water.

We constantly improve partnerships with service centers and thus optimize expenditures in all purchasing categories (direct and indirect). The purchasing department incorporated the »Buying Engine« application to further rationalize indirect procurement and improve user experience.

In 2021, the total purchase value increased slightly and amounted to 719 million USD (715 million in 2020). Of this, 323 million USD were indirect and 396 million USD were direct purchases. Our largest direct procurement markets remain Slovenia, Switzerland, Germany, China and India. Slovenia, Germany, the USA, Austria and Italy were the largest markets for indirect purchases.

31 GRI GS 102-9, 102-10

Supplier audit procedure[32]

Supplier audit is based on quality standards and Novartis guidelines. We have established uniform criteria that include prices, quality, delivery time, reliability, compliance with regulatory regulations and Novartis guidelines, innovation and the supplier's socially responsible attitude. The entire audit process and the criteria for the selection of suppliers are properly systematically documented.

We are committed to working with partners who operate in accordance with Novartis' and our principles, values and standards. With the Third Party Risk Management Guidelines (TPRM Guideline) and the **Third Party Code of Conduct**, we have implemented a single risk management framework designed to ensure consistency, compliance and greater transparency. This framework makes it easier to identify third-party exposures, thereby effectively managing risks and protecting ourselves and our stakeholders from negative impacts on the company's reputation and preventing potential financial damage.

In order to achieve Novartis' ambitious environmental goals, we also expect help and support from third parties with whom we cooperate. 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 is consistent with the principles of the pharmaceutical industry for managing a responsible supply chain related to ethical values, employee rights, health and safety, the environment, animal welfare, anti-corruption and fair competition, privacy and data protection, responsible use of minerals, quality assurance, problem reporting and appropriate management systems.

Adherence to the standards in the Third Party Code of Conduct is one of the evaluation criteria in Novartis' third party selection and evaluation processes. Preference is given to contractors with the same social and environmental values.

Through mutually constructive cooperation with third parties, we strive for additional improvements. This may include reviews, monitoring of development changes and progress of corrective action plans, third party referrals to outside experts, and other reasonable improvement plans.

We continuously monitor the performance of suppliers, thereby evaluating and monitoring their performance and identifying opportunities for improvement (credit rating, costs, quality, delivery, innovation and customer support).

Policy and practices for selecting local suppliers[33]

In 2021, the share of Slovenian based suppliers amounted to 293 million USD or 40.7% of total purchasing value. In terms of number, Slovenian suppliers represented as much as 55% of all our suppliers.

In direct purchasing by country, Slovenia accounts for a 16.5% share (65 million USD) and 70.3% share (65 million USD) in purchasing value. In indirect purchasing 70.3% (227 million USD).

70.3%

of direct purchasing and 16.5% of indirect purchasing amounted Slovenian suppliers.

32 GRI GS 103-1, 103-2, 103-3, GS 308-2, 414-2
33 GRI GS 103-1, 103-2, 103-3, GS 204-1

Environment

We promote environmental sustainability through our own operations, as well as through the operations of our suppliers. In doing so, we have set ambitious goals to reduce our impacts on the climate, waste and water. In 2021, we committed to becoming climate neutral by 2040.

2021 Highlights

– 0.7%

less energy consumption and improved energy efficiency by 7% in 2021.

– 7.9%

less greenhouse gas emissions (scope 1 and 2) in 2021, compared to the base year (2016) by 8.5%.

– 2.2%

less waste in 2021, and 34% less hazardous waste.

+ 0.5%

increased consumption of water in 2021 due to increased intensive production.

Health, Safety and Environment (HSE) policy[34]

The Health, Safety and Environment (HSE) policy is closely connected with the business strategy; its key focuses are integrated into all our activities and are at the center of our decisions. It defines the fundamental principles and management rules in this area and outlines approaches to reducing risks and impacts in the field. It contains a basic expectation for all employees and is the foundation on which we establish the internal HSE guidelines. In 2021, we passed the HSE Manual, which came into force in 2022.

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).

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 improving

By continuously improving business and production processes, we improve HSE efficiency 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 of 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 our 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

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

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 audited by an external auditor.

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

Compliance with HSE legislation 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.

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

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

New legal and other requirements are promptly and efficiently transferred into our work processes and practices. Authorized persons for HSE actively monitor and identify them, keep records of all relevant legislative requirements in the HSE Register 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 providing the provision of measures from the established conformity assessments.

In 2021, we had nine inspections, of which five were in the environmental field and four in the field of occupational health and safety (implementation of measures to prevent the spread of COVID-19). Environmental inspections were carried out at all sites, and legislative compliance was reviewed for the renewal of EMAS registration. No non-conformities were found during the inspections.[37]

At the same time, in 2021, we were also involved in inspections to check the quality of operations and products, namely in the field of health checks and waste management.

We regularly obtain environmental permits for all our projects and 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. Licences 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 (IPPC) for the Lendava site, Permit No. 35407-172/2006, dated 15 April 2010.
- Decision amending the environmental permit for the Lendava site, No. 35407-37/2011-33, dated 12 July 2012.

35 GRI GS 103-1, 103-2
36 See glossary on page 97
37 GRI GS 307-1

- Decision amending the environmental permit for the Lendava site, No. 35406-33/2012-4, dated 15 March 2013.
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2014-8, dated 23 January 2015.
- Decision amending the environmental permit for the Lendava site, No. 35406-39/2015-10, dated 27 January 2016.
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2016-7, dated 8 June 2017.
- 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 (IPPC) for the Mengeš site, Permit No. 35407-171/2006, dated 14 April 2010.
- Decision amending the environmental permit for Mengeš site, No. 35407-22/2010, dated 28 March 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.
- 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.
- Decision amending environmental permit for emissions into water and air for the Ljubljana site, No. 35440-14/2021-6, dated 28 August 2021.
- Decision amending environmental permit for emissions into water and air for the Ljubljana site, No. 35440-40/2022-2550-11, dated 13 September 2022.
- Environmental permit with regard emissions into water and air for the Prevalje site, permit no. 35444-36/2016-12, dated 21 March 2017.
- Environmental permit with regard emissions into water and air for the Prevalje site, No. 35440-29/2021-5, dated 30 September 2021.
- 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, 35483-53/2020 dated 21 December 2020 (Mengeš).

Active environmental policy implementation

The environmental aspects are already taken into account when business decisions are made, 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 direct 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 2021, we were not charged with any penalties or non-monetary fines for non-compliance with environmental laws.[38]

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 (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.

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.

Environmental protection investments and achievements[39]

When building or renovating production facilities, we always take into account environmental issues, especially by ensuring environmental compliance with emissions and energy-efficient implementation of technological systems. In doing so, we incorporate the best available technologies – both in existing and new productions. Environmental investments also include the renovation of roofs, facades and sewage systems. In 2021, we allocated 8 million euros for environmental projects. We report more on important projects in the field of environmental protection in 2021 in the chapters *Improvements in energy efficiency* and *Efficient water use*.

Verification of established standards[40]

HSE is an integral element of our HSE policies and Novartis' strategic direction, therefore we constantly ensure that we comply with all HSE legal regulations and requirements of international standards.

We voluntarily implement the Responsible Care Initiative (RCI); we again certified the environmental management system according to the ISO 14001: 2015 standard. The Occupational Health and Safety System ISO 45001:2018. 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 2022 that data and information in the Lek d.d. Sustainability Report 2021 gives a reliable, credible and accurate picture of all organization's 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 2021 (JAZMP, FDA, suppliers, etc.).

38 GRI GS 307-1
39 GRI GS 103-2
40 GRI GS 103-2

Key projects

Anti-explosive protection – ATEX

All stages of production processes at all sites where potentially explosive atmospheres are present 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 requirements for adequate implementation of explosion protection before the start of operation of new Ex-equipment. 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.

LOTO – LockOut/TagOut

Employees receive regular LOTO training. As part of the LOTO activities, we also focused on walkthroughs 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.

Indirect environmental impacts[41]

Indirect environmental impacts can be categorized as transport and distribution, which arise 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.

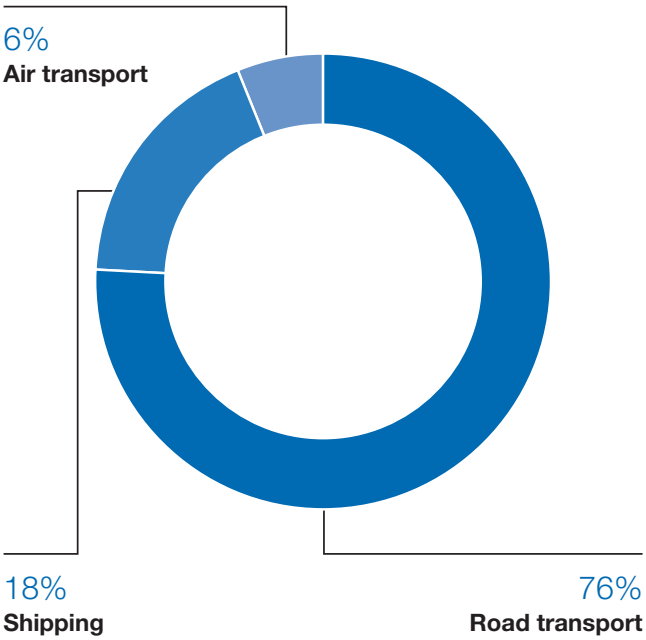
The agreement constitutes the supplier's guarantee to comply with all applicable HSE laws and regulations. Non-compliance with these standards is considered to be a material breach of the contract, which gives us the right to withdraw from the contract. Read more in *Cooperation with contractors*.

Transport in the urban environment is recognized as the key source of air pollution, mostly due to solid particles (PM particles). 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.

Environmental impacts in the distribution of goods are limited by replacing air transport with sea transport, as ship transport has a lower emission factor than other types of transport (ship 10-40 g/tkm, road 60-150 g/tkm, air transport 500 g/tkm; Source: Lufthansa Air cargo).

In 2021, we sent 9,487 shipments of products to customers from Lek's sites and dislocated warehouses, which is 3.2% less than in 2020, when there were 9,803 shipments. By gross weight, we had 76% road, 18% ship and 6% air shipments.

Shipments by means of transport



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.

41 GRI GS 305-1, 308-2

A total of 179 company cars were in use in 2021 (175 in 2020). A total traveling distance of 4,428,614km (4,284,362 in 2020) was recorded, with fuel consumption of 208,895 liters (199,917 in 2020). In addition to company cars, we had 17 other vehicles (fire engines, forklifts). Together all vehicles released 594 tons of CO_2 emissions (570t in 2020).

Raw materials and natural resources

Mass flow of materials[42]

In the production of medicines, we strive for the most efficient use of raw materials to preserve natural resources to the greatest extent possible. Due to changes in the composition and volume of production of pharmaceutical active ingredients, annual fluctuations in the mass flow of materials occur in some places. In 2021, we reduced the use of raw materials by a good 3%. The use of raw materials decreased at all sites, with the exception of Lendava, which increased use by 5% due to increased production.

Annual mass flow of different materials used* in t[43]

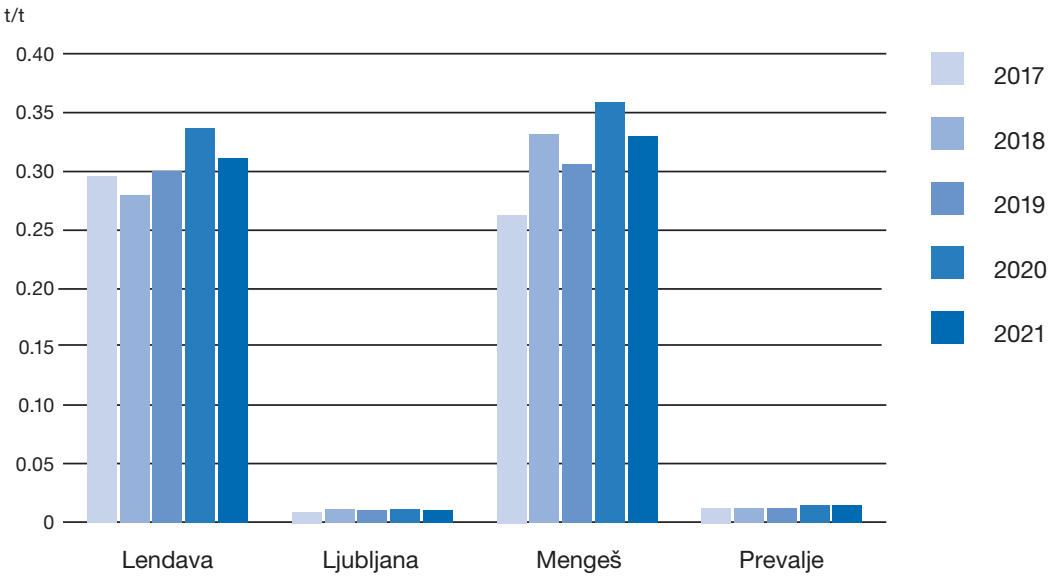
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2017	t	8,740	3,379	13,043	1,879	**27,041**
2018	t	8,549	3,324	14,253	1,998	**28,125**
2019	t	8,910	3,097	15,225	1,814	**29,046**
2020	t	10,044	3,378	11,227	1,925	**26,574**
2021	**t**	**10,579**	**2,787**	**10,461**	**1,835**	**25,662**

*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 equipment)

Efficiency of materials

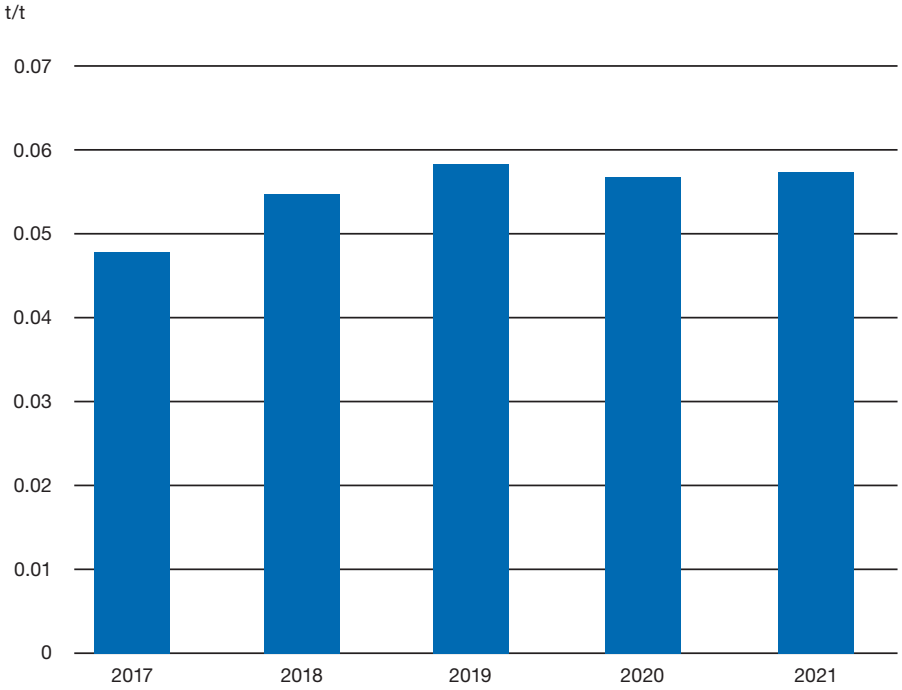
The efficiency of the use of raw materials is given by the indicator of the consumption of raw materials per product unit. As can be seen from the two graphs below, in 2021 the efficiency of raw materials used per ton of active substance or product produced improved at the Ljubljana (by 12%), Mengeš (by 8%), Lendava (by 7%) sites, but the efficiency was slightly lower in Prevalje (by 3%). At the level of Lek, the efficiency was similar to the previous year.

Efficiency of different materials used per product unit 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 raw materials per product unit – Lek in total



Sustainable packaging approach

In accordance with our objectives for the sustainable design of products and processes, we systematically include environmental aspects of sustainability in the planning of new and optimization of existing medicinal agents, devices and also in the handling of packaging.

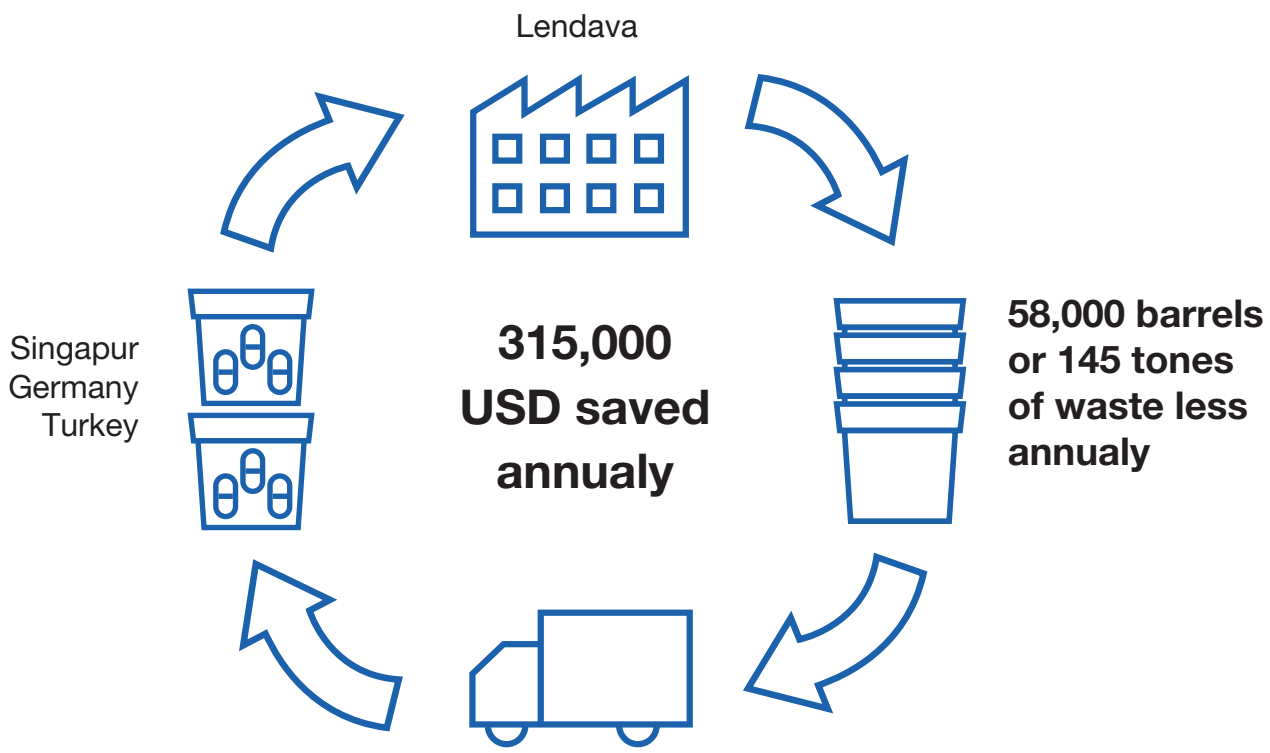
Lek's environmental sustainability efforts also include the use of packaging that must be made from as natural materials as possible and designed efficiently. It must meet relevant market criteria, meet product and consumer requirements and be affordable. It must be environmentally friendly throughout 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 a 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 2021, Lendava continued to return used plastic and metal barrels to Novartis sites in Singapore, Germany and Turkey. With this, we redirected 145t of packaging, which would otherwise become waste, to reuse.

Lendava replaced pre-printed gold cover foils with silver foil for online printing for Neoral products. Thus we standardized the primary packaging, reduced occupancy in the warehouse and saved on the purchase of material, and created savings in energy, water and emissions into the atmosphere throughout the supply chain.

Savings made by reusing plastic and metal barrels



Savings made by changing gold pre-printed cover films to silver

Supplier savings

–7% less energy used
–1% less water used

Lendava site savings

133,000 USD savings in purchased material
1.4 tones less weight of material
300 pallets less delivered to warehouse

Total savings accross whole supply chain

44 t CO_2 emissions reduced

Energy

Energy consumption

In 2021, our total energy consumption was 0.73% or 9,761 GJ lower than in the previous year. To improve energy efficiency, we prepared and implemented a large number of projects at all four sites. This led us to save a total of 40,752 GJ (3.1%) of energy and prevented 3,456 t of CO_{2e} from entering the atmosphere.

The multi-year review of energy consumption and carbon dioxide emissions is monitored with the starting year of 2016. Compared to the energy starting point, the total energy consumption thus increased slightly (by 0.87%), and the consumption of purchased energy (excluding solvents) was, despite the growth in production, mostly locations decreased by 2.48%. We are also gradually reducing CO_2 emissions, which in 2021 represented an 8.54% lower burden on the environment compared to the baseline year of 2016.

Compared to 2020, total energy consumption was reduced at the Prevalje (by 1.60%), Ljubljana (by 1.5%) and Lendava (by 0.8%) sites. In Mengeš, energy consumption increased slightly (by 0.40%), which can be attributed to the trend of producing more energy-intensive products.

Compared to the base year of 2016, we reduced total energy consumption at the Prevalje (by 15%), Ljubljana (by 6%) and Mengeš (by 2%) sites. In Lendava, the total energy consumption increased by 14% during this period, mainly due to the specifics of the technological process where the production of pharmaceutical active ingredients takes place, which, in contrast to the other sites, is very high in volume.

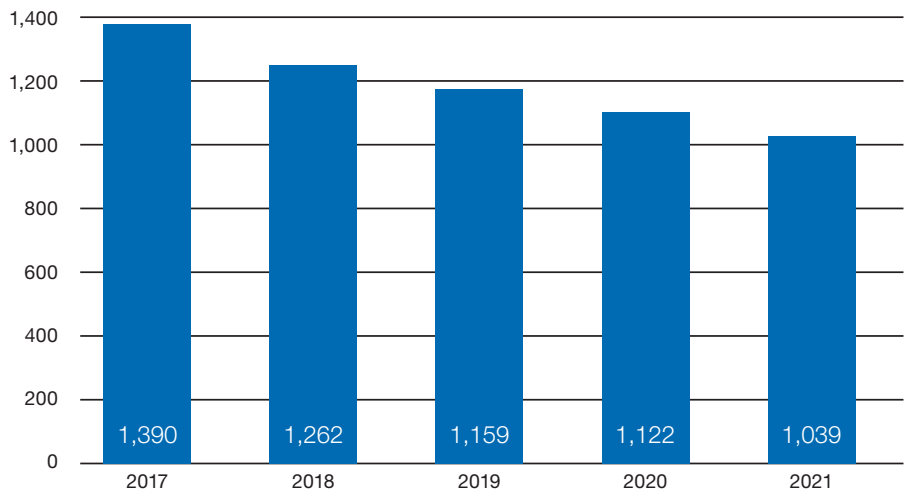
Total energy consumption*[45]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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	429,384	365,986	57,245	**1,329,232**
2021	**GJ**	**472,710**	**422,979**	**367,451**	**56,331**	**1,319,470**

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

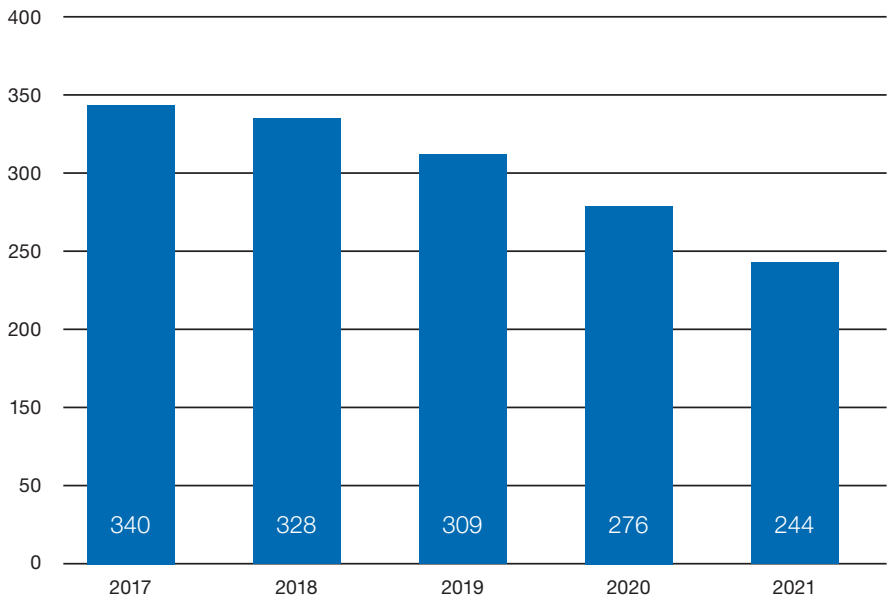
In the previous reports, the efficiency in the energy field was shown per product unit (in tons), but due to the very diverse product portfolio at the sites, it does not show an appropriate comparison between years. In this report, we show the efficiency of the use of energy products in Lek in terms of net income and the number of employees. Based on net revenues, the use of energy products improved by 7% in 2021, and by 29% compared to the base year of 2016. Based on the number of employees, efficiency increased by 13% in 2021, and by 34% compared to 2016.

Lek's energy efficiency per net income (GJ/mil. EUR)[46]



45 GRI GS 302-1
46 EMAS – Core Indicator, GRI GS 302-3

Energy efficiency (GJ) in relation to no. of employees at Lek (FTE)*



* The data for 2019 has been changed due to a calculation error in previous reports.

Energy used from waste solvents at Lendava and Mengeš

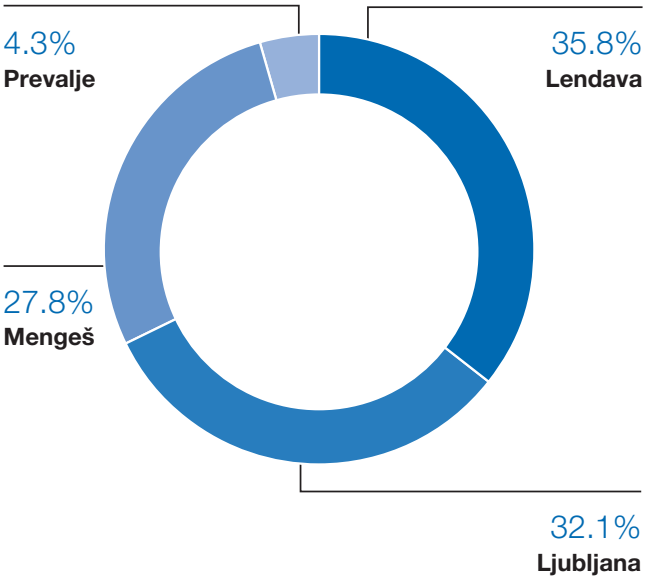
Year	Unit	Lendava	Mengeš	Lek (Total)
2017	GJ	4,658	57,082	**61,740**
2018	GJ	26,578	50,441	**77,019**
2019	GJ	30,364	63,542	**93,906**
2020	GJ	26,963	83,739	**110,702**
2021	**GJ**	**24,208**	**83,734**	**107,942**

By using waste solvents for the purpose of generating steam, we reduce the need for the primary resource (natural gas).

Energy used from biomass at Lendava

Year	Unit	Lendava
2017	GJ	4,191
2018	GJ	4,612
2019	GJ	3,417
2020	GJ	5,086
2021	**GJ**	**5,035**

Energy distribution by site



Lendava has the highest share in total energy consumption with 35.8%, followed by Ljubljana with 32.1%, Mengeš with 27.8% and Prevalje with 4.3%.

Electricity consumption[47]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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**
2021	**GJ**	**234,715**	**168,011**	**124,273**	**22,236**	**549,235**

Electricity is the main source of energy for driving production equipment, preparation and distribution of energy media for production (compressed air, cooling media...), lighting in facilities and cooling of non-production facilities.

Compared to the previous year, electricity consumption increased slightly (0.70%) and has been stable since the year of reference 2016, despite significantly increased production and a higher number of employees.

47 GRI GS 302-1

Distribution of energy resources

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.

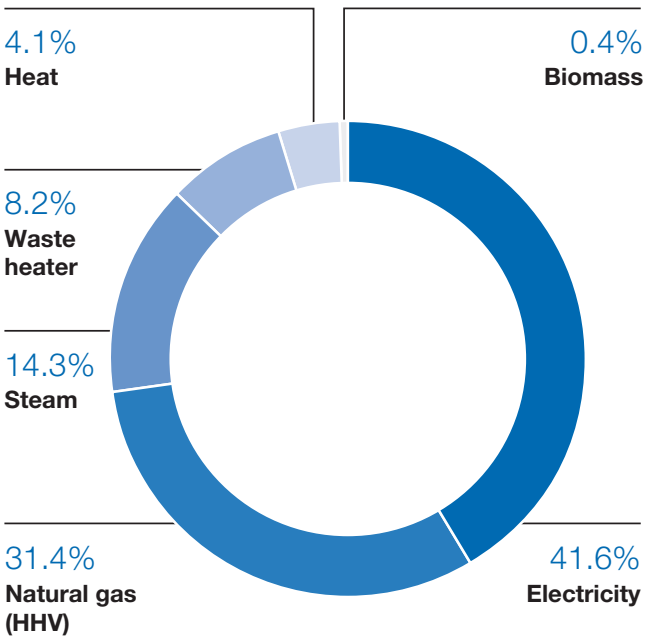
The share of renewable energy sources at the Lendava site is 0.4%; they are obtained by burning organic waste from fermentation production.

In the structure of purchased energy sources, electricity accounts for the largest share with 42%, followed by natural gas with 32%. These two energy sources are the primary source for three production sites. At the Ljubljana site – in addition to these energy sources, we also purchase industrial steam (14%) and heating water (4%).

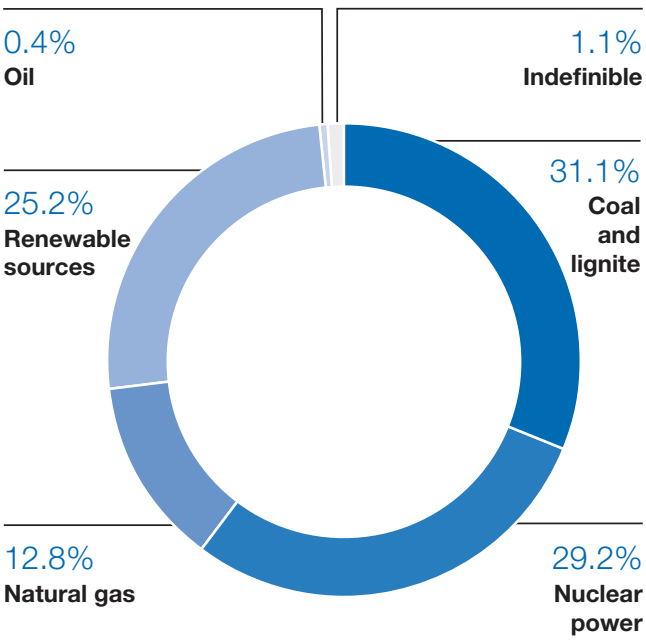
Distribution of energy consumption by type in 2021

Energy	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Electricity	GJ	234,715	168,011	124,273	22,236	549,235
Natural gas (HHV)	GJ	208,752	12,061	159,444	34,094	414,350
Heat	GJ	0	53,573	0	0	53,573
Steam	GJ	0	189,335	0	0	189,335
Waste heater	GJ	24,208	0	83,734	0	107,942
Biomass	GJ	5,086	0	0	0	5,035
TOTAL	**GJ**	**472,760**	**422,979**	**367,451**	**56,331**	**1,319,470**

Distribution of energy consumption by primary energy in 2021



Sources of purchased electricity*[48]



* Data on the composition of primary sources for electricity production, which we received from the electricity provider, are for 2020. At the time of compiling the report, data for 2021 were not yet available.

48 EMAS – Core Indicator, GRI GS 302-1

Energy efficiency improvements[49]

In 2021, we implemented several energy efficiency improvement projects, which together generated savings of 40.7 TJ of energy savings and consequently reduced CO_2 emissions into the atmosphere by 3,456 tons. The total savings of the estimated projects represent 3.1% of the savings of the total annual energy consumption.

	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Annual energy savings from energy projects (in GJ)	4,450	20,056	13,619	2,628	40,752
Annual reductions in greenhouse gases thanks to energy projects (in t CO_2)	320	2,224	846	66	3,456

The efficiency of the final use of energy in production and non-production premises is significantly influenced by the regulation, control and operation of energy systems, if we exclude the preliminary project design and their dimensioning. All projects are complex, and the full effect of the implemented measures can only be seen over a long period of time. Below are the major projects with which we improved the energy efficiency of individual systems and devices:

- regulation of the technical steam condensate system,
- expansion of humidity limits in production premises,
- optimization of the operation of cooling systems,
- optimization of cooling water distribution,
- ptimization of the operation of HVAC systems,
- replacing worn-out and energy-wasting equipment with new ones (heat exchangers, steam fittings, new cooling unit, distribution pumps, etc.),
- replacement of lighting with LED lamps,
- approach to the introduction of digitization (e.g. arrangement of automatic control at the PCS-heating station),
- optimization and modernization of energy stations,
- reconstruction of the compressed air system by replacing the dilapidated station with a new, more energy-efficient one,
- replacing the fermenter motor with a new, more energy efficient one,
- active energy management – regular monitoring of the operating parameters of energy systems and several initiatives to optimize the improvement of system performance.

Energy efficient company award

Our efforts for sustainable development and responsible use of energy have also been recognized more widely. We won the award for energy efficient company of the year, awarded by the association of energy managers and experts of Slovenia and the Finance newspaper.

The award confirms our environmentally responsible behavior, because with greater efficiency in the use of energy resources, we also create fewer emissions of greenhouse gases into the atmosphere. In the future, we want to achieve carbon neutrality at all sites and implement environmental criteria in contracts with suppliers. We are gradually transitioning to renewable energy sources and plan to be carbon neutral throughout our supply chain. An environmentally conscious employee culture, which is firmly embedded in Novartis' innovative circular economy project, is key.

Robert Hribar, Head of Engineering in Slovenia (left) and Gašper Antičevič, Head of Novartis' Technical Service in Slovenia, accepted the award for energy efficient company of the year.

49 GRI GS 302-4, 305-5

Water[50]

Pharmaceutical production, compared to some other industries, is not a water-intensive activity. Nevertheless, access to fresh water of good quality is extremely important. We are committed to the efficient and safe use of water throughout the product's life cycle. We consistently plan, monitor and control its consumption. We monitor its supply and consumption with regular quantity monitoring, and waste water with monitoring of quantities and pollution parameters.

We provide drinking water from the public water supply network and our own wells. We have established control of flows and quantities at key withdrawal points, which allows us to immediately notice any increase in drinking water and investigate the causes.

Depending on the technological purpose, drinking water is additionally purified in the production process. Pharmaceutical waters require a very high quality standard in their use. An important aspect of the preparation and distribution of this type of pharmaceutical water is the control system, which ensures optimal preparation and use in the production process.

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 addition to the annual risk assessment of active substances in the aquatic environment, we very carefully monitor discharges into waters, implement measures that ensure the reduction of antibiotic discharges into waters, and monitor the latest published studies.

Efficient water use

We attach great importance to improving the efficiency of water use, which is one of the most important natural resources. Despite slightly changed product ranges and increased production intensity, water consumption in 2021 was only 0.5% higher. The efficiency of water use at the level of Lek decreased by 4%, mainly due to the increase in consumption in Mengeš. All other sites reduced water consumption and improved its efficiency.

To optimize the consumption of technological and drinking water in the company, we took care of the following measures:

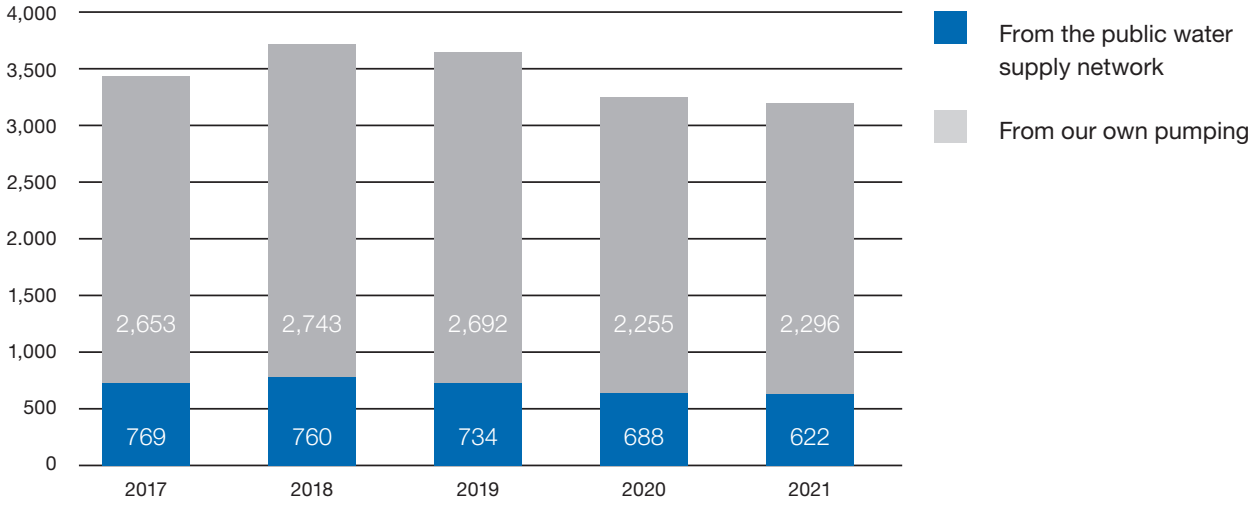
- by optimizing cooling water flows;
- by reusing water (RO, cooling systems, condensate);
- by optimizing water consumption in energy systems and systems for the preparation of pharmaceutical waters;
- with timely replacement of worn equipment;
- by connecting technological consumers to well water;
- with active monitoring of consumption - timely action and elimination of leaks;
- by raising awareness among employees about saving water.

Water use per 1,000 m³ [51]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2021	**1,000 m³**	**1,257**	**508**	**1,160**	**33**	**2,957**

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

Water sources in 1,000 m³

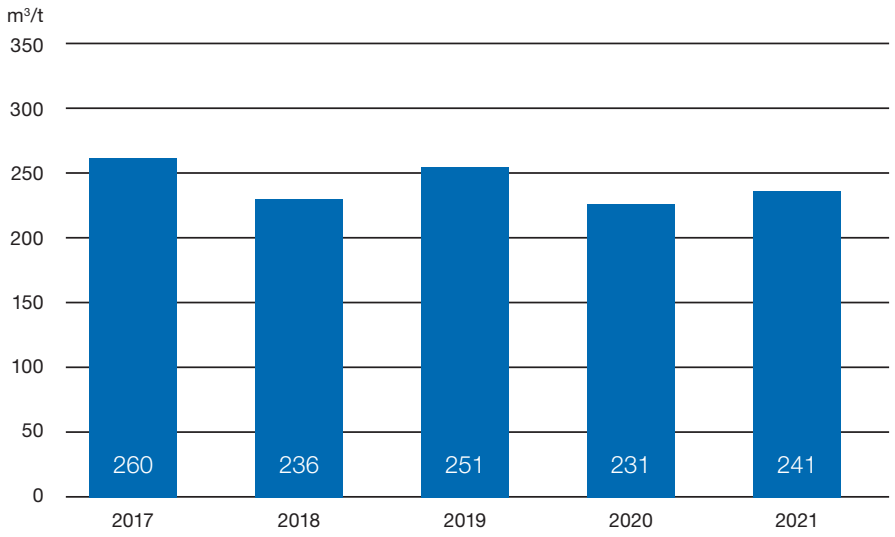


Efficiency of water use per produced unit* [52]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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**
2021	**m³/t**	**930**	**189**	**836**	**21**	**241**

* The table shows the efficiency of using only contaminated water (without cooling water).

Efficiency of water use per produced unit



52 EMAS – Core Indicator

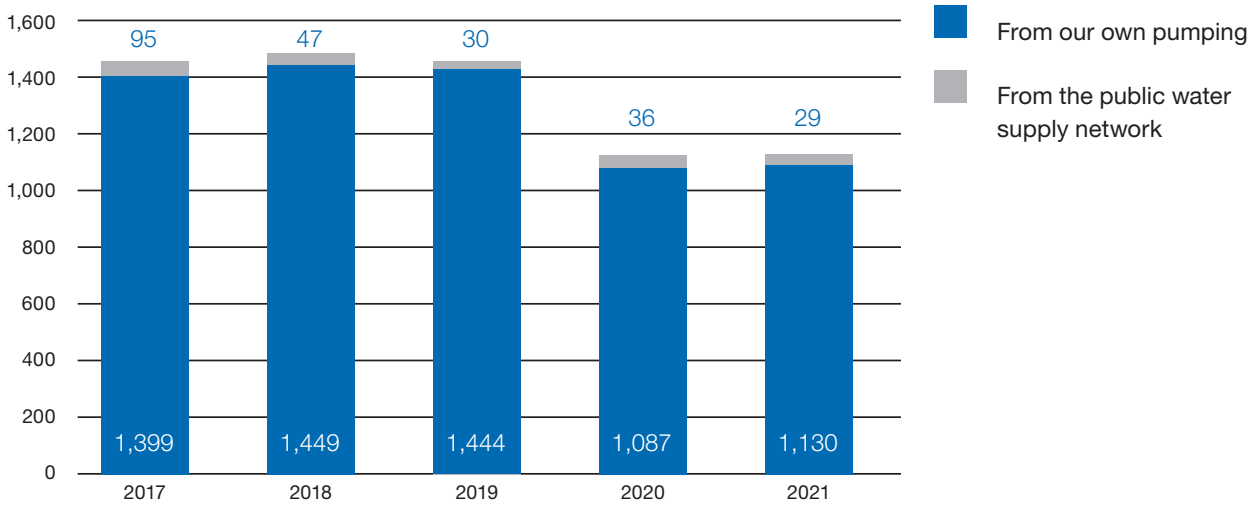
Water supply sources

Water from our own wells is used for technological purposes at the **Lendava** and **Mengeš** sites, for which we have obtained appropriate permits from the Ministry of Environment and Spatial Planning.[53]
We regularly monitor groundwater levels, with pressure sensors every hour on a continuous basis all year around. Based on all data, we determine the angles of groundwater levels, their direction and gradient.

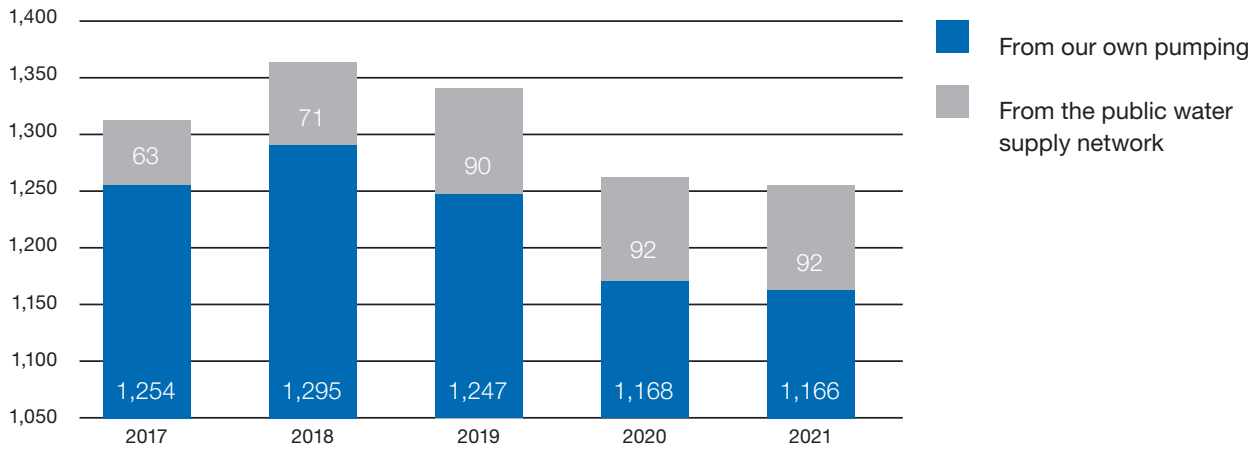
We have drilled piezometers for operational monitoring of groundwater pollution. The piezometers located to the south of the site (outlet water), showed groundwater has better quality than in piezometers north of the site (inlet water).

In Mengeš, the use of water from the public water supply system was reduced by a good 69% in five years, while in the last year by 19%. Water consumption from our own pumping station was 4% higher in 2021. In Lendava, we maintained both the use of drinking water and water from our own pumping station at the level of the previous year.

Amount and sources of water supply at Mengeš site in 1,000m³ [54]



Amount and sources of water supply at Lendava site in 1.000m³ [55]



53 Water permit no. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8
54 GRI GS 303-3
55 GRI GS 303-3

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. Recycled water is mostly used at most twice for the cooling system.

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.

Waste

Waste management[56]

The basis of the circular economy, which is also part of Novartis' environmental strategy, is the separate collection and sorting and reuse of waste. 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. The plan, which we prepared as part of the environmental management system, foresees technical and organizational measures to prevent the generation of waste. 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 waste is 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 decreased by 2.2% in 2021. In doing so, we significantly (by 34%) reduced the amount of hazardous waste, while we increased the amount of non-hazardous waste, the majority of which is biodegradable waste mycelium from Lendava production, by 2%.

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.

As can be seen from the table below, more than 92% of all generated waste is recycled or reused, it is almost completely (99.5%) recycled or we use again. Biodegradable waste accounts for 81% of all Lek waste.

Composition of generated waste in 2021 in t

	Generated waste	Waste directed to recycling and prepped for reuse	Waste directed to incineration, co-incineration or landfill*
Hazardous waste	3,179	1,738	1,441
Non-hazardous waste	37,926	37,633	293
Total	**41,106**	**39,371**	**1,734**

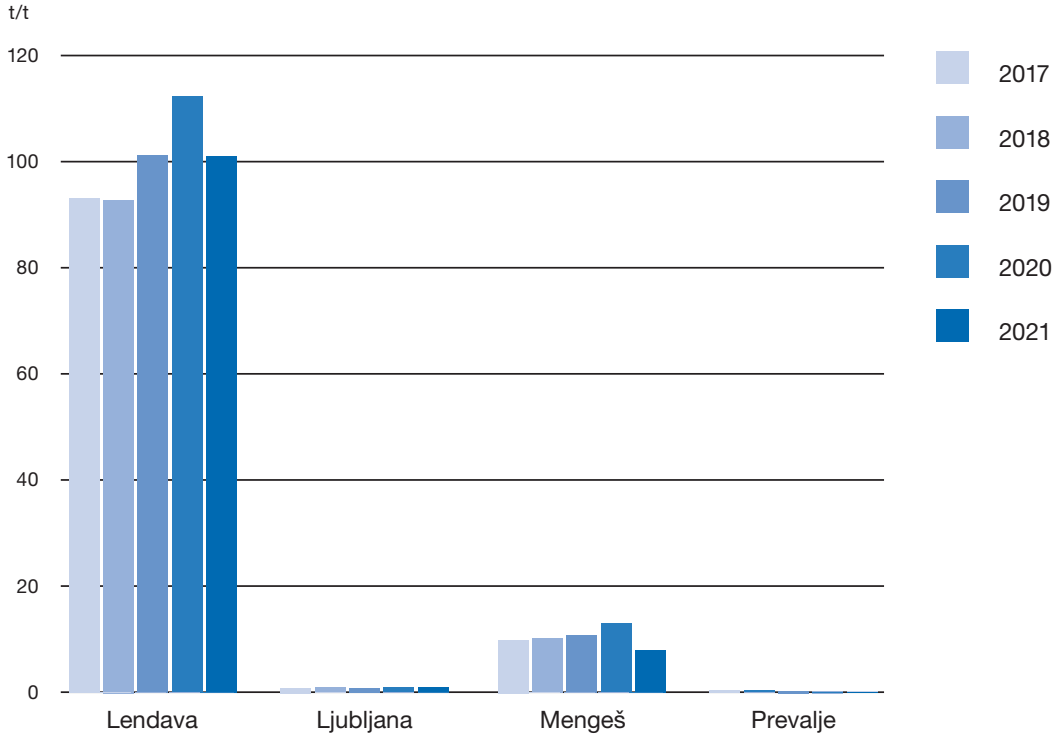
* We only put non-hazardous waste to landfill.

56 EMAS – Core Indicator, GRI GS 306-1, 306-2, 306-3, 306-4, 306-5

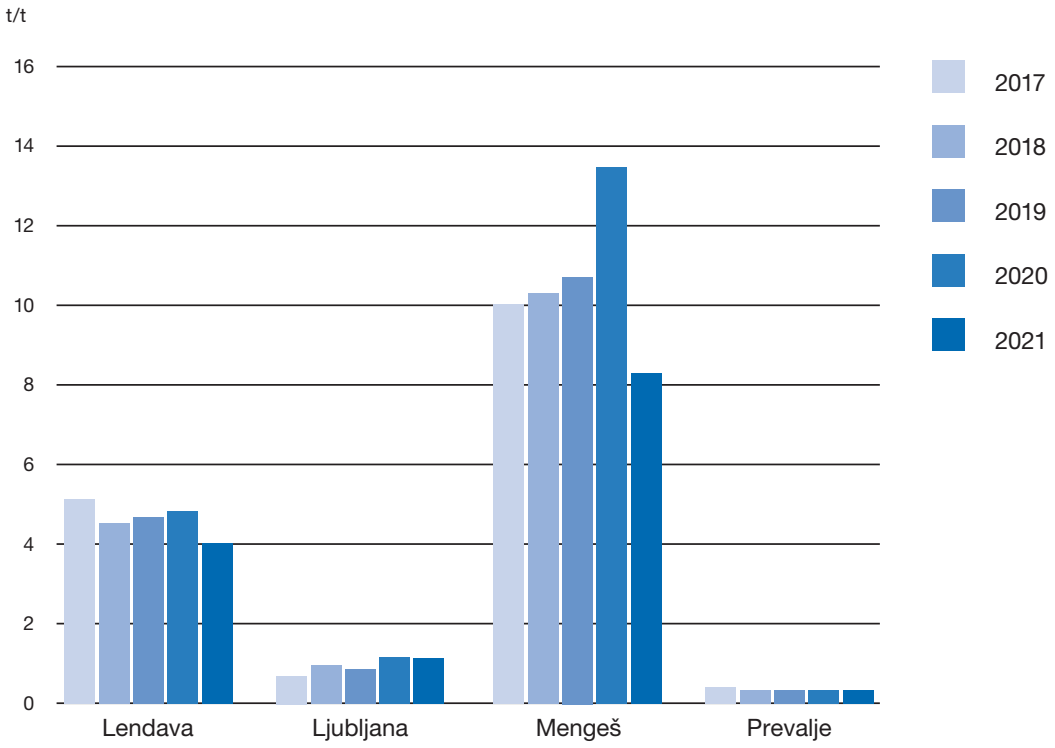
Composition of generated waste, in t by site

	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Hazardous waste					
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
2021	**52**	**959**	**1,994**	**174**	**3,179**
Non-hazardous waste					
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
2021	**34,752**	**2,222**	**592**	**360**	**37,926**

Amount of waste per t of product – efficiency



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



Hazardous waste disposal[57]

In the field of hazardous waste, our goals are to prevent and reduce their generation and to constantly increase their share for recycling or energy use. In 2021, we reduced the amount of hazardous waste by 34%, which is the result of a change in the portfolio and the development of products that require fewer solvents, as well as improved utilization of waste for energy purposes at our sites. We must also attribute part of the reduction to a 4% lower production volume. A slightly more relevant situation is shown by the indicator of the efficiency of hazardous waste management (t of waste/t of product), which shows a 31% improvement compared to 2020.

We processed and reused a good 90% of all organic solvents; in Lendava this share was as high as 97%. The total amount of waste solvents generated in Mengeš was 20% lower, and the share of reuse was on average 57%, and in some processes this share is more than 95%.

At the Mengeš site, high-energy waste solvents represent 82% of all hazardous waste. By co-incineration with natural gas, we removed 2,489t of waste solvents, which is equivalent to 35% of the primary energy for steam generation to supply site 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, we decreased hazardous waste by 13% which represents just fewer than 30% of the total amount of waste produced at the site. Among them, production waste and expired products or medicines returned from the market are important in terms of quantity. At the Prevalje site, hazardous waste represents 33% of all waste at the site and has decreased by a good 6% compared to previous years.

57 RCI OI 5, GRI GS 306-1, 306-2, 306-3, 306-4, 306-5

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

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2021	**t**	**18**	**797**	**854**	**69**	**1,738**

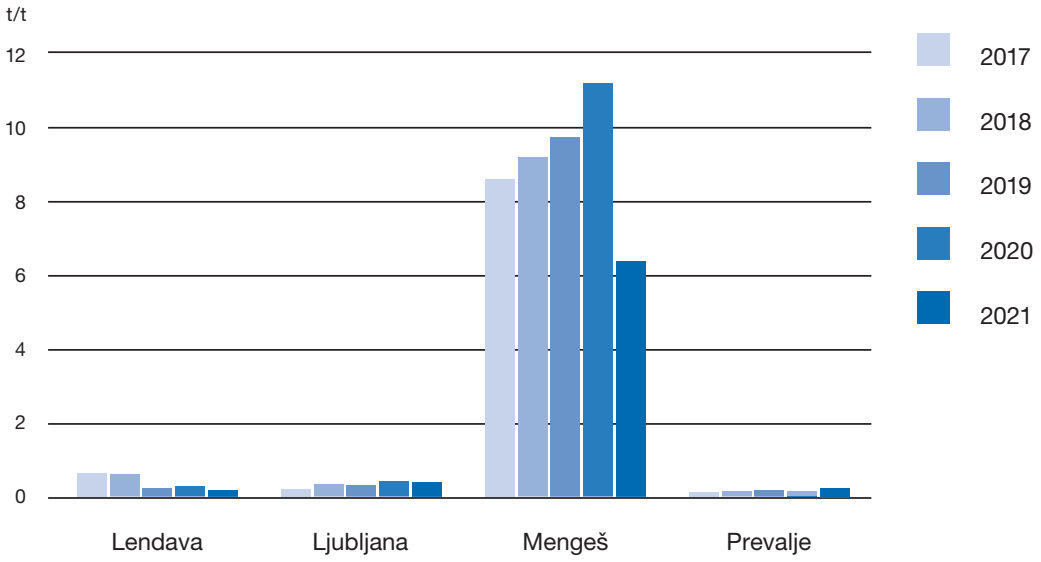
* The data shows the quantities of hazardous waste that we handed over to external authorized contractors.

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

	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2021	**t**	**34**	**162**	**1,140**	**105**	**1,441**

* 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



Disposal of non-hazardous waste[58]

Non-hazardous waste accounts for 92% of all Lek waste. The amount of non-hazardous waste increased by almost 2% in 2021 due to increased quantities of mycelium waste at Lendava.

Just over 81% of all biodegradable waste was mostly Lendava mycelium waste and the Lendava Treatment Plant sludge, a negligible amount of 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 0.4% of all non-hazardous waste, of which only 16% 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 2020, decreased 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)
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
2021	**t**	**34,752**	**2,222**	**592**	**360**	**37,926**	**34,199**

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
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
2021	**t**	**34,601**	**2,150**	**547**	**335**	**37,633**

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

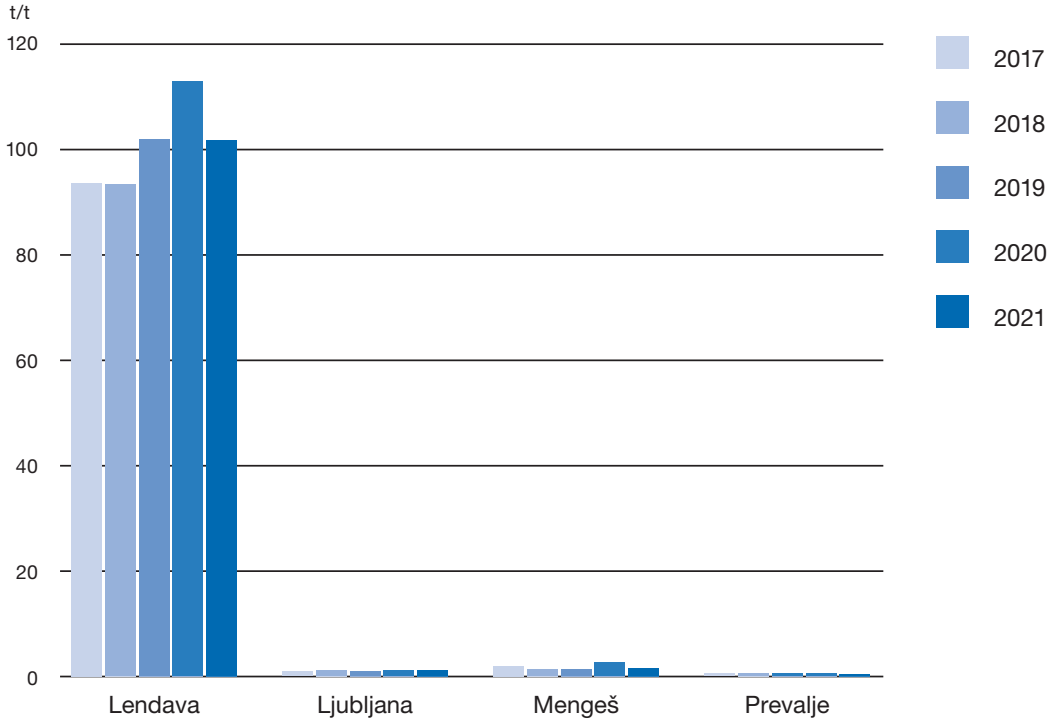
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
2017	t	240	55	83	37	414
2018	t	1	3	40	41	85
2019	t	0	1	62	28	91
2020	t	1	28	68	28	124
2021	**t**	**1**	**69**	**41**	**15**	**126**

Non-hazardous waste directed to landfill in t

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
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
2021	**t**	**151**	**3**	**3**	**11**	**167**

58 GRI GS 306-1, 306-2, 306-3, 306-4, 306-5

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



Air emissions[59]

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, achieve carbon neutrality throughout the value chain by 2030, including our supply chain. Our objective is by 2040 to be net-zero.

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.

Greenhouse emissions and emissions from stationary devices and ozone-damaging substances from air conditioning and refrigeration devices are monitored 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 (combustion), 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 20mg C/m^3.

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

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

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

Emissions from incinerators and co-incinerators

We burn waste in Lendava, where we only incinerate waste from our own production. This enables efficient management and control of the operation of the incinerator due to accurate knowledge of the composition of the waste. The range and quantity of waste for incineration are defined in the permit issued by the RS Environment Agency.

Waste co-incineration takes place in Mengeš, where we use our own waste, high-energy non-halogenated solvents in two of the four combustion plants that use natural gas as the primary energy source. Monitoring of all releases of substances into the air is regularly carried out by an external authorized institution.

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).

Sulfur oxide[60]

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, 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.

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. As stated by our supplier, natural gas does not contain sulfur.

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. In 2021, emissions were a good 82% lower.

Sulfur oxide emissions (SO_2)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) (kg SO_2/t product)
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
2021	**t**	**0.0300**	**0.0210**	**0.0000**	**0.0470**	**0.0980**	**0.0218**

Nitrogen oxide

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 decreased by 19% in 2021.

Nitrogen oxide emissions (NO_x)[61]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) (t NO_x/t product)
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
2021	**t**	**10.69**	**1.58**	**12.09**	**2.5**	**26.86**	**0.006**

60 EMAS – Core Indicator, RCI OI 7, GRI GS 305-7
61 EMAS – Core Indicator, RCI OI 8, GRI GS 305-7

CO_2 and other greenhouse gases

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. In the group of sources of direct CO_2 emissions (GHG1)[62], we also include some other gases that we use or produce in our processes, such as:

- dinitrogen oxide (N_2O) in CO_2 equivalents,[63]
- fluorinated hydrocarbons (hydrofluorocarbons – HFC) in CO_2 equivalents,[64] and
- other greenhouse gases (methane and others) in CO_2 equivalents.[65]

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

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

Carbon dioxide and other greenhouse gases contributing to the greenhouse effect[66]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency t (Lek) (t CO_2/t product)
GHG1	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
	2021	**t CO_2**	**13,453**	**2,590**	**14,549**	**1,702**	**32,294**	**7.2**
GHG2	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
	2021	**t CO_2**	**17,345**	**30,150****	**9,184**	**1,643**	**58,323**	**13.0**

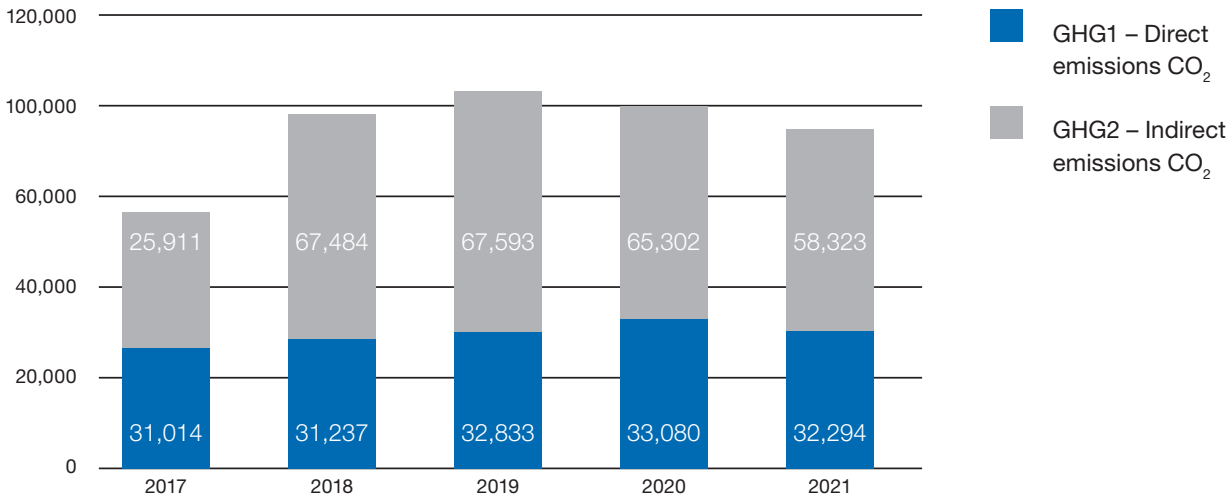
* *Purchase of green certificates for 2017 in the total value of CO_2 emissions from electricity, and CO_2 at the Ljubljana site comes from the supply of steam and hot water. The values are corrected according to the 2017 Sustainability Report, because certificates of origin were only purchased at the end of 2018.

** For the Ljubljana site, the purchase of green energy is considered for 2021, namely for steam in the share of 6.78% and for hot water in the share of 100%.

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

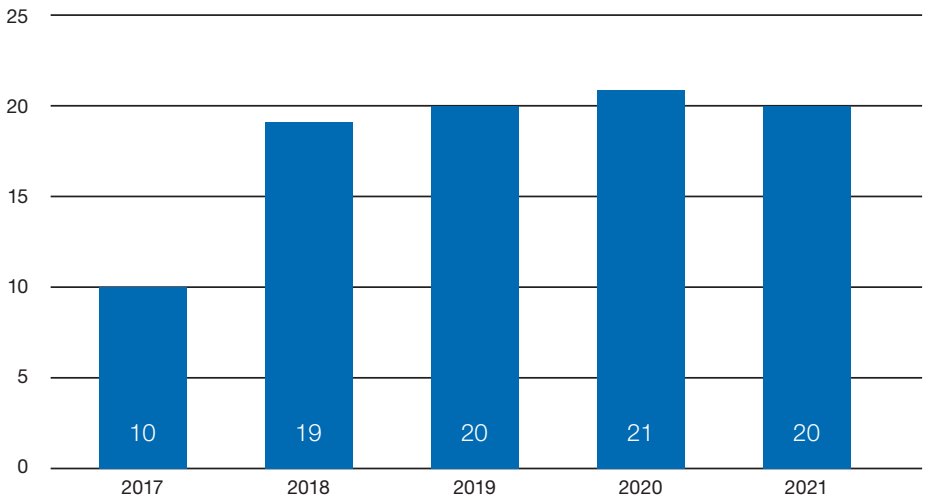
62 RCI OI 10
63 RCI OI 11
64 RCI OI 12
65 RCI OI 13
66 GRI GS 305-1, 305-2, 305-4

Total GHG at Lek (in tCO_{2e})



In 2021, we reduced the total amount of GHG emissions by 7.9%. In 2021, we reduced the amount of direct TGP1 emissions by 2.4%, and the amount of indirect TGP2 emissions by 10.7%, which is primarily the result of greater procurement of green energy at the Ljubljana location. Efficiency per ton of product also improved, namely by 4.8%. 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.

Total GHG at Lek – efficiency/product unit (in tCO_2/t product)



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 2020, the value of 0.0739 tCO_2/GJ or 0.26604 kg/kWh, as determined by the Novartis guidelines for Slovenia.

Volatile organic compounds – VOC[67]

The total amount of emissions of volatile organic compounds (VOCs) was reduced by 30% in 2021 and thus improved efficiency by 27%, 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 Mengeš site, there is also a halogenated solvents extraction device for outlet air, with the state-of-the-art cryogenic condensation technology.

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 VOC/t product))
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
2021	**t**	**22.5**	**5.9**	**42.6**	**0.6**	**71.5**	**0.016**

Water releases[68]

In line with Novartis' environmental sustainability strategy, we aim to achieve neutrality in all areas of our water impacts by 2030 and to improve water quality everywhere we operate. That is why we take great care when releasing water.

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 sites. 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 global 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 RCI OI 9
68 GRI GS 103-1, 103-2, 103-3

Waste water

The quantities of cooling and technological wastewater slightly increased (0.5%). Unpolluted waste cooling water in Lendava and Mengeš represents 62% 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[69]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Use of cooling water – unpolluted							
	2017	1000 m³	976	4.2	1,154	11	2,145
	2018	1000 m³	1,068	36	1,159	9	2,272
	2019	1000 m³	1,000	0	1,169	0	2,169
	2020	1000 m³	946	0	910	0	1,856
	2021	**1000 m³**	**940**	**0**	**894**	**0**	**1,834**
Discharge			Into the surface water	Into sewage system cleaning at WWTP	Into the surface water	Into sewage system	
Use of industrial water – unpolluted							
	2017	1000 m³	347	570	334	26	1,277
	2018	1000 m³	279	569	331	28	1,207
	2019	1000 m³	337	574	306	40	1,257
	2020	1000 m³	314	523	214	36	1,087
	2021	**1000 m³**	**317**	**508**	**265**	**33**	**1,123**
Discharge			Into sewage system cleaning at WWTP	Into sewage system cleaning at WWTP	Into sewage system cleaning at WWTP	Into sewage system	Into sewage system cleaning at WWTP

Phosphorus and nitrogen compounds and chemical oxide demand

Emissions of phosphorus and nitrogen compounds and chemical oxygen requirements were higher in 2021, which is the result of increased production and lower water use in Lendava.

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 22% increase 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 2021 increased by 40%.

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 2021, we recorded an increase in the chemical oxygen demand of 43%.

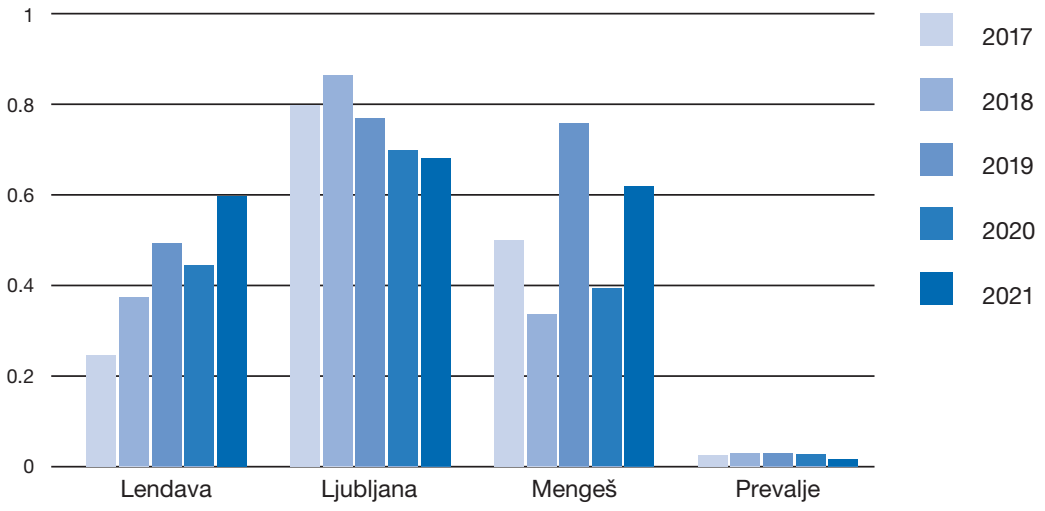
The amount of wastewater from the production of finished products in Prevalje and Ljubljana is low, which is also reflected in the contribution of the chemical oxygen demand. The sites together contribute 2% of the total pollution of waste waters with organic impurities.

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.

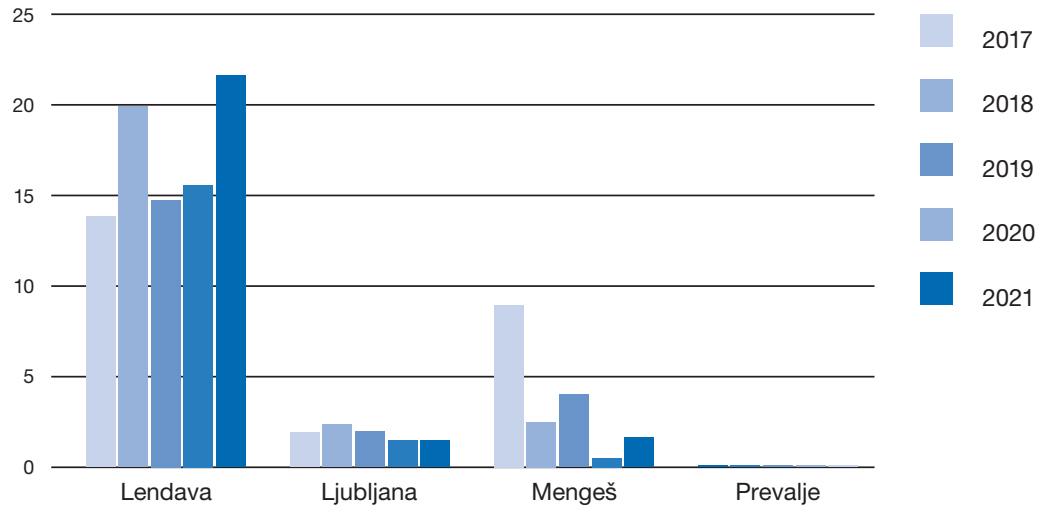
Wastewaters and the content of all the three parameters are constantly monitored by the authorized monitoring authorities. Monitoring is carried out three to twelve times a year, depending on the volumes of wastewaters at the respective site.

69 EMAS – Core Indicator, GRI GS 303-4

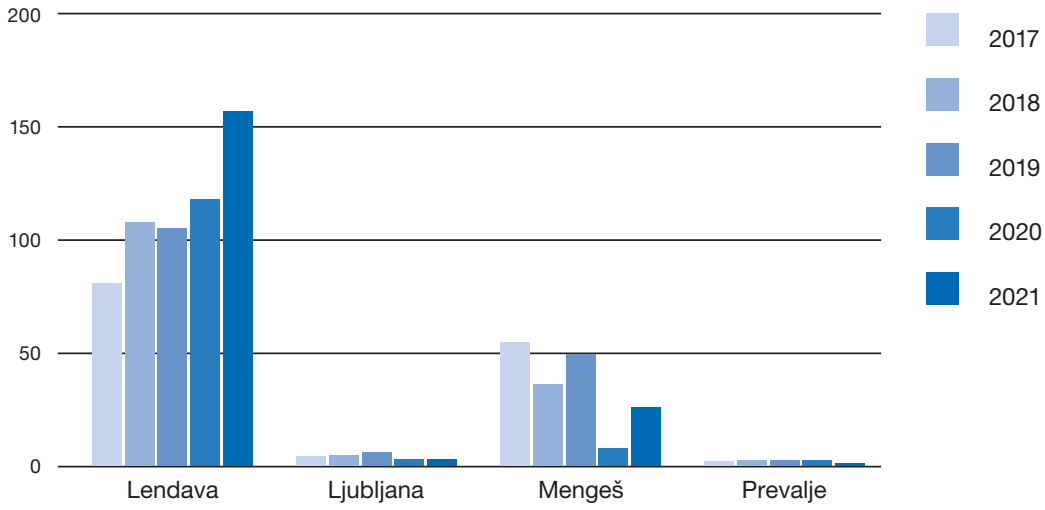
Emissions of phosphorous compounds in wastewater (in t)[70]



Emissions of nitrogen compounds in wastewater (in t)[71]



Chemical oxygen demand (in t O_2)[72]



70 RCI OI 15
71 RCI OI 16
72 RCI OI 14

Other environmental impacts

Odor

The odor is triggered by various volatile substances, mostly of organic origin. The area of environmental pollution with odors in Slovenia is not regulated, so there are no direct requirements in relation to odors in environmental permits.

Nevertheless, we have installed biofilters in accordance with good practice in controlling the release of emissions into the environment in all places where disturbing odors could occur for people living in the immediate vicinity (e.g. above leveling pools) or gas washers (e.g. on fermenter discharges), and on devices for heat treatment of volatile organic compounds from production. At these sites, the National Laboratory for the Environment and Food (NLZOH) regularly monitors odor emissions.

In addition to the aforementioned techniques, the method of waste management and the maintenance of cleanliness of the sites are of utmost importance for limiting the smell. In 2021, we did not receive anycomplaints from local residents.

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. 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.

We prevent potential soil pollution with systematic consideration of all technical and organizational measures, in the design, construction and operation, and maintenance of devices.

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.

This is of particular importance at the Mengeš and Ljubljana sites which are situated in a water protection area. We regularly check the leak-proof status of sewage systems, particularly those carrying industrial wastewater. 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 2021, we made a record of the zero soil condition for the Lendava site.

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 2021 we received no noise complaints in Lek.

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.

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.

Biodiversity

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[73]

	Lendava	Ljubljana	Mengeš	Prevalje	Lek
Total site surface area with parking lots (m^2)	140,663	144,669	154,167	19,981	459,480
Of which green surfaces (m^2)	80,560	26,350	52,030	1,430	160,370

Safety

Fire safety

We did not record any major cases at Lek's sites in 2021 in the field of fire protection. All sites regularly conduct fire drills. We also held annual fire drills and evacuation drills at all sites.

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 at the Administration for Civil Protection and Disaster Relief training centers in Ig, Sežana and Pekre. The brigades, in cooperation with the Ig Education Center for Protection and Rescue, conducted an all-day exercise, in which only Lek's firefighters participated. The topic was coordinated on the basis of the dangers present at Lek's sites, accordingly, the emphasis was on hazardous substances and fires in industry.

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 training for them. Volunteer firefighters also took part in training within the Fire Brigade Association of Slovenia.

In 2021, at Lek's sites, we also conducted practical training for extinguishing initial fires with a simulator for extinguishing initial fires and presented the entire range of fire extinguishers used in production, laboratories and warehouses to employees.

Biological safety

In Lek, we work with Group 1 and 2 biological agents, mostly in production and quality control. 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

73 EMAS – Core Indicator

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.

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.

In 2021, we obtained a permit from the Ministry of the Environment and Spatial Planning for two expansions of closed systems; one at the Ljubljana site and one at Mengeš. At Mengeš we also registered two new closed systems for work with GMOs, which includes all the measures for work with HG2 GMOs.

Warehouse and distribution safety

Lek's safe storage is based on knowledge of the hazardous properties of chemicals and their compatibility. The chemicals we use are classified into the appropriate hazard category according to their physical properties and health and environmental hazards. They are stored in technically organized warehouse zones, in accordance with Slovenian legislation and Novartis guidelines. Employees handling hazardous substances are practically and theoretically appropriately trained. Appropriate instructions for safe work have been drawn up which describe all the hazards, safety measures and methods of safe operation. We carry out regular monitoring and verification of organizational measures, staff qualifications and compliance with the instructions.

Storage of chemicals is carried out under the conditions defined in the legal provisions on technical and organizational measures for the storage of hazardous chemicals. In accordance with the stability conditions, we introduced the highest technical and safety measures to maintain the quality of chemicals used in production. The contractual partner, Kuehne + Nagel, has also introduced the highest standards of safe storage of chemicals, which ensure that Lek maintains the quality of raw materials, semi-finished and finished products and distributes them to pharmaceutical production and customers.

When transporting goods, we follow the guidelines of the requirements for the transport of dangerous goods and good distribution practices with contracted contractors. The goods are prepared and dispatched by qualified employees who know the measures for their safe preparation and dispatch and the requirements of the international agreement for the transport of dangerous goods (ADR).

A safety consultant for the transport of dangerous goods in Lek takes care of refreshing knowledge and constant supervision in this area. Due to specific dangerous properties, some raw materials for the production of medicines require additional protection during transport with packaging and a vehicle according to the criteria specified in the agreement.

In 2021, in the context of the transport of dangerous goods from Lek's production warehouses, we did not record any events or accidents that would be the result of the loading, transport and unloading of dangerous goods.

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.

Measurements of exposure to chemical 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.

Labor

Employees are key to fulfilling our vision and purpose - to co-create medicine to improve and extend people's lives. 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.

2021 Highlights

744

new jobs created. At the end of the year, Lek had 5,397 full-time employees.

560

employees had used their parental leave, 11% more than in 2021. 42% were male.

83.6

or 10.5 days average of training Lek employees which is 21% more than 2021.

– 6%

improvement in LTIR. Altogether we recorded 12 accidents which consequently meant temporary absence from work.

Human resource policy[74]

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. At the same time, we create an environment that supports the diversity and freedom of employees.

The priority is to design processes, tools and systems for recruitment, talent development and succession planning, achievement rewards, organizational development and education. In 2021, during the COVID-19 pandemic, we created new work models that enable employees to adjust work and private obligations and thus increase their performance.

Award-winning human resources practices of Novartis in Slovenia

Innovative human resources practices and long-term efforts to improve the working environment are reflected in the company's high reputation in the public.

This is confirmed by the international certificate for the best employer »Top Employer 2021« and the award of the most reputable employer in Slovenia. We received the title of the most reputable employer, awarded by the employment portal MojeDelo.com, for the third time, and the international certificate for the best employer for the second time in a row. The »Top Employer« certification is aimed at companies with excellent HR practices and employee development programs and covers six HR areas consisting of 20 topics such as people strategy, work environment, talent acquisition, learning, well-being, diversity and inclusion and others. On this occasion, Novartis in Slovenia obtained two titles »Top Employer Slovenia« and »Top Employer Europe« for outstanding evaluations at the European level. In 2021, we also received the LGBT-friendly company certificate, and since 2007 we have been the holder of the Family-Friendly Company certificate.

From the left: Luka Lamut, Darja Ferčej Temeljotov, Ognen Jakasanovski, Paulina Pazio, Raul Lombeida Intriago, Jure Vajs and Nives Fajfar

74 GRI GS 103-1, 103-2, 103-3

Employment

Total workforce by employment and employment contract[75]

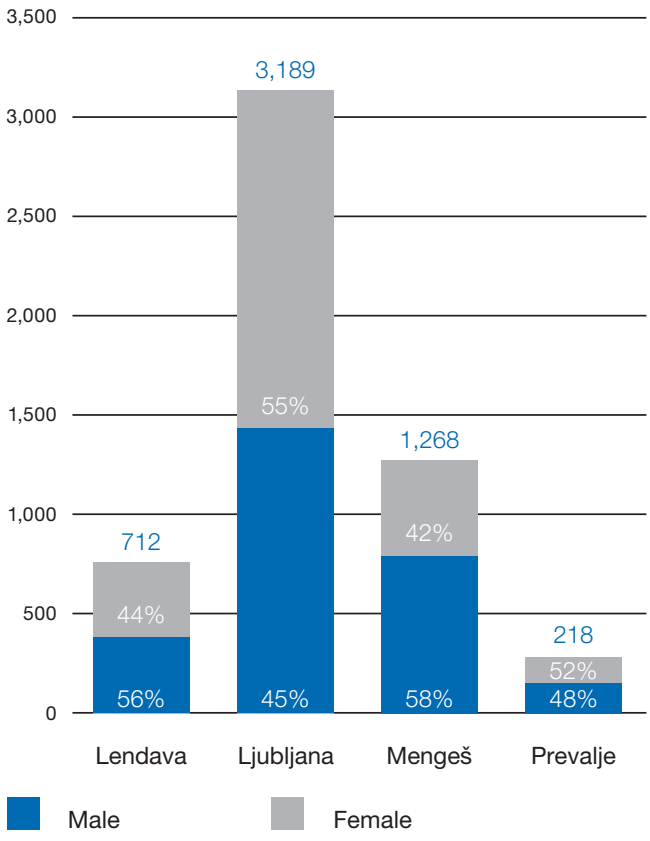
In 2021, we created 744 new jobs and finished the year with 5,397 full-time employees (12% more than 2020). At the end of the year, the proportion of women employed was 50%, 1% higher than the previous year. At year-end, 93.4% of all employees worked on a full-time permanent basis, and 6.6% were fixed-term employees and 1.7% of all employees worked on a part-time basis.

Number of full-time employees on 31. 12. 2021 by site and gender

Site	Male	Female	Total
Lendava	398	314	712
Ljubljana	1,421	1,768	3,189
Menges	741	527	1,268
Prevalje	104	114	218
Ostalo*	10	0	10
Total	**2,674**	**2,723**	**5,397**

* Leased warehouses (Brnik)

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



Number of new employees in 2021 by age (in %)

Age group	No. of new employees	%
18–25	111	14.9%
26–30	261	35.1%
31–35	171	23%
36–40	93	12.5%
41–45	66	8.9%
46–50	33	4.4%
51–55	9	1.2%
Total	**744**	**100%**

Percentage of employees covered by collective agreements[76]

The Collective Agreement covers 99.02% of the total workforce, a level similar to that in the previous years.

Liabilities from the pension plan[77]

In addition to all the obligations defined in Slovenian labor legislation, we also allow our employees to participate in a collective additional pension scheme, enabling them to receive an additional pension after their retirement. The company pays a monthly premium equal to the statutory percentage in the amount of 5.844% of the employee's gross salary, or an annual amount that cannot exceed 2,819 EUR. At the end of 2021, 97% of the workforce was included in the scheme.

Employment process and percentage of local employees in senior management[78]

The employment process is based on determining the competencies required to perform the job position. In line with Novartis' strategy of diversity and inclusion, we respect and promote the cultural, ethnic and sexual diversity of our employees. The proportion of local human resources in the senior management team was somewhat lower (84.62%) than in 2020 (87.1%).

Parental leave[79]

The growth in the number of employees taking parental leave has increased over the last 5 years, the return to work rate after parental leave remains high. Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act.

75 GRI GS 102-7, 102-8, 401-1
76 GRI GS 102-41
77 GRI GS 201-3
78 GRI GS 103-1, 202-2
79 GRI GS 103-1, 401-3

Parental leave and return to work rate

	2021	2020	2019	2018	2017
Number of employees having taken parental leave	**560**	506	479	458	397
Male	**236**	219	230	219	191
Female	**324**	287	249	239	206
Number and share (in %) of employees returning to work after parental leave	**553 (98.7%)**	503 (99.4%)	478 (99.8%)	458 (100%)	394 (99.2%)
Male	**232 (98.3%)**	219 (100%)	229 (99.6%)	219 (100%)	191 (100%)
Female	**321 (99.1%)**	284 (98.9%)	249 (100%)	239 (100%)	203 (98.5%)

Green corners at our Ljubljana site

At our Ljubljana site, we introduced three “green corners”, which enable a more pleasant working environment by working outdoors and encourage creativity and new creative solutions.

Occupational health and safety[80]

Safety and health priorities are to focus on maintaining employee health and limiting risks that could adversely affect our ability to provide products to our patients. 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. The basic pillars in 2021 were to promote, prevent, protect. In doing so, we sought to eliminate any dangers and minimize risks through effective preventive and protective measures. Our success depends on leadership, commitment and cooperation 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.

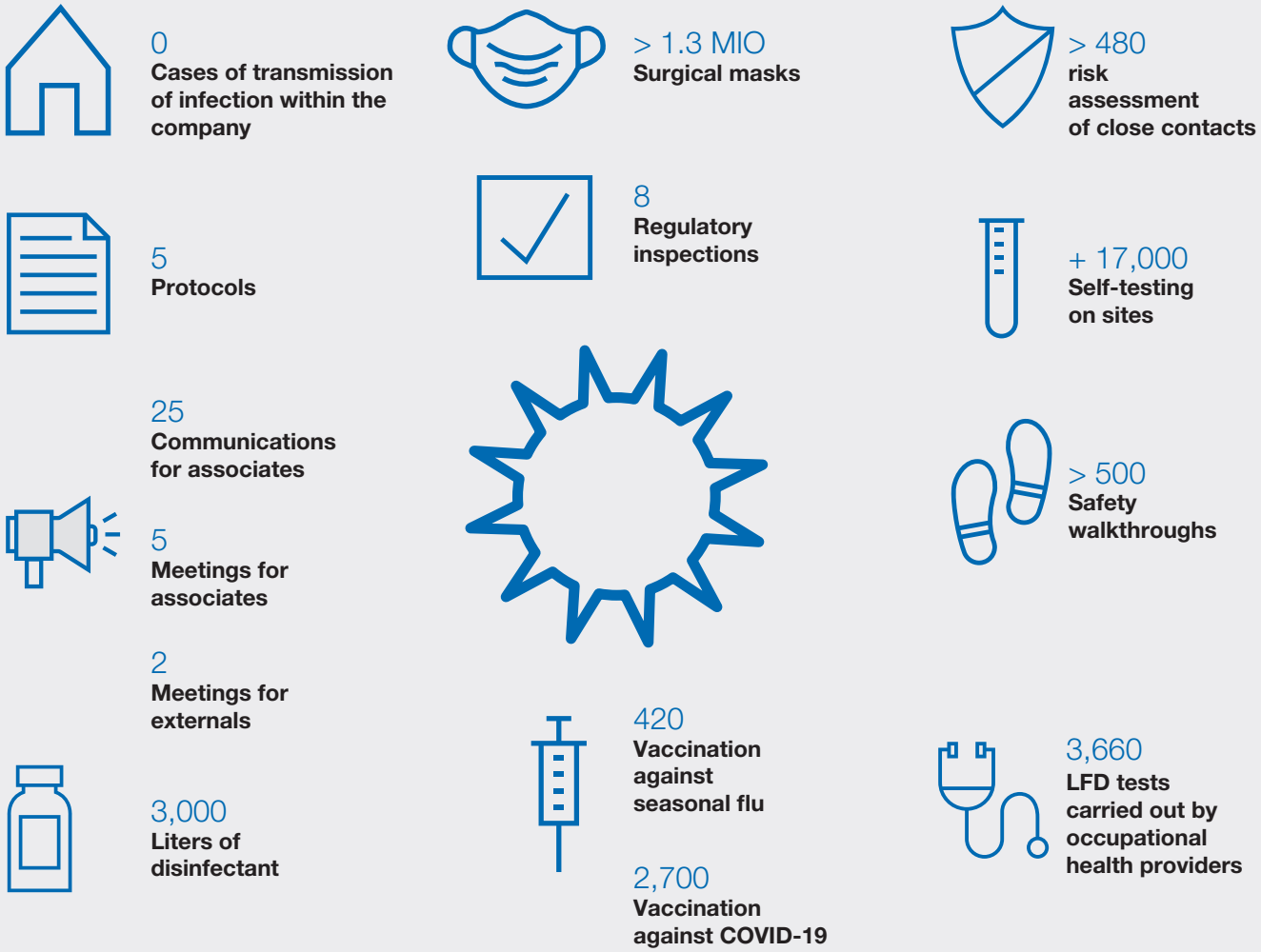
Despite all the challenges associated with COVID-19, we were able to carry out all the necessary operational activities with certain adjustments and new approaches. We have successfully renewed and recertified the ISO 45001 occupational health and safety management system.

Based on all organizational changes in 2021, we also revised the safety statement with a risk assessment. We actively involved occupational medicine and workers' representatives in the revision of this statement. We promoted current topics on a monthly basis to raise safety culture and awareness.

80 GRI GS 103-1, 103-2, 103-3, 403-1, 403-2

In 2021, the global and local situation with COVID-19 persisted and we had to dedicate a series of measures to prevent and control infections. The following graphic shows the complexity of our preventive measures.

Preventive measures to prevent COVID-19 infections in 2021



Frequency of absences due to injuries at work[81]

Measures within the system of health and safety at work and their adequacy are monitored on the basis of key statistical indicators, such as the frequency of accidents at work. 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).

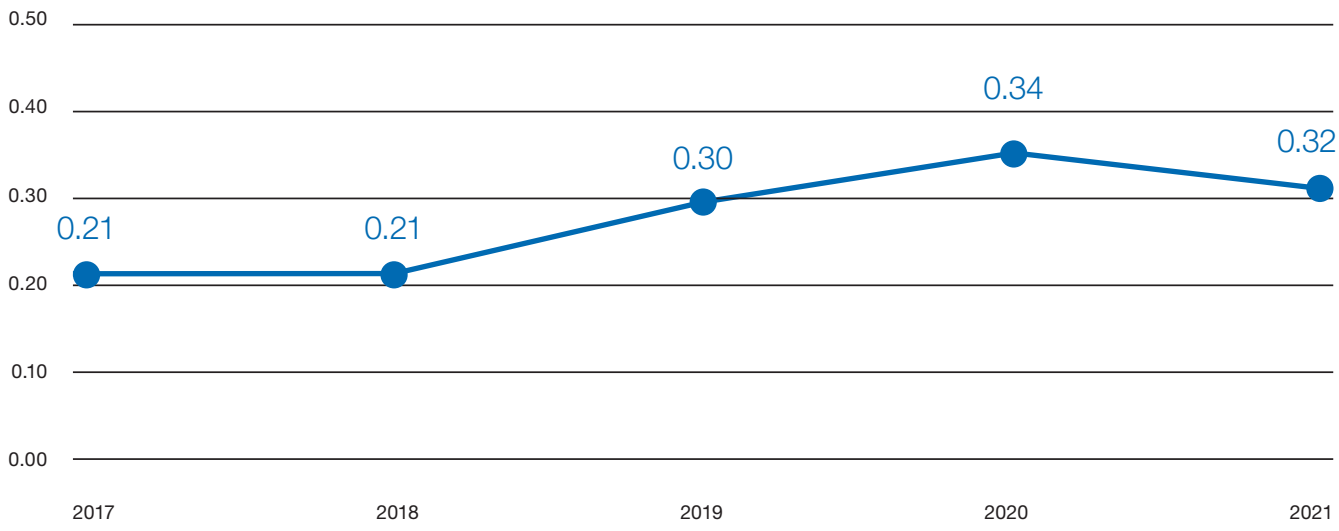
81 RCI OI 2, GRI GS 403-9

Lost Time Injury and Illness Rate

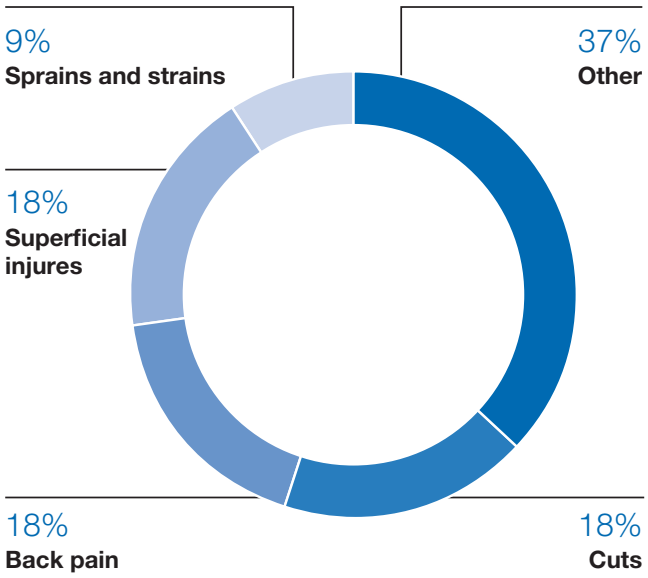
Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2017	0.00	0.10	0.32	0.79	0.21
2018	0.00	0.18	0.22	0.79	0.21
2019	0.12	0.24	0.11	1.24	0.30
2020	0.39	0.11	0.29	2.54	0.34
2021	**0.64**	**0.28**	**0.32**	**0.00**	**0.32**

In 2021, we did not record any serious injuries at work or illnesses that would have lasting consequences for the health of our employees. We recorded 12 cases where co-workers were on sick leave due to an injury at work. The LTIR indicator decreased from 0.34 to 0.32. The TRCR indicator also decreased and stood at 0.32 (0.34 in 2020). Both employees and agency workers are included in these statistics.

Trend of LTIR injuries



Categories of accidents based on cause (LTIR and TRCR) in 2021



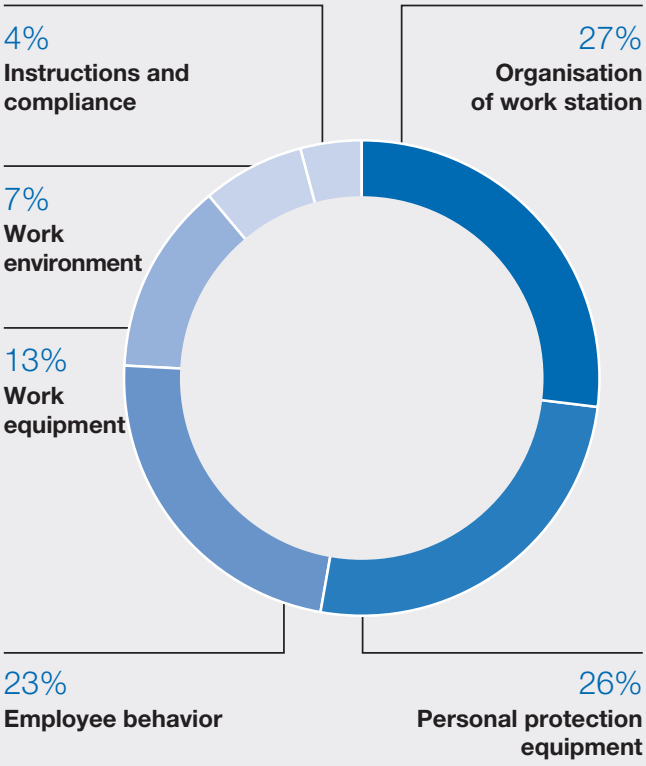
HSE system

Preventive activities to prevent accidents and injuries in 2021

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 2021, we recorded 6 such cases, which we investigated and prepared preventive measures to avoid a repeat in the future. Most of the pSIF events were related to exposure to hazardous substances, work at height, falling objects, hazardous energies and whilst using forklifts. Four of these pSIF cases were connected to external contractors. 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 2021, we continued to improve our safety walkthroughs system, which emphasis on walkthroughs performed by managers. We conducted more than 1,200 safety walkthroughs by managers, and improved the participation of managers by 21% in comparison to 2020.

Classification of risks noticed by area



Absenteeism[82]

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 2021, the proportion of sick leave was 6.04%, recording a slight increase compared to the previous year (4.87%).

Share of sick leave

	2021	2020	2019
Female	6.60%	5.91%	7.41%
Male	5.47%	3.88%	4.67%
Total	**6.04%**	**4.87%**	**6.00%**

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. Despite the situation with the covid-19 pandemic, the activities of external contractors were slightly higher compared to 2020. The preventive and protective measures taken against COVID-19 thus enabled safe work.

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.

82 GRI GS 403-9

In 2021, more than 340 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),
- familiarization with the HSE-documentation of all coordinators and work leaders,
- 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 2021, we conducted 4,245 training sessions for employees of external contractors through the Kiosk online application.

Although we are working hard for sustainable outsourcing, in 2021 we recorded one pSIF that was directly related to outsourcing activities. As a result, we will review our internal external management program next year, based on best practices, lessons learned and new global outsourcing procedures.

Number of work-related fatalities[83]

No fatalities were recorded amongst our employees or external contractors.

Occupational disease rate[84]

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.

Health promotion program[85]

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.

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 2021, we performed 2,900 employee preventive medical examinations. We also performed inspections of critical work equipment, investigated dangers in the work environment, revised risk assessments and carried out other planned preventive activities.

In order to maintain the physical and mental health of our employees, despite the persistent COVID-19 pandemic, we carried out activities within the health promotion program. The activities were carried out in compliance with measures to prevent the spread of coronavirus. Participation in all programs and activities was voluntary, with recommendations for inclusion in the programs in individual cases given by our contracted occupational medicine practitioners. As part of the program, we performed the following activities:

- active breaks (exercise at work),
- daily kinesiology workshops (remote),
- subsidized physical activities of employees outside the company (fitness, swimming, climbing, dancing),
- measurements of health indicators,
- mindfulness exercises,
- preventive dental examinations (awareness, information),
- vaccinations against seasonal flu, tick-borne meningoencephalitis, covid-19,
- preventive medical recovery in health resorts,
- lecture on the topic of psychological security and mental well-being,
- providing psychological help.

Training and education[86]

We invest constantly and systematically in the development, education and training of our employees, as the know-how and high qualifications of employees are of key importance for the growth and progress of the company. We provide employees with:

- 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.

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.

83 RCI OI 1 and RCI OI 3, GRI GS 403-9
84 GRI GS 403-10
85 GRI GS 403-3, 403-4, 403-5, 403-6
86 GRI GS 103-1, 103-2, 103-3

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.

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.

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, 2021 training that previously took place in classrooms was moved to a virtual form.

HSE organization, human resources and training

Production activities have their HSE representative, who is directly responsible to the head of the production unit for certain HSE tasks, while the remaining HSE personnel offer support for NO Development sites.

By the authority of the Board of Management, they are responsible for the compliance of areas of expertise with Slovenian laws and Novartis 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 expert assistance in the implementation of preventive measures at sites as well as communication of identified risks to the management team.

HSE training is divided into three categories: legally obligatory, specific and expert development. Legally mandatory and specific training and certification are the basis for work and tasks. Expert knowledge development ensures the high quality of work carried out by expert associates and authorized personnel.

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 NO 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 2021, 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. Thus, we managed to carry out periodic and pre-employment training for new employees in occupational health and safety and fire protection, and 4,425 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 forklift 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…

HSE aspects and monitoring achievement system

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 2021, two external audits of compliance were performed with ISO 14001: 2015 and ISO 45001: 2018 and an extension in the EMAS regulation. Once again, the auditors 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 sites.

Even the internal HSE assessments, which are otherwise planned on an annual basis, were not carried out in full due to the epidemic. Of the planned 24 internal audits, nine were carried out, the rest will be realized in 2022. In September, a global Novartis audit of legal compliance was planned, but it was postponed to February 2022 due to COVID-19.

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. Setting HSE performance goals 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 guidelines.

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.

Measures for risk prevention and mitigation

Likely scenarios for emergencies are identified with appropriate risk assessment methodologies for each site/business unit. In the context of risk assessment, we evaluate the potential impact and level of supervision and identify appropriate risk mitigation measures. We take into account potential incidents in all our operations and business activities, as well as possible external resources such as weather, security, suppliers and neighborhood activities. Quarterly we update HSE's set of risks based on risk assessments performed and the current situation in the company and the environment. For each location, we create a Site Threat Assessment, which is updated periodically every 5 years, or in case of major changes that could mean changes 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.

BCM in 2021

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 critical to the continued successful response to the covid-19 pandemic and extreme weather events in 2021. Managing the risk of human availability due to the pandemic continued to be critical this year. We upgraded the system for ensuring smooth operations, aligned it with the ISO 22301 standard and experience from past pandemics. The upgraded system for ensuring uninterrupted operations will thus allow us to better exchange experience between plants and thus better resilience in the procurement chain of our products.

NEM in 2021

In 2021, we updated the NEM structure in Slovenia with a new member due to changes in the management structure, while the existing structures at the site level were not changed. All Novartis departments were trained according to the NEM process.

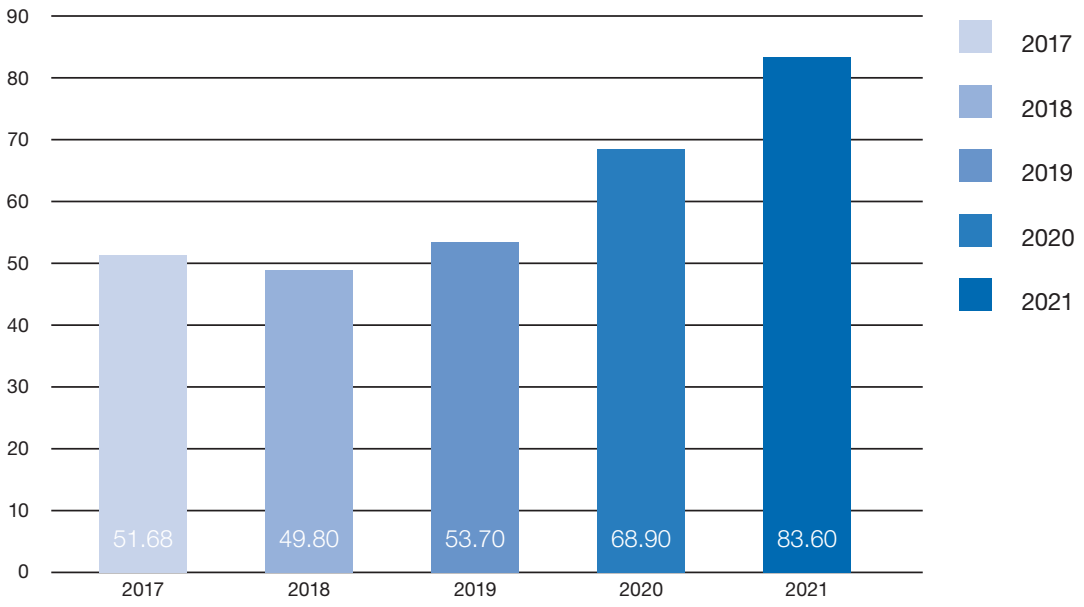
NEM training was held for the new member of the NEM group and for those who did not attend the previous training. The on-site teams did not train for additional scenarios as we faced a NEM-situation due to the covid-19 pandemic throughout the year.

Apart from handling COVID-19, we had no other NEM events in 2021.

Average hours of training per employee[87]

In 2021, as in previous years, paid even more attention to employee education. On average, a Lek employee received **83.6 hours** of training or **10.5 days**, which is 21% more than in 2020.

Average hours of training per employee



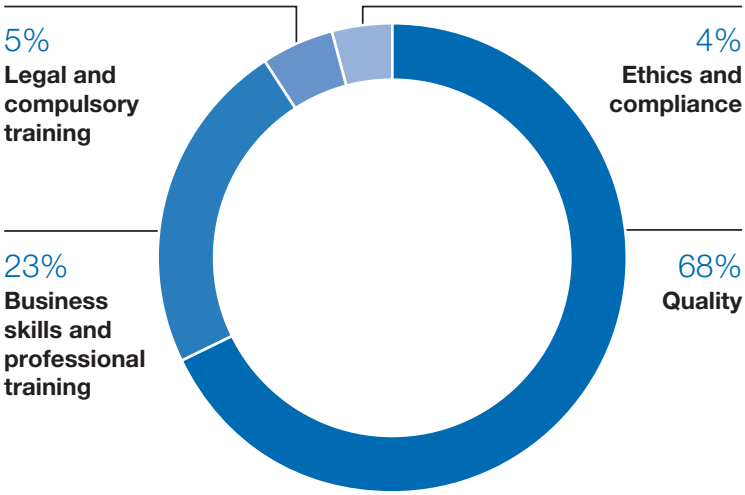
87 GRI GS 404-1

Training by area

Due to the COVID-19 pandemic 2021 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.

At Lek, we also enable our employees to study part-time. In 2021, we had 53 associates in undergraduate education and 78 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:



GRI content index

This report has been prepared in accordance with the GRI Global Standards: Core[88]

GENERAL STANDARD DISCLOSURES				
GRI standard	Disclosure	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	6		
102-2	Activities, brands, products and services.	24		
102-3	Location of headquarters	6		
102-4	Location of operations	25		
102-5	Ownership and legal form	22		
102-6	Markets served	24		
102-7	Scale of the organization	7, 82		
102-8	Information on employees and other workers	82	8 12	6
102-9	Supply chain.	46		3, 4, 5, 6, 8, 10
102-10	Significant changes to the organization and its supply chain.	25, 30, 46		
102-11	Precautionary Principle or approach.	33, 49		7
102-12	External initiatives	33		
102-13	Membership of associations.	33		1, 8
Strategy				
102-14	Statement from senior decision-maker	Letter from the President of the Board of Management		
Ethics and integrity				
102-16	Values, principles, standards and norms of behavior	44	16	1, 2, 3, 4, 5, 6, 8, 10
Governance				
102-18	Governance structure	31		
Stakeholder engagement				
102-40	List of stakeholder groups	38, 40		
102-41	Collective bargaining agreements	82	8	3
102-42	Identifying and selecting stakeholders	38		
102-43	Approach to stakeholder engagement	38, 42		
102-44	Key topics and concerns raised	40, 42		
Reporting practice				
102-45	Entities included in the consolidated financial statements.	30		
102-46	Defining report content and the topic Boundaries	30		
102-47	List of material topics	92		
102-48	Restatements of information	30		
102-49	Changes in reporting	30		
102-50	Reporting period	30		
102-51	Date of most recent report	July 2021		
102-52	Reporting cycle	30		

88 GRI GS 102-47, 102-55

102-53	Contact point for questions regarding the report	6			
102-54	Claims of reporting in accordance with GRI Standards	92			
102-55	GRI content index	92			
102-56	External assurance	30			

SPECIFIC STANDARD DISCLOSURES

Management approach disclosures	Topic-specific disclosures	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	4			
201-1	Direct economic value generated and distributed	7			
201-3	Defined benefit plan obligations and other retirement plans	82			
201-4	Financial assistance received from government	7			
GRI 202: : Market presence 2016					
103-1	Explanation of the material topic and its Boundary	4			
202-2	Proportion of senior management hired from the local community	82			
GRI 204: Procurement practices 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	47			
204-1	Proportion of spending on local suppliers	47			
GRI 206: Anti-competitive behavior 2016					
103-1 103-2	Explanation of the material topic and its Boundary	44			
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	45			
ENVIRONMENTAL TOPICS					
GRI 301: Materials 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	54			
301-1	Materials used by weight or volume	54		EMAS Core Indicator	
GRI 302: Energy 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	49			
302-1	Energy consumption within the organization	57		7 8 12 13	7, 8, 9
302-3	Energy intensity	57		7 8 12 13 EMAS Core Indicator	8
302-4	Reduction of energy consumption	61		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	50			
303-1	Interactions with water as a shared resource	62		6 12	7, 8
303-2	Management of water discharge-related impacts	62		6 12	7, 8, 9
303-3	Water withdrawal	62		6 12 EMAS Core Indicator	7, 8, 9
303-4	Water discharge	75		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	50		EMAS	
305-1	Direct (Scope 1) GHG emissions	72		3 12 13 14 15	7, 8
305-2	Energy indirect (Scope 2) GHG emissions	72		3 12 13 14 15	7, 8
305-4	GHG emissions intensity	72		13 14 15	8
305-5	Reduction of GHG emissions	61		13 14 15	7, 8, 9
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	71		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	50		EMAS Core indicator	
306-1	Waste generation and significant waste-related impacts	65, 67, 69		3 6 12 EMAS Core indicator	7, 8
306-2	Management of significant waste-related impacts	65, 67, 69		3 6 12 EMAS Core indicator	7, 8
306-3	Waste generated	65, 67, 69		3 6 12 EMAS Core indicator	7, 8
306-4	Waste diverted from disposal	65, 67, 69		3 6 12 EMAS Core indicator	7, 8
306-5	Waste directed to disposal	65, 67, 69		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	50		3 12	
307-1	Non-compliance with environmental laws and regulations	50			
GRI 308: Supplier environmental assessment 2016					
103-1 103-2	Explanation of the material topic and its Boundary	47, 53			
308-2	Negative environmental impacts in the supply chain and actions taken	47	The environmental responsibility of suppliers is one of the important criteria in the process of procurement and choosing suppliers.		
SOCIAL TOPICS					
GRI 401: Employment 2016					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	81			
401-1	New employee hires and employee turnover	82		5 8	6
401-3	Parental leave	82			
GRI 403: Occupational Health and Safety 2018					
103-1 103-2 103-3	Explanation of the material topic and its Boundary	83			
403-1	Occupational health and safety management system	83			
403-2	Hazard identification, risk assessment, and incident investigation	83			

403-3	Occupational health services	87			
403-4	Worker participation, consultation, and communication on occupational health and safety.	87			
403-5	Worker training on occupational health and safety	87			
403-6	Promotion of worker health	87			
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	42			
403-9	Work-related injuries	84		3 8	
403-10	Work-related ill health	87		3 8	
GRI 404: Training and education 2016					
103-1 103-2	Explanation of the material topic and its Boundary	87			
404-1	Average hours of training per year per employee	90	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	44			
406-1	Incidents of discrimination and corrective actions taken	45			
GRI 412: Human rights assessment 2016					
103-1 103-2	Explanation of the material topic and its Boundary	44			
412-2	Employee training on human rights policies or procedures	45			1
GRI 413: Local communities 2016					
103-1 103-2	Explanation of the material topic and its Boundary	42			
413-1	Operations with local community engagement, impact assessments, and development programs	42	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	47		5 8 16	
414-2	Negative social impacts in the supply chain and actions taken	47	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	42			
417-1	Requirements for product and service information and labeling	42	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	42			
417-3	Incidents of non-compliance concerning marketing communications	42			

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 2021 – Lek d. d.** chapters: Company profile, Stakeholder review and involvement, Cooperation with suppliers, Environment and Training and education" reflects a reliable, credible, and correct image of all organisation's 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

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Gregor Schoss:
Director of SIQ Ljubljana

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

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Glossary of key terms

EMAS (ECO – Management and Audit Scheme)

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

GRI (Global Reporting Initiative)

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

RCI (Responsible Care Initiative)

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

Generics are successors to pharmaceutical products whose patent protection has expired. A generic drug is a drug product that is comparable to a reference listed drug product in quality and quantity composition, active ingredient and dosage form, its bioequivalence being proven by means of respective bioavailability studies.[89]

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

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

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

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

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

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.

lek

a Sandoz company