Sustainability Report 2016 – Lek d.d.

lek

a Sandoz company

Contents

Sustainability Report 2016 – Lek d.d.

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

2016 key facts

895.3 mil. EUR

NET SALES IN 2016, 5% MORE THAN IN 2015.

1.9 bil. EUR

NOVARTIS' INVESTMENTS IN SLOVENIA OVER THE LAST 14 YEARS, OF WHICH 170 MIL. EUR WAS MADE IN 2016.

New strategic areas

Final biopharmaceutical products began to be developed in Mengeš.

+7%

EMPLOYEES AT THE END OF 2016.

93%

SHARE OF LOCAL EMPLOYEES IN SENIOR MANAGEMENT, 88% IN 2015.

0.05

VALUE OF IMPROVED LTIR INDEX, SHOWING THE FREQUENCY OF WORK-RELATED ACCIDENTS AND ILLNESSES, RESULTING IN THE USE OF SICK LEAVE. IN 2015, THE VALUE OF THE INDEX WAS 0.12.

–11%

REDUCED EMISSIONS OF VOLATILE ORGANIC COMPOUNDS.

+5%

IMPROVED WATER EFFICIENCY.

5.2 mio EUR

INVESTMENT IN ENVIRONMENTAL PROTECTION.

Letter from the President of the Board of Management

Dear associates, partners and stakeholders!

In the anniversary year of 2016, we celebrated 20 years of Novartis and seven decades of Lek; we celebrated the outstanding achievements of our teams and colleagues, whilst our thoughts were set on the future, as we were intensively preparing new development plans at all sites and achieving groundbreaking development milestones.

Among them, the acquisition of the development of the final biopharmaceutical products and the start of the production of the active ingredient for innovative medicine at the location of Mengeš stand out. The opportunity offered to us is not only ours, but also an opportunity for the social environment which we create. In order to bring young scientists home, who have gone abroad for the purpose of searching for professional challenges, we organized Bio Career Breakfast. We are glad to have already gained some new colleagues, top scientists and researchers from its participants. By this we best illustrated that creating good working conditions, employment opportunities and professional development and encouraging influence on local economic and social life is an essential part of Lek's attitude towards the community.

In a country where the pharmaceutical industry is one of the leading industries, we see our place not only in consistently achieving business coherence, but also in recruiting and expanding the volume of jobs with high added value and investing in environmentally responsible high technology. We will strive to continue contributing to this role of the pharmaceutical industry in the upcoming years. At Ljubljana, Mengeš, Lendava and Prevalje sites, we are planning to expand development and production capacities based on employees' knowledge, the top quality of all processes and products, environmental responsibility and efficiency, and the creation of new jobs.

Novartis has invested 1.9 billion EUR in Slovenia over the past 14 years, almost 170 million euros in 2016.

Of this, 5.2 million were invested in environmental protection, as environmentally responsible solutions are a condition and an integral part of all our development decisions. Yearly comparisons show the results of an active environmental policy. With increased production, we increased total energy consumption by 5%, while at the same time we increased the efficiency and lowered the consumption of energy and water per unit of production. The efficient use of raw materials advanced by 1%, while total emissions of volatile organic matter into the atmosphere fell by a further 11%. With the growth of production, the increased quantity of waste remains 7%, which is also associated with a change in the composition of production and a higher number of employees, and it is encouraging that the quantities of hazardous waste decreased by 17%. During the acquisitions at individual sites, I would point out the remediation of the noise source that occurred last

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

year in Prevalje, the introduction of additional regeneration of raw materials in Lendava and the permanent measurement of emissions from the new waste co-incineration plant in Mengeš. Of special importance are the results of inspections at sites, including the most demanding ones, which showed that no significant change of processes is required due to the quality achieved.

Our achievements, like our anniversaries, reflect our long-standing development. At the beginning of the year we opened a new laboratory facility for the development of finished biopharmaceuticals, technical development of biopharmaceuticals and quality control in Mengeš. We also opened a new production facility in Mengeš and acquired new projects for the production of a new active ingredient. The most important Novartis decision at the Prevalje site was its expansion, as production capacity does not currently meet all the needs of the market. In Lendava, we started investing in

"In a country where the pharmaceutical industry is one of the leading industries, we see our place not only in consistently achieving business coherence, but also in expanding the volume of jobs with high added value and investing in environmentally responsible high technology."

new isolation of the intermediate product in the production of potassium clavulanate, which will ensure completely closed handling of the product. We completed the investment in the expansion of the packing center by placing six new packing lines for blister packs. The decision to redirect the packaging of certain innovative medicines to Novartis Pharmaceuticals in Lendava was crucial for the long-term strategic development of Solids Lendava.

The quality of business results has long not been measured solely on the basis of financial indicators or quantitative production volume. This simply is not enough for successful future development and management of all the risks and opportunities that we face as part of the modern world and the Slovenian economy. The present report is intended to highlight the contents and impacts of our business in key areas: access to treatment, innovation, development and research, responsible management of natural resources, employment and transparency.

In 2016, we filed dossiers for 17 new key products for the most demanding global markets and introduced more than 10 new Sandoz molecules and more than 650 new products in 85 markets. We created 358 new jobs and ended the year with 7% more employees, which is 3,599 employees. Among them, 46% have at least higher education, of which over 13% are masters and doctors of science. We mostly employed in development and technical activities, and between locations in Mengeš and Lendava. We remain committed to preventing all forms of discrimination, promoting diversity and involving employees. The share of women among employees was almost 46% at the end of the year and somewhat higher than the previous year. We upgraded the safety culture and further reduced the incidents of occupational accidents and diseases with work-related hospitalizations.

We are aware that the ethics of business practices is a constant test for our industry, and the associated transparency requirement is an opportunity to build confidence in the social environment we are a part of. Last year, with the help of the internal information system, we introduced a global Novartis initiative to disclose potential or actual conflicts of employees' interests. We have again carried out training for all employees in key areas of compliance, as well as a series of training courses on data protection and fair competition.

At the time of completing this report, Novartis, in accordance with its policy of integrity, publicly published data for the past year on payments to doctors or health organizations for the second consecutive year. It was the first in the country to publish information about payments for all services, not only for innovative but also for generic products, information on payments to hospitals for education, event sponsorships, counseling, payments to lecturers, financing of clinical and other research and development of medicines. In doing so, we acted in the spirit of Lek's role as the ambassador of corporate integrity.

Over the past decade, I had the opportunity to lead a team of exceptional associates and colleagues. In this address, which expresses a common commitment to responsible management of Lek's economic, social and environmental impacts, I would like to thank them in particular. During this period, we began to publicly announce reports on sustainable development among the first in the country and among Sandoz companies, which are an important basis for building trust in relations with our stakeholders, especially with local communities. The following pages summarize our joint achievements and data that testify to the responsibility for society and its future, which we are aware of and dedicated to our employees in Lek and Novartis.

Vojmir Urlep,
President of the Board of Management

1. Company profile

Lek d.d.[2]

Company name: Lek Pharmaceuticals d.d.
Abbreviated name: Lek d.d.
Registered Office: Ljubljana
Business address: Verovškova 57,
1526 Ljubljana, Slovenia
Registration number: 1732811000
Standard Classification of Economic Activities in the European Community (NACE):
21.200 Manufacturing pharmaceutical preparations
Registered at: District Court in Ljubljana
under entry number: 1/36542/00

Telephone: + 386 1 580 21 11
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E-mail: info.lek@sandoz.com
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Mojca Bernik, Environmental Manager;
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[2] GRI GS disclosures 102-1, 102-3

[3] GRI GS disclosure 102-53

1.1 Key data for 2016

1.1.1 Operations in 2016

Table 1: Key figures for 2016

Indicator	Unit	31. 12. 2016	31. 12. 2015	31. 12. 2014	Index 2016/2015
Number of employees		3,599	3,361	3,124	107
- Ljubljana site		1,923	1,877	1,801	102
- Mengeš site		1,002	904	817	111
- Lendava site		423	355	308	119
- Prevalje site		246	225	198	109
Production output*	1,000t	5.20	5.22	4.69	99.6
Net sales	In mil. EUR	895.270	849.413	761.338	105
Liabilities	In mil. EUR	1,032,615	988.717	903.743	104
Equity	In mil. EUR	691.787	616.658	500.362	112

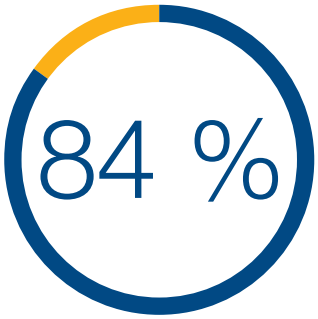
* Due to extremely large differences in the weight of various types of products and the manufacturing structure resulting from changes in demand, the annual data is difficult to compare. The comparison of production outputs between the years is therefore not entirely relevant. The differences in product weight should also be taken into account when reading data on the efficiency per tonne of product. For example, the weight of biosimilars is significantly lower compared to certain self-medication drugs, yet their manufacture requires larger quantities of water and energy resources. At the same time, the financial value of the manufactured biosimilars is higher.

Economic performance[4]

In 2016, Lek, a Sandoz company, created 895.270 million Euros of net sales, this represents a 5.4% increase compared to the previous year. Net profit for the accounting period amounted to 74.77 million Euros.

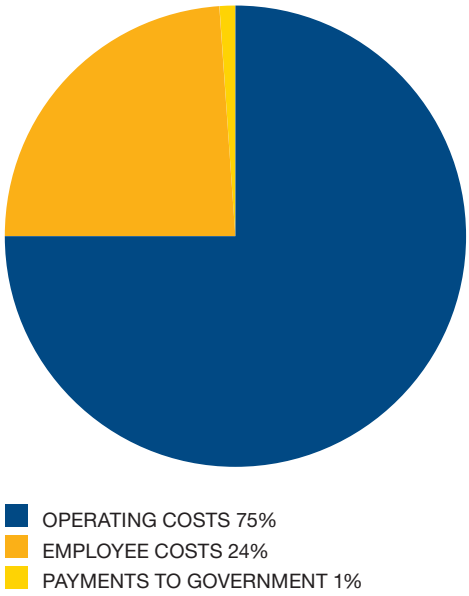
Direct economic value created reached 901 million Euros (895 in 2015), of which 84% (761.7 million Euros) was **economic value** distributed. The largest proportion of the economic value distributed belong to **Operating Costs** (75%), which reached more than 571 million Euros in total. **Employee Costs** were 182 million Euros (24%). In 2016, we made no **Payments to Providers of Capital; Payments to Government** totaled 9 million Euros (1%).

The tax relief value due to investment in research activity amounted to 5.713 million Euros (7.889 in 2015) and public subsidies in the amount of 543,000 Euros (874,671 in 2015).[5]



OF DIRECTLY GENERATED ECONOMIC VALUE REPRESENTED DISTRIBUTED ECONOMIC VALUE.

Chart 1: Structure of Economic Value Distributed



[4] GRI GS disclosures 201-1, 102-7
[5] GRI GS disclosure 201-4

Table 2: Major environmental and social impacts[6]

Indicator	Unit	31. 12. 2016	31. 12. 2015	31. 12. 2014	Index 2016/2015
Efficiency of energy resource use	GJ/t	247	236	255	105
Water use efficiency**	m^3/t	646	680	757	95
Waste volumes – efficiency	t waste/t product	7.2	6.7	7.4	107
VOC emissions – efficiency	t VOC/t product	0.016	0.018	0.021	89
LTIR* – showing the frequency of work-related accidents and illnesses, resulting in the use of sick leave		0.05	0.12	0.22	42
TRCR* – showing the frequency of work-related accidents and illnesses, resulting in the use of sick leave, requiring more than basic first aid		0.28	0.39	0.42	72

* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 3.3.1 Frequency of absences due to injuries at work.
** The table shows the efficiency of use for all waters at Lek (for technological and cooling purposes).

In 2016, we celebrated 20 years of Novartis and 70 years of Lek with numerous events.

1.1.2 Highlights and milestones of Lek's operations in 2016

2016 was an anniversary year. We celebrated 20 years of Novartis and 70 years of Lek, and were marked by our successful operations.

- **We continued our positive employment trend**. In Slovenia, **358 jobs were created and we ended** 2016 **with more than 3,500 full-time employees**. **46% of employees hold a university degree**, of which **more than 470 hold masters or doctoral degrees**. In the last five years, we have created **more than 1,400 jobs**.
- We introduced innovative human resource initiatives, among which were the sixth **Regional Bio Camp** and, a new addition, **Bio Career Breakfast**, to encourage Slovenian experts who work and study abroad to return to their home environment.

[6] GRI GS disclosures 302-3, 403-2

- **We consolidated our position as the leading Sandoz Development Center** – 25% of all Sandoz development projects originate from Slovenia. We filed registration dossiers for 17 new key products for the most demanding global markets, meaning in the last four years a total of 80 new products. We filed 4 new patent applications. In total, we have more than 800 patents around the world.

- As one of the **leading Sandoz sites for introducing new products to the market**, we launched more than 10 new molecules and more than 650 new products.

- **We headed in a new strategic direction**. In 2016, Novartis brought the first innovative pharmaceutical production in Slovenia with the opening of the first production facility for producing active ingredients for innovative medicines. At the Biopharmaceutical Mengeš, in addition to the development of active ingredients for biosimilars, started **to develop final biopharmaceutical products**.

- **We maintained our highly dynamic investment activities**. Novartis allocated almost **170 million Euros** to invest in Slovenia in 2016, meaning that since 2003 they have invested **more than 1.9 billion Euros**. More than 1 billion Euros was invested in development, with the rest being invested in upgrading and broadening production capacity.

- We also accomplished **total production capacity growth** in 2016. The products we manufacture in Slovenia are marketed around the world via the broad Sandoz and Novartis sales network. Certain key products also contain active ingredients which are the result of our own development and production.

- Together with other Novartis divisions, **we retain our position as the leading supplier of medical products in the Slovenian market**. We have consolidated our position as the second largest supplier of generic medicines in Slovenia. With the growth of our market share to **26.8%**, we have consolidated our leading position in over-the-counter medicines

- The most demanding audits performed by the US Food and Drug Administration (FDA) at two of our sites (Ljubljana and Mengeš) were successfully passed. Many other successfully passed national and international audits have further confirmed our commitment to quality, including HSE quality, and provision of safe and effective medicines for patients.

- **We continue to protect the environment**. In 2016, we implemented, maintained, developed and certified the environmental management system in accordance with the required ISO 14001:2004 standards, ES 1221/2009 regulations (**EMAS**) and occupational health and safety management systems in accordance with OHSAS 18001:2007 standards. In November, we were amongst the first companies in Slovenia to successfully meet the requirements of **ISO 14001:2015** standards. We met all requirements to extend our certification in accordance with **Responsible Care initiative**.

1.1.3 Awards and acknowledgements

In 2016, Lek and its employees received a number of awards and acknowledgements.

- President of the Board of Management of Lek and Novartis in Slovenia, **Vojmir Urlep**, received **a plaque "Pro universitate labacensi"** for his many years of successful co-operation with the Faculty of Pharmacy at the University of Ljubljana.

- Prof. **Zdenko Časar**, PhD, Head of Prototype Analytics at the Sandoz Development Center, received the **Puh Certificate of Recognition for Achievements in Development** and the **Pregl Award for outstanding achievements in Science** from the National Institute of Chemistry.

- Lek received **two Golden Innovation Awards**, from the Slovenian Chamber of Commerce.

- We were awarded the **Prometheus in Science Award for Communication Excellency** by the Slovenian Scientific Foundation (SZF).

- For the second time, we were awarded a full **Family Friendly Company** certificate

- We received our 14th **TOP 10 Education Management Award**.

- Amongst **the most reputable employers in Slovenia** according to a survey carried out by recruitment portal MojeDelo.com for the fifth time in a row.

- Lek received the **Certificate for Successful Sustainability Reporting**, which was awarded for the first time in Slovenia by Deloitte.

The President of the Republic of Slovenia, Borut Pahor, presented Prof. Zdenko Časar, PhD, with the Pregl Award for outstanding achievements in Science.

President of the Board of Management of Lek and Novartis in Slovenia, Vojmir Urlep, received a plaque “Pro universitate labacensi” for his many years of successful co-operation with the Faculty of Pharmacy at the University of Ljubljana.

The Certificate for Successful Sustainable Reporting was received by Mojca Bernik, Sustainability Reporting Manager and Environment Safety Authority (left) and Mojca Pavlin from Corporate Communications (right).

The gold innovators from Lek and the Faculty of Pharmacy have received two awards from the Slovenian Chamber of Commerce and Industry for innovations bringing the most benefits to end users – patients. The researchers focused primarily on improved quality, safety and lower price of active ingredients.

1.1.4 Health, safety and environment (HSE) objectives

In Lek, we are committed to responsible business operations and good practice in the field of HSE. Specific goals are defined with clearly defined responsibilities based on legal regulations and corporate guidelines, as well as our commitment to integrity and ethical principles.

In the field of HSE, we follow Novartis long-term plans, whilst realizing our annual short-term goals. We consider the HSE Policies when defining and realizing our targets. These policies are supplemented and amended with the revision of HSE Regulations.

We monitor targets for each individual site as well as on a corporate level. Data for reporting requirements is collected and confirmed in the Novartis Data Management System (DMS). We are constantly improving the efficiency of our environmental management by including all employees in the environmental care system, open communication with internal and external public and regular assessment of the system performance.

Production processes for pharmaceuticals and active pharmaceutical ingredients differ greatly from site to site, and so do their impacts, particularly those pertaining to the environment (waste, atmospheric emissions, and others).

By indicating impact management we present our annual objectives for 2016 and the realization of our long-term 2020 objectives.

The Solids and Sterile Units hosted their first Day of Quality and Safety, in which almost 900 employees participated. During the practical workshops, they got to know the different elements of quality and safety whilst also having fun.

Lek's short term HSE targets for 2016

Area	Indicator	Target	Reached in 2016 (for all of Lek)
Health	LTIR (own employees + employees hired through employment agencies)	0.14	**Reached.** The index amounted to 0.05.
	TRCR (own employees + employees hired through employment agencies)	0.4	**Reached.** The TRCR index reached a value of 0.28.
Safety	Identifying risks of injury	40 walkthrough inspections/200,000 working hours	**Reached.** 88.6 walkthrough inspections/ 200,000 working hours, total of 3,173 walkthrough inspections.
	Serious injuries and fatalities (SIF)	0	**Reached.** There were no serious or fatal accidents.
	Safe drive training with an instructor	> 90% of company car holders	**Reached.**
Environment	Reduction of VOC emissions to the air (nh-VOC and h-VOC)	Maintaining the 2015 level	**Reached.** An 11% reduction of VOC emissions to the air (nh-VOC in h-VOC).
	Reduction of pollutant emissions to water	100% assessment of ecotoxicity of APIs, prioritization prepared	**Reached.**
	Reduction of non-hazardous waste per ton of product	Project of increasing the proportion of waste to be recycled by 5%	**Partially Reached.** Projects at the sites were realized, the proportion of recycled non-hazardous waste per ton of product was reduced by 1.4%.
	Reduction of hazardous waste per ton of product	Project of increasing the proportion of waste to be recycled by 5%	**Partially Reached.** The total amount of hazardous waste per ton of product was reduced by 17%; the proportion of recycled hazardous waste was reduced by 3%.
Energy	Energy savings	– 1% vs. 2015	**Not Reached.** Various projects for improving energy efficiency resulted in total energy savings of 8.21 TJ. Due to increased production, energy use increased by 4% in comparison with 2015.
BCM index	Readiness for emergency response	> 21 points	**Reached.** BCM index almost 23 points.
NEM index	Readiness for emergency response	> 22 points	**Reached.** Average of almost 24 points.

* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 3.3.1 Frequency of absences due to injuries at work.

Novartis' long-term HSE targets for 2020

Area	Indicator	Target	Status 2016
Health	Exposure of employees to dangers exceeding permissible limits	0	0
	Reducing the rate of absenteeism	–10% vs. 2010	–6%
Safety	Serious injuries and fatalities (SIF)	0	0
Environment	Reduction of greenhouse gas (GHG) emissions	–30% vs. 2010	–34%
	Reduction of pollutant emissions to water	10-times below PNEC*	Established monitoring system to check the status of emissions and risk to the environment.
	Reduction of non-recyclable waste per ton of product	–30% vs. 2010	–67% 2010: 2.48t/t of product 2016: 0.82t/t of product

* Concentration of a substance below which no adverse effects on the environment are expected.

Lek's HSE targets for 2017

Area	Indicator	Target
Health	Exposure of employees to dangers exceeding permissible limits	0
Safety	Identifying risks of injury	12–15* walkthrough inspections/200,000 working hours, near-misses 35–50*/200,000 working hours
	Serious injuries and fatalities (SIF)	0
	Injuries with hospital visit, with the possibility of serious injury	0
Environment	Reduction of pollutant emissions to water	100% assessment of ecotoxicity of APIs with risk assessment
	Reduction of greenhouse gas (GHG) emissions	4%
	Reduction of non-recyclable waste per ton of product	Project to increase the proportion of recyclable waste by 2–4*%
Corrective measures	Implementation of corrective measures	Implementation without delay
BCM-Index	Readiness for emergency response	20–22* points
NEM-Index	Readiness for emergency response	20–22* points

* Values vary depending on site location.

1.2 About us

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.[7] We develop, manufacture effective, safe and high quality medicinal products, from standard generic drugs to state-of-the-art biosimilars.

We are a Sandoz company, the generics division of Novartis, pioneers amongst state-of-the art biosimilars and other generic drug manufacturers in the world. Our knowledge, quality and experience have leaded us to become a key part of Sandoz.

Social responsibility

Based on Novartis policies, corporate responsibility is integrated in all company operations and is an important part of our business strategy. It is directly associated with the fulfillment of our mission, vision and strategy. It focuses on two central areas: increasing access to treatment and responsible operations.

Key principles of our corporate responsibility

Accessible treatment

We believe all patients deserve quality treatment. Our sites in Slovenia are thus development and production centers seeking ways to innovative and affordable pharmaceutical products.

Responsible operations

Trust of patients and customers is based on the quality of our products, ethical management of the company and ethical behavior of the employees.

Reporting

Lek, a Sandoz company, regularly monitors and measures sustainability indicators of its operations. Each year, it publicly presents economic and environmental impacts and social aspects of its operations, and strives for transparency and comparability of information.

Our people and community

We strive to provide our employees with a stimulating work environment as well as safe and healthy jobs. We are actively involved in local communities, mostly through employees' volunteer work and our philanthropic activities.

Environmentally sustainable operations

The active environmental policy is implemented through a number of activities to protect the environment which often goes beyond mere fulfillment of statutory provisions. Business decisions are made in consideration of direct and indirect environmental impacts. We use natural resources with deliberation and increase the efficiency of their consumption.

We have been supporting the Pomežik soncu (laughing sun) campaign for 18 years at Lek, which aims to give children from socially disadvantaged backgrounds a summer holiday.

[7] GRI GS disclosures 102-1, 102-5

1.2.1 Key customers and markets[8]

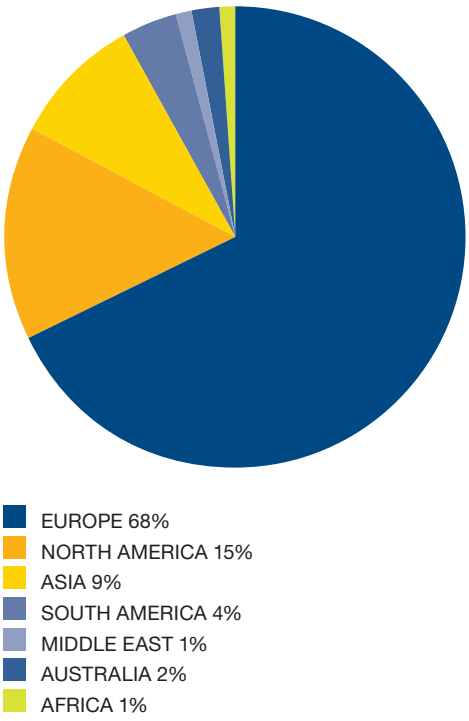
In accordance with strategic orientations, Sandoz Group companies are the key buyers of Lek products and active pharmaceutical ingredients. In 2016, the leading three buyers accounted for 74%, 8% and 3% of our net sales, respectively.

We sell our own products and the products of other Sandoz companies. The majority of our products, 95%, are sold directly to foreign markets (the USA, Russia and Western Europe), and the remaining 5% to Slovenia. The majority of sales (93%), came from pharmaceutical products, the remaining 7% came from APIs and biopharmaceutical products. Lek's key customers on the Slovenian market are pharmaceutical wholesalers, of which the three leading customers represent 68% of sales.

In 2016, the total value of the Slovenian pharmaceutical market was 655 million Euros. 45.2 million Euros of sales and a 6.9% market share makes Lek the second largest pharmaceutical company. On the generic market, with a market share of 29.3% we are also the second largest company in Slovenia. The entire over-the-counter market reached sales of 52.1 million Euros, where with a 26.8% market share we have been the market leader for some years now.

The leading markets for Lek in 2016 were the European markets (68%), followed by North America, Asia and other regions of the world.

Chart 2: Sales by region, recipients of goods in 2016



1.2.2 Major product groups and brands[9]

We develop, manufacture and market the following key therapeutic groups of medicinal products:

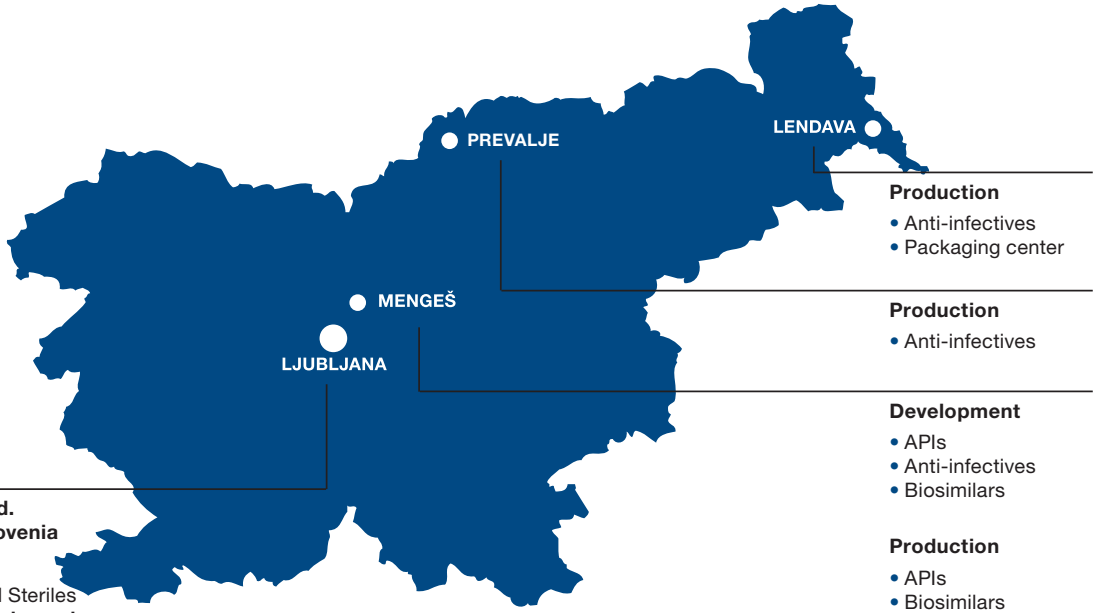
- cardiovascular drugs,
- anti-infectives,
- gastrointestinal drugs,
- biosimilars for the treatment of growth disorders, neutropenia and anemia, related to chronic kidney failure,
- medicines for the treatment and prevention of iron deficiency and anemia treatment,
- oncologics,
- other prescription drugs dispensed in pharmacies and covering a broad spectrum of therapeutic groups of drugs for the treatment of various diseases, and
- self-medication drugs.

In 2016, amongst the leading over-the-counter brands in Slovenia, were Coupet®, Amoksiklav®, Iroprem® and Ospen®. We achieved the highest sales with Lekadol®, Linex®, Lekadol plus C®, Operil® in Persen®.

[8] GRI GS disclosure 102-6

[9] GRI GS disclosure 102-2

1.2.3 Development and production sites and processes[10]



Ljubljana site

1.2.3.1 Ljubljana site

The Ljubljana site is home to our headquarters and Lek's specialist departments. It is also home to the leading and largest Sandoz development center and one of the largest Sandoz production sites. Production is organized in two organizational units – Solid Dosage Forms and Sterile Dosage Forms.

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

Solid Dosage Forms (SDF)

The Solids Unit produces approximately 500 solid pharmaceutical forms, for which more than 100 molecules are used. We package more than 2,400 finished pharmaceutical products for global, and also the most demanding markets, such as the USA and Japan. Our product range includes granules, tablets, film-coated tablets, dragees, pellets and micro-pellets.

Production growth continued in 2016. We produced more than 8.5 billion pieces of solid dosage forms and 200 tons of granules and micro-pellets. We saw an increase in the amount of complex products, particularly tablets with a functional lining and modified-release pellets. The Head of Solids clarifies further in the article that follows. We packaged 6.5 billion tablets and capsules in 150 million packages with almost 400 million blisters, glass bottles, plastic bottles and sachets. The strongest growth was seen in plastic bottle packaging. We launched more than 350 new products, which is more than the previous year. Despite the full occupancy of many production capacities, we maintained a high level of customer care.

We completed several investments for increasing capacity as well as quality and reliability of our production equipment and infrastructure. In the second half of the year, we began projects related to the creation of Novartis Technical Operations, and will continue in 2017.

New colleagues in all fields

Aleš Rokavec, Head of Solids Ljubljana

The Head of Solids, Aleš Rokavec clarifies that they are increasing the share of complex products and are expecting that the growing physical volume of production will stabilize. Due to the diverse portfolio, in the future the Unit will need smaller and more flexible lines, and they will continue to work responsibly in all areas of HSE.

Describe the site growth dynamics in 2016 in comparison to previous years.
We emphasize that growth continued in 2016. We produced more than 8.5 billion pieces of solid dosage forms and 200 tons of granules and micro-pellets. We packaged 6.5 billion tablets and capsules in 150 million packages with almost 400 million blisters, glass bottles, plastic bottles and sachets. We launched more than 350 new products, which is more than the previous year. The strongest growth was seen in plastic bottle packaging. Despite the full occupancy of many production capacities, we maintained a high level of customer care, which is why we can say, that every single department in our unit proved themselves.

In the future, we expect the physical volume of production to stabilize, but the composition of our portfolio of products will continue to change. In recent years, the share of demanding products has constantly been increasing, particularly products with modified-release and those with APIs with more demanding bioavailability.

What kind of profile and in what fields did you employ new personnel in 2016?
In 2016, the Solids Unit increased its staff by 40 employees. In total, more than 100 new employees joined us, as we needed replacements for colleagues who had gone to other Lek, Sandoz or Novartis Units, and some natural outflow. We employed in all areas. From 40 additional employees, more than half have a university education; the majority are pharmacists, chemists and electrical engineers.

Have you also increased the production capacity? What type of site development are you foreseeing, what are the needs?
Last year, we continued mostly with the upgrading of production equipment and infrastructure, new equipment means an increase in capacity and usually also the flexibility of production. The establishment of Novartis Technical Operations bring new opportunities and challenges. If we are successful, the role of our unit in the Novartis network will be strengthened, and there will also be more opportunity for further development and investment. Products which come to us will continue to be complex, technologically diverse and for the majority, low volume. In the future, the Unit will probably need smaller and more flexible lines, and will continue to work responsibly in all areas of HSE. We build on quality, productivity, reliability, flexibility and more complex products. The common denominator for the aforementioned is experienced colleagues with the right values and knowledge.

Sterile Dosage Forms

The Steriles Unit produces sterile dosage forms which are filled into ampoules and vials. We also produce solutions, nasal sprays and syrups. We are a Novartis center of excellence for ampoules and a Sandoz center of excellence for the production of lyophilized vials.

In 2016, we successfully reached our target in the areas of compliance, volume, customer service and costs. The growth of various pharmaceutical forms as well as transfers and launches of new products on the market continued. An important achievement was the validation of our first biosimilar drug in a vial.

We invested in Track and Trace equipment, which prevents substandard products getting to the buyer. We began our investment project for the recapitalization of the first of our vial filling lines, thus creating new capacities for the future.

Production of sterile dosage forms

Having the right personnel means more than having state-of-the-art-technology

Bettina Krausenbaum, Head of Steriles Ljubljana

Looking back at her path with her colleagues in 2016, the Head of Steriles Bettina Krausenbaum, highlights the validation of the production of the first biosimilar vial and numerous successful HSE inspections. She gives special significance to the challenges of leading in a new and constantly changing environment.

How does the growth development of your Steriles unit compare to the previous year?
Overall, 2016 has been a successful year for Ljubljana Steriles. We moved forward in the fields of compliance, production volume, customer service and cost optimization, with continued growth for all dosage forms, with a 17% increase in bulk. In many aspects, our focus was on vials, the filling line went back into production having been modified, and giving the site improved technical capabilities and an increase in capacity. Technical transfer activities for future products have been progressed and the validation for the site's first biosimilar based vial has been completed. Packaging was one unit that made significant efficiency gains through operational excellence allowing it to respond to volume increase with ease. The entire year was marked by many successful quality and health & safety inspections demonstrating the sites continued high compliance standard.

What kind of expertise was valued and hired most in 2016?
The sites greatest assets are our people and we are continuing to develop our talents for both their technical and personal development capabilities. Due to the incessantly increasing regulatory requirements for steriles, we invested in the development of our personnel, created our own steriles training area, thus majorly improving the steriles techniques of our people. It is vital to employ the right capabilities to fulfill these high technical and quality requirements. With our internal tool for managing performance and human resource development, we put additional focus on leadership skills and behaviors ensuring we have the right people appointed to lead our personnel. There is a big shift in mindset, paying high attention not only to technical skills but also ensuring people bring the right leadership qualities.

How will the site development impact the human resource needs and what opportunities are there for site expansion?
We are working on a building extension that will allow us to start recapitalizing one of our vials filling lines. With this we will create future capacities but even more importantly upgrade to state of the art equipment. The importance of having the right personnel here is even more essential. New equipment has advanced technologies and is highly computerized. This again requires very specific education and skills for those we hire new to the organization as well as development and upskilling for those people already employed. Especially our leaders are highly challenged preparing our personnel for future challenges in a continuously changing environment.

Development Center Slovenia

We are the leading Sandoz development center, where a quarter of all there development activities take place. We are specialized in technologically demanding development projects. At the Ljubljana and Mengeš sites, there are close to 280 different experts employed at the Development Center Slovenia, out of which a third have a PhD. In 2016, we successfully launched more new products onto the Sandoz company markets, the majority being in Europe, Canada, Australia, the USA and Japan. We also increased the number of launches of established products onto new Sandoz group markets. We invested in pharmaceutical development and upgraded our equipment for preparing pharmaceutical products, including our devices for filling final pharmaceutical forms. We upgraded our analytical technics with the newest analytical devices for monitoring the structure of organic molecules.

Development Center Slovenia, site Ljubljana

Key upskilling and new know-how

Matjaž Tršek, Head of Development Center Slovenia

Sandoz's development center Slovenia develops new products and launches them onto global markets. Head Matjaž Tršek shares information on the most significant development projects in 2016 and how his colleagues are actively gaining new know-how.

Which significant development projects took place in your unit in 2016?

At the end of 2016, several development projects for finished pharmaceutical products and APIs were underway, with the leading drugs being those for lowering cholesterol and elevated blood pressure, to treat diabetes, allergic rhinitis, migraines, insomnia, urological and gastric diseases and also non- steroidal anti-flammatory drugs.

Our operational excellence program aimed to improve work processes in various fields was also underway through the year. Within the program, we addressed 30 different improvements, with which we significantly contributed to improved efficiency and quality of work, consequently maintaining and raising our competitiveness.

What is the key to introducing new approaches to development and increasing access to high quality medicines?

This can only be achieved through continuous improvement of skills and acquiring new know-how. Our colleagues were actively involved in numerous lectures at international scientific conferences and congresses, in addition to writing more than 20 scientific articles and 10 contributions to international conferences. Among other things, 35 colleagues also participated in programs for obtaining academic titles at various levels. The innovativeness of our researchers is thus confirmed by numerous awards received in Slovenia and within Sandoz.

Mengeš site

1.2.3.2 Mengeš site

Mengeš production

The most important API produced at Mengeš is tacrolimus, followed by atorvastatin, amlodipine and rosuvastatin. As well as being an important supplier of generic APIs, the Mengeš site is also becoming a supplier of APIs for original medicines, which are still patented. We produced the API for the Sandoz generic Rosuvastatin, which Sandoz launched onto the American market in 2016. We successfully completed the validation process for the production of an API which enters in to the Novartis original medicines. In July we opened a new production facility and received new projects from Novartis, where we will produce new APIs for them. This will be the first launch of a finished originator product with an API produced in Mengeš.

We put a lot of emphasis on environmental protection and improving the safety culture of our employees and external contractors. We had numerous customer testings of our APIs, ISO 14001 standard assessments and OHSAS as well as EMAS, where no irregularities were found but rather lots of examples of good practice. Also the Seveso inspection in 2016 showed no legislative incompliances.

Biopharmaceuticals Mengeš

Biopharmaceuticals Mengeš is one of the key biotechnological centers of excellence for Sandoz in Novartis. We achieved growth in all areas of operations and continued investments in biopharmaceutical development projects. At the beginning of the year, having invested 10 million Euros, we opened a new laboratory facility for the development of final biopharmaceutical products, technical development of biopharmaceuticals and quality control. This created 100 new jobs for various experts. We also successfully passed **all national and international health inspections.**

This year once again, PORT, production plant for recombinant technology, produced record volumes of erythropoietin, used for treating anemia.

We were also successful at public tenders this year. The Ministry for Education, Science and Sport of the Republic of Slovenia, for the public tender for encouraging research and development programs (TRL3-6), chose the project “A new generation of biopharmaceuticals (BioPharm.Si)”, where Lek is one of the consortium partners.

The purpose of the BioPharm.Si program is to develop high technological solutions for a cheaper, safer and faster production of bio APIs. The project is worth 8.81 million Euros, the subvention from the ministry amounts to 5.97 million Euros. Regarding content, the research also relates to the European project “Preparing a New Process of Isolating Proteins for Biopharmaceutical Purposes”, which we started to execute in March 2015 within the EU research and innovation program Horizon 2020.

New laboratory at Biopharmaceuticals Mengeš for developing finished pharmaceutical products, quality controls and technical development.

Production of innovative APIs for long-term development

Egidij Capuder, Head of APIs Mengeš

After the turning point of the production of the first innovative API in Slovenia, new innovative APIs are already in the phase of transfer from development into production in Mengeš, explains Egidij Capuder, Head of APIs Mengeš. Both municipalities and neighboring local communities are cooperating in the long-term spatial planning procedures needed to expand the site in the upcoming years.

The opening of Lek's first production facility for innovative APIs in Mengeš is a turning point also for the Slovenian pharmaceutical industry. What do you attribute this achievement to?
In the past, Lek was focused on the production of generic drugs with added value. This demands the management of new and complex technology as well as competences, which is the basis for operating in the innovative field of the pharmaceutical industry. We have always had a leading role in assuring the highest quality standards. Novartis recognized our direction and decided to produce one of their key innovative APIs at Mengeš. In 2016, we famously opened our first facility marking our entrance into Novartis' network of 67 production sites in the world. This is of course a first step and we have some new innovative APIs in the phase of development to production.

What are the expected impacts of these investments on the local environment?
Mengeš is one of the rare Novartis sites, where we produce APIs for both generics and as a part of Novartis' finished drugs. Focusing on the innovative part means higher added value for the company, for our site it mean more security, as the lifespan of innovative APIs is longer than generics. This dictates a higher level of education from our employees and job positions with higher added value in addition to the newest technology and highest standards in the area of HSE.

This year was marked by preparations for site expansion. How did you co-operate with the local communities?
By taking a look at the trends in recent years, we saw that the site was too small and that in the long-term we would need to expand outside of the current land boundaries. The growth in operations and employees is constant and high. We began procedures for changing the Municipal Spatial Plan with the municipalities of Mengeš and Domžale. These procedures are complex and long-lasting as we border with farmland and we are in direct proximity are small villages. Co-operation with both municipalities has been incredibly good. Al those involved understand the importance of the operations as well as a responsible approach to the environment. As well as this, we are in talks with the local community of Preserje, which is in direct proximity with us, and we are trying to find the optimal solution for both the company and for our direct neighbors and wider local community.

We want to keep know-how and talents in Slovenia

Matjaž Oven, Head of Biopharmaceuticals Mengeš

With its state-of-the-art technology and superior know-how, Biopharmaceuticals Mengeš has an exceptional opportunity for continuing development, believes director Matjaž Oven. Expertise and experience are the foundation for continuing Novartis' investments in Slovenia and confirm the importance of Mengeš as one of its key centers for biopharmaceutics.

You have opened new laboratories for the development of finished biopharmaceuticals, quality control and technical development of biopharmaceutics. How was this acquisition reflected in the operation of the unit in 2016?
With the new laboratory facility, we gained an additional development role in Sandoz and Novartis. From now on, in addition to the development of substances, also the development of finished biopharmaceuticals takes place in Mengeš. At the same time, we have expanded the laboratory capacities for quality control and technical development. The need for biological medicines is constantly growing, so with state-of-the-art technology and cutting-edge know-how we have exceptional opportunities for further development and work in biopharmaceuticals.

What is the role of Biopharmaceuticals Mengeš in the development of modern biotechnologies in Slovenia and Novartis?
Biopharmaceuticals Mengeš is one of the key Novartis' development and production centers for similar biological medicines and the only center for the early development of biopharmaceutical substances from cell lines. We are involved in the development of all Sandoz's similar biological medicines, both substances and finished products. We are also Sandoz's strategic location for the production of erythropoietin alfa for the treatment of anemia. Our expertise and experiences are undoubtedly the foundation for which Novartis continues its investing in Slovenia and confirms the importance of Mengeš as one of its key centers for biopharmaceutics.

What career opportunities do you offer to young scientists who join your team of experts?
There are more than 400 experts from various fields working in Biopharmaceuticals Mengeš, of which more than 80% have university education or higher, as many as 38% of them are Masters and Doctors of Science. We provide jobs for domestic experts, especially pharmacists, biotechnologists, microbiologists, chemists, biochemists, physicists and other professionals. As a part of a global pharmaceutical company they have a priceless opportunity to work in their home country and at the same time to gain experience and knowledge around the world. We also invite Slovenian experts currently studying or working abroad to join our team. For the second year in a row we have prepared a career event Bio Career Breakfast, where we introduce the opportunities for professional development in the home environment. In 2016, we employed ten Slovenian experts who attended the first Bio Career Breakfast, thus keeping domestic knowledge and talents in Slovenia.

Prevalje site

1.2.3.3 Prevalje site

At the Prevalje site, we manufacture the broad-spectrum antibiotic. We manufacture it in the form of tablets, powders for orals suspensions (POS) as well as in mixtures and granules. We have decided to purchase a new POS line, space has already been made and will be installed and start operation in 2017. We also recorded production growth of mixtures and finished mixtures.

The decision of the Novartis executive board to expand the site was of the highest importance for Prevalje. Numerous inspections by national institutions and customers from different countries once again confirmed our high quality standards, which we follow. We successfully remedied the noise emissions into the environment and continued to take care of efficient and responsible environmental impact management.

State-of-the-art technology available at the time of construction

Zlatko Ajd, Project manager

Alenka Kramarič, Head of the investment project

By investing in new capacities for production of final pharmaceutical product in Prevalje, a quantitative production will significantly increase. The implementation of the project will take place in phases and will result in a uniform system of automated production management and control. Special emphasis will be placed on environmental protection, in particular the high quality of waste water, noise emissions and waste air treatment.

What are the biggest challenges of expansion and how will domestic suppliers be involved?
The new investment certainly means a long-term stability of the Prevalje location. The construction will take place on the building plot, which we bought directly next to our premises from Koratur company, therefore the existing production will not be disrupted. The project will definitely be a great challenge for all expert services in Lek, especially for our Engineering and employees at the site. We will introduce numerous innovations, especially in the field of high automation of processes and connection of various information systems into a unified system of automated production management and control. Slovene suppliers will also be to a great extent involved in the implementation of the project. We estimate that their share will reach almost 40% of the project value, which is estimated at total of 105 million euros.

What is the significance of environmental technologies in the investment itself, how do you choose the most appropriate?
As with all our investments, we will implement all the requirements of Slovenian and Novartis' environmental standards and regulations. Novartis is characterized by the fact that when it comes to investments it always takes into account the principle of installing state-of-the-art technology at the time of investment. Novartis' requests are often stricter than legislative ones, and we must fully comply with them. Within the expansion project of site Prevalje, special emphasis will be placed on environmental protection, in particular the high quality of waste water, noise emissions and waste air treatment. I am convinced that also regarding the new facility, we will fully meet all environmental requirements, as we already fulfill in the current production.

The project and the expansion will be implemented in phases. What are the specifics of such a way of expansion?
The pace of the project implementation is mainly related to the gradual assembly of equipment and individual production support systems. As part of the construction work, we will set up facilities in the planned size at the very beginning. These are three sets of constructions: a high rack warehouse, an acceptance/delivery warehouse and production facilities with corresponding infrastructure. The final works on the premises will expectedly be carried out in two phases; their dynamics will follow the needs of the market. All activities will be planned in such a way that the production on already installed lines and consequently the supply of our customers will not be disturbed.

Production of the broad-spectrum antibiotic on Prevalje site.

Among the most important employers in Koroška

Roman Burja, Director of Anti-infectives Prevalje

In Anti-infectives Prevalje, the number of employees increased by more than 40% in past four years. In 2016, they successfully completed the elimination of increased noise, which was recognized the year before, pointed out their director Roman Burja.

At the Prevalje site you produce an antibiotic, which belongs to one of Sandoz's top selling products. Has a high demand continued in 2016?
The demand for a broad spectrum antibiotic is increasing and despite continuous process improvements our production capacities cannot keep up this increase. Novartis' decision to expand the site confirms that further demand growth is expected. In order to achieve a greater production scale, good cooperation between all the functions at the site, high product quality, high productivity and the advantages of producing various product shapes, such as tablets, powders, blends and granulates, are key factors.

In 2016, you were striving to expand the current capacities and in the beginning of 2017, you obtained the approval of the largest Novartis investment in Slovenia. What can be its contribution to the development of the region?
The production capacities will significantly expand and modernize the existing capacities, increase the competitiveness and the importance of the location in Lek as well as Lek's role in Novartis. The total estimated value of the multi-annual project is 105 million euros. With the investment, we will presumably create around 150 new high-value added jobs at the site, with an emphasis on recruiting staff from the local environment. With new production facilities, we will strengthen our role of one of the largest and most stable employers in the Prevalje Municipality and in Koroška. In the last four years, the number of employees has already increased by more than 40%. At the same time, the educational level of our employees is constantly increasing, and we estimate that among the new employees one fourth will be university-educated.

In managing environmental impacts, you apply Novartis standards, some of which are more stringent than Slovenian legislation. You have announced measures to reduce noise. Have you implemented them and who took part in it?
In Prevalje, we received two noise complaints in 2015 and immediately adopted the necessary measures based on a study of the measurements of its sources. Remediation measures for noise reduction were fully completed in 2016. The measurements of an authorized independent institution have shown that the permissible noise level was not exceeded at any place, and the appropriate noise level was confirmed by all previous measurements in previous years. We considered the aspect of noise separately and have taken it into account also in the expansion project.

Lendava site

1.2.3.4 Lendava site

Anti-infectives

The Anti-infectives Production Unit produces APIs with the help of classical biotechnology. We manufacture two products: potassium clavulanate and gentamycin sulphate. The production volume of our main product potassium clavulanate, continued to grow in 2016, meaning that our production capacity was fully occupied. Gentamycin sulphate saw lower production volume, due to the lower market need.

We are reducing the specific consumption of raw materials and energy

Gizela Štampar, Head of Anti-infectives Lendava

Our employees, with their technological know-how, take part in finding solutions on other Novartis sites and contribute to their greater efficiency; thus the expertise of their colleagues is thoroughly explained by Gizela Štampar, director of Anti-infective Lendava, explaining what is of main importance to increased production at the same consumption of raw materials and energy.

The production growth of the pharmaceutical substance has significantly improved in recent years; it is directly related to the consumption of raw materials and energy. How do you manage to control their spending?

Our production is a classical biotechnology, where micro-organisms for the production of a substance need food and energy. Therefore, we improve the production abilities of micro-organisms, thus ensuring greater production at the same consumption of raw materials and energy. We also intensively improve technological processes both at the stage of the active molecule synthesis and its purification. This helps us to reduce the specific consumption of raw materials and energy per product unit from year to year and to achieve greater competitiveness in the world market.

How do you succeed to achieve these continuous improvements, what is the contribution of domestic staff?

Naturally, they require a lot of know-how, effort and work. All the improvements achieved are the result of domestic know-how; of technology team in Lendava and development team in Mengeš. I would like to emphasize that the technological know-how of our colleagues is at a very high level, which is also recognized abroad. Our experts are often invited to other production sites, where they help to solve problems or contribute to better efficiency.

Where are the development opportunities and potentials of Anti-infective Lendava?

We produce a substance for the best-selling Sandoz product. The need for our product on world markets is still growing and here we see a great opportunity for further growth and development. Of course, we need to remain rational and effective, as this is a condition for achieving lower product prices and gaining a higher market share.

In July, we celebrated the opening of four new packaging lines. The ribbon was cut by the Heads of Site Production Unit Andreja Krpan and Daniel Vidmar.

In 2016, we started important investments with an aim of increasing production volumes in the upcoming years. One of the more important investments is in new isolation of the intermediary product in the production of potassium clavulnate, which will assure closed handling in production as in accordance with Strictly Controlled Conditions required by REACH registration of intermediates. This will significantly contribute to environmental protection and improvement of product quality. We strengthened the activity with the Development department in Mengeš, especially in the field of genetic improvements in the productivity of microorganisms' production and improvements in biotechnological processes. We want to continue improvements and ensure a higher competitiveness of the product through our development work.

We successfully completed all inspections and assessments and reached out targets in the fields of quality and HSE

Solids Lendava

The Packaging Center Lendava was renamed in 2017 to Solids Lendava. 2016 saw continued growth and within the Novartis Technical Operations framework, were confirmed as a strategic packaging facility for solid forms.

We finished our largest investment in the Packaging center expansion with the establishment of 6 new full packaging lines for blisters. In comparison with 2015, the production volume growth was 38%, almost 4.6 billion tablets/capsules were packaged into 125 million packages. Meanwhile, the complexity of the product portfolio also increased, we packaged 85 different molecules into 2,600 final pharmaceutical forms. This was followed by employment, at the end of 2016 the total number of employees reached 310.

Of key importance to the strategic development of PCL was the decision that the packaging of certain innovative medicines of Novartis Pharmaceuticals were directed to Lendava. This will mark next year and further encourage site development.

In 2016, we had no work-related injuries that resulted in sick leave. In 2016, we reached our key targets in quality, HSE and successfully passed several quality system inspections, which were carried out by foreign health authorities, e.g. the Brazilian agency Anvisa.

We grew up a third

Simon Rečnik, Director of Solids Lendava

The concept of introducing permanent improvements is of strategic importance for the development of Solids Lendava. As illustrated by the director Simon Rečnik, the Lendava unit will continue to strive to remain one of the most propulsive packaging plants in Novartis.

How has the impact of a large investment into expansion of the Packaging center Lendava in 2015 been reflected in the achievements of the previous year?
Investments in the expansion of logistics and production capacities in previous years unlocked the potential for growth and development of the production site in the direction of the key strategic Novartis packaging plant. In practice, investments have enabled the transfer of many new products to our packaging center. Thus, the product portfolio and the production volume in 2016 increased by around one third due to the transfers from other Novartis production sites and organic growth in production scale.

What would you point out as a feature of the year and where do you see the development opportunities for your unit?
The production site has simultaneously accelerated its development towards operational excellence by intensively introducing the concepts of continuous improvements, representing one of its strategic development pillars. Future growth and development of the production site will continue to depend on the development of skills and know-how of employees. This will strengthen the foundations of competitiveness and the ability of the Lendava site as one of the most propulsive packaging plants in Novartis, both for generic and innovative programs.

1.3 Development and reporting framework

In accordance with the Novartis Corporate Citizenship Policy, we strive for transparent and comparable public reporting. Every year since 2010, we have compiled a comprehensive report on sustainable development, at the same time reporting in compliance with the requirements of the Responsible Care Initiative (RCI), EMAS Scheme and GRI Guidelines. Even before 2010, we prepared environmental reports and reports within the RCI.[11] The Sustainability Report was last published in July 2016.

Until now, we have reported in accordance with the international GRI (Global Reporting Initiative), in 2016 we upgraded and used their newest Global Standards (GS), which came out at the end of 2015. The competent departments co-operated in the process of determining the content of the report, which stems from the key features of Lek's activities and position. We also identified aspects that were exposed in different ways by our stakeholders: through questions raised on Community Partnership Days, interaction with the professional public at expert meetings, questions raised by employees (Workers' Council, Workers' Assembly and their representatives in the company's management bodies), contact with regulators (Agency for Medicinal Products and Medical Devices) and through media questions.[12] The essential aspects of sustainable business are recognized and are evident in the GRI Index in Point 7. We have not yet decided to seek external assurance for our sustainability reporting.[13]

The Sustainability Report which contains the EMAS Environmental Statement is available at http://www.lek.si/en/corporate-responsibility/reporting/.

Comprehensive reporting is also carried out within Novartis, which in turn performs internal controls and assesses the conformity of the reporting indicators. Furthermore, Lek's data for a broad set of indicators is included in Novartis' indicators (available at: www.novartis.com, www.novartisfoundation.org and www.corporatecitizenship.novartis.com). Their collection is performed in compliance with the improvement guidelines provided by Novartis internal HSE audits.

1.3.1 2016 reporting characteristics[14]

Reporting in accordance with RCI requirements

Lek's reporting has been based on the RCI for several years now, the present report being an upgrade of the previous reporting model.

Reporting in accordance with EMAS Eco-Management Scheme requirements

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

Reporting in accordance with GRI Guidelines

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

- Reporting refers to Lek d.d. and all its manufacturing sites in Slovenia. All disclosures in the present report refer to the 2016 calendar year.
- Employee data, key data on financial operations, and economic impacts of business operations were acquired in the financial reporting process for the purpose of compiling the company's annual report in accordance with International Accounting Standards (MRSP) and Slovenian legislation.
- The objective of Lek's HSE reporting is compliant with Novartis' and Sandoz' objectives to provide a fair and well-balanced picture in the field of HSE. The system of monitoring HSE achievements and the reporting methodology are described on pages 68–69.
- Sustainable development reports are compiled annually and also include the Environmental Statement (EMAS) amended and upgraded at every major change. The reports contain the key data for all sites of Lek in Slovenia.
- We expect the report will be used by the company's associates and management team, local communities within which the company operates, professional organizations assessing the compliance with the RC Initiative and EMAS Scheme, as well as members of the pharmaceutical associations.
- Lek d.d. holds a 100% ownership stake in the following subsidiaries (as of 31 December 2016): Sandoz d.d., Hotel Lek d.o.o., and Lek Ljubljana Holding GmbH, Austria, as well as a 74.5% ownership stake in Čistilna naprava Lendava d.o.o.
- In 2016, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures.
- To improve reporting accuracy, the following adjustments in the data collection were made for 2016, also impacting the comparability of data with previous years:
  - Due to the purchase of green certificates at the end of 2015, the quantities of indirect GHG emissions for 2015 were corrected.

[11] GRI GS disclosures 102-51, 102-52
[12] GRI GS disclosure 102-46
[13] GRI GS disclosure 102-56
[14] GRI GS disclosures 102-45, 102-50, 102-10, 102-48, 102-49, 102-54

1.4 Governance, commitment and inclusion

1.4.1 Governance and management[15]

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 2016, the members of the Board of Management were as follows:

- **Vojmir Urlep**, President of the Board of Management,
- **Zvonko Bogdanovski**, Member of the Board of Management, Commercial Operations,
- **Ksenija Butenko Černe**, Member of the Board of Management, Legal Affairs,
- **Aleš Rokavec**, Member of the Board of Management, Technical Operations,
- **Samo Roš**, Member of the Board of Management, Human Resources,
- **Daniel Michalek**, Member of the Board of Management, Finance,
- **Marjan Novak**, Member of the Board of Management, Workers' Director.

The Board of Management runs the company, independently and on its own responsibility. In their function, Supervisory Board members act to the benefit of the company and with due diligence, bound by an obligation of confidentiality. All members of the Supervisory Board avoid any conflict of interest. Upon their appointment, they have to sign a statement pursuant to Article 255 of the Companies Act (ZGD-1), an obligation set for all Novartis Group employees in the Novartis internal Conflict of Interest Policy (the same applies to the supervisory board).

The individual members of the Board of Management are obligated to provide the President of the Board of Management with complete, comprehensive, accurate and ongoing information about any major event and development of individual transactions in the areas of their responsibility. Provision of information to the Supervisory Board and the General Assembly is the responsibility of the President of the Board of Management who reports to the Supervisory Board Chairman on:

- Profitability of the company, particularly its return on equity.
- Draft business policy and other fundamental business issues.
- Transactions that can significantly impact the company's profitability and financial solvency.
- Development of transactions under way, in particular the company's turnover and financial standing.
- Issues regarding the business operations of the parent company and its associated companies.
- Other matters in compliance with the law and according to the requirements of the Supervisory Board.

Supervisory Board

In 2016, the members of the Supervisory Board were as follows:

- **Francesco Balestrieri**, Chairman,
- **Richard Francis**, Deputy Chairman,
- **Martin Jeffrey Rope** (until 4. 3. 2016),
- **Miguel Pagan Fernandez** (from 5. 3. 2016),
- **Knut Ulrich Mager**,
- **Peter Svete**, Workers' Representative,
- **Vesna Premović**, Workers' Representative.

The management of the company business is overseen by the Supervisory Board, in accordance with its mandates and responsibilities. The Board can perform reviews and verification of the company's books and documentation, its treasury, securities and goods in stock, as well as other matters. The Supervisory Board can request the Board of Management to provide any information needed for the Board to perform its supervisory role. This allows the Board to perform comprehensive control of the company's economic, environmental and social impacts, and receives this information as part of its competency of approving the company's annual report, which also encompasses all relevant information related to environmental protection. The main responsibilities of the Supervisory Board include the following:

- Supervision of company management.
- Verification and approval of annual reports.
- Checking and proposing to the General Assembly the use of distributable net profit, together with the Board of Management.

[15] GRI GS disclosure 102-18

- Providing the General Assembly with a written report on the verification of the annual report and of the management of the company during the business year.
- Reviewing reports by the Board of Management.
- Reviewing and verifying the company's books and documentation.
- Appointment and recall of Board of Management members.
- Granting the right to and setting criteria for buying stock options.
- Signing contracts with Board of Management members.
- Other competencies in accordance with the law.

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

In 2016, the Supervisory Board had four correspondence sessions, where they conducted a regular review of company operations, checked company targets and familiarized themselves with the basic aspects of operations of subsidiaries and branch offices.

Diversity in management and supervisory bodies

Lek respects the diversity of employees, patients and other stakeholders, and strive for their equal inclusion in our operations. The company encourages diversity in the gender of representatives in both management and supervisory bodies, which is written in the annual targets of the Diversity and Inclusion Initiative. The company has no independently adopted policies that would further regulate the diversity of representation in these bodies in the light of the other personal circumstances of members of these bodies.

1.4.2 Employee participation in company management[16]

Employee participation in company management is carried out in accordance with the Worker Participation in Management Act (e.g. ZDR-1, ZVZD-1). They exercise their duties and rights individually and collectively through the Workers' Council, Workers' Assembly and their representatives in the company's management bodies.

The Workers' Council serves as a form of collective and indirect participation of employees in the management of the company. It has fifteen members that represent workers' interests, form opinions and forward proposals and initiatives to management on improvements to the quality of the work environment. Two representatives of the employees are the Supervisory Board members, while the Workers' Director is also a member of the Board of Management and represents workers interest in human resources and social area for a five-year term.

The 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 2016, the Workers' Council was regularly informed at its meetings about the economic situation of the company and its development objectives, organizational changes in individual units, topical issues which were subject to management decisions, and other topical events in the company and in the syndicate. It also took note of various reports (annual report, report on innovation, report on the annual assessment of performance, on the operations of the Pokojninska družba A, d.d. pension fund, etc.).

The Workers' council successfully concluded several initiatives which were accepted by employees and forwarded to management. The objectives of the initiatives were improvements to the quality of the work environment and work relationships as well as improvements in the area of Health and Safety. Their introduction also improved morale amongst employees (opening a new entrance at sites, changing the bus timetable, etc.).

The Workers' Assembly is organized at all four locations, which in 2016 was called "Do you already know?". Employees were familiarized with the key points of importance in Novartis, Sandoz and Lek operations, with the activities of the Workers' Director and Worker's Council in the past year and received information on activities in the promoting health program.

The Workers' Council regularly published the minutes of their monthly meetings and other relevant information useful for employees (information on labor legislation, tax, links to more important laws, institutions…) on their intranet page. Another important channel for notification was the monthly email sent to employees after each meeting of the Workers' Council.

1.4.3 Stakeholder overview and inclusion[17]

Our activities, in accordance with Novartis corporate responsibility policies, are focused on five key groups of stakeholders: patients, employees, shareholders, healthcare partners (healthcare professionals, regulators, professional associations, buyers, suppliers) and society (local communities, non-governmental organizations, scientific and educational institutions, and the media).

[16] GRI GS disclosure 103-1

[17] GRI GS disclosures 102-40, 102-42, 102-43

We include our stakeholders in our operations in several ways in order to understand their needs and expectations, and subsequently improve access to healthcare. We constantly strive to improve their inclusion, and consequently understand our operations more easily, make strategic adjustments to our business practice and build trust between stakeholders.

We try to understand patients' needs through focus groups and cooperation with patient groups organized in associations and initiatives. At scientific conferences, we cooperate with academia and the scientific community, with professional organizations, educational institutions, research institutions and researchers in the field of chemistry, biology and healthcare. In order to learn about the satisfaction and views of our employees, we use a Novartis global survey carried out among the employees. The survey planned for 2016 was postponed by Novartis to 2017. We meet with our suppliers to learn about their expectations and experience.

We involve patients, doctors, pharmacists, wholesalers and retailers through the use of new technologies and information channels. We provide balanced, accurate and easy-to-understand scientific information on diseases, treatments and treatment policies that concern patients. We pursue an interest in providing information to the public through building open and proactive relations with the media.

An open dialogue with our key stakeholders forms part of our company vision to be a respectable and successful healthcare company in Slovenia and abroad. It is maintained through a prompt response to the questions received, and by means of a responsive policy and practice of complaint handling.

As a part of the Novartis Global Community Partnership Day initiative, over 12 years, 3,900 employees have volunteered through Slovenia, and have helped more than 60 different organizations and more than 12,000 people.

At Sciencetival, a festival of science and adventures, Zlatko Pflaum, project manager at Biopharmaceuticals Mengeš, presented chromatography together with his colleagues, in a simple and fun way.

Family day is a favorite at all our sites.

Lek's stakeholders and their recognized interests:[18]

Stakeholders	Stakeholders' interests
Employees	• Continuous care for healthy and safe work environment • Improving knowledge and skills • Equal opportunities for career development • Employment safety • Balance between professional and private life • Awareness on responsible treatment of the environment • Diversity and inclusion • Participation in company development and management • Awareness and participation in decision-making regarding the policies and measures for health and safety at work, and environmental protection
Patients	• Safe, efficient and high-quality medicinal products • Affordable medicinal products • Development of new and efficient medicinal products • Functional packaging of medicinal products with low environmental impact • Responsible handling of medicinal products and waste medicines • Cooperation with patient groups
Owners	• Accountable business practices • Good business results • Company's high developmental capacity • Patient trust • Satisfaction of employees, • Compliance with the regulations and Novartis' health, safety and environmental standards • Efficiency in consumption of natural resources • Company's reputation
Healthcare professionals and healthcare providers	• Safe, efficient and high-quality medicinal products • Accountable business practices • Providing information on new medicinal products • Providing information on proper medicine use • Proper product labeling • Responsible handling of medicinal products and waste medicines
Customers	• Safe, efficient and high-quality medicinal products • Affordable medicinal products • Proper product labeling and information clarity • Responsible handling of medicinal products and waste medicines
Regulators	• Safe, efficient and high-quality medicinal products • Adherence with legislative requirements regarding pharmaceutics, health, work safety, protection of the environment, marketing, and product advertising, etc. • Proper product labeling
Academia and scientific community	• Participation in development and research projects • Knowledge and practice exchange • Inclusion of environmental aspects into the development of new products
Professional and industry associations	• Exchange of opinions and promotion of good HSE practices in industry and professional associations • Industry reputation
Suppliers	• Good business relations • Awareness of risk factors in work environment • Adherence to legislative and Novartis' standards in protection of the environment • Timely deliveries, adequate prices for goods and services
Local communities	• Involvement in life of the local community • Support for cultural, sports and humanitarian organizations • Employment of workers from the local area • Cooperation with institutions and vendors from local area • Efficiency in consumption of natural resources • Development and expansion of sites • Successful management of environmental impacts and adherence to safety and environmental legislation
Media	• Providing information on business and events in the company • Open dialogue and accessibility of data related to environmental and social impact in public interest
Non-governmental institutions	• Support and cooperation on projects • Good social accountability practices • Accessibility of data related to environmental and social impact in public interest

[18] GRI GS disclosures 102-40, 102-44

Open day at Mengeš.

1.4.3.1 Co-operation with the local communities

Each organization is inextricably linked to the environment in which it operates, and therefore open dialogue is imperative to create and maintain long-term positive relationships with residents in the local community. Since we began our operations 70 years ago, we have had regular and transparent relations with our local communities. Good knowledge of operations and the orderliness of our sites and HSE information is very important for the residents in neighboring towns and villages. Our open days are more active and structured than a decade ago, and are now regularly organized at all our locations across Slovenia. The feedback that we receive during or after the event itself is very valuable to us, as they show us the path to improvement and tell us in which direction we should move forward.

In 2016, we organized **an open day at Mengeš**. There was a lot of interest, it attracted around 600 residents from the surrounding areas. We recorded more than 200 visitors' questions, most of them were related to employment opportunities, followed by issues related to HSE protection, medicines, general questions about Lek and technology.

The sustainable impact of our operations has also been brought closer to the local community through various publications in local media.

Mechanism for addressing complaints[19]

By effectively addressing complaints from the field of HSE and by implementing the appropriate corrective measures, we ensure a safe and an environmentally friendly work environment, reduce environmental risks in carrying out business activities and contribute to the creation of a good company name. Complaints are solved according to internal procedures, which require the responsible person to open an enquiry within 24 hours. Depending on the completion of the enquiry and the eligibility of the complaint, the Site Head of HSE shall ensure that the corrective measures are taken and fulfilled. The entire procedure is documented and archived.

In 2016, we received one complaint from a local resident of the Ljubljana location due to noise. It was the same resident whose complaints were already dealt with in the years 2011 to 2015. In the past years, we installed noise dampers on the outlets at the site, as well as in the places of air intake for production, thus reducing the level of noise well below the threshold value. Detailed measurements of environmental noise in 2015 and 2016 have shown that our company is not the source of the noise that was disturbing for the local resident.

In 2016, we completed the remediation work to reduce noise at Prevalje, based on remedial measures prepared by the Institute of Occupational Safety in Ljubljana.

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 http://www.lek.si/en/corporate-responsibility/.

1.4.4 Lek's commitment to external initiatives and principles[20]

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

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

In addition, Novartis is a member of the Workplace Wellness Alliance of the World Economic Forum (WEF) (http://www.weforum.org/issues/workplace-wellness-alliance). Their guidelines were also embraced by Lek, a Sandoz company.

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.[21]

[19] GRI GS disclosures 103-1, 103-2, GS 413-1

[20] GRI GS disclosures 102-12, 102-13

[21] GRI GS disclosure 102-11

2. Environment

Health, safety and environment policy (HSE)[22]

All our considerations and operations are aimed at contributing to the sustainable development of the company.

Priority is given to the following:

- the health and safety of our employees and all those affected by our operations, and
- environmental protection.

We implement Novartis' and Sandoz' HSE Policy and Guidelines, and meet the respective health, safety and environmental legislation requirements. Our operations are based on the pillars of Novartis Corporate Citizenship policy focusing on the improved access to treatment, responsible operations, transparent reporting on our impacts, employees and the community, and environmental protection.

We are raising public awareness of health and safety at work, without any excessive impact on the environment. In order to improve HSE efficiency and accountability, we set measurable long-term and annual goals.

We make rational use of natural resources and verify and reduce the impact of our operations on the environment. The goals we set reflect our environmental impacts, which are comprehensively managed within the Novartis Environmental management System, EMS.

Lek, a Sandoz company, is open to the public. We actively cooperate with local communities, responding to their initiatives and seeking common solutions for further improvements.

HSE Policy guidelines

We implement the HSE system on the basis of clear guidelines integrated into our operations. Fulfillment of legal requirements and corporate orientations constitutes a platform for our HSE risk management system. We adhere to the ISO 14001 standard, the international OHSAS 18001 occupational safety and health standard, and the Responsible Care Initiative for the chemical industry, coupled with the EMAS Eco-Management Scheme.

Our key guidelines are:

- Health, safety and protection of the environment constitute the basic responsibility of all our employees.
- We play a proactive role in protecting health, providing safety, and protecting the environment.
- We regularly check conformity of our operations with the relevant acts, regulations and guidelines. We are committed to observing all legal regulations and other pharmaceutical industry regulations as well as Novartis standards relating to any relevant aspect of health, safety and environment.
- We raise awareness among our employees regarding HSE policies and provide them with continuous training enabling them to implement the policies. This is how we ensure they work safely and understand the risks involved.

[22] GRI GS disclosures 102-11, GS 103-1, 103-2

- By introducing the best performing and cost-effective technologies available, we strive to become one of the leading environmentally-committed companies.
- Through continuous improvement of business and production processes, we improve HSE efficiency and reduce environmental impacts.
- We have systems and measures in place to prevent environmental pollution, which are regularly verified and upgraded.
- The HSE policy and its implementation is recorded, the set guidelines are updated and consistently realized, and keep informing our employees thereof.
- We strive to make continuous progress in our use of raw materials and energy resources, and in the reduction of environmental impacts, which is constantly monitored through regular measurements and data follow-up.
- At our production sites, we regularly identify, monitor, manage and document HSE risks.
- To achieve risk management goals, we propose and implement preventive and corrective measures whenever necessary.

We provide our stakeholders with well-balanced information on our corporate responsibility, which forms a solid basis for dialogue and formation of views and decisions. Information on the sustainability aspect of our operations are publicly available on our website www.lek.si/en/.

Compliance with HSE laws and standards[23]

Complying with legal and other requirements is the basis of our responsible operations. The key environmental management regulation is the Environmental Protection Act, which in 2016 underwent a significant change. 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 IPPC[24] (Directive of industrial emissions) certified company, our Lendava and Mengeš sites operate in compliance with Decree on activities and installations causing large-scale environmental pollution. Both existing IPPC permits also cover the release of greenhouse gases from cooling devices, whereas these types of emissions at the Ljubljana and Prevalje sites are included in permits dealing with atmospheric emissions. All Lek sites comply with the Decree on Limit Values for Atmospheric Emissions of Volatile Organic Compounds from Installations Using Organic Solvents. As a low-risk source, the Mengeš site is obligated to adhere to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences.

New legal and other requirements are promptly and efficiently transferred in our work processes and practices. Authorized persons for HSE actively monitor and identify them, ensuring appropriate internal publication after a gap analysis in the Corrective measures application, making them promptly available to persons responsible for HSE at all sites and other interested employees. Responsibility for effective application in practice lies with the site heads/representatives of the HSE units.

In 2016, a total of 9 inspections were carried out at all of the four sites, all from the area of environmental protection. None of the sites were found to have fineable incompliances.[25] In Mengeš, we filed for a change in environmental permit, in which we asked for an exception in determining the annual AOX content in waste cooling water. At Lendava, following an inspector warning, we repainted the catchment basin of the Wastewater Treatment Plant, so it does not become overburdened with time. All three decisions resulting from inspectoral procedures in 2015 at Prevalje and on which we appealed due to incorrectly established facts, were stopped at the beginning of 2017.

In 2016, we were involved in inspections covering the quality of operational processes and products (e.g. JAZMP, FDA, etc.) related to the area of health checks and waste management.

Environmental permits are the result of complying with all stipulated legal requirements for all projects or changes at all our sites. By respecting the provisions of the environmental permits issued by the Slovenian Environment Agency and specify the limit values for all atmospheric and water emissions, waste management, measures to reduce light pollution, methods for safe storage of raw materials and products for the company's sites. Our adherence to these values results in the safe operation of our production plants without excessive impact on the environment.

Environmental permits and their changes at all our sites:

- Environmental permit for operation of a device with a high pollution potential (IPPC) for the Lendava site, Permit No. 35407-172/2006, dated 15 April 2010.
- Decision amending the environmental permit for the Lendava site, No. 35407-37/2011-33, dated 12 July 2012.
- Decision amending the environmental permit for the Lendava site, No. 35406-33/2012-4, dated 15 March 2013.
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2014-8, dated 23 January 2015.

[23] GRI GS disclosures 103-1, 103-2

[24] See the glossary on page 83

[25] GRI GS disclosure 307-1

- Decision amending the environmental permit for the Lendava site, No. 35406-39/2015-10, dated 27 January 2016.
- Environmental permit for operation of a facility with a high pollution potential (IPPC), for the Mengeš site, Permit No. 35407-171/2006, dated 14 May 2010.
- Decision amending the environmental permit for the Mengeš site, No. 35407-22/2010, dated 28 December 2010.
- Decision amending the environmental permit for the Mengeš site, No. 35407-54/2011, dated 16 May 2012.
- Decision amending the environmental permit for the Mengeš site, No. 35406-24/2012-3, dated 23 August 2012.
- Decision amending the environmental permit for the Mengeš site, No. 35406-25/2013-6, dated 11 November 2013.
- Decision amending the environmental permit for the Mengeš site, No. 35406-42/2014-4, dated 10 September 2014.
- Decision amending the environmental permit for the Mengeš site, No. 35406-7/2015-7, dated 20 April 2015.
- Decision amending the environmental permit for the Mengeš site, No. 35406-33/2015-20, dated 9 February 2016.
- Environmental permit for risk facilities (SEVESO risks) for the Mengeš site, Permit No. 35415-26/2006-9, dated 25 May 2015.
- Decision amending the environmental permit for the Mengeš site, Permit no. 35406-43/2016-8 dated 30 March 2017.
- Environmental permit with regard emissions into water and air for the Ljubljana site, permit no. 35431-6/2016-9, dated 22 November 2016.
- Environmental permit with regard emissions into water and air for the Prevalje site, permit no. 35444-36/2016-12
- 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 35536-90/2014-2, 35536-17/2013-2 and 35536-19/2011), and dated 4 April 2016.
- Water use permits for direct use of water No. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8.
- Permits for the release of greenhouse gases No. 35485-53/2014, dated 22 October 2014, and No. 35485-54/2014, dated 15 December 2014.

2.1 Active environmental policy implementation

Environmental responsibility is a top priority of our operations, along with the continuous search for improved efficient use of raw materials and limiting the impact of our activities on the environment. Direct and indirect environmental impacts, including the identified risks and benefits, are taken into account when adopting business decisions. In the area of innovation and development of new products, we carefully consider the opportunities to improve environmental aspects as well as risks in a scientific and transparent manner. In doing so, we carry out numerous environmental protection activities which often exceed the legal requirements.

The primary direct environmental aspects and impacts of Lek's operations include the use of energy and water, emissions to the air, water pollution, waste and noise, and attention to odor and the use of soil. Indirect environmental aspects mainly include impacts from suppliers/contractual service providers.

In 2016, we were not charged with any penalties for non-compliance with environmental laws;[26] however, we received one external complaints, which is described under Item 1.4.3.1, together with action taken.

2.1.1 Specifics of business operations and disparities in data collected

When preparing data for the sustainability report, we find some disparities which when assessing and interpreting our environmental impacts, need to be taken into account.

Namely, there are considerable differences in product and API weight. On the one hand you have biosimilars, where production is measured in kilograms, on the other hand you have self-medication drugs which are in more than ten tons. Disparity is also seen due to the versatile product portfolio of each location, especially where there is an extensive portfolio (Mengeš, Ljubljana). Moreover, our operations are also characterized by year-to-year adjustments of the production program to the changes in demand. The manufacturing structure therefore varies from year to year.

[26] GRI GS disclosure 307-1

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.

2.1.2 Environmental protection investments and achievements[27]

We take into account environmental compliance in emissions and energy-saving implementation in technological systems for all of our investments in production facilities. In 2016, we invested 5.2 million euros in environmental protection. The major environmental protection projects were:

- noise reduction measures at Prevalje,
- completion of the study with all measurements and analyzes of noise pollution and the purchase and installation of an additional three noise dampers in Ljubljana,

Isolation of intermediary products by providing strictly controlled REACH SCC conditions in Lendava.

- installation of RTO device (regenerative thermal oxidation device) in Lendava,
- installation of weight scales for weighing waste in Lendava,
- completed project in the fully-closed process by providing strictly controlled REACH SCC conditions in Lendava,
- establishment of a new closed-loop cooling cycle for the use of well water in Lendava,
- introduction of additional regeneration of raw materials in Lendava,
- connection of additional production emissions to RTO in Mengeš,
- launch of another steam boiler for incineration of waste solvents in Mengeš and installation of a device for the permanent measurement of emissions,
- the purchase of additional 7m^3 containers for the collection and better separation of mixed municipal waste,
- installation of more economical LED outdoor lighting at all locations.

2.1.3 Verification of established standards[28]

All four sites are included in the EMAS scheme, the EU Eco-Management Audit System, Prevalje and Lendava are the only company in their municipality that is included. In 2016, the environmental verifier (the Slovenian Institute of Quality and Metrology – Accreditation Number SI-V-0001) confirmed that the Sustainability Report of Lek d.d. for the year 2015 reflects a reliable, credible and correct image of all the organizations/sites activities, within the scope mentioned in the environmental statement.

We successfully certified the environmental management system in accordance with the required ISO 14001:2004 standards, ES 1221/2009 regulations (EMAS) and Environmental Management Systems Certification in accordance with OHSAS 18001:2007 standards. In November, we were amongst the first companies in Slovenia to successfully meet the requirements of ISO 14001:2015 standards. We met all requirements to extend our certification in accordance with Responsible Care initiative.

The compliance of our HSE operations was also confirmed by external verification in 2016 (JAZMP, FDA, etc.).

[27] GRI GS disclosure 103-2

[28] GRI GS disclosure 103-2

2.1.4 Key projects for optimizing business processes

Anti-explosive protection – ATEX

In 2016, the new ATEX directive 2014_34_EU came into effect and the new Rules on Anti-explosive Protection (Official Gazette RS no.: 41/2016). We successfully prepared for the changes and provided smooth operations for reconstructions, new constructions and regular maintenance. Currently, we have 77 facilities at all our sites, for which corresponding ATEX certifications need to be obtained. Of these, eight facilities are in the recertification phase. Concurrently, we regularly educate our maintenance personnel and all other employees, who in any way access the explosion-hazard areas.

LOTO

We continued with the introduction of the Lockout-tag out (LOTO) system in all of our sites. Also, preparation of detailed instructions for the use of the system and training of personnel in charge of using the system during intervention in production equipment are also carried out. We also started to inform and train outsourcers on introducing the system at sites. By doing so, we commit them to adhering to our internal standards and to improving the safety of the work of employees carrying out work on our facilities.

Th!nk Sandoz initiative

The development of ingenuity is promoted through online management of ideas and numerous events for the exchange of good practices and opportunities. Within **Th!nk Sandoz initiative, our employees** passed 1,213 ideas in 2016, of which 722 were accepted. The improvements were suggested by 649 different employees. There were quite a few ideas from the field of health, safety and environment, such as clips for more secure opening of the tube, waste separation bins, protective fences and other improvements that contribute to safer and more environmentally friendly work. In 2017, the initiative celebrates its fifth year of existence. Up until now, all implemented ideas already helped to save more than 34 million euros.

Slovenia contributes a third of all ideas in the Th!nk Sandoz program. Pictured here, Matic Stare and Saša Lukić, winners with the most accepted ideas in 2015.

2.1.5 Indirect environmental impacts[29]

Indirect environmental impacts of Lek, a Sandoz company, mainly include impacts from suppliers. Therefore we expect our suppliers to observe the principles of the Novartis Corporate Citizenship policy. The environmental responsibility of a contractor is one of the key criteria for their selection/approval.

The signing of a supply agreement should be preceded by an environmental audit of the supplier's operations. The agreement constitutes the supplier's guarantee to comply with all applicable HSE laws and regulations, fair work practices and unlawful discrimination.

For waste management, we only select suppliers that have all the required authorizations, and only those suppliers that are recorded as contracting providers with the respective Ministry.

In addition to the above, transport is also a significant indirect environmental impact of our operations. In the urban environment, transport is recognized as the key source of air pollution, mostly due to solid particles (PM particles). We are substituting the air transport for a greater volume of goods with maritime transport, which is described in greater detail in section 2.9.3.2 Distribution. We restrict transport by using more frequently teleconferences and videoconferences instead of long business trips. We regularly monitor fuel consumption, mileage and CO_2 emissions for all the fleet cars. This data is reported quarterly into the Novartis database.

For 106 company cars in 2016 (133 in 2015), a total traveling distance of 3,643,293 km (3,514,690 in 2015) was recorded, with fuel consumption of 216,279 liters (221,756 in 2015) and CO_2 emissions of 448 tons (444 in 2015). In addition to company cars, we had 19 other vehicles (fire engines, forklifts), which had an additional total of 56 tons of CO_2.

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.

[29] GRI GS disclosures 305-1, 308-2, 414-2

2.2 Raw materials and natural resources

2.2.1 Mass flow of materials

We recorded a decreased use of raw materials (by 2%), mostly due to decreased production volume at Prevalje and Mengeš.

Changes in the structure and volume of APIs cause an annual fluctuation of mass flow of materials. There is minimal fluctuation at the Lendava Production and Prevalje sites, because only one to two products are manufactured there, and the increase in API production also means an increased use of raw materials.

Table 3: Annual mass flow of various materials used* in tons[30]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	t	7,548	9,861	15,707	3,979	37,095
2013	t	8,594	8,177	14,497	4,285	35,552
2014	t	8,891	9,901	15,646	5,063	39,501
2015	t	9,152	10,188	16,091	5,698	41,130
2016	t	8,844	10,396	15,557	5,629	40,426

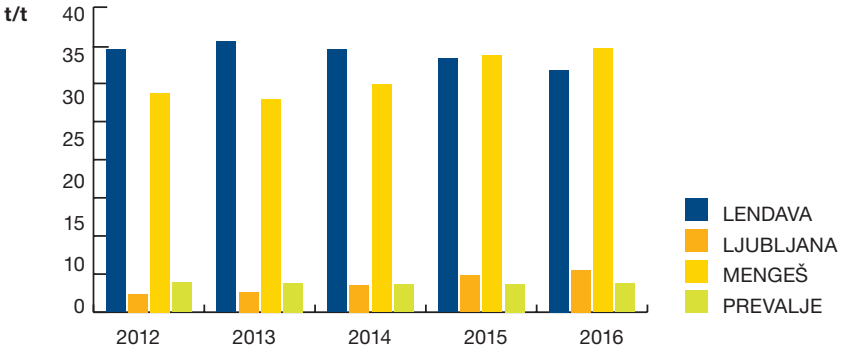
* Total quantity of materials purchased within the reporting period to ensure seamless progress of the manufacturing process to the finished product phase (including packaging but exclusive of fuels, water and manufacturing equipment).

2.2.2 Efficiency of materials

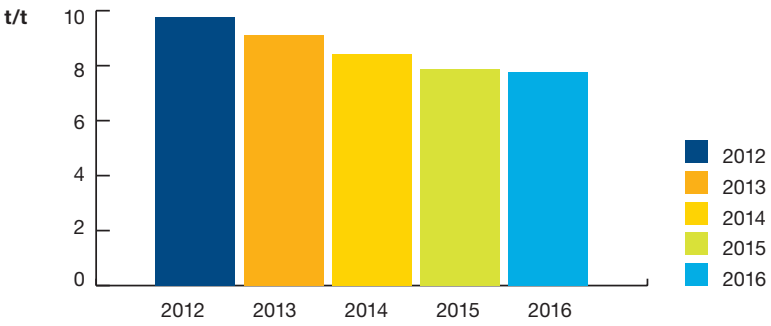
The graphic display of the efficiency of the use of all the raw materials at Lek, a Sandoz company, reflects the intensive efforts to reduce the consumption of raw materials per unit of product. The quantity of raw materials used per ton of API/product has been decreasing for a number of years. In 2016, we increased the efficiency of the use of materials by more than 1% compared to the previous year, and by more than 20% between 2012 and 2016.

Chart 3: Efficiency of the use of various materials per unit of product[31] – by site and total

Efficiency of the use of raw materials per unit of product



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



[30] EMAS core indicator, GRI GS disclosure 301-1

[31] EMAS core indicator , GRI GS disclosure 103-1

2.2.3 Sustainable packaging approach

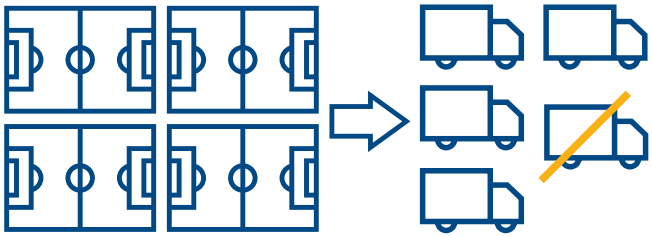
Lek, a Sandoz company, defined the basic principles of packaging design and production in accordance with the Novartis policy of sustainable use of the packaging and the binding waste management hierarchy.

A comprehensive selection of recommended materials for the packaging, dimensions and types of primary and secondary packaging is written in the **Sandoz global packaging catalogue**. The basic principle of the guidelines is that the packaging material must, in addition to meeting all regulatory requirements, generate minimum waste and use minimum amount of energy in production. We are constantly looking for improvements to the packaging, as they can have a great environmental and financial impact.

In Lendava, in 2016, we thus reduced the size of the blister for irbesartan mono & combo and consequently reduced the box with the final product. By doing so, we saved a corresponding quantity of material purchased, which could, at the annual level, cover the surface of four football fields or, we reduced the volume by 40 pallets of the finished product. With the product sildenafil, we optimized the consumption of design and cover foils, saving 46% of the material or reducing the number of pallets by 46% at the annual level. With the product quetiapine, we reduced the cost of material by 27% by replacing the type of design foil.

The two production sites manufacturing finished dosage forms are the major consumers of packaging material: Ljubljana with 63% and Prevalje with 34.2%. At the Mengeš and Lendava sites, packaging consumption accounts for less than 3% of the total packaging consumption of Lek, a Sandoz company.

Product: IRBESARTAN MONO & COMBO-ALU/ALU BLISTER



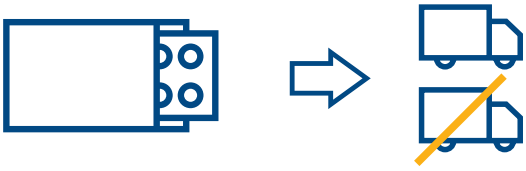
DESCRIPTION:

With the reduction of the size of the blister we consequently reduced the box with the final product

SAVINGS:

- At the annual level, the surface of four football fields
- We reduced the volume by 40 pallets of the finished product, or every fifth truck less

Product: SILDENAFIL

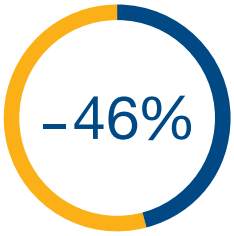


DESCRIPTION:

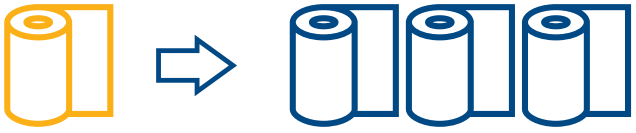
Optimization of the consumption of design and cover foils

SAVINGS:

- Saving of the material by 46%
- Reducing the number of pallets by 46%, or every second truck less



Product: QUETIAPINE



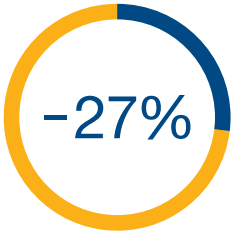
CoC Triplex

DESCRIPTION:

Replacement of the type of design foil (CoC in Triplex)

SAVINGS:

- Reduction of the cost of material by 27%



2.3 Energy

2.3.1 Energy consumption

The overall annual energy consumption was a good 4% higher than in the previous year. The largest increase was recorded at the Lendava site (by 8%), where production volume was increased, followed by the Ljubljana site (by 5%). Almost 3% less energy was used at the Prevalje site, and energy consumption at the Mengeš site remained unchanged.

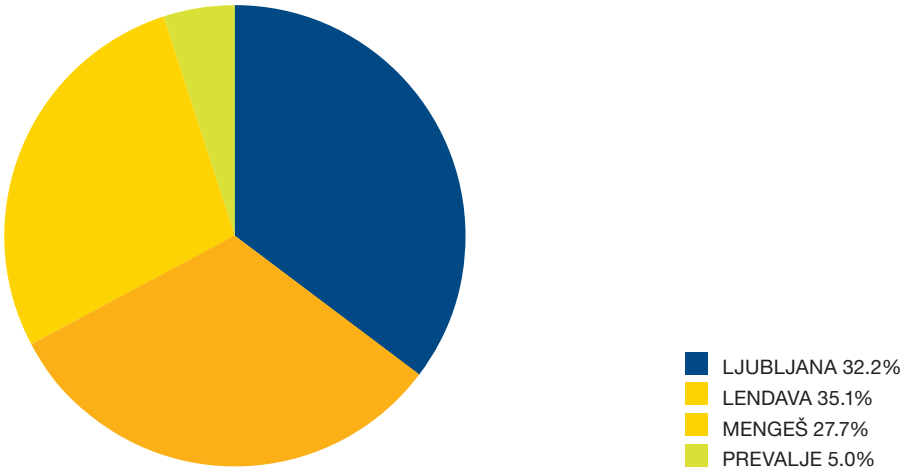
Table 4: Overall energy consumption[32]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	GJ	371,988	381,552	335,652	57,434	1,146,626
2013	GJ	382,122	387,740	334,561	62,691	1,167,114
2014	GJ	387,500	412,023	330,623	64,043	1,194,189
2015	GJ	382,018	428,121	355,886	66,147	1,232,172
2016	GJ	412,721	450,709	355,584	64,432	1,283,446

In terms of the total energy consumption, the Ljubljana and Lendava sites have the highest proportion with a 35% and 32% share, followed by Mengeš with 28% and Prevalje with 5%.

[32] GRI GS disclosure 302-1

Chart 4: Distribution of energy by sites



At the Mengeš site, waste solvents are utilized as secondary fuel for the operation of the steam boiler that generates heat and steam for technological purposes. At the Lendava site, the share of renewable energy amounts up to 1%. It is obtained from the incineration of organic waste generated in fermentation production.

Table 5: Efficiency of energy resource use per unit of product[33]

Year	Unit	Lendava	Ljubljana*	Mengeš	Prevalje	Lek (total)*
2012	GJ/t	1,697	190*	613	56	302
2013	GJ/t	1,577	191*	645	56	299*
2014	GJ/t	1,501	164	632	46	255
2015	GJ/t	1,389	146	744	43	236
2016	GJ/t	1,483	151	791	44	247

* Due to changes in the data on the realization of finished sterile pharmaceutical products at the Ljubljana site, there was a change in the data for previous years.

Table 6: Electricity consumption[34]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	GJ	167,994	152,638	116,215	24,551	461,398
2013	GJ	189,032	155,394	116,498	25,686	486,610
2014	GJ	198,955	169,269	117,140	26,601	511,965
2015	GJ	201,421	173,523	124,413	28,139	527,496
2016	GJ	213,819	178,554	126,025	27,810	546,208

In 2016, we used 3.5% more electricity than in the previous year, due to increased production volumes.

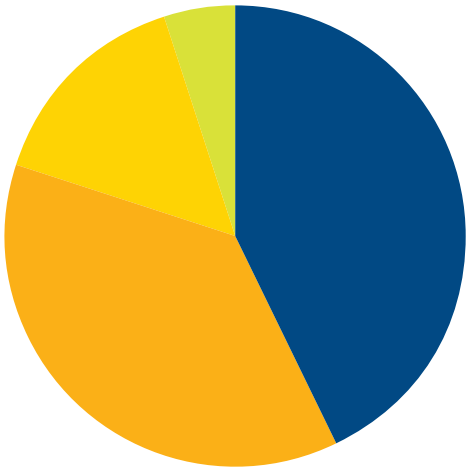
[33] EMAS core indicator, GRI GS disclosure 302-3

[34] GRI GS disclosure 302-1

2.3.2 Distribution of energy by energy sources

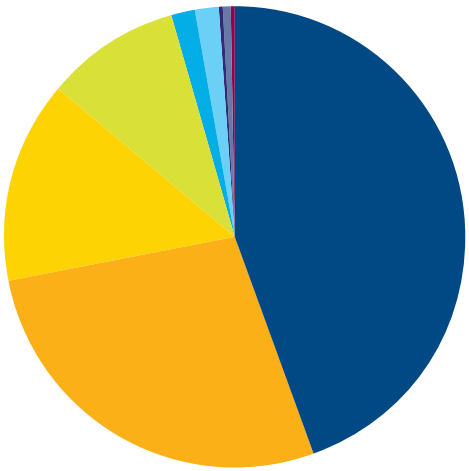
In the structure of purchased energy sources, electricity accounts for the largest share with 42.6%, followed by natural gas with 37.2%. These two energy sources are the primary source for three sites. At the Ljubljana site – in addition to these energy sources, we also purchase industrial steam (15.2%) and heating water (5.1%).

Chart 5: Distribution of energy used by primary energy sources



ELECTRICITY 43%
NATURAL GAS 37%
STEAM 15%
HEATING 5%

Chart 6: Structure of purchased electricity sources



COAL AND LIGNITE 44.5%
NUCLEAR FUEL 27.72%
HYDROPOWER 14.01%
NATURAL GAS 9.48%
BIOMASS 1.64%
SOLAR ENERGY 1.56%
UNIDENTIFIABLE SOURCES 0.48%
WIND 0.36%
OIL DERIVATES 0.19%
UNIDENTIFIABLE SOURCES 0.05%
GEOTHERMAL ENERGY 0.01%

Table 7: Structure of purchased electricity sources

	Share in %
Fossil fuels	**54.65**
• Coal and lignite	44.50
• Natural gas	9.48
• Oil derivates	0.19
• Unidentifiable sources	0.48
Nuclear fuel	**27.72**
Renewable sources	**17.63**
• Hydropower	14.01
• Wind	0.36
• Solar energy	1.56
• Geothermal energy	0.01
• Biomass	1.64
• Unidentifiable sources	0.05
Total	**100.00**

2.3.3 Energy efficiency improvements[35]

We have been continuously increasing the production of complex products with smaller quantities, yet a higher added value. Complex production processes dictate the use of more complex production equipment which usually entails more demanding energy consumption. Ensuring energy efficiency is therefore an integral part of our production processes. We constantly make our employees aware of the efficient use of energy.

In 2016, additional measures were taken to improve energy efficiency, generating energy savings of 8.21 TJ in total and by 278 tons lower CO_2 air emissions. These results were reached with the following projects:

- At the **Mengeš site**, we carried out several small projects to increase energy efficiency. We renovated the isolation of condensate collectors and steam distribution, installed the "free cooling" system for the preparation of cooling water in the winter by using low ambient air temperatures and eliminated the leakage at the distribution of compressed air in individual production facilities. With these projects, we reduced the annual energy consumption by 4,132 GJ.
- At the **Ljubljana site**, we saved 1,419 GJ of electric energy by installing a new more efficient compressor.
- At the **Lendava site**, we reduced the energy consumption by 2,637 GJ per year with the following projects:
  - we upgraded the cooling system by installing a more efficient and high performance cooling generator,
  - we changed the type of cooling medium in the cooling system -5/0°C, thus improving the energy efficiency of the system,
  - with an increase of the cooling system capacity -5/0°C we relieved the cooling system 7/14°C, where we improved the efficiency of the cooling system by selecting the optimal settings of the operating parameters.
- At the **Prevalje site**, we reduced our energy consumption by 20 GJ per year, which was achieved through the replacement of windows and the renovation of the condensing tube on the cooling tower.

[35] GRI GS disclosures 302-4, 305-5

2.4 Water

2.4.1 Water use efficiency

In the pharmaceutical industry, water is an indispensable natural resource. Efficiency of its use is therefore one of our major aims. In 2016, we reduced the amount of water used by 5% and increased our efficient use of water by the same amount.

Water consumption per kg of product at the Lendava site:

- 2012: 5.8 m^3 of water/kg of product
- 2013: 5.4 m^3 of water/kg of product
- 2014: 5.3 m^3 of water/kg of product
- 2015: 4.8 m^3 of water/kg of product
- 2016: 4.7 m^3 of water/kg of product

Table 8: Water use in 1,000 m^3 [36]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	1.000 m^3	1,272	452	1,409	35	3,168
2013	1.000 m^3	1,316	477	1,452	39	3,284
2014	1.000 m^3	1,380	570	1,557	42	3,548
2015	1.000 m^3	1,315	569	1,627	42	3,553
2016	1.000 m^3	1,304	588	1,433	36	3,361

Table 9: Efficiency of water use per unit of product*[37]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	m^3/t	745	216	496	29	236
2013	m^3/t	772	218	570	31	246
2014	m^3/t	650	196	532	24	208
2015	m^3/t	645	183	670	21	204
2016	m^3/t	753	185	852	17	225

* Table 6 only provides the data on water use efficiency for industrial wastewaters (cooling waters excluded).

[36] EMAS core indicator, POR OI 21, GRI GS disclosure 303-1

[37] EMAS core indicator

2.4.2 Water supply sources

Water from our own wells is used for technological purposes at the Lendava and Mengeš sites, for which we have obtained appropriate permits from the Ministry of Environment and Spatial Planning.[38] We regularly monitor groundwater levels, with pressure sensors every hour on a continuous basis all year around, and report the results to the respective ministry.

At the Mengeš site, the impact of the well on the level and direction of groundwater is also monitored simultaneously with this annual monitoring. Monitoring of groundwater levels clearly showed that the dynamic groundwater supplies of Mengeško Polje are extensive. A longer time interval in monitoring the groundwater levels in the area of the Lek Mengeš facility shows an upward trend in groundwater levels (in the last decade). The precipitation in 2016 were average, but very unevenly distributed.

The IED Regulation, adopted in August 2015, requires that the operation of the plant does not cause deterioration in the quality of soil or groundwater. Operators must prepare a so-called initial report enabling a quantitative comparison between the situation in the IED plant area and its situation after the definitive termination of the activity. Thus it can be determined whether the soil or groundwater pollution has increased significantly.

The condition of soil and groundwater pollution for the Mengeš site was analyzed by the National Laboratory for Environment and Food, and the initial report was sent to ARSO within the prescribed time limit. The initial report for the Lendava site is still under construction, and it needs to be submitted to ARSO at the first major modification of the environmental permit.

Table 10: Water supply quantities and sources at the Mengeš and Lendava sites in 1.000 m³ [39]

Mengeš	2012	2013	2014	2015	2016
From our own pumping station (in 1,000m³)	1,335	1,376	1,480	1,510	1,330
From the public water supply network (in 1,000m³)	80	81	83	123	108

Lendava	2012	2013	2014	2015	2016
From our own pumping station (in 1,000m³)	1,228	1,297	1,340	1,261	1,318
From the public water supply network (in 1,000m³)	61	58	58	53	60

2.4.3 Recycling and reuse[40]

The water we use is, to the largest possible extent, recycled and reused. The share of is constantly being increased. Recycled water is mostly reused for the cooling of processes, mainly at the Mengeš site, where a three-level cooling water system operating at different temperature regimes enables the water from one system to be fed into a higher-temperature system, while a portion of water (spill) is discharged into the sewage system. The quantities of reused water vary greatly and depend on individual processes, so they cannot be accurately calculated on the basis of the existing data capture method. It has been estimated that the entire cooling water volume is reused at least twice.

At the Lendava site, the use of best available techniques (BAT) has had a large impact on water use. As the cooling cycles are of the closed-loop type, the trend of water consumption has been reversed and has improved in 2016.

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

[39] GRI GS disclosure 303-1

[40] GRI GS disclosure 303-3

2.5 Waste

2.5.1 Waste management[41]

A good 74% of all Lek waste and 69% of Lendava waste represent a waste mycelium - a biodegradable waste generated during the fermentation production of substances in Lendava, its predominant part is water. In addition to the mycelium that is released for processing into the biogas plant, the entire amount of waste sludge from the Lendava treatment plant is also considered as a biodegradable waste.

Among the volume important non-hazardous waste in Lendava belongs also waste packaging that is produced in the packaging of final forms of medicinal products and is being disposed of for recycling to authorized contractors.

More than 80% of all waste in Mengeš is hazardous waste, of which 94% is non-halogenated waste solvents. In two steam boilers, we process almost 30% of high-calorific waste solvents into the energy used for the preparation of technological steam. At the beginning of 2016 we obtained an environmental permit for the co-incineration of high-calorific waste non-halogenated solvents also in a new steam boiler with better thermal efficiency. In doing so, we ensured the further growth of the use of our own waste solvents to supply the location with technological steam. By processing waste solvents at the site, we reduce the transport of waste solvents and consequently the CO_2 emission. The remaining waste solvents are given to authorized companies that remove waste in an environmentally acceptable manner.

Due to the change in the production composition and an increased number of employees, the quantities of waste produced increased in total by 7% in 2016. The reduction in the amount of waste was achieved only in Mengeš, to wit by 19%.

For all quantitative data presented below it applies, that since 2011, only data for the volume of waste released for treatment outside the production site has been reported.

[41] EMAS core indicator, GRI GS disclosure 306-2

Table 11: Volumes of waste generated in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	t	13,572	2,210	4,904	676	21,363
2013	t	24,624	2,230	4,670	698	32,222
2014	t	26,147	2,739	5,146	636	34,667
2015	t	25,588	2,748*	5,692	766	34,794*
2016	t	28,862	3,010	4,597	800	37,269

* The 2015 data for the Ljubljana site is corrected. Sandoz d.d., Novartis Animal Health and Novartis Pharma were excluded from reporting as they are legal persons who independently report to the ministry.

Chart 7: Volume of waste per ton of product – efficiency

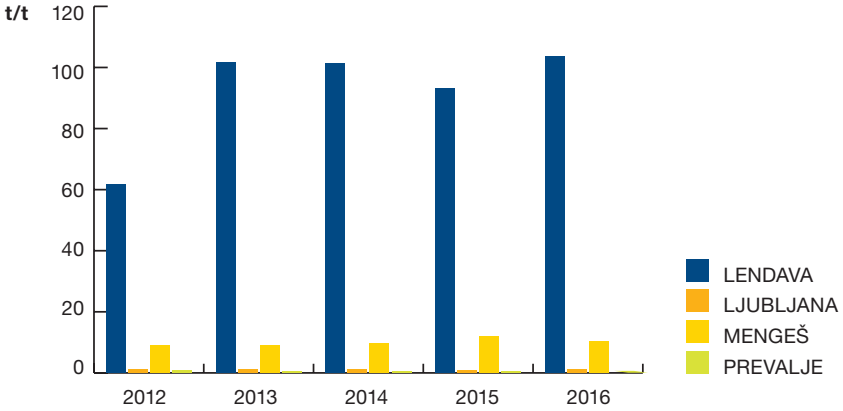
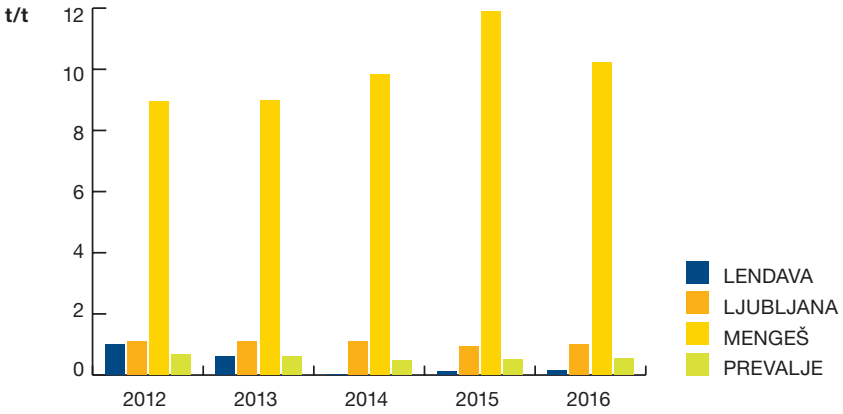


Chart 8: Volume of waste per ton of product – efficiency/disregarding mycelium waste



2.5.2 Disposal of hazardous waste[42]

Absolute quantities of hazardous waste fell by 17%, mainly due to Ljubljana and Mengeš sites. In Mengeš, a part of the hazardous waste reduction is due to the own processing of waste solvents.

In addition to preventing and reducing waste production, we are trying to continually increase their share for recycling or energy use. We processed and reused 85% of all organic solvents, which is 3% less than in 2015. In Lendava, the share of reused organic solvents reached a high 96% (the same as in the previous year), and in Mengeš an average of 74% (in some of the processes in Mengeš, this share reaches more than 95%). After a project completion of the additional solvent regeneration in 2016, the share of regeneration in Lendava will increase.

Non-halogenated waste solvents, which are extremely pure and high-energetic, represent 94% of all hazardous waste at the Mengeš site. The mixtures of halogenated waste solvents represent just over 2% of all waste solvents and are disposed separately by processors or disposers. In 2016, the share of waste halogenated solvents decreased by 40% compared to the year before due to the abolition of the production using methylene chloride in the technological process. By co-incineration with natural gas we removed 1,644 tons of waste solvents (1,504 tons in 2015), equivalent to 1.4 million Sm^3 of natural gas.

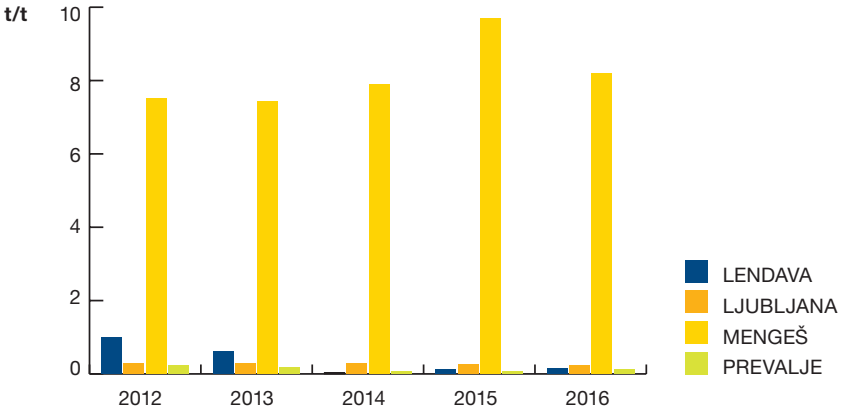
A large amount of hazardous waste at the Ljubljana site represent written-off medicines, but it cannot be reduced due to the inventory management method. Since 2011, however, we have performed intensive segregation of the waste packaging of hazardous substances (also in case a hazardous substance is only present in traces), which we release for incineration with energy recovery.

Table 12: Volume of hazardous waste in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	t	220	572	4.111	247	5.150
2013	t	148	575	3.855	215	4.793
2014	t	6	747	4.136	89	4.978
2015	t	30	744*	4.646	129	5.549*
2016	t	38	673	3.691	191	4.593

* The 2015 data for the Ljubljana site is corrected. Sandoz d.d., Novartis Animal Health and Novartis Pharma were excluded from reporting as they are legal persons who independently report to the ministry.

Chart 9: Volume of hazardous waste per ton of product – efficiency



[42] POR OI 5, GRI GS disclosure 306-2

2.5.3 Disposal of non-hazardous waste[43]

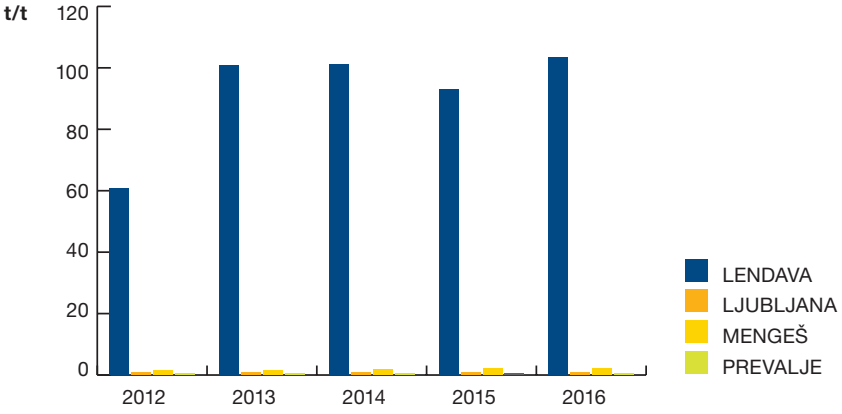
Nearly 88% of total Lek waste volume is non-hazardous waste. In 2016, biodegradable industrial waste, sent to a certified biogas plant, accounted for 75% of total waste. At the Mengeš site, this is largely biologically degradable waste generated by the manufacture of fennel and purple coneflower (Echinacea) juices, at the Lendava site mycelium waste.

Municipal waste accounted for a mere 1%, whereas the share of waste packaging (paper, plastics, wood, metal, glass) and disposal, while waste packaging is mainly recycled (until 2016 through the Slopak system, since 2017 through Gorenje Surovina system), and the same applies to construction waste. Other non-hazardous wastes are disposed of by authorized companies by means of incineration.

Table 13: Non-hazardous waste volumes by site in tons

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Lek (recyclable non-hazardous waste without packaging)
2012	t	13,353	1,637	793	430	16,213	14.393
2013	t	24,476	1,655	815	483	27,430	25.493
2014	t	26,141	1,991	1,010	547	29,689	27.411
2015	t	25,558	2,005	1,046	637	29,245	26.742
2016	t	28,824	2,337	906	610	32,677	29.787

Chart 10: Volume of non-hazardous waste per ton of product – efficiency



[43] GRI GS disclosure 306-2

2.6 Air emissions[44]

2.6.1 Eco-Management and Audit Scheme (EMAS)

We implement Novartis' corporate social responsibility policy and strive to minimize our impacts on the atmosphere. In doing so, we are also committed to respecting Slovenian and European legislation, which is described in detail in point 2. Compliance with legislation and standards in the field of Environmental Protection act (ZVO).

We separately monitor greenhouse emissions and emissions from immobile devices, VOC and dust emissions being of key importance. Emission metering points are established on individual manufacturing devices and lines where the presence of emissions of VOCs, dust particles and other substances is expected in the exhaust air. These are used for measurements of substances and/or dust in the air and collection of samples for analysis. For all the outlet ducts measured, assessments of substance and/or dust emissions have been made as prescribed.

To reduce organic substance emissions, various devices are used: for thermal oxidation of waste gas, absorbers, gas washers, and others.

Based on the results of periodic measurements, balance of solvents used, assessment of emission dispersion, and other data, we prove the conformity of total VOC emission values with the emission limit value expressed as a percentage of organic solvent input. For new devices this value amounts to less than 5%, for existing devices it is below 15%, whereas VOC emissions in captured waste gases do not exceed the limit concentrations (20 mg C/m^3).

We also maintain our compliance with the limit value for total dust, amounting to 150 mg/m^3 and with the limit value for the mass flow of total gas in excess of 0.2 kg/h, which amounts to 20 mg/m^3.

When using devices for thermal oxidation, we not only measure VOCs quantified as total organic carbon (TOC), but also the emissions of nitrogen oxides and carbon monoxide (LV = 100 mg/m^3). According to the stated parameters, these devices comply with statutory requirements as well.

2.6.2 Emissions from waste incinerators and co-incinerators

Incineration and co-incineration are carried out at two sites, Lendava and Mengeš. As operators of industrial complexes performing single or multiple activities covered by Regulation (EC) No. 166/2006, the Lendava and Mengeš sites have the obligation of reporting the volume of releases to the European Pollutant Release and Transfer Register (E-PRTR).

The Lendava site carries out mainly the incineration of waste generated at the site. The incineration process is controlled via a control system and flue gas parameters are regularly measured. The set limit/alarm values prevent the waste incineration process from running outside the permissible limits. By incineration of waste and natural gas as supporting fuel, process steam is obtained.

At the Mengeš site, thermal oxidation of industrial fumes is carried out in two of the four combustion plants using natural gas as a primary source of energy. By co-incineration of natural gas and non-halogenated solvents of high purity and calorific potential, process steam is obtained. Emission monitoring is regularly performed at all the emission release points. Permanent emission measurements were provided on the waste solvent co-incinerator for the parameters prescribed in the environmental permit.

[44] EMAS core indicator, POR OI 7, POR OI 10, GRI GS disclosures 103-1, 103-2

The gas detector at Fermentation in Lendava, where it is treated with water and without the use of chemicals that absorb odors from the fermenter air emmissions.

2.6.3 Sulphur dioxide[45]

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. In 2016, we recorded a decrease in these emissions as a result of occasional fluctuations in incineration of waste containing sulphur. The content of sulphur in natural gas is practically non-existent, as also confirmed by a supplier's statement.

Table 14: Sulphur dioxide emissions (SO_2)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (kg SO_2/t of product)
2012	t	0.00	0.0001	0.00	0.00	0.0001	0.000
2013	t	0.00	0.0004	0.0029	0.006	0.009	0.002
2014	t	0.13	0.00	0.004	0.0105	0.145	0.031
2015	t	0.10	0.00	0.005	0.0064	0.108	0.021
2016	t	0.0008	0.00	0.0017	0.0066	0.0091	0.0018

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

2.6.4 Nitrogen oxides

Nitrogen oxide emissions arise mainly from incinerators and co-incinerators, burning devices and to a lesser extent the manufacture of nitrooxine at the Mengeš site. Regular emission checks are carried out at all sites. In 2016, nitrogen oxide emissions were reduced by 9%. Significantly lower emissions were recorded at the Ljubljana site and Mengeš, Prevalje levels increased and the Lendava site were similar to those in 2015.

Table 15: Emissions of nitrogen oxides (NO_x)[46]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t NOx/t product)
2012	t	7.58	2.33	9.94	1.27	21.12	0.006
2013	t	10.57	1.04	9.35	1.43	22.39	0.006
2014	t	14.48	0.86	16.36	1.45	33.15	0.007
2015	t	13.55	0.11	15.79	1.47	30.92	0.006
2016	t	13.58	0.08	11.80	2.55	28.01	0.005

[45] EMAS core indicator, POR OI 7, GRI GS disclosure 305-7

[46] EMAS core indicator, POR OI 8, GRI GS disclosure 305-7

2.6.5 CO_2 and other greenhouse gases

The sources of direct CO_2 emissions (GHG1) at our sites remain as follows: burning of fuels and the incineration/treatment of flammable organic substances, production processes (e.g. fermentation) and the use of company cars.

Direct emission (GHG1)[47] data reported also includes:

- dinitrogen oxide (N_2O) in CO_2 equivalents,[48]
- fluorinated hydrocarbons (hydrofluorocarbons – HFC) in CO_2 equivalents,[49] and
- other greenhouse gases (methane and others) in CO_2 equivalents.[50]

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

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

The total amount of direct GHG emissions (GHG1), has slightly increased (by almost 1%) in comparison with last year, while the efficiency expressed as a ton of CO_2 emissions per product deteriorated (by more than 1%).

The increasing GHG1 emission volumes were also due to new highly complex products. Consequently, emission abatement is our top-priority task. It is mainly achieved through systemic energy management, process changes, implementation of new technological solutions in the phase of product development/transfer, and installation of energy- and environmentally efficient devices.

At the Mengeš site, the main source of direct CO_2 emissions (GHG1) is natural gas combustion (>90%) in the burning devices.

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.

Table 16: Carbon dioxide and other gases contributing to the greenhouse effect[51]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t CO_2/t product)
GHG1	2012	t CO_2	10,801	2,928	13,484	1,821	29,034	7.6
	2013	t CO_2	10,774	2,792	13,966	2,053	29,585	7.6
	2014	t CO_2	10,691	3,273	14,139	2,068	30,171	6.4
	2015	t CO_2	10,591	2,737	15,429	2,109*	30,866	5.9
	2016	t CO_2	11,642	3,118	14,375	2,032	31,168	6.0
GHG2	2012	t CO_2	12,438	27,793	3,870	816	44,917	11.8
	2013	t CO_2	1,575	24,242	970	214	27,001	6.9
	2014	t CO_2	9,351	31,976**	5,506	1,250	48,083**	10.3
	2015	t CO_2	1,072***	26,158***	662***	150***	28,042***	5.4
	2016	t CO_2	1,695	28,158	999	221	31,074	6.0

* The amendment comes from a data transfer mistake in Sustainability Report 2015 – Lek d.d.
** The quantity for the Ljubljana site for 2014 was corrected due to a data transfer error into DMS.
*** The quantity for 2015 was corrected due to the purchase of green certificates, at the Ljubljana site due to a data transfer error into DMS.

[47] POR indicator OI 10
[48] POR OI 11
[49] POR OI 12
[50] POR OI 13
[51] GRI GS disclosures 305-1, 305-2, 305-4

2.6.6 Volatile organic compounds VOC[52]

Novartis' recommendations on the use of alternative solvents in production are implemented through a systematic introduction of innovations in technological manufacture processes, where halogenated solvents are replaced with non-halogenated ones. Therefore, in Mengeš in 2016 we terminated one of the productions which used Methylene chloride in the technological process.

At the site, there is also a halogenated solvents extraction device for outlet air, with the state-of-the-art cryogenic condensation technology. In Prevalje, the use of halogenated solvents was already abolished years ago with the final replacement of methylene chloride with ethanol.

In 2016, the total VOC emissions saw a decrease of a further 11% from 2012 a total of 60%. The efficiency per ton of product also improved by 11%.

Table 17: Total emissions of volatile organic compounds

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t VOC/t product)
2012	t	23	43	71	5.4	142	0.038
2013	t	24	28	68	5.8	126	0.032
2014	t	23	13	57	7.2	100	0.021
2015	t	25	9	56	5.3	95	0.018
2016	t	24	10	48	2.7	85	0.016

2.7 Water releases[53]

Protection of waters from pollution is one of the most complex areas of environmental protection, as pollutants pose a risk to human health and the environment. We are therefore looking for solutions to achieve the set goals in a technically and cost effective manner.

We monitor the effects of pharmaceutical substances on the aquatic environment for several years, even before the requirements of Slovenian legislation and European directives were set. The substances from our industry can pass through to waste waters, and from there, through the treatment plants to surface waters. It was found that the proportion of pharmaceutical substances in water only to a lesser extent comes from pharmaceutical production and predominantly from end-users of pharmaceutical products. 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 physico-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.

Lek's wastewaters are directed into the public sewage system through technological, cooling and municipal ducts. For industrial wastewaters, all the sites have equalization basins installed before being discharged into the sewer system. The Prevalje site industrial wastewater is also technologically neutralized.

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.

Reports on the Monitoring of Industrial Wastewaters Discharge for 2016 show that no excessive pollution was identified at any of the sites.

2.7.1 Waste waters

At the Mengeš and Lendava sites, waste cooling waters account for 78% of the total water quantity used. In 2016, their consumption decreased by a good 12% or by almost 300,000m^3, which was contributed to by Ljubljana and Mengeš. The consumption of industrial water at all increased by 10%.

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

[52] POR OI 9

[53] GRI GS disclosures 103-1, 103-2

Table 18: Wastewater volumes by discharge quality and destination[54]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
Use of cooling water - unpolluted							
	2011	1000 m³	1,170	34	1,243	10	2,457
	2012	1000 m³	1,109	18	1,138	5	2,270
	2013	1000 m³	1,129	35	1,156	5	2,325
	2014	1000 m³	1,212	75	1,278	8	2,573
	2015	1000 m³	1,137	33	1,307	9	2,486
	2016	1000 m³	1,095	34	1,050	11	2,190
Discharge			into the surface water course	into sewage system cleaning at WWTP	into the surface water course	into sewage system	
Use of industrial water - polluted							
	2012	1000 m³	163	434	271	30	898
	2013	1000 m³	187	442	296	34	959
	2014	1000 m³	168	494	279	34	975
	2015	1000 m³	177	536	320	33	1,067
	2016	1000 m³	209	554	383	25	1,172
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

2.7.2 Phosphorus and nitrogen compounds, chemical oxygen demand

Nitrogen compound emissions mostly result from the fermentation production. The Lendava site accounts for the largest share of these emissions, followed by Mengeš, also at the expense of the 5-NOK production. In third place in nitrogen compound emissions in water is Ljubljana, and, at a negligible level, the Prevalje site. In 2016, the total volume decreased by almost 24%, mostly due to the reductions at Mengeš.

Phosphorous compounds also result from residual inorganic substances from the fermentation production, the Mengeš site is also the major generator. In 2016, we recorded a significant 44% decrease in the amount of such compounds in comparison with the previous year.

As the annual amounts of phosphorus and nitrogen compounds are reported after treatment in the wastewater treatment plant, they largely depend on the efficiency of the wastewater treatment. Wastewater from the Mengeš site is transferred to the Central Wastewater Treatment Plant Domžale-Kamnik, which in 2016 finished an extensive upgrade of the existing aerobic treatment stage, in order to increase the level of treatment of nitrogen and phosphorus by 40%. The upgrade of treatment plant has an important impact on both the improved ecological state of Kamniška Bistrica and assuring the protection of groundwater.

To provide an assessment of the level of pollution with organic impurities, chemical oxygen demand is an important parameter, providing the quantity of oxygen needed for chemical oxidation of organic pollution in wastewater. Chemical oxygen demand measurements are carried out at the point of discharge of waste cooling waters into the sewage system. In 2016, we recorded a decrease in the chemical oxygen demand parameter in comparison with 2014 on account of the Mengeš and Lendava sites. The Prevalje and Ljubljana sites together contribute only 5% of total wastewater pollution with organic impurities.

Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute parameters for the calculation of the environmental fee. The highest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds each represent about 10% of the pollution.

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

[54] EMAS core indicator, GRI GS disclosure 306-1

Chart 11: Emissions of phosphorus compounds in wastewater[55]

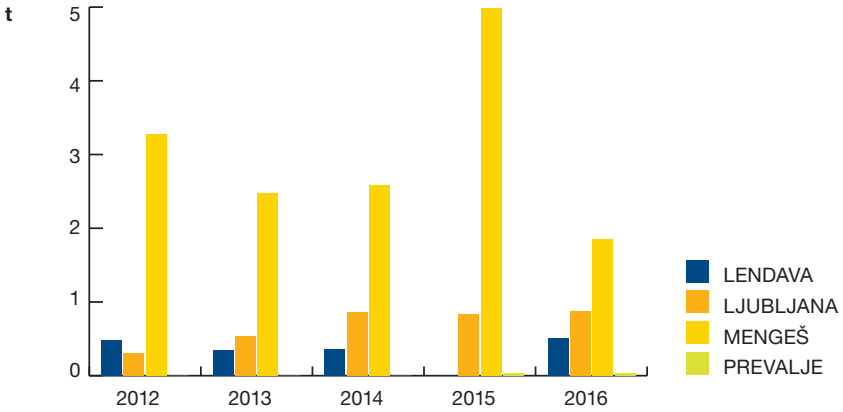


Chart 12: Emissions of nitrogen compounds in wastewater[56]

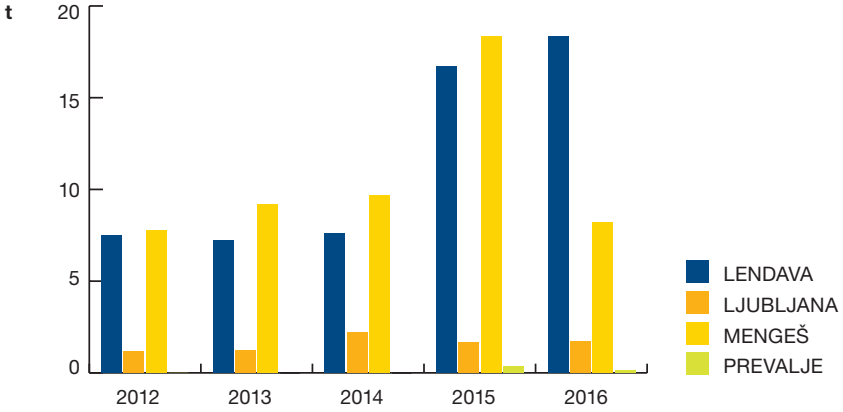
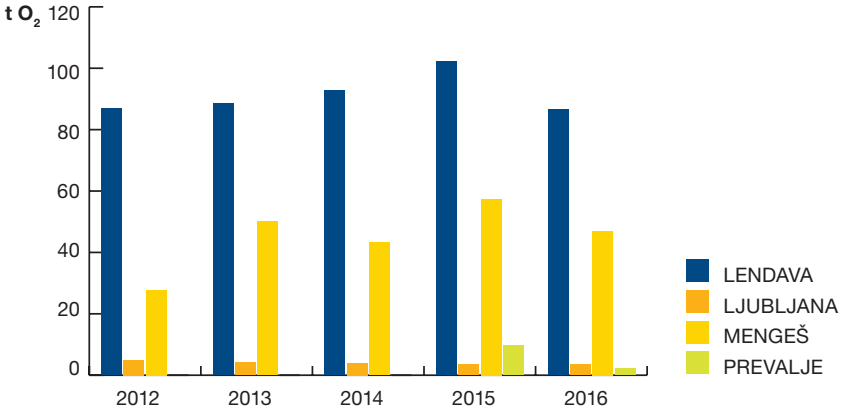


Chart 13: Chemical oxygen demand (in tons O_2)[57]



[55] POR OI 15
[56] POR OI 16
[57] POR OI 14

2.8 Other environmental impact

2.8.1 Odor

Europe and Slovenia's environmental regulations do not cover environmental odor pollution, and are not planned for the future. However, in accordance with good practice of environmental emissions management, we have installed biofilters wherever odor from industrial processes is expected, thus preventing it from affecting the local population, for example, above wastewater equalization ponds. We also perform thermal treatment of waste gases from production. In addition to the aforementioned techniques, the method of waste management and the maintenance of cleanliness of the sites are of upmost importance for limiting the smell.

2.8.2 Soil

The ground is the balance between living and non-living nature. Soil is the primary resource for food and biomass production, and is therefore of key importance in water treatment processes, organic mass cycle, and carbon binding. The main sources of soil contamination are polluted air from industry and household furnaces (smoke, soot, acid rain), traffic, intensive agricultural production and wild waste dumps. As the environmental impact on soil pollution is usually irreversible, this area is of special concern to us.

We consistently fulfill the requirements with regard to hazardous substance storage and transport, which are the major soil pollutants. We regularly check the leak-proof status of sewage systems, particularly those carrying industrial wastewater. This is of particular importance at the Mengeš and Ljubljana sites which are situated in a water protection area.

We introduced preventive measures in the production processes and the construction of facilities. Provisions from the Industrial Emissions Directive stipulate the requirement for operational monitoring of soil contamination and sanctions in the case of an impact on the quality of soil after the termination of the industrial plant is found. To date, no remedial action due to soil pollution has been needed at Lek.

2.8.3 Noise

At Lek, the main identified source of noise is manufacturing activity, particularly the operation of fermenters, compressor stations, as well as ventilation and cooling devices. At the Ljubljana site, the noise levels are increased due to the immediate vicinity of busy roads.

Already in the phase of project planning, we take into account possible excessive burden on the environment with noise when searching for solutions, and we monitor the existing resources through regular measurements and analyzes.

In 2016, we re-checked the resident's complaint, who supposedly detected the noise from some noisy Lek's sources, especially at night. Direct measurements of the noise level were complemented in this area by recording with an acoustic camera, bypassing a wider area and investigating the impact of noisy sources from other companies located near Lek. The measurements confirmed our expectations that Lek is not the cause of excessive noise pollution. The noise-related complaint is described in section 1.4.3.1.

Based on a program of remedial measures prepared by the Institute for Occupational Safety, Ljubljana, remediation works at the Prevalje site were completed in 2016, which is also described in section 1.2.3.3 (discussion with the Head of Anti-infectives Prevalje).

2.8.4 Biodiversity

Our sites are not located in areas of natural values, Natura 2000 areas, protected areas or other areas of importance for the conservation of biodiversity. Our facilities are located within industrial zones where there are no major environmentally critical habitat types or protected vegetation.

By consistent adherence to statutory requirements and proactive measurements in handling waste and industrial water management requirements we strive to mitigate any impact on the quality of the environment and consequently contribute to preservation of the biodiversity in the areas surrounding our production sites.

2.8.5 Light pollution

The legislative regulation makes the light pollution management a great challenge for Lek. The existing legislative regulation on light pollution requires the reduction of external illumination of production and parking areas, while on the other hand meeting minimum standards for working conditions dictates sufficient illumination. Also, studies show that people exposed to warmer color shades of outdoor lighting feel better.

With the help of experts, we elaborated comprehensive studies on light pollution management for our locations. The outdoor lighting was arranged using the lighting with greater efficiency (LED) and at the same time we reduced its operation during the time when labor needs are reduced. The total electrical power of the lamps at any location does not exceed 50 kW, therefore Lek is not obliged to provide the performance of operational monitoring. However, all locations, according to legislation, have an elaborated lighting plan with basic information on the light source.

2.9 Safety

2.9.1 Fire safety

There were no major fire safety interventions in 2016. There were some minor cases, which did not have any impact on the safety of employees and did not cause significant damage to equipment and facilities or have environmental consequences.

Fire drills take place at all sites. The most drills in 2016 were at the Lendava site.

Due to the intervention of internal firefighters in charge, these extraordinary events were already limited at their initial stage.

A part of our responsibility is the competence and preparedness for natural and other disasters. Fire service drills are being carried out regularly at all four sites. Once a year, a major firefighting exercise is carried out at each of the sites, including the external intervention units. In 2016, the biggest exercise was held in Lendava. We wanted to check the functionality of all parts of Lek's security system and the adequacy of procedures and instructions at such a critical event. We also checked whether employees have all the necessary skills to act properly in case of a real danger.

At the time of the exercise, there were around 120 employees and outsourcers at the site, carrying out the exercise according to the anticipated plan and leaving the premises in shortest possible time. More than 100 firefighters from 10 voluntary and professional fire departments and associations from Slovenia and Croatia and 38 vehicles participated in the event.

In 2016, 25 volunteer firefighters from PIGD Lek and PIGD Lek Lendava refreshed their knowledge at exercises at the Educational Protection and Rescue Center Ig.

2.9.2 Biological Safety

In various work processes we employ cell lines of mammals, bacteria and fungi. The work with organisms is carried out in research or analytical laboratories, and especially in the production of active substances.

According to the risk of infection, biological agents are arranged in four groups. Lek deals exclusively with Risk Groups 1 and 2 with negligible or little risk of being released into the environment[58]. Biological agents of the first safety class are used in laboratories or in the production of active substances, while biological agents of the second safety class are used exclusively in quality control laboratories.

Biological safety is ensured by various measures, with a combination of physical barriers, chemical containment measures, biological containment measures, principles of good microbiological practice and organizational measures. All our laboratories and production plants are closed systems and represent an obstacle between the environment and the place where we deal with microorganisms, and the staff is specially trained for this kind of job.

In addition to the Biological Safety Officer, other responsible persons are also appointed in Lek: project managers for working with genetically modified organisms (GMOs), deputy commissioners for biological safety at sites Mengeš, Ljubljana and Lendava, Biological Safety Committee, responsible persons for surveillance and safety in the premises where the work is carried out with the GMO, as well as caregivers of the contingency plans in case of an accident or an exceptional event with GMOs. The basic task of all is to ensure safety at the workplace, safety for the environment and human health and compliance with Slovenian legislation and Novartis guidelines.

2.9.3 Providing storage and distribution safety

2.9.3.1 Storage

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.

2.9.3.2 Distribution

Following a good distribution practice (GDP) and guidelines for the transport of dangerous goods, we provide for safe transport and distribution without accidents. Employees who prepare and dispatch dangerous goods are trained in an internal procedure for the transport of dangerous goods.

In 2016, we successfully completed the project of transport route qualification for all types of transport (road, air, sea) in both critical periods (winter, summer). The processes of preparing the shipments and the transport itself were then adjusted to the findings and we modernized global and local general procedures. By doing this, we ensured compliance with the GDP and set up the system of shipment monitoring and thermal protection for air shipments.

In the course of 2016, 7,296 consignments of finished products and substances were dispatched into 83 countries from Lek's sites. The mass of distributed goods was slightly lower compared to the previous year and amounted to about 22,000 tons (23,327 tons in 2015).

For all types of transport, we have concluded a "Contingency Plan" with all our service providers, thus ensuring the quality of the goods transported even in case of unforeseen events. In 2016, we substituted the air transport for a greater volume of goods with maritime transport, thus creating savings (78% in maritime transport and 22% in air transport).

2.9.4 Chemical safety

We keep our employees informed of their hazardous properties in accordance with the legal requirements for the handling of chemicals and the Novartis' guidelines. In addition, we also take care of technical improvements in existing production equipment and in laboratories, thus preventing direct exposure to chemicals and their impact on the environment.

[58] For more explanations on biological factors, see Glossary of Important Terms.

3. Labor

3.1 Human resources policy[59]

Gifted, talented and responsible people are key to achieving the strategic objectives of the company, which is why people are at the heart of the entire business operation – "It's all about people". Human resources policy highlights three principles regarding this: "Cooperation. Development. Excellence." The priority task is to design processes, tools and systems in the field of human resource management.

Considerable emphasis is placed on talent development, succession planning, compensation of achievements, appropriate organizational development and training. The HR policy supports the basic business orientations, aiming to achieve a high level of innovation, growth and better productivity.

We are constantly creating a working environment of business opportunities and personal challenges, characterized by creative and dynamic work. We offer our employees a unique opportunity in Slovenia to work in an international research and development team in the pharmaceutical field.

3.2 Employment

3.2.1 Total workforce by employment type and employment contract[60]

In 2016, we created 358 new jobs and finished the year with 3,599 employees. More than 46% have at least higher education, of which 13% have a Master's and PhD. The majority of new colleagues were employed in the development and technical activities. At the end of the year, the proportion of women employed was almost 46% and is somewhat higher than last year. At year-end, 91% of all employees worked on a full time permanent basis, and 7% were fixed-term employees and 2% of all employees worked on a part-time basis.

Table 19: Number of full-time employees on 31. 12. 2016 by site

Site	Number of full-time employees
Ljubljana	1,923
Mengeš	1,002
Lendava	423
Prevalje	246
Other*	5

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

[59] GRI GS disclosures 103-1, 103-2

[60] GRI GS disclosures 102-7, 102-8, 401-1

3.2.2 Percentage of employees covered by collective bargaining agreements[61]

In 2016, the Collective Bargaining Agreement covered 99% of the total workforce, a level identical to that in the previous years.

3.2.3 Coverage of the organization's defined benefit plan obligations[62]

In addition to all the obligations defined in the labor legislation, we allowed our employees to participate in collective additional pension scheme, enabling them to receive an additional retirement 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 EUR 2,819. At the end of 2016, 88.69% of the workforce was included in the scheme.

3.2.4 Procedures for local hiring and proportion of senior management hired from the local community[63]

The employment process is based on determining the competencies required to perform the job vacancy. In line with Novartis' strategy of diversity and inclusion, we respect and promote the cultural, ethnic and sexual diversity of our employees.

The proportion of local human resources in the senior management team in 2016 is 93%, slightly higher than in the previous year (88%).

In 2016, we employed 10 new Slovenian experts, who participated in the Bio career breakfast, and supported keeping home-grown expertise and talent in Slovenia.

[61] GRI GS disclosure 102-41

[62] GRI GS disclosure 201-3

[63] GRI GS disclosures 103-1, 202-2

3.2.5 Parental leave[64]

Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act. In recent years, we have seen growth in the number of employees taking parental leave, the return to work rate after parental leave remains high (99% in 2016).

Table 20: The rate of use of parental leave and returning to the job

	2016	2015	2014
Number of employees having taken parental leave	**357**	**241**	**225**
• Men	205	118	110
• Women	152	123	115
Number and share (in%) of employees returning to work after parental leave	**354 (99%)**	**238 (99%)**	**221 (98%)**
• Men	205 (100%)	118 (100%)	110 (100%)
• Women	149 (98%)	120 (98%)	111 (96%)

3.3 Occupational safety and health[65]

Health and safety of employees, local inhabitants, customers, consumers and others affected by our business, as well as environmental protection, is a priority task of our operations. By ensuring health and safety at work and by preventive actions and maintaining our health, we implement Lek's policy of the ZVO. In doing so, we are constantly striving for improvements in the management systems of this area. For the smooth implementation of safe and healthy work, we are properly organized and provide the necessary material and human resources.

The risk assessment of workplace with a health assessment is an integral part of the Safety Statement, which recognizes, eliminates and/or diminishes all forms of risks for employees. All specified preventive measures from risk assessments are carried out regularly.

3.3.1 Frequency of absences due to injuries at work[66]

Detailed records of work-related incidents involving our employees have been kept for several years by means of the LTIR (lost time injury and illness rate: number of work-related injuries resulting in absence from work or the use of sick leave per 200,000 hours worked) index and TRCR (total recordable case rate: number of all major and minor work-related injuries per 200,000 hours worked).

Table 21: LTIR Index (Lost Time Injury and Illness Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	0.48	0.00	0.00	0.00	0.05
2013	0.00	0.00	0.17	0.00	0.04
2014	0.00	0.22	0.26	0.49	0.22
2015	0.31	0.10	0.00	0.43	0.12
2016	0.00	0.00	0.00	0.82	0.05

Table 22: TRCR Index (Total Recordable Case Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2012	0.97	0.14	0.74	0.00	0.35
2013	0.00	0.42	0.52	0.00	0.38
2014	0.69	0.43	0.26	0.49	0.42
2015	0.61	0.31	0.36	0.87	0.39
2016	0.00	0.34	0.11	0.82	0.28

[64] GRI GS disclosures 103-1, 401-3

[65] GRI GS disclosures 103-1, 103-2

[66] POR OI 2, GRI GS disclosure 403-2

In 2016, the LTIR rate amounted to 0.05 (0.12 in 2015), meaning that we recorded 2 cases of workplace accidents requiring sickness absence. We recorded no serious work-related injuries, which would leave health consequences due to the injury. The TRCR indicator amounted to 0.28 (0.39 in 2015). In total of 13 ascertained cases no serious injury was recorded.

The most common causes of injuries were hits at an object or work equipment (36%), followed by lighter sprains, burns and slips and falls.

Chart 14: Classification of causes of work-related incidents (LTIR and TRCR) for 2016

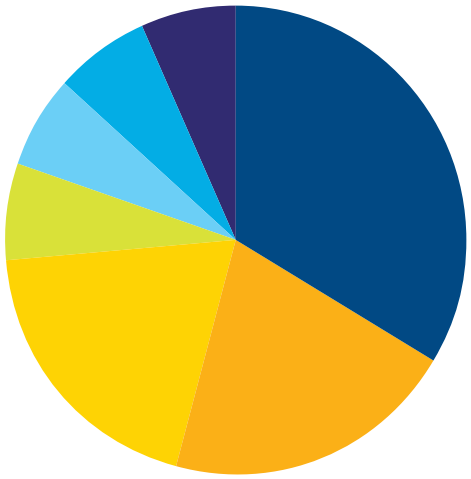
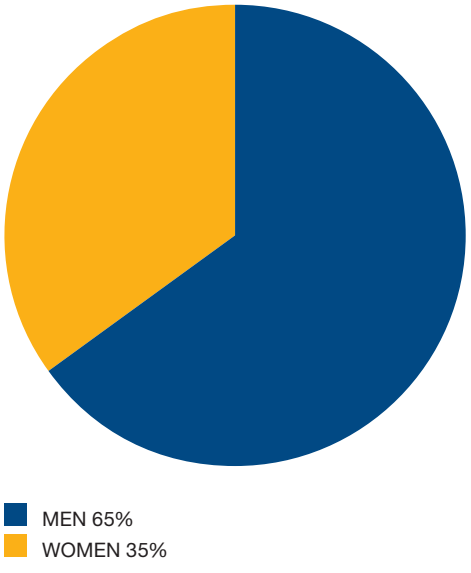


Chart 15: Classification of work-related incidents (LTIR, TRCR) by gender



In 2016, management and the promoters of safety carried out 3,173 safety walk-throughs. Pictured from left to right: Leon Baumkirher, Margita Gal and Tanja Šinigoj.

Health, safety and environment systems

Successful prevention activities for preventing incidents and injuries

In addition to all regular preventive activities, in 2016 we paid great attention to safety patrols, as they represent one of the most important preventive measures for improving security culture and preventing incidents. By implementing them, we influence the behavior of our employees and thus prevent dangerous behavior and situations that can lead to incidents or injuries.

We strive to ensure that all employees who come to work return home healthy. We expect our coworkers to take care of their colleagues and to alert them to dangerous acts or situations.

We carried out 3,173 safety patrols, founding out that in 176 cases, in different circumstances, there could occur injuries or health disorders due to a variety of dangerous situations or inappropriate behaviors. We continued the activities after the research and the implemented measures without compromising employees.

In addition, we carried out a number of other preventive measures to prevent and reduce dangers and risks at work: STOP, risk assessment according to pSIF (Potential Serious Injuries and Fatalities) program, active role of security promoters (meetings, patrols), safety patrols of site managers, informing and familiarizing employees with work instructions, training of employees, risk assessment, prevention/analysis of work accidents and almost events, assistance in internal meetings - security moment (prepared presentations for internal meetings), assuring of preventive healthcare and health promotion, organization of work environment examinations and work equipment examinations and testing, and implementation of legislative requirements, implementing regulations and internal safety and occupational health standards.

3.3.2 Absenteeism[67]

In order to determine the degree of absenteeism, the number of absent employees' working hours is divided by the working hour's fund. In 2016, the proportion of sickness absence was 4.79%, recording a slight increase compared to the previous year (4.33%).

Table 23: Share of sick leave

	2016	2015	2014
Women	5.59%	5.38%	4.65%
Men	4.12%	3.47%	2.96%
Total	**4.79%**	**4.33%**	**3.80%**

[67] GRI GS disclosure 403-2

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

Outsourced contractors mainly perform construction and maintenance activities. With each outsourcer we sign an agreement specifying security measures for specific work. We also have an elaborated security plan for work sites. In 2016, we recorded 4 LTIR cases among outsources, compared to 5 cases in the previous year.

Protected work areas in ventilation channel at Mengeš.

New preventive system for construction sites surveillance

Gorazd Sušnik, HSE Manager

After establishing a new system for construction sites surveillance, we can already observe improvements in the security culture, usage of safer work equipment and methods, and a significant improvement in communication in outsourcers, reveals Gorazd Sušnik from the Health, Safety and Environment service. Based on the opinions and suggestions of shareholders on construction sites, we are already preparing changes.

You have developed a System for construction sites surveillance. What is its purpose?
Building site control is an important part of the system for controlling the outsourcers. Regarding the level of risk to safety, health and the environment, the systemic regulation of this area was in 2016 placed on the Novartis priority list. The new control system was fully established in July and is based on Novartis guideline, legislative requirements and good practice. Its main purpose is to prevent serious or fatal accidents in performing activities by outsourcers at Lek locations. The objective of the system is also to prevent fire, explosion, negative environmental impacts and material damage, and to ensure a high safety culture and behavior.

What results of the system have you already identified?
At construction sites we already notice an improvement in the safety culture, the use of a man and environmentally safer work equipment, the methods used, and a significant improvement in communication. Despite substantially increased surveillance we observe significantly less breaches of security measures.

Will the existing system be supplemented in the future?
The mere fulfillment of legislative requirements does not mean success in fighting against the possible negative consequences of poorly managed building sites. The actual characteristics of the system in practice, such as number of operators, work equipment, work methods, human resources, etc., must also be taken into account. Together with sites, we have upgraded the existing system based on the choice of outsourcers prior to the conclusion of a contract or order, access to the site and the introduction of outsourcers, monitoring and controlling, as well as a review of the condition and audits. For each activity, we assess whether it represents a higher risk to safety, health and the environment, and we make a risk assessment with measures that individual operators have to consider. We are aware that without continuous maintenance and improvement, the system is doomed to failure, so we are already preparing changes. We take into account the opinions and suggestions of all shareholders on construction sites.

3.3.4 Number of work-related fatalities[68]

No fatalities were recorded amongst our employees or external contractors.

3.3.5 Occupational disease rate[69]

So far, no confirmed occupational diseases, as defined by the Pension and Disability Insurance Act (ZPIZ-2) and Rules concerning the list of occupational diseases, have been recognized at Lek.

3.3.6 Health promotion program

Again, we successfully implemented a program of education and training for employees in the field of prevention and preservation of health at work. Participation in the programs is voluntary, and the interest of employees to be included in various programs is growing from year to year.

Preventive programs for health promotion among employees in 2016

- A program of various exercises (fitness, swimming, climbing, dancing), attended by 390 employees.

Around 1,750 employees from all sites in Slovenia, participated in Healthy Life Week.

[68] POR OI 1 and POR OI 3, GRI GS disclosure 403-2
[69] GRI GS disclosure 403-3

- GCC (Global Corporate Challenge), where a total of 875 Novartis employees received pedometers and recorded steps. In 2015, 623 employees took part in GCC, compared to 357 employees in 2014. An average office worker makes only 3,000 steps a day, which is much less than recommended by the World Health Organization - 10,000 steps a day.
- Preventive Health Recovery Program: 65 employees participated.
- Vaccinations: 111 employees were vaccinated against influenza, and 845 against tick-borne meningoencephalitis.
- The Healthy Life Week, which took place between 19 and 23 September, was attended by approximately 1,750 employees from all sites in Slovenia.

The 6th regional BioCamp again saw young people from different countries accessing the highest of expertise, exchanging experiences and getting to know elite experts.

3.4 Training and education[70]

The pharmaceutical industry is a knowledge-based industry, therefore, without continuing investments in the skills and competencies of our employees, we cannot remain competitive on the global market. Education is therefore closely intertwined with our business strategy, since employee education at various levels is crucial for the growth and progress of the company. We are constantly and intentionally investing in the development, education and training of our employees, and last year, we received the TOP 10 education management award.

Our employees can attend regular educational programs prescribed in the Education Catalog, tailored workshops according to the needs of the target group, formal forms of education such as in-service courses, and informal forms of education and workshops, where participation is voluntary. We also conduct mentoring and the so-called coaching.

Among experts are highly desirable meetings where co-workers as knowledge holders or who attended some external or internal conferences or a work visit abroad transfer their knowledge to other colleagues. In many units, especially development ones, these are regular meetings.

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

HSE organization, human resources and training

HSE function

The HSE function employs a management's representative for HSE (Director) and persons responsible for individual fields of expertise. By the authority of the Board of Management, they are responsible for the compliance of areas of expertise with Slovenian laws and Novartis'/Sandoz' standards, for representation of Lek in the area of expertise conducting inspections, conducting periodic internal audits, and monitoring the implementation of corrective measures, consulting and professional assistance in the implementation of preventive measures at sites as well as communication of identified risks to the management team.

HSE department

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

[70] GRI GS disclosures 103-1, 103-2

Top know-how must circulate

Dr. Darja Ferčej Temeljotov, Head of Innovation at Lek

Mixed research groups, dozens of joint projects with academic and research institutions, cooperation in the development of study programs, mentoring in the preparation of tasks, regional BioCamp - Lek's cooperation with the academic and research sphere is wide, describes dr. Darja Ferčelj Temeljotov, Head of Innovation, and highlights the importance of a strong research team.

How important is cooperation with academic and scientific institutions?

Extremely important. We are aware that today we cannot possess all the specialist know-how inside the house. It is necessary to connect with external experts, which we need to be able to recognize. Here we meet the so-called open innovation field, when we create mixed research teams composed of our experts and experts with faculties and institutes, and together we develop new knowledge. We work with faculties in several projects. Our experts also mentor young people in creating their graduate, master's, doctoral theses, and occasionally lecture students. With professors at faculties, we also co-operate in continuous updating of study programs.

What is the flow of know-how between academic and scientific institutions and the economy?

Lek's cooperation with scientific and academic institutions is extensive. Each year more than ten major projects take place, involving many young professionals. Of these, at least half remain connected with us, either through projects, or by becoming our employees. We also work together with student organizations and career centers, to which we occasionally present trends in the pharmaceutical industry and employment opportunities for young professionals. An important target group that the country is not encouraging enough are our postgraduate students who study abroad and can bring in invaluable experiences and international connections. In 2017, we have organized the Regional Bio Camp for the seventh time - an event that aims to enable young people from different countries access to top-level know-how, create a space for sharing experiences and help them personally meet top experts. A good many of these young experts, who were the most successful at Bio Camp, have already been employed by us.

How important is a strong development team for the company?

It is indispensable, necessary and irreplaceable. A strong development team is the keystone of a successful development work, which must be rapid and effective, and it has to ensure the high quality, safety and efficacy of developed drugs. Only by continuously investing in the development of know-how and expertise, by upgrading the know-how and sharing good practices can we remain competitive and successful in the long run.

The largest unit having a suitable HSE organization in place is the Host. The Host sets internal standards for individual sites that also apply to the Guests.

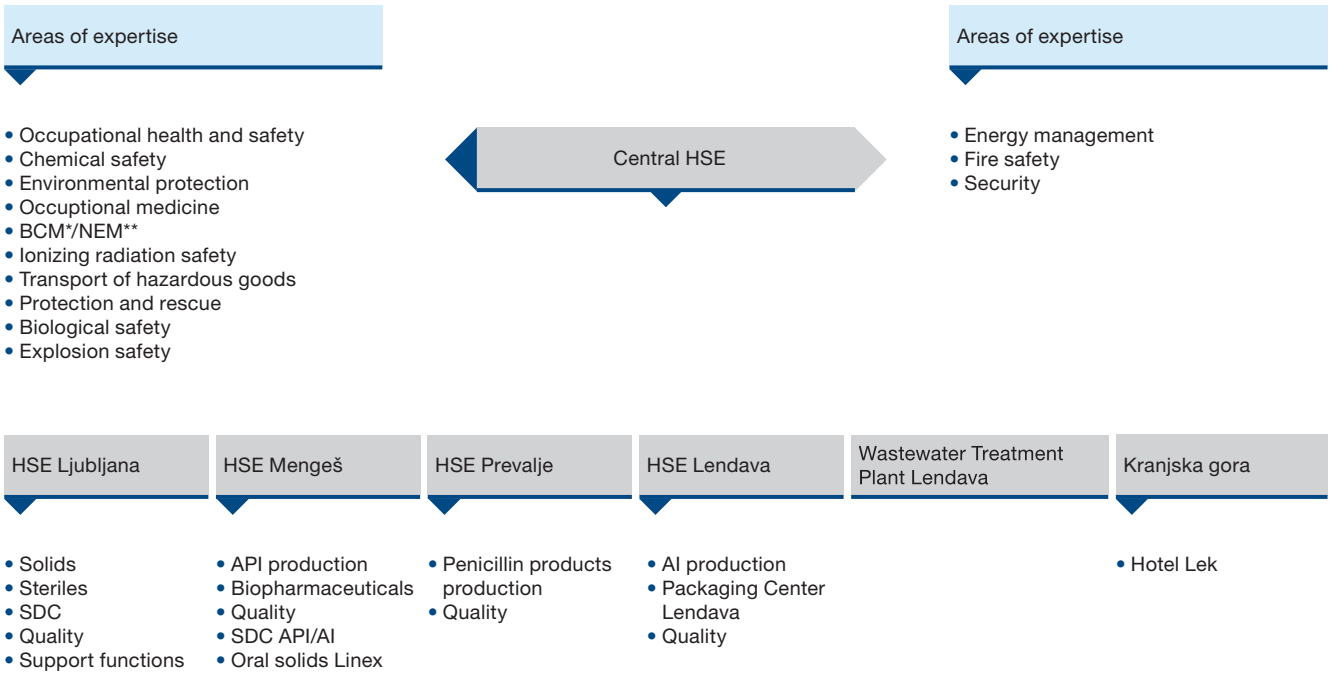
By organizing appropriate training programs, we provide our employees with a level of HSE qualification sufficient for them to manage HSE aspects of their work. In cooperation with unit heads, the HSE unit prepares annual training plans and selects training topics for inclusion in the Training and Education Catalogue. Training programs are organized into three clusters: onboarding, continuing education, and training for promotion. We promoted direct involvement of employees in different roles, functions and units, exceeding the formal HSE organization.

HSE aspects and system of achievement monitoring

Pursuant to the Novartis guidelines, environmental aspects at Lek d.d. were upgraded into so-called HSE aspects. For a specific area of expertise, they are created at the proposal of the authorized person for each site separately. In addition to environmental aspects, we thus also have HSE, chemical safety, fire safety, explosion safety and biological safety aspects and others.

A standard selection of aspects for individual areas of expertise is determined by the head of the respective area at Lek d.d. The site's HSE responsible person makes an assessment based on the results of the Gap Analysis, audits (internal, Novartis'),

Figure 1: HSE Organization Scheme on 31. 12. 2016



*BCM: Business Continuity Management
** NEM: Novartis Emergency Management

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 2016, external auditing of the company's compliance with ISO 14001:2004 and ISO 14001:2015, BS OHSAS 18001:2007 was carried out and an audit according to the EMAS Directive.

Internal audits of the HSE service planned on an annual basis were performed. Concurrently, internal audits of the company's compliance with ISO 14001:2004, ISO 14001:2015 and OHSAS 18001:2007 requirements were carried out. Internal Novartis and Sandoz audits are more extensive, covering all areas of HSE on the part of the site being audited: environmental protection, occupational safety and health, chemical safety, fire safety, biological safety, explosion safety, as well as BCM and NEM. The frequency of audits depends on the nature of production at API production sites. They take place every two to three years, whereas at pharmaceuticals production locations they are performed every three to four years. These audits also assess compliance with ISO 14001:2004, OHSAS 18001:2007, and the EMAS Directive. In 2016, we had a Sandoz HSE audit at Prevalje. The results of internal audits performed in 2016 showed the high level of the company's compliance with the statutory requirements as well as internal and external standards in all areas. Corrective action was taken on an ongoing basis. In 2016, we used Novartis' application HSE Net for recording all corrective measures following assessments, inspections and safety walkthroughs.

Environmental performance assessment with regard to our general and individual objectives is an integral part of the management review procedure and regular monthly and quarterly reporting to Lek and Novartis management.

In 2016, we met the basic EMAS requirement for verification of compliance with the provisions of the EMAS Directive. From the environmental verifier we obtained a statement that we operate in compliance with applicable legal requirements with regard to the environment and furthermore, that the data and information from the environmental statement provide a reliable, credible and true picture of the organization's operations at all Lek sites. In line with Novartis and Sandoz policy, Lek is committed to continuous improvement of environmental performance in compliance with local and national programs.

Reporting methodology

The reporting methodology used at Lek, enables monitoring of absolute indicators and trends for individual critical HSE aspects.

The data is included in the main indicators and other current indicators of environmental success in future environmental statements.

HSE data is collected, recorded, verified and confirmed within a uniform Novartis reporting system in the Data Management System (DMS), whereby their transparency and comparability is ensured. 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 review performed by the organization's top management according to the EN ISO 14001:2015.

Measures for risk prevention and mitigation

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 associates involved.

Risk assessment is made for the following:

- Risk Portfolio,
- Workplace Health Risk Assessment – WHRA,
- Capital expenditure projects: with priority use of the Zurich Hazard Analysis (ZHA) or the Hazard and Operability Study (HAZOP Study) in the project qualification phase,
- Facilities and production lines: the Zurich Hazard Analysis (ZHA) or the Process Risk Assessment (PRORA),
- Process Risk Assessment (PRORA) for new products and production lines,
- Assessment of product quality risks: priority use of the FMEA method.

The Risk Portfolio provides the management team with an overview of major HSE risks and levels of risk management by individual site, country, business group, and in the corporation as a whole.

The Risk Portfolio development and compilation are carried out in three steps:

Once again we received the full Family Friendly Company certificate. Pictured from left to right: Marjan Novak, Member of the Board of Management and Workers' Director, Vesna Premović, president of Workers' Council and Fikret Basanović, Learning and Training Manager.

Samo Roš, Member of the Board of Management and Head of Human Resources, received the Most Reputable Employer 2015 award on behalf of Lek.

- Risk assessment and preparation of a Risk Portfolio for individual sites,
- Preparation of a Risk Portfolio for Lek d.d. (Slovenia) and Sandoz,
- Annual review of the Risk Portfolio for business groups at the corporate level.

In 2016, we performed all the risk management activities required in accordance with the Novartis HSE guidelines. Special care was given to identifying HSE risks in our operations and processes. On this basis, we implemented the measures to minimize risks, such as avoiding potential risks, limiting the risk of exposure to hazards, and taking action to mitigate the negative impacts of any hazardous occurrence that actually took place.

3.4.1 Average hours of training per year per employee[71]

The average amount of time spent for education of Lek's employee was 3.49 days, and if adding compulsory education at the workplace (3.30 days) and training in compliance (0.26 days) it amounted to total of 7.05 days. We also offer our employees the opportunity of in-service education, with 67 employees involved in undergraduate studies, and 70 in post-graduate studies, mainly in biotechnology and biomedicine, as well as chemistry.

[71] GRI GS disclosures 404-1

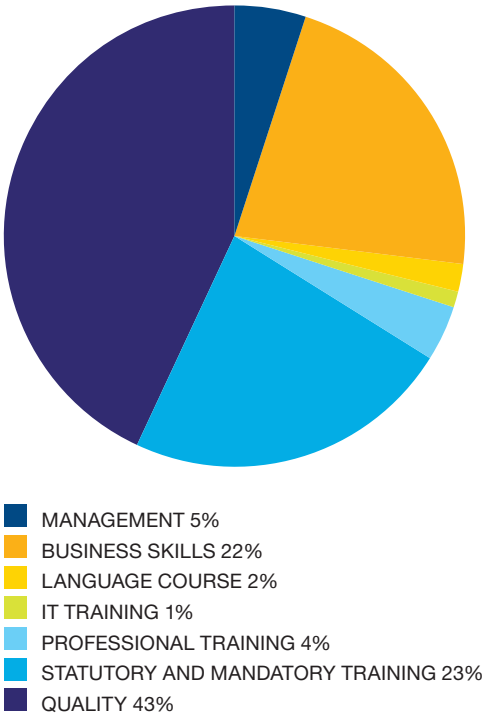
Table 24: Average hours of training hours/employee

Year	Number of hours/employee
2012	54.32
2013	56.36
2014	61.68
2015	71.44
2016	56.40

3.4.2 Training by area

The highest participation rate was recorded in quality (43%), statutory and mandatory training (23%) and business skills (22%).

Chart 16: Training in 2016 by topic (attendance)



4. Products

The Rules on advertising of medicines stipulates that the professional public consists of prescribing doctors, pharmacy masters dispensing prescription drugs and non-prescription drugs. Pharmaceutical technicians may only dispense and recommend non-prescription drugs.[72]

The latest professional information on prescription drugs and non-prescription drugs, their performance and properties are brought to clinics and pharmacies by qualified professionals. We inform the professional public about disease conditions and their treatment also through various publications, websites and organized professional meetings. In 2016, we organized numerous expert meetings for various specialties of doctors, pharmacy masters and pharmaceutical technicians for non-prescription drugs in the field of self-treatment. Also in 2016, the inspection authority at JAZMP instituted no inspection procedure in the field of information and labeling of products.[73]

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. In 2016, there were no cases of violations of marketing communication rules, standards and non-binding codes, including those related to advertising, promotion and sponsorship.[74]

Customer satisfaction[75]

The satisfaction of the professional public is measured by opinion surveys among doctors of various specialties and pharmacy masters. By means of these surveys we determine the company's reputation, satisfaction with our employees and activities. The results of the last survey in the professional public which was carried out at the end of 2016 show that Lek is among the most reputable companies in Slovenia with the best professional associates. By conducting consumer researches we establish their satisfaction with individual brands. In addition to customer satisfaction and their knowledge of specific brands, the research results tell us in which areas we can further improve our communication to better understand the use of branded self-treatment products.

[72] GRI GS disclosures 103-1, 103-2, 417-1

[73] GRI GS disclosure 417-2

[74] GRI GS disclosure 417-3

[75] GRI GS disclosures 102-43, 102-44

5. Human rights and antitrust compliance[76]

The business operations of Lek, a Sandoz company, are based on a strong commitment to ethical business practices. We are guided by a basic principle, promoting the culture of integrity. We have incorporated the **Novartis' Code of Conduct** into the internal regulations as early as 2003. It is the key act defining the principles of our ethical and accountable decision-making. The Code of Conduct regulates our corporate and environmental responsibility and our compliance with the regulations and Good Business Practice. It provides a basis for the trust of our key stakeholders.

In 2016, we further intensified our efforts for ethical and accountable business practices in line with the highest ethical standards. We introduced Novartis' global initiative enabling to disclose potential or actual conflict of employees' interests through the **internal information system.** This strengthens our conviction that in addition to business success, the way in which we achieve success is extremely important. In doing so, we have zero tolerance to any inappropriate behavior.

We are aware that our employees represent the foundation of our success, therefore, we constantly provide for their development. We continue to pay great attention to the regular and continuous education of our employees in the field of compliance. Therefore, in 2016, we organized **online education** for all employees in **all key areas of compliance:** Code of Conduct, Personal Data Protection, Reporting Side Effects of Medicines, Prevention of Bribery, Use of Social Media, Information Management and Data Integrity Protection. On average, more than 98% of employees successfully completed education. We have also conducted a number of targeted trainings in the fields of personal data protection, professional practices in advertising of medicines and relations with the professional public, as well as in the field of fair

[76] GRI GS disclosures 103-1, 103-2, 102-16

competition. All the above stated areas are also a part of the regular introduction program for all new employees in Lek.[77]

In order to prevent corruption and to ensure compliance with the law and our internal rules, we follow Novartis' global policy regulating this area, and our internal regulations. Compliance standards which apply for Novartis' employees and their companies are implemented also in relations with third parties.

The Code of Conduct explicitly prohibits any form of employee discrimination in respect of personal employee characteristics such as citizenship, gender, age, nationality, religion, sexual orientation or disability. We treat our employees equally, with integrity and respect, thereby creating an inclusive working environment. Our initiative **"Diversity and Inclusion"** and **"Novartis Initiative for Women's Inclusion"** are important contributors to this policy. We thus support inclusion of various people with different profiles.

Inclusion is understood as appreciating and connecting differences by focusing on the common goal and respect for our core values. Teams of diverse employees are more creative and more successful in coping with the challenges, as they contribute the views from different angles. Working in a diverse environment is much more stimulating, interesting and vibrant. We treat our employees equally, with integrity and respect in and we expect them to treat each other with respect and not allow any form of discrimination.

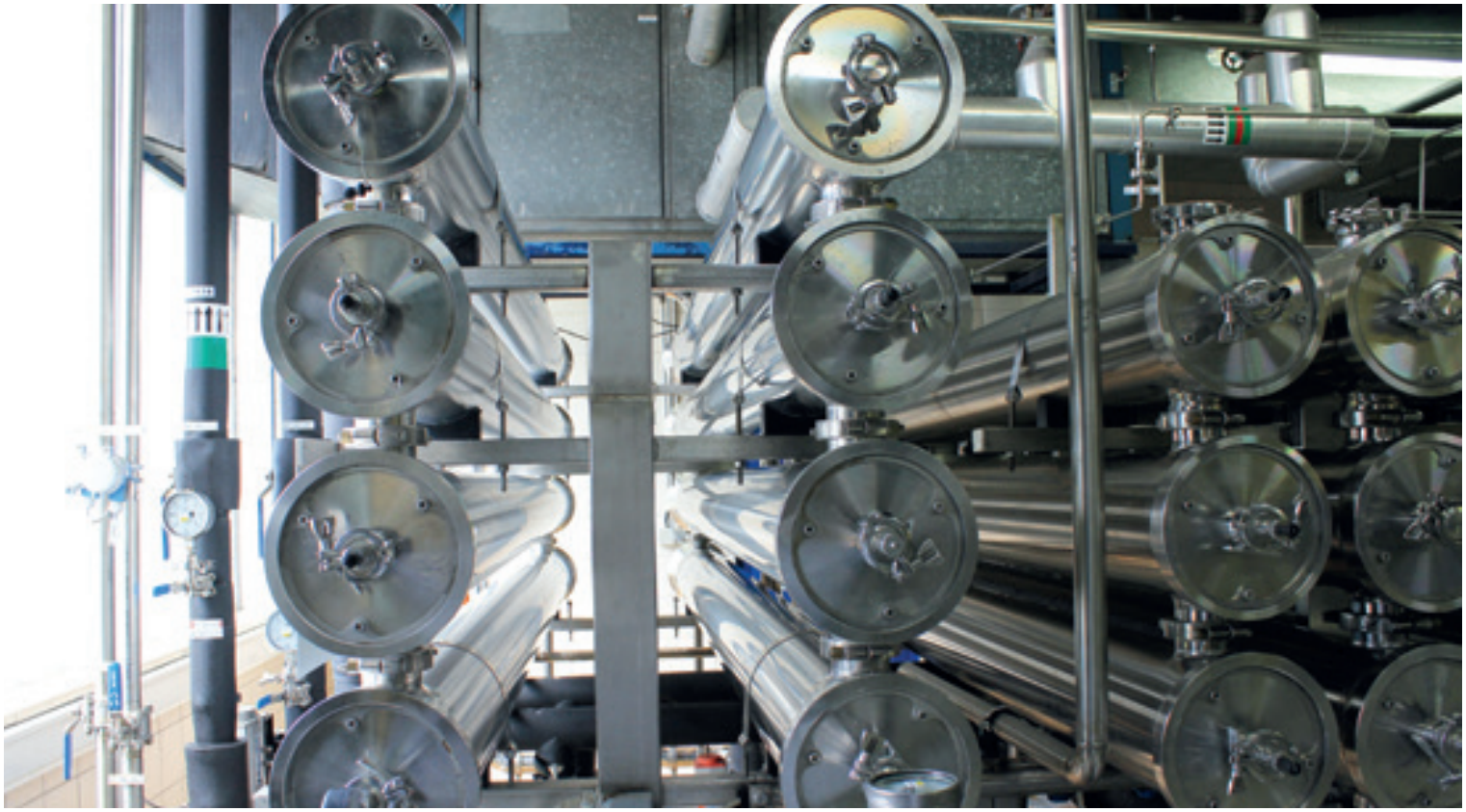
Lek, a Sandoz company, refuses any form of child, forced or compulsory labor.

In 2016, there were no cases of discrimination and no requests to remedy any violation in this area in Slovenia.[78] The company was also not involved in any antitrust procedure for any violation of antitrust regulations.[79]

[77] GRI GS disclosure 412-2

[78] GRI GS disclosure 406-1

[79] GRI GS disclosure 206-1



6. Suppliers

6.1 Purchasing policy and system[80]

At all purchase stages, employees are committed to following the purchasing procedures laid down by the Novartis guidelines, international agreements and local regulations. Novartis associates are not allowed to take advantage of the business relations between the Novartis Group and its suppliers for private purposes.

Roles and responsibilities within purchasing activities (customer need identification, supplier selection, conclusion of agreements, and purchase orders) are clearly defined. The Head of Purchase is fully responsible for the implementation of and adherence to the guidelines, laws and internal procedures determining the purchasing processes. Purchasing managers have to inform employees of the guidelines, their obligations and responsibilities in the purchasing process, and to monitor compliance. The purchase department is a separate organizational unit, responsible for purchase of direct and indirect material and services.

In the field of purchase, we continued the transformation of our activities in order to provide quality services to all our users in line with the efforts of Novartis business services. Thus, we introduced **a business partnership model** for all key users/ functions and transferred transaction and tactical purchasing activities to service centers.

In 2016, the **purchase value** totaled USD 541 million, of which USD 267 million was indirect purchase and USD 274 million direct purchase. We achieved a substantial growth in the value of purchases, which is due to the increased business volume of production units Unpredictable developments in commodity markets and the raising of industrial standards tightened the delivery conditions of the pharmaceutical industry this year as well. In order to achieve more competitive prices and more reliable deliveries, we increased the active risk management and associated with the global Novartis purchase function.

Our biggest markets in field of Direct Purchases were Slovenia, Germany, Switzerland, China and India.

In the field of Indirect purchases, the largest markets were Slovenia, Italy, Germany, Great Britain, Canada and Austria.

6.2 Supplier audit procedures[81]

Novartis promotes the social and environmental values of the suppliers with whom it cooperates, and expects them to comply with the laws and business ethical principles established by the Novartis Code. The supplier is obliged to provide all information on work, health, safety, environmental and animal protection, corruption prevention and fair competition and the protection of personal data. The data allow the Novartis' authorized persons to monitor and verify compliance of actions. In case

[80] GRI GS disclosures 102-9, 102-10

[81] GRI GS disclosures 103-1, 103-2, GS 308-2, 408-1, 409-1

of established discrepancies, the supplier must eliminate them and report on the progress of their elimination.

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

In selection processes, priority is given to third parties who share our societal and environmental values. They must implement the supply agreement in strict compliance with all applicable HSE laws and regulations as well as the fair labor practice and unlawful discrimination policy. Priority is given to contractors who respect human rights including freedom of association and collective rights, rejection of forced and child labor. In purchasing, we continually measure the performance of suppliers, thus evaluating and monitoring the performance of suppliers, and identifying areas (credit rating, costs, quality, supply and customer support) of necessary improvements.

6.3 Policy and practices for selecting local suppliers[82]

The criteria for selecting suppliers are predetermined and equal for all. In this process, priority is given to suppliers offering the best quality, price and service. In certain categories of items where the delivery date is a key competitive advantage, along with appropriate price and quality, we build close relations and cooperate mainly with local suppliers.

In 2015, the level of deliveries from the Slovenian market amounted to 233 million USD or 43.1% of total purchasing cost.

Among individual countries, Slovenia maintains the largest share in the direct purchasing structure.

In 2016, the volume of supplies from the Slovenian market amounted to 39 million USD or 15%. (2015: 17%). In the domestic market we mainly purchase domestic products. We mainly purchase packaging and raw materials from the Slovene chemical industry and merchandise from domestic distributors. Also in the indirect purchasing structure among individual countries, Slovenia maintains the largest share with 72.6% (194 million USD).

[82] GRI GS disclosures 103-1, GS 204-1

7. GRI content index

GRI content index GS – Core[83]

GENERAL STANDARD DISCLOSURES

GRI standard	Disclosure	Reporting boundaries (within and outside the organization)	Section/Page numbers	Remarks/Omissions
GRI 101: Foundation 2016				
GRI 102: General Disclosures 2016				
Organizational Profile				
102-1	Name of the organization	Lek d.d.	1/6, 1.2/14	
102-2	Activities, brands, products and services	Lek d.d. and all Lek sites	1.2.2/15	
102-3	Location of headquarters	Lek d.d.	1/6	
102-4	Location of operations	Lek d.d.	1.2.3/16	
102-5	Ownership and legal form	Lek d.d.	1.2/14	
102-6	Markets served	Lek d.d.	1.2.1/15	
102-7	Scale of the organization	All Lek sites	1.1.1/7, 3.2.1/61	
102-8	Information on employees and other workers	Lek d.d.	3.2.1/61	
102-9	Supply chain	Lek d.d.	6.1/75	
102-10	Significant changes to the organization and its supply chain	Lek d.d.	1.2.3/16, 1.3.1/27, 6.1/75	
102-11	Precautionary Principle or approach	Lek d.d., local communities, patients and customers	1.4.4/34, 2/35	
102-12	External initiatives	Lek d.d., Lek stakeholders	1.4.4/34	
102-13	Membership of associations	Lek d.d.	1.4.4/34	
Strategy				
102-14	Statement from senior decision-maker	Lek d.d.	4	
Ethics and integrity				
102-16	Values, principles, standards and norms of behavior	Lek d.d.	5/73	
Governance				
102-18	Governance structure	Lek d.d.	1.4.1/28	
Stakeholder engagement				
102-40	List of stakeholder groups	Lek d.d.	1.4.3/29, 1.4.3/32	
102-41	Collective bargaining agreements	Lek d.d.	3.2.2/62	
102-42	Identifying and selecting stakeholders	Lek d.d., Lek stakeholders	1.4.3/29	
102-43	Approach to stakeholder engagement	Lek d.d., Lek stakeholders	1.4.3/29	
102-44	Key topics and concerns raised	Lek d.d., Lek stakeholders	1.4.3/32, 4/72	
Reporting practice				
102-45	Entities included in the consolidated financial statements	Lek d.d.	1.3.1/27	
102-46	Defining report content and the topic Boundaries	Lek d.d.	1.3/27	
102-47	List of material topics	Lek d.d.	7/77–81	
102-48	Restatements of information	Lek d.d.	1.3.1/27	

[83] GRI GS disclosure 102-55

102-49	Changes in reporting	Lek d.d.	1.3.1/27	
102-50	Reporting period	Lek d.d. and all Lek sites	1.3.1/27	
102-51	Date of most recent report	Lek d.d. and all Lek sites	1.3./27	
102-52	Reporting cycle	Lek d.d. and all Lek sites	1.3./28	
102-53	Contact point for questions regarding the report	Lek d.d.	1/6	
102-54	Claims of reporting in accordance with GRI Standards	Lek d.d.	1.3.1/27	
102-55	GRI content index	Lek d.d.	7/77	
102-56	External assurance	Lek d.d.	1.3/27	

SPECIFIC STANDARD DISCLOSURES

Management approach disclosures	Topic-specific disclosures	Reporting boundaries	Section/Page numbers	Remarks/Omissions
ECONOMIC TOPICS				
GRI 201: Economic performance 2016				
103-1	Explanation of the material topic and its Boundary	Lek d.d., local communities	Letter from the President of the Board of Management/4	
201-1	Direct economic value generated and distributed	All Lek sites, owners, employees	1.1.1/7	
201-3	Defined benefit plan obligations and other retirement plans	All Lek sites, employees	3.2.3/62	
201-4	Financial assistance received from government	All Lek sites	1.1.1/7	
GRI 202: Market presence 2016				
103-1	Explanation of the material topic and its Boundary	Lek d.d., local communities	Letter from the President of the Board of Management /4	
202-2	Proportion of senior management hired from the local community	All Lek sites, local communities	3.2.4/62	
GRI 204: Procurement practices 2016				
103-1	Explanation of the material topic and its Boundary	Lek d.d., suppliers	6.2/75	
204-1	Proportion of spending on local suppliers	All Lek sites, local communities, suppliers	6.3/76	
GRI 206: Anti-competitive behavior 2016				
103-1 103-2	Explanation of the material topic and its Boundary		5/73	
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Lek d.d., local communities	5/74	

ENVIRONMENTAL TOPICS				
GRI 301: Materials 2016				
103-1	Explanation of the material topic and its Boundary		2.2.2/40	
301-1	Materials used by weight or volume	All Lek sites	2.2.1/40	
GRI 302: Energy 2016				
103-1 103-2	Explanation of the material topic and its Boundary		2/36	
302-1	Energy consumption within the organization	All Lek sites	2.3.1/42, 43	
302-3	Energy intensity	All Lek sites	1.1.1/8, 2.3.1/43	
302-4	Reduction of energy consumption	All Lek sites	2.3.2/45	
GRI 303: Water 2016				
103-1 103-2	Explanation of the material topic and its Boundary		2/36	
303-1	Water withdrawal by source	All Lek sites, local communities	2.4.1/46, 2.4.2/47	
303-3	Water recycled and reused	All Lek sites, local communities	2.4.3/47	
GRI 305: Emissions				
103-1 103-2	Explanation of the material topic and its Boundary		2/36, 2.6/52	
305-1	Direct (Scope 1) GHG emissions	All Lek sites, local communities	2.1.5/39, 2.6.5/54	
305-2	Energy indirect (Scope 2) GHG emissions	All Lek sites, local communities	2.6.5/54	
305-4	GHG emissions intensity	All Lek sites, local communities	2.6.5/54	
305-5	Reduction of GHG emissions	All Lek sites, local communities	2.3.2/45	
305-7	Nitrogen oxides (NO_x), sulfur oxides (SO_x), and other significant air emissions	All Lek sites, local communities	2.6.3/53, 2.6.4/53	
GRI 306: Effluents and waste 2016				
103-1 103-2	Explanation of the material topic and its Boundary		2.7/55	
306-1	Water discharge by quality and destination	All Lek sites, local communities	2.7.1/56	
306-2	Waste by type and disposal method	All Lek sites, local communities	2.5.1/48, 2.5.2/50, 2.5.3/51	
GRI 307: Environmental Compliance 2016				
103-1 103-2	Explanation of the material topic and its Boundary		2/36	
307-1	Non-compliance with environmental laws and regulations	All Lek sites	2/36, 2.1/37	
GRI 307: Supplier environmental assessment 2016				
103-1 103-2	Explanation of the material topic and its Boundary		6.2/75	
308-2	Negative environmental impacts in the supply chain and actions taken	Lek d.d., suppliers	2.1.5/39, 6.2/75	The environmental responsibility of suppliers is one of the important criteria in the process of procurement and choosing suppliers.

SOCIAL TOPICS				
GRI 401: Employment 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		3.1/61	
401-1	New employee hires and employee turnover	All Lek sites, employees	3.2.1/61	
401-3	Parental leave	Lek d.d., employees	3.2.5/63	
GRI 403: Occupational Health and Safety 2016				
103-1 103-2	Explanation of the material topic and its Boundary		3.3/63	
403-2	Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	All Lek sites, employees	1.1.1/8, 3.3.1/63, 3.3.2/65, 3.3.4/66	
403-3	Workers with high incidence or high risk of diseases related to their occupation	Lek d.d., employees	3.3.5/66	
GRI 404: Training and education 2016				
103-1 103-2	Explanation of the material topic and its Boundary		3.4/67	
404-1	Average hours of training per year per employee	Lek d.d., employees	3.4.1/71	We do not yet record education by gender and by employee category.
GRI 406: Non-discrimination 2016				
103-1 103-2	Explanation of the material topic and its Boundary		5/73	
406-1	Incidents of discrimination and corrective actions taken	Lek d.d., employees	5/74	
GRI 408: Child labor 2016				
103-1 103-2	Explanation of the material topic and its Boundary		6.2/75	
408-1	Operations and suppliers at significant risk for incidents of child labor	Lek d.d., suppliers	6.2/75	
GRI 409: Forced or compulsory labor 2016				
103-1 103-2	Explanation of the material topic and its Boundary		6.2/75	
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	Lek d.d., suppliers	6.2/75	
GRI 412: Human rights assessment 2016				
103-1 103-2	Explanation of the material topic and its Boundary		5/73	
412-2	Employee training on human rights policies or procedures	Lek d.d., employees, local communities	5/74	
GRI 413: Local communities 2016				
103-1 103-2	Explanation of the material topic and its Boundary		1.4.3.1/34	
413-1	Operations with local community engagement, impact assessments, and development programs	All Lek sites, local communities	1.4.3.1/34	The data collected for now does not allow us to calculate the share, but we report the number of activities.
GRI 414: Supplier social assessment 2016				
103-1 103-2 103-3	Explanation of the material topic and its Boundary		6.2/75	

414-2	Negative social impacts in the supply chain and actions taken	Lek d.d., suppliers	2.1.5/39	By signing a contractual agreement, the supplier undertakes to comply with all applicable laws and regulations related to fair working practice.
GRI 417: Marketing and labeling 2016				
103-1 103-2	Explanation of the material topic and its Boundary		4/72	
417-1	Requirements for product and service information and labeling	Lek d.d., regulators	4/72	
417-2	Incidents of non-compliance concerning product and service information and labeling	Lek d.d., regulators, patients, healthcare workers and healthcare service providers, buyers	4/72	
417-3	Incidents of non-compliance concerning marketing communications	Lek d.d., regulators, patients, healthcare workers and healthcare service providers, buyers	4/72	

8. Environmental Auditor's statement

Izjava okoljskega preveritelja o dejavnostih preverjanja in potrjevanja št. O-006

Slovenski institut za kakovost in meroslovje,
z registracijsko številko okoljskega preveritelja SI-V-0001,
akreditirani za preverjano dejavnost organizacije (NACE: 21.200),

izjavlja, da smo preverili, ali organizacija na lokacijah

Lek farmacevtska družba d.d., Verovškova 57, 1526 Ljubljana

z registrsko številko SI-00006,

izpolnjuje vse zahteve Uredbe (ES) št. 1221/2009 Evropskega parlamenta in Sveta z dne 25. novembra 2009 o prostovoljnem sodelovanju organizacij v Sistemu Skupnosti za okoljsko ravnanje in presojo (EMAS).

S podpisom tega dokumenta izjavljamo, da:
- sta bila preverjanje in potrjevanje izpeljana popolnoma v skladu z zahtevami Uredbe (ES) št. 1221/2009;
- rezultati preverjanja potrjujejo, da ni dokaza o neskladnosti z veljavnimi zakonskimi zahtevami v zvezi z okoljem;
- podatki in informacije iz okoljske izjave **»Poročilo o trajnostnem razvoju družbe Lek d.d. za leto 2016, julij 2017«** podajajo zanesljivo, verodostojno in pravilno sliko o vseh dejavnostih organizacije v obsegu, navedenem v okoljski izjavi

Ta dokument ni enakovreden registraciji EMAS. Registracijo EMAS lahko podeli le pristojni organ na podlagi Uredbe (ES) št. 1221/2009. Ta dokument se pri sporočanju javnosti ne uporablja samostojno.

EMAS

Datum validacije: 2012-04-06
Izdaja: 06/2017-07-17
Velja do: 2017-12-31

Igor Likar:
Direktor SIQ

SLOVENSKA AKREDITACIJA
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9. Glossary of key terms

EMAS (ECO – Management and Audit Scheme)

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

GRI (Global Reporting Initiative)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a Sandoz company

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