Empowering a society of knowledge

Sustainability Report 2022
Lek d.d.

lek
a Sandoz company

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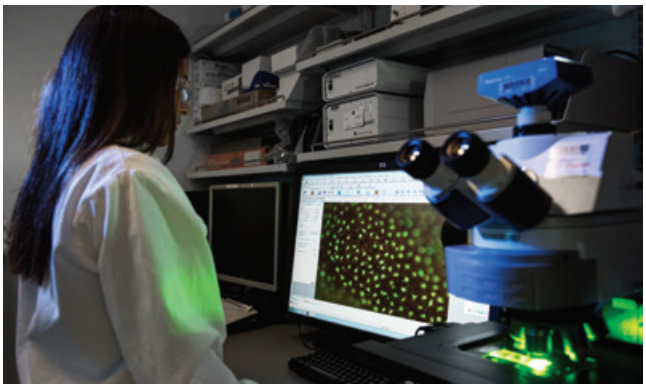

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* The EU Ecolabel or EU Flower the manufacturer's commitment to continual environment management improvements.

2022 Highlights

1,549 million EUR

net sales in 2022, 22% more than 2021.

5,771

employees at the end of 2022, 7% more than 2021.

74.2 hours

of education and training per employee in 2022.

4.65 million EUR

saved thanks to 239 submitted and implemented Th!nk Novartis ideas in 2022.

– 2.4%

decrease in hazardous waste in 2022.

10.5 million EUR

investment in environmental protection in 2022.

49.6 TJ

of energy and 4,463t CO_2 saved thanks to numerous environmental projects in 2022.

In 2022, we successfully completed our strategic goals and key objectives despite the complex environment and in the face of intense processes of internal transformation.

Robert Ljoljo

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

However, with knowledge, the successful digitization of our operations and thanks to our diligent colleagues at all four sites, we successfully responded to the needs of Novartis and the international market and designed new solutions. We developed and produced pharmaceutical products for patients all over the world; providing a constant supply of safe and high-quality medicines without interruption despite inflationary pressures, rising costs of energy products and internal organizational preparations for the separation of Sandoz.

With the new strategy Lek, a member of the Sandoz group, will focus entirely on generics and biosimilars, while Novartis, which in Slovenia will come to life as an independent company in the second half of 2023, will focus on innovative medicines. Both will continue their operations and intensive development in Slovenia. They will keep efforts to improve patients' quality of life and access to treatment at the forefront while maintaining a sustainable business orientation.

Record investments in 2022 illustrated the extraordinary trust earned by our associates. Novartis invested 346 million euros in Slovenia to strengthen development and production capacities, which was reflected in the scope of new projects. We started construction of a new facility in Ljubljana, which will house the production of aseptics – vials and syringes. In Ljubljana Aseptics, we installed a new modern filling line for nasal sprays, we also acquired a new vial packaging line and an optical controller for automatic vial inspection. Ljubljana Solids started production of the innovative medicine Eucreas on a completely new production line with HME technology.

Record investments in 2022 illustrated the extraordinary trust earned by our associates.

New and long-term plans were also confirmed in Drug Substance Bioproduction Mengeš. These bring investments for the construction of laboratories for Manufacturing Sciences and Technologies and viral vector production units, as well as the expansion of production with new

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bioreactors. A new Biologics Center will also be created in Mengeš, which will include clinical manufacturing to support the early phase clinical trials. The breadth of our development momentum is evidenced by Sandoz's decision to invest 400 million euros in a new high-tech production of biosimilars, which will create around 300 jobs in Lendava and is expected to start operating in 2026. This largest investment in Lek's history is also one of the largest foreign direct investments in the country so far.

Increased operations in 2022 was accompanied by careful management of environmental impacts. We allocated 10.5 million euros for investments in environmental protection, the most in the last decade. Through projects to improve energy efficiency, we saved 49.6 TJ of energy at all four locations. With our active energy management, despite the growth of business, we successfully reduced the total energy consumption by 3.4%, and the total amount of greenhouse gas emissions (scope 1 and 2) by 4.4%. We increased water consumption by 1%, which we regard as a favorable result, since the changed range of our products is more energy and water intensive. The amount of waste generated increased by 1.8%, while the amount of hazardous waste was reduced by 2.4%. Once again, we successfully passed the ISO 14001, the demanding EMAS and the ISO 45001 assessments.

Our sustainability culture was built by our colleagues at all levels. We ended the year in which 374 new employees joined us, with 5,771 full-time employees. We dedicate a number of programs to their advancement and well-being, as well as to the acquisition and retention of personnel, with which they can balance their professional and private lives and develop their talents. We are extremely proud of the awards we have received for outstanding quality in the field of human resources. For the third year in a row, and for the fourth time in total, we were delighted to receive the title of the most reputable employer in Slovenia and the prestigious international certificate »Top Employer« for the best employer both at the Slovenian and European level, also for the third time in a row.

Our commitment to innovation, excellence and connectivity has once again been recognized and rewarded.

We have taken important steps towards a more inclusive and diverse organization. Among other things, we undertook a gradual renovation of the premises, which will ensure accessibility for people with physical disability. We strengthened our collaboration with employment centers and companies that employ disabled people, and equipped employees with knowledge and skills for better integration and creation of a safe space in the company for which we received the certificate of Disability-Friendly Employer.

Our commitment to innovation, excellence and connectivity has once again been recognized and rewarded. We received the »Best of the Best« award from the American Chamber of Commerce for a joint project together with the Ljubljana University Incubator and the University of Ljubljana, Industry and University – Together we are building a society of knowledge and well-being. Such awards are a great encouragement to us, as our activity and development are closely intertwined with partnerships with domestic and foreign scientific research institutions. Over many years of operation, we have created a wide range of collaborations; research projects, final theses, practicums, hackathons, summer schools, international consortia and exchange of expertise. All of these are ways in which we nurture mutual contacts, meet new talents, supplement our knowledge and experience, and above all, lay new foundations for future challenges and opportunities.

We are embarking on a new chapter, for which we are well prepared. We will continue to co-create the society of knowledge and contribute to solving global health challenges.

Robert Ljoljo,
President of the Lek
Board of Management

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):
21.100 Manufacturing ob basic pharmaceutical products
21.200 Manufacturing pharmaceutical preparations
Registered at: District Court in Ljubljana
under entry number: 1/36542/00

Telephone: + 386 1 580 21 11
Fax: + 386 1 568 35 17
E-mail: info.lek@novartis.com
Website: https://lek.si/en/

Contacts

Legal Representative:
Robert Ljoljo, President of the Board of Management

Qualified person:
Eva Podgoršek, Head of Health, Safety and Environment (HSE) Slovenia;
eva.podgorsek@novartis.com

Contact person for reporting on sustainable development:[3]
Mojca Potočnik, Environment Safety Authority;
mojca.potocnik@sandoz.com

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Key data for 2022

Performance in 2022

Key performance figures[4]

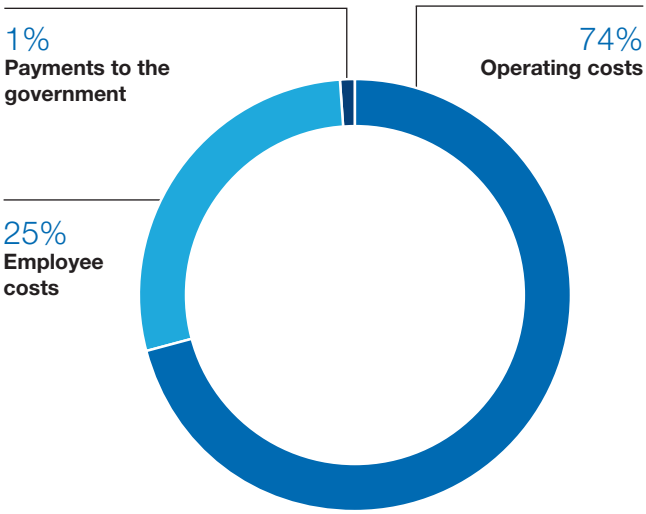
Indicator	Unit	31. 12. 2022	31. 12. 2021	31. 12. 2020	Index 2022/2021
Number of employees		**5,771**	5,397	4,823	107
Ljubljana site		**3,467**	3,189	2,755	109
Mengeš site		**1,378**	1,268	1,134	109
Lendava site		**720**	712	699	101
Prevalje site		**197**	218	226	90
hired warehouse		**9**	10	9	90
Net sales	mil. EUR	**1,548.608**	1,270.235	1,184.431	122
Liabilities	mil. EUR	**1,673.539**	1,470.291	1,231.563	114
Capital	mil. EUR	**1,259.147**	1,086.285	940.771	116

Economic performance[5]

In 2022, Lek created 1,548.608 Euros of net sales, this represents a 22% increase compared to the previous year (1,270.235). Net profit for the accounting period amounted to 163.665 million Euros (147.010 in 2021).

Direct economic value reached 1,598 million Euros (1,299 in 2021), of which 85% (1.358 million Euros) was **economic value distributed**. The largest proportion, 71%, representing **Operating Costs**, which reached 1,011 million Euros. **Employee Costs** were 333 million Euros (25%), **Payments to Government** amounted to 13.5 million Euros (1%). **Payments to Providers of Capital** were not made. We received 233,000 EUR of subsidies directly from the state (35,000 in 2021).[6]

Structure of economic value distributed



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Major environmental and social impacts[7]

Indicator	Unit	31. 12. 2022	31. 12. 2021	31. 12. 2020	Index 2021/2020
Energy efficiency	GJ/t	**823**	1,039	1,122	79
Water efficiency*	m^3/t	**803**	659	626	122
Amount of waste – efficiency	t waste/ t product	**11.3**	9.1	8.9	124
VOC emissions – efficiency	t VOC/ t product	**0.016**	0.016	0.022	100
LTIR** – Lost time injury and illness rate		**0.52**	0.32	0.34	162

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

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

Highlights and milestones of Lek's performance in 2022

In 2022, intensive investment in the increase and renovation of existing production capacities continued in order to achieve greater productivity, adapt to market needs and regulatory requirements, and ensure new development capacities. The investments are the result of outstanding achievements and agility, excellent process quality and effective management of the sustainable aspects of the business and represent an excellent foundation for the future business of Novartis and Sandoz.

Key performance highlights in 2022:

- At production sites in Slovenia, we launched **800 new products** with 83 different molecules in more than 80 countries around the world. We produced and packaged **64 innovative medicines**.
- Novartis **allocated a record 346 million euros for investments** in Slovenia in 2022. Most of the investments were aimed at strengthening development and production capacities in the direction of greater digitization and automation, as well as the modernization and upgrading of existing capacities:
  - We have started the construction of a new facility in Ljubljana, where the production of aseptic products - vials and syringes - will take place.
  - An investment of US$110 million has been announced to build a new Biologics Development Center in Mengeš, which will enable new development capabilities, including clinical manufacturing to support early stage clinical trials.
  - We allocated 10.5 million euros for investments in environmental sustainability, the most in the last decade.
- The Mengeš biological active ingredient production unit received the honored title of **Factory of the Year 2022** and recognition for the most sustainably oriented factory, awarded by the Finance newspaper.
- We **increased the number of employees by 374**. At the end of the year, there were 5,771 full-time employees in Lek and more than 5,800 in Novartis in Slovenia.
- For the third consecutive year, for the fourth time in total, we have been awarded the title of the **Most Reputable Employer in Slovenia**, by MojeDelo.com. For the third year in a row, the independent institution Top Employers Institute recognized our personnel excellence and awarded Novartis Slovenia the prestigious international certificate **»Top Employer« for the best employer** both in Slovenia and Europe.
- In all four pillars of the strategy (Disabled Persons, LGBTQI+ Community, Intergenerational Cooperation and Diverse Talents), we have taken important steps towards a more inclusive and diverse organization. Among other things, we adapted several locations for people with disabilities and received the title of **disabled-friendly company** and joined the network of **dementia-friendly institutions**.
- We introduced and enabled Slovenian patients to be treated with new and breakthrough medicines:
  - In less than a year since launch, more than 300 patients have received our breakthrough medicine inclisiran (Leqvio) for the treatment of elevated LDL cholesterol, and more than 130 patients with multiple sclerosis have received ofatumomab (Kesimpta).
  - The most advanced cell and gene therapies are also available to Slovenian patients. Five patients received CAR-T therapy to treat blood cancer, and two patients received gene therapy for spinal muscular atrophy.
  - We published a website www.rakdojk.si for breast cancer patients and their caregivers
- We renewed the requirements of the **RCI** responsible management certificate and regulation ES122/2009 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**.

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Health, safety and environment (HSE) objectives

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

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

Special attention is paid to efficient use of natural resources, reducing the climate change and environmental impacts of its activities and products throughout the life cycle. 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.

General and specific HSE objectives are determined by site 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. 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) and HSE net. We are constantly improving the efficiency of our environmental management by including all employees, 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 water use).

Realization of short-term Lek's HSE objectives in 2022*

Area	Indicator	Target	Status 2022
Health and Safety	Serious injuries and fatalities (SIF)	0	0
	Walkthrough inspections per 200,000 working hours	>15	37
	Employee exposure to chemicals and other hazardous substances that exceed the permitted values	0	0
Environment	Decrease energy use	Mengeš ≥ 4% than 2021 Prevalje ≥ 2% than 2021 Lendava ≥ 3% than 2021 Ljubljana ≥ 4% than 2021	Mengeš: – 7% Prevalje: – 9% Lendava: – 1% Ljubljana: – 1%
	Decrease water use	Mengeš ≥ 4% than 2021 Prevalje ≥ 2% than 2021 Lendava ≥ 3% than 2021 Ljubljana ≥ 4% than 2021	Mengeš: + 7% Prevalje: – 9% Lendava: – 4% Ljubljana: + 2%
	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	Mengeš: + 3% Prevalje: – 29% Lendava: + 2% Aseptics Ljubljana: – 5% Solids Ljubljana: + 4%
Corrective measures	Actions implemented after inspection	100%	100%
	Number of overdue larger or critical actions (CAPA)	0	0

* When achieving the objectives in Ljubljana, it must be taken into account that the location expanded its scope and activity in 2022. In Mengeš, water consumption was higher due to a higher number of validations. Environmental indicators are being monitored at all locations in 2023 as well, the annual objectives will be determined at a later date due to the planned division (spin-off).


EVA & FRANCO
MATTES
DEAR
IMAGINARY
AUDIENCE

A high reputation is a reflection of a sustainable approach

Lek has received several awards for human resources, amongst those recognition as Top Employer 2022. From left: Darija Brečevič, Jure Vajs, Iris Slamič, Robert Ljoljo, Paulina Pazio, Mojca Pavlin and Tea Vizjak Kvas.

Over the years, we have received numerous domestic and foreign awards for the quality of our HR management. To understand why this is the case and how we build human resources, we spoke to Paulina Pazio, People and Organization Head for Lek and Sandoz Slovenia, and Darija Brečevič, People and Organization Head at Novartis in Slovenia.

Novartis' culture is inspiring, curious and empowering. It sounds simple, but the path to achieving it is probably not so easy.

Darija Brečevič: Many elements contribute to building this culture; an important element are leaders who build culture in their teams and that have to be role models for their colleagues. That is why we dedicate a lot of attention to their education and training and there are many other tools to help them. We measure employee engagement with the quarterly Our Voice survey, in which every employee can participate. Leaders are responsible for talking to their teams about how we see our shared culture and what each of us is responsible for in the process of building it. Individual conversations, which are part of performance management and within which we set long- and short-term goals, also contribute to this.

Paulina Pazio: The Energised for Life program, which takes care of the physical, mental and social well-being of employees, is a key building block of our culture. Diversity and inclusion programs, which enable employees to be who they are, also make a significant contribution. It includes gender equality, inter-generational and intercultural collaboration of people from different countries and backgrounds, and efforts for equal opportunities for people with special needs.

What opportunities do employees have for personal and professional development and advancement?

Darija Brečevič: The development of our colleagues is planned strategically. We have established a methodology for their targeted advancement. Colleagues have many tools at their disposal for achieving growth, e.g., the Coursera program, where they can choose any virtual course from our portfolio and the TalentMatch platform, where they can explore opportunities within the global company. They can develop their career together with mentors and we also have special programs for researchers. An important element is learning through experience in different job positions. The process sometimes already starts when a student is preparing their university thesis with us and then gets a job and advances in the company. They can focus either on a research or technical career or other support positions. As a global company, we offer opportunities for professional development, leadership and working with people, in countries around the world.

Paulina Pazio: There really are a lot of programs available to employees, they are intended both for managers and for the development of individuals, to improve their technical skills and competencies needed not only today, but also in the future. Digitization, which is becoming more and more important in our industry, is being given a lot of attention at all levels.

How do you identify and develop talents?

Paulina Pazio: Talents are identified through an internal standardized organizational process. This includes identifying key talents in each unit and planning development opportunities for them.

Novartis Slovenia has received numerous HR awards, including Top Employer 2022. In your opinion or according to research findings, what is decisive for achieving high employee satisfaction and winning awards?

Paulina Pazio: These kinds of awards mean a lot to us, as they reflect our constant dedication to our colleagues. I believe that the high reputation we enjoy as an employer comes from our commitment to the made promises and to fulfilling them. Employees are always at the forefront. Managers are committed to supporting them, we recognize their efforts and contributions through the salary and rewards system, we provide development opportunities through employment and learning as well as opportunities to obtain higher education, internships and scholarships. We start building our reputation with the very young generations and maintain the commitment of our employees.

Darija Brečevič: It is true, it is a long-term, sustainable approach to working with employees.

Paulina Pazio: It is worth pointing out that we are a local company with a very important heritage and at the same time we use the benefits of being a part of a multinational company in which we implement global programs that are well received by employees.

There is also a growing shortage of skilled labor in Slovenia. The new investments in Mengeš and Lendava will require employing new expert personnel from various fields. How do you usually attract new personnel?

Darija Brečevič: With such large investments, it is necessary to think long-term. In a few years, when, according to the plans, the work in laboratories and the production will begin, it will be too late. We have already started recruiting talents and determining where and how to attract them. We always use this sustainable and long-term approach. We look for staff in various ways: from collaborations with high schools and universities to providing scholarships, opportunities for students to learn about our work and opportunities for employment of colleagues from other countries.

Paulina Pazio: We have a very good team in strategic programs, which works on identifying talents by connecting with scientific research institutions. Our internal innovation initiatives and programs are highly recognized. We also maintain and develop partnerships with academic institutions, not only in Slovenia, but also in neighboring countries. We have partnership agreements with universities in the region, we actively participate in the Erasmus program and are present in technical high schools. We also collaborate with recruitment agencies and career fairs and we organize internal events to promote our company, such as BioCamp and ScienceBeat. We are trying to show young people that Lek, that is Novartis and Sandoz, are an excellent place for their future work.

According to surveys, such as the Mojedelo survey, we are a highly desirable company among job candidates. We are convinced that with a sustainable model we will be able to attract young talents. Recruiting hundreds of new employees will not be easy, not only due to market restrictions, but also due to high expectations on our side. Our workplaces are demanding, many policies and procedures need to be learned and everyone has to complete many trainings.

Darija Brečevič: I completely agree. Let me just add that we are part of a highly regulated industry. Also work in production requires a lot of training and knowing the procedures. That is why onboarding is so important.

Partnerships supporting new knowledge and talent development

At Lek, we nurture long-standing partnerships with Slovenian universities as well as domestic and foreign research institutes. This allows our experts to share and expand their knowledge, develop talents and together create breakthrough solutions to improve the health of patients around the world.

Klemen Kreft, Scientist in pharmaceutical development from Sandoz Development center Slovenia.

Klemen Kreft is a scientist in pharmaceutical development from the Sandoz Development center Slovenia. He manages the process development and the technology transfer of solid and liquid dosage forms from the development to the production environment. In a conversation with him, he shared his view and the advantages of established partnerships with scientific research institutions.

You have participated in several research projects with the academic sphere and competitions such as Biocamp. Why?

I am a big supporter of collaboration with external institutions for two main reasons; to spread knowledge and develop talents. In my experience, external stakeholders contribute a different type of knowledge than we have. We often find ourselves in established ruts, where we are unable to see the solution that is in front of us. Through collaborations we resolve research challenges from different angles. If I consider all of my collaborations, I believe they gave me the greatest opportunities for career growth. Hence I feel responsible for giving back to younger generations, encouraging their curiosity as well as professional and personal growth. In this way, the cycle of acquiring knowledge continues. Moreover, the company is strengthening its reputation and solidifying relationships with new talents.

Lek's work with academia and scientific research institutions is extensive. What is the purpose of established partnerships? What are the advantages of researchers in industry and those in independent external scientific research institutions?

Lek has a contractual relationship with all three Slovenian universities. At Development center Slovenia,

we primarily collaborate with the natural sciences faculties of the University of Ljubljana and Slovenian and foreign institutes. In my opinion, working with the academic sphere is crucial. Our joint achievements contribute to the exchange of expertise, the development of colleagues, growth and innovation.

In companies, we are partly limited by short project timelines and by being result oriented. Hence, we cannot delve into fundamental research and theoretical frameworks, whereas the academic sphere is limited in reaching practical application and by lesser familiarity with market needs. This gap connects us and creates opportunities for collaborations. By working together, we enable the transfer of research knowledge into practice, while academic institutions coordinate their research efforts with market needs.

What are the achievements of joint integration and collaboration with external institutions?

I would like to highlight our now traditional event, Researcher's Day, where we celebrate our greatest achievements with our academic partners by giving short presentations. Under the auspices of Slovenian universities, the event has grown into the online science festival UNI.MINDS. Today it represents a meeting point for interlacement of knowledge in companies, start-ups and academic institutions. The main goal of the project is to establish a research community that encourages open communication, exchange of good practices and cooperation between spheres. Such ecosystem positively impacts the wider society and strengthens development opportunities in Slovenia. The contribution of Lek and Novartis in Slovenia was recognized as the best business practice with the Best of the Best 2022 award, which is awarded by the American Chamber of Commerce in Slovenia.

Where do you see opportunities for an even closer relationship between science and the Slovenian economy?

I think that most affiliations with academic institutions are based on short-term projects. It is clear that companies are protecting their competitive advantages from others. But the economy can get caught in its own loop and forgo the benefits of working with external partners to ensure data protection. I believe we should think more long-term and form strategic partnerships based on mutual trust.

Jure Vajs, Maša Abrič (University of Ljubljana Incubator), Darja Ferčej Temeljotov, Klemen Kreft and Neja Lenart Dvoršak accepting the Best of the Best award for the Industry and University – together building society of knowledge and well-being project.

Advanced molecular biological tools will lead to higher quality medicines

»Genesis Labs is a testament to Novartis' unwavering commitment to advancing healthcare, and underlines the company's belief in the potential of internal start-ups to revolutionize drug development« highlights project manager, Aleksander Krajnc.

Novartis' Genesis Labs program invites innovators to think outside the box and thereby contribute new approaches to drug development. This vital platform for internal start-ups has funded 15 projects to date. The team from Biologics Technical Development Mengeš, led by researcher Aleksander Krajnc, was one of four newly selected projects that received funds for the development of an efficient method to remove host cell protein impurities from innovative medicines.

Your team from Biologics Technical Development Mengeš was included in the Genesis Labs program for the »Journey to impurities-free innovative medicines« project. Can you share the goal of the project with us?

One of the challenges we face in the development of innovative medicines is the presence of impurities, specifically host cell proteins (HCPs). Although these impurities are typically eliminated during the development process to meet regulatory requirements, there is still a possibility of residual HCP impurities causing issues. This can potentially impact the safety profile and quality of the medicine, consequently affecting patient health.

Our project aims to develop a method or »lens« to detect problematic protein impurities, which could aid later in discovering the means (“the recipe”) to eliminate them. The current industry standard for the development and release of innovative drugs, the ELISA method, is inadequate. It only provides information about the quantity of impurities present, offering no insight into their identity. On the other hand, proteomic methods, which can usually identify critical impurities, tend to be expensive and complex.

To overcome those limitations, we aim to capitalize on the advancements in molecular biological technologies, which have gained prominence in various scientific disciplines. By harnessing these cutting-edge tools, we can develop the “lens” with enhanced capabilities. Moreover, by combining this »lens« with an artificial intelligence system capable of identifying critical impurities, we can introduce an additional safety measure into the biologic drug development process.

What do you expect from being part of the Genesis Labs program and this kind of collaboration?

The program is meticulously organized, allowing for multidisciplinary, cross-functional, and cross-site collaboration to address complex problems from various perspectives. Given the nature of these challenges, a comprehensive approach is crucial since partial solutions often fail to yield desired outcomes. This synergy nurtures our shared mindset, knowledge, and relentless pursuit of scientific progress. Furthermore, we have substantial funding at our disposal to bolster the project, enabling us to venture into uncharted territory, take calculated risks, and push the limits of scientific innovation.

It is through the power of networking and financial support that we can transform revolutionary ideas into transformative and innovative breakthroughs.

What possibilities are there for Novartis experts in Slovenia and globally to connect and think beyond established frameworks?

Within Novartis, there are abundant opportunities for experts to engage in networking and brainstorming, fostering innovation and collaboration.

We facilitate various internal events, such as conferences, symposia, and workshops, bringing together experts from diverse departments, functions, and geographical locations. These gatherings serve as platforms for connecting, exchanging ideas, and leveraging collective intelligence to tackle complex challenges. Novartis actively cultivates an innovative culture, encouraging employees to actively participate in innovation programs and initiatives that push the boundaries of conventional thinking. Through open innovation platforms, experts have the chance to explore unconventional approaches, collaborate with colleagues worldwide, and contribute to transformative solutions in drug development.

Additionally, Novartis actively collaborates with external partners, including academic institutions, research organizations, and industry associations. By combining these diverse opportunities, we foster a vibrant and dynamic ecosystem dedicated to collaboration, knowledge sharing, and pushing traditional boundaries. These interactions and initiatives create a culture of continuous learning, innovation, and research, positioning Novartis as a leading force in the global development of innovative medicines.

Researchers from Biologics Technical Development, who are included in the Genesis Labs program.
From left to right: Alexander Hanke, Matjaž Vogelsang, Aleksander Krajnc and Monika Pintar-Hitzl.

Circular economy principles are front and centre

Solids Lendava warehouse team dispatching the first drums from Lek to Singapore. This project successfully reduced waste by 175 tons.
From left: Damir Lukežić, Aleš Cigut, Goran Zavec, Kristjan Gabor.

At Novartis and Lek, we pursue ambitious environmental goals; plastic, water and carbon neutrality of the entire value chain. How does the team from Lendava contribute to these goals? We talked about this with Damir Lukežić, project manager in the production at Solids Lendava.

How do you and your colleagues manage the environmental impacts in the work processes, given that the production volume is constantly increasing? What role do circular economy principles play in this?

At Solids Lendava, we have set ourselves the goal, in all projects, to follow circular economy principles, to the greatest possible extent, so as to reduce our consumption of natural resources. At meetings, we regularly present project achievements or examples of good practice that have influenced the reduction of waste and water consumption, and examples of reuse and recycling. We want to stimulate curiosity so that circular

economy principles become second nature to each of our employees. This encourages proposals in the process of continuous improvements.

Even with new projects and products coming to Lendava, we always keep the principles of the circular economy in mind. In the past years, we have thus improved many products and processes when transferring products to Lendava. We reduce the environmental impact of product transfer in several ways; increasing the number of tablets on blister, for example, we can reduce the surface of the blister by 46% for one product. This allows us to better fill the surface of the packaging and eliminate unused space, which results in a reduction in the consumption of aluminium and plastic, and last but not least, a smaller volume when transporting the same amount of medication. By reducing the number of packages, i.e. the boxes containing the tablets, we contribute to a lower consumption of cardboard. We have already saved almost one ton of paper per year just by releasing paperless products.

Can you highlight a stand-out project that you implemented in 2022? Are there any bigger plans in the works for the coming years?

As I already mentioned, over the past years we carried out many projects that successfully reduced our environmental impact. Among the more significant ones is the return of metal drums to an internal supplier in Singapore. This project prevented the generation of 100 tons of waste in Lendava annually and returned around 30,000 metal drums to reuse. This was a completely new process for us involving a multidisciplinary team from production, warehouse, tax, finance, customs, treasury, to health and safety at work. We repeated this process with the new products that were transferred to Lendava from Germany. Since delivery began, we have been storing drums, which were then regularly returned to Germany for reuse. This also prevented the generation of 25 tons of metal waste.

In 2022, we established a similar return process of plastic drums to the internal supplier in Turkey. This prevented around 50 tons of plastic waste annually. We now return 70% of all metal and plastic drums to internal suppliers for reuse. Another improvement in production, we introduced washable coats in the primary part of the production line replacing disposable coats. This reduced the amount of hazardous waste by 14 tons, which is 6% of all hazardous waste in Solids Lendava. We also optimized cardboard boxes for transporting finished products from five-layer to three-layer cardboard. This change helped us to reduce the annual consumption of cardboard by 300 tons, or to illustrate, saved 5,100 trees from being cut down. Also, by redesigning the dimensions of the transport box for a customer in Germany, we delivered an average of 48% more finished products per pallet, which eliminated 25 deliveries annually.

Regarding future plans, I would like to highlight two projects with which we want to optimize our environmental impact. We plan to introduce a smaller size of anti-slip paper on the pallet between the cardboard boxes and reduce its annual consumption by 16 tons. We are also looking for opportunities to collaborate with companies for the processing of waste blisters and scraps, which would process them into raw materials for other industries.

Drums prepared for dispatch and reuse.

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 31.12.2022, Lek had 100% ownership share in Sandoz Pharmaceuticals d.d. and 74.5% ownership share in Wastewater treatment plant Lendava d.o.o. In 2022, there were no changes to the size, structure or ownership of Lek, moreover no merging activities or joint investments were made.

8 GRI 2-1

Mission

Reimagining medicine to improve and extend people's lives.

We use innovative science and technology to solve some of society's most challenging health challenges. We discover and develop breakthrough treatments and find new ways to bring them to as many people as possible.

Vision

To be the most valued and reliable 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.

Inspired

- Engage our people
- Strive for patients
- Live our purpose

Curious

- Learn
- Be open
- Be self-aware

Unbossed

- Create clarity
- Serve others
- Own your actions

Integrity

- Be honest
- Have courage
- Do what is right

Key customers and markets[9]

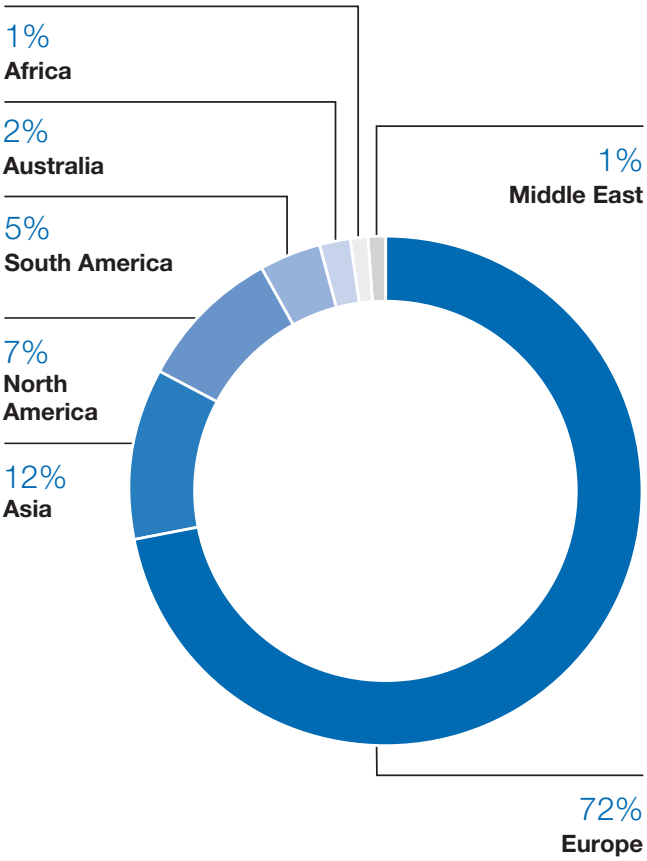
In accordance with organizational and strategic orientations, Sandoz Group and Novartis companies are the key buyers of our products and active pharmaceutical ingredients. In addition to our own products, we also sell Sandow and Novartis products.

The majority of our products were sold on the European market (72%). The majority of sales, 84%, came from pharmaceutical products, the remaining came from APIs and biopharmaceutical products.

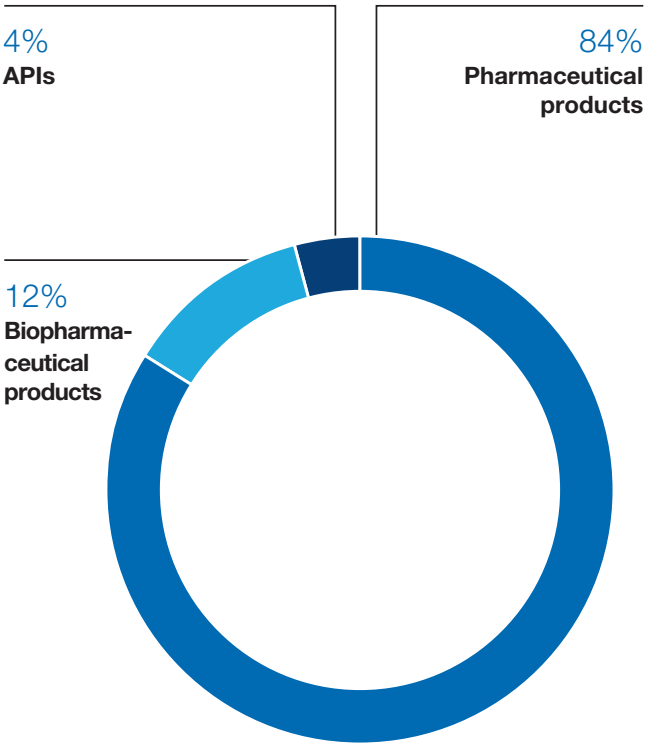
In the Slovenian pharmaceutical market, Novartis, with all its divisions, remains the leading provider of medicines with a 14% market share. Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 74% of sales. Lek is in first place on the market of over-the-counter medicines, second in the sale of generic medicines with a 29% market share.

9 GRI 2-6

Lek product markets by geographical region 2022



Sales structure by program 2022



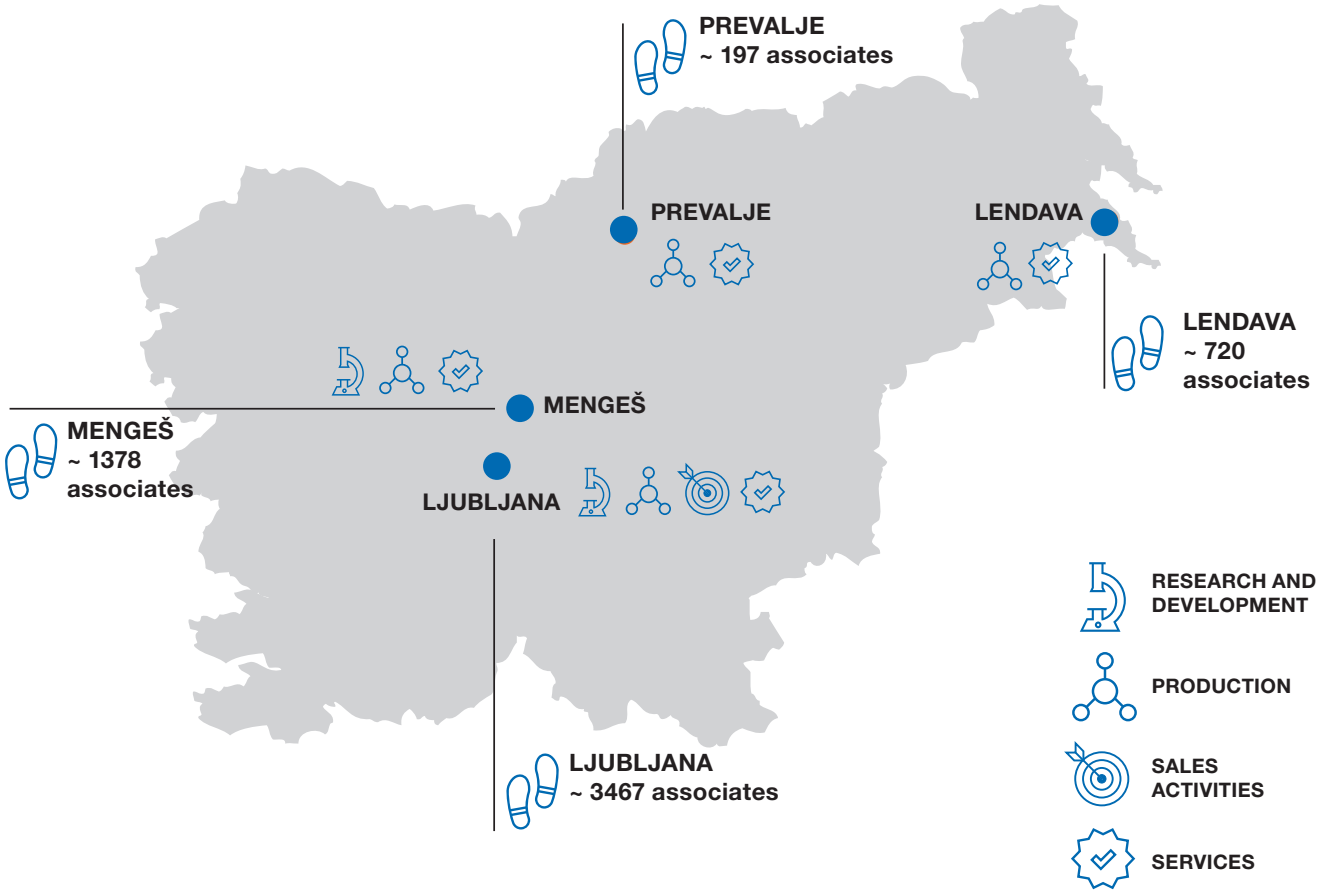
Major product groups and brands[10]

Our key therapeutic groups are:

- cardiovascular drugs,
- anti-infectives,
- drugs for the treatment of the urogenital tract,
- biosimilars for the treatment of growth disorders, neutropenia and anemia, rheumatoid arthritis, 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.

10 GRI 2-6

Development and production sites and processes[11]



Novartis and Sandoz 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

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

11 GRI 2-1, 2-6

Ljubljana site

Lek is headquartered in Ljubljana, where production takes place in two organizational units: Solids and Aseptics. The Ljubljana site also houses a business center where we manage several business services. These fields are Novartis Corporate Center, regulatory affairs, procurement, legal affairs, supplying, corporate communication, Novartis Pharma and Novartis Oncology and others. The leading and largest Sandoz development center and one of the largest Novartis production facilities also operate in Ljubljana.

Solids Ljubljana

In the unit, which is part of the Small molecules team, 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.

At the beginning of 2022, we were still seeing significant disruptions in the market due to the global pandemic, but with the dedication of our employees, we managed to successfully provide our medicines to customers and patients. We also produced a record number of batches (development, clinical and registration) for innovative and generic drugs and received regulatory approvals and started production of important oncology innovative drugs such as Promacta, Tafinlar and Votrient.

One of the most important milestones was the start of production of the innovative drug Eucreas on a completely new production line with equipment for hot melt extrusion (HME) technology and advanced analytical equipment such as NIR to measure the uniformity of the content of Eucreas tablets. We supported the introduction of new generic products, produced initial quantities and supported the resupply of Sitagliptin and Sitagliptin

Daniela Zaccara,
Head Solids Ljubljana

Metformin products. We also began packaging nine additional innovative products for the US market.

We continued process automatization by introducing an automatic packer for boxes with a palletizer on the packaging line and the introduction of a completely new automatic line dedicated to the packaging of products in doses and in pocket sets.

Quality and safety remain the foundation of our business, so we have successfully passed all inspections by health authorities and customers, including the very demanding US FDA inspection.

Aseptics Ljubljana

We produced 120 million ampoules, 20.3 million vial products and 20.1 million nasal sprays. Throughout the year, we implemented optimization projects, which increased productivity. We focused on optimizing the production of the biosimilar drug Rixaton, the product Ferumoxytol and the new product in our portfolio, Sugammadex.

We are proud of three new investments in 2022. At the end of the year, we installed a new modern nasal spray filling line, which will begin regular operation in the second half of 2023. We acquired a new packaging line in the packaging plant, where we will also pack vial products produced in aseptic production in Switzerland. The third

Tjaša Bantan Polak,
Head Aseptics Ljubljana

acquisition is an optical control for automatic inspection of vials.

At the same time, we focused on the development of two new biosimilars, one innovative biological drug and one demanding generic sterile product. In cooperation with our development center, we introduced a new nasal product and submitted an application to the US FDA for the registration of a new biosimilar drug, which is scheduled to be launched in 2024.

We successfully passed the inspections of both regulatory authorities and potential buyers and the internal inspection of the GCA, thereby securing new buyers of medicines.

Development Center Slovenia

The Development Center Slovenia specializes in the development of technologically demanding products and is the leading development center for generic drugs in Sandoz. At the end of 2022, it housed half of all global development projects of Sandoz, the generic division of Novartis. This is dominated by oncological drugs, drugs for the treatment of cardiovascular diseases, drugs for the treatment of diabetes, allergic rhinitis, migraines, insomnia, anemia, urological and stomach diseases, as well as non-steroidal anti-inflammatory drugs.

We have reached several important milestones in the field of digitization

Matjaž Tršek,
Head Development Center Slovenia

and automation. Completed initiatives in the areas of operational excellence and digitization contributed to cost reduction and added more than 5 million euros in value.

We organized various events that contributed to strengthening the culture of innovation, agility and visibility of our company and, last but not least, to the well-being of our associates.

Our experts have been achieving enviable success at the international level for many years and are deservedly the recipients of awards for breakthrough solutions in the development and production of demanding generic drugs. They cooperate with the Slovenian academic sphere and also in many international projects. 2022 was also very rich in the recognition of our work, as our associates once again received a series of awards for outstanding scientific achievements.

Mengeš site

Chemical Operations Mengeš

At Chemical Operations Mengeš, we closed the year with record production, to which the production of Everolimus SD and Ferumoxytol contributed significantly. We successfully started the production of Everolimus SD on an additional dryer and carried out important projects that contributed to the increase of productivity on both production lines.

Roman Pogačar,
Head Chemical Operations Mengeš

We completed the technological transfer of Iptacopan (LNP023) into production. With the Iptacopan project, we also introduced new analytical methods. After the validations were completed, we performed a Mock PAI inspection, which means that we will also be included in the primary regulatory role as a production site. In the Mengeš Pharmaceuticals Quality Department, we have introduced routine testing of lithium carbonate with ion chromatography. For the third consecutive year, we renewed the NOSSCE Class A certificate and underwent an in-depth Novartis assessment of standards in the field of health, safety and the environment.

Drug Substance Bioproduction Mengeš

At Drug Substance Bioproduction Mengeš, we produce active ingredients for biological and biosimilars. In 2022, investments were confirmed in our unit for the construction of new MS&T (Manufacturing Science and Technology) laboratories, virus vector production units and the expansion of production with new bioreactors. We filed a registration dossier with the US Food and Drug Administration (FDA) for Denosumab, completed the transfer of Hyrimoz, and produced multiple clinical runs of many new drugs. High yields were recorded on both erythropoietin production lines. We also carried out a project to prepare production reports in electronic form.

Polonca Kuhar, Head Drug Substance Bioproduction Mengeš

The year was once again dynamic in terms of assessments, both internal and external. We conducted an audit by the Public Drug and Medical Device Agency, the South Korean Drug Agency, and Novartis' internal inspection in preparation for the FDA audit.

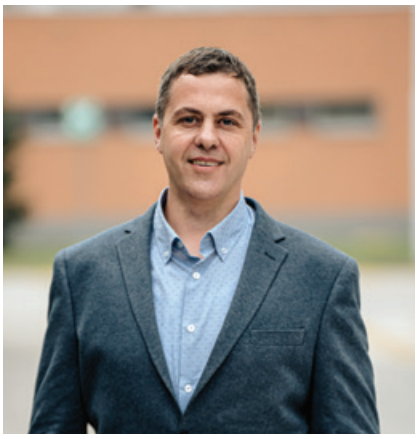
Biologics Technical Development Mengeš

With an investment of US$110 million in clinical manufacturing and technical development capabilities, Novartis will establish a biopharmaceuticals development center in Mengeš. The announcement of the investment will have a significant impact on the future of Biologics Technical Development Mengeš, as it will strengthen our position in the development of biological medicines externally and within Novartis.

Throughout the year, around 30 development projects in various development stages took place in the unit, of which approximately half were for innovative biological medicines and half were for biosimilars. We have also successfully completed inspections and assessments, where the GMP inspection of the Public Agency of the Republic of Slovenia for Medicines and Medical Devices (JAZMP) is of great importance.

In addition to the increase in the volume of work, the number of employees also grew, which increased by 10 percent compared to

Špela Jalen, Head Biologics Technical Development Mengeš



Saša Sankovič, Head Anti-infectives Prevalje and Lendava

Simon Rečnik, PhD, Head Solids Lendava

last year. We pay a lot of attention to the culture of innovation and the Diversity and Inclusion initiative, and we are particularly proud of the successful inclusion of people with disabilities in the work process. We already work with 14 colleagues from the Most institute, and the infrastructure in the buildings has been further upgraded and adapted to the needs of persons with disabilities.

Reducing environmental impacts is an important part of our operations, which is why, among other things, we introduced the »My green lab« certification in all our laboratories. Nine departments and more than 200 employees participated in the program in 2022. The My green lab certification is considered the gold standard of best practices in the sustainable development of laboratories worldwide.

Prevalje site

The mission of the Prevalje site has been slowly changing throughout its rich history, but in 2022 we were operating smoothly and providing regular supply of medicines to patients at home and around the world. The broad-spectrum antibiotic Amoxiclav, which we produce on site, is sold in more than 75 of the world's most demanding markets.

Last year, we adjusted the volume of production to the dynamics of demand. We produced more than 306 million tablets, more than 25 million packages of our products and more than 300 tons of mixtures. Despite a greater turnover of employees, we ensured a reliable supply of quality medicines produced in a safe manner to patients from our location.

Lendava site

Anti-infectives Lendava

In Anti-infectives Lendava, we continued the production of two active ingredients - potassium clavulanate, the location's leading product, and gentamicin sulfate, which we produce in smaller quantities. The production of potassium clavulanate at full production capacity was slightly higher than planned. Record quantities were achieved in the production of API mixtures (potassium clavulanate with inert material), where we exceeded the planned production of 165 tons.

We confirmed a high level of quality and good practices and achieved the expected goals, while at the same time raising the safety of processes and the safety culture of employees. All customer reviews and the JAZMP review in 2022 were successfully conducted.

Solids Lendava

Solids Lendava is Sandoz's largest solid pharmaceutical packaging plant with more than 4,000 finished product codes, as well as one of the key suppliers to the Sandoz portfolio. We reached the set goals and made great strides in increasing efficiency, automation, digitization and innovation, and within the framework of the established Competitiveness Movement we ventured into the unknown and showed the way for others.

With 150 million packages on 25 packaging lines, we served patients in more than 150 markets worldwide in 2022. Of these, as many as 7.7 million packages were new products. We successfully and on-time launched new drugs: the innovative drug Tabrecta (Capmatinib) for the EU market and the drugs Sitagliptin HCL and Sitagliptin + Metformin HCL for the European and Australian markets.

We reduced the E2E flow time by more than 20% and the flow time from the start of packaging to the release of the drug to the market by more than 19%. By introducing the most affordable suppliers, optimizing the use of input materials and transport, we created high savings that strengthened our position as the leading packaging unit in Sandoz Services. Concern for a positive impact on the environment and improvement projects complement each other. When the projects were introduced, we thus reduced the amount of waste by a total of approximately 20 tons, which is 2% of the amount of all waste on an annual basis.

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 Standards. 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.

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.[12]

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 *Stakeholder overview and inclusion.*

We have not yet decided to seek external assurance for our GRI reporting. 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 in 2022[13]

When reporting, we use the international sustainability reporting standards GRI. For 2022, we used the latest version of the standards, which was issued in 2021. Within the framework of the Chemical Industry Association, we report according to RCI (Responsible Care) requirements. At the same time, we follow the requirements of Annex IV of Regulation (EC) no. 1221/2009 as amended (EMAS), whereby the prescribed indicators are disclosed at the level of Lek and for all four sites.

- Reporting refers to Lek and all its manufacturing sites in Slovenia and is prepared annually. All disclosures in the present report refer to the 2022 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 (AJPES).
- The objective of Lek's HSE reporting is compliant with Novartis' objectives to provide a fair and well-balanced picture of HSE. The system of monitoring HSE achievements and the reporting methodology are described on pages 85 and 86.
- The content structure of the Sustainability Report is comparable to previous annual reports of Novartis.
- In 2022, 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

EMAS

GRI

RESPONSIBLE CARE®
OUR COMMITMENT TO SUSTAINABILITY

SUSTAINABLE DEVELOPMENT GOALS

12 GRI 3-1
13 GRI 2-2, 2-3, 2-4, 2-6

Governance and management[14]

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

Board of Management

In 2022, the members of the Board of Management were as follows:

- **Robert Ljoljo**, President
- **Ksenija Butenko Černe**, Member – Legal Affairs
- **Andreja Bucik Primožič**, Member - Finance
- **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 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 employees in the Novartis internal Conflict of Interest Policy (the same applies to the supervisory board). In 2022, the Board of Management discussed topics within its competences at 30 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 2022, the members of the Supervisory Board were as follows:

- **Matthias Weber**, Chairman
- **Ingrid Sollerer**, Vice Chairman
- **Nastik Kumar Amit**, Member
- **Peter Svete**, Member – Workers' Representative (from 19. 1. 2022)
- **Fikret Bašanović**, Member – Workers' Representative (until 18. 1. 2022)
- **Manda Firm**, Member - Workers' Representative (from 18. 1. 2022)

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. In 2022, the Supervisory Board held 4 regular and 3 extraordinary sessions.

14 GRI 2-9, 2-10, 2-11, 2-14, 2-15, 2-18

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. In 2023, the company will adopt policies that further regulate the diversity of representation in these bodies.

Employee participation in company management[15]

Employee participation in company management is carried out in accordance with the Worker Participation in Management Act (e.g. ZDR-1, ZVZD-1, etc.). They exercise their duties and rights individually and collectively through the Workers' Council, Workers' Assembly and their representatives in the company's management bodies. Two representatives of the employees are the Supervisory Board members, while the Workers' Director is also a member of the Board of Management and represents workers' interest in human resources and social areas for a five-year term.

The Workers' Council serves as a form of collective and indirect participation of employees in the management of the company. It has twenty-one members that represent workers' interests, form opinions and forward proposals and initiatives to management on improvements to the quality of the work environment. The President of the Board of Management, the Workers' Director and the HR Director attend the Workers' Council meetings and respond to questions and initiatives of the employees and the Workers' Council.

In 2022, the Workers' Council was regularly informed at its meetings about the company's economic situation and its development goals. Members of the works council attended 10 regular and 1 extraordinary meeting of the workers' council. The extraordinary meeting was aimed at the separation of the company, its impact as well as the consequences on the operation of the Workers' Council.

They familiarize themselves with organizational changes in individual units, current topics decided by the management, and other current events in the company and the trade union.

We carried out consultations related to the transformation of Novartis, the area of Activities and the Development Center Slovenia, and a consultation related to the separation of Sandoz from Novartis.

The Workers' Council participated in changes to regulations (example: Regulations on the prohibition of smoking, consumption of alcohol and other illegal psychoactive substances), we discussed the covid-19 guidelines for autumn/winter 2022 and conducted a consultation related to the 2022 health promotion program.

We established an intranet page where we publish frequently asked questions and proposals from colleagues, monthly minutes of Workers' Council meetings and also other current information that is helpful to employees, such as: information in the field of labor legislation, taxation, links to important laws, institutions, etc.

Other activities of the Workers' Council in 2022:

- weekly meetings of the Workers' Council members and the Workers' Director, at which we discussed the events by units and sites 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,
- monthly meetings with the management of individual units and personnel by site, where we discussed events by units and sites and familiarize ourselves with the situation in the company,
- activities in the Novartis Euro Forum,
- operations in the Supervisory Board.

15 GRI 2-29

Lek's commitment to external incentives, principles and initiatives[16]

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

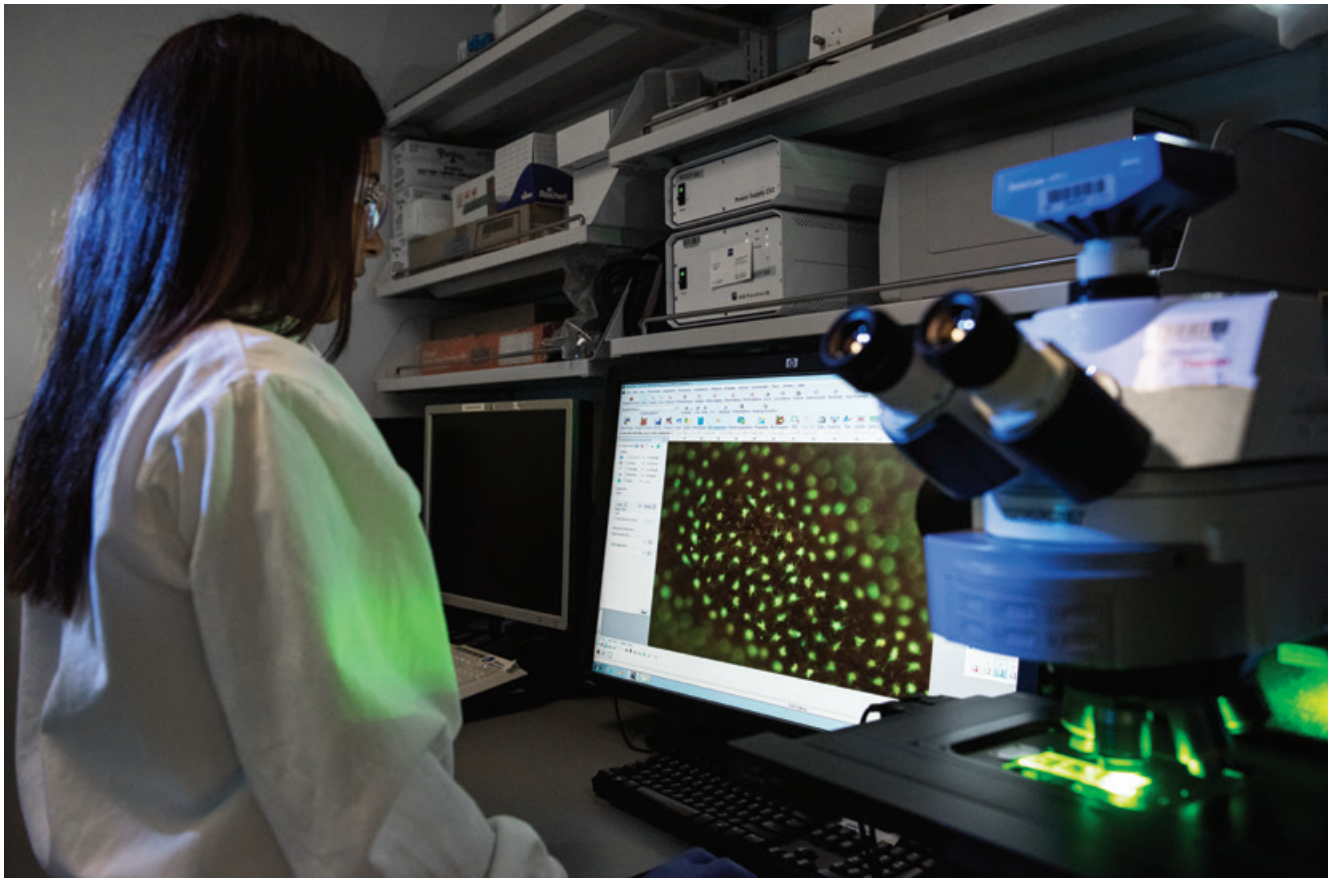
- American Chamber of Commerce
- Business women's society
- Maintenance Association
- European patent institute
- Slovenian Chamber of Commerce
- Fire brigade of Slovenia
- Chamber of Engineers of Slovenia
- ICS, Ljubljana (Institute for Corporate Security Studies)
- Agriculture and Forestry Chamber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

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

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

When developing and manufacturing pharmaceuticals, we use the Precautionary Principle; we strictly comply with Pharmacopoeia requirements, WHO and OECD standards; requirements of the FDA and the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), and the Good Laboratory Practice recommendations. The development of medicinal products, APIs and manufacturing procedures is based on precautionary measures such as gradual approach, inclusion of independent scientists, as well as open and transparent consideration of strengths and weaknesses.[17]

16 GRI 2-28
17 GRI 3-3



Access to healthcare

We strive to increase access to our medicines for patients worldwide, while maintaining high ethical standards. Accessible treatment, which is one of Novartis' strategic priorities, is directly included in all our activities and thereby contributes to the realization of the mission, which is to co-create medicine to improve the quality and extend the lives of people around the world.

2022 Highlights

≥ 30

development projects in various development phases took place in 2022 in the Biologics Technical Development Mengeš. Of this, approximately half for innovative biologics and half for biosimilars.

26

dossiers for generic drugs. We completed development and filed 26 generic drug dossiers in key markets and launched 21 generic drugs for the treatment of cancer, cardiovascular disease, diabetes, glaucoma and pulmonary fibrosis.

510

ideas for introducing changes and optimizing processes were submitted by employees, of which 239 were approved for implementation. The approved ideas resulted in 4.65 million euros in directly calculated savings.

300

experts from natural sciences and other fields attended the 7th Novartis career breakfast. In seven years more than 550 experts participated, and we employed more than 40 of them.

Supporting innovativeness

We are improving access to care through extensive investments in data science and technology, increasing our efficiency, supporting innovation, and thus better responding to the needs of patients and physicians. At the same time, we are expanding interest in science among young people, implementing an affordability strategy and, with governmental and non-governmental organizations and other partners, looking for opportunities to reduce local barriers to improving healthcare 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

The announced investment by Novartis in the **Biologics Technical Development Mengeš** is one of the key milestones of the past year, which will have a significant impact on the future of the unit. Namely, the new Biopharmaceuticals Development Center Mengeš will bring new development capabilities, including clinical manufacturing to support the early stages of clinical trials.

Throughout the year, around 30 development projects took place in the unit in various development phases, of which approximately half were for innovative biologics and half were for biosimilars. At the same time, we continued to upgrade our knowledge and capabilities, especially in the development of innovative biologics and with the »in silico« and mechanistic modeling approaches in drug development processes.

In the portfolio area, we have successfully implemented a critical infrastructure for testing the compatibility of biological drugs with materials for parenteral use before the first application in the human body. We have introduced advanced »in-silico« techniques in the development of complex biological molecules, which enable in-depth understanding at the molecular level and thus faster and more effective development of stable formulations. We were the first in Novartis to develop and introduce into production in Mengeš an innovative process for the production of biological active ingredients, called »intensified fed-batch«, which enables a significantly higher yield of the active ingredient and shorter production processes.

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 2022, it housed half of all global development projects of Sandoz, the generic division of Novartis. This is dominated by oncological drugs, drugs for the treatment of cardiovascular diseases, drugs for the treatment of diabetes, allergic rhinitis, migraine, insomnia, anemia, urological and stomach diseases, as well as non-steroidal anti-inflammatory drugs.

In 2022, we completed the development and submitted 26 registration applications for drugs in the key markets of the USA, Europe, Canada, Russia, Japan, Brazil, Australia, Mexico and Turkey, and supported the launch of 21 generic drugs for the treatment of cancer, cardiovascular diseases, diabetes, glaucoma and pulmonary fibrosis in the US, Europe, Canada, Japan, Brazil, China, South Korea and Australia markets.

Facilitating mass inventive culture

In 2022, we hosted, co-created and participated in more than 80 events for the development of innovation, talent and cooperation with educational and research institutions. We opened new horizons and career opportunities in the pharmaceutical industry to young people through company visits, “speed dating” and career fairs. We presented them with opportunities for scholarships, practical training and academic work.

Mixed research teams of our researchers with researchers from all three universities were looking for new scientific, technological and digital solutions for the real challenges of our experts from the development center, the production of biological medicines and the Lendava packaging center. With this, the research teams created a new solid basis for further long-term collaborations.

Th!nk Novartis 2022

We support mass innovations with the Th!Nk Novartis web application, through which employees actively participate in introducing changes and improving work processes. In 2022, 242 different employees submitted 510 ideas, of which 239 were approved for implementation. The approved ideas brought a total of €4.65 million in directly calculated savings. From the introduction of the application in 2012 to the end of December 2022, employees have contributed a total of 8,183 ideas, 4,176 of which were implemented, which resulted in a total saving of €65.55 million.

Pharma Data Science Hack

Together with the IT company Axiologo, we organized the Pharma DataHack 2.0 online hackathon, where competitors from eight countries solved four concrete data challenges of Novartis Slovenia. The participants

had the opportunity to test themselves in various challenges of the pharmaceutical industry, such as the development of an application for monitoring the process of employee education, the development of a tool for searching online data in the development of pharmaceutical products and the collection, statistical processing and visualization of internal and external data.

In addition to the competition, the event also enabled the participants to network with key experts from Novartis Slovenia and Axiologa and to collaborate with data analytics experts from around the world. They also gathered new knowledge at expert lectures and workshops on topics related to digitization.

12th BioCamp

In 2022, at the twelfth **BioCamp** scientific event, we hosted 36 of the most promising students of natural, economic and technical sciences from the region and wider area. Already a traditional event, it gives young people from all over the world an insight into the pharmaceutical industry, offers a unique platform for networking and opens doors to career opportunities.

The topic of the online event was new methods of treatment and co-creation of medicine in the age of the metaverse. Young talents learned about the opportunities and challenges that digitalization, automation and artificial intelligence bring to pharmacy. In twelve years, BioCamp has connected almost 500 young talents, of which more than 50 have been employed at Novartis.

Novartis career breakfast

At the seventh Novartis career breakfast, we presented the career opportunities in Slovenia to local and foreign young talents and experts in the natural sciences and other sciences. The virtual event was attended by around 300 individuals from a wide variety of professions, who listened to more than 30 Novartis experts in 15 thematic sections. The central theme of this year's career breakfast was the competencies of the future. So far, more than 550 top professionals have attended the career breakfasts, 40 of whom were later employed by Novartis.

Novartis' Researchers Day

UNI.MINDS, the largest Slovenian online festival for building an innovation community and long-term partnerships between the academic sphere and the economy, organized by the Knowledge Transfer Office of the University of Ljubljana, took place this year within the Month of Science. The first day of this year's festival was marked by our event: Researchers' Day, where we shared knowledge and challenges related to the latest achievements of joint research teams, consisting of academic and business experts, in the fields of basic and applied research, technology and operational excellence.

Awards for innovation

Gold and Silver from the Chamber of Commerce and Industry Slovenia

On the Innovation Day, during which the Chamber of Commerce of Slovenia awards the best innovations in the country, we received a gold and silver award among the 45 best innovations at the national level. The innovation was awarded gold for the development of a generic version of ferumoxytol, which is used to treat anemia. The drug makes the treatment of anemia with the most modern nanotechnological drugs more accessible.

The innovation of developing cell lines for the production of similar biological drugs received a silver national award. It is a breakthrough approach to the development of biosimilars that involves the introduction of automated cell cultivation and genetic engineering of production cell lines.

Lek is the recipient of the gold and silver awards for innovation.

Innovation enables efficient, rapid and high-quality development, which brings savings in the production of biosimilars and enables the development of treatments that could not be developed before.

GZS also recognized the innovative IDEAL concept, which was developed by employees from the Development Center Slovenia in cooperation with the Slovenian company Axiologo. The innovation allows scientists to conduct experiments and analyzes in a virtual environment, reducing the need for real-time experimentation. In total, in the 20 years since the Chamber of Commerce and Industry has been awarding awards for innovation, we have received as many as 13 gold awards.

AmCham

The project Industry and the University – Together we build a society of knowledge and well-being, which the Lek company implements together with the Ljubljana University Incubator and the University of Ljubljana, received the title of best business practice »Best of the Best«. The competition is organized by AmCham Slovenia, and it is aimed at identifying the best business practices that inspire the business community and bring innovation, motivation and integration for growth and progress.

The winning project was created as a result of close cooperation with the University of Ljubljana and developed into a natural partnership over the years. Both partners are aware of the opportunities and responsibilities arising from a joint mission, and they realize it through a rich range of collaborations: research projects, final works, practicals, hackathons, summer schools, international consortia, exchange of knowledge, experts and much more.

Sandoz science awards

At the research and development days, Sandoz paid tribute to its scientists from all over the world with prestigious awards. Among the 18 awards presented, researchers from the Development Center Slovenia and the Development of Biopharmaceuticals Mengeš received as many as ten scientific awards, including two of the highest awards for scientific excellence. They also received five awards for the best posters.

Every year, Sandoz also awards the best researchers with many years of outstanding achievements in research and development. This year, the award for scientific excellence went to **Matjaž Vogelsang** from the Development of Biopharmaceuticals Mengeš and Ivana Gazić Smilović from the Development Center Slovenia.

The researchers and research teams of the Development Center Slovenia and the Development of Biopharmaceuticals Mengeš also received awards for innovative breakthroughs in analytics and technology, clinical study excellence, breakthrough in the field of operational excellence, exceptional support role, rising star among colleagues, most inspiring leader and ambassador award cultures.

PHARM Connect for excellence in the pharmaceutical industry

At the PHARM Connect congress, the largest business meeting of pharmaceutical and biotechnology companies from Central and Eastern Europe, awards for excellence in pharmaceutical production were awarded for the seventh consecutive time. Our colleagues from the Development Center Slovenia proved themselves to the jury by impressing them with the project Products for the treatment of oncological diseases - Highly potent products - from vision to reality for which they received the 7th SEE Award for excellence in pharmaceutical production.

The recipients of the Sandoz awards for scientific excellence Matjaž Vogelsang and Ivana Gazić Smilović.

Stakeholder overview and inclusion[18]

To implement our strategy, we cooperate with individuals and groups that are important to our business. Involving these stakeholders helps us understand their needs and expectations and work together towards common goals. In our operations, in line with Novartis' environmental, social and governance (ESG) considerations, we focus on five key stakeholder groups:

- 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).

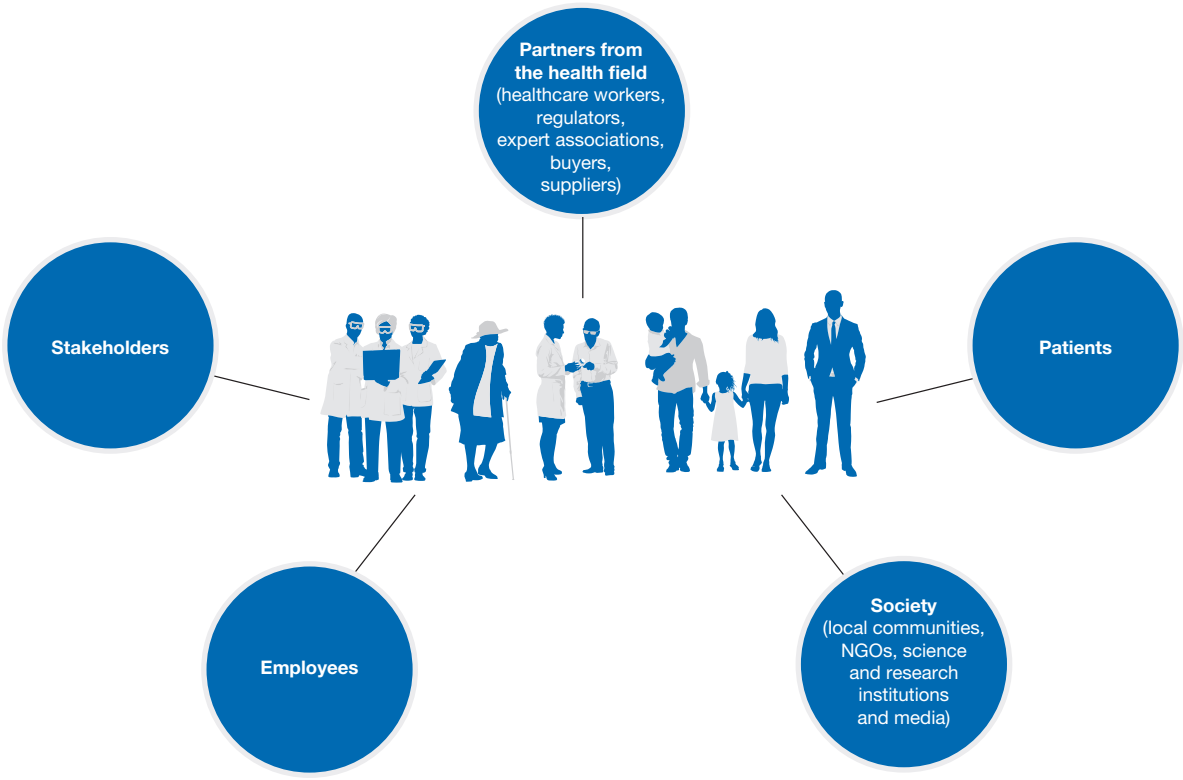
We try to understand patients' needs through focus groups and cooperation with patient groups organized in associations and initiatives. At scientific conferences, we cooperate with academia and the scientific community, with professional organizations, educational institutions, research institutions 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.

Lek's key stakeholders



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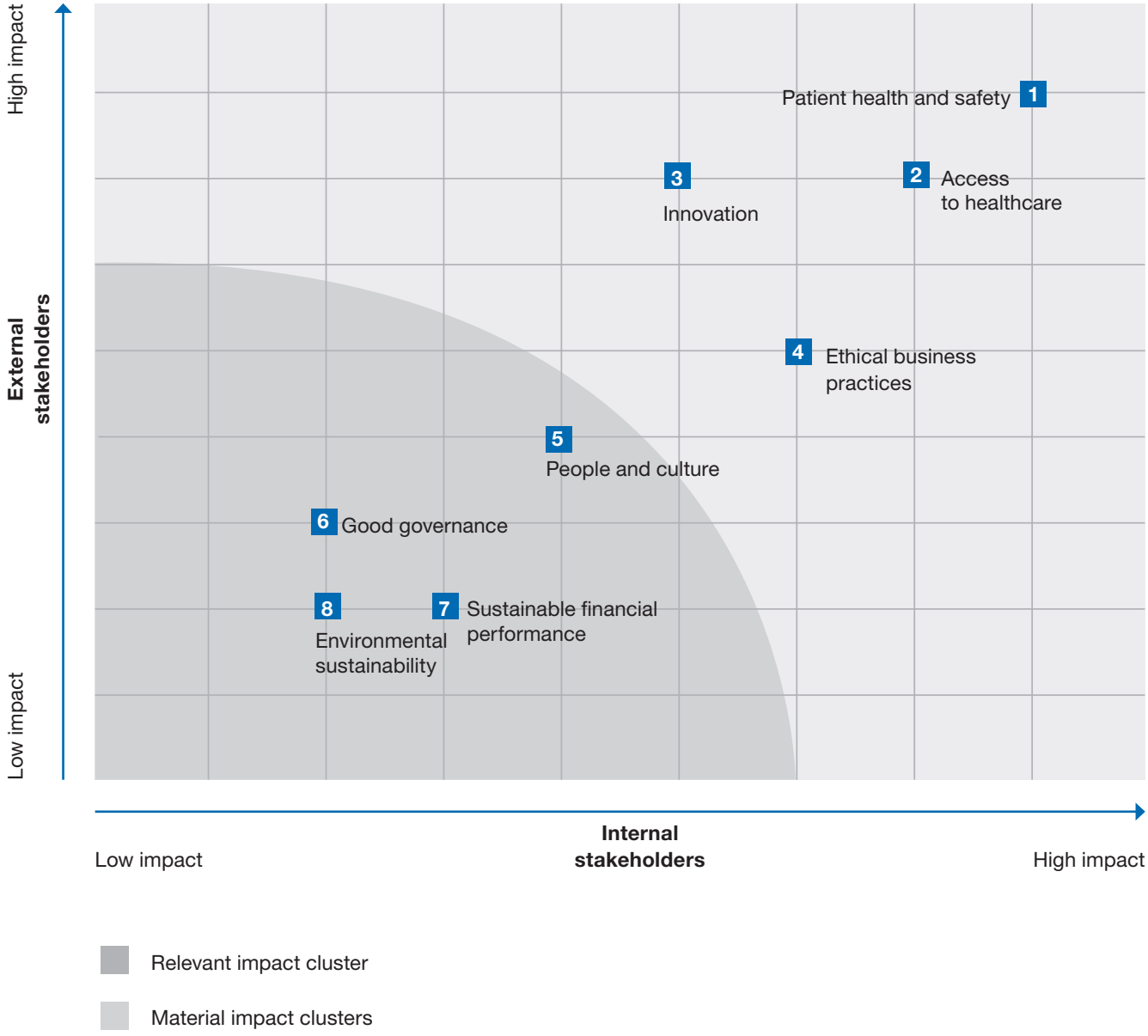
Novartis' key areas of social responsibility

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.

Ranking of impact clusters



Lek's stakeholders and recognized interests:[19]

Stakeholders	Stakeholder's 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

19 GRI 2-29

Supporting different communities

We create and maintain long-term positive relationships with various communities through constructive and ongoing dialogue. We try to listen and, through joint cooperation, contribute to building a world that is safer and more inclusive. In the past year, our activities were mainly aimed at helping vulnerable groups, children, young people, the elderly and the disabled.

We have maintained all our traditional partnerships. We cooperated with the Association of Friends of the Youth of Slovenia in the Wink to the Sun program, within the framework of which children from socially disadvantaged families spend carefree holidays by the sea. We supported the Mountaineering Association of Slovenia with the inPlaninec program, which strives to bring the beauty of our mountains and mountains closer to the blind and visually impaired; the Seniors for Seniors project of the Association of Pensioners' Associations of Slovenia; therapy dogs Helper Paws and their handlers, who devote volunteer hours to the helpless and those in need of therapy; A small house in Pilštanje, which is a safe haven for many children and families in times of need.

In 2022, we actively entered the world of people with disabilities. The purpose of the cooperation with the Association for Sports of the Disabled in Slovenia - the Paralympic Committee was to support Slovenian para-athletes, while at the same time helping to promote the inclusion of disabled people in wider society. As a silver sponsor, we responded to the invitation and some of our colleagues joined the Paralympic camp for families through voluntary work.

With the commitment to patients and caregivers, which we signed in 2018, we undertook to take into account the views and needs of patients for more effective treatment and earlier disease detection. In 2022, we further strengthened partnerships with patient groups and, through joint activities, contributed to a greater awareness of society about the knowledge and prevention of individual diseases and the development of modern technologies. Thus, in the 39th week of the fight against cancer, we joined the efforts of institutions that support cancer patients. The importance of early detection, diagnosis and treatment of blood diseases was highlighted on the occasion of the International Day of Newborn Screening and Blood Disease Month.

We volunteered at the paralympic camp for families.

Mechanisms for resolving complaints[20]

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 2022, we did not receive any direct complaints from local residents. At the Lendava site, there was an incident when, due to human error, the pumping of otherwise properly captured water with a low pH into the wrong sewage system occurred. Due to the reduced pH value of municipal wastewater, it was therefore possible to detect more intense unpleasant odors in the vicinity of the pumping station of the public sewage network. The inspector concluded that there was no direct release into the environment, and he proposed five measures to improve the control of sewage systems, which we implemented within the deadline.

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[21]

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.

We have established policies and control systems related to product quality and pharmacovigilance. In doing so, we maintain a robust quality management system for our medicines, in full compliance with the requirements of health authorities and other regulators. We have the appropriate licenses, ISO and Good Manufacturing Practices (GMP) certificates for production.

In order to improve the level of medical care and raise awareness about diseases and their treatment, we connect with medical professionals and patients. 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.

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.

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 2022, 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.[22]

Customer satisfaction[23]

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 2022 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.

20 GRI 2-26, 3-3, 413-1
21 GRI 3-3, 403-7, 417-1
22 GRI 417-2, 417-3
23 GRI 2-29

Responsible business

Society has high expectations for our industry, so we strive to maintain high ethical standards and ensure compliance with applicable laws and regulations. In addition, we pay close attention to respecting human rights and reducing social and environmental risk throughout our value chain.

2022 Highlights

≈ 100%

all employees successfully completed e-training on ethics, risks and compliance in 2022.

4

priority areas highlighted by the Novartis human rights commitment statement: health, environment, technology and labor rights.

1,010

million USD total procurement value in 2022. Of this, 561 million USD was direct and 449 million USD was indirect procurement.

42.5%

share of the total purchase value of Slovenian suppliers. In figures, Slovenian suppliers represented 55% of all our suppliers.

Ethics, business compliance and human rights[24]

Lek has zero tolerance to any form of inappropriate behavior. The **Code of Ethics** defines who we are, what we believe in, and sets out the 23 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 always encourage open communication and the reporting of inappropriate behavior. We have an established system of anonymous reporting of inappropriate behavior and we are expanding the so-called »speak up« culture, which also enables ethical issues to be addressed.

Novartis constantly conducts a due diligence review of human rights in its operations and thus in 2022 updated the Declaration on respect for human rights https://www.novartis.com/sites/novartis_com/files/novartis-human-rights-commitment-statement.pdf, which we are also committed to in Lek and highlights four priority areas. These include the most serious actual or potential negative impacts on human rights (right to health, labor rights, human rights and the environment, human rights and technology).

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.

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 2022, and they continue to be topics in training new Lek employees.[25]

Obligations and duties to disclose conflicts of interest, prevent bribery and ensure compliance with applicable laws and internal rules are clearly defined in Novartis' global policies and our internal regulations.

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 2022, there were no cases of discrimination and no requests to remedy any violation in this area.[26] The company was also not involved in any antitrust procedure for any violation of antitrust regulations.[27]

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.

24 GRI 2-23, 3-3
25 GRI 412-2
26 GRI 406-1
27 GRI 206-1

Disabled-friendly company

At Lek, we are committed to equality and inclusion of persons with disabilities in employment.

Within the framework of the Diversity, Equality and Inclusion initiative, which works in four areas: people with disabilities, intergenerational cooperation, diverse talents and the LGBTQI+ community, we made important moves in 2022 for which we also received recognition for good practice in employing persons with disabilities and the title of a disabled-friendly company.

Tanja Sinigoj (second from the left), Head of the Diversity, Equality and Inclusion initiative and Kristina Lampič (second from the right), Head of the Group for the Inclusion of Disabled persons into the work environment accepted the Disabled-friendly company certificate.

In 2021, we already carried out a careful inspection of the buildings of the two largest sites and last year undertook a gradual renovation of the premises, taking into account the guidelines for ensuring accessibility for people with mobility impairments. We also follow these guidelines for new constructions.

On the way to becoming a disabled-friendly company, we prepared Guidelines for the employment of persons with disabilities, and we actively cooperate with many organizations: the Association of Paraplegics of Slovenia, the Association of Blind and Visually Impaired Associations of Slovenia, the Association of Deaf and Hard of Hearing Associations of Slovenia, Šentprima, the Association for Sport of the Disabled of Slovenia - Slovenian the Paralympic Committee and the Association of Disabled Students of Slovenia. Among other things, we regularly provide them with information about published jobs and other opportunities for cooperation. We included two students with an autistic spectrum disorder in the work practice and enabled the student work of a person with a hearing disorder.

Although Lek employs more than 90 colleagues with disabilities, we also cooperate in the long term with employment centers and companies that employ disabled people. For lighter psychophysical work, we thus include more than 70 disabled people in protected workplaces.

We expanded our traditional career breakfast event and invited people with disabilities with the help of partner organizations. In addition, with internal training, we bring the topic of disability closer to our colleagues and equip them with knowledge and skills to help them better integrate and create a safe space in the company.

Cooperation with external contractors

Purchasing system and policy[28]

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.

28 GRI 2-6

In the field of procurement, we are constantly improving partnerships with service centers and thus optimizing expenditures in all procurement categories (direct and indirect). At the same time, we are developing the automation and digitization of procedures, and using the introduced tools we are improving the transparency of the use of resources, increasing the rationalization and simplification of procedures.

In 2022, the total purchase value increased and amounted to 1,010 million USD (719 million in 2021). Of this, 449 million USD were indirect and 561 million USD were direct purchases. Our largest direct procurement markets remain Slovenia, Switzerland, Germany, China and India. Slovenia, Germany, Austria, Switzerland and India were the largest markets for indirect purchases.

Supplier audit procedure[29]

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 T**hird 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[30]

In 2022, the share of Slovenian based suppliers amounted to 429 million USD or 42.5% 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 14.8% share (83 million USD) in purchasing value. In indirect purchasing 77.2% (346 million USD).

72.2%

of direct purchasing and 14.8% of indirect purchasing from Slovenian suppliers.

29 GRI 3-3, 308-2, 414-2
30 GRI 3-3, 204-1

Environment

In accordance with our environmental sustainability strategy, we continue to reduce air emissions, water consumption and waste in our activities and the entire value chain. With this, we aim to become climate neutral by 2040.

2022 Highlights

– 3.4%
less energy consumption and improved energy efficiency compared to net revenue by 22% in 2022.

– 4.4%
less greenhouse gas emissions (scope 1 and 2) and 10.6% less greenhouse gas emissions in scope 1.

+ 1.8%
more waste generated in 2022. 2.4% less hazardous waste.

+ 1.1%
increased consumption of water in 2022 due to increased intensive production and range of products.

Environmental Sustainability Strategy

As part of Novartis, we promote sustainable business through our own operations and through the value chain. In the field of environmental sustainability, we have an adopted strategy and activities connected in four pillars: planet, patients, people and policies.[31]

Areas of 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 technologies
- Plastic neutrality

Water use efficiency

- 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 development 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 is 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«)

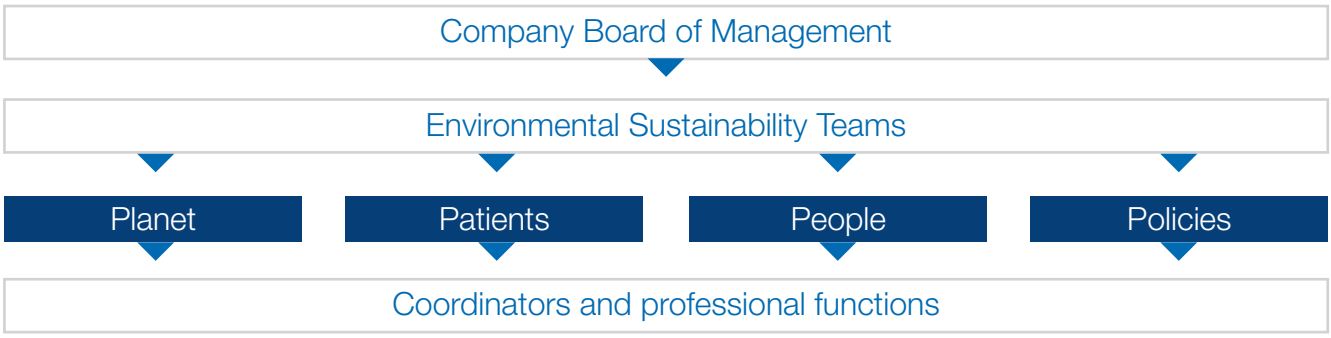
4 Policies

We influence the sustainability policies by strengthening 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)

31 GRI 2-12, 2-13, 2-16, 2-17

Environmental sustainability governance at Lek



Novartis Environmental Sustainability targets, 2025 and 2030

	Climate **Carbon neutrality**	Waste **Circular economy & plastic neutrality**	Water **Water sustainability**
2025	Carbon neutral own operations Scope 1 and 2 Environmental criteria in all supplier contracts	Eliminate PVC in packaging Waste disposal reduced by half	Water consumption reduced by half in our operations No water quality impacts from manufacturing effluents
2030	Total carbon footprint neutrality scope 1, 2 & 3	Plastic neutral All new products meet sustainable design principles	Water neutral in all areas Enhance water quality wherever we operate

Health, Safety and Environment (HSE) policy[32]

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.

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

32 GRI 2-23, 2-24, 2-25, 3-3

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

We build partnerships

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

We report publicly and comprehensively

We report on the HSE results comprehensively, transparently and publicly. We disclose our environmental, social and economic impacts in our annual Sustainable Development Report, which is publicly published and available on our website. We use internationally recognized guidelines and standards in our reporting. The veracity of the information provided in the report relating to environmental impacts shall also be 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[33]

The key environmental management regulation is the Environmental Protection Act, which came into force in 2022. It dictates the contents of other implementing regulations in the field of water, noise, waste, packaging materials, atmospheric emissions, light pollution, storage of hazardous liquids, and other areas related to environmental protection.

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

Being an IED (Industrial emissions directive)[34] 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 2022, we had 11 inspections, of which 4 in the environmental field and four in the field of health and safety at work (supervision of construction sites in Ljubljana and Mengeš and implementation of measures to prevent the spread of covid-19), one each in the field of fire protection, biological safety and transport of dangerous goods (ADR). During one inspection at the Lendava site, we received a decision with five measures, which we implemented within the prescribed period. Once again, we successfully completed the ISO 14001 recertification audit, the regular ISO 45001 audit, the environmental management system documentation audit and the EMAS audit, as well as the internal Novartis legal and Novartis compliance audit. In 2022, we were also involved in inspections to check the quality of operations and products, especially in the field of health checks and waste management. In 2022, we did not receive any fines due to possible non-compliance with HSE regulations.[35]

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

33 GRI 3-3
34 See Glossary on page 94.
35 GRI 2-27

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.
- 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 No. 35407-171/2006, dated 14 May 2010.
- Decision amending the environmental permit for the Mengeš site, No. 35407-22/2010, dated 28 December 2010.
- Decision amending the environmental permit for the Mengeš site, No. 35407-54/2011, dated 16 May 2012.
- Decision amending the environmental permit for the Mengeš site, No. 35406-24/2012-3, dated 23 August 2012.
- Decision amending the environmental permit for the Mengeš site, No. 35406-25/2013-6, dated 11 November 2013.
- Decision amending the environmental permit for the Mengeš site, No. 35406-42/2014-4, dated 10 September 2014.
- Decision amending the environmental permit for the Mengeš site, No. 35406-7/2015-7, dated 20 April 2015.
- Decision amending the environmental permit for the Mengeš site, No. 35406-33/2015-20, dated 9 February 2016.
- Environmental permit for risk facilities (SEVESO risks) for the Mengeš site, Permit No. 35415-26/2006-9, dated 25 May 2015.
- Decision amending the environmental permit for the Mengeš site, Permit no. 35406-43/2016-8 dated 30 March 2017.
- Decision amending the environmental permit for the Mengeš site, Permit no. 35406-77/2017-5, dated 15 November 2018.
- 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.
- Clean copy of environmental permit for Ljubljana site, No. 35447-40/2022-2550-14, dated 25 October 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

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.

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.

Specifics of business operations and deviations in data collected

Environmental indicators are difficult to compare between years and sites 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

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 2022, we allocated 10.5 million euros for environmental projects, the most in the last decade. We report more on important projects in the field of environmental protection in 2022 in the chapters *Improvements in energy efficiency* and *Efficient water use.*

Verification of established standards[36]

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 20232 that data and information in the Lek d.d. Sustainability Report 2022 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 2022 (JAZMP, FDA, suppliers, etc.).

36 GRI 2-5

Key projects

Active energy management

We continued with the implementation of the active energy management (AcEM) project - active monitoring of energy systems, performance analysis and thus active energy management. We established new tools for a quick and transparent review of our energy systems, and we are continuing with the introduction of automatic comparison of optimal operating parameters with the current operation of each system. On the basis of real-time inspections, comparative analyzes and determination of key performance indicators, we can take immediate measures to improve regulation, adjust operating points, display errors in operation and select the most efficient devices. In doing so, we use appropriate information tools to identify potential future savings projects.

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[37]

Indirect environmental impacts can be categorized as transport and distribution, which are recognized as a key source of air pollution in the urban environment, mainly due to solid particles (PM particles). These impacts 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*.

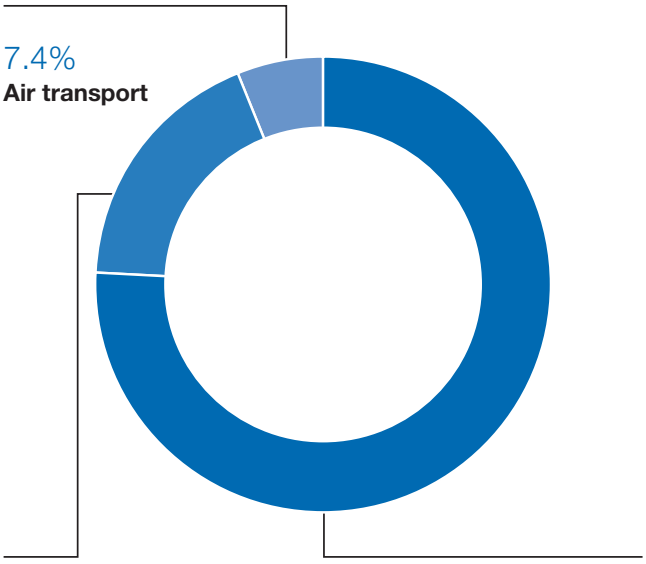
The indirect impact of transport is also taken into account in the process of selecting suppliers in categories such as placing orders for packaging materials.

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 2022, we sent 9,865 shipments of products to customers from Lek's sites and dislocated warehouses, which is 4% more than in 2021, when there were 9,487 shipments. By gross weight, we had 76% road, 16% ship and 7% 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.

A total of 188 company cars were in use in 2021 (179 in 2021). A total traveling distance of 4,942,224 km (4,428,614 in 2021) was recorded, with fuel consumption of 346,604 liters (208,895 in 2021). In addition to company cars, we had 17 other vehicles (fire engines, forklifts). Together all vehicles released 669 tons of CO_2 emissions (594 in 2021).

37 GRI 305-1, 308-2

Raw materials and natural resources

Mass flow of materials[38]

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 2022, the use of raw materials was at a similar level as the previous year, 3%. The use of raw materials decreased at all sites, with the exception of Lendava, which increased use by 11% due to increased production.

Annual mass flow of different materials used* in t[39]

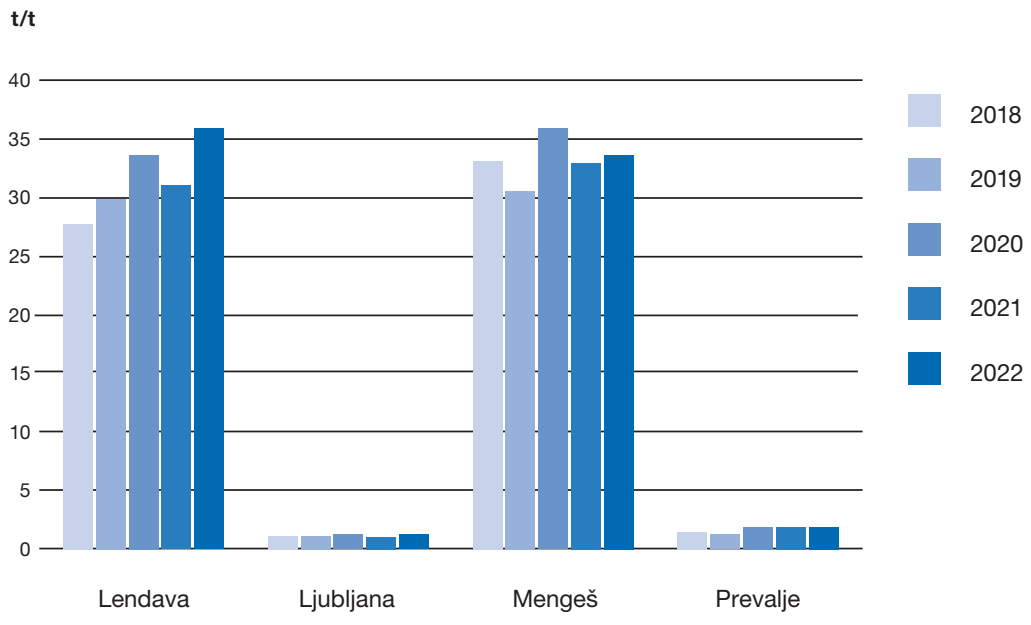
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2018	t	8,549	3,324	14,253	1,998	**28,125**
2019	t	8,910	3,097	15,225	1,814	**29,046**
2020	t	10,044	3,378	11,227	1,925	**26,574**
2021	t	10,579	2,787	10,461	1,835	**25,662**
2022	**t**	**11,776**	**2,589**	**9,975**	**1,396**	**25,736**

* 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 2022 the efficiency of raw materials used per ton of active substance or product produced improved at Prevalje (by 0.65%), at the other sites it was lower; Lendava (by 15%), Ljubljana (by 14%), Mengeš (by 1.2%). At the level of Lek, the efficiency was lower (21%).

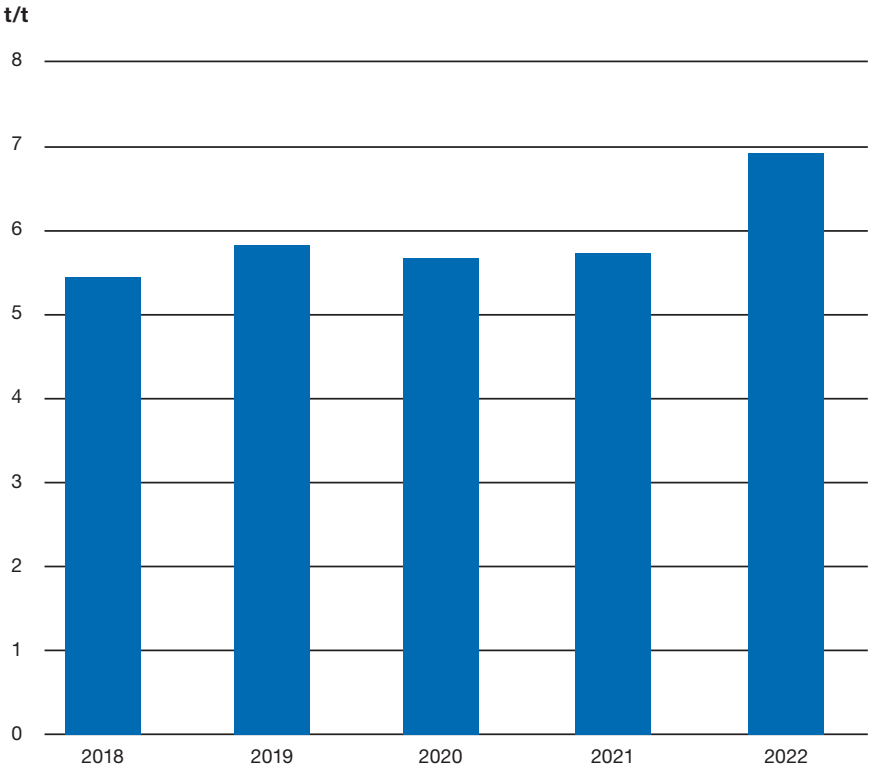
Efficiency of different materials used per product unit by site*[40]



* In the 2021 Sustainability Report, the wrong units of measurement were used in the graph.

38 GRI 3-3
39 EMAS – Core indicator, GRI 301-1
40 EMAS – Core indicator

Efficiency of raw materials per product unit – Lek in total*



* In the 2021 Sustainability Report, the wrong units of measurement were used in the graph.

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.

Energy

Energy consumption

At the level of Lek, the total energy consumption in 2022 was 3.37% or 12,351 GJ lower than in the previous year. With projects to improve energy efficiency at all four sites, we saved 49,665 GJ of energy and prevented 4,463 t of CO_{2e} from entering the atmosphere.

Compared to 2021, we reduced total energy consumption at all sites; Prevalje (by 9.2%), Mengeš (by 7.3%), Ljubljana (by 1.4%) and Lendava (by 1.4%).

We monitor the multi-year review of energy consumption and carbon dioxide emissions with the baseline year of 2016. Despite the growth in production at most sites, compared to the energy baseline, total energy consumption decreased by 2.53%, and the consumption of purchased energy (excluding solvents) by 2.45 %.

Total energy consumption[41*]

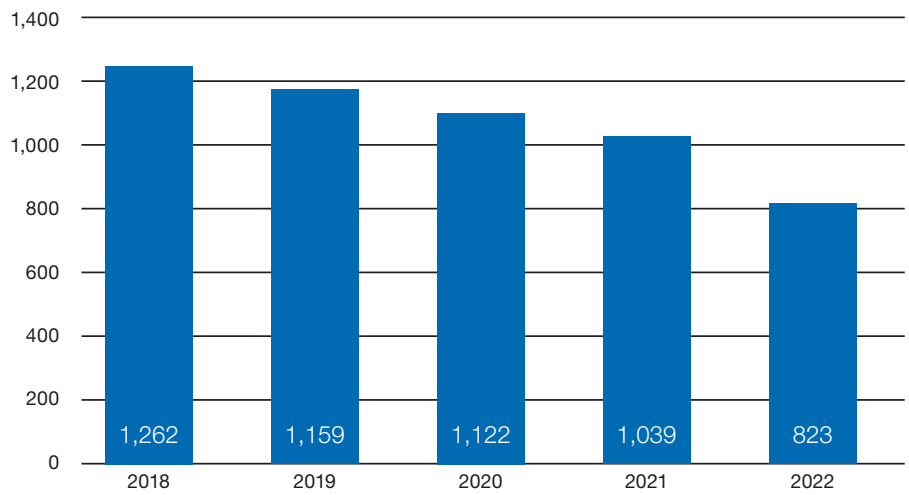
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2018	GJ	470,766	441,039	364,387	63,013	**1,339,204**
2019	GJ	469,189	442,506	370,440	62,747	**1,344,882**
2020	GJ	476,617	428,502	365,986	57,245	**1,328,350**
2021	GJ	472,710	422,979	367,451	56,331	**1,319,470**
2022	**GJ**	**466,046**	**417,052**	**340,778**	**51,131**	**1,275,008**

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

The production of APIs takes place at the Lendava site, which, in contrast to the other sites, is very intensive in terms of volume. Its production is constantly increasing and, compared to the base year of 2016, reached an increase of 19%, while energy consumption increased by only 12.5% during this period.

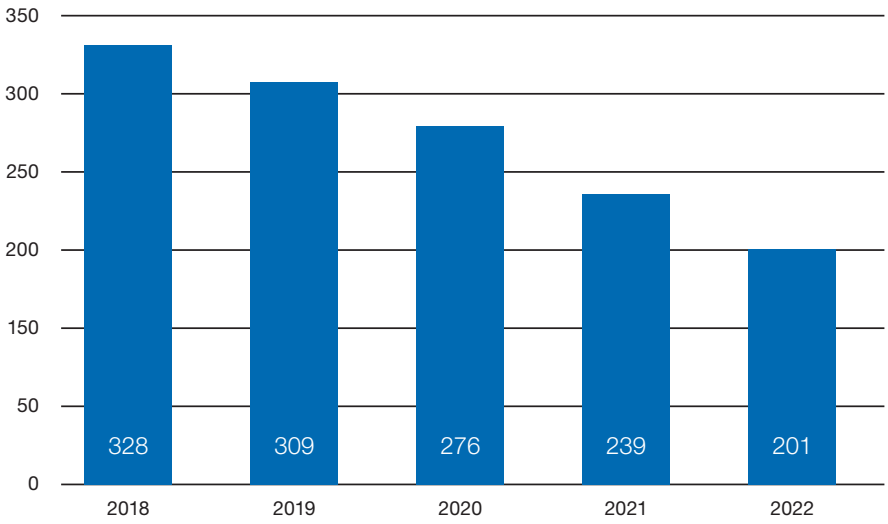
In terms of net revenues, the use of energy products improved by 21% in 2022, and even by 44% compared to the base year of 2016. Based on the number of employees, efficiency increased by 16% in 2022, and by 45% compared to 2016.

Energy efficiency regarding Lek net income (GJ/mil. EUR)[42]



41 GRI 302-1
42 EMAS – Core indicator, GRI 302-3

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



* Data for 2019 and 2021 have 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)
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**
2022	**GJ**	**22,605**	**40,686**	**63,291**

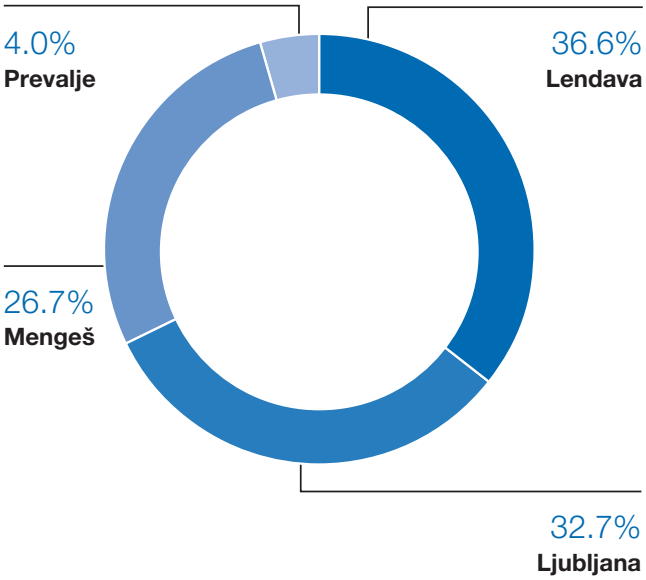
By using waste solvents for the purpose of generating steam, we reduce the need for the primary resource (natural gas).

Energy used from biomass at Lendava

Year	Unit	Lendava
2018	GJ	4,612
2019	GJ	3,417
2020	GJ	5,086
2021	GJ	5,035
2022	**GJ**	**4,795**

Lendava has the highest share in total energy consumption with 36.6%, followed by Ljubljana with 32.7%, Mengeš with 26.7% and Prevalje with 4.0%.

Energy distribution by site



Electricity consumption[43]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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**
2022	**GJ**	**230,894**	**170,340**	**123,749**	**20,372**	**545,355**

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 decreased slightly (0.71%) and has been stable since the year of reference 2016, despite significantly increased production and a higher number of employees.

43 GRI 302-1

Distribution of energy resources

Among the consumed energy products that we buy on the market, the largest share is electricity with just under 43% and natural gas with 33%. Electricity represents the primary source of energy for three production sites. The Ljubljana site is specific, where in addition to the mentioned energy products, we additionally purchase technological steam, which represents a 15% share, and heating water with a 3% share.

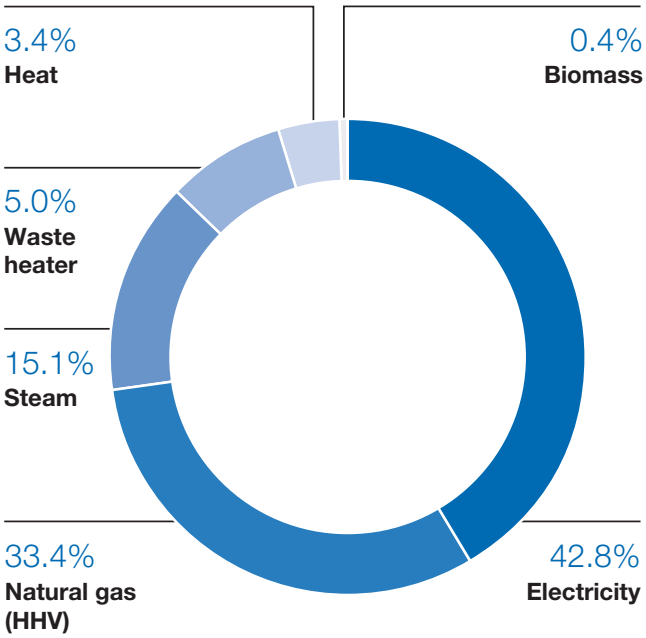
In addition to natural gas, the Mengeš and Lendava sites also use waste solvents from production to produce steam in co-incineration. The share of waste solvents in the total consumption of energy products is 5% and has decreased compared to the previous year due to lower volumes of waste solvents from production, which are the result of a changed product portfolio.

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

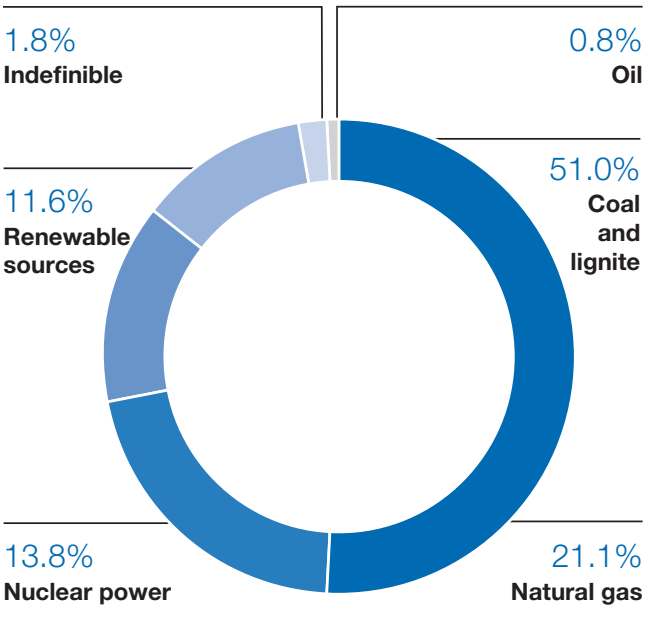
Distribution of energy consumption by type in 2022

Energy	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Electricity	GJ	230,894	170,340	123,749	20,372	545,355
Natural gas (HHV)	GJ	207,753	11,668	176,344	30,759	426,523
Heat	GJ	0	42,908	0	0	42,908
Steam	GJ	0	192,136	0	0	192,136
Waste heater	GJ	22,605	0	40,686	0	63,291
Biomass	GJ	4,795	0	0	0	4,795
TOTAL	**GJ**	**466,047**	**417,052**	**340,778**	**51,131**	**1,275,008**

Distribution of energy consumption by type in 2022



Sources of purchased electricity*[44]



* Data on the composition of primary sources for electricity production, which we received from the electricity provider, are for 2021. At the time of compiling the report, data for 2022 were not yet available.

44 EMAS – Core indicator, GRI 302-1

Energy efficiency improvements[45]

We pay special attention to increasing the efficient use of energy from the reduction of primary sources. The improvements are the result of many years of systematic activities as part of active energy management and investments.

In 2022, several energy efficiency improvement projects were implemented, which created 49.6 TJ of total energy savings and with which we consequently prevented 4,463 tons of CO2 emissions into the atmosphere.
The total savings of the estimated projects represent 4% of the total annual energy consumption savings.

	Lendava	**Ljubljana**	**Mengeš**	**Prevalje**	**Lek** (Total)
Annual energy savings from energy projects (in GJ)	12.647	17.059	14.959	5.000	49.665
Annual reductions in greenhouse gases thanks to energy projects (in t CO_2)	1.073	2.061	1.029	300	4.463

Below are the major projects with which we improved the energy efficiency of individual systems and devices:

- installation of solar panels,
- optimization of HVAC system settings in warehouses and offices,
- optimization of the operation of pumps, fans, flows, level regulation on cooling systems,
- ensuring the tightness of condensate lines and technical steam condensate drains,
- upgrade of HVAC and energy control systems,
- replacement of worn out and energy-consuming equipment with new ones (steam fittings, new cooling unit, new HVAC aggregates, distribution pumps, new compressor),
- change of engine and mixer configuration,
- new thermal station,
- ensuring tightness of compressed air distribution lines,
- optimization of set-point parameters for dehumidification, heating and cooling of HVAC systems,
- coordination of production needs for the supply of energy products,
- optimization of flows and temperatures on technological consumers,
- optimization of the operation of WFI generators and distribution lines,
- upgrade of the steam boiler – upgrade of the co-incineration plant,
- replacement of a worn-out cooling tower,
- replacement of lighting with LED lamps,
- approach to the introduction of digitization (ENIS machine learning),
- optimization and modernization of power stations (systematic inspections, detection of mechanical faults, weak points, upgrades...),
- active energy management – regular monitoring of the operating parameters of energy systems and several initiatives to optimize the improvement of system performance.

45 GRI 302-4, 305-5

Water[46]

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.

By monitoring the operation of systems, appropriate preventive maintenance and the use of the best available techniques, we ensure the preparation of high-quality water, extend the operating life of devices, reduce the consumption of incoming drinking water and the amount of waste water after its production.

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 2022 was only 1.1% higher, which we attribute to proper management and maintenance of water preparation and distribution systems, active monitoring of consumption and immediate action in case of leakage.

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

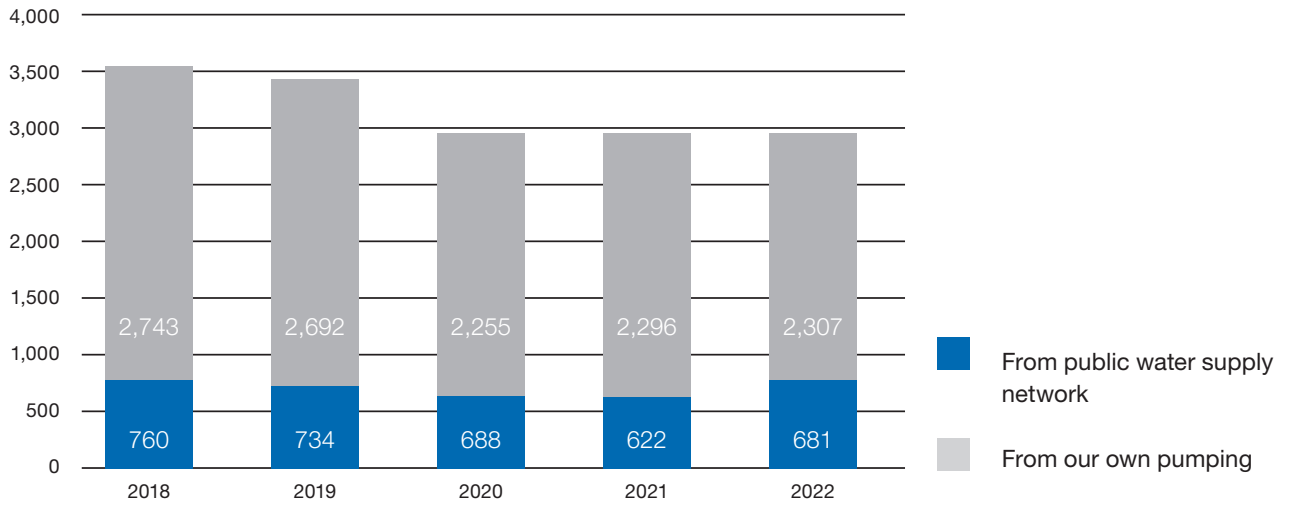
- by optimizing cooling water flows;
- by reusing water (RO, cooling systems, condensate);
- by optimizing water consumption in energy systems and systems for the preparation of pharmaceutical waters;
- with timely replacement of worn equipment;
- by connecting technological consumers to well water;
- 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 [47]

Year	**Unit**	**Lendava**	**Ljubljana**	**Mengeš**	**Prevalje**	**Lek** (Total)
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
2022	**1,000 m³**	**1,201**	**520**	**1,238**	**30**	**2,989**

46 GRI 303-1, 303-2
47 EMAS – Core indicator, RCI OI 21, GRI 303-3

Water sources in 1,000 m³ at Lek*



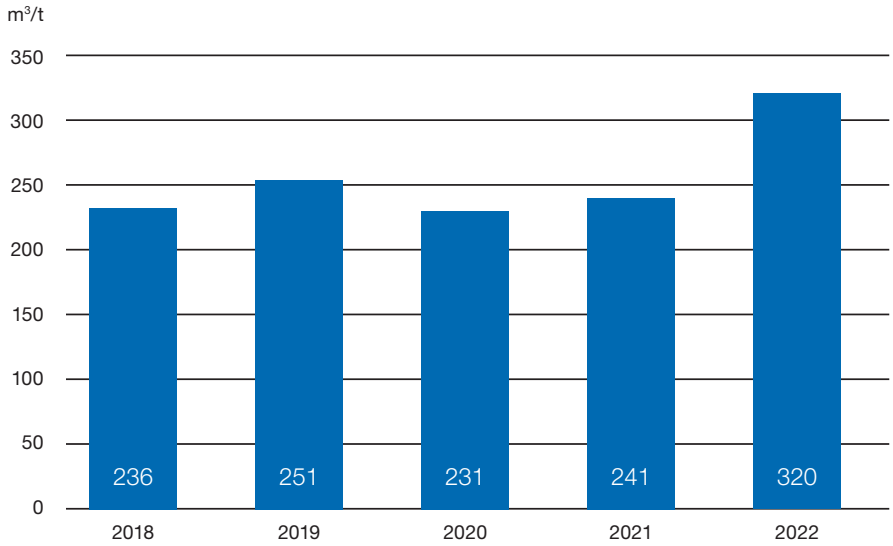
* In the previous report, the data regarding water from public supply network for 2018 was incorrect due to an input error.

Efficiency of water use per ton of produced unit*[48]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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**
2022	**m³/t**	**1,034**	**230**	**1,087**	**25**	**320**

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

Efficiency of water use per produced unit



48 EMAS – Core indicator

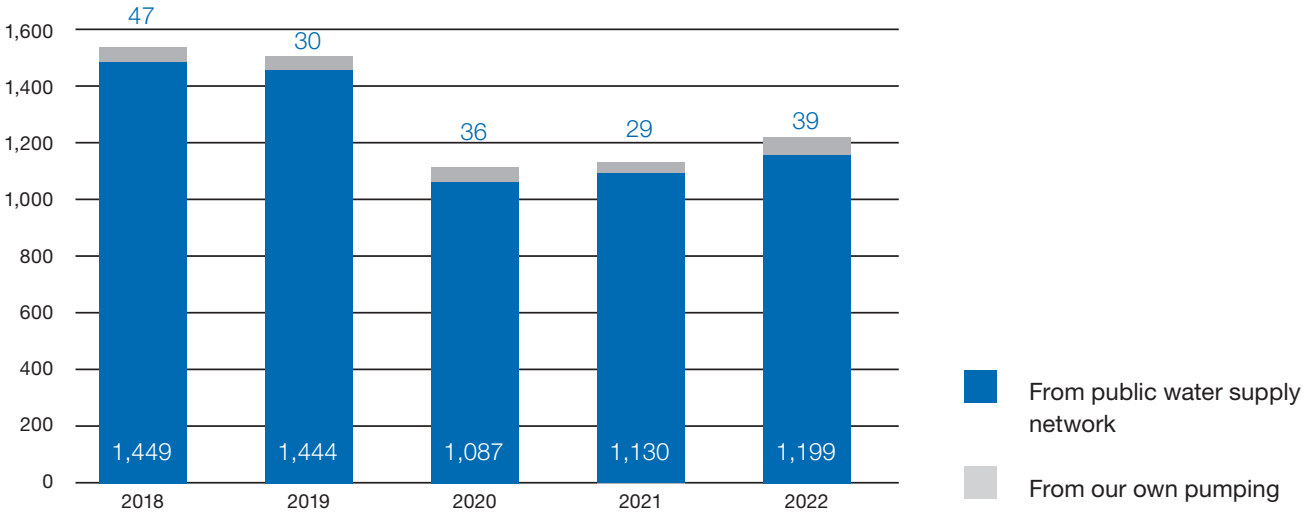
Water supply sources

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.[49] 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.

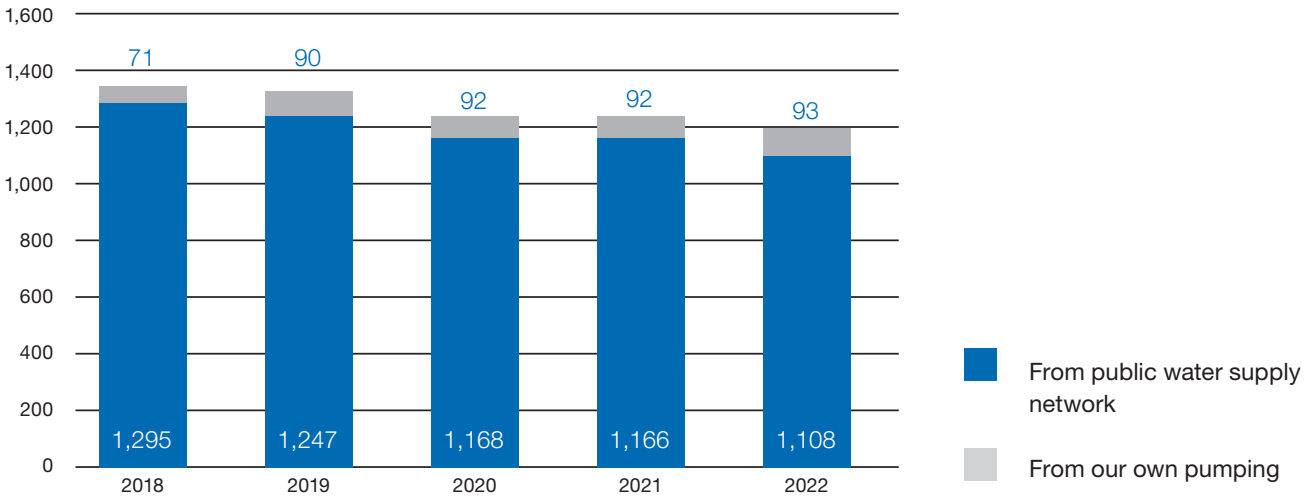
We have drilled piezometers for operational monitoring of groundwater pollution. The piezometers located to the south of the site (outlet water), showed groundwater has better quality than in piezometers north of the site (inlet water).

In Mengeš, the use of water from the public water supply has been reduced by 17% in five years, and by 64% compared to the base year of 2016. In the last year, the consumption was higher by 34%, which is the result of the temporary use of water from the public water supply network instead of the internal well system during the validation of the new systems. The consumption of water from our own pumping station was 6% higher in 2022. In Lendava, the use of drinking water was maintained at the level of the previous year, while the use of water from our own pumping station was reduced by 5%. In Ljubljana, total water consumption was 2% higher due to additional production units.

Amount and sources of water supply at Mengeš site in 1,000 m³ [50]



Amount and sources of water supply at Lendava site in 1,000 m³ [51]



49 Water permit no. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8
50 GRI 303-3
51 GRI 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. We estimate that the share of recycled water is constantly being increased, mainly at the Mengeš site. Recycled water is mostly used 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[52]

The concept 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 in Lek increased by 1.8% in 2022. In Prevalje it was lower by 29%, in Mengeš it was higher by 3.3%, in Lendava by 2.3% and in Ljubljana by 0.2%. The amount of hazardous waste was reduced by 2.4%, while the amount of non-hazardous waste, the majority of which is biodegradable waste mycelium from Lendava production, was increased by 2.1%.

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 92.6% of all generated waste is recycled or reused, it is almost completely (99.3%) recycled or we use again. Biodegradable waste accounts for 82% of all Lek waste.

Composition of generated waste in 2022 in t

	Generated waste	Waste directed to recycling and prepped for reuse	Waste directed for incineration, co-incineration or landfill*
Hazardous waste	3,102	1,832	1,270
Non-hazardous waste	38,741	38,463	278
Total	**41,843**	**40,295**	**1,548**

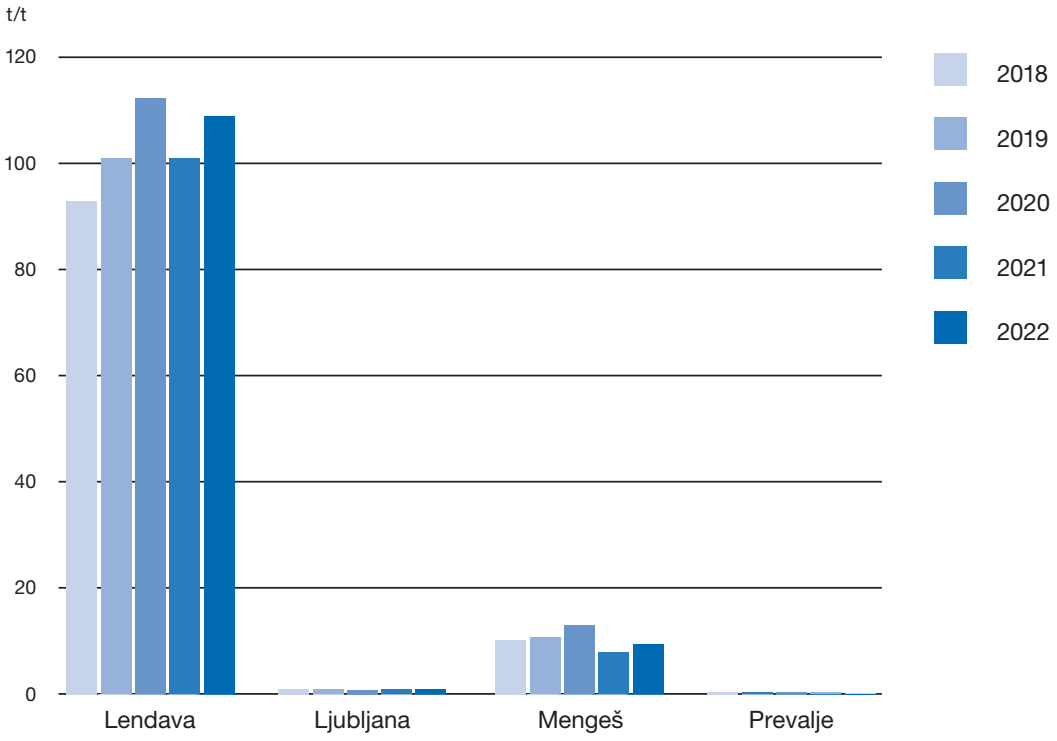
* We only put non-hazardous waste to landfill.

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

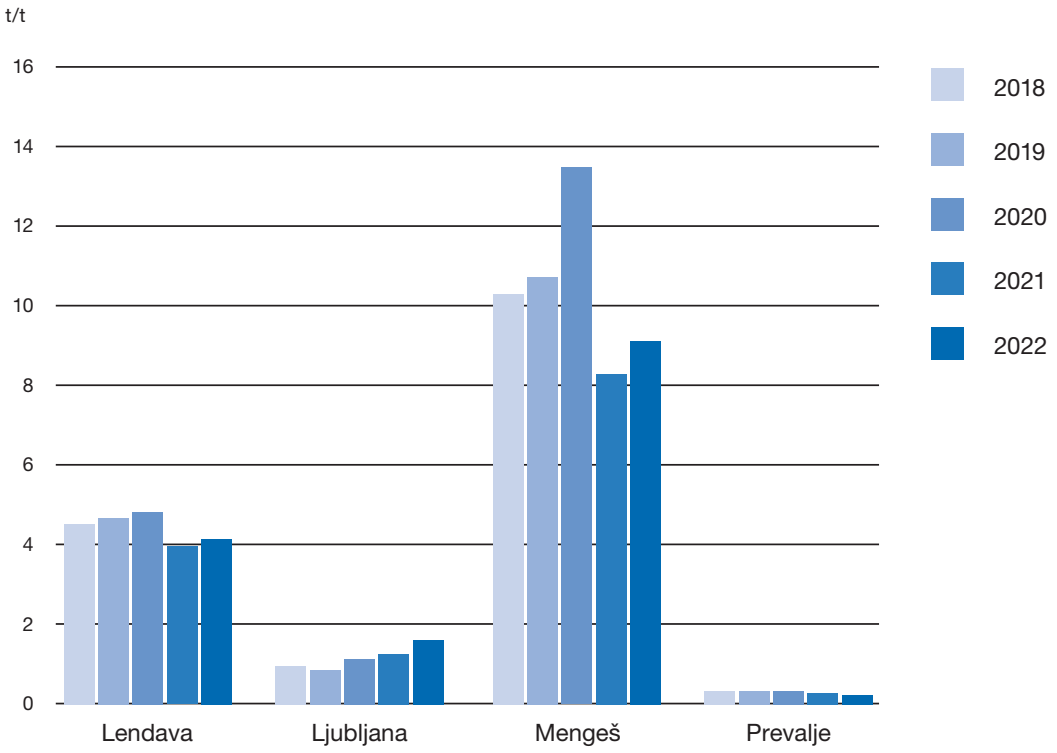
Composition of generated waste, in t by site

	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
Hazardous waste					
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
2022	**57**	**965**	**1,940**	**140**	**3,102**
Non-hazardous waste					
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
2022	**35,546**	**2,224**	**733**	**238**	**38,741**

Amount of waste per t of product - efficiency



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



Hazardous waste disposal[53]

When dealing with hazardous waste, our main goals are to prevent and reduce their generation and to constantly increase their share for recycling or energy use. We reduced the amount of hazardous waste by 2.4% in 2022, 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 locations.

In Ljubljana, the amount of hazardous waste, which otherwise represents 30% of all waste at the site, was slightly higher (by 0.6%) compared to 2021. Quantitatively, the most important of them are waste from production and expired products, or drugs returned from the market. At the Prevalje site, hazardous waste represents 37% of all waste and has decreased by almost 20% compared to the previous year. In Lendava, the amount of hazardous waste was higher by 9.6%, while in Mengeš it was lower by 2.7%.

In Lek, we processed and reused almost 90% of all organic solvents, in Lendava this share was more than 97%. The total amount of generated waste solvents was 24% less in Mengeš, and the proportion of reused solvents was on average 55%, in some processes this proportion is almost 95%.

In Mengeš, 82% of all hazardous waste is high-energy waste solvents. By co-incinerating with natural gas, we removed 1,324 tons of them, which is equivalent to about 19% of the primary energy to generate steam to supply energy processes at the site. Compared to the previous year, we removed 53% less waste solvents through co-incineration due to lower production volumes and the introduction of new products. By processing waste solvents, we reduce the consumption of energy for the preparation of steam, transport of waste solvents and, consequently, CO_2 emissions. In total, we processed 2,248 high-energy waste solvents for energy purposes at the Mengeš and Lendava sites. The rest of the waste solvents are given to authorized companies that dispose of the waste in an environmentally acceptable way, mostly using the waste as fuel in accordance with the R1 process.

53 RCI OI 5, GRI 306-1, 306-2, 306-3, 306-4, 306-5

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2022	**t**	**0**	**763**	**1,003**	**66**	**1,832**

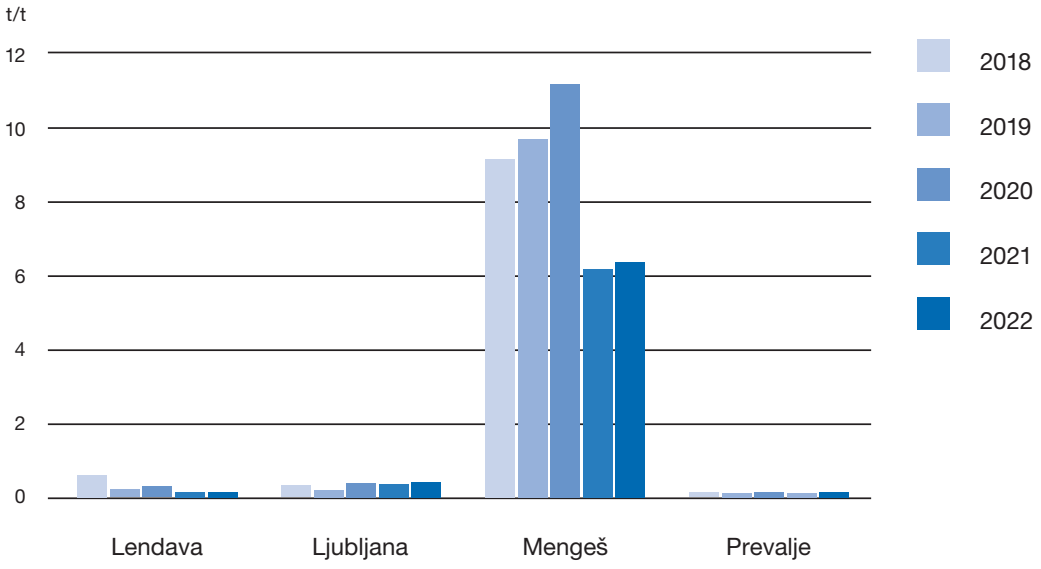
* The data shows the quantities of hazardous waste that we handed over to external authorized contractors.

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2022	**t**	**58**	**202**	**936**	**74**	**1,270**

* 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[54]

Non-hazardous waste accounts for 92.6% of all Lek waste. The amount of non-hazardous waste increased by almost 2% in 2022.

Just over 82% 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 17% is put to landfill. Packaging accounts for a good 9% of non-hazardous waste and is recycled in sections (paper, plastic, wood, metal, and glass). 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 packaging as it is recycled)
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
2022	**t**	**35,546**	**2,224**	**733**	**238**	**38,741**	**35,194**

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
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
2022	**t**	**35,379**	**2,192**	**678**	**214**	**38,463**

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

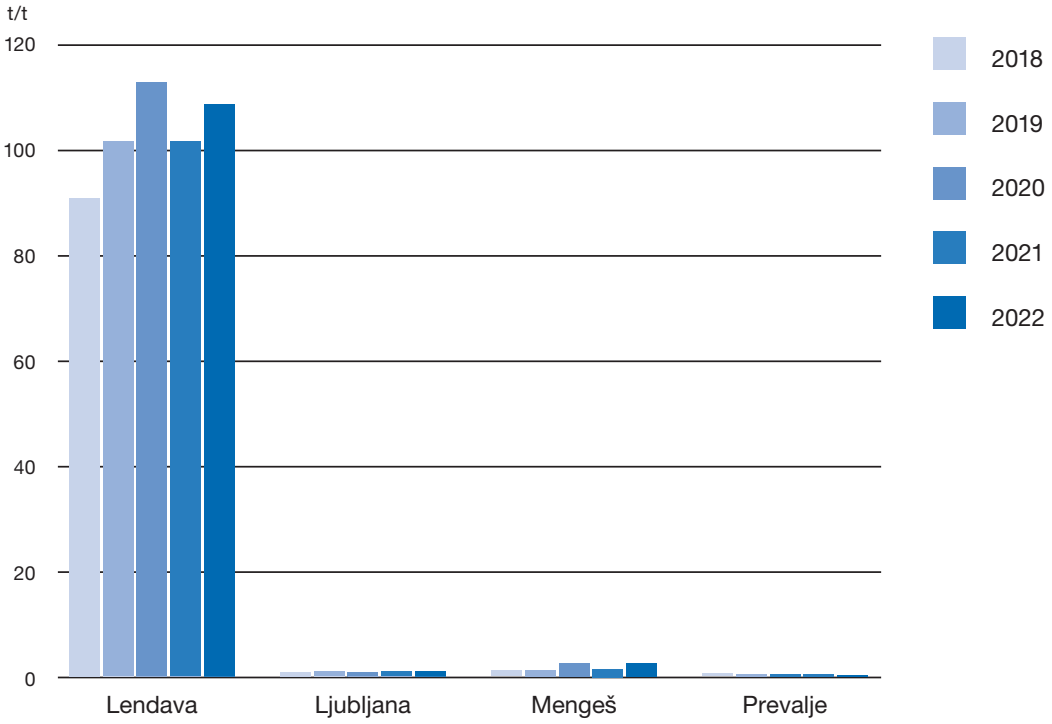
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
2018	t	1	3	40	41	85
2019	t	0	1	62	28	91
2020	t	1	28	68	28	124
2021	t	1	69	41	15	126
2022	**t**	**0**	**29**	**49**	**16**	**94**

Non-hazardous waste directed to landfill in t

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)
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
2022	**t**	**167**	**3**	**6**	**8**	**184**

54 GRI 306-1, 306-2, 306-3, 306-4, 306-5

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



Air emissions[55]

Our objective is by 2040 to be net-zero, which is why our environmental sustainability strategy focuses on limiting emissions into the atmosphere. We will achieve a reduction of air emissions by efficient energy use.

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.

55 EMAS – Core Indicator, RCI OI 7, RCI OI 10, GRI 3-3

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 Slovenian 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 dioxide[56]

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. Their emissions were higher in 2022, mainly due to greater energy use of waste in Lendava.

Sulfur dioxide emissions (SO_2)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)	**Efficiency (Lek)** (kg SO_2/t product)
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
2022	**t**	**0.3980**	**0.0130**	**0.0000**	**0.0500**	**0.4610**	**0.1242**

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 in 2022 were less than almost 3%.

56 EMAS – Core Indicator, RCI OI 7, GRI 305-7

Nitrogen oxide emissions (NO_x)[57]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)	**Efficiency (Lek)** (t NO_x/t product)
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	5.2	33.03	0.007
2021	t	10.69	1.58	12.09	2.5	26.86	0.006
2022	**t**	**10.69**	**0,93**	**12,00**	**2,5**	**26,12**	**0,007**

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)[58] we also include some other gases that we use or produce in our processes, such as:

- dinitrogen oxide (N_2O) in CO_2 equivalents,[59]
- fluorinated hydrocarbons (hydrofluorocarbons, – HFC) in CO_2 equivalents [60] and
- other greenhouse gases (methane and others) in CO_2 equivalents.[61]

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 (in t CO_2)[62]

	Year	Lendava	Ljubljana	Mengeš	Prevalje	**Lek** (Total)	**Efficiency (Lek)** (t CO_2/t product)
GHG1	2018	13,213	2,261	13,916	1,846	31,237	6.1
	2019	13,693	2,569	14,627	1,944	32,833	6.6
	2020	14,134	2,675	14,551	1,719	33,080	7.0
	2021	13,453	2,590	14,549	1,702	32,294	7.2
	2022	**12,658**	**2,652**	**11,977**	**1,595**	**28,882**	**7.8**
GHG2	2018	17,066	39,047	9,432	1,940	67,484	13.2
	2019	16,961	39,275	9,585	1,772	67,593	13.5
	2020	16,685	37,816	9,107	1,695	65,302	13.9
	2021	17,345	23,247*	9,184	1,643	51,419*	11.5*
	2022	**17,063**	**23,453**	**9,143**	**1,506**	**51,165****	**13.8****

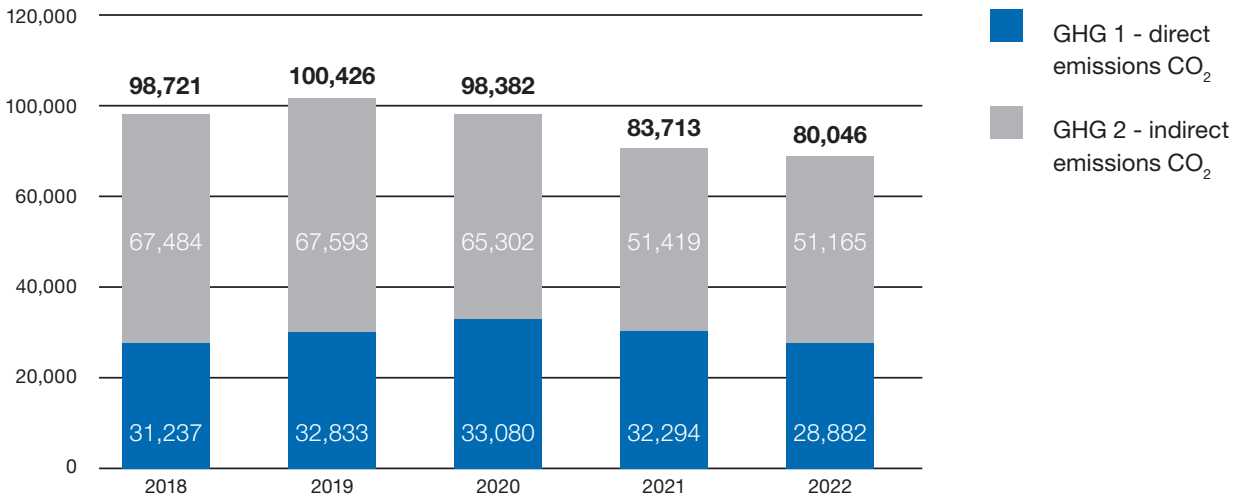
* The information for the Ljubljana location was corrected for 2021, as we obtained a verification report for green energy (steam and heat) from the use of biomass, excess heat and returned steam condensate from the heat supplier. For 2021, the purchase of green energy for steam was taken into account in the proportion of 6.79% and for hot water in the proportion of 100%. For 2022, the purchase of green energy for steam in the proportion of 8.3% and for hot water in the proportion of 100% is taken into account.

** GHG emissions related to electricity consumption are offset from the end of 2022 by EU PPA Certificates of Origin in Spain.

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.

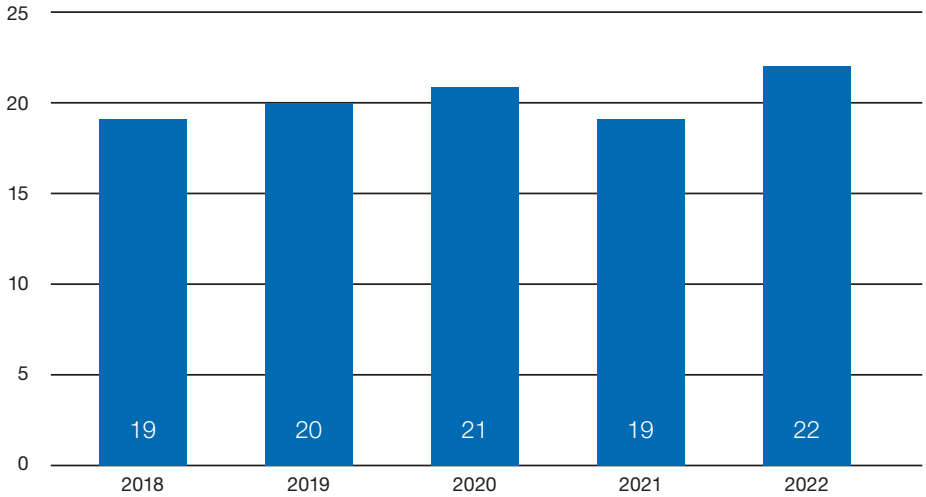
57 EMAS – Core Indicator, RCI OI 8, GRI 305-7
58 RCI OI 10
59 RCI OI 11
60 RCI OI 12
61 RCI OI 13

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



In 2022, we reduced the total amount of GHG emissions by 4.4%. In 2022, we reduced the amount of direct GHG emissions (GHG1) by 10.6%, and the amount of indirect emissions (GHG2) by 0.5%. The efficiency per ton of product decreased slightly, as the trend of introducing new products with high added value, which are more energy demanding and produced in smaller volumes, is increasing. For this reason, we have made it a priority to limit these emissions through systematic energy management, process changes, the introduction of new technological solutions in the product development/transfer phase, and the 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[63]

In 2022, we reduced the total amount of emissions of volatile organic compounds (VOCs) by 17%, which is mainly the result of the reduced use of organic non-halogenated solvents in Mengeš and the smooth operation of the RTO plant in Lendava.

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 HOS/t product)
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
2022	t	**21.3**	**5.1**	**32.3**	**0.8**	**59.5**	**0.016**

Water releases[64]

In line with our 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

63 RCI OI 9
64 GRI 3-3

regulations. Studies have shown that the proportion of pharmaceutical ingredients coming into the water from the pharmaceutical industry is low compared to the source represented by the end-users of pharmaceutical products.

Wastewater

The quantities of cooling and technological wastewater slightly increased (0.7%). Unpolluted waste cooling water in Lendava and Mengeš represents 60% 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.

Wastewater by quality and outlet location[65]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Use of cooling water – unpolluted							
	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
	2022	**1000 m³**	**901**	**0**	**893**	**0**	**1,794**
Discharge			Into the surface water	Into sewage system, cleaning at WWTP	Into the surface water	into sewage system	
Use of industrial water – polluted							
	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
	2022	**1000 m³**	**333**	**522**	**302**	**30**	**1,186**
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

Due to the increased volume of production, the emissions of phosphorus and nitrogen compounds and the chemical need for oxygen in 2022 were slightly higher than in the previous year.

Emissions of phosphorus compounds in water are caused by the remains of inorganic substances from fermentation production, the highest in Mengeš and Ljubljana. Compared to the previous year, we recorded a 16% increase in the quantities of these compounds, which is the result of a greater volume of fermentation production for the Tacrolimus product.

Emissions of nitrogen compounds in water are also caused by fermentation production, their largest share is in Lendava, followed by Ljubljana and Mengeš, in Prevalje these emissions are negligible. The total amount of these emissions increased by 1.3% in 2022.

The annual amounts of phosphorus and nitrogen compounds are recorded after treatment in the treatment plant, so they largely depend on the efficiency of wastewater treatment. In Mengeš, we discharge technological waste water to the Domžale-Kamnik Central Wastewater Treatment Plant.

Pollution with organic impurities shows the chemical oxygen demand indicator, which reflects the amount of oxygen required for the chemical oxidation of organic pollution in the wastewater. Load measurements of

65 EMAS – Core indicator, GRI 303-4

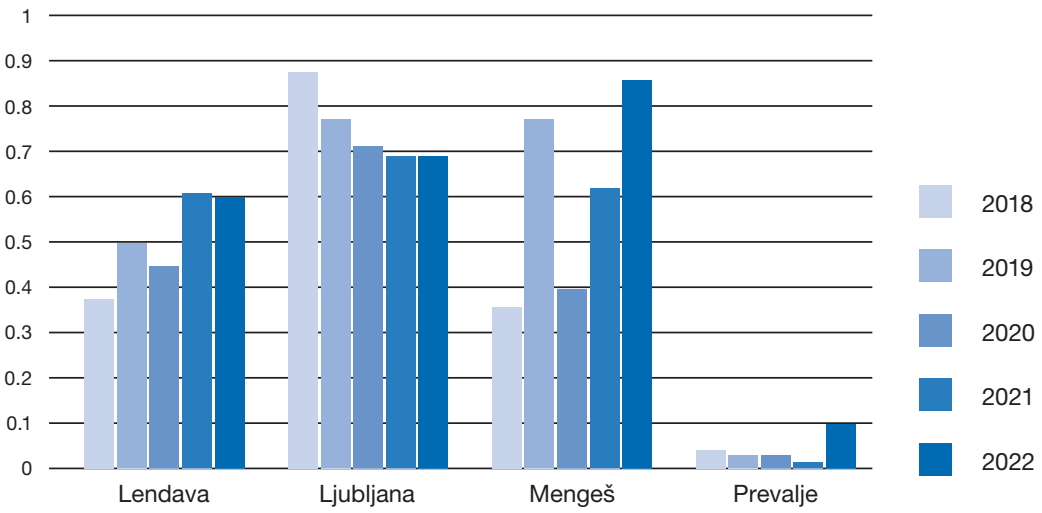
the chemical oxygen demand are carried out at the wastewater outlet into the sewer. In 2022, the chemical oxygen demand parameter remained at approximately the same level as in the previous year (0.1%).

In Prevalje and in Ljubljana, waste water from the production of finished products has little load, which is also reflected in its contribution to the chemical need for oxygen. Together, they contribute less than 2% of the total wastewater pollution with organic impurities to the site.

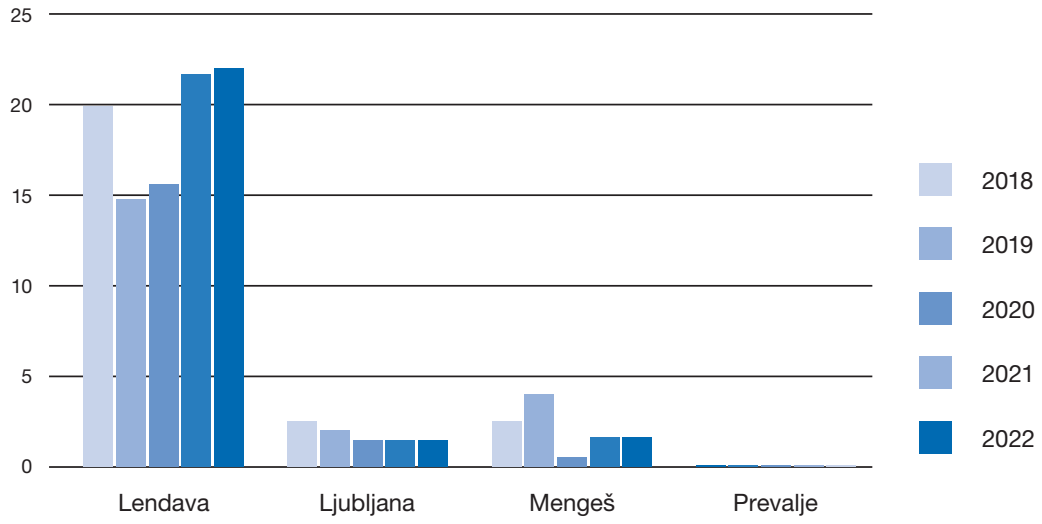
The parameters for calculating the environmental charge are the total phosphorus and nitrogen compounds in the wastewater and the chemical oxygen demand. The largest share of the load, more than 80%, is represented by the chemical demand for oxygen, while phosphorus and nitrogen compounds have a share of about 10%.

Wastewater and the content of all three parameters are regularly monitored by authorized monitoring operators, who carry out the monitoring from three to twelve times a year, depending on the amount of wastewater at each site.

Emissions of phosphorous compounds in wastewater (in t)[66]

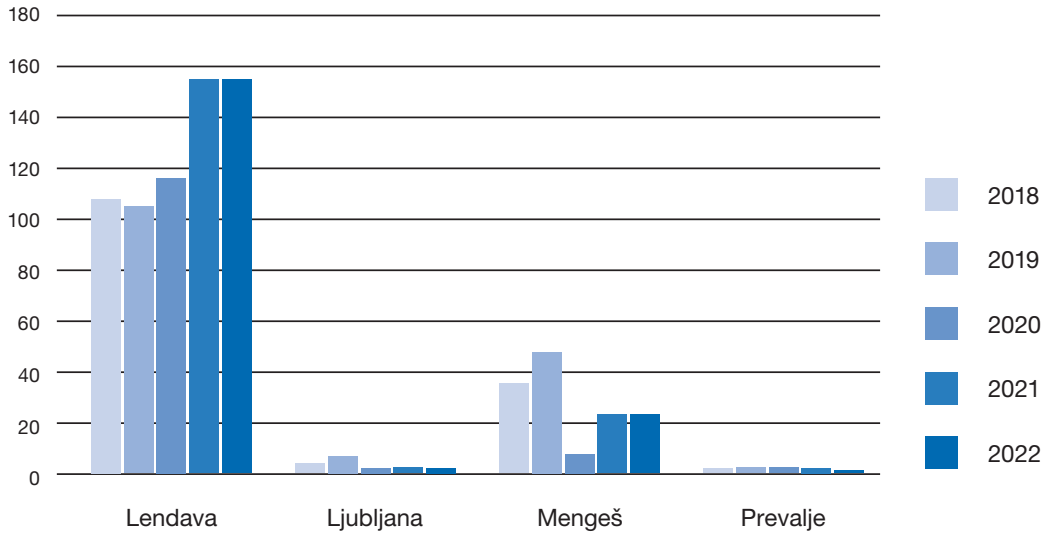


Emissions of nitrogen compounds in wastewater (in t)[67]



66 RCI OI 15
67 RCI OI 16

Chemical oxygen demand (in t O_2)[68]



Other environmental impacts

Odor

The odor is triggered by various volatile substances, mostly of organic origin. With regard to the burden of odors on the environment in Slovenia, a new regulation on the emission of substances into the air from stationary sources of pollution was adopted in 2022. Its annex, which determines the limit values, comes into force in two years.

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.

Maintaining the cleanliness of the site and the orderly way of handling waste with regular removals from the sites further contribute to the fact that no unpleasant odors are detected at the sites.

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 2022 we completed Novartis' internal record of soil and groundwater condition (sampling and analysis of soil and groundwater) at all locations.

68 RCI OI 14

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 2022 we received no noise complaints in Lek.

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[69]

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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

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 dictate 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.

69 EMAS – Core indicator

Safety

Fire Safety

We did not record any major cases at Lek's sites in 2022 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. In 2022, volunteer firefighters also took part in training within the Fire Brigade Association of Slovenia.

During the year, a training plan was prepared for employees for persons responsible for initial extinguishing and evacuation and how to act in the event of an earthquake. The employees completed the theoretical part via the UP4Growth application, while the practical part was carried out at quarterly events in the field of fire protection, namely with a simulator for extinguishing initial fires and a presentation of how to act in the event of an earthquake. Absorption means were also presented in case of spillage of dangerous substances in the laboratory or in production/warehouse.

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 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 Lek, we currently have 11 closed systems for work with GMOs registered at the Ministry of Environment, Climate and Energy, ten in Mengeš and one in Ljubljana. In 2022, we had an external audit by the Environmental Inspectorate in a closed system for working with GMOs in Ljubljana, where there was no non-compliance. We also obtained the first permit from the Ministry of the Environment and Space to work with GMOs classified in the 2nd safety class in the Developmental Bioanalytics laboratory in Mengeš.

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.

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. Employees and chemical consultants at Lek actively recognize the dangerous properties of chemicals from the content of the Safety Data Sheets and take into account protective and organizational measures at the workplace, taking into account the properties and quantity of the chemical as well as the process and equipment on which the chemical is used.

Ensuring measures to protect employees and the environment in the production of pharmaceutical agents are also a key content of REACH registrations (Registration, Evaluation and Authorization and Restriction of Chemicals) of strategic chemicals at the European Chemicals Agency (ECHA). Registrations ensure the Lek company smooth import and isolation of raw materials in the production of pharmaceutical active ingredients.

Measurements of exposure to chemicals in the work environment

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

Biological monitoring

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

Labor

We are building a culture that encourages curiosity and enables learning and acceptance of all diversity. With various HR programs, we provide our employees with a safe and stimulating work environment, and we try to develop, attract and retain talent for the future.

2022 Highlights

608

jobs created. At the end of the year Lek had 5,771 employees.

621

employees had used their parental leave, 11% more than in 2021. 41% were male.

74.2

hours or 9.3 days of education and training average per Lek employee in 2022.

93.4%

full-time employees, 47.2% women.

Human resource policy[70]

With our personnel policy, we highlight the principles of cooperation, development and excellence. We support fundamental business orientations aimed at a high level of innovation, growth and productivity improvement. At the same time, we create an environment that supports the diversity and freedom of employees.

The priority task is the design of processes, tools and systems for recruitment, talent development and succession planning, rewarding achievements, organizational development and education.

Employment

Total workforce by employment and employment contract[71]

At the end of 2022, Lek had 5,771 full-time employees (7% more than in 2021), 576 agency workers and 2,371 external workers. At the end of the year, the proportion of women was 47.2%, which was three percentage points lower than the year before. At the end of the year, 93.94% of employees were employed for an indefinite period, while 6.06% were employed for a fixed period of time. 1.7% of employees had a part-time contract.

Number of full-time employees on 31.12.2022 by site and gender

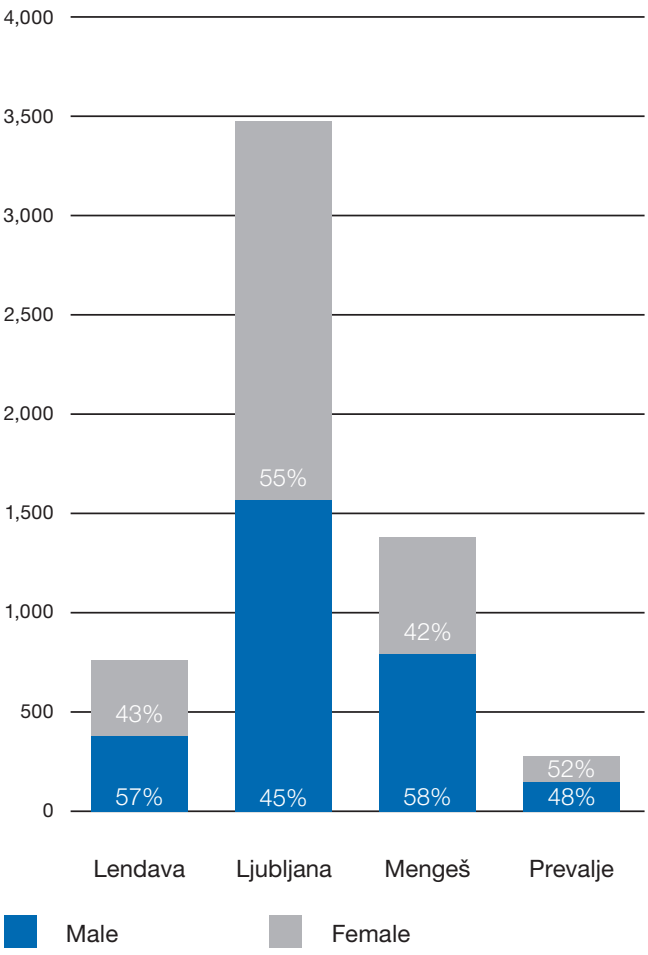
Site	Male	Female	Total
Lendava	411	309	720
Ljubljana	1,558	1,909	3,467
Mengeš	794	584	1,378
Prevalje	95	102	197
Other*	9	0	9
Total	**2,867**	**2,904**	**5,771**

* Rented warehouse (Brnik)

Number of new employees in 2022 by age group (in%)

Age group	No. of employees	%
18-25	113	18.6%
26-30	223	36.7%
31-35	117	19.2%
36-40	89	14.6%
41-45	43	7.1%
46-50	17	2.8%
51-55	5	0.8%
56 +	1	0.2%
Total	**608**	**100%**

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



70 GRI 3-3
71 GRI 2-7, 2-8, 401-1

Percentage of employees covered by collective agreements[72]

The Collective Agreement covers 98.94% of the total workforce, a level similar to that in the previous years.

Liabilities from the pension plan[73]

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 2022, 97.9% of the workforce was included in the scheme.

Employment process and percentage of local employees in senior management[74]

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. In 2022, the proportion of local human resources in the senior management team was 86.89% (2021: 84.62%).

Parental leave[75]

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.

Parental leave and return to work rate

	2022	2021	2020	2019	2018
Number of employees having taken parental leave	**621**	560	506	479	458
Male	**258**	236	219	230	219
Female	**363**	324	287	249	239
	609	553	503	478	458
Number and share (in %) of employees returning	**(98.1%)**	(98.7%)	(99.4%)	(99.8%)	(100%)
	256	232	219	229	219
Male	**(99.2%)**	(98.3%)	(100%)	(99.6%)	(100%)
	353	321	284	449	239
Female	**(97.2%)**	(99.1%)	(98.9%)	(100%)	(100%)

Occupational health and safety[76]

Occupational health and safety are placed at the center of the culture and code of ethics at Lek. We are committed to promoting and maintaining healthy and safe workplaces. With this, we ensure the well-being of our colleagues and their good psychophysical condition.

Together, we constantly promote good practices, protect ourselves, others and the environment, thereby preventing risks and their impacts. We also foster a culture where every employee feels empowered and able to contribute to our shared occupational health and safety culture. With the health assessment, which is an integral part of the safety statement, we identify, eliminate and reduce all forms of risk for employees. We regularly implement all preventive measures adopted in risk assessments.

In 2022, we further upgraded the management's commitment to health, safety and environment policy with the slogan »Together let's encourage, prevent, protect«. Even such a small action counts and is important in the system of continuous improvement, achievement of goals and excellence of the company.

The situation related to covid-19 also dictated a number of preventive and operational activities in 2022, which we carried out with all seriousness in order to prevent the spread of infections, ensure health and safety in the work environment, and ensure smooth operations. Remote work was still popular, so we further upgraded the existing guidelines with detailed instructions for colleagues and also prepared a video with recommendations and warnings about what is key to ensuring both mental and physical health in this form of work.

Even after the improvement of the situation in April, we maintained key preventive measures and defined procedures in case of a relapse situation. In addition to managing new and existing construction sites, safety culture represented a large part of the activity. Thus, we improved the management safety walkthroughs, trained managers and set goals.

72 GRI 2-30
73 GRI 201-3
74 GRI 3-3, 202-2
75 GRI 3-3, 401-3
76 GRI 3-3, 403-1, 403-2

In addition to managing new and existing construction sites, safety culture represented a large part of the activities in 2022.

In 2022, we successfully completed a regular audit according to the ISO 45001:2018 standard. The findings of the audit confirmed our compliance and continuous improvement of the occupational health and safety system. The review was concluded without deviations, with some recommendations for further improvement.

We also improved the risk assessment methodology, incident procedure, process safety and many other procedures. We promoted current topics monthly to raise safety culture and awareness. Thus, in 2022, we discussed 15 different topics, which we presented to all colleagues.

Frequency of absences due to injuries at work[77]

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).

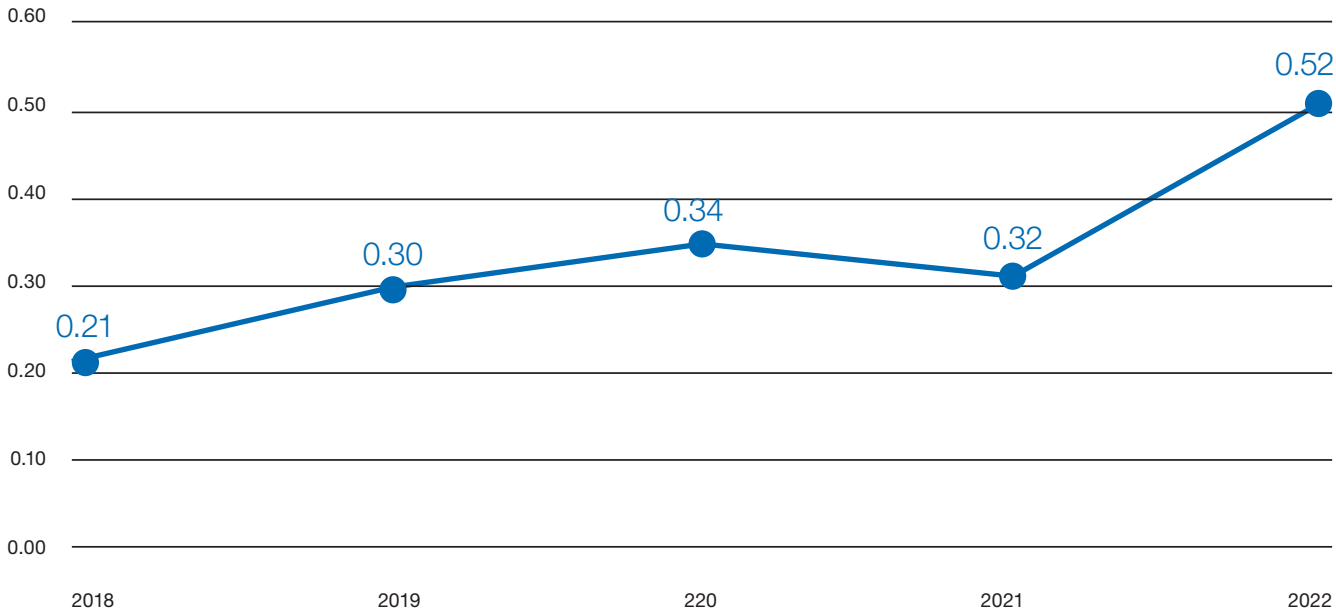
Lost Time Injury and Illness Rate

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
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
2022	**0.22**	**0.46**	**0.44**	**2.15**	**0.52**

77 RCI OI 2, GRI 403-9

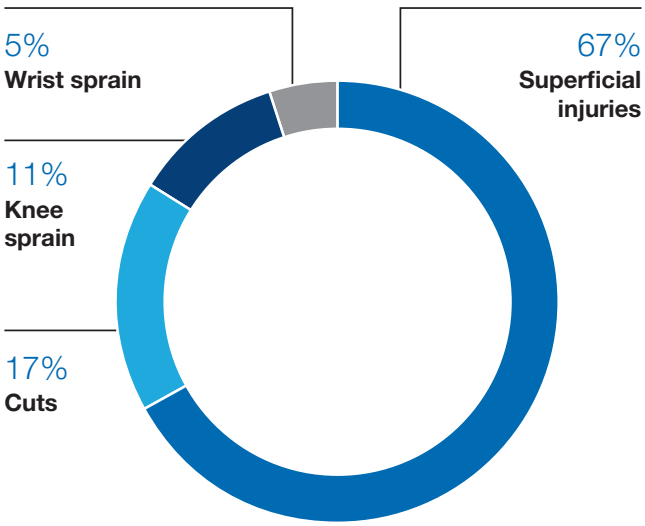
In the past year, we had no serious injuries at work or injuries with permanent health impairments. There were 18 accidents at work (employees and agency workers) that resulted in injuries with temporary absence from work: minor surface injuries, minor cuts and in three cases, sprains. Both employees and agency workers are included in the statistical processing. The work-related injury and illness frequency index (LTIR) was 0.52 per 200,000 effective hours.

Trend of LTIR injuries



Despite the lighter forms of injuries (84% minor surface injuries and cuts), we detected an increased amount of sick leave. Absence due to such forms of injuries has been significantly lower in the past years.

Categories of accidents based on cause (LTIR and TRCR) in 2022



HSE System

Preventive activities to prevent accidents and injuries in 2022

In 2022, we focused on the verification of work with increased risk in the field (work at height, lifting, fire-hazardous work, work in confined spaces, etc.). In addition to periodic training with proficiency testing, we also conducted other training related to safe work in confined spaces, work at height, first aid, work with forklifts, training of persons responsible for the safety of storage systems based on revised training programs. The emphasis of this training was mainly on practical competences for correct and safe work.

In 2022, we conducted and documented more than 1,300 safety walkthroughs by representatives of the management of individual organizational units. The improvement of the safety culture is also reflected in the increase in the number of reported near misses that could have negative consequences.

Absenteeism[78]

Absenteeism rate or the proportion of sick leave is the ratio between the number of working hours of absent employees and the total working hours. Sick leave up to 30 days, over 30 days and care are included in the share. In 2022, the share of sick leave amounted to 6.53% and was higher than the year before (6.04%).

Share of sick leave

	2022	2021	2020
Women	3.74%	6.60%	5.91%
Men	2.79%	5.47%	3.88%
Total	**6.53%**	**6.04%**	**4.87%**

Frequency of external contractor absence from work due to injuries in the workplace

We largely focused on managing the occupational health and safety of external contractors who worked at our sites. Due to the restrictions related to covid-19 in the past two years, the activities of external service providers were significantly more intensive in 2022. Among other things, we familiarized them with site regulations, instructions for external contractors, checked work permits and work programs with risk assessment.

Over 100 external contractors participated in the annual overhauls at our sites, who also carried out activities with increased risk (lifting, work at heights, work in confined spaces, fire-hazardous work, etc.). There were no injuries to co-workers or outside contractors during these works.

In 2022, we recorded five events where external service providers were involved and which could potentially lead to more serious injuries at work. For all of these near misses, we conducted detailed research and defined measures to prevent such and similar events in the future.

In addition to regular visits to construction sites and work sites, we also carried out annual assessments of external contractors who carried out work with increased risk.

Number of work-related fatalities[79]

There were also no fatalities recorded amongst our employees or external contractors.

Frequency (level) of occupational disease rate[80]

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[81]

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.

78 GRI 403-9
79 RCI OI 1,RCI OI 3, GRI 403-9
80 GRI 403-10
81 GRI 403-3, 403-4, 403-5, 403-6

In 2022, we carried out 2,882 preventive health examinations of employees. We also carried out inspections of critical work equipment, investigations of harmfulness in the work environment, revised risk assessments and other planned preventive activities. During the preparation and implementation of the health promotion program, occupational health and safety representatives collaborated with the human resources department.

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:

- vaccinations against seasonal flu, tick-borne meningoencephalitis,
- guided exercises and measurement of body composition,
- daily kinesiology workshops (remote),
- active breaks in the office (online),
- active breaks in production,
- afternoon exercise,
- SIM training (basic resuscitation procedures - TPO and automatic external defibrillator - AED),
- subsidized sport activities,
- preventive medical recovery,
- providing psychological help,
- event »How are you?«.

Training and education[82]

Continuous education and training of employees is crucial for the growth and progress of the company. We invest continuously and plan the development, education and training of our employees. Employees can participate in:

- 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.

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.

82 GRI 3-3

HSE organization, human resources and training

In 2022, the HSE department was still part of the organizational unit NO Development sites, which implements and provides optimal infrastructure, energy and professional services to production sites and also to organizations located at Lek's sites.

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 2022, 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 3280 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 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 2022, one external audit of compliance was performed with ISO 14001: 2015 and ISO 45001: 2018, whereby the ISO 14001:2015 audit was a recertification one. 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.

In 2022, 25 internal HSE audits were carried out, and a global Novartis audit of legal compliance in February.

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) was supplemented in 2022 with a reporting system in the HSE net application. Bots systems enable 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 activities in 2022

With the business continuity management (BCM) system, we enable operations in the event of major negative impacts on our key products and business processes and our employees. In addition to the successful response to the covid-19 pandemic, BCM and NEM are currently extremely important in ensuring the continuous supply of medicines during the Russian-Ukrainian geopolitical conflict, the energy crisis and negative macroeconomic impacts. We constantly upgrade our business continuity processes, mainly based on the experience of past events and the exchange of good practices between individual sites. In 2022, we focused on cyber security and the establishment of effective processes to ensure business continuity of our key suppliers, who are an important element in the entire supply chain of our medicines to patients.

NEM activities in 2022

In 2022, we updated the Novartis Emergency Management (NEM) structure in Slovenia with a new member at the site level. All Novartis departments have been trained according to the NEM process. In 2022, the NEM manual was revised, where we updated and added NEM plans with the latest potential emergencies such as a cyber-attack and geopolitical tensions.

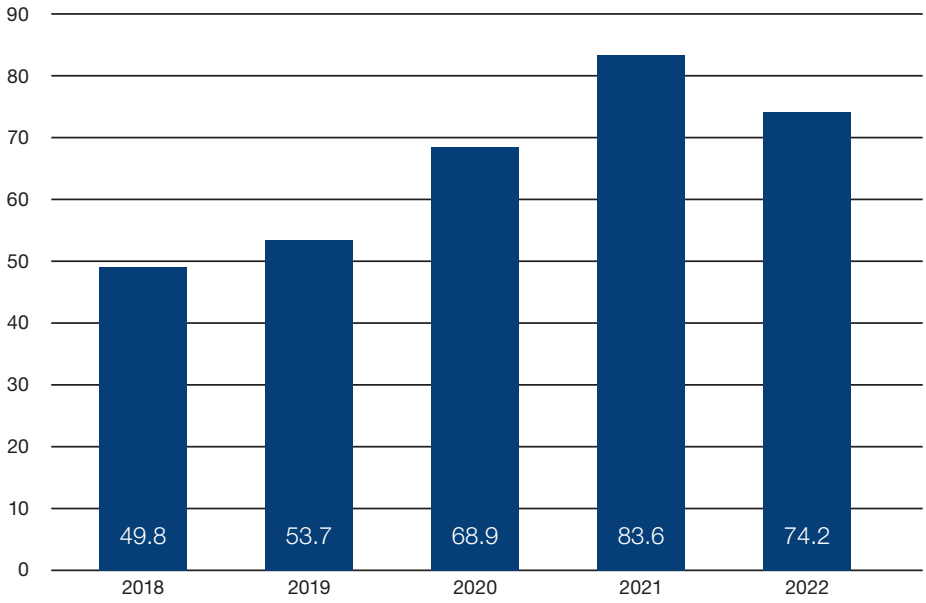
NEM training was held for a new member of the NEM group and refresher training for all members of NEM teams who completed training two or more years ago. All members of the NEM teams in Slovenia have familiarized themselves with the latest version of the NEM manual.

In 2022, we still devoted most of our time to managing the covid-19 pandemic, we had no other NEM events.

Average hours of training per employee[83]

We pay a lot of attention to the training of our colleagues and maintain a high volume of training. Thus, on average, in 2022, Lek's employees received **74.2 hours** of training, or **9.3 days**.

Average hours of training per employee



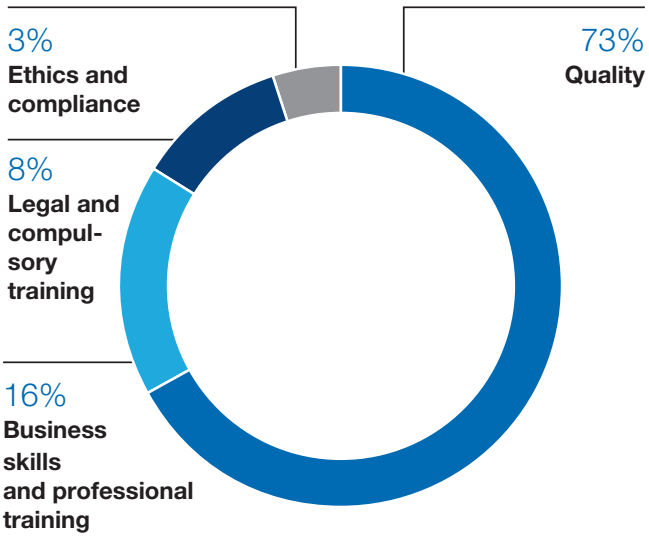
Training by area

In the first half of 2022, due to Covid-19, training was carried out online, and in the second half of the year, when the measures related to Covid were relaxed, we carried out skills training physically in classrooms. The decision to resume training in the classroom was well received by the training participants.

At Lek, we also enable our colleagues to study while working; we had 36 colleagues in undergraduate education, and 49 in postgraduate education, of which the majority were in biotechnology and biomedicine and chemistry.

As can be seen from the graph below, in terms of the number of hours of training, we provided the most training in the following three areas: quality (73%), business skills and professional training (16%) and statutory and compulsory training (8%).

Training by area in 2022 (average no. of hours per employee)



83 GRI 404-1

GRI content index

Statement of Use	Lek has reported in accordance with the GRI (Global Reporting Initiative) Standards for the period from 1 January 2022 to 31 December 2022.
GRI 1 used	GRI 1: Foundation 2021
Applicable GRI Sector Standard(s)	At the time of the preparation of the report there were no relevant sector standard(s).

GRI 2: GENERAL DISCLOSURES

GRI-standard	Disclosure	Page	Requirement(s) omitted	Reason and explanation
The Organization and its reporting practices				
2-1	Organizational details	6, 20, 23		
2-2	Entities included in the organization's sustainability reporting	27		
2-3	Reporting period, frequency and contact point	27		
2-4	Restatements of information	27		
2-5	External assurance	50		
Activities and workers				
2-6	Activities, value chain and other business relationships	7, 21, 22, 23, 27, 42		
2-7	Employees	79		
2-8	Workers who are not employees	79		
Governance				
2-9	Governance structure and composition	28		
2-10	Nomination and selection of the highest governance body	28		
2-11	Chair of the highest governance body	28		
2-12	Role of the highest governance body in overseeing the management of impacts	45		
2-13	Delegation of responsibility for managing impacts	45		
2-14	Role of the highest governance body in sustainability reporting	28		
2-15	Conflicts of interest	28		
2-16	Communication of critical concerns	45	2-16 b.	Information unavailable
2-17	Collective knowledge of the highest governance body	45		
2-18	Evaluation of the performance of the highest governance body	28		
2-19	Remuneration policies		Information unavailable	Information unavailable
2-20	Process to determine remuneration		Information unavailable	Information unavailable
2-21	Annual total compensation ratio		Information unavailable	Information unavailable
Strategy, policies and practices				
2-22	Statement on sustainable development strategy	4		
2-23	Policy commitments	41, 47		
2-24	Embedding policy commitments	47		
2-25	Processes to remediate negative impacts	47		
2-26	Mechanisms for seeking advice and raising concerns	39		
2-27	Compliance with laws and regulations	48		
2-28	Membership associations	30		
Stakeholder engagement				
2-29	Approach to stakeholder engagement	29, 35, 37, 39		
2-30	Collective bargaining agreements	80		

GRI-standard	Disclosure	Page	Requirement(s) omitted	Reason and explanation	EMAS Core indicators
GRI 3: MATERIAL TOPICS					
3-1	Process to determine material topics	27			
3-2	List of material topics	90–92			
ECONOMIC TOPICS					
GRI 201: Economic performance 2016					
3-3	Management of material topics	Letter from the President of the Board of Management/4			
201-1	Direct economic value generated and distributed	7			
201-3	Defined benefit plan obligations and other retirement plans	80			
201-4	Financial assistance received from government	7			
GRI 202: Market presence 2016					
3-3	Management of material topics	80			
202-2	Proportion of senior management hired from the local community	80			
GRI 204: Procurement practices 2016					
3-3	Management of material topics	43			
204-1	Proportion of spending on local suppliers	43			
GRI 206: Anti-competitive behavior 2016					
3-3	Management of material topics	41			
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	41			
ENVIRONMENTAL TOPICS					
GRI 301: Materials 2016					
3-3	Management of material topics	52			
301-1	Materials used by weight or volume	52			EMAS Core indicator
GRI 302: Energy 2016					
3-3	Management of material topics	48			
302-1	Energy consumption within the organization	54			
302-3	Energy intensity	54			EMAS Core indicator
302-4	Reduction of energy consumption	58			
GRI 303: Water and effluents 2018					
3-3	Management of material topics	48			
303-1	Interactions with water as a shared resource	59			
303-2	Management of water discharge-related impacts	59			
303-3	Water withdrawal	59			EMAS Core indicator
303-4	Water discharge	72			EMAS Core indicator
GRI 305: Emissions 2016					
3-3	Management of material topics				EMAS
305-1	Direct (Scope 1) GHG emissions	51, 69			
305-2	Energy indirect (Scope 2) GHG emissions	69			
305-4	GHG emissions intensity	69			
305-5	Reduction of GHG emissions	58			
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	68			EMAS Core indicator

GRI-standard	Disclosure	Page	Requirement(s) omitted	Reason and explanation	EMAS Core indicators
GRI 306: Waste 2020					
3-3	Management of material topics	62			
306-1	Waste generation and significant waste-related impacts	62, 64, 66			EMAS Core indicator
306-2	Management of significant waste-related impacts	62, 64, 66			EMAS Core indicator
306-3	Waste generated	62, 64, 66			EMAS Core indicator
306-4	Waste diverted from disposal	62, 64, 66			EMAS Core indicator
306-5	Waste directed to disposal	62, 64, 66			EMAS Core indicator
GRI 308: Supplier environmental assessment 2016					
3-3	Management of material topics	43			
308-2	Negative environmental impacts in the supply chain and actions taken	43, 51		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					
3-3	Management of material topics	79			
401-1	New employee hires and employee turnover	79			
401-3	Parental leave	80			
GRI 403: Occupational Health and Safety 2018					
3-3	Management of material topics	80			
403-1	Occupational health and safety management system	80			
403-2	Hazard identification, risk assessment, and incident investigation	80			
403-3	Occupational health services	83			
403-4	Worker participation, consultation, and communication on occupational health and safety	83			
403-5	Worker training on occupational health and safety	83			
403-6	Promotion of worker health	83			
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	39			
403-9	Work-related injuries	81, 83			
403-10	Work-related ill health	83			
GRI 404: Training and education 2016					
3-3	Management of material topics	84			
404-1	Average hours of training per year per employee	88		We do not yet record education by gender and by employee category.	
GRI 406: Non-discrimination 2016					
3-3	Management of material topics	41			
406-1	Incidents of discrimination and corrective actions taken	41			

GRI-standard	Disclosure	Stran	Requirement(s) omitted	Reason and explanation	EMAS Core indicators
GRI 412: Human rights assessment 2016					
3-3	Management of material topics	41			
412-2	Employee training on human rights policies or procedures	41			
GRI 413: Local communities 2016					
3-3	Management of material topics	39			
413-1	Operations with local community engagement, impact assessments, and development programs	39	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					
3-3	Management of material topics	43			
414-2	Negative social impacts in the supply chain and actions taken	43		By signing a contractual agreement, the supplier undertakes to comply with all applicable laws and regulations related to fair working practice.	
GRI 417: Marketing and labeling 2016					
3-3	Management of material topics	39			
417-1	Requirements for product and service information and labeling	39		We operate in a strictly regulated industry; this information is obligatory for us to have a license to operate.	
417-2	Incidents of non-compliance concerning product and service information and labeling	39			
417-3	Incidents of non-compliance concerning marketing communications	39			

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: 21.10, 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 2022 – Lek d. d.** chapters Company profile and Environment " 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

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Gregor Schoss:
Director of SIQ Ljubljana

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

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

RCI (Responsible Care Initiative)

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

Generics are successors to pharmaceutical products whose patent protection has expired. A generic drug is a drug product that is comparable to a reference listed drug product in quality and quantity composition, active ingredient and dosage form, its bioequivalence being proven by means of respective bioavailability studies.[84]

Innovative drugs or originator drugs contain a new active ingredient or a combination of active ingredients for which marketing authorization has been obtained, as a rule, on the basis of the manufacturer's own studies, which prove its quality, safety and effectiveness[85]

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.[86] 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,

84 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).
85 Source: European Medicines Agency and Pharmaceutical terminology dictionary.
86 Source: Humar M., Šmid-Korbar J., Obreza A. Pharmaceutical terminology dictionary. Ljubljana 2011.

rheumatic, cardiovascular and some other types of diseases. Over the past years, biologics have saved lives, prolonged survival and improved the quality of life for patients with severe and often chronic diseases.

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

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