



a Sandoz company



Sustainability Report  
2015 – Lek d.d.

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## **Sustainability Report 2015 - Lek d.d.**

Published by: Lek d.d.

Text: Mojca Bernik, Lek d.d.

Edited and counselling provided by: Studio Kernel d.o.o.

Design: Intesa RD d.o.o.

Photography: Lek d.d. Archive, Fotolia

Cover: Within the Community Partnership Day our employees painted walls at the Janez Levec Centre in Ljubljana.

Printed by: Silveco d.o.o.

Number of printed copies: 100

Ljubljana, August 2016

This report is printed on environmentally friendly, 100% recycled uncoated Cocoon Offset paper, made from 100% post-consumer PCF (Process Chlorine Free) fibres, with EU Ecolabel (No. FR/011/03)\* and heavy metal absence certificate. The paper has been manufactured in a paper mill that holds an ISO 14001 certificate. The carbon footprint of the Arjowiggins Graphic manufacturer is 602 kg CO<sub>2</sub>/t of paper (Bilan Carbone® methodology).

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## 2015 KEY FACTS

Lek, a pharmaceutical company, is one of the key pillars of Sandoz, the generic pharmaceuticals division of Novartis, a pioneer in the field of biosimilar medicinal products and world's second largest generics pharmaceuticals company.

**849.4 mio EUR**

sales net income in 2015 or 11.6% more than in 2014

**1.7 mrd EUR**

of Novartis' investments in Slovenia in 13 years

**88%**

proportion of senior management hired from the local community

**+ 8%**

employees at the end of 2015

**- 45%**

improved LTIR index, showing the rate of accidents, resulting in absence from work or the use of sick leave, reached the value of 0.12.

**- 5%**

reduced emissions of volatile organic compounds

**3.2 mio EUR**

investment in environmental protection

**14.7 TJ**

energy saved by energy efficiency improvement projects

**+ 10%**

improved water use efficiency



## A LETTER FROM THE PRESIDENT OF THE BOARD OF MANAGEMENT

Dear readers, associates, partners and stakeholders!

Lek, a Sandoz company, ends its 7th decade as a responsible element of the Slovenian economic and social life. Environmental, social and economic impact of our business in 2015 confirms that our ability to adapt is at one of its peaks. At the same time Novartis continues to invest in Slovenia.

We have seen extraordinary achievements in development and productions at all sites, in Ljubljana, Mengeš, Prevalje and Lendava. It is particularly gratifying to see that we have again had a positive impact on Slovenian social environment, as we contributed to employment opportunities for high level human resources, which is particularly important for employment of young educated professionals. In the previous year at Lek, a Sandoz company, we have added 268 new employees at all locations to our work force of 3,350. More than 47 percent of our employees have acquired tertiary education, four percent are participating in off-the-job education and the number of training hours was increased by ten percent. We not only participate in the life of the local community

economically, but also by cooperating with scientific and research organizations, various non-governmental organisations and as volunteers.

The trust placed in us by Sandoz and Novartis, as well as our patients and partners, was gained by knowledge, hard work, and high quality standards in all business segments. Maintaining the confidence is a demanding and an on-going process. Outstanding achievements in product and process development reflect our teams' knowledge and skill. It is an often overlooked fact that the quality results and permanent improvement in health protection, safety and environmental protection are a prerequisite for obtaining new projects at Novartis and Sandoz. The results from mandatory national and international auditing and monitoring show that we at Lek have fully met this condition.

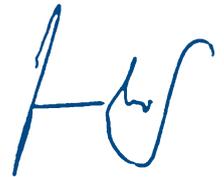
The data from the presented report show that our daily efforts are reflected in a higher safety culture, better efficiency in energy and water consumption, waste disposal and reduction in total organic compound emissions. The increased volume of production and number of employees as well as production structure add significance to the presented results.

Lek, a Sandoz company, remains committed to accountable business practices related to health protection, safety and environmental protection, which is particularly important for local communities in which we operate. In the light of our development potential together we search for opportunities to expand the research and development, and production sites. It should be emphasized that Lek has a long-term commitment to managing environmental impacts and natural resources. Our investments in expansion of research and development facilities remain inseparably related to cooperation with local suppliers and with the investments in health, safety and environment protection. Each process and product is evaluated in terms of impact on all the above factors, and the best possible related technological solutions are being incorporated during investment times in order to further direct the development toward good Slovenian and international practice.

We are aware that sustained and sustainable business practices in our environment are too often perceived as a pleasing idea without specific goals or actions.

Equally, the economic practices are often separated from the business concept itself. On the other hand, accountable business practices have the central place in Novartis' business strategy with clearly defined responsibilities and goals, related to our challenges at all levels. Their actualisation is reported publicly, which is among basic principles of Novartis' social accountability.

As a part of an international generics pharmaceutical group developing and selling high-quality, safe and efficient products, we contribute to accessible treatment. Our development and production achievements are also devoted to this mission. However, we aren't forgetting that the accountable business practice is more than just a high quality product and the production or development process. It includes ethical conduct and transparency of our relations with stakeholders in the health care. This is the field in which we need to make important steps in order to contribute to improve the image and accountable conduct in the entire sector.



**Vojmir Urlep**  
President of the Lek Board of Management

# 1. COMPANY PROFILE



## Lek, a Sandoz company<sup>1</sup>

Company name:  
 Abbreviated name:  
 Registered office:  
 Business address:  
 Registration number:  
 Standard Classification of Economic Activities  
 in the European Community (NACE):  
 Registration number:

Telephone:  
 Fax.:  
 E-mail:  
 Website:

**Lek Pharmaceuticals d.d.**  
**Lek d.d.**  
**Ljubljana**  
**Verovškova 57, 1526 Ljubljana, Slovenia**  
**1732811000**

**21.200 Manufacture of Pharmaceuticals**  
**District Court in Ljubljana under entry number:**  
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**+ 386 1 568 35 17**  
[info.lek@sandoz.com](mailto:info.lek@sandoz.com)  
<http://www.lek.si/en>

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<sup>1</sup> GRI Indicators G4-3, G4-5, G4-7 | <sup>2</sup> GRI Indicator G4-31

## 1.1 Key data for 2015

### 1.1.1 Operations in 2015

Table 1: Key figures for 2015<sup>3</sup>

Indicator	Unit	31 Dec 2015	31 Dec 2014	Index 2015/2014
<b>Number of employees</b>		<b>3,361</b>	<b>3,124</b>	<b>108</b>
- Ljubljana site		1,877	1,801	104
- Mengeš site		904	817	111
- Lendava site		355	308	115
- Prevalje site		225	198	114
Production output*	1,000 t	5.22	4.69	111
Net sales revenues	In EUR m	849.413	761.338	112
Liabilities	In EUR m	988.717	903.743	109
Equity	In EUR m	616.658	500.362	123

\* 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<sup>4</sup>

In 2015, Lek, a Sandoz company, realized 11.6% higher net sales revenue compared to the previous year, i.e. EUR 849.413 million. The revenue in foreign markets increased by 11.8%, and the revenue in the Slovenian market by 8.4%.

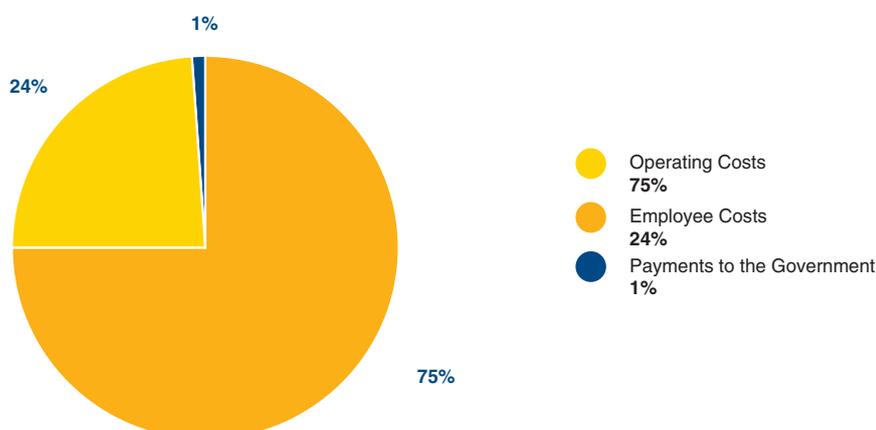
**Direct Economic Value Generated** was also higher compared to the previous year, amounting to EUR 895 million. 81% (EUR 723 million) of this was **Economic Value Distributed**.

**Operating Costs** amounted to 75%, or EUR 543 million, of Economic Value Distributed. **Employee Costs** amounted to

24%, or EUR 170 million, and **Payments to Government** to 1%, or EUR 10 million. **Payments to Providers of Capital** were not realized in 2015.

The tax relief value due to investment in research activity dropped to EUR 7.889 million (9.133 million in 2014). In 2015, the tax relief for investments amounted to EUR 26.637 million (17.468 million in 2014). We also received public subsidies amounting to EUR 874,671 (EUR 401,002 in 2014).<sup>5</sup>

Chart 1: Structure of Economic Value Distributed



## 1.1.2 Highlights and milestones of Lek's operations in 2015

- The **employment** kept growing. In Slovenia, 348 new jobs were created, and there were more than 3,350 employees at the end of year. More than 47% of employees hold a university degree, and more than 410 hold master's or doctoral degrees. Most new jobs were opened in Development and Technical Operations. In the last four years, there were more than 1,100 new jobs created in Slovenia.
- In 2015, **21 new products** suitable for the most demanding world markets were developed. The majority of them were launched to markets in Europe, Canada, Australia, USA and Japan. In the last four years, more than 100 new products have been developed. Through this, we are consolidating our position as the leading Sandoz Development Center because as much as one fourth of all Sandoz development projects originate from Slovenia.
- The production volume has been increasing at our sites across Slovenia also in 2015. Products manufactured in Slovenia are marketed via the Sandoz global sales network in 160 countries across the world. Novartis also continued to invest in Slovenia in 2015, and has invested more than **EUR 1.7 billion** in Slovenia over thirteen years.
  - In April, new facilities for printing and visual control of tablets were opened in Solids, and a new production line in Steriles at the Ljubljana site.
  - In September, a new high-shelving warehouse was opened at the Lendava Packaging Center, the largest individual investment of Novartis in Slovenia.
  - Due to the increase in volume, the plant for manufacturing our probiotic product at Mengeš was expanded.
  - At the Penicillin Products Production at Prevalje, a new packaging line was set up in November, which will increase the capacities in the phase of packing tablets in blisters by 40%.
- The most demanding audits performed by the US Food and Drug Administration (FDA) at three of our sites (Ljubljana, Mengeš and Lendava) 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 are the key Sandoz site for the introduction of new products. There were 760 launches of new products to the markets all over the world performed from Slovenia, accounting for 36% of all new launches in Sandoz.
- Lek, a Sandoz company, together with other Novartis divisions, has retained its 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 and have increased the sales and market share in prescription medicines (+8% vs. previous year). We have consolidated our leading position and have increased our market share in over-the-counter medicines.
- In 2015, we invested EUR 3.2 million for investments into environmental protection. We extended our registration in the EU Eco-Management and Audit Scheme (**EMAS**) for another three years. We successfully passed the regular audit for **ISO 14001** Environmental Management Systems Certification and the certification audit for the **OHSAS 18001** occupational health and safety management system.
- The most promising science students from the Alpe-Adria region were enabled to take part at the regional BioCamp offering them an insight into pharmaceutical industry guidelines.
- For the eleventh year, our employees participated as volunteers at the Novartis Community Partnership Day, celebrating the establishment of Novartis in 1996. Over the eleven years, the Novartis employees in Slovenia have performed 26,000 hours of volunteer work, helping more than 11,000 people and 50 organizations.

### 1.1.3 Awards and acknowledgements



*Jasna Kos, M. Sc. and Fikret Bašanović receiving the TOP 10 Education Management award*



*Packaging center Lendava, winner of the 'TOP – 5' Lendava municipality award*



*Samo Roš, member of the Lek, a Sandoz company, Management Board, winner of the award for involvement in practical training of students from Faculty of Chemistry and Chemical Technology.*



*Lek's researchers receiving two Chamber of Commerce and Industry of Slovenia's awards for best innovations.*

Through their outstanding achievements, our experts once again proved their first-class knowledge, expertise and experience.

Again, we received the **Responsible Care** initiative (RCI) certificate for chemical industry. Our statements about the importance of responsibility to patients, employees, the environment and local communities are pursued in concrete objectives, about which we report transparently and comprehensively, in compliance with the RCI requirements for open communication with stakeholders and the public, using internationally renowned and comparable indicators (**Global Reporting Initiative, GRI**) in the present Sustainability Report 2015 – Lek, a Sandoz company.

- For the fourteenth time in a row, we received the **TOP 10 Education Management Award** for our investments in **development, education and training** of our employees.
- The researchers from Lek, a Sandoz company, were awarded **two golden awards from the Chamber of Commerce and Industry of Slovenia for the best**

**innovations at the national level** for the development of artificial stomach and gut to analyze the development of complex solid pharmaceutical forms and for the discovery and development of the catalytic synthetic method to prepare the key intermediate for the active ingredient intended for the treatment of Parkinson's disease.

- On the occasion of the 19th anniversary of Lendava Community, the Lendava Packaging Center of Lek, a Sandoz company, was awarded the **TOP-5 Lendava municipal award** for the 2015 achievements in economy.
- We were recognized for the participation of students in the practical training of students of the Faculty of Chemistry and Chemical Technology once again in 2015.
- We extended the full **Family Friendly Certificate** and proved our efforts to create a work environment which contributes to a better work-life integration.

**Table 2: Major environmental and social impacts<sup>6</sup>**

Indicator	Unit	31 Dec 2015	31 Dec 2014	Index 2015/2014
Efficiency of energy resource use	GJ/t	236	255	92.6
Water use efficiency**	m <sup>3</sup> /t	680	757	89.8
Waste volumes – efficiency	t waste/t product	6.7	7.40	90.5
VOC emission – efficiency	t VOC/t product	0.018	0.021	85.7
LTIR* – work-related injuries and illnesses involving days away from work (Lost Time Injury and Illness Incidence Rate)		0.12	0.22	54.5
TRCR* – work-related injuries and illnesses requiring more than basic first aid (Total Recordable Case Rate)		0.39	0.42	92.9

\* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 3.3.1.

\*\* The table shows the efficiency of use for all waters at Lek (for technological and cooling purposes).

### 1.1.4 Health, safety and environment (HSE) objectives and their realization<sup>7</sup>

In the field of HSE, we follow Novartis long-term plans. At the same time, we realize our annual short-term goals monitored for each site and for the entire company. Data for reporting requirements is collected and confirmed in the Novartis Data Management System (DMS). We are committed to enhancing our environmental performance according to the principles of:

- regular assessment of the system performance,
- open communication with internal and external public, and
- involvement of all employees in the environmental care system.

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 2015 by individual Lek sites together with the progress each site made towards the realization of our long-term objectives over the period up to 2015.

**Objectives are set and implemented on the basis of the Lek HSE Policy. It is amended, if necessary, at every revision of the Health, Safety and Environment Rules.**



Lek's associates cleaning the Kočevska region within the Community Partnership Day Initiative.

HSE objectives for the 2010 – 2015 period	Status 2015	
Improving water use efficiency by 10% over 2010.*	<b>Realized.</b>	Water use efficiency improved by <b>37%</b> . 2010: 1,079 m <sup>3</sup> /t 2015: 680 m <sup>3</sup> /t
Improving energy efficiency by 10% over 2010.	<b>Realized.</b>	Energy efficiency improved by <b>32%</b> . 2010: 348 GJ/t 2015: 236 GJ/t
Reducing VOC emissions (h-VOC and nh-VOC) to the air by 20% over the 2010 figures.	<b>Realized.</b>	Emissions reduced by <b>63%</b> . 2010: 258 t 2015: 95 t
Reducing waste volumes by 10% over 2010.	<b>Realized.**</b>	2010: 13,125 t 2015: 34,876 t or 10,156 t (excluding mycelium waste)
Reducing LTIR to 0.1.	<b>Not realized.***</b>	0.12

\* The efficiency of use for all waters at Lek (for technological and cooling purposes) is shown.

\*\* Since 2011, in accordance with Novartis' reporting methodology, waste includes only the waste leaving the site and not that treated on the site. In 2012, mycelium waste generated by the fermentation production process at Lendava was redirected from the site's incinerator to a contractor biogas plant for treatment; therefore, the total mycelium waste volume is now reported as waste treated outside the site. Comparison of the volume of waste between 2010 and 2015 is realistic only if mycelium waste is subtracted from the total amount of waste. In 2015, the volume of mycelium waste amounted to 24,720 tonnes. Total waste in this year thus amounted to 10,156 tonnes, corresponding to a slightly less than 23% reduction in volume compared to 2010. Also see the explanation under Item 2.5.3.

\*\*\* Since 2014, we have been recording injuries of all associates (Lek's own employees and those employed through agencies). In previous years, the index was only evaluated in cases when Lek's associates were injured.

## Lek's HSE targets for 2015

Short-term targets for 2015	Realization in 2015 (for entire Lek, a Sandoz company)
Ecotoxicity assessment of APIs	<b>Realized.</b> Continuous evaluation for all APIs for which ecotoxicity data is available in the literature.
Non-halogenated VOC emissions to the air (nh-VOC) Target: ≤99 t	<b>Realized.</b> Emissions reached 94 tonnes.
Halogenated VOC emissions to the air (h-VOC) Target: 1 tonne	<b>Realized.</b> Emissions reached 0.84 tonnes.
Energy savings	<b>Projects realized.</b> Various projects were carried out to improve energy efficiency, resulting in energy savings of 14.7 TJ. Due to the increased production, the total energy consumption was by 3% higher compared to 2014.
Reducing hazardous waste volumes	<b>Partly realized.</b> The projects at Lendava and Mengeš sites were realized, but the hazardous waste volume per tonne of product increased by 2%.
Reducing non-hazardous waste volumes	<b>Realized.</b> Non-hazardous waste reduced by 1.5%. Weighbridge at the Ljubljana site installed. The proportion of recyclable packaging among non-hazardous waste increased by 1.1%.
LTIR* (own employees + employees hired through employment agencies) Target: ≤0.12	<b>Realized.</b> The index reached 0.12.
TRCR* (own employees) Target: ≤0.46	<b>Realized.</b> TRCR index reached 0.39.

\* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 3.3.1.

## Long-term Novartis HSE targets for 2020

Area	Indicator	Target
Health	Exposure of employees to dangers exceeding permissible limits	0
	Reducing the rate of absenteeism	-10% vs. 2010
Safety	Serious injuries and fatalities (SIF)	0
Environment	Reduction of greenhouse gas (GHG) emissions	-30% vs. 2010
	Reduction of pollutant emissions to water	10-times below PNEC*
	Reduction of non-recyclable waste per tonne of product	-30% vs. 2010

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

## Lek's HSE targets for 2016

Area	Indicator	Target
Health	LTIR (own employees + employees hired through employment agencies)	0.14
	TRCR (own employees + employees hired through employment agencies)	0.4
Safety	Identifying risks of injury	40 walkthrough inspections / 200,000 working hours
	Serious injuries and fatalities (SIF)	0
	Safe drive training with an instructor	>90% of company car holders
Environment	Reduction of VOC emissions to the air (nh-VOC and h-VOC)	Maintaining the 2015 level
	Reduction of pollutant emissions to water	100% assessment of ecotoxicity of APIs, prioritization prepared
	Reduction of non-hazardous waste per tonne of product	Project of increasing the proportion of waste to be recycled, by 5%
	Reduction of hazardous waste per tonne of product	Project of increasing the proportion of waste to be recycled, by 5%
Energy	Energy savings	-1% vs. 2015
BCM index	Readiness to continue key business activities in case of major disruptive events	>21 points
NEM index	Readiness to protect our employees, environment and our assets in case of emergency	>22 points



Process control in the bioreactor in the Anti-infectives production Unit at the Lendava site.

## 1.2 About us



**Lek**, a Sandoz company, is a joint-stock company, 100% owned by Novartis Pharma AG. It is based in Ljubljana, it has its development centers in Ljubljana and Mengeš and operates at four production sites: in Ljubljana, Mengeš, Prevalje and Lendava. In 2015, all the sites were included in the EMAS scheme and registered in the EMAS register.<sup>8</sup>

The knowledge and experience of our associates allow us to develop, manufacture and market standard generic drugs and state-of-the-art biosimilars. We provide effective, safe and quality medicinal products, available to a wide range of people around the world.<sup>9</sup>

For more information about Lek, a Sandoz company, please visit [www.lek.si/en/](http://www.lek.si/en/).

### Lek as part of Sandoz and Novartis

- **A leading Sandoz' development center** for technologically demanding products and technologies (medicinal products for oral use, injectables)
- **A global manufacturing center** for pharmaceutical ingredients and medicines (medicinal products for oral use, injectables)
- **A competence center** for the development of vertically integrated products
- **A Center of Excellence** in the field of development and manufacturing of biosimilars
- One of the leading Sandoz' global **supply centers**
- **Responsible for sales in the Slovenian market** and sales services for global Sandoz markets
- **A global IT competence center** for production information systems; **regional center for IT infrastructure** for the countries of South-East Europe, Bulgaria and the Baltic region and for technical operations and quality for Central and East Europe

We are an important member of the Novartis Group. Among others, we manufacture active pharmaceutical ingredients for Novartis innovative medicines (Mengeš site), we are a center of excellence for ampoules (Ljubljana site) and take part in joint development projects.

We develop new knowledge and introduce many new technologies in areas such as biopharmaceuticals (research in the field of monoclonal antibodies), steriles and other products.

**Sandoz, a Novartis company**, is a global leader in generics and biosimilars. It strives for sustainable access to high-quality healthcare and provides a broad range of affordable products for patients and customers. The company is a global leader in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines. The registered office of Sandoz is located in Holzkirchen, Germany. Its portfolio covers approximately 1,100 molecules and enabled it to reach the sales of USD 9.2 billion in 2015.

**Novartis**, headquartered in Basel, Switzerland, offers a healthcare portfolio to meet the increasing needs of patients and society at large. It is the only global company with leading positions in innovative medicines, eye care products and cost-saving generic pharmaceuticals. Novartis products are available in more than 180 countries around the world. In 2015, the Novartis Group achieved net sales of USD 49.4 billion. Investments into R&D amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 119,000 people.

For more information, please visit <http://www.novartis.com>.

## Corporate responsibility

Our corporate responsibility is aligned with Novartis policies and is an important part of our business strategy. It involves all of our operations and is directly associated with the

fulfilment of our mission, vision and strategy. It focuses on five key stakeholders: patients, employees, shareholders, healthcare partners and society.

### 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.

We are seeking ways to discover new innovative and affordable medicines at our development & production centers in Slovenia.

Our research and development achievements go hand in hand with the Slovenian academic environment. They are successfully integrated into the production of quality, safe and efficient pharmaceutical products.

#### Responsible operations

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

#### Environmentally sustainable operation

The active environmental policy is implemented through a number of activities to protect the environment which often go beyond mere fulfilment 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.



Lek, a Sandoz company, provides free holidays for children from socially deprived families through the Wink at the Sun initiative

## The ever-present values



*Ksenija Butenko Černe, member of the Board of Management, Head Legal and Head Integrity & Compliance*

### How would you assess the integrity culture at Lek, a Sandoz company?

Similar to other organizations, our integrity culture is under continuous development, in which all employees take part. Progress can only be achieved when we do it constantly, every day. We are proud that Novartis high integrity standards, one of our key values, apply at Lek. With its highly set system, Novartis has exceeded strict regulatory requirements and the area of compliance. We do what is right, also in terms of high ethical principles. In our environment, we are several steps ahead of some other companies, but there is still room for improvement.

### Has the sensitivity of the associates to practical actions in the field of integrity changed?

The changes are considerable. Almost ten years ago, when the line for reporting misconduct was introduced, this was considered inappropriate denouncing of others. Now we understand that it is used for our own and for patients' safety, for the hygiene in our work environment, the company's reputation and introduction of right values in society. The number of reported misconducts has not been decreasing, which however does not mean that the number of misconducts grows. On the contrary, it means that we want to work in an environment of which we are proud. The contents of the reports have changed as well. The reports do not relate as much to the reporter as to a wider environment. This is a proof we want changes and that our integrity culture is developing and strengthening. At the same time, the pattern of our conduct is being established and carried forward. Our values do not stay at our workplace, they accompany us everywhere we go.

### How are our efforts concerning integrity seen by the public, notably doctors?

We make progress in the same direction, i.e. in the direction of assuring compliance, and we are all aware that this is for the benefit of patients.

Our efforts and persistence in implementing the standards of compliance and integrity have paid off. Doctors' expectations are quite different than they were ten years ago. Younger generations in particular support compliance, expect impartiality and maintain independence. They are sympathetic with our decision not to invest in gifts, and accept our understanding and help in fostering knowledge to the benefit of the patient. The changes can be seen in the market too.

## The dynamic atmosphere in the leading Sandoz development center



*Matjaž Tršek, Director of Development Center Slovenia*

### Development Center Slovenia specializes in technologically demanding development projects. It carries out a quarter of global Sandoz development activities. How would you present the employees at the Ljubljana Center?

Through continuously enhancing our knowledge and abilities, we are following strategic directions and developing a portfolio of products to be launched in the market in the following years. We employ more than 280 experts from various fields, a third of them holding a scientific doctorate. In 2015, 35 employees were being in the process of obtaining academic degrees at different levels. Our associates authored nearly 30 scientific articles and many papers at international conferences. Their innovation ability and excellent professional competence were recognized at various levels. They obtained golden awards by the Chamber of Commerce and Industry for the best two innovations at the national level, and several Sandoz awards for the excellent work.

### What were the key characteristics of the development work and in which direction it is headed?

The complexity of our development projects is growing, which is in line with the company's development strategy. We have continued to introduce the state-of-the-art research and production platforms and upgraded the key sections of the pharmaceutical development. The most recent production technologies also include machines for filling finished pharmaceutical forms. In the field of analytical techniques, we have obtained global state-of-the-art analytical instruments for monitoring physical forms. We have successfully introduced new products to Sandoz markets, mostly from Lek production plants, and increased the number of launches of the established products in new markets. We have successfully launched 16 new products and filed 7 patent applications to protect innovative approaches in the synthesis of active pharmaceutical ingredients and development of finished pharmaceutical products. We have completed the development of 21 new generic pharmaceutical products. As of the end of the year, there were more than 240 ongoing development projects for finished pharmaceutical products and 14 for active pharmaceutical ingredients.

## The breakthrough volume of production



*Aleš Rokavec, Head ChemOps Menges*

### You have had a successful year. What would you emphasise?

We were successful in three areas – production growth, investments and quality. The production in almost all our units has exceeded 10%. Over 8 billion manufactured and over 7 billion packaged pieces of solid dosage forms is a unique achievement, because such growth had not been planned, we just responded to the opportunities that had arisen. Our associates were highly committed and most lines were occupied for 6 or 7 days a week. Despite such strong growth, high level of customer supply was maintained.

### This year was also intense in terms of investments.

We have implemented or initiated many investments to increase capacity, mostly in solids production, and to improve the infrastructure. Despite the ongoing investment work in many units, we were able to ensure maximum production without any negative impact on the safety of the employees and on the quality.

### Last year will also be remembered for many inspections and audits.

All areas of our operations were inspected – quality, health, safety and environment (HSE), reliability and security of the operations and business practice. High standards, in particular regarding quality and HSE, are a tradition in all units of Lek, a Sandoz company, but tradition does not mean much in the area of good practices. Over and over again, we have to prove ourselves, and we are only as good as the most recent inspection shows. In 2015, the Solids Unit employees have proven this several times and in all areas.

## Investments created the conditions for growth and expansion to new markets



*Bettina Krausenbaum, Head Steriles*

### How will investments into development affect future results?

By upgrading one of vial production lines, which is currently underway, we will have a state-of-the-art technology available to respond to any new and incoming quality standards as well as to improve flexibility. The investment into the filling and packaging line for liquid products has considerably increased the production volume, and has created conditions for several years of growth and expansion to new markets, including the USA. One of the priorities in the aseptic part of production is the preparation for a new launch of a biosimilar in a vial planned for 2017, which further consolidates our position of Sandoz center of excellence for lyophilized vials. We have a good production pipeline, covering almost 20 molecules, and we plan to introduce new products in 2016. Our greatest fascination are biosimilars. This is a big step for us and for the future of biopharmaceutical production.

### Which activities do you implement to follow the technological progress?

In order to ensure good results for the future, we invest in the development of our employees. A strong emphasis is placed on management skills and on introducing new standards for sterile production. The entry of biosimilars into production requires an in-depth expertise of our employees, and constitutes attractive opportunities for professional development of the associates in Production, Production Engineering, Technology of Processes and Products, and Quality.

## 1.2.1 Key customers and markets<sup>10</sup>

In accordance with the strategic orientations, Sandoz Group companies are the key buyers of Lek products and active pharmaceutical ingredients. We sell our own products and the products of other Sandoz companies.

In 2015, the leading three buyers accounted for 76%, 9% and 4% of Lek net sales, respectively. Our major external direct sales markets include Central and Eastern Europe with 94% of products, and in Slovenia 6%.

The share of sales in pharmaceutical products (90%) was increased compared to the previous year (87% in 2014), while APIs and biopharmaceutical products account for the remaining share amounting to 10% (13% in 2014).

The total value of the Slovenian pharmaceutical market increased by 5.7% while the generic market value increased by 5.6%, excluding any discounts offered by the manufacturers of medicinal products. In 2015, the Health Insurance Institute of Slovenia introduced no new therapeutic groups of medicines. The reduction in reference price levels for medicines affected both generic and innovative pharmaceutical companies. In 2015, the value of the OTC market increased by 6% and its volume by 1.8%.

## 1.2.2 Major product groups and brands<sup>11</sup>

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 anaemia, related to chronic kidney failure,

- medicines for the treatment and prevention of iron deficiency and anaemia 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.

The leading brands of Lek, a Sandoz company, in Slovenia include Lekadol<sup>®</sup>, Amoksiklav<sup>®</sup>, Coupet<sup>®</sup>, Linex<sup>®</sup>, Iroprem<sup>®</sup>, Lekadol plus C<sup>®</sup>, Fluimukan<sup>®</sup> and Tulip<sup>®</sup>.

In the export markets, our leading medicines include drugs with amoxicillin-clavulanic acid, tacrolimus, epoetin alpha, mycophenolate mofetil and omeprazol.

## 1.2.3 Development and production sites and processes<sup>12</sup>

### 1.2.3.1 Ljubljana Site

The Ljubljana site features the **headquarters** and the following specialist services: Finance, Sales and Marketing, Procurement, Supply, Quality, Human Resources, Legal Affairs, HSE, Corporate Communication and others.

On Verovškova street, in the Šiška industrial zone, the leading and the largest **Sandoz's development center** and one of the largest **Sandoz's production plants**, which is also the largest Lek's plant in Slovenia, operate.

**Production** in Ljubljana began as early as in 1975. Today, production is organized in two organizational units – Solid Dosage Forms and Sterile Dosage Forms. In addition to standard products, the Ljubljana site develops for the entire Sandoz Group the most technologically demanding products, such as modified-release formulations and nasal sprays. Many new products we develop are subsequently manufactured in Ljubljana.



HSE team Ljubljana

**Investing in capacities and infrastructure** continued also in 2015, by increasing the wet granulation capacity, tableting and coating capacity, as well as enhancing and upgrading the infrastructure.

**In the area of quality**, we have successfully passed many inspections by state agencies and customer audits and reaffirmed the high level of quality of our manufacturing. The same applies to the HSE audits performed.

#### Solid Dosage Forms (SDF)

The Solids Unit covers a wide range of products. Our pipeline includes approximately 550 solid pharmaceutical forms, for which more than 96 molecules (active ingredients) are used. We package more than 3,000 finished pharmaceutical products for almost 90 markets around the world. The majority of our products are manufactured on multi-purpose production lines which are highly automated and controlled through advanced information systems. The automation and computer-assisted systems allow for a reliable complexity management, with faster response to market needs and a short and reliable lead time from receiving raw materials to dispatching the finished product to the market.

In 2015, our tableting plant achieved a new production volume record with more than 8 billion pcs and 200 tonnes of granules produced. We packaged more than 7.5 billion tablets and capsules, and around 70 million bags in over 170 million packages. The Solids Unit has launched more than 240 finished products, and more than 2,000 over the last three years.

#### Sterile Dosage Forms

In the Steriles Unit, the trend of strong production growth has continued for all pharmaceutical forms. We manufactured 152 million ampoules and exceeded the results from the previous year by 20%. Additional growth (25% vs. 2014) was recorded in vial production, achieving 24 million units. The new investment project worth EUR 2.3 million will further increase its flexibility and capacity.

A major investment of EUR 6.4 million into a new, advanced line for nasal spray production was completed. The new acquisition was the main reason for the 33% growth in production volume and Sandoz supply with the key nasal spray. A total of 16 million nasal sprays were manufactured.

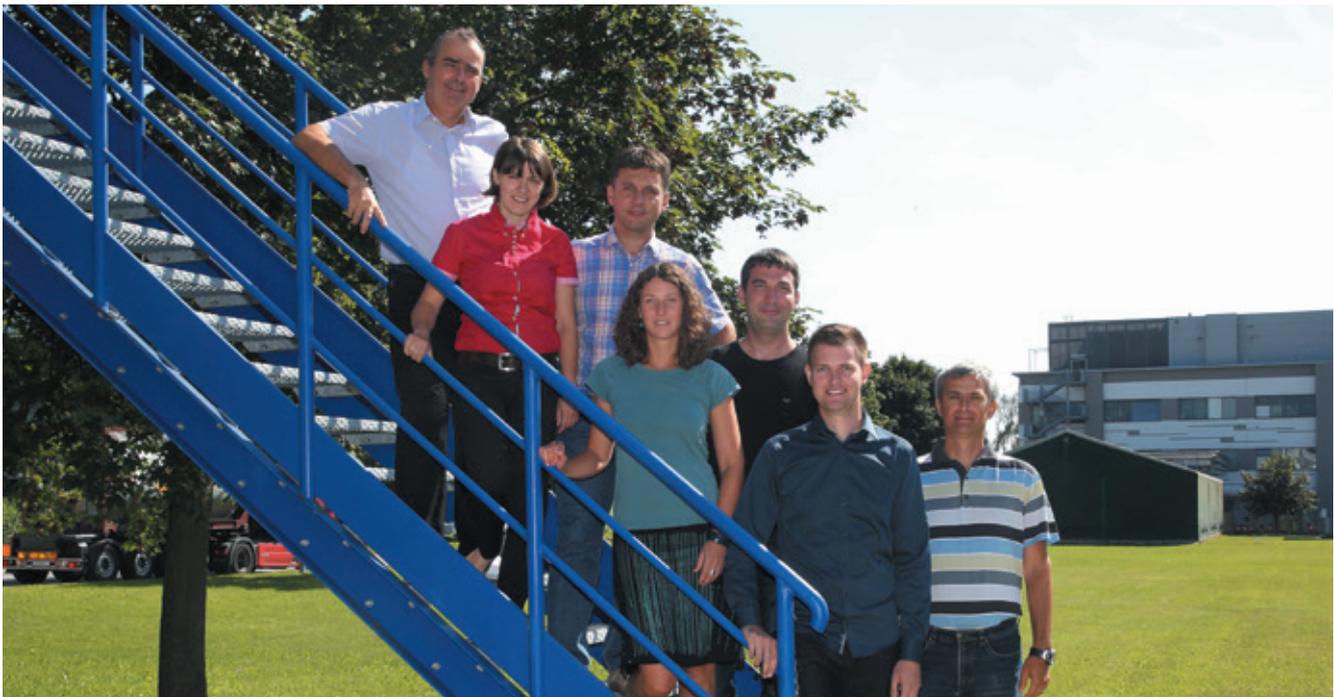
- By transferring new products to our production lines, the role of Sandoz center of excellence for the production of lyophilized vials and ampoules has consolidated.
- The successfully passed regulatory and other inspections, including FDA inspection, have proven our high standards in quality and HSE.

#### 1.2.3.2 Mengeš site

The Mengeš site comprises Active Pharmaceutical Ingredients (API) Mengeš, Biopharmaceuticals, Development of Pharmaceutical Ingredients, a part of Production of Solid Dosage Forms and Development of Anti-infectives. The development and production of the active pharmaceutical ingredients at this site have been carried out since 1946, while its growth was driven by the expansion of the active pharmaceutical ingredient pipeline, both in processes of biosynthesis as well as organic synthesis. In the last 15 years, it has witnessed a rapid ongoing development of biopharmaceuticals.

In 2015, our **production program** included more than 20 pharmaceutical ingredients, and products from Mengeš have an important share in the entire Novartis product pipeline. The trend of increased production volume and high level of utilization of production capacities has continued. Growth was recorded for our standard active ingredients atorvastatin, rosuvastatin, tacrolimus and amlodipin.

The **investment** into production capacities for a Novartis new active ingredient has been completed. The production plant was approved by the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia JAZMP and healthcare institutions from some other countries. The production of validation batches for the new active



HSE team Mengeš

ingredient began in 2015 and will be completed by the beginning of 2016. Through this successfully managed and completed project, we earned trust to produce further Novartis active ingredients at the Mengeš site. We have completed the transfer of the next active ingredient into the existing production capacities, and the Mengeš site obtained two new projects for exclusive production of a pharmaceutical ingredient for Novartis.

Two older lines, in which active ingredients were produced for decades, were renovated – the line for producing bromocriptine was transferred and renovated, and a comprehensive reconstruction of the line for 5-Nitroxiline was initiated.

We were also successful in **quality and safety**. In the autumn, we passed the FDA inspection without any observations, and no LTI was recorded.

**For Biopharmaceuticals Mengeš**, this year was characterized by growth and excellent business results, as the production volume increased, and investments into development projects continued.

This year was also marked by **high growth of the number of employees**. Biopharmaceuticals Mengeš employs professionals with high added value. As of the end of year, there were 359 employees (286 in 2014), of whom 80% hold a university degree and 34% a master's or doctoral degree.

The **investment** worth over EUR 10 million was used to build a new laboratory facility for the development of finished biopharmaceutical products, technical development of biopharmaceuticals products, and quality control. This enabled Biopharmaceuticals Mengeš to gain additional developmental role within Sandoz and Novartis to combine the existing development of active ingredients for biosimilars with the development of finished biopharmaceutical products.

The Technical Development of Biopharmaceuticals started to implement the project Preparing a New Process of Isolating Proteins for Biopharmaceutical Purposes within Horizon 2020, EU Programme for Research and Innovations. This introduces a new technology for biosimilar production, which will contribute to increased patient access to safe, effective and quality biosimilars.

This year once again, PORT, production plant for recombinant technology, produced record volumes of erythropoietin, used for treating anemia, mostly in patients with renal disease and in cancer patients.

In 2015, we also achieved an important milestone in the development of biosimilars, because the FDA approved Sandoz biosimilar filgrastim, which is the first biosimilar launched in the USA. Its development involved a group of experts from Lek, mostly from Biopharmaceuticals Mengeš.



Laboratory Mengeš

## High quality standards are the key success indicator



*Egidij Capuder, Mengeš Production and Development Site and API Production Head*

### API production at the Mengeš site is controlled through regular internal and external quality controls. What were their results?

Among state inspections, the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia and South Korean State Inspection performed audits of the new production plant for the new active ingredient everolimus. In May, a highly demanding Novartis internal audit took place according to all quality systems checking the uniformity of the Novartis quality system at all production sites and in all processes, irrespective of the country and the intended market. In September, we were inspected by the FDA, which was a precondition for selling our products in the highly demanding US market. All inspections and audits were passed without any major deviations and observations. In particular, we are proud of the outcome of the FDA inspection, because it was the fourth in the row since 2006 without any non-compliances detected.

### Does the development potential of the Mengeš site reflect the results from such inspections?

High standards of quality and HSE are the key indicators of success for any Novartis site. They are reflected in the allocation of products or acquisition of development projects. In order to acquire projects enabling future development of the site, high culture of quality and safety must be guaranteed. The sites compete with each other, and meeting the standards is therefore our obligation, as well as the confirmation of our competent team being able to deal with increasingly high demands.

## Among leaders in science and innovation



*Matjaž Oven, Head Biopharmaceuticals Mengeš*

### The scientific project coordinated by the Biopharmaceuticals was selected by the European Commission as the best project in the BIOTECH-4 category in the prestigious Horizon 2020. How will this project increase access to medicines for patients?

We are proud to be one of the leading companies in science and innovation. The project increases the competitiveness of Slovenian and European area, as it improves productivity, reduces costs and environmental impacts, and provides new jobs with high added value. Since prices of biosimilars might be lower, and the medicines will continue to be of high-quality, patient access to them will be facilitated, and the pressure on public finances might be relieved.

### How are you involved in the development of Sandoz biosimilars?

We participate in the development of all Sandoz biosimilars for all target markets, of both active ingredients and finished products. Sandoz Biopharmaceuticals currently features the leading development pipeline, including monoclonal antibodies, the largest and fastest growing share of global biosimilars market. There are several biosimilar molecules in different development stages, several biosimilar authorization applications can be expected by 2017. The successful investment into the new laboratory facility has consolidated our role of an importance center of biotechnological excellence for Sandoz and Novartis. In addition to active ingredients, we have started to develop finished biopharmaceutical products in vials, in liquid and lyophilized forms, in all development stages, from the initial phase to transfer into sterile production. At the same time, we have assured excellent working conditions for around 100 new associates.

## Incorporating the best available technology into investments



*Gizela Štampar, Head Lendava Production*

### Which environmental measures go hand in hand with your production achievements and plans?

For a few years now, we have annually invested into the development and modernization of environmental infrastructure. Examples of such investments include constructing containment pools for firefighting water and redirecting the outflow of the used cooling water from the Kopicca stream into the Mura river. In 2015, we reduced the energy costs through successful implementation of projects aimed at energy efficiency. Setting up a new isolation for the intermediate is currently the most important among our investments and will be finished by the end of 2016. It will ensure fully closed handling of the product in accordance with SCC (Strictly Controlled Conditions) requirements under REACH registration of intermediates. The investment includes the formation and centrifugation of wet crystals, as well as drying and packing in the final phase. When choosing technological equipment, Novartis policies were observed and we chose the best currently available equipment. We have initiated two projects and one of them will make a large contribution to environmental protection.

### What measurements of environmental impacts are taken on site?

In accordance with the requirements of the environmental permission, which lays down limit values, emissions to the water and air are regularly monitored. These measurements are taken by the authorized and accredited operators of operational monitoring. Annual operating reports show that no limits were exceeded in 2015. The continuous measurements of emissions at the incineration plant are taken via a control system. The constant monitoring of flue gas parameters assures that the incineration of waste is carried out within the permitted limits.

## The largest single investment of Novartis in Slovenia



*Simon Rečnik, Head Packaging Center Lendava*

### How has the high-tech upgrade of the Packaging Center changed the manner of work and what is its impact on employment?

The change is considerable. By building a logistics center within the Packaging Center Lendava, we obtained a fully automated high-shelving warehouse, a low-shelving warehouse with a receiving and dispatching area, sampling rooms, offices, laboratories and a logistic bridge connecting the high-shelving warehouse with the production building.

This allowed us to move all warehousing areas from the production building and provided preconditions for one of the largest packaging pharmaceutical facilities in the world, giving us the opportunity to further increase our production capacities. The production volume and new production lines led to an increase in the number of employees. As of the end of 2015, we had 252 associates, which is a more than 30% more compared to the previous year, when we had 174 employees. Further growth of the production volume is planned.

### 1.2.3.3 Lendava site

The Lendava site comprises the Anti-infectives Production unit and the Packaging Center.

**The Anti-infectives Production** unit manufactures potassium clavulanate, the key ingredient of a broad-spectrum antibiotic, one of Lek's and Sandoz's leading products. At the Lendava site, gentamycin sulphate is also manufactured and subsequently sold to the most demanding global markets. The manufacture is based on standard biotechnology which is the result of the company's own know-how.

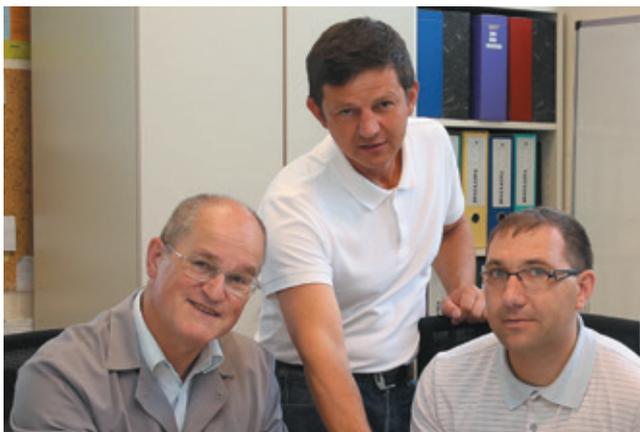
2015 saw a 7% production growth, which satisfied the increasing market needs and achieved a record result in producing potassium clavulanate. By modernizing technological equipment, improving processes, as well as energy and environmental performance, production costs were reduced, which allowed us to increase the competitiveness of the products. Our high level of quality and related good practices was confirmed, as we successfully passed all inspections.

**The Packaging Center Lendava (PCL)** is one of the fastest-growing Sandoz production plants. It is where the filling and packaging of pharmaceuticals in solid dosage forms, which are then released to the markets in more than 60 countries,

takes place. In September 2015, the largest single investment of Novartis in Slovenia was opened, a new PCL logistic center worth EUR 24 million. It comprises a fully automated high-shelving warehouse with more than 11,000 pallet spots, a low-shelving warehouse and a logistic bridge to the production building. In December, we increased our production capacities with two new modern packaging lines.

More than 3.3 billion tablets and capsules were packaged within the year, which is 30% more than in 2014. As of the end of 2015, the number of employees exceeded 250. Further investments into production and auxiliary capacities are planned for the next years.

The number of employees, who come mainly from the local community, is growing constantly. The Lendava facility continues to strengthen its position as one of the major economic entities in this part of Slovenia. The vision of PCL is to become the best Sandoz packaging plant with a high level of customer service. The objectives are an efficient management of packaging complexity and supply of generic portfolio, high responsiveness to changing market needs, internal flexibility, and a comprehensive development of the organization and competences of the employees.



HSE team Lendava (on both photos)

#### 1.2.3.4 Prevalje site

At the Prevalje site, manufacture of a broad-spectrum antibiotic Amoxiclav, one of Lek's and Sandoz's leading products, takes place. It is manufactured in the form of tablets or powders for oral suspensions, and in the form of mixtures and granules, sold in more than 60 countries worldwide.

In 2015, new milestones in the producing of tablets and powders for oral suspensions were reached. The production of tablets increased by 10%, and by a half in the last two years. The production of powders for oral suspensions increased by almost a quarter compared to the previous year, while the production volume of mixtures and finished granules remained at more or less same level.

At the end of the year, a new line for blister packaging was opened, providing additional production capacities and higher flexibility. In 2015, we assured additional funds to prepare projects for further expansion of the Prevalje site.

The total consumption of energy increased by 3.2%, but we managed to reduce the energy per product unit by 8%.

In the last year once again, the Prevalje site successfully passed many customer audits as well as ISO 14001, OHSAS 18001 and EMAS audits.



*HSE team Prevalje*

#### 1.2.3.5 Tenants of business premises

Lek sites also feature business premises that are leased to tenants. Their environmental management is defined in tenancy agreements; a separate article requires them to comply with Lek's officially published and adopted internal regulations related to appropriate and safe use of business premises, including issues such as health, safety and environment.

For tenants, uniform HSE standards apply, according to the principle guest - host, for which the HSE unit provides consulting services and periodical monitoring (see also item Organization, human resources and education in the field of health, safety and environment). Tenants are responsible for the legality of their environmental management.

## Importance of managing production processes



Zlatko Ajd, Head Penicillin Products

### The Lendava site produces potassium clavulanate, while the Prevalje site uses most of this raw material to make one of the best-selling Sandoz products. How do you cooperate?

Both sites are a typical example of what we call vertical integration, so it is highly important the sites function successfully as individual units and at the same time cooperate with each other to ensure the best result for each site, for Lek and the Sandoz Group. Certain business functions from both sites cooperate on a daily basis, and this cooperation is very smooth. Timely deliveries, sufficient volumes and suitable quality – this means that production processes at Prevalje and Lendava are well-managed in every aspect. There are almost no problems. If a problem arises, it is just a minor one and experts from both sites immediately try to find a joint solution and implement corrective measures. For us, it is very important that the Lendava site achieve good production results. With their high quality, regular delivery, fast response and the price of the raw material, they allow our products to be competitive in the largest global markets. I am convinced we will continue to cooperate well.

### What are the development challenges for the site?

Despite many process improvements and high productivity, we are faced with a great lack of production capacities, as the needs for our products keep growing. We are preparing a project to expand our facility in order to provide additional capacities and further development of the site.

## Production improvements as the path to efficient use of natural resources



Roman Burja, Head Production at Prevalje

### In the last years, the production volume at Prevalje has been constantly increasing. Which natural resources are most used and how do you assure efficient use?

For our large growth, it is essential that the use of resources stays behind the growth of production. This allows us to manage our environmental impacts and achieve long-term competitiveness of our products and our site. Natural gas, electricity and water are the main resources used at Prevalje, with electricity constituting more than 50% of costs for energy. Our use of natural resources in the last years has been increasing by 5% on the average, which is approximately by one third more slowly than the production volume.

### How do you achieve such level of efficiency?

In addition to suitable organization and planning of operations in all of our units, the system for continuous improvement of processes plays an important role. This system is highly successful in eliminating steps without added value and seeking improvements in production.

## 1.3 Development and reporting framework

In accordance with the Novartis Corporate Citizenship Policy, we strive for transparent and comparable public reporting. In addition to the economic impacts of our business operations, we also monitor and measure their societal and environmental impacts.

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. The Sustainability Report was last published in September 2015. Even before 2010, we prepared environmental reports and reports within the RCI.<sup>13</sup>

In addition to environmental disclosures, a growing selection of qualitative and quantitative indicators of economic and social impacts (EMAS and GRI core indicators) were included in the report. The process of their identification and selection was carried out by the qualified services, based on the key characteristics of Lek's business activity and situation.

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

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](http://www.novartis.com), [www.novartisfoundation.org](http://www.novartisfoundation.org) and [www.corporatecitizenship.novartis.com](http://www.corporatecitizenship.novartis.com)).

Their collection is performed in compliance with the improvement guidelines provided by Novartis internal HSE audits. For 2015 we report according to GRI G4 guidelines. We have not yet decided to seek external assurance for our sustainability reporting.<sup>14</sup>

In the process of determining the content of the report on sustainable development, 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.<sup>15</sup> In this way we shaped the economic, environmental and social impacts of Lek d.d. operations:

### Material aspects of sustainable development of Lek d.d.<sup>16</sup>

<b>Economic impact</b>	<ul style="list-style-type: none"> <li>- Economic performance</li> <li>- Market presence</li> </ul>			
<b>Environmental impact</b>	<ul style="list-style-type: none"> <li>- Materials</li> <li>- Energy</li> <li>- Water</li> </ul>	<ul style="list-style-type: none"> <li>- Emissions to the air</li> <li>- Waste water</li> <li>- Waste</li> </ul>	<ul style="list-style-type: none"> <li>- Transport</li> <li>- Compliance</li> </ul>	<ul style="list-style-type: none"> <li>- Supplier environmental assessment</li> <li>- Environmental grievance mechanisms</li> </ul>
<b>Social aspects</b>	<b>Labour practices and decent work</b>	<b>Human rights</b>	<b>Society</b>	<b>Responsibility for products</b>
	<ul style="list-style-type: none"> <li>- Employment</li> <li>- Health and safety at work</li> <li>- Training and education</li> <li>- Equal remuneration for men and women</li> </ul>	<ul style="list-style-type: none"> <li>- Non-discrimination</li> <li>- Child labour</li> <li>- Forced labour</li> </ul>	<ul style="list-style-type: none"> <li>- Local communities</li> <li>- Anti-competitive behaviour</li> </ul>	<ul style="list-style-type: none"> <li>- Consumers' health and safety</li> <li>- Labelling of products and services</li> <li>- Marketing communication</li> </ul>

The material aspects listed apply to Lek d.d. and our stakeholders: patients, employees, shareholders, healthcare partners and local communities.

<sup>13</sup> GRI Disclosures G4-28, G4-29, G4-30 | <sup>14</sup> GRI Disclosure G4-33 | <sup>15</sup> GRI Disclosure G4-18 | <sup>16</sup> GRI Disclosures G4-19, G4-20, G4-21

## 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 G4 Guidelines, achieving the core level.

### 1.3.1 2015 reporting characteristics<sup>17</sup>

- Reporting refers to Lek d.d. and all its manufacturing sites in Slovenia.<sup>18</sup>
- All the indicators and disclosures in the present report refer to the calendar year 2015.
- Employee data, key data on financial operations, and economic impacts of business operations were acquired in the financial reporting process for the purpose of the company's annual report compilation in accordance with International Accounting Standards and the 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 health, safety and environmental impacts (HSE). The system of monitoring HSE achievements and the reporting methodology are described on page 63.
- Sustainable development reports are compiled annually and also include the Environmental Statement (EMAS) amended and upgraded at every major change. The reports contains the key data for all sites of Lek, a Sandoz company, 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.
- The report covers the major economic, environmental and social impacts of the organization.
- Lek d.d. holds a 100% ownership stake in the following subsidiaries (as of 31 December 2015): 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 2015, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures.<sup>19</sup>
- To improve reporting accuracy, the following adjustments in the data collection were made for 2015,<sup>20</sup> also impacting the comparability of data with previous years:
  - Because the factor to calculate CO<sub>2</sub> from the electricity supplied changed, the total volume of indirect emissions of greenhouse gases changed in 2014.

## 1.4 Governance, commitments, inclusion

### 1.4.1 Governance and management<sup>21</sup>

#### Lek d.d. Board of Management

In 2015, the Lek d.d. Board of Management was composed of the following members:

**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,  
**Marjan Novak**, Member of the Board of Management, Workers' Director,  
**Daniel Michalek**, Member of the Board of Management, Finance (from 20 April 2015).

#### Lek d.d. Supervisory Board:

**Francesco Balestrieri**, Chairman,  
**Richard Francis**, Deputy Chairman,  
**Martin Jeffrey Rope**, Member,  
**Knut Mager**, Member,  
**Peter Svete**, Member – Workers' Representative,  
**Vesna Premovič**, Member – Workers' Representative.

Lek d.d., a Sandoz company, is a company with 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.

#### Board of Management

The Board of Management runs the company, independently and on its own responsibility. The members of the Board of Management are obligated to provide to the President of the Board of Management 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 an ongoing basis in all the cases important to the company's operations, as follows:

- Profitability of the company, particularly its return on equity.
- Draft business policy and other basic 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.

<sup>17</sup> GRI Disclosures G4-22, G4-23, G4-28, G4-29, G4-30 | <sup>18</sup> GRI Disclosure G4-17 | <sup>19</sup> GRI Disclosure G4-13 | <sup>20</sup> GRI Disclosures G4-22, G4-23 |

<sup>21</sup> GRI G4-DMA, GRI Disclosure G4-34

- 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

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.

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

The Supervisory Board performs due supervision of the company's management through the reports provided by the Board of Management on a regular basis at Supervisory Board meetings, and on the basis of other notifications the Board of Management assesses as significant in accordance with statutory and internal regulations. In this way, the Board performs 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.

For their work, the members of the Supervisory Board of Lek d.d. receive no compensation or other rewards. Being also Lek/Novartis employees, their duties as Supervisory Board members form part of their job-related obligations.

Appointment of the members of the Supervisory Board of Lek d.d. is confirmed by the Executive Committee of Novartis, the highest governance body, based on the skills 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. Similarly to other levels of the company's functioning, supervisory bodies also operate in accordance with the Diversity & Inclusion initiative. 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 ZGD-1, an obligation set for all Novartis Group employees in the Novartis internal Conflict of Interest Policy.

## 1.4.2 Employee participation in company management<sup>22</sup>

At Lek, a Sandoz company, employee participation in company management is carried out in accordance with the Worker Participation in Management Act (e.g. ZDR-1, ZVZD1). 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, and comprises fifteen members. 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' interests 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. Regular and smooth communication between the stakeholders contributes to smooth cooperation and achievement of high co-management level.

In 2015, 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 the annual assessment of performance, on the operations of Pokojninska družba A, etc.).

Workers' Council committees carried out joint consultations regarding staffing issues and the issues of employees' health and safety. In cooperation with the syndicate, the specialist services and the Workers' Director, amendments to internal acts regarding the rules on disciplinary responsibility, the management of vacation units and supplementary pension insurance were discussed and harmonized. The Workers' Council gave its consent to the 2016 work calendar, revised workplace risk assessments, certain internal acts, pricelist for renting holiday units and the adjusted model for performance remuneration.

All Lek sites hosted Workers' Assemblies featuring the project "I Work Safely and Responsibly", and presenting the role and responsibilities of the Workers' Council and the Workers' Directors, as well as the topical information from the company's management.

The members of the Workers' Council were actively involved in the Community Partnership Day, and provided their own funds to support the collection of food and personal hygiene items for the families in need.

At the end of the year, the external audit of internal and external communication of the Workers' Council representatives was successfully passed. The Workers' Council regularly posts monthly minutes from meetings and other topical information relevant for the employees (information regarding labour legislation, taxes, links to important acts, institutions etc.). The communication also takes place through monthly e-mails after each Workers' Council meeting.

Participation of employees in key projects to optimize business processes and improve environmental performance is described under Item 2.1.4.

<sup>22</sup> GRI G4-DMA

### 1.4.3 Shareholder overview and inclusion<sup>23</sup>

We include diverse groups of stakeholders in our operations in order to understand their needs and expectations, and subsequently improve access to healthcare. On the basis of corporate citizenship principles, we endeavour to maintain an open dialogue, seeking the most appropriate forms of cooperation.

Our activities 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).

#### Lek's stakeholders scheme



<sup>23</sup> GRI Disclosures G4-24, G4-25

### 1.4.3.1 Stakeholder engagement<sup>24</sup>

In accordance with the Novartis policy, we include stakeholders in different ways. 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 2015 was postponed by Novartis to 2016. 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 endeavour 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.

A large part of our work is devoted to local communities, by listening to the initiatives provided by the local population, and, pursuant to Slovenian laws, implement them in practice, where possible.

## Lek's stakeholders' interests<sup>25</sup>

Stakeholders	Stakeholders' interests
Employees	<ul style="list-style-type: none"> <li>• Continuous care for healthy and safe work environment</li> <li>• Improving knowledge and skills</li> <li>• Equal opportunities for career development</li> <li>• Employment safety</li> <li>• Balance between professional and private life</li> <li>• Awareness on responsible treatment of the environment</li> <li>• Diversity and inclusion</li> <li>• Participation in company development and management</li> <li>• Awareness and participation in decision-making regarding the policies and measures for health and safety at work, and environmental protection</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Safe, efficient and high-quality medicinal products</li> <li>• Affordable medicinal products</li> <li>• Development of new and efficient medicinal products</li> <li>• Functional packaging of medicinal products with low environmental impact</li> <li>• Responsible handling of medicinal products and waste medicines</li> <li>• Cooperation with patient groups</li> <li>• Accountable and transparent business practices</li> </ul>
Owners	<ul style="list-style-type: none"> <li>• Accountable and transparent business practices</li> <li>• Good business results</li> <li>• Company's high developmental capacity</li> <li>• Patient trust</li> <li>• Satisfaction of employees</li> <li>• Compliance with the regulations and Novartis' health, safety and environmental standards</li> <li>• Efficiency in consumption of natural resources</li> <li>• Company's reputation</li> </ul>
Healthcare professionals and healthcare providers	<ul style="list-style-type: none"> <li>• Safe, efficient and high-quality medicinal products</li> <li>• Accountable and transparent business practices</li> <li>• Providing information on new medicinal products</li> <li>• Providing information on proper medicine use</li> <li>• Proper product labelling</li> <li>• Responsible handling of medicinal products and waste medicines</li> </ul>

<sup>24</sup> GRI Disclosures G4-26, G4-27 | <sup>25</sup> GRI Disclosures G4-24, G4-27

## Stakeholders

## Stakeholders' interests

Customers	<ul style="list-style-type: none"> <li>• Safe, efficient and high-quality medicinal products</li> <li>• Affordable medicinal products</li> <li>• Proper product labelling and information clarity</li> <li>• Responsible handling of medicinal products and waste medicines</li> </ul>
Regulators	<ul style="list-style-type: none"> <li>• Safe, efficient and high-quality medicinal products</li> <li>• Adherence with legislative requirements regarding pharmaceuticals, health, work safety, protection of the environment, marketing, and product advertising, etc.</li> <li>• Proper product labelling</li> </ul>
Academia and scientific community	<ul style="list-style-type: none"> <li>• Participation in development and research projects</li> <li>• Knowledge and practice exchange</li> <li>• Inclusion of environmental aspects into the development of new products</li> </ul>
Professional and industry associations	<ul style="list-style-type: none"> <li>• Exchange of opinions and promotion of good practices, including HSE practices, in industry and professional associations</li> <li>• Industry reputation</li> </ul>
Suppliers	<ul style="list-style-type: none"> <li>• Good business relations</li> <li>• Timely deliveries, adequate prices for goods and services</li> <li>• Awareness of risk factors in work environment</li> <li>• Adherence to legislative and Novartis' standards in protection of the environment</li> </ul>
Local communities	<ul style="list-style-type: none"> <li>• The company's involvement in life of the local community</li> <li>• Support for cultural, sports and humanitarian organizations</li> <li>• Employment of workers from the local area</li> <li>• Cooperation with institutions and suppliers from local area</li> <li>• Efficiency in consumption of natural resources</li> <li>• Successful management of environmental impacts and adherence to safety and environmental legislation</li> </ul>
Media	<ul style="list-style-type: none"> <li>• Providing information on business and events in the company</li> <li>• Open dialogue and accessibility of data related to environmental and social impact in public interest</li> </ul>
Non-governmental institutions	<ul style="list-style-type: none"> <li>• Support and cooperation on projects</li> <li>• Good social accountability practices</li> <li>• Accessibility of data related to environmental and social impact in public interest</li> </ul>



In 2015, we received seven complaints from local residents.<sup>26</sup>

The Ljubljana site received four complaints. In the first case, the complaint was filed by a local resident who had also filed complaints in 2011, 2012, 2013 and 2014. In the past years, silencers had been installed and the noise level was reduced significantly below limit values. In 2015, additional noise measurements in the environment were carried out, which showed that our company is not the source of the noise that was disturbing for the local resident. In the second case, the authorized contractor disposed confidential documentation in the public container for paper packaging. The documentation was immediately removed from the container. The third case concerned a complaint regarding food smell; however, our investigation showed that it did not

originate from Lek's kitchen. Another complain at the Ljubljana site concerned the ignition of waste at our waste collector, and, following the investigation, proved to be irrelevant.

The Mengeš site received a complaint regarding water pollution, i.e. the Pšata spillway, which originated in the washing of the trafficked areas for trucks of external contractors at our site. The water was analyzed and discussions were held with the external contractors.

At the Prevalje site, we received two noise-related complaints. In both cases, dusted filters were subsequently replaced. We continued to implement technical measures to reduce noise, and the restoration work is expected to be completed by the first half of 2016.



*Open Doors Day at the Lendava site*

The local community is also involved through Open House Days. In 2015, an Open House Day was organized in Lendava and near-by residents were able to come. The interested visitors were presented both key areas of work that take place at the site, Anti-infectives Production and Packaging Center Lendava. The response was excellent, with more than 300 people attending the event.

The information about the impacts of our business is published in Lek's Sustainability Reports for each year, and the most recent one is available at <http://www.lek.si/en/corporate-responsibility/>.

<sup>26</sup> GRI Indicators G4-EN34, G4-SO1

## Open House Day for the local community residents



Corporate communications team (from left): Mojca Pavlin, Špela Jurak and Katarina Klemenc.

**Katarina Klemenc, at the Corporate Communication department you are in charge of the involvement of Lek, a Sandoz company, in the life of the local community. The Open House Day gives an opportunity to strengthen this cooperation. Is it well-accepted in the local communities?**

We are the largest company or one of the leading employers in every local community we operate in, so the public interest in our work is high. People tend to accept industry in their environment with more trust if they have the opportunity to see it from the inside, hear the presentations and talk to the employees. Trust from the local community has not been achieved overnight. For seven decades, we have fostered regular and transparent relationships with the local communities. Lek, a Sandoz company, started to organize Open House Days more actively and in a more structured manner more than a decade ago. Now, they take place at each Lek site in Slovenia.

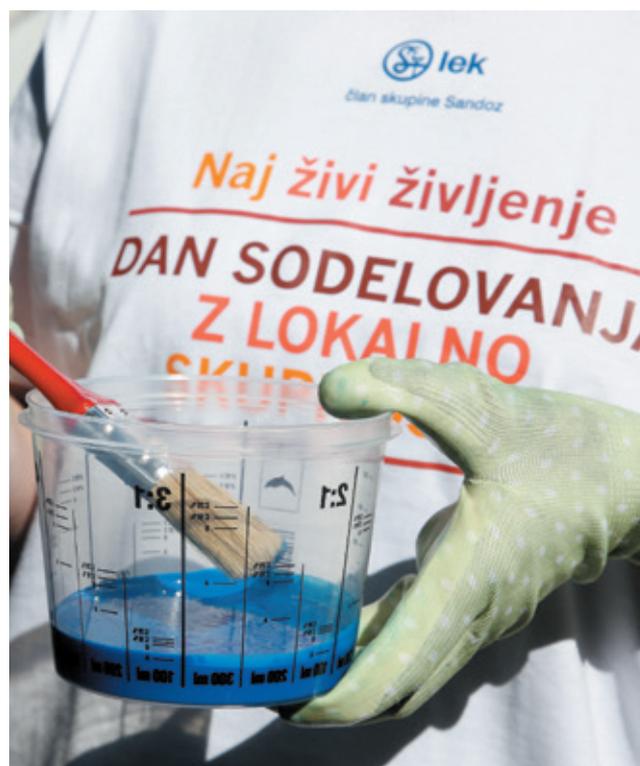
**What are the most common questions asked, what is most interesting to the nearby residents?**

In the recent period, they inquire about employment possibilities in our company, which is a reflection of our time and the current social situation. In the last four years, we have opened more than 1,100 new positions, so their interest is easy to understand. The visitors want to know about our environmental responsibility, how we define and implement it, and how the growth of our operations affects the environment they live in. Increased attendance at inaugurations of new facilities such as Packaging Center Lendava demonstrates their strong interest in our new achievements. Feedback we receive during or after the event is very precious.

**Many employees take an active role in organizing Open House Days, they provide tours of the site and reply to questions. How do they accept their role?**

They participate with interest and for many of them this is a completely new experience. They provide help to the main organizational team in the Corporate Communications in preparing the contents and develop skills of public speaking. The event is demanding in terms of contents and organization, as up to 600 visitors tour the site at the same time. Nevertheless, each spontaneous praise pays off the invested effort.

## Unselfish help to people around Slovenia



*With almost 26,000 hours of voluntary work, we helped more than 11,000 people and nearly 50 organizations.*

For the eleventh year, our volunteers helped individuals and non-governmental organizations through the **Community Partnership Day**. In April and May, employees from all Novartis divisions in Slovenia (Ljubljana, Mengeš, Lendava, Kranjska Gora and Prevalje) provided unselfish help to people around Slovenia. We tidied up the surroundings and premises of non-governmental organizations, donated blood, socialized with pensioners and children with special needs, collected food and sanitary items for the homeless and the Slovenian Association of Friends of Youth.



## Students transferring knowledge into practice



On the photo (from the left): President of the Organizational Board of regional BioCamp 2015 Darja Ferčej Temeljotov, PhD, BioCamp winners Julian Kellner and Žiga Perko, and the President of the Board of Management of Lek, a Sandoz company, Vojmir Urlep.

Lek, a Sandoz company, organized a science event for the most promising science students from the region, **Regional BioCamp 2015**, for the **fifth time in a row**. At the three-day forum, the students met with acclaimed professionals and leading managers, thus obtaining experience in pharmaceutical industry research. The forum was attended by 35 students from 13 countries, and they discussed new strategies for the treatment of autoimmune diseases, with

an emphasis of rheumatoid arthritis, the most common autoimmune disease. The winners of the Regional BioCamp 2015 were **Žiga Perko** and **Julian Kellner**, who were, as a reward, invited to participate in the global Novartis BioCamp 2015 in Basel, Switzerland. The award for the **best team** went to the group composed of Laura Avogaro, Andonela Janeva, Zlatko Joncev, Julian Kellner, Daniela Milosheska, Janja Mirtič and Omar Naneh.

## Rdeči noski Clowndoctors with our support in Murska Sobota

Lek, a Sandoz company, has been cooperating with the Rdeči noski Clowndoctors association for seven years, caring for the youngest as well as adult patients. Sincerity and humor of clowndoctors, professional artists, make hospital days easier for the patients. In 2015, we provided additional funds allowing them to make regular visits to the pediatric department of Murska Sobota General Hospital.



First regular clown physicians visit at the Murska Sobota general hospital

### 1.4.4 Lek's commitment to external initiatives and principles<sup>27</sup>

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) (<https://www.weforum.org/>). Their guide-lines were also embraced by Lek, a Sandoz company.

At Lek, the development and manufacture of medicinal products strictly comply with Pharmacopoeia requirements, WHO and OECD standards; requirements of the FDA and the 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.

<sup>27</sup> GRI Disclosures G4-14, G4-15, G4-16, G4-56

## 2. ENVIRONMENT



*The employees visited the Permacultural zone Dole, where they learnt about the water self-sufficiency, food production, energy production and the biomass.*



*Apart from employment opportunities, local community residents are particularly interested in environmental impacts and their management.*

## Health, safety and environment systems

### Health, safety and environment policy (HSE)<sup>28</sup>

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 efficacy 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. Fulfilment 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.

- 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 sustainability aspects of our operation are published on our website [www.lek.si/en/](http://www.lek.si/en/).**

### Compliance with HSE laws and standards<sup>29</sup>

We operate in compliance with legal and other requirements. The key environmental management regulation is the Environmental Protection Act. It dictates the contents of other implementing regulations in the field of water, noise, waste, packaging materials, atmospheric emissions, light pollution, storage of hazardous liquids, and other areas related to environmental protection.

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

Being an IED<sup>30</sup> certified company, our Lendava and Mengeš sites operate in compliance with High Large-Scale Pollution Potential. Both existing IED permits also cover the release of greenhouse gases from cooling devices, whereas these types of emissions at the Ljubljana and Prevalje sites are included in permits dealing with atmospheric emissions. All Lek sites comply with the Decree on Limit Values for Atmospheric Emissions of Volatile Organic Compounds from Installations Using Organic Solvents. As a low-risk source, the Mengeš site is obligated to adhere to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences.

<sup>28</sup> GRI Disclosures G4-14, G4-DMA | <sup>29</sup> GRI G4-DMA | <sup>30</sup> See Glossary of key terms on page 84

## Health, safety and environment systems

New legal and other requirements are promptly and efficiently transferred in our work processes and practices. Authorized persons 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 2015, a total of 7 inspections were carried out at all of the four sites. In the area of environmental protection three rulings were issued at the Prevalje site with an imposed fine. The rulings were contested due to incomplete or erroneously established actual state, and incorrect application of substantive law. In one case the proceedings were suspended. In the second case, the body of appeal found that the appeal was justified and returned the case to the court of first instance. We are still waiting on the resolution of the third case. No irregularity was found in the environmental area. In the field of fire safety at the Lendava site, we received a warning regarding identified deficiencies which were resolved within the prescribed period. In the field of health and safety at work, we received a temporary ban for working with certain work equipment at the Mengeš site (certain deficiencies of work equipment) due to an injury of an associate. In 2015, we were involved in inspections covering the quality of operational processes and products (e.g. JAZ-MP, FDA, etc.) related to the area of health checks and waste management.

### All our sites implement the Novartis Environmental Management System, EMS.

Environmental permits issued to Lek, a Sandoz company, by the Slovenian Environment Agency, 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.

In accordance with legal requirements, all Lek sites have acquired environmental permits with related amendments.<sup>31</sup>

- Environmental permit for operation of a device with a high pollution potential (IED) for the Lendava site, Permit No. 35407-172/2006, dated 15 April 2010.
- Decision amending the environmental permit for the Lendava site, No. 35407-37/2011-33, dated 12 July 2012.
- Decision amending the environmental permit for the Lendava site, No. 35406-33/2012-4, dated 15 March 2013.
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2014-8, dated 23 January 2015.
- Decision amending the environmental permit for the Lendava site, No. 35406-39/2015-10, dated 27 January 2016.
- Environmental permit for operation of a facility with a high pollution potential (IED), 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.
- Environmental permit for operation of a facility using VOCs, for the Ljubljana site, Permit No. 35430-19/2006, dated 30 January 2008.
- Decision amending the environmental permit for operation of a facility using VOCs, for the Ljubljana site, No. 35430-6/2010, dated 4 March 2011.
- Decision amending the environmental permit for the Ljubljana site, No. 35430-9/2012-4, dated 11 September 2012.
- Decision amending the environmental permit for the Ljubljana site, No. 35431-15/2012-2, dated 20 November 2012 – permit extension.
- Decision amending the environmental permit for the Ljubljana site, No. 35431-1/2015-4, dated 8 April 2015.
- Environmental permit for operation of a facility with regard to emissions into waters for the Ljubljana site, Permit No. 35441-339/2006, dated 8 November 2010.
- Decision amending the environmental permit with regard to emissions into waters for the Ljubljana site, Permit No. 35444-58/2013-2, dated 18 March 2014.
- Decision amending the environmental permit with regard to emissions into waters for the Ljubljana site, Permit No. 35444-68/2014-2, dated 7 October 2014.
- Environmental permit for operation of a facility with regard to emissions into waters for the Prevalje site, Permit No. 35441-338/2006, dated 2 February 2011.
- Decision amending the environmental permit with regard to emissions into waters for the Prevalje site, Permit No. 35444-49/2015-2, dated 28 September 2015.
- Environmental permit for operation of a facility using VOCs, for the Prevalje site, Permit No. 35430-1/2013-6, dated 21 August 2013.
- 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, 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.

<sup>31</sup> GRI G4-DMA

## Health, safety and environment systems

- 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), 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), 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<sup>32</sup>

The primary direct environmental aspects and impacts of Lek's operations include the use of energy and water, emissions to the air, emission to water, waste, noise and, to a lesser extent, odour and the use of soil. Indirect environmental aspects mainly include impacts from suppliers/contractual service providers (Items 2.1.5 and 6.1.2).

Our active environmental policy is focused on the implementation on a number of activities to protect the environment which often go beyond mere fulfilment of statutory provisions. The most important among them are the upgrading and improvements of existing measures and the introduction of new ones. 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.

With efficient resolution of HSE related complaints and by taking appropriate corrective action, we provide a safe and employee-friendly work environment, mitigate business related environmental risks and contribute to creating the company's goodwill. Resolving HSE related complaints is carried out in accordance with internal procedures which require the person responsible to start an investigation within 24 hours. With respect to the investigation outcome and justification of the complaint, the head of the HSE site ensures that necessary corrective measures are taken. The entire process is documented and archived.

In 2015, we were not charged with any penalties for non-compliance with environmental laws; however, we received seven external complaints, which are described under Item 1.4.3.1, together with action taken.

### 2.1.1 Specifics of business operations and disparities in data collected

When assessing and interpreting our environmental impacts, certain factors have to be taken into account. They primarily refer to the efficiency of the use of materials, energy resources, water, waste, atmospheric emissions and wastewater per tonne of product. Namely, there are considerable differences in product and API weight. For example, the weight of biosimilars is lower compared to certain self-medication drugs, yet their manufacture requires larger quantities of water and energy resources, and their financial value is higher as well. These disparities become particularly noticeable when seeking a common basis for the preparation of data for Lek, a Sandoz company. They are also apparent at the Ljubljana and Mengeš sites, which have an extensive and versatile product portfolio.

In addition, our operations are also characterized by year-to-year adjustments of the production program to the changes in demand, which was rather noticeable this year. The manufacturing structure therefore varies from year to year.

As a result of the above, year-on-year comparability of efficiency data and of individual production sites is compromised.

<sup>32</sup> GRI G4-DMA, Disclosure G4-14, GRI Indicators G4-EN29, G4-EN34

## Exchange in good environmental practice



Panels with photos of protected plants in the wider environment of our sites on the occasion of the World Environment Day.

### 2.1.2 Environmental protection investments and achievements<sup>33</sup>

The basis for our environmental policy is continuous improvement of environmental efficiency of our production processes and investing in environment protection in order to restrict our environmental impacts. In 2015, such investments amounted to EUR 3.2 million.

Major investments, improvements and achievements are given below:

- Building of a new intermediate isolation at **Lendava** was initiated to be completed by the end of 2016. It will ensure fully closed handling of the product in accordance with SCC (Strictly Controlled Conditions) requirements under EU REACH Regulation. Another investment was made at Lendava, i.e. procedure for waste reagent regeneration.
- We continued projects aimed at reducing atmospheric emissions and carried out additional redirection of emissions from production plants to a Regenerative Thermal Oxidizer – RTO at the **Mengeš** site. In the last seven years, Lek, a Sandoz company, built four facilities for a more efficient and economic reduction of emissions based on thermal gas oxidation: two at Ljubljana, one at Mengeš and one at Prevalje. Setting up an identical facility is planned for Lendava as well.
- A new emissions washer for waste air at the joint discharge from fermentation was installed at **Mengeš**. An environmental permit for the combustion boiler with an option for co-incineration of high-calorific non-halogenated waste solvents was also obtained.
- We continued the project of testing water-based coating of tablets at the **Prevalje** and **Ljubljana** sites.
- A weighbridge was installed at **Ljubljana** facilitating the control of the volume of waste produced. The heat station was renovated and a noise study conducted.
- At the **Prevalje** site, a study involving noise emission measurements was conducted, and elimination of noise sources has been initiated. Additionally, at Prevalje, old windows were replaced with energy-efficient windows.
- At the company level, we continued the project "packaging", reducing the use of raw materials. With smaller packaging sizes, we also reduced the impact of transport on the environment (lower fuel consumption, lower CO<sub>2</sub> emissions).

In June, on the occasion of the World Environment Day, Lek's environmental week entitled **Protect the Environment** was organized at all our sites.

We set up panels to present protected plants in our wider environment, and posted many useful pieces of advice on the bulletin board on how to make savings in energy and other resources, where and how to recycle used objects, and so on. Through our intranet, our associates shared some useful suggestions and their experience in how to protect the environment at home and at workplace. They told us how they reduce electricity and water consumption and their impact on the environment by using home-made cosmetic preparations, hygienic measures, and even shared some cooking advice. All participants were awarded an energy-saving light bulb.

- The Environment Directorate-General of the European Commission awarded us with the "EMAS Early Bird Certificate", recognizing us as one of the first companies in Slovenia registered with the EMAS scheme, the EU Eco-Management Audit System.

### 2.1.3 Verification of established standards<sup>34</sup>

In 2012, Lek, a Sandoz company, with all of its four sites, became the first Slovenian pharmaceutical company to join the EMAS scheme, the EU Eco-Management Audit System. 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 2014 reflects a reliable, credible and correct image of all the organizations/sites activities, within the scope mentioned in the environmental statement.

To a series of successful audits and inspections, we added new ones in 2015. Other external checks also confirmed the compliance of our operations with the quality standards of conduct in the field of the environment ISO 14001, health and safety at work OHSAS 18001 and the Responsible Care Initiative.



<sup>33</sup> GRI Indicator G4-EN31 | <sup>34</sup> GRI G4-DMA

## 2.1.4 Optimization of business processes

Our efficiency is continuously improved through many projects aimed at optimizing business processes. This is also integral to our business strategy and environmental policy. The key business process optimization projects include:

### THINK SANDOZ Initiative

In 2012, the THINK SANDOZ Initiative, a web-based idea management program, went live. The initiative brings excellent results, as the ideas implemented brought more than EUR 6.2 million of directly measurable savings. In 2015, our associates from all four sites contributed 1,174 ideas (959 in 2014), of which around 566 were adopted. Over 421 ideas have already been applied in practice. Interesting suggestions and ideas were proposed by as many as 680 different associates, which represents 12% of the employees.

### European Integrated Facilities Management (EIFM)

In 2015 once again, the IFM was adapted to the newly chosen corporate directions. Through NBS (Novartis Business Services), Novartis decided to amend the IFM model of co-operation with a selected supplier, and replaced it with another model. As a result, the past year had been characterized by the preparation for the planned changes which entered into force on 1 January 2016. The changes will be considerable and will bring many new developments in the field of charging for the services and allocating costs within the corporation. There will be new developments in the field of measuring quality of service providing better control of cost effectiveness of the services performed.

### Anti-explosive protection – ATEX

The anti-explosive protection is continuously maintained at all Lek units. Preventive visual and detailed inspections of each piece of equipment are carried out in accordance with the Rules on Anti-explosive Protection and the standard regulating the types of inspection for each type of anti-explosive equipment (IEC 60079-17:2013, Explosive Atmospheres – Part 17: Electrical installations inspection and maintenance).

### LOTO

Lockout-tagout (LOTO) system has been introduced to all of our four sites. The system is aimed at increasing the safety of our associates during maintenance on the installations and reconstruction work during major annual maintenance work.

Detailed inspections of the installations and identifying pieces of equipment to be secured using the LOTO system are underway in order to prevent any energy that might harm the people present or the equipment from being activated during maintenance.

## 2.1.5 Indirect environmental impacts<sup>35</sup>

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. Indirect environmental impacts are restricted by signing an agreement, because 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.<sup>36</sup> 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 restrict transport by using more frequently teleconferences and videoconferences instead of long business trips. We regularly monitor fuel consumption, mileage and CO<sub>2</sub> emissions for all the fleet cars. This data is reported quarterly into the Novartis database.

For 133 company cars in 2015 (124 in 2014), a total traveling distance of 3,514,690 km (3,227,342 in 2014) was recorded, with fuel consumption of 221,756 litres (231,360 in 2014) and CO<sub>2</sub> emissions of 444 tonnes (430 in 2014).

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 (see Item 2.2.4).

## 2.2 Raw materials and natural resources

### 2.2.1 Recycling of hazardous and non-hazardous waste

Waste reuse and recycling are integral parts of our API production processes. We recycled and reused 88% of the total quantity of organic solvents, which is by 3% less than in 2014. In Lendava, the leading site in terms of waste reuse in recycling, the percentage of reused organic solvents amounted to as much as 96% (1% less compared to the previous three years), and to 75% in Mengeš. Upon completing the project of

regenerating additional solvent in 2016, the share of regeneration in Lendava is expected to further increase. The remaining solvents which, according to the pharmaceutical industry criteria, fail to achieve a level of purity sufficient for reuse are collected separately in accordance with their composition and calorific value. Further treatment or disposal is the responsibility of authorized contract providers.

At the Mengeš site, non-halogenated solvent waste with solvent content above 80% suitable for co-incineration in a natural gas burning device is used as a secondary fuel for

<sup>35</sup> GRI Indicator G4-EN30 | <sup>36</sup> GRI Indicators G4-EN33, G4-LA15

the operation of a device generating heat and vapour for manufacturing purposes, saving almost 20% of the natural gas volume. Since adequate combustion conditions are provided, emissions generated in the process are comparable to those resulting from the combustion of environment-friendly energy resources such as natural gas and light industrial fuel. In 2014, we replaced the existing steam boiler at the Mengeš site with a new boiler with better thermal efficiency. In the beginning of 2016, we obtained the environmental permit for co-incineration of non-halogenated waste solvents in the new boiler.

In the field of non-hazardous waste, systemic upgrades of segregation, collection and preparation of waste for recycling are continuously carried out. All biodegradable waste (waste mycelium, waste purple coneflower (*Echinacea*) and fennel plants, was redirected to a bio-gas works for reprocessing.

## 2.2.2 Mass flow of materials

Changes in the structure and volume of pharmaceutical production cause an annual fluctuation of mass flow of materials at some of our sites. There is no such 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. In 2015, we recorded an increased use of raw materials (by 4%) due to increased production volume at all sites.

**Table 3: Annual mass flow of various materials used\* in tonnes<sup>37</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	t	6,811	8,804	16,898	3,858	36,371
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

\* 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).

## 2.2.3 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

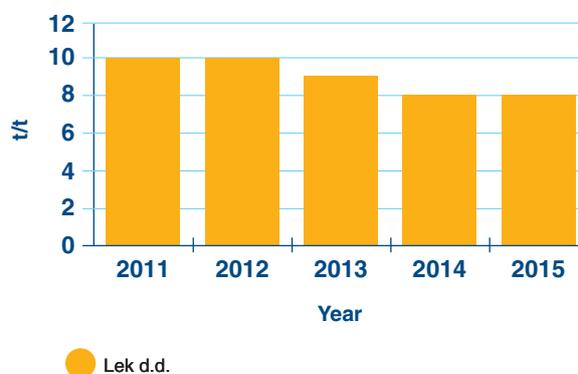
of product. The quantity of raw materials used per tonne of API/product has been decreasing for a number of years. In 2015, we increased the efficiency of the use of materials by almost 7% compared to the previous year, and by more than 18% between 2011 and 2015.

**Chart 2: Efficacy of the use of various materials per unit of product<sup>38</sup> – by site and total**

Efficacy of the use of raw materials per unit of products



Efficacy of the use of raw materials per unit of product – Lek total



## 2.2.4 Sustainable packaging approach<sup>39</sup>

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 revised **Sandoz global packaging catalogue** entered into force in 2015 serving as a mandatory guideline for all Sandoz sites. Our associates from the Packaging Center Lendava played an important role in revising the catalogue. The Sandoz global packaging catalogue prescribes a comprehensive selection of recommended materials for the packaging, dimensions and types of primary and secondary packaging, and includes other Sandoz guidelines concerning packaging material and packaging. According to the basic principle of the guidelines, the packaging material must, in addition to meeting all regulatory requirements, generate minimum waste and use minimum amount of energy in production.

Sustainable principles also apply to the selection of suppliers, who must provide packaging which is free of any heavy metals or hazardous substances and is packed rationally. The Sandoz suppliers of packaging must meet at least another one of the following conditions: the packaging can be re-used, recycled or reprocessed in terms of energy or organic substance.

The two production sites manufacturing finished dosage forms are the major consumers of packaging material: Ljubljana with 62% and Prevalje with 34.5%. At the Mengeš and



*Team of associates from the Packaging Center Lendava participating in the revision of the Sandoz global packaging catalogue*

## 2.2.5 Efficiency of water and energy resource use

For a number of years, we have been continuously increasing the production of products manufactured with complex and energy demanding processes. The improvement of energy efficiency is therefore a permanent task.

Due to changes in the volume and structure of production, the consumption of energy and water at our sites fluctuates. Major variations recorded at the Ljubljana and Mengeš sites are due to the versatility of the sites' portfolios. The manufacture of individual products at the mentioned sites is subject to major market fluctuations. In Prevalje and Lendava, the product portfolio is relatively stable. Therefore, between-year comparison reflects the trends in efficiency of water and energy resource use.

Lendava sites, packaging consumption accounts for less than 4% of the total packaging consumption of Lek, a Sandoz company.

### Results of improvements in 2015

The **EFB (Efficient Folding Box)** global initiative managed by the Sandoz Global Packaging Development enables project teams to cooperate with sales service to identify potential opportunities to improve the existing solutions.

- In 2015, the Lendava MS&T team improved the use of foils by 50% and by 35% the size of cardboard cartons for Amlopin.
- The MS&T team from Solids in Ljubljana renewed the packaging for Levetiracetam, providing the customers with containers instead of large cardboard cartons. By changing the trade dress, it reduced the size of primary and secondary packaging for two Candesartan strengths.

At Lek, a Sandoz company, improvements in packaging are a continuous process, because they can have a large environmental and economic effect. By reducing primary and secondary packaging, better yield in tertiary packaging (pallets) is achieved, which saves the money for transport.

The capacity and efficiency of packaging lines also increase, and the deviations in the packaging process are smaller.

Lower costs allow for a lower product price, which increases the competitiveness of our medicines for both the users and patients.



*MS&T team from the Solids unit in Ljubljana*

In fact, efficiency for the Lendava site is higher, as only the production outputs for the Lendava Production site are included in reporting. The activities of the other unit, Packaging Center Lendava, are not included, because no finished dosage forms are manufactured there. The production output of the Packaging Center Lendava is not recorded in the uniform Novartis DMS (Data Management System) in order to avoid the duplication of quantitative data. This is because the Lendava site also packs products from other Novartis sites around the world. These sites report their production outputs to DMS, even though they are packed in Lendava. In 2015, despite the increased capacities of the packaging center, the use of water and energy was decreased, not only per tonne of product but also in the absolute measure.

<sup>39</sup> GRI G4-DMA

**Table 4: Efficiency of energy resource use per unit of product<sup>40</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)*
2011	GJ/t	2,004	185*	677	53	307*
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

\* Due to the improved method for acquiring data on the realization of various finished pharmaceutical products manufacture and on the mass flows of raw materials at the Ljubljana site, there was a change in the data for previous years.

The efficiency of energy use was increased at all sites except Mengeš, where it was reduced by 18%. The improvement in efficiency was highest at the Ljubljana site (11%), followed by Lendava (7.5%) and Prevalje (7%). At the level of Lek, the efficiency increased by slightly more than 7%. Compared to 2011, the use of energy per tonne of product was reduced by 71 GJ, or 23%.

Lendava is still the best example of continuous reduction of energy consumption per unit of product due to the uniform production portfolio over a longer period of time. As shown in Table 4, energy consumption per tonne of product at Lendava was reduced by 615 GJ, or 31%, between 2011 and 2015. If the production realized in the Packaging Center Lendava production were taken into account, the reduction would be even higher.

## 2.2.6 Abandoning the use of hazardous volatile organic compounds

Hazardous volatile organic compounds are being continuously replaced by less harmful substances, thereby significantly improving the process of tablet film-coating. At the Prevalje site, the studies for replacing the ethanol phase by the water phase in the film-coating process were continued after methylene chloride had been fully replaced with

ethanol in 2011. At the Ljubljana site, ethanol-based coating of one omeprazole category was successfully replaced with waterbased coating. Our efforts to replace more hazardous chemicals with less hazardous continue at the Mengeš site. In 2014, a modified production process of one of the active ingredients was successfully implemented and the use of dichloromethane and oxalyl chloride was eliminated from the technological process. The number of optimized technological processes always positively influences the environment, in particular because developmental processes always include environmental aspects.

## 2.3 Energy

### 2.3.1 Energy consumption

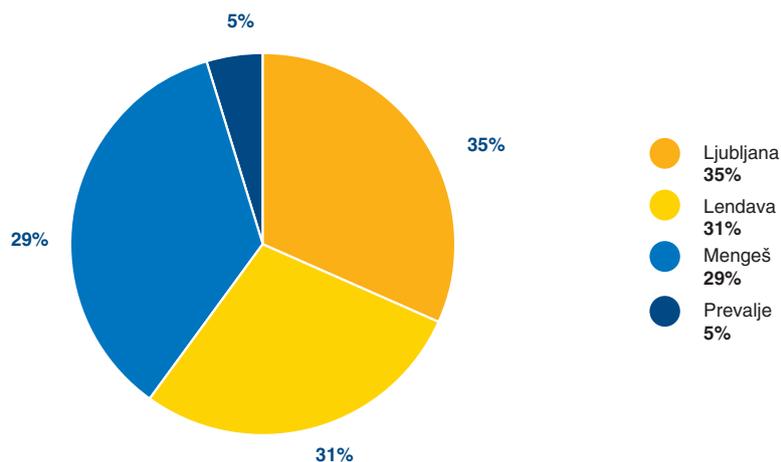
**Table 5: Total consumption of energy<sup>41</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	GJ	391,965	358,339	350,825	60,253	1,161,382
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

At the Lek level, the overall energy consumption was by more than 3% higher than in the previous year. The largest increase was recorded at the Mengeš site (by 6%), where three new production units began to operate, followed by the Ljubljana site (by 3.9%) and the Prevalje site (by 3.3%). Less energy was used at the Lendava site, by 1.4%.

In terms of the total energy consumption, the Ljubljana and Lendava sites have the highest proportion with a 34.7% and 31% share, followed by Mengeš with 28% and Prevalje with 5.4%.

**Chart 3: Distribution of energy by sites**



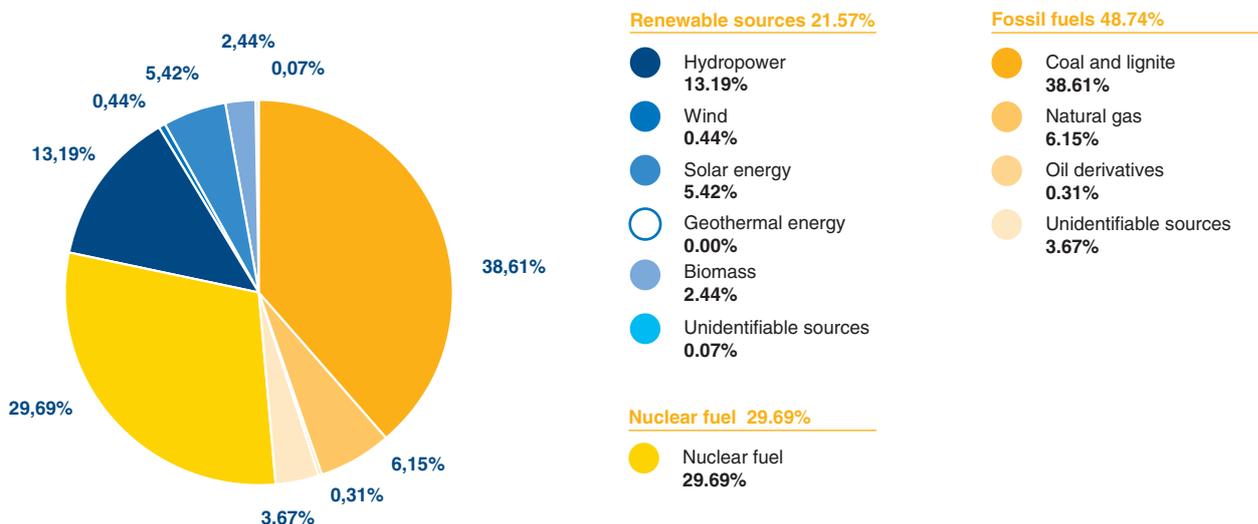
At the Mengeš site, waste solvents are utilized as secondary fuel for the operation of the steam boiler that generates heat and steam for technological purposes. At the Lendava

site, the share of renewable energy amounts up to 1%. It is obtained from the incineration of organic waste generated in fermentation production.

**Table 6: Structure of purchased electricity sources**

	Share in %
<b>Fossil fuels</b>	<b>48.74%</b>
Coal and lignite	38.61
Natural gas	6.15
Oil derivatives	0.31
Unidentifiable sources	3.67
<b>Nuclear fuel</b>	<b>29.69%</b>
<b>Renewable sources</b>	<b>21.57%</b>
Hydropower	13.19
Wind	0.44
Solar energy	5.42
Geothermal energy	0.00
Biomass	2.44
Unidentifiable sources	0.07
<b>Total</b>	<b>100%</b>

**Chart 4: Structure of purchased electricity sources**



**Table 7: Electricity consumption**

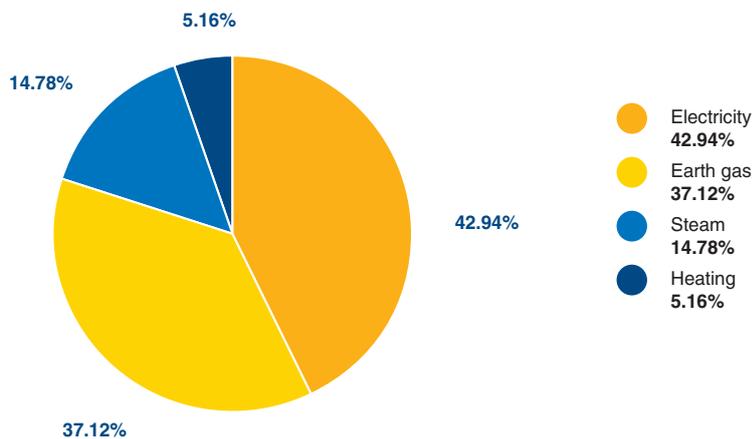
Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	GJ	155,551	140,221	115,898	24,111	435,781
2012	GJ	167,994	152,638	116,215	24,551	461,398
2013	GJ	189,032	155,394	116,498	25,686	486,610
2014	GJ	198,955	169,269	117,140	26,601	511,965
2015	GJ	201,421	173,523	124,413	28,139	527,496

In 2015, Lek, a Sandoz company, used 3% more electricity than in the previous year.

### 2.3.2 Distribution of energy by energy sources

In the structure of purchased energy sources, electricity accounts for the largest share with 42.94%, followed by natural gas with 37.12%.

These two energy sources are the primary source for three sites. The Ljubljana site is slightly different – in addition to these energy sources, we also purchase industrial steam (14.78%) and heating water (5.16%).

**Chart 5: Distribution of energy used by primary energy sources**

### 2.3.3 Energy efficiency improvements<sup>42</sup>

Our efforts to ensure energy efficiency and raise awareness among employees on the efficient use of energy are integral parts of our production processes. We have been continuously increasing the production of difficult-to-make products with a higher added value. Complex production processes dictate the use of more complex production equipment which usually entails more demanding energy consumption.

In 2015, additional **measures** were taken to **improve energy efficiency**, generating energy savings of 14.7 TJ in total and by 498 tonnes lower emission of CO<sub>2</sub> into the air:

- At the **Mengeš site**, a major investment into a new steam boiler with the economizer and the option of co-incineration of solvents was completed. The capacity for co-incinerating solvents increased by five times and will generate savings in purchasing gas. A recovery plan for the insulation of steam pipes has been prepared, which will have visible effects in 2016. Findings from an energy inspection of the site will lead us to decide for new projects to improve energy efficiency.

- At the **Lendava site**, different projects were implemented to reduce energy consumption by 8,815 GJ per year. At the incineration facility, the pre-processing of waters containing low concentrations of solvents was suspended. These waters are now being discharged directly into the stationary furnace of the incineration facility to be incinerated. By installing a flap on the cooling system hydraulic clutch, losses of cooling due to cooling water mixing were reduced.
- At the **Ljubljana site**, several minor projects were implemented to reduce energy consumption by 4,400 GJ per year, notably the improvement of air-conditioning systems and cooling towers regulation as well as the renovation of the heat station.
- At the **Prevalje site**, energy consumption was reduced by 1,520 GJ per year. This was achieved by installing a system for target monitoring of energy consumption with integrated option to control energy source consumers, and by replacing windows in some buildings at the site.

<sup>42</sup> GRI Indicators G4-EN6, G4-EN19

## 2.4 Water

### 2.4.1 Water use efficiency<sup>43</sup>

In the pharmaceutical industry, water is an indispensable natural resource. Efficiency of its use is therefore one of our major aims. In 2015, water consumption per kg of product at the Lendava site was again reduced, despite the fact that the quantitative realization of the Packaging Center Lendava was not taken into account in the quantitative realization at the site level. The consumption of fresh water dropped by 65.260 m<sup>3</sup> per year, mainly due to an improved system for reusing waste water and other saving measures.

**Table 8: Water consumption in 1,000 m<sup>3</sup><sup>44</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	1,000 m <sup>3</sup>	1,333	415	1,502	34	3,284
2012	1,000 m <sup>3</sup>	1,272	452	1,409	35	3,168
2013	1,000 m <sup>3</sup>	1,316	477	1,452	39	3,284
2014	1,000 m <sup>3</sup>	1,380	570	1,557	42	3,548
2015	1,000 m <sup>3</sup>	1,315	569	1,627	42	3,553

At the level of Lek, a Sandoz company, the efficiency of water use was improved by 0.5%. At the Mengeš site, water is used mainly for technological purposes. In 2015, only 7.5% of water was supplied from the public supply network, and the rest

#### Water consumption per kg of product at the Lendava site

- 2011: 6.8 m<sup>3</sup> of water/kg of product
- 2012: 5.8 m<sup>3</sup> of water/kg of product
- 2013: 5.4 m<sup>3</sup> of water/kg of product
- 2014: 5.3 m<sup>3</sup> of water/kg of product
- 2015: 4.8 m<sup>3</sup> of water/kg of product

(92.5%) came from our own pumping station (groundwater). Table 9 only provides the data on water use efficiency for industrial wastewaters (cooling waters excluded).

**Table 9: Efficiency of water use per unit of product<sup>45</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	m <sup>3</sup> /t	833	214	500	22	227
2012	m <sup>3</sup> /t	745	216	496	29	236
2013	m <sup>3</sup> /t	772	218	570	31	246
2014	m <sup>3</sup> /t	650	196	532	24	208
2015	m <sup>3</sup> /t	645	183	670	21	204

### 2.4.2 Water supply sources<sup>46</sup>

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.<sup>47</sup> 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 2015 was very irregular: in June the rainfall was twice the average, while in

December there was no precipitation; the downfall in the rest of the months was mostly under average.

In mid-august of 2015 the regulation establishing types of activities and facilities which may cause large-scale pollution entered into force, and the rules on operational monitoring of state of groundwater were released. The purpose of both regulations is to prevent the entry of hazardous substances into the groundwater. At Lek, a Sandoz company, it is demonstrated by contamination prevention measures and thus ensuring that our activities do not cause deterioration, but on the contrary, reduce the concentrations of existing contaminants in the groundwater.

At the Mengeš site, the sampling of the groundwater by an authorised contractor and under the supervision of a hydrogeologist was introduced as early as 2015; the final report is expected in the beginning of 2016. Mengeš will be followed by Lendava, which as an IED facility is also bound to carry out the analysis of groundwater and produce the baseline report.

<sup>43</sup> GRI G4-DMA | <sup>44</sup> EMAS Core Indicator, RC KPI 21, GRI Indicator G4-EN8 | <sup>45</sup> EMAS Core Indicator | <sup>46</sup> GRI Indicator G4-EN8

<sup>47</sup> Water permits No. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8

**Table 10: Water supply quantities and sources at the Mengeš and Lendava sites in 1,000 m<sup>3</sup>**

Mengeš	2011	2012	2013	2014	2015
From our own pumping station (1,000 m <sup>3</sup> )	1,432	1,335	1,376	1,480	1,510
From the public water supply network (1,000 m <sup>3</sup> )	77	80	81	83	123

Lendava	2011	2012	2013	2014	2015
From our own pumping station (1,000 m <sup>3</sup> )	1,325	1,228	1,297	1,340	1,261
From the public water supply network (1,000 m <sup>3</sup> )	39	61	58	58	53

### 2.4.3 Recycling and reuse<sup>48</sup>

Portion of recycled water is constantly being increased at all sites. 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 re-used 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 project of fermentation production expansion by installing two additional fermentation vessels was performed using the best available techniques (BAT). As the cooling cycles are of the closed-loop type, the trend of water consumption has been reversed.

## 2.5 Waste

### 2.5.1 Waste management<sup>49</sup>

Mycelium waste accounts for almost 97% of all waste at the Lendava site and 71% of the total waste from the entire operation of Lek. The major part of the mycelium waste is water therefore we are investigating the possibility of centrifuging the waste before being removed to a biogas plant. This would reduce the volume of waste and save on fuel consumption for transport (and consequently reduce CO<sub>2</sub> emissions as well). As recommended by Novartis, sewage sludge from the Lendava Wastewater Treatment Plant has been added to other Lendava site waste.

Because of two technologically different forms of production (bio-fermentative production of active ingredients and packaging of finished dosage forms), the Lendava production site faces different types and quantities of waste. By changing the product range, major quantitative fluctuations occur in packaging.

At the Mengeš site, more than 80% of the total waste is accounted for as hazardous waste, and more than 95% of all hazardous waste are waste non-halogenated solvents. More than one-fourth of high-calorie waste solvents is converted into energy in a steam boiler at the site. The energy obtained is utilized for preparation of process steam, thus reducing the transport of waste solvents and CO<sub>2</sub> emissions. The rest is transferred to authorised companies for environmentally acceptable disposal.

Despite increasing production outputs, changes in the production structure and the rising number of employees, the quantities of waste per tonne of product have decreased by more than 9% in 2015 as a result of reductions in non-hazardous waste.

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.

**Table 11: Volumes of waste generated in tonnes**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	t	3,550	1,800	4,392	590	10,332
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	2,831	5,692	766	34,876

<sup>48</sup> GRI Indicator G4-EN10 | <sup>49</sup> EMAS Core Indicator, GRI Indicator G4-EN23, G4-DMA

**Chart 6: Volume of waste per tonne of product – efficiency****Chart 7: Volume of waste per tonne of product – efficiency/disregarding mycelium waste**

## 2.5.2 Disposal of hazardous waste<sup>50</sup>

**Increasing production outputs and changes in the product range towards technologically more advanced products manufactured at the Mengeš site in smaller quantities by using complex techniques also result in increased absolute quantities of hazardous waste and quantities per unit of product. We are limiting this growth by implementing environmentally advanced manufacturing solutions and measures to reduce the volume of waste of this type, with special attention to the increase in total amount of recycled waste.**

Apart from prevention and reduction of waste production, our policy also includes increasing the portion of waste for recycling and energy recovery. The basis for a successful material processing is the adequate waste separation, which is provided at the source of waste generation.

At the Mengeš site, non-halogenated waste solvents, being extremely pure and having a high calorific potential, account for 85 to 95% of total hazardous waste. The mixtures of

halogenated waste solvents account for only 2 to 5% of total hazardous waste in Mengeš. This waste is disposed of separately by authorised contractors. By means of co-incineration with natural gas, 1,504.9 tonnes of solvents or an equivalent to 1,403,336 Sm<sup>3</sup> of natural gas were removed in 2015. Due to insufficient co-incineration capacity, 676.2 tonnes of solvents (equivalent to 630,500 Sm<sup>3</sup> of natural gas), otherwise appropriate for disposal by local co-incineration, were transported from the site.

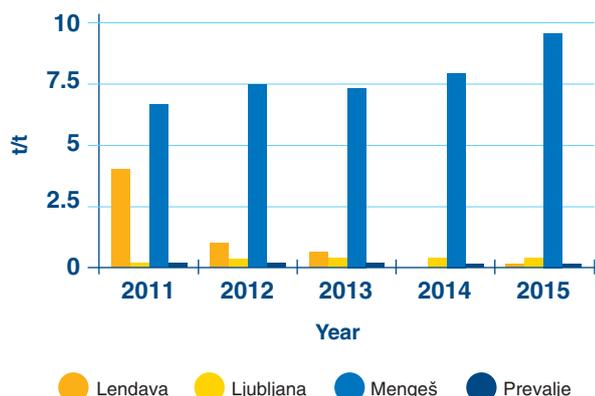
At the Ljubljana site, out-of-date products account for a considerable portion of the generated hazardous waste. The inventory management method in place, however, makes it impossible to reduce their volume. Since 2011, however, we have performed intensive segregation of the waste packaging of hazardous 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 tonnes**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2011	t	783	412	3,416	228	4,839
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	826	4,646	129	5,631

<sup>50</sup> GRI Indicator G4-EN23 and RC KPI 5

**Chart 8: Volume of hazardous waste per tonne of product – efficiency**



### 2.5.3 Disposal of non-hazardous waste<sup>51</sup>

Nearly 84% of total Lek waste volume is non-hazardous waste. At the Mengeš site, the biologically degradable waste generated by the manufacture of fennel and purple coneflower (Echinacea) juices is directed to a biogas plant. Similarly, we direct the mycelium waste generated at the Lendava site, to an external contractor biogas plant.

Due to redirecting the mycelium waste to a certified contractor biogas plant, the structure of non-hazardous waste changed

considerably compared to 2011. Municipal waste accounted for a mere 1%, whereas the share of waste packaging (paper, plastics, wood, metal, glass) amounted to just above 7%. In 2015, due to mycelium waste, biodegradable industrial waste accounted for 72% of total waste or 85% of all non-hazardous waste.

Municipal waste is discarded through disposal, and packaging waste is usually recycled (through the packaging waste handling scheme), which also applies to building waste. Biodegradable waste is used for the manufacture of biogas, and other non-hazardous wastes are disposed of by certified companies by means of incineration.

**Table 13: Non-hazardous waste volumes by site (in tonnes)**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Lek (non-hazardous waste recyclable packaging not included)
2011	t	2,767	1,388	975	362	5,492	3,933
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

**Chart 9: Volume of non-hazardous waste per tonne of product – efficiency**



*Strict waste segregation in laboratories*

<sup>51</sup> GRI Indicator G4-EN23

## 2.6 Air emissions<sup>52</sup>

### 2.6.1 Abatement of air emission

We separately monitor greenhouse emissions and emissions from stationary 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, adsorbers, 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<sup>3</sup>).

Lek, a Sandoz company, maintains its compliance with the limit value for total dust, amounting to 150 mg/m<sup>3</sup> 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<sup>3</sup>.

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<sup>3</sup>). According to the stated parameters, these devices comply with statutory requirements as well.

### 2.6.2 Emissions from waste incinerators and co-incinerators

The Lendava site carries out mainly the incineration of waste generated at the site. Due to the release of mycelium waste to a biogas plant for treatment, its scope of operation has diminished. 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 one 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. In 2011, permanent emission measurements were provided on the waste solvent co-incinerator for the parameters prescribed in the environmental permit.

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).

### 2.6.3 Sulphur dioxide (SO<sub>2</sub>)<sup>53</sup>

The volumes of SO<sub>2</sub> emissions at our sites have always been low, and were mainly generated by the devices for the thermal treatment of volatile organic compounds. In 2014, we recorded a decrease in these emissions (by 25%) 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<sub>2</sub>)<sup>54</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (kg SO <sub>2</sub> /t of product)
2011	t	0.00	0.01	0.00	0.00	0.01	0.003
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

The values of SO<sub>2</sub> emission volumes by year are based on the data on their concentration at individual measuring points and on the time of device operation.

<sup>52</sup> EMAS Core Indicator, GRI Indicators G4-EN21, GRI G4-DMA, RC KPI 7, RC KPI 10 | <sup>53</sup> EMAS Core Indicator, RC KPI 8, GRI Indicator G4-EN21

<sup>54</sup> EMAS Core Indicator, RC KPI 7, GRI Indicator G4-EN21

## 2.6.4 Nitrogen oxides (NO<sub>x</sub>)<sup>55</sup>

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. At all the sites, regular emission monitoring is carried out.

In 2015, a decline in nitrogen oxide emissions was reduced by 7%. Significantly lower emissions were recorded at the Ljubljana site; at the Mengeš and Lendava sites the reductions were slightly lower, whereas at the Prevalje site levels similar to those in the previous year were maintained.

**Table 15: Emissions of nitrogen oxides (NO<sub>x</sub>)<sup>56</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t NO <sub>x</sub> /t product)
2011	t	7.17	1.33	15.06	1.40	24.96	0.007
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

## 2.6.5 CO<sub>2</sub> and other greenhouse gasses<sup>57</sup>

The sources of direct CO<sub>2</sub> 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)<sup>58</sup> data reported also includes:

- dinitrogen oxide (N<sub>2</sub>O) in CO<sub>2</sub> equivalents,<sup>59</sup>
- fluorinated hydrocarbons (hydrofluorocarbons – HFC) in CO<sub>2</sub> equivalents,<sup>60</sup> and

- other greenhouse gasses (methane and others) in CO<sub>2</sub> equivalents.<sup>61</sup>

The group of direct CO<sub>2</sub> emission sources also includes some other gases used in or arising from our processes.

CO<sub>2</sub> 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.

**Table 16: Carbon dioxide and other gases contributing to the greenhouse effect**

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t CO <sub>2</sub> /t product*)
GHG1	2011	t CO <sub>2</sub>	11,839	3,699	15,135	1,999	32,672	8.6
	2012	t CO <sub>2</sub>	10,801	2,928	13,484	1,821	29,034	7.6
	2013	t CO <sub>2</sub>	10,774	2,792	13,966	2,053	29,585	7.6
	2014	t CO <sub>2</sub>	10,691	3,273*	14,139	2,068	30,171*	6.4
	2015	t CO <sub>2</sub>	10,591	2,737	15,429	1,109	30,866	5.9
GHG2	2011	t CO <sub>2</sub>	16,023	35,117	11,938	2,482	65,560	17.3
	2012	t CO <sub>2</sub>	12,438	27,793	3,870	816	44,917	11.8
	2013	t CO <sub>2</sub>	1,575	24,242	970	214	27,001	6.9
	2014	t CO <sub>2</sub>	9,351**	16,935**	5,506**	1,250**	33,042**	7.05
	2015	t CO <sub>2</sub>	1,672	16,501	1,033	234	19,439	3.72

\* Changes of data as a result of changed data on production output for the Ljubljana site.

\*\* Quantities for 2014 were adjusted due to the change in the conversion factor introduced by the electricity supplier.

In 2014, the electricity supplier changed the conversion factor for the calculation of CO<sub>2</sub> emissions from the electricity supplied, which depends on its structure. Consequently, the indirect greenhouse gas emissions (GHG2) in 2014 were increased by 22%, and in 2015 were reduced by 44%.

The total volume of direct greenhouse gas emissions (GHG1) was slightly increased compared to the previous year (by 2%), and the efficacy, expressed as a tonne of CO<sub>2</sub> emissions per 1 tonne of product, increased (by 8%).

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<sub>2</sub> emissions (GHG1) is natural gas combustion (>90%) in the burning devices. One of the contributory factors is also the manufacture of technologically advanced products of higher energy complexity.

The Lendava and Mengeš sites participate in trading with CO<sub>2</sub> 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.

## 2.6.6 Volatile organic compounds (VOC)<sup>62</sup>

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.

In 2015, total VOC emissions saw a decrease of 5%. The efficiency per tonne of product was significantly increased, along with the growth in production.

At the Mengeš site, a device for removal of halogenated solvents from exhaust air using state-of-the-art cryogenic condensation is in operation. With the final replacement of methylene chloride with ethanol, the halogenated solvents at the Prevalje site were discontinued even prior to that.

**Table 17: Total emissions of volatile organic compounds**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)	Efficiency (Lek) (t VOC/t product)
2011	t	24	36	146	6.2	212	0.056
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

## 2.7 Water releases<sup>63</sup>

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 2015 show that no excessive pollution was identified at any of the sites.



*Pumping site for cooling wastewater outflow into the Mura river*



Central Wastewater Treatment Plant Domžale-Kamnik

### 2.7.1 Waste waters<sup>64</sup>

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.

At the **Mengeš** and **Lendava** sites, waste cooling waters account for 70% of the total water quantity used. In 2015, their consumption increased by 3%, and the consumption of industrial water at all sites, except at Prevalje, increased by total of 9%.

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

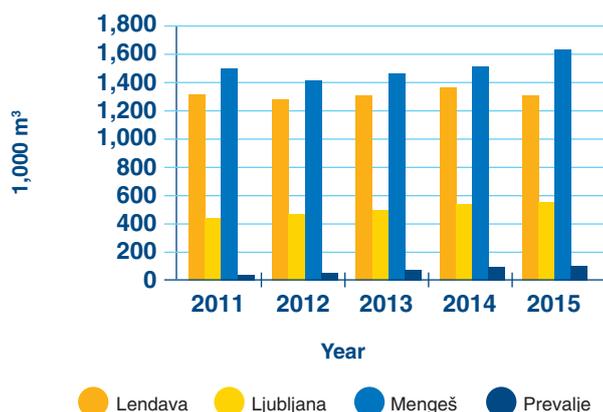
Wastewater from the Mengeš site is transferred to the Central Wastewater Treatment Plant Domžale-Kamnik, which in

September of 2014 started to upgrade the existing aerobic treatment stage, in order to achieve the appropriate level of treatment of nitrogen and phosphorus. Renovation of the entry plant and construction of the new system for treatment of wastewater from the anaerobic stage are under way. The reconstruction is expected to be finished by August 2016.

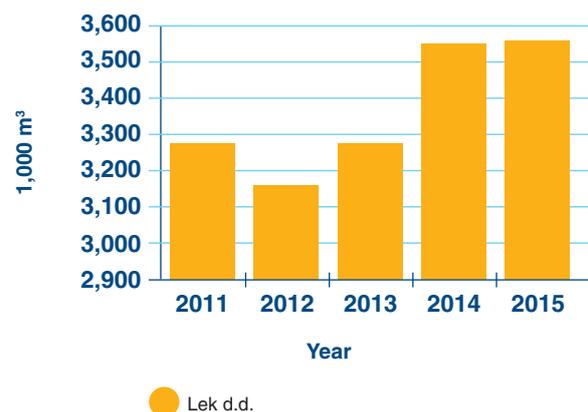
The wastewater treatment has had a valid environmental permit since the first day of trial operation (No. 35441-82/2010-17, 24 January 2012). The composition of inflow and outflow water is constantly being monitored by on-line meters, and by periodic sampling and laboratory analyses. The sampling and analyses are carried out by an authorised laboratory – National Laboratory of Health, Environment and Food (NLZOH). The results of the on-line measurements, the official measurements by National Laboratory of Health, Environment and Food and internal measurements of ammoniacal nitrogen, show that throughout 2015 the wastewater treatment plant provided the outflow of appropriate quality at the Kamniška Bistrica outlet, and that the watercourse burden was not too high.

Chart 10: Wastewater volumes in 1,000 m<sup>3</sup>

Wastewater volumes



Wastewater volume Lek d.d.



<sup>64</sup> GRI G4-DMA

## Central Wastewater Treatment Plant Domžale-Kamnik upgrade



*Marjeta Stražar, Head of the Central Wastewater Treatment Plant Domžale-Kamnik*

### What is the importance of the implementation of tertiary treatment with removal of nitrogen and phosphorus from the wastewater?

Our wastewater treatment plant was built in 1980 and it treats the wastewater from approximately 60,000 inhabitants. All major industrial sources in the municipalities of Domžale, Kamnik, Mengeš, Komenda, Trzin and Cerklje na Gorenjskem are connected to it. The initial technology became outdated through the years and would not fulfil the regulatory requirements for treatment of wastewaters, set in August 2016. The municipal owners decided for an upgrade, which includes the construction of new biological stages for removal of nitrogen and phosphorus compounds and a new inflow facility, providing for larger quantities of wastewater. The chosen technology includes the advanced sequencing batch reactors (SBRs) with selectors and an up-to-date deammonification process for treatment of highly burdened internal return waters. The efficacy of removal of nitrogen and phosphorus compounds causing the eutrophication of surface waters will increase from approximately 40% to over 80%. We will thus improve the ecological status of Kamniška Bistrica river and provide for groundwater protection as well as the appropriate treatment of wastewater for at least next 30 years.

### How will the project affect the operational safety of the plant?

The completion of works, planned for July of 2016, will be followed by a 10-month trial operation. Current total load of the Central Wastewater Treatment Plant is approximately 110,000 PE, whereas the capacity of the upgraded plant will be 149,000 PE and it will be capable of processing all wastewaters, suitable for release into the sewage system. The construction of new biological stages will provide for sufficient volume of aeration basins, as well as a new inlet facility for appropriate pre-treatment of wastewaters and reception of higher quantities of wastewater, including the first wave of precipitation water. This will provide the operational safety and exclude the possibility of over-burdening the environment.

## On-going modernisation



*Miro Škalič, Head of the Wastewater Treatment Plant Lendava*

### Lek's manufacturing at the Lendava site has expanded considerably since the construction of the wastewater treatment plant in 2001. Are you considering an expansion or an upgrade?

The common wastewater treatment plant, used by Lek, a Sandoz company, and Lendava municipality, is still sufficient for treatment of wastewaters for the local community and the industry. It serves its purpose in full and no upgrades are needed.

### Which upgrades did you implement recently?

No upgrades were needed for tertiary treatment, as it has been meeting the requirements since the very beginning. The compliance of operation with the legislation is ensured and improved by continuous maintenance. For instance, in 2011, the ventilation system in one of the basins was upgraded. An important event for rounding-up of technology of treatment of excess mud, was the construction of a low-temperature mud dryer with a closed drying air circuit. This acquisition enabled the reduction of excess mud mass and reduced the foul odour during the interim storage, since the dry mud is stored in closed metal containers prior to transport. It also ensured that the plant operates in accordance with the national operational waste management plans. We intend to maintain it in optimal condition and keep its operation within all legal limits.

## We aim for maximum energy self-sufficiency



*Cirila Bordon, Ecology Associate, JP VO-KA Ljubljana, Central Wastewater Treatment Plant Ljubljana*

### How do you detect irregularities in inflow of individual waters into the plant, for example, a release of hazardous polluted waters?

Our relationship with most users from industry is fair. Based on the reports on operational monitoring of wastewaters, we identify the amounts of pollutants, calculate the price of removal and cleaning of wastewaters, and charge the pollutant. We also carry out unscheduled measurements of

industrial wastewater prior to inflow into the public sewage system, if our employees notice any unusual conditions in the network during scheduled and unscheduled measurements and maintenance.

### How do you monitor the operation of Central Wastewater Treatment Plant Ljubljana and how do you upgrade it?

By secondary treatment, removal of carbon compounds and nitrification. In order to meet the requirements for tertiary treatment, the construction of the second phase of Central Wastewater Treatment Plant Ljubljana is planned. It comprises the increase in capacity from 360,000 PE to 555,000 PE and the addition of tertiary treatment.

In addition to providing appropriate treatment of wastewater, we will strongly focus on mud treatment. We aim to achieve maximum energy self-sufficiency and produce as much biogas as possible, which will then be used at the plant or as an alternative to solid fuels.

The operation of the central wastewater treatment plant is being monitored by on-line measurements of all relevant parameters. The results show that the technological processes are managed carefully and professionally. Daily measurements of all relevant indicators are carried out at our accredited laboratory. The existing process is sufficient for achieving approximately 50% efficacy in removal of nitrogen and phosphorus compounds. The new required parameters will be achieved after the project completion, presumably by the end of 2018 or beginning of 2019.

**Table 18: Wastewater volumes by discharge quality and destination<sup>65</sup>**

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
Use of cooling water - unpolluted							
	2011	1,000 m <sup>3</sup>	1,170	34	1,243	10	2,457
	2012	1,000 m <sup>3</sup>	1,109	18	1,138	5	2,270
	2013	1,000 m <sup>3</sup>	1,129	35	1,156	5	2,325
	2014	1,000 m <sup>3</sup>	1,212	75	1,278	8	2,573
	2015	1,000 m <sup>3</sup>	1,137	33	1,307	9	2,486
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							
	2011	1,000 m <sup>3</sup>	163	381	259	25	828
	2012	1,000 m <sup>3</sup>	163	434	271	30	898
	2013	1,000 m <sup>3</sup>	187	442	296	34	959
	2014	1,000 m <sup>3</sup>	168	494	279	34	975
	2015	1,000 m <sup>3</sup>	177	536	320	33	1,067
Discharge			into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system	

<sup>65</sup> EMAS Core Indicator, Indicator GRI G4-EN22

## 2.7.2 Phosphorus and nitrogen compounds, chemical oxygen demand

Nitrogen compound emissions mostly result from the fermentation production. The Mengeš site accounts for the largest share of these emissions, also at the expense of the 5-NOK production, followed by Lendava and Ljubljana, and, at a negligible level, the Prevalje site. In 2015, the total volume increased by almost 100%, mostly due to the emissions from Lendava and Mengeš sites.

The Mengeš site is also the major generator of phosphorus compounds, their source being residual inorganic substances. 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.

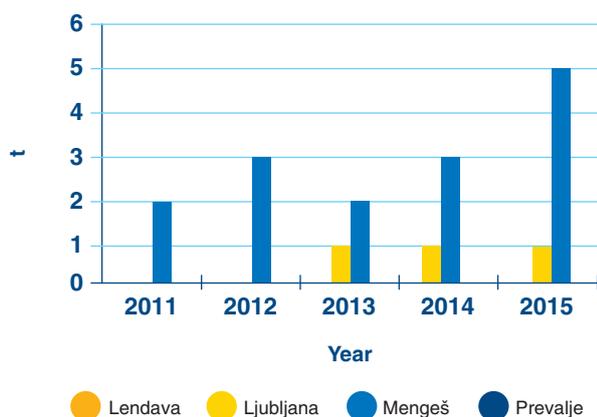
To provide an assessment of the level of pollution with organic impurities, chemical oxygen demand is an important parameter, providing the quantity of oxygen needed for chemical oxidation of organic pollution in wastewater.

Chemical oxygen demand measurements are carried out at the point of discharge of waste cooling waters into the sewage system. In 2015, we recorded a slight increase in the chemical oxygen demand parameter (18%) on account of the Mengeš and Lendava sites. The Prevalje and Ljubljana sites together contribute to less than 3% 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.

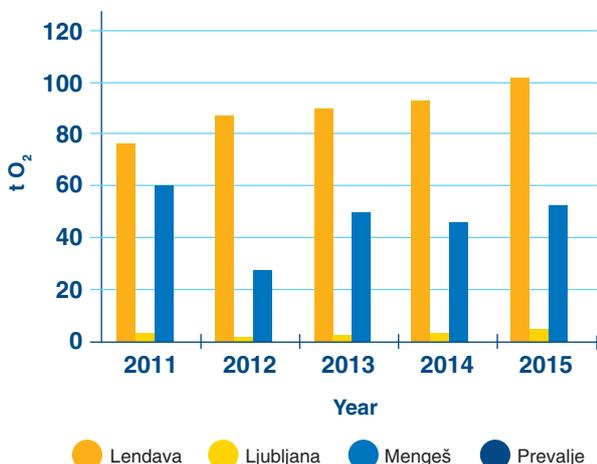
**Chart 11: Emissions of phosphorus compounds in wastewater<sup>66</sup>**



**Chart 12: Emissions of nitrogen compounds in wastewater<sup>67</sup>**



**Chart 13: Chemical oxygen demand (in tonnes O<sub>2</sub>)<sup>68</sup>**



Ecotoxicity data of APIs are regularly reviewed, evaluated and proper action is taken.

Through increasing knowledge of chemical substances Lek started, even before the respective Slovenian and EU laws were implemented, to research the impact of active pharmaceutical ingredients potentially entering wastewaters as a result of our operations. From there, they pass through wastewater treatment plants into surface waters.

The environmental risk assessment is carried out based on the experimental and modelled data on pharmaceutical ingredients, such as physical and chemistry data, data on destiny and behaviour of substances in the environment, and aquatic toxicity data. It has been established that only a small portion of APIs present in the wastewaters are generated by the production of pharmaceuticals and that the major part results from the final users of pharmaceutical products.<sup>69</sup>

## 2.8 Other environmental impact

### 2.8.1 Odour

Slovenia's environmental regulations do not cover environmental odour pollution, however, we have installed biofilters wherever odour from industrial processes is expected, thus preventing it from affecting the local population, for example, above wastewater equalization ponds.

The monitoring of biofilters' operation and waste air loads is carried out by the National Laboratory for Health, Environment and Food in Maribor.

### 2.8.2 Soil

Soil, as an integral part of the environment, 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. As the environmental impact on soil pollution is usually irreversible, this area is of special concern to us. We consistently fulfil 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. Furthermore, we introduce preventive measures in the production processes and the construction of facilities.

At the end of 2013, provisions from the European Industrial Emissions Directive (IED) from 2010 were transposed into the Slovenian legislation. This decision, among other things, introduces a requirement for operational monitoring of soil contamination at least once every 10 years, as well as remediation and return to its original state in case of an identified impact on the quality of soil after the termination of the industrial plant. Conditions and criteria for preparation of the report based on monitoring at the national level were adopted in July 2015, however the regulation on soil condition, setting the standards for environment quality and criteria for pollution classes or levels, has not been released yet.

To date, no remedial action due to soil pollution has been needed at Lek, a Sandoz company.

**Table 19: Land use by site<sup>70</sup>**

	Mengeš	Lendava	Ljubljana	Prevalje	Lek
Total site surface area with parking lots (in m <sup>2</sup> )	138,062	140,662	121,015	18,527	418,266
Production site surface area/product (in m <sup>2</sup> /t)	289	511	41	12	87

### 2.8.3 Noise

At Lek, a Sandoz company, the main identified source of noise is manufacturing activity, particularly the operation of fermentors, 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.

In order to control any excessive environmental noise pollution, we perform regular monitoring and analyses. None of the measurement results indicates any noise overload at any of our sites during the day, evening and night time. An exception in 2015 was the Prevalje site, where excessive noise was recorded during regular operation monitoring in the night time. In 2015 it was shown that regenerative thermal oxidizer (RTO) is not the only source of noise, as the noise levels were exceeded in spite of the RTO remediation. New measurements were thus carried out in order to identify and rank the contribution of individual noise sources at the site, and a study including the analysis of specific noise cancelling measures at or near individual noise sources was added to the report. Based on the program for remedial measures, prepared by the Institute of Occupational Safety the remedial works should be finished by mid 2016.

In 2015, we received three noise-related complaints. These are described under Item 1.4.3.1, along with the actions taken.

### 2.8.4 Biodiversity<sup>71</sup>

At Lek, a Sandoz company, the commitment to protecting the environment is shown by consistent adherence to statutory waste and industrial water management requirements. We thereby strive to mitigate any impact on the quality of the environment and consequently on the biodiversity of the areas surrounding our production sites.

Lek facilities are located within industrial zones where there are no major environmentally critical habitat types or protected vegetation.

### 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 colour shades of outdoor lighting feel better.

For this reason, Lek has had comprehensive expert studies for its sites. The outdoor lighting was remedied using modern technologies; however at the same time we reduced its operation in the period of time when labour needs are reduced.

<sup>70</sup> EMAS Core Indicator | <sup>71</sup> GRI Indicator G4-EN12, G4-DMA

## 2.9 Safety

### 2.9.1 Fire safety

At Lek, a Sandoz company, evacuation fire drills are being carried out at all our four sites. Awareness of the importance of evacuation drills is very high among employees. The evacuation drills are followed by demonstrations of extinguisher use, and in 2015 at the Mengeš site a demonstration of basic CPR procedures with an automated external defibrillator and the presentation of alarms took place.

There were no major fire safety interventions at none of the four sites. There were some minor cases of scorching in the

#### Open Doors Day at the volunteer industrial firefighting team LEK station in Mengeš

In October, during the Quality Week, an Open Doors Day took place at the fire station Mengeš. The employees were shown the facilities, the firefighting equipment and its use. The promotion of the internal emergency number 01 721 7306 was emphasized. Participants saw films on evacuation and sprinkler system operation, tried the basic CPR procedure with an AED, and tested the alarm and extinguishing system with an extinguish simulator. The event included the presentations on process safety, importance of safe storage of chemicals and fire safety on site.

We extended our invitation to the fire brigades operating at the Mengeš site, and representatives of local communities Mengeš and Domžale.

### 2.9.2 Biological safety

We define biological material (cell lines, micro-organisms, small mammals) used in our laboratories or production as biological agents or genetically modified organisms (GSO). Lek, a Sandoz company, deals exclusively with biological agents from Risk Groups 1 and 2 with negligible risk of being released into the environment (see also Glossary of key terms).

In the production, we handle exclusively the biological agents of Risk Group 1 for which risk assessments have been made. In the risk assessment we take account of the risk that biological material poses to a worker and containment measures to mitigate the risks and potential exposure of workers.

At the Mengeš site, one of the existing closed systems for handling GMOs of Risk Group 1 was registered in 2015 as closed system of Risk Group 2. The purpose of the closed system is to test biological activity of biologicals for human use on a laboratory scale.

To ensure adherence to biological safety, we appointed a Biological Safety Officer at the corporate level, with deputy

energy facilities. They were detected by the automated fire alarms and remedied by professional firefighters in charge of fire safety.

Volunteer fire fighters from the volunteer fire brigade Lek and the volunteer industrial firefighting team Lek Lendava took part in training at the regular operational drills at individual sites. In June, a one-day practical exercise at the Safety and rescue training center Ig took place. 24 volunteer firefighters participated.



*Open Doors Day at the volunteer industrial firefighting team LEK station in Mengeš*

commissioners also at the Mengeš Ljubljana and Lendava sites. Deputy commissioners for biological safety mitigate potential risks in handling biological agents and ensure compliance with Slovenian law and Novartis' guidelines. Persons responsible for ensuring safety of work with GMOs are also appointed.

Lek also has a 10-member Biological Safety Committee. Its tasks include checking the accuracy of biological agents' classification into risk groups and, consequently, the adequacy of proposed containment measures, and approving individual projects in accordance with the risk assessment.

Biological medicinal products have become an indispensable part of modern medical practice. Due to the highly complex and time-consuming research and development, however, they are extremely costly. Sandoz plays a pioneering role in the supply of similar biological medicinal products, making them accessible to the public by offering quality, safety and efficacy comparable to reference products, yet at a more affordable price. All Sandoz biosimilar drugs are also available to patients in Slovenia.

## 2.9.3 Providing storage and distribution safety

### 2.9.3.1 Storage

Handling and storage of hazardous chemicals are carried out in accordance with both statutory requirements and Novartis' guidelines. All of our warehouses for hazardous liquids were declared with the Ministry of Health, whereas specific sites have plans for the management of hazardous liquids.

In above-ground tank storage of hazardous liquids, we provide appropriate retarding catchment systems preventing liquid spillage into the environment. In addition, the tanks are fitted in a way to enable detection of any spillage at any time.

Chemicals for manufacture and storage purposes, and in the field of waste management are classified and labelled according to the GHS (Globally Harmonized System).

### 2.9.3.2 Distribution<sup>72</sup>

In 2015, from our production sites, 7,442 consignments of finished products and APIs were dispatched to 97 countries. Compared to the previous year, the volume of distributed goods increased slightly and amounted to 23,327 tonnes (21,218 tonnes in 2014). During the transport of both non-hazardous and hazardous goods, no accidents occurred.

In 2015, we carried out transport route classification for all types of transport (road, air, sea) in both critical periods (winter, summer) and on transport routes selected on the basis of risk analyses. We thus met the requirements of GDP (Good Distribution Practice). Based on the GDP results, we set up the system of shipment monitoring and thermal protection for air shipments.

In the organization of international road transport, we continued with the concept of the "Control Tower" business model organized by DHL Belgium.

In the organization of air transport, we successfully upgraded the cooperation with our partner DHL Global Forwarding,

Lek's only air transport provider. We focused on setting up a common procedure for the implementation of activities in the quality of the executed transport service in line with GDP guidelines.

The trend of transition from air to sea transport continued in order to reduce cost and provide better quality service in terms of GDP. With this type of transportation we replaced air transportation for larger volumes of goods in 2015 and generated savings (we achieved the ratio of 74% sea transport and 26% air transport).

## 2.9.4 Chemical safety

Safe handling of chemicals in laboratories as well as in the API and finished products manufacturing process is ensured by numerous measures.

We keep our employees informed of their hazardous properties in accordance with the legal requirements for the handling of chemicals and the Novartis' guidelines. By taking into account the type of technology used in the manufacture, and the procedures for using chemicals in laboratories, we assess the risks and determine technical and organizational measures to ensure safety in their use. We have established a system for collecting data on the manipulation of chemicals subject to statutory reporting, a system for the preparation of registration dossiers for the registration of strategic raw materials and intermediates pursuant to the REACH Regulations (Registration, Evaluation, Authorization and Restriction of Chemical Substances), and the Globally Harmonized System (GHS) of labelling to meet the requirements of the manufacturing process and of the buyers of our APIs.

In the area of toxicology and pharmacology, we determine exposure limit values for APIs and strategic intermediates. By determining the exposure limit values and performing measurements in the working environment, we determine appropriate technical and organizational measures, allowing safe work in production and in laboratories.

## Health, safety and environment systems

### 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.

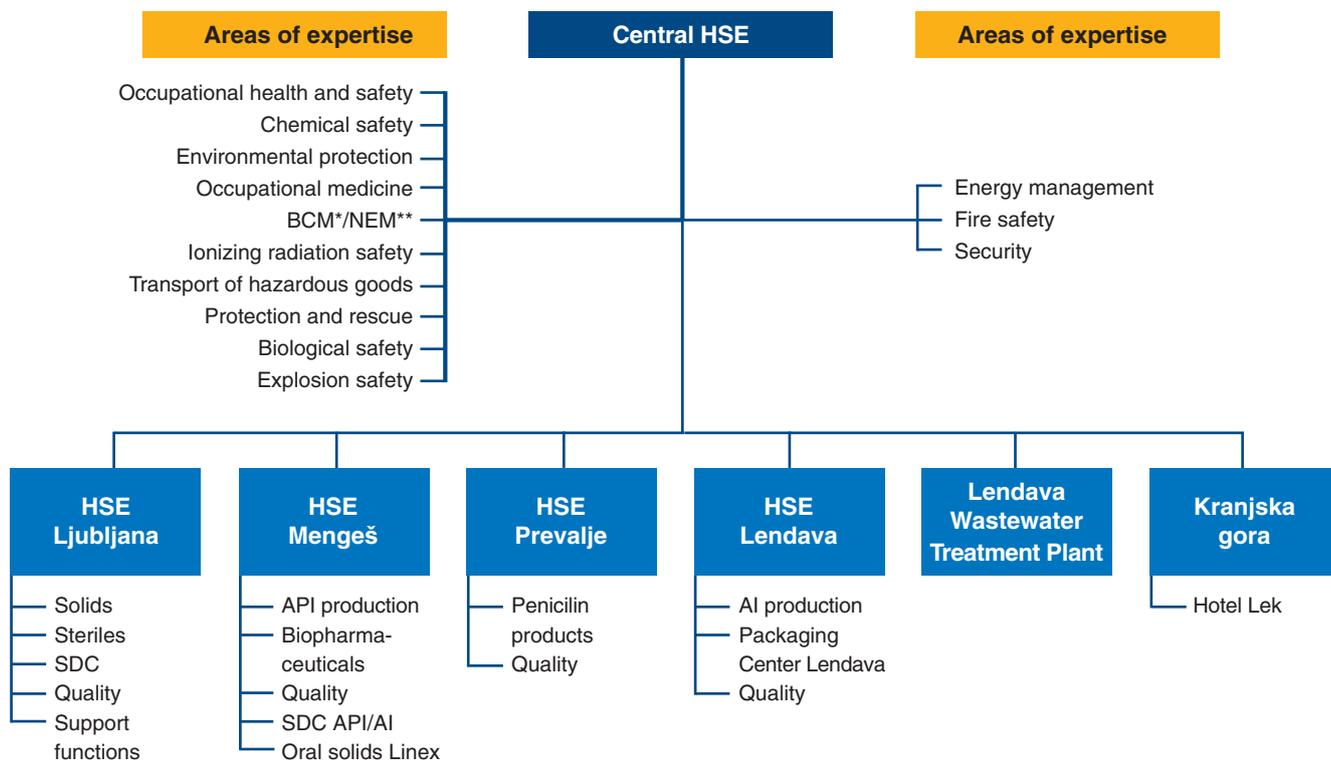
#### HSE department

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. 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.

<sup>72</sup> RC KPI 22, GRI Indicator G4-EN30, G4-DMA

## Health, safety and environment systems

Figure 1: HSE organization scheme



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

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 organisation.



Part of associates of the HSE team

## Health, safety and environment systems

### Environmental impact and risk assessment

In accordance with legal requirements, Lek, a Sandoz company, has acquired environmental permits for operation for all of its sites (see Compliance with laws and standards).

When planning an intervention and its potential impact on the environment, an impact and stress admissibility assessment is made. The assessment is carried out in accordance with legal environmental guidelines, data from public sources, monitoring and studies carried out by authorized institutions, the current environment status and pollution, anticipated emissions resulting from the planned activities, and applicable environmental regulations. Impacts of the individual interventions are evaluated according to elements of the environment, and separately for the construction time and the operation time. If any environmental impact has been identified, mitigation measures are proposed.

Pursuant to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences (OG of RS, No. 22/2016) Lek, a Sandoz company, with the exception of the Production Plant Mengeš, is characterized as a negligible source of risk. At the Mengeš production plant, classified as a source of minor environmental risk mainly due to the presence of flammable substances at the site, hazardous substances were detected as anticipated. By applying the measures planned for emergency cases which may result in large-scale emissions, fire or explosion, and by means of response measures, the necessary action was taken to prevent major incidents. At the beginning of 2015, we obtained an environmental permit for a minor environmental risk plant.

In 2015 at Lek, a Sandoz company, there were no environmental incidents.

### Safety policy

Lek's safety policy is an integral part of our business policy with an established system for managing major accidents involving hazardous substances in order to prevent any unforeseen events, and timely and effective emergency response. **The Safety Policy** of the Mengeš facility that is classified as a minor environmental risk plant with regard to the type and quantity of hazardous substances, obliges us to do everything necessary to avoid major accidents involving hazardous substances.

The safety policy as available at: [http://www.lek.si/media/witlof/attachments/2016/06/23/12/36/05/Varnostna\\_politika.pdf](http://www.lek.si/media/witlof/attachments/2016/06/23/12/36/05/Varnostna_politika.pdf).

#### 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),
- 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:

- 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 2015, 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.

### 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.

A standard selection of aspects for individual areas of expertise is determined by the head of the respective area at Lek d.d. The site's HSE responsible person makes an assessment based on the results of the Gap Analysis, audits (internal, Novartis'), inspections, complaints, and in consideration of hazardous occurrences (near-misses). The aspects are evaluated in consideration of the criteria of legal compliance, profitability and the company's reputation, using the risk assessment methodology.

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.

## Health, safety and environment systems

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 2015, external auditing of the company's compliance with ISO 14001:2004 and 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 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 2015, we had Novartis' HSE audit at Ljubljana. The results of internal audits performed in 2015 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.

Environmental performance assessment with regard to our general and individual objectives is an integral part of the management review procedure.

In 2015, 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, a Sandoz company, enables monitoring of absolute indicators and trends for individual critical HSE aspects.

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 14001:2004.

## 3. LABOUR



*Quality control at the Ljubljana site*

### 3.1 Human resources policy<sup>73</sup>

Lek's human resources policy places people at the heart of the entire business operation ("It's all about people"), along with three principles: "Cooperation. Development. Excellence." At Lek, a Sandoz company, 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. Our HR team continually strives to ensure that all the processes are performed professionally and in accordance with applicable

standards. The HR policy supports the basic business orientations, aiming to achieve a high level of innovation, growth and better productivity.

We are creating a working environment of business opportunities and personal challenges, characterized by creative and dynamic work, which offers a unique opportunity of working in international pharmaceutical development and research teams.

<sup>73</sup> GRI G4-DMA

## 3.2 Employment

### 3.2.1 Total workforce by employment type and employment contract<sup>74</sup>

At the end of 2015, the proportion of women in Lek's total workforce was 45%, a level identical to that in the previous year. At year-end, 93% of all employees (91% in 2014), worked on a full time permanent basis, and 7% were fixed-term employees (6.7% in 2014). 2% of all employees worked on a part-time basis, a level nearly identical to that in the previous year (2.3% in 2014).

### 3.2.2 Percentage of employees covered by collective bargaining agreements<sup>75</sup>

The Collective Bargaining Agreement covers 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<sup>76</sup>

Since 2001 Lek has been providing its employees additional pension insurance (Pillar II) to a maximum premium amount. Lek enabled the employees to join the collective additional pension scheme in 2001, and the opportunity was taken by a large majority. At the end of 2015, 87.12% (85.57% in 2014) of the workforce was included in the scheme. The premium is calculated on the basis of 5.844% of the employee's gross salary.

### 3.2.4 Procedures for local hiring and proportion of senior management hired from the local community<sup>77</sup>

At Lek, a Sandoz company, the employment process is performed through implementation of the guidelines on diversity, equal opportunities and fair treatment. Decisions are taken only on the basis of employment related elements. The employee's basic salary depends on the level of education and other elements associated with the workplace, and is not gender or site-dependent. The process of hiring foreign employees is compliant with established corporate practice following EU recommendations. The proportion of local human resources in the senior management team (consisting of unit heads and board of management members) is 88%, slightly lower than in the previous year (91%).

### 3.2.5 Parental leave<sup>79</sup>

Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act. In 2015, the number of employees having taken the parental leave was the following:

	Men	Women	Total
Number of employees having taken parental leave	118	123	241
Number of employees returning to work after parental leave	118	120	238
Percentage of employees returning to work after parental leave	100%	97,6%	98,8%

## 3.3 Occupational safety and health

### 3.3.1 Standard injury, lost day and absentee rates<sup>80</sup>

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).

We recorded four cases of workplace accidents requiring sickness absence and the 2014 LTIR rate amounted to 0.12 (0.22 in 2014). We have recorded no serious work-related injuries, and none of the injured employees will have health consequences due to the injury.

The TRCR value in 2015 was 0.39 (0.42 in 2014). In total of 13 cases no serious injury was recorded. All cases were investigated and effective corrective measures to prevent recurrence of such incidents were taken.

#### Standard injury rate<sup>81</sup>

At Lek, we also record hazardous occurrences and near misses. In high-risk organizational units, walkthrough inspections with senior managers on site are performed and safety meetings are held. In the case of minor accidents, we encourage an alternative work system, a decision on such work being made by the individual employee concerned.

Among the primary causes of injuries are blows against objects or by objects, followed by slips, trips and falls. All accidents are investigated by the TapRoot analysis.

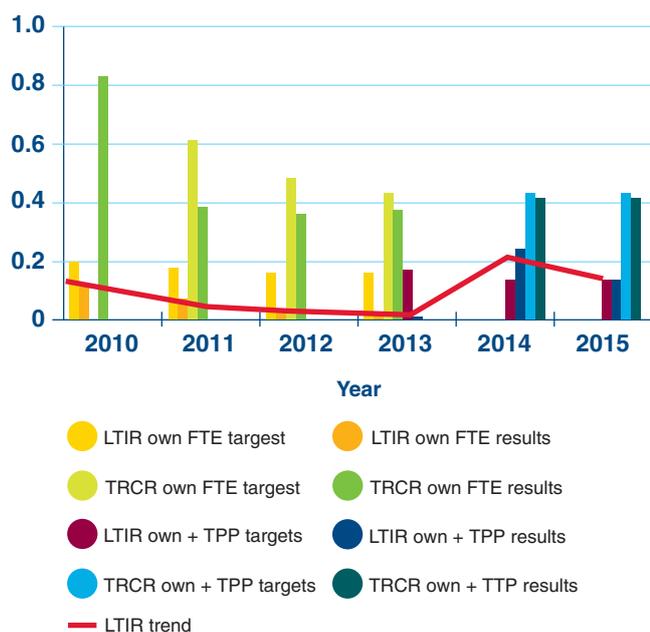
**Table 20: LTIR Index (Lost Time Injury and Illness Rate)**

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2011	0.52	0.00	0.00	0.00	0.05
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

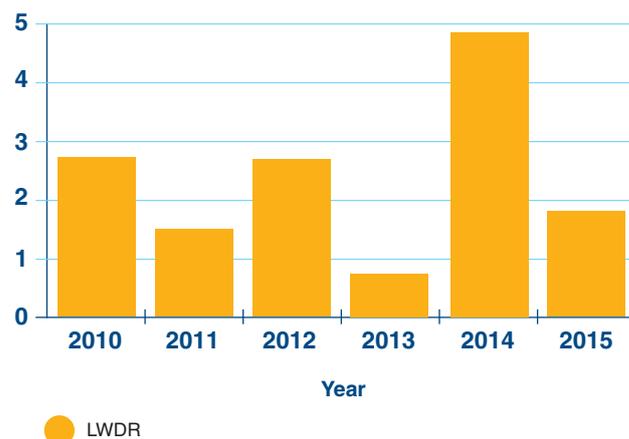
**Table 21: TRCR Index (Total Recordable Case Rate)**

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2011	1.04	0.16	0.39	1.49	0.39
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

**Chart 14: Annual overview of work-related injuries LTIR and TRCR 2010-2015**



**Chart 15: LWDR value (lost time work-day rate) for Lek**



**Incident rate (IR)**

The incident rate (IR) for accidents with recorded sickness absence amounted to 0.6.

It is calculated using the following formula:

$$\text{Incident rate: IR} = \frac{\text{No. of work-related injuries} \times 1,000,000}{\text{No. of hours worked}}$$

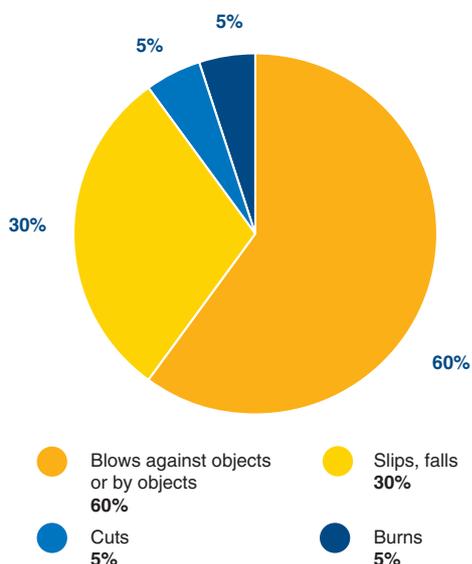
**Lost Time Work-Day Rate – LWDR** defines employee sickness absence due to work-related accidents.

It is calculated by using the following formula: LWDR = number of lost days x 200,000/number of hours worked.

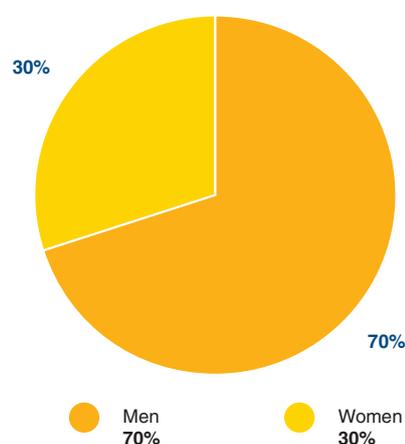
The LWDR value for 2015 was 1.9. Compared with the previous year, it decreased (4.9 in 2014), and, as previously stated, it is a result of 4 cases of work-related injuries requiring sickness absence from work.

By understanding minor accidents, it is possible to set effective preventive measures to prevent accidents at the workplace. We therefore also record the cases where first aid was administered and the employee was able to return to his/her working environment. The annual number of first aid cases (>30) is high which can be attributed to intensified reporting and to the implementation of our guidelines to boost the safety culture, including employee activities to reduce the risk of accidents and other incidents, conduct of walkthrough inspections, safety meetings, and involvement of occupational medicine specialists in every workplace incident.

**Chart 16: Classification of causes of work-related incidents (LTIR and TRCR) for 2015**



**Chart 17: Classification of work-related incidents (LTIR, TRCR) by gender**



## Improved safety culture



*Robert Hribar, Head of HSE*

The successful implementation of the STOP program contributed significantly to the improved safety culture. The program, however, in spite being extensive, did not include all our activities. The special program "pSIF" focused on potential risk of serious injury. It incorporated the detailed evaluation of high risk activities, such as working at heights, working indoors and unscheduled maintenance.

In the area of technical safety we evaluated the risks according to the HAZOP technology and introduced the "Lockout-tagout" system, which ensures the absence of power supply during maintenance procedures. In the area of environmental protection, the so-called environmental walkthroughs were introduced.

## Managers' key roles



*Miroslav Gorza, person in charge of occupational safety and health*

### **How are aims of occupational safety and health set?**

The purpose of preventing occupational illnesses and sources of work related injuries is enabling workers to live through their active period healthy and free of injury. Any injury is one too many. The long standing monitoring has shown that the number of injuries is declining. In the previous year, no serious injuries with health consequences were recorded.

Different risk assessment methods are used to detect increased risks at various workplaces, which are common in our work operations. We keep proving that appropriate safety culture can help us manage the risks and perform work operations without accidents.

### **Do you intend to continue the training for STOP managers in 2016?**

Everybody who works on occupational safety and health is aware that it is an interdisciplinary field, and that achieving a high level of safety is related to many different types of knowledge and skills. The STOP program helped the participants obtain new skills for safety walkthroughs by observing work operations.

Any successful preventive activity should be retained or improved. We will therefore aim to train all managers according to this program. It is the managers who play a key role in safety walkthroughs, and they can contribute to safety culture in their working environment.

### 3.3.2 Absenteeism<sup>82</sup>

In 2015, the proportion of sickness absence was 4.33%, recording a slight increase compared to the previous year (3.80% in 2014). In men, the proportion was 3.47% and in women 5.38%. The rate is calculated on the basis of absence hours as follows: the number of lost working hours of an employee in the period is divided by the organizational unit's total number of working hours in the period.

### 3.3.3 Standard injury, lost day and absentee rates in external contractors

In 2015, we recorded 5 injury cases among contracting providers, which is 50% less than in the previous years (10 cases in 2014).

Contracting providers perform construction and maintenance activities. Injuries result from insufficient measures to

## Health, safety and environment systems

### Improving safety culture and health promotion

The **health and safety at work board** (Safety Board) contributes to the strengthening of safety culture by regularly monitoring current events and taking initiatives for preventative activities. The support of the top management provides openness to such initiatives and confirms comprehensive involvement of the organization in reducing accidents. Improved safety culture is reflected in continuous reduction in the number of work-related incidents.

In 2015, we continued to disseminate information with regard to health and safety at work. We supported the analyses of incident and near-misses investigations by communicating causes and measures for prevention of occupational accidents in similar work environments. In units with increased risk we continued to carry out walkthrough inspections and safety meetings.

In addition to the regular preventative activities, we are paying more attention to walkthrough inspections, as they are in our opinion one of the most important measures for improving safety culture and preventing incidents. They influence the behaviour of the employees and thus prevent hazardous behaviours and conditions, which could lead to incidents and injuries. Our employees are expected to take care of their co-workers and draw their attention to such behaviours and conditions.

An Internet survey recorded more than 2,700 walkthrough inspections between February and the end of the year. In 123 walkthroughs it was revealed that a serious incident or work-related injury could occur in a similar case under different conditions. Adequate measure eliminated these irregularities and ensured the safe continuation of work without impact on employees or environment.

prevent falling from a height and careless handling of tools. We strive to improve their conduct and strengthen their preventive attitude by means of walkthrough inspections, training, and building awareness.

### 3.3.4 Number of work-related fatalities<sup>83</sup>

In this group of associates, no accidents resulting in fatalities were recorded.

### 3.3.5 Occupational disease rate<sup>84</sup>

In the process of detecting occupational illness, risk assessment and workplace stress identification we closely cooperate with occupational medicine specialists. At Lek, no occupational illness has been identified and confirmed to date.



Walkthrough inspections are monitored by an Intranet survey.

The **STOP program** (Safety Training Observation Program, a licensed duPont program) was implemented for safety walkthroughs. Using this program we trained 34 STOP managers, who then further trained more than 300 additional managers for safety walkthroughs on various levels.



Tools for implementing safety walkthroughs according to the STOP program on the Intranet

### 3.3.6 Health promotion program<sup>85</sup>

The duties of employers with respect to ensuring health and safety at work and promoting health in the workplace are laid down in the Health and Safety at Work Act (ZVZD-1). According to the Act, the employer should develop a comprehensive preventive policy that includes workplace health promotion programs.

We again encouraged employees to embrace a more active and healthier lifestyle with the **Health promotion program**. We offered preventative active recovery with healthcare programs, guided exercise and in a preventative vaccination program, e.g. against seasonal influenza and against tick-borne meningoencephalitis.

Annual perpetuated safety, health and environmental activities became our standard:

- regular periodic training on health and safety at work and fire safety for the employees;
- regular training on establishing and maintaining the safety culture (Behaviour Based Safety – BBS) for new hires and managers;

At Lek, a Sandoz company, health promotion is a process that enables employees to take control of health in their own hands and represents a joint effort of both the company and workers to improve their health and well-being.

- workshops on different areas of health and safety at work, such as industrial hygiene, incident investigations, process risks, etc.;
- targeted education in the individual organizational units on health and safety at work, safety culture, chemical safety, fire safety and NEM (Novartis Emergency Management) as an integral part of the BCM (Business Continuity Management);
- tactical fire drills, in accordance with the risk portfolio, for checking the responsiveness of protection and rescue teams, their equipment and action in case of unforeseen events;
- evacuation drills with practical fire extinguishing training;
- regular annual training in first aid.

**Novartis' "Be Healthy" program** is an initiative aiming to improve the health of our employees, designed on the basis of risk assessments for individual jobs, reports from periodic medical examinations and individual medical reports. It is

designed to promote a healthy lifestyle, share knowledge and experience, as well as prevent injuries and illnesses which could affect associates' private and professional life.

#### Four pillars of the "Be Healthy" program:

#### Move

to increase exercise.

#### Choose

for healthy food options and appropriate diet at home as well as at work.

#### Know

for knowing the values of key health indicators.

#### Manage

for support for employees on stress management.



*We were working out with Petra Majdič again.*



*Among other things, we measured our blood pressure within the "Be Healthy" program.*

Activities organized during the Health Week were attended by approximately 1,900 employees from all sites. These activities were combined with the family day in order to promote a healthy family lifestyle.

<sup>85</sup> GRI G4-DMA



Guided exercise took place outside our offices.



We were visited by representatives of the Europa Donna society and learned how to recognize the breast cancer.

Programs/initiatives during the Health Week	Ljubljana	Mengeš	Lendava	Prevalje	Total
Health indicator measurements	71	58	31	40	200
MOVE initiative with Petra Majdič	238	167	100	30	535
Farming for food self-sufficiency					49
Healthy meals at the canteen					420
Stress and burnout	150	92	5	18	265
Family day	100	60	31	50	241
First aid	114	12	15	23	164
Europa Donna/Presentation	32	11	2	4	49
<b>Total</b>					<b>1,923</b>

## 3.4 Training and education

### 3.4.1 Average hours of training per year per employee by employee category<sup>86</sup>

For several years, we have been increasing the scope of training provided to our employees. Compared to the previous year, in 2015, the average number of hours training per employee increased by nearly 10%. The average amount of time given to training per employee was 5.84 days per year, or 8.93 days if compulsory on-the-job-training is included.

**Table 22: Average training hours/employee**

Year	Number of hours/ employee
2011	40.07
2012	54.32
2013	56.36
2014	61.68
2015	71.44

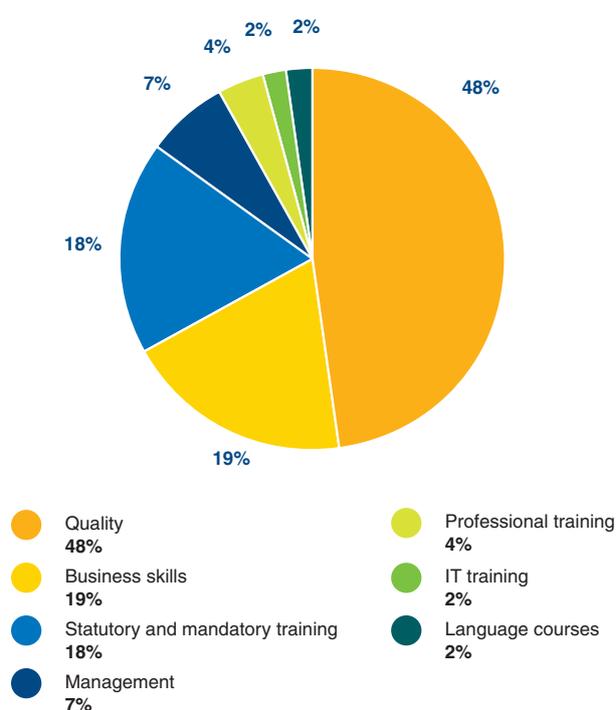
Our employees were provided the opportunity of part-time studies upgrading the level of their formal education. Last year, in total, 4.08% of the workforce was involved in part-time studies, which was nearly at the same level as in the previous year. With the company's support, 67 employees were involved in undergraduate studies, and 70 in post-graduate studies, mainly in biotechnology, biomedicine and chemistry.

### 3.4.2 Training by area

The largest number of training hours was dedicated to three areas: business skills (25%), quality (23%), and language courses (19%).

The highest participation rate was recorded in quality (48%), business skills (19%), and statutory and mandatory training (18%).

**Chart 18: Training in 2015 by topic (attendance)**



<sup>86</sup> GRI Indicator G4-LA9

## 4. PRODUCTS<sup>87</sup>



*Pharmaceuticals development laboratory*

Lek provides the professional public in Slovenia with information on the properties and action of medicinal products on the basis of the Summaries of Product Characteristics approved by the JAZMP. The users are informed by Patient Information Leaflets, in which we openly and transparently communicate all the relevant information regarding the safety and efficacy of medicinal products, as well as posology and administrative information. Similar practice applies to non-prescription medicinal products. Communication of information related to pharmaceuticals<sup>88</sup> is regulated by the Medicinal Products Act.

In informing users we ensure compliance with the Novartis Promotional Practices Policy which, in several cases, is even more restrictive than Slovenian legislation. Every communication we provide to the professional public is supported by reasonable scientific evidence, particularly those related to safety such as contraindications, warnings, interactions, etc. In pharmacies and health institutions, various free health information materials are available for users of medicinal products, and medical advice can be obtained on our website <http://www.lek.si/en/>.

The key therapeutic groups of medicines that we develop, produce and market are listed under Item 1.2.2.

### **Compliance with regulations concerning products<sup>89</sup>**

The inspection authority at JAZMP instituted no offence procedure against Lek in 2015.

### **Practices of measuring customer satisfaction<sup>90</sup>**

To gain an insight into the satisfaction of the professional public, a series of expert meetings were held. Based on participants' feedback, Lek once again proved to be enjoying a good reputation with the professional public which manifests a high degree of satisfaction with our product range. In 2015, we conducted a survey among young physicians, who place us among the most respectable pharmaceutical companies.

### **Adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship<sup>91</sup>**

In drug advertising, promotional activities and other non-promotional activities, including the cooperation with health workers, health organizations, patients and patient groups, we act in accordance with the Medicinal Products Act, Rules on Advertising of Medicines, and internal rules, framed by the SP3 – Promotional Practices Policy. Conformity of conduct is ensured by permanent awareness-raising in employees, and prior review and approval of all above mentioned activities.

In 2015, there were no cases of violations of marketing communication rules, standards and non-binding codes, including those related to advertising, promotion and sponsorship. The JAZMP instituted no procedures for any drug advertising in violation of local regulations. There was no sponsorship involving drug promotion. In corporate sponsorship, there were no non-compliance cases.

## 5. HUMAN RIGHTS AND ANTITRUST COMPLIANCE<sup>92</sup>



*On the International Day of People with Disabilities, Lek Ljubljana hosted representatives of the Slovenian Association of Disabled Students. They arranged empiric workshops with the title "Change through experience" for our associates to experience the role of a blind, partially-sighted person, deaf and hard of hearing person, as well as a person with disabilities or mobility difficulties.*

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 2014, Lek, a Sandoz company, signed the **Slovenian Corporate Integrity Guidelines** and joined the **ambassadors of corporate integrity**.

In 2015, we further intensified our efforts for ethical and accountable business practices and conduct of all our employees. We implemented **Novartis' global initiative** to improve the culture of integrity and firmly incorporate these values into our operations.

Our employees participated in **regular and ongoing training** in the area of compliance of our operations. We organized online training on all key areas of compliance (Code of Conduct, conflicts of interests, reporting of adverse effects of medicinal products, prevention of bribery) in which areas of change were emphasized.

The training was successfully completed by 99% of employees. We also organized a series of trainings on protection of personal data, professional practices in medicinal product advertising and interactions with the professional public as well as fair competition. All trainings are a part of a regular education program for all new employees at Lek. They provide the freshening of familiarity with simple and generally clear principles of compliant conduct.

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.

<sup>92</sup> GRI Disclosure G4-56, GRI Indicator G4-DMA

Compliance standards which apply for Novartis' employees and their companies are implemented also in relations with third parties.

Together with our policies and guidelines, the **Code of Conduct** provides guidance for all our employees since any violation of its rules may severely damage the company's reputation.<sup>93</sup> In particular, the Code of Conduct prohibits any form of discrimination on the basis 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 different profiles, which differ in ways of thinking and managing, gender, race, religion, sexual orientation, age, experience, etc. Teams

with diverse members are more creative and successful in meeting challenges, as they see things from different angles. Work in such environment is a lot more stimulative, interesting and lively. The individual diversity and personal characteristics of our employees constitute an asset and the strength of our company, and are the source of our teams' creativity. They connect us with our patients and customers, and we are convinced that they are crucial for mutual understanding and viability.

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

In 2015, there were no cases of discrimination and no requests to remedy any violation in this area in Slovenia.<sup>94</sup>

The company was also not involved in any antitrust procedure for any violation of antitrust regulations.<sup>95</sup>

## 6. SUPPLIERS<sup>96</sup>



*Building of high-shelving warehouse in Lendava*

### 6.1 Purchasing policy

We perform systematic control over the purchasing process for goods and services in every aspect that has the potential to affect the company's ethical and business interests and financial outcomes. At all levels, employees of the purchasing department are committed to following the purchasing procedures laid down by the Sandoz guidelines, international agreements and local regulations. Sandoz Group associates are also not allowed to use the business relations between the Group and its suppliers for private purposes.

#### 6.1.1 Purchasing system

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

In 2015, we recorded substantial growth in the value of direct purchases, which is largely due to the increased business volume of production units. The internal system optimization resulted in a lower total value of purchases. The volatility of commodity markets and the raising of industry standards again tightened the pharmaceutical company's supply conditions thus additionally narrowing the range of suppliers. In order to achieve more competitive prices and a more reliable supply chain we further increased the scope of active risk management and partnership with the Sandoz and Novartis global supply function.

Our leading direct purchasing markets were Slovenia, Germany, Switzerland, China, India, Austria and Italy.

In the field of indirect purchasing, the largest markets were Slovenia, Italy, Germany, Austria, Switzerland and Canada.

<sup>96</sup> GRI Disclosures G4-12, G4-13

## 6.1.2 Supplier audit procedures<sup>97</sup>

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

Before the actual purchasing takes place, written comparable offers must be obtained from various suppliers. This applies to both new purchasing projects and to regular purchases with fixed annual purchasing quantities.

## 6.2 Policy and practices for selecting local suppliers<sup>98</sup>

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.

Among individual countries, Slovenia maintains the largest share in the direct purchasing structure. In 2015, the level of deliveries from the Slovenian market amounted to USD 51 million or 17% of total purchasing cost (16% in 2014).

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 78% (USD 245 million).

# 7. GRI G4 CONTENT INDEX – CORE

## General standard disclosures

Disclosure	Boundaries	Chapter/Page
<b>Strategy and Analysis</b>		
G4-1	Statement from the most senior decision-maker of the organization about the relevance of sustainability to the organization and the organization's strategy for addressing sustainability.	Lek d.d. Page 4
<b>Organizational Profile</b>		
G4-3	Name of the organization.	Lek d.d. 1/6
G4-4	Primary brands, products, and/or services.	Lek d.d. and all Lek's sites 1.2/13, 1.2.2/17, 1.2.3/17
G4-5	Location of organization's headquarters.	Lek d.d. 1/6, 1.2/13
G4-7	Nature of ownership and legal form.	Lek d.d. 1/6, 1.2/13
G4-8	Markets served.	Lek d.d. 1.2.1/17
G4-9	Scale of the organization.	All Lek's sites 1.1.1/7
G4-10	Total number of employees by employment type, employment contract, region and gender.	Lek d.d. 3.2.1/65
G4-11	Percentage of total employees covered by collective bargaining agreements.	Lek d.d. 3.2.2/65
G4-12	Organization's supply chain.	Lek d.d. 6/76
G4-13	Significant changes during the reporting period regarding the organization's size, structure, ownership, or its supply chain.	Lek d.d. 1.2.3/17, 1.3.1/26, 6/76
G4-14	Explanation, whether and how the precautionary approach or principle is addressed by the organization.	Lek d.d., local community, patients and customers 1.4.4/35, 2/37, 2.1/39
G4-15	Externally developed economic, environmental and social charters, principles, or other initiatives to which the organization subscribes or which it endorses.	Lek d.d., Lek's stakeholders 1.4.4/35
G4-16	Memberships of associations and national or international advocacy organizations.	Lek d.d. 1.4.4/35
<b>Identified Material Aspects and Boundaries</b>		
G4-17	List of all entities included in the organization's consolidated financial statements or equivalent documents.	Lek d.d. and all Lek's sites 1.3.1/26
G4-18	The process for defining the report content and the Aspect Boundaries.	Lek d.d., Lek's stakeholders 1.3/25
G4-19	Material Aspects identified in the process for defining report content.	Lek d.d., Lek's stakeholders 1.3/25
G4-20	Limitations regarding the Aspect Boundary within the organization.	Lek d.d., Lek's stakeholders 1.3/25
G4-21	Limitations regarding the Aspect Boundary outside the organization.	Lek d.d., Lek's stakeholders 1.3/25
G4-22	Effect of any restatements of information provided in previous reports, and the reasons for such restatements.	Lek d.d. 1.3.1/26
G4-23	Significant changes from previous reporting periods in the Scope and Aspect Boundaries.	Lek d.d. 1.3.1/26
<b>Stakeholder Engagement</b>		
G4-24	List of stakeholder groups engaged by the organization.	Lek d.d. 1.4.3/28, 1.4.3.1/29
G4-25	Basis for identification and selection of stakeholders with whom to engage.	Lek d.d., Lek's stakeholders 1.4.3/28
G4-26	Approach to stakeholder engagement, including frequency by type and by stakeholder group.	Lek d.d., Lek's stakeholders 1.4.3.1/29
G4-27	Key topics and concerns that have been raised through stakeholder engagement, and how the organization has responded to those key topics and concerns, including through its reporting.	Lek d.d., Lek's stakeholders 1.4.3.1/29

Disclosure		Boundaries	Chapter/Page
<b>Report Profile</b>			
G4-28	Reporting period.	Lek d.d. and all Lek's sites	1.3/25, 1.3.1/26
G4-29	Date of most recent previous report.	Lek d.d. and all Lek's sites	1.3/25, 1.3.1/26
G4-30	Reporting cycle.	Lek d.d. and all Lek's sites	1.3/25, 1.3.1/26
G4-31	Contact point for questions regarding the report or its contents.	Lek d.d.	1/6
G4-32	GRI Content Index.	Lek d.d.	Page 78
G4-33	The organization's policy and current practice with regard to seeking external assurance for the report.	Lek d.d.	1.3/25
<b>Governance</b>			
G4-34	The governance structure of the organization, including committees of the highest governance body.	Lek d.d.	1.4.1/26
<b>Ethics and Integrity</b>			
G4-56	Organization's values, principles, standards and norms of behavior such as codes of conduct and codes of ethics.	Lek d.d.	1.4.4/35, 5/74

## Specific standard disclosures

Material Aspects	Disclosures on Management Approach (DMA) and Indicators	Boundaries	Chapter/ Page	Omission and/or Deviating Presentation
<b>ECONOMIC</b>	<b>DMA</b>		<b>3.1/65, 6.1.2/77 6.2/77</b>	
Economic Performance	G4-EC1	Direct economic value generated and distributed.	All Lek's sites, owners, employees	1.1.1/7
	G4-EC3	Coverage of the organization's defined benefit plan obligations.	All Lek's sites, employees	3.2.3/65
	G4-EC4	Financial assistance received from government.	All Lek's sites	1.1.1/7
Market presence	G4-EC6	Ratios of standard entry level wage by gender compared to local minimum wage at significant locations of operation.	All Lek's sites, local community	3.2.4/65
Procurement Practices	G4-EC9	Proportion of spending on local suppliers at significant locations of operation.	All Lek's sites, local community, suppliers	6.2/77
<b>ENVIRON- MENTAL</b>	<b>DMA</b>		<b>2/37-38, 2.1/39, 2.1.3/40, 2.2.4/43, 2.4.1/47, 2.5.1/48, 2.7/53, 2.7.1/54, 2.7.2/57, 2.8.4/58, 2.9.3.2/60, 6.1.2/77</b>	
Materials	G4-EN1	Materials used by weight or volume.	All Lek's sites	2.2.2/42
Energy	G4-EN3	Energy consumption within the organization.	All Lek's sites	2.3.1/44
	G4-EN5	Energy intensity.	All Lek's sites	1.1.3/10, 2.2.5/4
	G4-EN6	Reduction of energy consumption.	All Lek's sites	2.3.3/46
Water	G4-EN8	Total water withdrawal by source.	All Lek's sites, local community	2.4.1/47, 2.4.2/47
	G4-EN10	Percentage and total volume of water recycled and reused.	All Lek's sites, local community	2.4.3/48

Material Aspects	Disclosures on Management Approach (DMA) and Indicators	Boundaries	Chapter/ Page	Omission and/or Deviating Presentation
Biodiversity	G4-EN12 Description of significant impacts of activities, products, and services on biodiversity in protected areas and areas of high biodiversity value outside protected areas.	All Lek's sites, local community	2.8.4/58	
Emissions	G4-EN15 Direct greenhouse gas (GHG) emissions (Scope 1).	All Lek's sites, local community	2.6.5/52	
	G4-EN16 Energy indirect greenhouse gas (GHG) emissions (Scope 2).	All Lek's sites, local community	2.6.5/52	
	G4-EN19 Reduction of greenhouse gas (GHG) emissions.	All Lek's sites, local community	2.3.3/46	
	G4-EN21 NO <sub>x</sub> , SO <sub>x</sub> and other significant air emissions.	All Lek's sites, local community	2.6/51, 2.6.3/51, 2.6.4/52	
Effluents and waste	G4-EN22 Total water discharge by quality and destination.	All Lek's sites, local community	2.7.1/56	
	G4-EN23 Total weight of waste by type and disposal method.	All Lek's sites, local community	2.5.1/48, 2.5.2/49, 2.5.3/58	
Products and services	G4-EN27 Extent of impact mitigation of environmental impacts of products and services.	Lek d.d., patients, customers	2.7.2/57	
Compliance	G4-EN29 Monetary value of significant fines and total number of non-monetary sanctions for non-compliance with environmental laws and regulations.	All Lek's sites	2.1/39	
Transport	G4-EN30 Significant environmental impacts of transporting products and other goods and materials for the organization's operations, and transporting members of the workforce.	Lek d.d., suppliers	2.1.5/41 2.9.3.2/60	
Overall	G4-EN31 Total environmental protection expenditures and investments by type.	All Lek's sites	2.1.2/40	
Supplier Environmental Assessment	G4-EN33 Significant actual and potential negative environmental impacts in the supply chain and actions taken.	Lek d.d., suppliers	2.1.5/41	Supplier environmental responsibility is one of the important criteria in the tendering process and selection of suppliers.
Environmental Grievance Mechanisms	G4-EN34 Number of grievances about environmental impacts field addressed, and resolved through formal grievance mechanisms.	Lek d.d., sites Ljubljana, Mengeš and Prevalje, local community	1.4.3.1/31, 2.1/39	
<b>SOCIAL</b>				
<b>Labour practices and decent work</b>	<b>DMA</b>		<b>1.4.2/27, 3.1/64, 3.3.6/70, 5/74 6.1.2/77</b>	
Employment	G4-LA1 Total number and rates of new employee hires and employee turnover by age group, gender, and region.	All Lek's sites, employees	1.1.1/7	
	G4-LA3 Return to work and retention rates after parental leave, by gender.	Lek d.d., employees	3.2.5/65	

Material Aspects	Disclosures on Management Approach (DMA) and Indicators	Boundaries	Chapter/ Page	Omission and/or Deviating Presentation	
Occupational Health and Safety	G4-LA6	Work-related injury rates.	All Lek's sites, employees	1.1.3/10, 3.3.1/66, 3.3.2/69, 3.3.4/69	
	G4-LA7	Workers with high incidence or high risk of diseases related to their occupation.	Lek d.d., employees	3.3.5/69	
Training and Education	G4-LA9	Average hours of training per year per employee by gender, and by employee category.	Lek d.d., employees	3.4.1/72	Records of training by gender and by employee category are not yet kept.
Equal Remuneration for Women and Men	G4-LA13	Ratio of basic salary and remuneration of women to men by employee category, by significant locations of operation.	Lek d.d., employees	3.2.4/65	
Supplier Assessment for Labour Practices	G4-LA15	Significant actual and potential negative impacts for labour practices in the supply chain and actions taken.	Lek d.d., suppliers	2.1.5/41	By signing a contractual agreement the supplier undertakes to comply with all applicable laws and regulations related to fair labour practices.
<b>Human rights</b>	<b>DMA</b>			<b>5/74, 6.1.2/77</b>	
Investment	G4-HR2	Total hours of employee training on human rights policies or procedures concerning aspects of human rights that are relevant to operations, including the percentage of employees trained.	Lek d.d., employees, local community	5/75	
Non-discrimination	G4-HR3	Total number of incidents of discrimination and corrective actions taken.	Lek d.d., employees,	5/75	
Child Labour	G4-HR5	Operations and suppliers, identified as having significant risk for incidents of child labour, and measures taken to contribute to the effective abolition of child labour.	Lek d.d., suppliers	6.1.2/77	
Forced or Compulsory Labour	G4-HR6	Operations and suppliers, identified as having significant risk for incidents forced or compulsory labour, and measures to contribute to the elimination of all forms of forced or compulsory labour.	Lek d.d., suppliers	6.1.2/77	

Material Aspects	Disclosures on Management Approach (DMA) and Indicators	Boundaries	Chapter/ Page	Omission and/or Deviating Presentation	
<b>Society</b>	<b>DMA</b>		<b>5/74</b>		
Local Communities	G4-SO1	Percentage of operations with implemented local community engagement, impact assessments, and development programs.	All Lek's sites, local community	1.4.3.1/31	Currently, the data acquisition system does not allow the calculation of the proportion, however we do report on the number of activities.
Anti-competitive Behavior	G4-SO7	Total number of legal actions for anti-competitive behavior, anti-trust, and monopoly practices and their outcomes.	Lek d.d., local community	5/75	
<b>Product responsibility</b>	<b>DMA</b>		<b>4/73</b>		
Product and Service Labeling	G4-PR3	Type of product and service information required by the organization.	Lek d.d., regulators	4/73	
	G4-PR4	Total number of incidents of non-compliance with regulations and voluntary codes concerning product and service information and labeling, by type of outcomes.	Lek d.d., regulators, patients, health professionals and health care providers, patients, customers	4/73	
	G4-PR5	Results of surveys measuring customer satisfaction.	Lek d.d., Professional associations, Patients	4/73	
Marketing Communications	G4-PR7	Total number of incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship, by type of outcomes.	Lek d.d., regulators, patients, health professionals and health care providers, customers	4/73	

## 8. GLOSSARY OF KEY TERMS

### **EMAS (ECO – Management and Audit Scheme)**

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

### **GRI (Global Reporting Initiative)**

GRI Guidelines represent one of the world's most prevalent standards for corporate responsibility and sustainable development reporting. They require planning and reporting according to the measurable indicators of the economic, social and environmental impact of an organization. Depending on the scope of disclosures and measurable indicators, reports are classified into two application levels, core and comprehensive.

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.<sup>99</sup>

**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.<sup>100</sup> 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 characterisation 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, anaemia, rheumatic, cardiovascular and some other types of diseases. Over the past years, biologics have saved lives, prolonged survival and improved the quality of life for patients with severe and often chronic diseases.

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

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

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

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

- Class 1 biological agent/genetically modified organism poses minimum risk to human health and the risk of being spread into the environment is negligible;
- Class 2 biological agent/genetically modified organism of this class may cause human disease and may be hazardous for workers; the risk of being spread into the environment is minimal, in the majority of cases and effective prevention or treatment is available.

<sup>99</sup> Source: Medicinal Products Act – ZZdr-1 (Official Gazette of the RS, No. 31/06 of 24.3.2006) and the Act Amending the Medicinal Products Act – ZZdr-1A (Official Gazette of the RS, No. 45/08 of 9. 5. 2008).

<sup>100</sup> Source: Humar M., Šmid-Korbar J., Obreza A. Dictionary of Pharmaceutical Terminology. Ljubljana 2011.

**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).

## Novartis Community Partnership Day

Volunteer work undertaken by many employees at Lek, a Sandoz company, enriches life in local communities. Priority is given to intergenerational cooperation, assistance in social inclusion of sensitive groups and concern for the natural environment. Together with schools and educational institutions, the employees share their expertise with children and adolescents and give them a glimpse of their professions, increasing their curiosity.

The main initiatives endorsed by Lek, a Sandoz company, for improving ties with the local environment, are the Novartis Community Partnership Day and the Open House Day. In 2015, these days of precious socializing were attended by a high number of visitors, which indicates that the activities at our sites, particularly the options for employment, create much interest, and demonstrates the desire and willingness of the employees to contribute to the prosperity of local communities.

For more details, please see pages 32 and 33.



*We took part in the "Let's Clean Kočevska" clean-up action.*



*We took a walk around the zoo with the residents of the Ljubljana Vič-Rudnik Retirement Home, Bokalce unit.*



*We enjoyed creative socializing with the Janez Levec Centre users in Ljubljana.*



*We helped tidy up holiday resorts owned by the Slovenian Association of Friends of Youth in Pacug and Piran.*



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