



**lek**

a Sandoz company

# Sustainability Report 2013 Lek d.d.





# Table of Contents

<b>1. COMPANY PROFILE</b>	<b>3</b>
1.1 Letter from the President of the Board of Management	4
1.2 Key data for 2013	8
1.3 About us	10
1.4 Development and reporting framework	17
1.5 Governance, commitments, inclusion	18
<b>2. ENVIRONMENT</b>	<b>25</b>
2.1 Implementation of active environmental policy	28
2.2 Raw materials and natural resources	32
2.3 Energy	26
2.4 Water	28
2.5 Waste	30
2.6 Air emissions	32
2.7 Water releases	35
2.8 Other environmental impacts	42
2.9 Safety	43
<b>3. LABOUR</b>	<b>48</b>
3.1 Human resources policy	48
3.2 Employment	50
3.3 Occupational health and safety	50
3.4 Training and education	56
<b>4. PRODUCTS</b>	<b>57</b>
<b>5. HUMAN RIGHTS AND ANTITRUST COMPLIANCE</b>	<b>58</b>
<b>6. SUPPLIERS</b>	<b>59</b>
6.1 Purchasing policy	59
6.2 Policy, practices, and proportion of spending on locally-based suppliers	59
<b>TABLE OF CONTENTS ACCORDING TO GRI G4 REPORTING GUIDELINES</b>	<b>60</b>
<b>GLOSSARY OF KEY TERMS</b>	<b>63</b>

## Sustainability report 2013 – Lek d.d.

Published by: Lek d.d.

Text: Mojca Bernik, Lek d.d.

Edited by: Studio Kernel

Designed by: Intesa RD

Photography: Lek d.d. Archive; Fotolia;

Cover: Sandoz Prevalje Site

Printed by: Silveco d.o.o.

Number of printed copies: 100

Ljubljana, September 2014

The report is printed on environmentally friendly, 100% recycled, uncoated paper CocoonOffset. The paper is manufactured from 100% genuine post-consumer fibers, Process Chlorine Free, EU Ecolable (No. FR/011/03)\* certified, and Heavy metal free certified. It is produced at mills that hold ISO 14001 certificate. The carbon footprint of the paper used by Arjowiggins Graphic, the manufacturer: 602 kg of CO<sub>2</sub>/tonne of paper (Bilan Carbone® methodology).

\*The Ecolabel reflects the manufacturer's commitment to continual environment management improvements.

# 1. Company profile



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

Company name:	<b>Lek Pharmaceuticals d.d.</b>
Abbreviated name:	<b>Lek d.d.</b>
Registered office:	<b>Ljubljana</b>
Business address:	<b>Verovškova 57, 1526 Ljubljana, Slovenia</b>
Registration number:	<b>1732811000</b>
Standard Classification of Economic Activities in the European Community (NACE):	<b>21.200 Manufacture of pharmaceuticals</b>
Registered at:	<b>District Court in Ljubljana under the registry number: 1/36542/00</b>
Telephone:	<b>+ 386 1 580 21 11</b>
Fax.:	<b>+ 386 1 568 35 17</b>
E-mail:	<b><a href="mailto:info.lek@sandoz.com">info.lek@sandoz.com</a></b>
Website:	<b><a href="http://www.lek.si/en">http://www.lek.si/en</a></b>
<b>Contacts</b>	
Legal representative Vojmir Urlep, President of the Board of Management; <a href="mailto:vojmir.urlep@sandoz.com">vojmir.urlep@sandoz.com</a>	Contact person Mojca Bernik, Environmental Manager; <a href="mailto:mojca.bernik@sandoz.com">mojca.bernik@sandoz.com</a>
Qualified person Robert Hribar, Head HSE; <a href="mailto:robert.hribar@sandoz.com">robert.hribar@sandoz.com</a>	Contact person for information on sustainable development reporting <sup>2</sup> Igor Boševski, Head Global Manufacturing AI/API; <a href="mailto:igor.bosevski@sandoz.com">igor.bosevski@sandoz.com</a>

<sup>1</sup> GRI Disclosures G4-3, G4-5, G4-7 | <sup>2</sup> GRI Disclosure G4-31

## 1.1 Key Data for 2013

### 1.1.1 Operations in 2013

Table 1: Key figures for 2013<sup>3</sup>

Indicator	Unit	31. 12. 2013	31. 12. 2012	Index 2013/2012
<b>Number of employees</b>		<b>2,972</b>	<b>2,780</b>	<b>107</b>
- Ljubljana site		1,762	1,713	103
- Mengeš site		739	655	113
- Lendava site		296	245	121
- Prevalje site		175	167	105
<b>Production output*</b>	<b>000 tonnes</b>	<b>3.85</b>	<b>3.79**</b>	<b>102</b>
<b>Net sales revenues</b>	<b>in EUR m</b>	<b>745.334</b>	<b>660.435</b>	<b>113</b>
<b>Liabilities</b>	<b>in EUR m</b>	<b>852.332</b>	<b>869.540</b>	<b>98</b>
<b>Equity</b>	<b>in EUR m</b>	<b>524.287</b>	<b>505.451</b>	<b>104</b>

\* Due to extremely large differences in the weight of various types of products, and due to the manufacturing structure being adjusted to changes in demand, the data is difficult to compare. We therefore believe that the comparison of production outputs is irrelevant. Differences in product weight should also be taken into account when reading data on the efficiency per ton of product. For example, the weight of biosimilars is low 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.

\*\* The change in the value over that reported for 2012 is the result of adjustments made to the data on production output and use of raw materials. The changes occurred in the data on production output for various finished pharmaceuticals at the Ljubljana site.

#### Economic performance<sup>4</sup>

In 2013, Lek, a Sandoz company, realized net sales revenue in the amount of EUR 745.334 million, a 13% increase over the previous year. Revenue increased by 13% in foreign markets and by 9% in the domestic market.

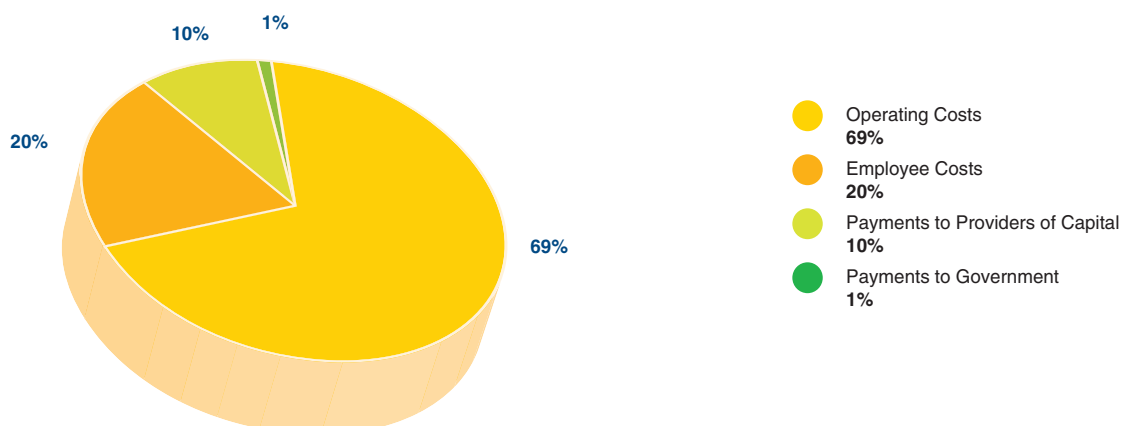
**Direct Economic Value Generated** amounted to EUR 775 million, of which **Economic Value Distributed** totalled EUR 705 million (91%) and **Economic Value Retained** amounted to EUR 70 million (9%).

Within Economic Value Distributed, **Operating Costs** amounted to EUR 485 million (69%). **Employee Costs** amounted to EUR 143 million (20%), **Payments to Provi-**

**ders of Capital** reached EUR 70 million or 10%, and **Payments to Government** totalled EUR 8 million or 1% of Economic Value Distributed.

The tax relief value due to investment in research activity amounted to EUR 13.872 million (23.811 million in 2012). For investments, tax relief amounted to EUR 20.096 million. We also received public subsidies amounting to EUR 454,000.<sup>5</sup>

Graph 1: Structure of Economic Value Distributed



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

Indicator	Unit	31. 12. 2013	31. 12. 2012	Index 2013/2012
Efficiency of energy resource use	GJ/t	303	302	100
Water use efficiency	m <sup>3</sup> /t	853	835*	102
Waste volumes – efficiency	t waste/t product	8.27	5.05*	164***
VOC emission – efficiency	t VOC/t product	0.033	0.038*	87
LTIR** – work-related injuries and illnesses involving days away from work		0.04	0.05	80
TRCR** – work-related injuries and illnesses requiring more than basic first aid		0.38	0.35	109

\* The figures differ from those published in the Sustainability Report 2012 due to adjustments made to the data on production output and use of raw materials previously stated under the Notes of Table 1. These result in changes in the calculation of efficiency in all the areas.

\*\* The definition of LTIR and TRCR indicators as well as the formula for their calculation are indicated under Item 3.3.2 Monitoring work-related accidents.

\*\*\* See explanation in Section 2.5.1.

### 1.1.2 Health, safety and environment (HSE) objectives and their realization

In the field of HSE, we pursue Novartis long-term global objectives set for the period up to 2015, while implementing annual short-term goals. Progress is monitored annually for individual sites and for the company as a whole, Data for reporting requirements is collected and confirmed in the Novartis DMS (Data Management System) system.

Our environmental performance is being improved through:

- regular assessment of the HSE system performance,
- open communication with internal and external publics and

- involvement of all employees in the system of care for the environment.

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). To ensure better transparency of our efforts to manage the relevant environmental impacts, in this year's report we present our annual objectives by site, thereby enabling us to track the role of each site in 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 which is amended, if necessary, at every revision of the Health, Safety and Environment Rules.

Objectives by 2015	Status 2013
Improving water use efficiency by 10% over 2010.	<b>Realized.</b> Water use efficiency improved by <b>24%</b> . Year 2010: 1,124 m <sup>3</sup> /t Year 2013: 853 m <sup>3</sup> /t
Improving energy efficiency by 10% over 2010.	<b>Realized.</b> Energy efficiency improved by <b>17%</b> . Year 2010: 363 GJ/t Year 2013: 303 GJ/t
Reducing VOC emissions (h-VOC and nh-VOC) into the air by 20% over the 2010 figures.	<b>Realized.</b> Emissions reduced by <b>51%</b> . Year 2010: 258 t Year 2013: 126 t
Reducing waste volumes by 10% over 2010.	<b>Partly realized.*</b> Year 2010: 11,000 t Year 2013: 31,857 t or 8,401 t (excluding mycelium waste)
Reducing LTIR to 0.1.	<b>Realized.</b> 0.04

\* 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. The volume of mycelium waste amounted to 23,456 t in 2013. Comparison of the volume of waste between 2010 and 2013 is realistic only if mycelium waste is subtracted from the total amount of waste. Total waste in 2013 thus amounted to 8,401 tons, corresponding to a 24% reduction in volume compared to 2010.





## HSE targets for 2013

Objectives for 2013	Realization in 2013 (for entire Lek, a Sandoz company)
Ecotoxicity assessment of APIs, % of APIs in production	<b>Realized.</b> Evaluation for all APIs for which ecotoxicity data is available in literature. Due to changing of the API range in the production this is an ongoing task.
Non-halogenated VOC emissions to the air (nh-VOC) Target: ≤142 tonnes	<b>Realized.</b> Emissions reached 126 tonnes.
Halogenated VOC emissions to the air (h-VOC) Target: 1 tone	<b>Realized.</b> Emissions reached 0.7 tonnes.
Energy savings	<b>Projects realized.</b> Despite the increase in production we managed to maintain the use of energy on the same level as in 2012.
Reducing hazardous waste volumes	<b>Realized.</b> Hazardous waste reduced by 7%.
Reducing non-hazardous waste volumes	<b>Not realized.</b> Despite disregarding mycelium waste, the non-hazardous waste volume increased by 3%.
LTIR* (own employees) Target: ≤0.14	<b>Realized.</b> Realization 0.04.
LTIR* (own employees + employees hired through employment agencies) Target: ≤0.16	<b>Realized.</b> Realization 0.03.
TRCR* (own employees) Target: ≤0.43	<b>Realized.</b> Realization 0.38.

\* Definition of LTIR and TRCR indexes and formula for their calculation are given under Item 3.3.2 Monitoring of work-related incidents.



## HSE targets for 2014

		Mengeš	Ljubljana	Lendava	Prevalje
Ecotoxicity assessment of APIs	% of APIs in production	100	100	100	Inclusion of results in PRORA*
Non-halogenated VOC emissions to the air (nh-VOC)	t	70 t Project Reduction of emissions from facilities 34 and B04	Maintaining the 2013 level	25 t	Maintaining the 2013 level
Halogenated VOC emissions to the air (h-VOC)	t	<1 t	No emissions	No emissions	No emissions
Energy savings	J	3 projects	3 projects	3 projects	3 projects
Reducing hazardous waste volumes	t/t (efficiency)	Project Coincineration of waste solvents	Project Reduction of write-down finished products	Project Dipede recycling	Maintaining the 2013 level
Reducing non-hazardous waste volumes	t/t (efficiency)	0.6	Project Packaging	Maintaining the 2013 level	
LTIR (own employees + employees hired through employment agencies)		0.13	0.14	0.14	0.14
TRCR (own employees + employees hired through employment agencies)		0.44	0.46	0.46	0.46

\* Process Risk Assessment



## 1.2 Letter from the President of the Board of Management<sup>7</sup>

Dear readers,  
dear shareholders of  
Lek, a Sandoz company,



**A strategy should not only inspire, it should also be realistic.** This report demonstrates that the strategy of our corporate responsibility for 2014 has solid foundations. It focuses on increasing access to affordable, high-quality health care for patients in developing and developed countries. The focus of our corporate responsibility is fully aligned with our mission in which accessibility is core. Translated into the language of different business functions and in the language of our culture, the new strategy primarily means the following: environmental integration; innovation; knowledge; flexible, lean and technologically advanced production; efficient and improved products; rational consumption of energy and materials; and a safe, encouraging and healthy work environment.

In order to achieve all of the above, one year is not enough. The foundations for these accomplishments should be built earlier and for Lek, a Sandoz company, this is clearly true. But despite good intentions, it is particularly challenging to contribute to greater accessibility in the economic situation in which Slovenia has found itself. However, even in these circumstances our targets were highly development-oriented.

**Return on inputs.** The efforts made throughout the extremely tough year of 2013 have paid off. We increased our production output by 2% and with hard work achieved more than EUR 745 million net sales revenues, a 13% increase over the previous year.

The revenue and volume growth resulted in positive developments in many areas at all production sites. I would particularly like to mention that we remained a stable and safe employer and created new jobs. We employed 285 new associates, the majority in biopharmaceuticals and production, thereby increasing our workforce by 7%.

We became the most desired employer in Slovenia, continued to hold the Family Friendly Company certificate and for the eleventh year in a row received an award for outstanding investment in employee education. By extending the Be Healthy initiative and a range of preventative programs, we strived to maintain and improve the health and wellbeing of our associates.

Yes, we are well aware that high-quality and satisfied human resources are of key importance to our competitiveness in the pharmaceutical industry. A clear indication of how valuable their contribution is, among a number of Sandoz and Novartis team and individual recognitions, are two high awards for outstanding research achievement in biotechnology and comparative genomics for targeted industrial strain improvements and in organic chemistry for a major, more sustainable improvement by introducing  $\beta$ -borylation of a wide range of organic molecules in a water medium.

**Strategic element at Sandoz and Novartis.** In 2013, Lek, a Sandoz company, strengthened its position as a leading development center and one of the leading production centers within Sandoz. By acquiring the position of the leading company in introducing new products into production, we finally proved our openness to innovation and the ability to transfer research results into production. The Mengeš site became Sandoz's competence center for the development of biopharmaceutical products, which is of special significance due to the complexity of this area and its prospects for development. In the domestic market we were, along with products from other Novartis divisions, the leading supplier of medicines and number one in the OTC products segment. We were the first to offer patients a generic nasal spray with the active ingredient mometasone, developed in Ljubljana. Here we built our second Quality Control Center, and the site also houses the Regulatory Competence Center SND for Southeast Europe and the most productive Sandoz packaging center for solid dosage forms in the region. The Lendava Packaging Center, a strategic packaging production site for Sandoz, was also the fastest growing Sandoz production facility in 2013. The Prevalje site is among the most modern Novartis plants and manufactures one of the best-selling Sandoz products. On the occasion of its 35<sup>th</sup> anniversary, we organized an Open Door Day for the local population, our partners and development partners.

**Long-term performance of the company.** At Lek, a Sandoz company, we conceive of long-term performance as economic growth, supported by a positive social impact and further steps towards an even greater reduction in environmental impacts. Development and production require not only knowledge, but also raw materials and energy resources; they produce waste and emissions to the water and air.

<sup>7</sup> GRI Disclosure G4-1



Therefore, all our investment projects go hand in hand with technological innovation and improved process efficiency. We invested EUR 2.8 million in improved environmental protection. We launched a new thermal oxidizer for thermal oxidation of VOC emissions at the Prevalje site and an ozonizer for effective cleaning of pharmaceutical ingredients in waste water in Mengeš. Due to the increased scale and fluctuations of the product mix, electricity consumption increased by 5%; however, we managed to maintain total energy consumption at the same level as that in 2012. Even energy efficiency per tonne of product remained unchanged which is noteworthy due to fluctuations in the production program structure and changes in the direction of complex (demanding) products.

With numerous ongoing energy projects at all sites, we aim to conserve resources and increase efficiency, while at the same time reducing our carbon footprint. With these projects we saved 57,600 GJ energy and reduced CO<sub>2</sub> emissions by 3,455 tonnes in 2013. We achieved greater efficiency in other areas also. Relative to the base year 2010, the efficiency of water consumption improved by 24%. In 2013 the total amount of emissions of volatile organic compounds was reduced by 11%, and efficiency per tonne of product was also improved.

For Lek, a Sandoz company, waste management is also particularly challenging. The largest proportion of our waste includes biodegradable waste transferred to nearby biogas plants. Without accounting for such waste, we improved waste management efficiency by nearly 5% and reduced the volume of hazardous waste by 7%.

Our impact on the environment is successfully limited by strict control over emissions, regular measurements and

fulfilling all legal requirements and Novartis guidelines, which are often stricter than Slovenian laws.

We successfully passed a number of inspections, including the most demanding audits by the FDA. External audits once again proved the compliance of our operations with environmental standards (ISO 14001), health and safety at work standards (OHSAS 18001) and the Responsible Care program. Through preventative measures and training sessions for safe behaviour at work, we achieved a low rate of sick leave due to work-related injuries in 2013. The LTIR index dropped to 0.04 and was reduced by a fifth.

**Thousands of contributors.** These results did not come automatically. They are the result of the work of a growing family, which, with its professional, diligent and dedicated work co-creates the development of the company and further success of the Sandoz Group. Our home remains in the local communities with whom we share and respect natural resources, exchange knowledge and jointly acquire irreplaceable experience at humanitarian events and through mutual assistance.

With particular responsibility we extend our hand to children, the elderly and groups of patients and remain faithful partners of many non-profit organizations. Their cooperation and joint contributions to society helped create the contents of the report on sustainability indicators of Lek's operations. We are proud that thousands of contributors helped prepare this report.

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



## 1.3 About us

**Lek is a pharmaceutical company, one of the pillars of Sandoz, the generic division of the Novartis Group and the second-largest global generics manufacturer.**

Its role within Sandoz is to act as:

- a leading Sandoz' development center for products and technologies (medicinal products for oral use, injectables),
- a global manufacturing center for active pharmaceutical ingredients and medicines (medicinal products for oral use, injectables),
- a competence center for the development of vertically integrated products,
- Center of Excellence in the field of development and manufacturing of biosimilar products,
- one of the leading Sandoz' global supply centers, responsible for sales on the Slovenian market and selling services for global Sandoz markets,
- global IT competence center for production information systems; regional center for IT infrastructure for countries of South-East Europe, Bulgaria in the Baltic region.

**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 2013, all the sites became EMAS certified, and registered in the EMAS Register.<sup>8</sup>

Lek develops, manufactures and markets effective, safe and quality medicinal products, from standard generic drugs through to state-of-the-art biosimilars.<sup>9</sup>

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

**Sandoz**, the generic pharmaceuticals division of Novartis, is a global leader in the generic pharmaceutical sector. Sandoz employs over 26,500 employees across more than 160 countries, offering a broad range of high-quality, affordable products that are no longer protected by patents. With USD 9.2 billion in sales in 2013, Sandoz has a portfolio of approximately 1,100 molecules, and holds the #1 position globally in biosimilars as well as in generic injectables, ophthalmics, dermatology and antibiotics, complemented by leading positions in the cardiovascular, metabolism, central nervous system, pain, gastrointestinal, respiratory, and hormonal therapeutic areas. Sandoz develops, produces, and markets these medicines, as well as active pharmaceutical and biotechnological substances. Nearly half of Sandoz's portfolio is in differentiated products, which are defined as products that are more difficult to scientifically develop and manufacture than standard generics.



For more information, please visit [www.sandoz.com](http://www.sandoz.com).

\* Sandoz is on Twitter. Follow @Sandoz\_global at: <http://twitter.com/sandoz>.

**Novartis** offers a highly diversified drug portfolio that addresses the evolving needs of patients and societies. It is the only global company with leading positions in the areas of innovative medicines, eye care products, affordable generic pharmaceuticals, preventative vaccines, diagnostic tools, over-the-counter and animal health products.

In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 136,000 full-time-equivalent associates and operate in more than 140 countries around the world.

For more information, please visit [www.novartis.com](http://www.novartis.com).

\* Novartis is on Twitter. Follow @Novartis at: <http://twitter.com/novartis>.



## Corporate Citizenship

**Corporate Responsibility at Lek, a Sandoz company, is based on the Novartis and Sandoz corporate responsibility program and is a strategic priority for our business.**

The objectives of the Sandoz Corporate Responsibility program are the following:

- increasing access to affordable medicines and
- being a responsible and ethical employer, an active community member and leading company in the industry.

Through implementation of the corporate responsibility program, we further our business mission by developing programs, social business models and other initiatives which increase accessibility, affordability and availability of high-quality medicines for patients around the world.

The Sandoz Corporate Responsibility program focuses on:

<b>Access to medicines</b> We strive to increase access to health services, medicines and raising awareness about health.	<b>People and community</b> We are a responsible and ethical employer and benefit our wider community.	<b>Sustainable business operation</b> We adopt a preventive approach, striving to make efficient use of natural resources and minimizing our environmental impact.	<b>Ethical business conduct</b> Setting and maintaining the highest standard of ethical business conduct.
--	---	---	--

## Corporate volunteering

### By helping others we enrich ourselves

Lek, a Sandoz company, is one of the pioneers of corporate volunteering in Slovenia. The numerous volunteers among our employees have for many years been showing great respect to others and a sense of belonging to the community in which we work and live. With their activities, they are embedded in this humanitarian endeavour throughout the year.

April was especially festive as the Slovenian Friends of Youth Association (SAFY) celebrated 60 years of operation. Because of this remarkable jubilee of our partner with whom we have a 15-year partnership in a joint effort for the welfare of children, we gladly kicked-off the activities for the Novartis traditional global Community Partnership Day early, in the month of April. Cooperation with an organization that brings together 91 associations and 5,000 volunteers gave us invaluable experience and brought us closer to children and families in need. In this unfavourable economic situation its mission is even more valuable as children's social rights and status are even more frequently compromised.

As Miran Šinigoj, one of the Lek volunteers said, we forged close ties with the Slovenian Friends of Youth Association and were delighted to help them celebrate their remarkable jubilee on 12 April. A team of 12 associates joined the many participants involved in the organization of the festive event and helped in the call center by responding to donor calls. They helped raise funds for the operation of the TOM telephone help line for children and youth. Donations raised on that day amounted to EUR 28,509.

Among key SAFY projects is also the humanitarian campaign A Wink at the Sun, enabling children from socially deprived families to go on free holidays. SAFY implements this campaign in partnership with Lek, a Sandoz company. In June 2013, 312 children whose parents cannot afford to take holidays were taken to the seaside. For over 15 unforgettable years, 10,500 children from disadvantaged families have been able to enjoy free, healthy and relaxing holidays. Lek, a Sandoz company, has allocated more than 215,000 Euros to this charity campaign. Of course, the experience that our volunteers have gained is priceless.



The associates from the Mengeš site brightened up the day in the home for the elderly.



Director of Mala Hiša in Plišan Ada Požeg (left) and her deputy, child-carer Simona Simon (right), handed a certificate of appreciation for the long-term cooperation to Katarina Klemenc, Head of Corporate Communication.

With the Wink at the Sun campaign we also concluded more than a month of activities marking the Novartis Global Volunteer Day. They included various activities on the occasion of the Novartis Community Partnership Day in May. Again we dedicated a lot of attention to children, youth and the elderly. More than 250 Lek volunteers donated blood or lent a helping hand to individuals and organizations in the local community. We also visited Mala Hiša in Pilštanj in the Kozjansko area, which is committed to caring for children and families in need. Lek has been supporting its activities since 2007.

Lek Corporate Communication is the owner and implementer of all initiatives in the field of corporate volunteerism. As declared the Head of Corporate Communication, Katarina Klemenc, the special value of corporate volunteering lies in forging close ties between the company and the local community which benefits everyone.



A part of a 12-member Lek team that helped the Slovenian Friends of Youth Association raise funds for the operation and development of the TOM telephone help line for children and youth.

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

In accordance with the Group's strategic orientation and organizational structure, Sandoz Group companies are the key buyers of Lek products and active pharmaceutical ingredients. In 2013, the leading three buyers accounted for 27%, 9% and 5% of net sales.

Lek as a part of the global company Sandoz sells its own products and the products of other Sandoz companies. Our major external direct sales markets include Central and Eastern Europe with 88%, and Slovenia with 5%. The majority of sales (84%) are realized by pharmaceutical products (86% in 2012), whereas APIs and biopharmaceuticals account for the remaining 16% (14% in 2012).

The total value of the Slovenian pharmaceutical market increased by 0.4%. A reduction in generic drug price levels by 7.1% resulted in a 3.2% reduction in the generic market value. The main contributors to the market shrinkage were measures taken by the Ministry of Health to curb spending on medicinal products reimbursed by the Health Insurance Institute of Slovenia. In October the Health Insurance Institute of Slovenia introduced the first therapeutic group of medicines that included medicinal products for treatment of excessive gastric acid secretion (proton pump inhibitors). Reduced reference drug price levels, resulting in a lower sales volume of these drugs, affected both generic as well as innovative pharmaceutical companies. The non-prescription drug market grew by 2.3%.

### 1.3.2 Major groups of products and brands<sup>11</sup>

The key therapeutic groups of medicinal products developed, manufactured and marketed by Lek, a Sandoz company, include the following:

- cardiovascular drugs,
- anti-infectives,
- gastrointestinal drugs,
- 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.

Our leading brands in Slovenia include Lekadol®, Amoksi-klav®, Coupet, Tulip®, Linex®, and in our export markets drugs with amoxicillin-clavulanic acid, atorvastatin and omeprazole APIs.

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

#### 1.3.3.1 Ljubljana site

The Šiška industrial zone on Verovškova road in Ljubljana is the location of Sandoz's leading development center and one of Sandoz's major global production plants, and the largest in Slovenia.

The Development Center in Ljubljana develops medicinal products for the entire Sandoz with special focus on technologically complex products. We act as a Sandoz Center of Excellence for nasal sprays, for example, and the majority of novel products are manufactured in Ljubljana.

The production function consists of the production units for solid and sterile dosage forms. On this location, manufacturing activities started in 1975 and expanded significantly in 1992 through the opening of a new tablet production plant which was further expanded in 2004, and the growth and modernization trend continues. The year 2013 was also marked by a number of investments aimed at upgrading production capacities and activities in the field of quality, and we successfully passed various inspections.

#### Solid dosage forms (SDF)

With about 90 molecules (active ingredients) in about 500 solid dosage forms manufactured and packaged, Lek Ljubljana offers the broadest range of solid dosage forms in one place within Sandoz. Manufacturing, which is mostly highly automated and centrally computer-controlled, takes place on multi-purpose production lines.

Our portfolio includes more than 2,700 finished products sold in more than 70 countries around the world. In 2013, our tablet manufacturing plant produced over 6 billion pcs, which is similar in scope to the previous year. We packaged more than 400 million units in more than 160 million packages. We remain the leading Sandoz location for launching new products, 700 of which were launched in 2013, and in the period 2010–2013 as many as 2,300 were launched (40% of all Sandoz launches).

<sup>10</sup> GRI Disclosure G4-8 | <sup>11</sup> GRI Disclosure G4-4 | <sup>12</sup> GRI Disclosures G4-4, G4-13



## Quality

### The new Quality Control Center in Ljubljana

Successful completion of construction of the second control center in a row for the implementation of quality control was one of Lek's most important investments in 2013. This helped us overcome the spatial limitations of the first building constructed at the Ljubljana site in 2008, as our needs have grown rapidly due to production expansion.

This investment confirmed the importance of quality control performed at all stages of drug manufacture. It first starts with the raw material tested. During manufacture, samples are then taken to perform testing and analysis of the finished products. Before entering the market, drugs have to obtain final approval of conformity and all the packaging elements need to be checked before the packaging process is started.

In the new building we perform the same activities as we have so far, but in improved conditions: control of raw materials, regular testing of products and finished products, stability testing and the testing of samples for validation studies of technological processes. The new Control Center also houses a microbiological laboratory, changing rooms and storage for materials required for the microbiological laboratory.



*With our second Quality Control Center in Ljubljana we overcame spatial constraints which arose from the growing volume of operations.*

### Sterile dosage forms

The unit for sterile dosage forms manufactures parenteral drugs (injected directly in the body) filled into ampoules and vials. In 2013 we started regular production of lyophilized vials in the new Vials 2 facility and thereby increased annual production by 16.5 mio vials. The facility has state-of-the-art equipment; in addition to a filling line with a capacity of 300 vials per minute, the new facility has three lyophilizers with an automated transport system. With this new acquisition the sterile dosage forms unit became one of the key Sandoz global production sites. Because of the additional capacities and knowledge gained and built up over many years, the Ljubljana site acquired the role of center of excellence for vial and ampoule production within Novartis.

### Company headquarters

The Ljubljana site also features the company headquarters with a number of specialist services – Legal Affairs, Registration Competence Center SND/SEE, Supply, Quality, Health, Safety and Environment, and others.



### 1.3.3.2 Mengeš site

The Mengeš site features the development and manufacture of active pharmaceutical ingredients, the production of solid dosage forms, the Anti-infectives - Genetics development department and the Quality unit. Production at this site has been carried out since 1946, and since 2000 it has witnessed fast development of biopharmaceuticals.



The Mengeš site is Sandoz's key site for the manufacture and development of vertically-integrated active ingredients for pharmaceutical products which are finalized into finished dosage forms in the production network.

APIs are manufactured by means of biological processes (fermentation), chemical processes (organic synthesis), physical-chemical processes for isolation and purification of active ingredients.

More than 20 active ingredients are included in the production program. In 2013 the API production volume and utilization of production capacities again grew by more than 10%, primarily due to newly launched products. In 2013 we also became an important supplier of pharmaceutical ingredients for Novartis.

In order to meet all market needs for APIs, we started the construction of a new production plant in Mengeš, where the production of a new active ingredient is planned for 2015.

Today, this site also successfully operates the Sandoz Biopharmaceuticals Development and Production Center, one of the most important biopharmaceutical development and production centers within Sandoz, a global leader in biosimilars. In 2013 Biopharmaceuticals Mengeš fully realized all production and development objectives. We have demonstrated that the process for manufacturing an active ingredient for a biosimilar product, as carried out in Mengeš, is stable and reproducible despite its high technological complexity. In parallel with a continually increasing sales market share, the Biopharmaceuticals Development Center Mengeš has also increased its number of employees. In development activities it is necessary to highlight that we deal not only with so-called “early development activities” (e.g. development of cell lines, cell banks, and production processes), but have also achieved major success in the area of “late development”, including characterization of production processes and genetic characterization of cell banks. With this growing range of knowledge and experience we have been strengthening our role within Sandoz Biopharmaceuticals and within the entire Novartis Group.

The Mengeš site successfully passed all inspections in 2013.

#### 1.3.3.3 Lendava site

The Lendava site comprises the anti-infectives production unit and a packaging center.

Lendava is the leading site for the manufacturing of potassium clavulanate in the Sandoz Group, the key ingredient of a broad-spectrum antibiotic, one of Lek's and Sandoz's leading products. At the Lendava site we also manufacture gentamycin sulphate. The manufacture is based on standard biotechnology which is the result of the company's own know-how. In 2013 we again achieved record production as a result of the modernization of technological equipment and process improvements. All market needs were met by increasing our competitiveness and capacities.

Additional investment in production capacities and auxiliary infrastructure and several improvements to manufacturing processes resulted in lower production costs as well as improved energy and environmental efficiency. The site successfully passed all inspections.

The Packaging Center Lendava (PCL), which is among the fastest growing Sandoz production plants and where the filling and packaging of pharmaceuticals takes place, supplies markets in more than 60 countries worldwide. In 2013 we significantly increased our capacity with three new high-capacity packaging lines and nearly two billion tablets and capsules were packaged. The key strategic goal of the plant is to become the best Sandoz packaging plant providing a high level of customer service. Another goal is to effectively manage the complexity of packaging and to supply the generic pharmaceutical portfolio with high responsiveness to volatile market needs and internal flexibility.

The total investment in PCL exceeds EUR 35 million and for 2014 a production capacity of a further 12 packaging lines is planned. Through investments in warehouse and production capacities, we will further expand these capacities in the future.

This will consolidate our position as a strategic manufacturing site within the Sandoz global production network.



The Lendava production plant is strengthening its position as one of the major business entities of the south-eastern region of Slovenia. The number of employees, mostly from surrounding localities, is still growing.

#### 1.3.3.4 Prevalje Site

At the Prevalje site, a production plant for penicillin products, we manufacture a broad-spectrum antibiotic, one of Lek's and Sandoz's leading products. It is manufactured in the form of tablets or powders for oral suspensions, and in the form of mixtures and granules, intermediate products sold for further processing.

For the Prevalje site, 2013 was very successful as production volumes, in comparison with previous years, increased again and achieved a record despite a minor incident at the site which resulted in a 14-day halt in production. We manufactured 416 million tablets (6% more than in 2012) and 13.6 million units of oral suspensions (a 4% increase over the previous year).



We successfully passed all inspections and again proved our commitment to quality. We installed a new coating process drum and a device for regenerative thermal waste air oxidation.

In 2014 further growth in production is expected, with volumes expected to grow by nearly 30% in comparison to 2013.



**1.3.3.5 Lek sites** are also utilized by tenants of business premises. 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 the 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 the environment). Tenants are responsible for the legality of their environmental management.

## 1.3.4 Highlights and milestones of Lek's operations in 2013

The year 2013 was marked by **successful development projects, a high percentage of new launches of Sandoz products produced by Lek in Slovenia, new investments and continued recruitment of new employees.**

### Highlights of the year:

- We are consolidating our position as the **leading Sandoz Development Center**. We developed 31 novel products for the most demanding global markets; at the end of 2013, more than 270 development projects were under way in the Sandoz Development Center Slovenia. Their complexity is increasing in line with the company's strategy.
- In 2013, we successfully passed the most demanding audit carried out by the US Food and Drug Agency (FDA) and several other international audits, proving the **high level of our quality management system** to ensure **patient safety**. Through outstanding performance, we consolidated our position as one of Sandoz' key entities.
- Despite increasingly harsh economic conditions, Novartis also continued its investments in Slovenia in 2013 – **more than EUR 1.44 billion** invested in Slovenia over eleven years.
  - More than half of these funds were dedicated to **development**. The other half was invested in **modernization and expansion of production capacities**, enabling us to continue our high level of innovation, growth and continuous improvement of productivity.
  - One of the major investments was the **second Quality Control Center in Ljubljana**, as the first center, built in 2008, is no longer sufficient for all our needs.
  - In Mengeš we initiated the **largest direct investment of Novartis in Slovenia** to date – a new production plant for one of the key products.
- We retained the **leading position in over-the-counter drugs** and through many activities consolidated our position as the second largest supplier of generic drugs. Together with products from other Novartis divisions **we are the leading supplier in the Slovenian market**.
- We were the first in Slovenia to offer patients a **generic nasal spray with mometasone** for the treatment of seasonal or perennial rhinitis and symptomatic treatment of nasal polyps. This technologically demanding product was developed in Sandoz Development Center Slovenia in Ljubljana.
- In 2013 we continued to create new job positions – we hired **285 new employees** and finished the year with more than 2,900 employees. Most of them were employed

in Biopharmaceuticals and in Production. 43% of all our employees hold a university degree, of which more than 330 hold a master's degree or a doctorate.

- We celebrated the **35<sup>th</sup> anniversary of operation of our Prevalje site**, which has developed into one of the key parts of Sandoz and has retained its role as an important employer in the region with more than 200 employees. The Prevalje site manufactures one of the best-selling Sandoz products, which is exported to more than 60 countries, including the USA – the largest global pharmaceutical market.

## 1.3.5 Awards and acknowledgements

Through their outstanding achievements, our experts once again proved their first-class knowledge, expertise and experience. In 2013 they received the following recognitions:

- Vojmir Urlep, President of the Board of Management of Lek, a Sandoz company, received an award for outstanding business achievement.
- We were recognized as the most reputable employer in Slovenia in 2013.
- We received the Invest Slovenia FDI Award that recognizes Novartis's investments in the business development of one of the most successful Slovenian companies.
- We extended the full Family Friendly Certificate and proved our efforts to create a work environment which contributes to better work-life integration.
- For the sixth time in a row we received the RCI certificate (the so-called Responsible Care® certificate) as a part of the Responsible Care Initiative (RCI) for responsible operation with regard to health, safety and environment and for transparent communication with stakeholders and the public. Our statements about the importance of responsibility to patients, employees, 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 (GRI) in our Sustainability Report 2012.



*We received the Invest Slovenia FDI Award*

## Leadership excellence

### Prestigious national award for business achievement

**Vojmir Urlep**, President of the Board of Management of Lek, a Sandoz company, is the winner of the Chamber of Commerce and Industry of Slovenia (CCIS) award for outstanding business achievement in 2012 among large companies. The CCIS awards are the oldest and most prestigious awards of their kind in Slovenia and highlight the important correlation between the leading manager and the company itself that becomes written into the history of the Slovenian economy.

As the Chamber of Commerce and Industry of Slovenia pointed out, Lek, a Sandoz company, under the leadership of the company's President Vojmir Urlep became the leading Sandoz development center and increased production at all Slovenian sites. Of particular note is that he focused on technologically demanding processes and opened new job positions. Over the past ten years following Novartis's acquisition of Lek, investment in development and expansion of production amounted to over 1.3 billion Euros. Lek, a Sandoz member, has its own development team of 550 experts, of whom more than 170 hold a doctorate in science, and is constantly working together with Slovenian research institutes and faculties. Within Novartis and Sandoz, Lek, a Sandoz company,

has acquired status demonstrating its high development and production competencies. Vojmir Urlep dedicated his acknowledgement to all associates and stressed that Lek, a Sandoz company, is today the leading development center of the second largest global supplier of high-quality and affordable generics. Investment in knowledge is reflected in an average of 20 patent applications every year and over 1,200 patent rights obtained around the world.



*Vojmir Urlep, President of the Board of Management, with associates upon receiving the award for outstanding achievement*

## Research achievements

### Discovery of high applicable value

Sandoz/Lek researchers **Dr Zdenko Časar** and **Dr Gaj Stavber** were the first in the world to discover a catalytic system for asymmetric borylation of organic compounds in water medium. For this high-profile scientific discovery, the Chamber of Commerce and Industry of Slovenia (CCIS) honoured them with the Gold Innovation Award for the best innovation at the national level.

They discovered and developed a considerably more efficient, economical and above all more environmentally friendly catalytic system, which can be very successfully applied in the key step of alternative synthesis of the active pharmaceutical ingredient for the treatment of type II diabetes, currently affecting more than 400 million people worldwide. Such sustainable innovations can therefore be an important contribution to the welfare of both the environment and society through more accessible and safer pharmaceutical ingredients and medicines, which is also a part of Sandoz's mission. By doing this they opened an entirely new perspective on greener and more sustainable technologies in organic chemistry.

Upon receiving this recognition, Dr Časar and Dr Stavber highlighted the quality of projects and complexity of issues that Lek/Sandoz researchers face. The discovery of asymmetric  $\beta$ -borylation of organic molecules in a pure water medium is an innovation with high applicable value. The catalytic method for asymmetric borylation of organic compounds has until now been carried out in hazardous, toxic and expensive organic compounds. As explained, organic molecules, reagents and catalysts are usually not very compatible with water. Thus, it was necessary to develop a catalyst system which is compatible with water and at the same time allows the desired transformation in an asymmetrical mode. Their novel solution is

based on the use of copper in a +2 oxidation state and can be applied in industry. The active ingredient obtained by this method is also purer than it has been up to now. Patients deserve effective active pharmaceutical ingredients, safe target active ingredients and finished dosage forms, stressed both researchers whose achievement reinforced Sandoz's policies. The innovation was successfully granted international patent protection, and the findings were presented in a distinguished international scientific journal for applied chemistry.

A detailed interview with the winners is also available on the portal MMC website: <http://www.rtvsl.si/uspesna-slovenija/nase-znanje-je-ustvarilo-novo-znanje-kar-je-bistvo-napredka/334527>.



*Dr Zdenko Časar (left) and Dr Gaj Stavber (right) attending the national recognition for innovation ceremony*



## 1.4 Development and reporting framework<sup>13</sup>

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 RCI, EMAS Scheme and GRI Guidelines. The Sustainability Report was last published in September 2013. Even before 2010, we prepared environmental reports and reports within the Responsible Care Initiative (RCI).<sup>14</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.

All the reports, also containing the EMAS Environmental Statement, are available at <http://www.lek.si/en/social-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.corporate-citizenship.novartis.com](http://www.corporate-citizenship.novartis.com) and [www.novartisfoundation.org](http://www.novartisfoundation.org)). Their collection is performed in compliance with the improvement guidelines provided by Novartis internal HSE audits. For 2013 we report according to GRI G4 guidelines. We have not yet decided to seek external assurance for our sustainability reporting, but we are considering this possibility. In the process of determining the content of the report on sustainable development, we identified the material aspects, presented in the table below, with regard to economic, environmental and social impacts of Lek d.d. operations.<sup>15</sup>

### Material aspects of sustainable development of Lek d.d.

<b>Economic impact</b>	<ul style="list-style-type: none"> <li>- Economic performance</li> <li>- Market presence</li> </ul>			
<b>Environmental impacts</b>	<ul style="list-style-type: none"> <li>- Materials</li> <li>- Energy</li> <li>- Water</li> </ul>	<ul style="list-style-type: none"> <li>- Air emissions</li> <li>- Waste waters and 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> <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> <li>- Labour practices grievance mechanisms</li> </ul>	<b>Human rights</b> <ul style="list-style-type: none"> <li>- Non-discrimination</li> <li>- Child labour</li> <li>- Forced labour</li> </ul>	<b>Society</b> <ul style="list-style-type: none"> <li>- Local communities</li> <li>- Anti-competitive Behaviour</li> </ul>	<b>Responsibility for products</b> <ul style="list-style-type: none"> <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, associates, shareholders, healthcare partners and local communities).

<sup>13</sup> GRI Disclosure G4-18 | <sup>14</sup> GRI Disclosures G4-28, G4-29, G4-30 | <sup>15</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 Annex IV to Regulation No. 1221/2009 (EMAS) and prescribed indicators disclosing them also at the site level.

### Reporting in accordance with GRI Guidelines

Lek's reporting in compliance with the GRI Guidelines uses the basic version of reporting G4 guidelines.

## 1.4.1 2013 reporting characteristics<sup>16</sup>

- All the indicators and disclosures in the present report refer to the calendar year 2013.
- 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 pages 6 and 7.
- Sustainable development reports are compiled annually and also include the Environmental Statement (EMAS) amended and upgraded at every major change. Reports contain 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, and members of the pharmaceutical associations.
- The report covers the major economic, environmental and social impacts of the organization.
- Reporting refers to the company Lek d.d. and to all of its manufacturing sites in Slovenia.<sup>17</sup>
- The company Lek d.d. holds a 100% ownership stake in the following subsidiaries (as of 31 December 2013): Sandoz, d.d., Hotel Lek, d.o.o., Novartis Animal Health, d.o.o. and Lek Ljubljana Holding GmbH, Austria. In the USA, Lek d.d. (through Lek Ljubljana Holding GmbH) Lek d.d. indirectly owns the company Lek Pharmaceuticals, Inc., whereas in the Lendava Wastewater Treatment Plant it holds a 74.5% ownership stake.
- In 2013, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures.<sup>18</sup>
- To improve reporting accuracy, the following adjustments in the data collection<sup>19</sup> were made for 2013, also impacting the comparability of previous years' data:
  - On the basis of additional information, we improved the method of collecting data on the realization of the production plan for various finished dosage forms at the Ljubljana site. Following corrections to the production plan realization / use of starting materials, the calculations of resource use efficiency changed as well.
  - When reporting on wastes, we followed Novartis' request that reporting from and 2011 including should only cover wastes leaving the site. Consequently, the waste thermally treated at the site was no longer reported in 2011. We reported however on the ashes and slags resulting from such thermal treatment. In 2012, mycelium waste generated by the fermentation process at the Lendava site was redirected from the site incinerator to a contracting biogas plant for processing. As a result, the total volume of mycelium waste is now reported as waste treated outside the site.

## 1.5 Governance, commitments, inclusion

### 1.5.1 Governance and management<sup>20</sup>

At the year end, the **Lek d.d. Board of Management** was composed of the following:

**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

**Patrick Bernard Donnelly IV**, Member of the Board of Management, Finance (since 7 January 2013)

**Aleš Rokavec**, Member of the Board of Management, Technical Operations

**Samo Roš**, Human Resources

**Bojan Dolenc**, Member of the Board of Management, Workers' Director

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

**Peter Goldschmidt**, Chairman (until 7 July 2013)

**Francesco Balestrieri**, Chairman (since 9 July 2013)

**Jeffrey Pilgram George**, Deputy Chairman

**Cesare Frontini**, Member (until 22 April 2013)

**Martin Jeffrey Rope**, Member (since 23 April 2013)

**Knut Mager**, Member

**Peter Svete**, Member, Workers' Representative

**Aleksander Koren**, Member, Workers' Representative (until 17 December 2013)

**Vesna Premovič**, Member, Workers' Representative (since 18 December 2013)

Lek d.d. 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.

The Board of Management runs the company to the benefit of 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,
- Issues regarding the business operations of the parent company and its associated companies, and
- Other matters in compliance with the law and according to the requirements of the Supervisory Board.

The primary function of the Supervisory Board is to oversee the policy pursued by management. The Board can perform reviews and verification of the company's books and documentation, its treasury, securities and goods in stock, and 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.

In accordance with its competencies and responsibilities, the Supervisory Board performs due supervision of the company's management, monitoring it 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. Information on these impacts is also provided to the Supervisory Board as part of its competency of approving the company's annual report, which also encompasses the business report containing, inter alia, all the major environmental protection information.

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, with the aim of providing the best people, based on their skills and competencies, 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.

## 1.5.2 Employee participation in company management<sup>21</sup>

Lek d.d. adheres to the methods and conditions for worker participation in management as provided by the Slovenian Worker Participation in Management Act.

The employees exercise their rights to participation in management individually and collectively through the Workers' Council, Workers' Assembly and their representatives in the company's management bodies. The workers' representatives also act as Supervisory Board members, while the Workers' Director also performs the function of Board of Management member.

The Workers' Council consists of several committees:

- For general issues,
- Economic,
- Status-related, and
- Human resources and social issues.

Workers' Council members serve on various boards of the company:

- Innovation,
- Occupational safety,
- Diversity and inclusion, and
- Supervisory committee of the Lek Trade Union.

In 2013 the employees proposed no initiatives to the Supervisory Board. However, they maintained direct contacts with the Workers' Director who provided them with answers and assistance in finding suitable solutions with regard to job changes and working conditions, and gave them additional information.

At the Workers' Council meeting, questions and initiatives provided by employees are answered and responded to immediately by the President of the Board of Management, Workers' Director and HSE Director. The issues raised most frequently included working hours, working conditions, business results and plans, holiday facilities, organizational changes and additional pension insurance. Also presented was a report on Supervisory Board meetings, a report on the work of the Workers' Council in the past year, the Lek d.d. Annual Report 2012, a report on the work of the innovation Committee, the HSE report and various initiatives. Answers and/or any additional information are also provided after the meetings.

Monthly records of meetings and other information (links to important laws, institutions...) useful for the employees are regularly published on the Worker's Council intranet site.



The Workers' Council of Lek d.d.

<sup>21</sup> GRI G4-DMA



Th!nk Sandoz Initiative

In 2013 additional members of the Workers' Council from all sites were appointed at the Workers' Council meeting in order to help the HSE specialist service carry out a risk assessment review.

At employee meetings held at each of the sites, company results and results of individual business units as well as compliance issues were presented to employees. Employees actively participated and put forward their questions, which were answered on the spot by the President of the Board of Management, Board of Management members and respective heads of business units.

A member of the Lek Stars committee participated in the process of Lek Stars selection.

A member of the Diversity and Inclusion committee (D&I) took part in the committee's work, presenting the "Project 50+" initiative dealing with opportunities for better utilization of the skills and knowledge of employees older than 50 years. Together with the Head of Human Resources, he participated in the preparation of an agreement with the Association of Lek's pensioners under which individual gatherings for employees nearing retirement will be organized, and assistance in active preparation for retirement given.

In 2013, the previous Innovation Committee and Th!nk Sandoz Commission merged into a single Innovation Committee. A member of this joint committee, who was appointed by the Workers' Council, was actively involved in the assessment of Th!nk Sandoz proposals.

Due to the expiry of the mandate, a new Workers' Council was elected in the elections at the end of November. The constituent assembly session took place in December. A Chairperson and a Deputy Chairperson were elected and a meeting schedule for 2014 was confirmed.

The engagement of employees in key projects aimed at optimizing the business processes and improvement of environmental performance is explained under item 2.1.5.

### 1.5.3 Shareholder overview and inclusion<sup>22</sup>

Lek, a Sandoz company, focused its activities 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). These diverse stakeholders are included in our operations in order to understand their needs and expectations and to improve access to healthcare. We identify them on the basis of their impact on our company and vice versa. On the basis of corporate citizenship principles, we endeavour to maintain an open dialogue, seeking the most appropriate forms of cooperation.

The well-branched network of our stakeholder relations is associated with their various interests and a wide spectrum of Lek's operations. Our understanding of and dialogue with stakeholders are based on the following Novartis principles: commitment to patients, Lek employees and local communities; respect for the natural environment; and adherence to the ethical principles of corporate governance.

## Cooperation with patient groups

### Dihec Mihec teaches children about proper breathing

Cooperation with groups of patients, including children, plays an important role at Lek, a Sandoz company. Asthma can develop at any time in life; however, it is most common in childhood. Research performed at Golnik hospital showed that Slovenian patients have poor knowledge about asthma.

To mark the World Asthma Day in early May, we taught kindergarten children, as a part of the Asthma and Sports programme, about the importance of proper breathing. We prepared a workshop on healthy breathing and helped with publishing the educational story about Dihec Mihec and Tačko Dlačko. Proper breathing and a healthy lifestyle are the keys to the quality of life of those with asthma.

According to the World Health Organization, nearly two million people visit emergency departments each year because of asthma. Asthma is the most common chronic disease among children globally. According to some estimates, around 14% of school children in Slovenia suffer from asthma.



Through attending a healthy breathing workshop and listening to an educational story, children learned about the importance of proper breathing.

<sup>22</sup> GRI Disclosures G4-24, G4-25



The Novartis/Sandoz model of stakeholder relationship management enables us to play an active role in the life of the society and to upgrade the knowledge of our activity and stakeholders' expectations.

We participate in social discussions where we present our views, being open to the opinions of others, and we are improving the company's performance through strategic adjustments to our corporate practice.

#### 1.5.3.1 Stakeholder participation<sup>23</sup>

In accordance with Novartis policy, we include stakeholders in different ways. For better understanding of patient's needs, we use focus groups and cooperate with groups of patients, organized in associations and initiatives. We participate together with academia and the scientific community at scientific conferences, and cooperate with professional organizations, educational institutions, research institutions and researchers in the field of chemistry, biology and health-care. We learn about the satisfaction and views of our employees through a survey that is carried out every second year. At meetings with our suppliers, we endeavor to learn about their expectations and experiences.

We include stakeholders (patients, doctors, pharmacists, wholesalers and retailers) in 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 endeavours to be a respectable and successful healthcare company in Slovenia and abroad. It is maintained through prompt response to the questions received, and by means of a responsive policy and practice of complaint handling.

We pay considerable attention to local communities, listen to the initiatives provided by the local population, and, pursuant to Slovenian laws, implement them in practice, where possible.

In 2013, we received four complaints from local residents<sup>24</sup>. The Ljubljana site received two; one was noise-related and the other referred to grease deposits in one of our connections to the public sewer. In the first case, the complaint was filed by a local resident who also filed complaints in 2011 and 2012. In previous years we installed silencers, whereby the noise level was considerably reduced significantly below limit values; therefore, no additional activities were carried in 2013 with regard to this issue. Compliance with laws was confirmed by regular measurements of noise emissions. In the second case, we cleaned the sewer system and tightened control over emissions of fats into the sewer system by the company that carries out catering services for us. The complaints in Mengeš related to unpleasant odours and noise. In the case of unpleasant odours, the investigation discovered that the source was the cultivation of agricultural land and not Lek, a Sandoz company. The noise-related complaint was justified, as a failure of the compressed air valve occurred at one of the production facilities. By replacing the valve and installing a noise silencer on the exhaust pipe, the problem was remedied.

The inclusion of the local community is also carried out through Open House Days. In 2013 they were held in Prevalje as a part of the site's 35<sup>th</sup> anniversary.

The information about the impacts of our business is published in Sustainability Reports for Lek d.d., available at <http://www.lek.si/en/social-responsibility/>.

## Development jubilee of the site

### 35 successful years at the Prevalje site

The Prevalje site of Lek, a Sandoz company, awaited the 35<sup>th</sup> anniversary of its operation as one of the best Novartis plants for the production of generics in the world. A small plant for the production of penicillin product has developed into an important part of Novartis's generic division Sandoz, the second largest global generic pharmaceutical company. With more than 200 employees, the Prevalje site is an important employer in the region. Products from the Prevalje site are exported to more than 60 countries, including the USA, with the largest global pharmaceutical market.

*"When in 1978 just over 40 associates started production of penicillin products at Prevalje as a part of Lek Pharmaceuticals, this was the first and the only production plant from the former Eastern Europe with a separate penicillin production. From the initial manual preparation of granulate, manual filling and manual packaging of capsules and oral suspensions, we have evolved into a modern pharmaceutical production plant. Today, at Prevalje we produce one of the best-selling Sandoz' products and allocate two to three million Euros for investments annually," said Bojan Dolenc, then the site Head at Prevalje.*

In addition to a ceremony marking 35 years of operation, the employees of the Prevalje site organized an Open House Day that attracted a large number of local residents. We showed them around the site and presented our work, achievements and plans for the future. On this occasion, we also financially supported the Prevalje Volleyball Club and Carinthia Fire Service. Our company namely also integrates itself in the Carinthian community through cooperation with organizations and individuals operating in the fields of humanitarian aid, health care, education, learning and culture.



Local population took great interest in viewing the production at Prevalje.

### 1.5.4 Lek's commitment to external initiatives and principles<sup>25</sup>

As a Sandoz company and as a part of the Novartis Group, Lek is 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 in International Business Transactions, and
- Voluntary commitment to reduce greenhouse gas emissions in accordance with the Kyoto Protocol.

Novartis is a member of the Workplace Wellness Alliance of the World Economic Forum (WEF) (<http://www.wforum.org/issues/workplace-wellness-alliance>). Their orientations 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 Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), and the Good Laboratory Practice recommendations. The development of medicinal products, APIs and manufacturing procedures is based on precautionary measures such as progressivity, inclusion of independent scientists, as well as open and transparent consideration of strengths and weaknesses.

## 2. Environment

### Health, safety and environment systems

#### Health, safety and environment policy (HSE)

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
- Environment 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 four pillars of the Novartis Corporate Citizenship policy: focus on patients, business management, people and community, and concern for the environment.

We are raising public awareness of health and safety at work, without any excessive impact on the environment. To improve HSE efficacy and accountability, we set measurable goals.

We make rational use of natural resources and verify and reduce the impacts of our operations on the environment.

Lek is a company, 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<sup>26</sup> are:

- Health, safety and protection of the environment constitute the basic responsibility of all our associates.
- 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 raise HSE awareness of our employees and provide them with training opportunities, thereby enabling them a safe working environment and knowledge of risks.
- By introducing the best performing and cost-effective technologies available, we strive to become one of the leading environmentally-committed companies.
- We strive to make continuous progress in our use of raw materials and energy resources, and in reduction of environmental impact, which is constantly monitored through regular measurements and data follow-up.
- At our production sites, we regularly define, monitor 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.**

<sup>25</sup> GRI Disclosures G4-14, G4-15, G4-16, G4-56 | <sup>26</sup> GRI Disclosure G4-14, G4-DMA



## Health, safety and environment systems

### Compliance with HSE laws and standards<sup>27</sup>

#### **We operate in compliance with legal and other requirements.**

The Environmental Protection Act, the key environmental management regulation, 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.

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

Being an IPPC<sup>28</sup> certified company, our Lendava and Mengeš sites operate in compliance with the Decree on the Type of Activities and Installations with a High Large-Scale Pollution Potential. Both existing IPPC permits also cover the release of greenhouse gases from cooling devices, whereas these types of emissions at the Ljubljana and Prevalje sites are included in permits dealing with atmospheric emissions. All Lek sites comply with the Decree on Limit Values for Atmospheric Emissions of Volatile Organic Compounds from Installations Using Organic Solvents. As a low-risk source, the Mengeš site is obligated to adhere to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences.

We focus on timely and effective application of new legal and other requirements in our work processes and practices. Authorized persons actively monitor and identify them, ensuring appropriate internal publication after a GAP analysis. Responsibility for effective application in practice lies with the site heads / representatives of the HSE units.

In 2013 a total of six inspections were carried out at all of the four sites, revealing our overall compliance with the applicable regulations in the majority of cases. The majority of the inspections covered the environmental aspect of our operations, and one each in the field of fire safety, biological safety and risks according to the Seveso Directive. We received a warning about identified safety deficiencies with regard to fire safety at the Ljubljana site, which were resolved within the prescribed period. In 2013 we were involved in inspections covering the quality of operational processes and products 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.

An accordance with legal requirements, all Lek sites have acquired environmental permits with related amendments.

- Environmental permit for operation of a device with a high pollution potential (IPPC) for the Lendava site, Permit No. 35407-172/2006, dated 15. 4. 2010
- Decision amending the environmental permit for the Lendava site, No. 35407-37/2011-33, dated 12. 7. 2012
- Decision amending the environmental permit for the Lendava site, No. 35406-33/2012-4, dated 15. 3. 2013
- Environmental permit for operation of a device with a high pollution potential (IPPC), for Mengeš site, Permit No. 35407-171/2006, dated 14. 5. 2010
- Decision amending the environmental permit for the Mengeš site, No. 35407-22/2010, dated 28. 12. 2010
- Decision amending the environmental permit for the Mengeš site, No. 35407-54/2011, dated 16. 5. 2012
- Decision amending the environmental permit for the Mengeš site, No. 35406-24/2012-3, dated 23. 8. 2012
- Decision amending the environmental permit for the Mengeš site, No. 35406-25/2013-6 dated 11. 11. 2013
- Environmental permit for operation of a device using VOCs, for Ljubljana site, Permit No. 35430-19/2006, dated 30. 1. 2008
- Decision amending the environmental permit for operation of a device using VOCs, for the Ljubljana site, No. 35430-6/2010, dated 4. 3. 2011
- Decision amending the environmental permit for the Ljubljana site, No. 35430-9/2012-4 dated 11. 9. 2012
- Decision amending the environmental permit for the Ljubljana site, No. 35431-15/2012-2, dated 20. 11. 2012 – permit extension
- Environmental permit for operation of a device with regard to emissions into waters for the Ljubljana site, Permit No. 35441-339/2006, dated 8. 11. 2010
- Decision amending the environmental permit with regard to emissions into waters for the Ljubljana site, Permit No. 35444-58/2013-2, dated 18. 3. 2014
- Environmental permit for operation of a device with regard to emissions into waters for the Prevalje site, Permit No. 35441-338/2006, dated 2. 2. 2011
- Environmental permit for operation of a device, using VOCs, for the Prevalje site, No. 35430-1/2013-6, dated 21. 8. 2013
- 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. 7. 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. 4. 2013
- Water use permit for direct use of water, Permit No. 35536-20/2008 and 35536-45/2012-5 and 35536-65/2013-8
- Greenhouse gas emission permits No. 35433-88/2009 dated 19. 8. 2009 and No. 35433-87/2009 dated 18. 8. 2009
- Decision extending the permit granting the manufacturer an exemption status for sites Mengeš and Lendava, No. DT 4231-77/2011 dated 30. 11. 2011
- Decision on termination of the permit granting the manufacturer an exemption status for sites Mengeš and Lendava, No. 4231-88/2013-1 dated 3. 9. 2013

## 2.1 Implementation of active environmental policy<sup>29</sup>

The key direct environmental aspects of our operations include the use of energy, water, emissions to the air, emission to water, waste, and, to a lesser extent, odour, noise and the use of soil. Indirect environmental aspects mainly include impacts from suppliers (Items 2.1.6 and 6.1.2).

The active environmental policy of Lek, a Sandoz company, is implemented through a number of activities to protect the environment which often goes 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. Business decisions are made in consideration of direct and indirect environmental impacts. In the area of innovation and development of new products, we carefully consider all benefits and risks in a scientific and transparent manner.

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. With efficient resolution of HSE related complaints and by taking appropriate corrective actions, we provide a safe and employee-friendly work environment, mitigate business related environmental risks and contribute to creating the company's goodwill.

In 2013 we were not charged any penalties for non-compliance with environmental laws; however, we received four external complaints, which are described under Item 1.5.3.1, together with action taken.

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

When identifying 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. Consequently, there are considerable differences in product and API weight. Compared to some self-medication drugs, similar biological drugs, for example, have low weight, 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, and they are also apparent at the Ljubljana and Mengeš sites, which have an extensive and versatile product portfolio.

Our operations are also characterized by interim adjustments of the production program to changes in demand, which could again be observed in 2013. 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.

### 2.1.2 Major environment protection achievements

By implementing our environmental policy, we improve the environmental performance of our processes. In 2013:

- Continued projects aimed at reducing atmospheric emissions and replaced the existing devices for air

emissions treatment (adsorbers) at the Prevalje site with a control device (Regenerative Thermal Oxidizer – RTO) of higher performance and improved energy efficiency, the emissions of which reach lower values than prescribed. Over the last six years, Lek, a Sandoz member, installed four such devices: two in Ljubljana, one in Mengeš and one in Prevalje;

- By removing adsorbers in Prevalje, we reduced hazardous waste volumes (wastewater containing ethanol) produced during the process of the adsorber's operation;
- By installing a device for effective removal of pharmaceutical ingredients in wastewater by means of ozone at the Mengeš site, we additionally reduced environmental impacts;
- By more intensive waste separation, we reduced the amount of municipal waste for disposal. To the largest extent the amount of this waste was reduced at the Prevalje site. On account of waste for recycling, there was 58% less waste compared to 2012; and
- At the level of Lek, a Sandoz company, we continued the "sustainable packaging" project and reduced the use of raw materials, and with smaller packaging sizes we reduced the impact of transport on the environment (lower fuel consumption, lower CO<sub>2</sub> emissions).

### 2.1.3 Investments in environmental management<sup>30</sup>

Environmental investments are part of our everyday business operations. In 2013 they amounted to EUR 2.8 million.

The major investment projects included the following:

- Completion of investment in a new device for thermal oxidation of emissions to reduce VOC emissions to the air at the Prevalje site;
- Investment in a device (ozonizer) for effective filtering of pharmaceutical ingredients in wastewater in Mengeš;
- Installation of effective filtration systems of air-conditioning outlets and technological ventilation systems. The installation was carried out in the context of projects to increase production capacities at all sites;
- Restoration and improvement of energy efficiency of the roof at the manufacturing plant in Ljubljana; and
- Additional reconnections and amendments to the system of removal of organic solvents from technological exhausts at the Mengeš site.

### 2.1.4 Verification of compliance with implemented standards

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

To a series of successful audits and inspections, we added new ones in 2013. 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>29</sup> GRI G4-DMA, Disclosure G4-14, Indicators G4-EN29, G4-EN34 | <sup>30</sup> GRI Indicator G4-EN31





## 2.1.5 Optimization of business processes

Based on Lek's business strategy and environmental policy, the company's environmental performance improved, being part of Lek's projects aimed at optimizing the business processes. The key business process optimization projects include:

### TH!NK SANDOZ Initiative

TH!NK SANDOZ, a web-based idea management program, was launched as a pilot project in April 2012 and has brought excellent results. In 2013, our associates from all four sites contributed 866 ideas (600 in 2012), of which 45% were adopted and approved for implementation. Over 300 ideas have already been applied in practice. Interesting suggestions and ideas were proposed by as many as 454 different associates, which represent 11% of all application users (employees, including external associates). The ideas adopted resulted in direct measurable savings of over EUR 3 million. According to our estimates, more than 10% of improvements are directly HSE-related, and at least 5% are environment-related.

### European Integrated Facilities Management (EIFM)

Project-related activities are performed simultaneously in several European regions. Slovenian sites are comprised in the region that includes Novartis organizational units in Germany, Austria and Switzerland. We are creating a uniform basis for effective facility and equipment maintenance, waste management, landscaping, and other factors. The new working method will be supported by appropriate information technology solutions, and will improve the business transparency, contributing to long-term savings. With regard to Integrated Facility Management (IFM), the year 2013 was the first year of the project and has been declared as the most productive project to have been rolled out in the past year. Its performance across countries varied in accordance with the level of facility management (FM) development in these countries.

For Slovenia, IFM was a challenging project, as this is an area that our market is only gradually adopting. The same applies to the ISS company which was selected by Novartis as a five-year contractual partner in Slovenia and as it lacks some of the major FM functions therefore it struggles to give the necessary contractual support to its partner – Novartis. As a result, waste management by ISS had to be cancelled during the course of last year.

### Explosion safety – ATEX

In 2013 we continued with the maintenance certification for individual buildings, especially at the Mengeš and Ljubljana sites, as these sites have a larger number of buildings for which such certification is required. We managed to certify an additional 11 buildings (4 in Mengeš and 7 in Ljubljana). We renewed the certification of competence of the maintenance personnel for the Ex-equipment maintenance. Maintenance teams at Ljubljana, Mengeš and Lendava sites already received their certificates. The Prevalje team has already become qualified; however, the receipt of the certificate is expected in 2014.

### We are Sandoz initiative

The "We are Sandoz" initiative is instrumental in developing the organization and creating an excellent working environment.

It gives every employee the opportunity to contribute to the company's future and openly express their opinions:

- **Great people.** Sandoz' global success would not be possible without numerous individual achievements of our associates worldwide. The focus of the initiative is to improve employee visibility and recognition at both the local and global level.
- **Outstanding achievements.** We foster cross-functional alignment of operations, particularly in the Product Development, Quality Management and Technical Operations units.
- **Customer focus.** At Sandoz, customers play an important role. Each and every employee therefore focuses on cooperation with customers and on how to improve their satisfaction.

### Leading Solution, Leading Breakthrough, and Leading Manager awards

The ideas coming from employees, contributing to the quality of the work process, are awarded as a part of the innovative award scheme: Leading Solution, Leading Breakthrough, and Leading Manager. Initiatives received are collected on a monthly basis, and assessed by a special committee which will reveal the results for 2013 after the publication of this report. The Lek Leading Solution award 2012 was given to the BCS-biowaiver project, a novel approach to the registration of fast-release solid dosage forms. The leading Breakthrough 2012 award was presented to Dušan Teslić and his team from the department Development of Pharmaceutical Active Ingredient Processes for their project Pharmaceutical Particle Engineering. The Leading Manager award was given to Vatroslav Spudić, Head of the Bioprocess Development at Technical Development in Biopharmaceuticals. In year 2012, his department contributed the largest number of ideas per employee and also implemented most of them.

## 2.1.6 Indirect environmental impacts<sup>31</sup>

As indirect environmental impacts we consider primarily impacts on the suppliers' side. Therefore we expect our suppliers to be committed to the principles of the Novartis Corporate Citizenship policy. By signing a supply agreement, the supplier undertakes the commitment to mitigate his environmental impact, environmental accountability being one of the key supplier selection or confirmation criteria. 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>32</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.

Transport is one of the major sources of indirect environmental impact. It is mitigated by more extensive use of teleconferencing and videoconferencing which replace long-distance business travel. For all the fleet cars used by Lek employees, fuel consumption, mileage and CO<sub>2</sub> emissions are monitored on a regular basis.<sup>34</sup> For the 115 fleet cars in 2013 (96 in 2012), a total traveling distance of 3,380,216 km was recorded, with fuel consumption of 209 m<sup>3</sup>, and CO<sub>2</sub> emissions of 465 tonnes.<sup>33</sup>

<sup>31</sup> GRI Indicator G4-EN30 | <sup>32</sup> GRI Indicators G4-EN33, G4-LA15 | <sup>33</sup> GRI Indicator G4-EN30

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. In 2013, we recycled and reused 91% of the total quantity of organic solvents, an increase of 2 percentage points over the previous year. In Lendava, the leading site in terms of waste reuse in recycling, the percentage of reused organic solvents amounted to as much as 97% (identical to the figure recorded in 2011 and 2012). Currently, a study of a project aiming to increase this proportion is being designed. 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 having a solvent content higher than 80% and being suitable for co-incineration in a natural gas burning device is used as a secondary fuel for the operation of a device generating heat and vapour for manufacturing purposes. 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 possibly industrial fuel.

In the field of non-hazardous waste, systemic upgrades of segregation, collection and preparation of waste for recycling are continuously performed. 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 the annual fluctuation of mass flow of materials at the corporate level. The increase of mass flow of materials in 2011 and 2012 was followed by a decrease in 2013 at both the Mengeš as well as Ljubljana site. There is no such fluctuation at the Lendava production and Prevalje sites, where one to two products are manufactured and as there, the change in the volume of API production also means an increase in the use of raw materials.

**Table 3: Annual mass flow of various materials used\* (in t)<sup>34</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	t	6,080	7,232	11,467	3,473	28,252
2010	t	6,456	9,015	14,404	3,513	33,388
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

\* Total quantity of materials purchased within the reporting period to ensure smooth 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 d.d. 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 started to fall after 2010. In 2013, the reduction was more than 5%, compared to the previous year and in the 2010-2013 period an almost 13% reduction.

The increasing efficiency of the use of materials is demonstrated in Graph 2.

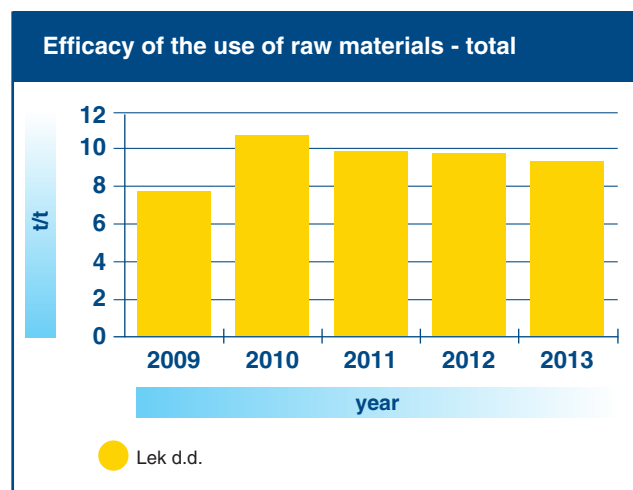
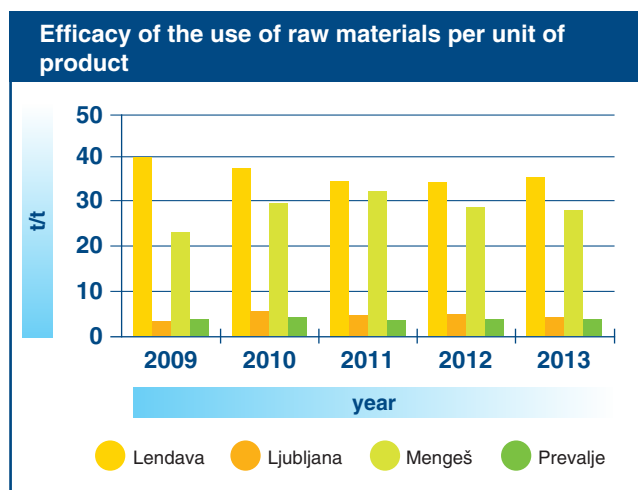
Due to the extensive range of active ingredients and products, and as a result of changes to the product portfolio, the efficiency of the use of raw materials at the Ljubljana

and Mengeš site cannot be seen from the graph. For this purpose, an overview by product would be required since their production output varied significantly. Efficiency of the use of raw materials strongly depends on the range of products manufactured at the Mengeš site. These are integrated into the product only to a minor extent, and are mostly used in the process of finished product manufacture.

By reviewing the method for acquiring data on the realization of finished pharmaceutical products at the Ljubljana site, the accuracy of the data on the efficiency of the use of raw materials improved in 2013.

<sup>34</sup> EMAS Core Indicator, GRI Indicator G4-EN1



Graph 2: Efficacy of the use of various materials per unit of product<sup>35</sup> – by site and total

## 2.2.4 Sustainable packaging approach<sup>36</sup>

The two production sites manufacturing finished dosage forms are the major consumers of packaging material: Ljubljana with 62% and Prevalje with 33%. At the Mengeš and Lendava sites packaging consumption accounts for less than 5% of the total packaging consumption of Lek d.d.

In accordance with the Novartis' policy of sustainable use of the packaging and binding waste management hierarchy, we defined the basic principles of packaging design and production:

- **Selection of materials:**
  - Using materials of lower environmental impact (naturally light materials, recycling-based materials, recyclable materials from renewable sources that contain no toxic ingredients),
  - Using a small number of various materials that have to be recyclable.
- **Packaging shaping and size:**
  - Reducing the total weight of materials (thinner and lighter materials),

- Reducing the volume (reduced environmental impact of transport),
- Reducing the number of packaging types (including integration of primary and secondary packaging into one, uniform packaging to meet various customer needs).

- **Ordering packaging materials:**

- Cooperation with environmentally and socially responsible suppliers,
- Using exclusively environmentally certified / recommended materials (e.g. non-chlorine bleached paper, certified cotton...),
- Cooperation with local/regional packaging suppliers (lower environmental impact of transport).

**Results of improvements in 2013:**

- By optimizing packaging of the product containing fluvastatin we reduced the blister surface by 25%, the box volume by 20% and the packaging weight by 5%.
- In one product, blisters were replaced by plastic bottles which reduced the blister volume by 50%. The number of packs per pallet was increased by the same proportion, resulting in environmentally more optimal use of transport (lower fuel consumption, less CO<sub>2</sub>).

### The change in blister dimension for the product containing fluvastatin active ingredient

Previous blister dimension:  
88 x 138 mm



New blister dimension:  
56 x 146 mm



• 25% reduction of blister surface

• 20% reduction of folding box volume

## 2.2.5 Water consumption and energy efficiency

Previously mentioned fluctuations resulting from the changes in production volume and structure, are also the major cause of absolute and relative variations in the energy and water consumption at individual sites. As the production outputs of a single product or a small number of products at the Lendava and Prevalje sites are relatively stable, a year-on-year comparison of water and energy use efficiency provides a true picture of trends recorded at these two sites. Major variations in the specific use of water and energy resources 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.

Performance indexes for the Lendava site do not provide a true picture as only the production outputs by the Lendava production site is included in reporting. The operations of the other unit, the Lendava Packaging Center, however, are not included as they are not considered as production of finished products. The quantitative realization of the Packaging Center is namely not recorded in the uniform Novartis DMS system (Data Management System) in order to avoid the duplication of quantitative data. In Lendava, products from other Novartis sites around the world are also packaged. These sites report into the DMS system their quantity realizations, although the packaging is done in Lendava. Due to increased capacity of the Packaging Center, the use of water and electricity also increased in 2013.

In 2013 the energy efficiency level was the same as that in the previous year.

**Table 4: Efficiency of energy resource use per unit of product<sup>37</sup>**

Year	Unit	Lendava	Ljubljana*	Mengeš	Prevalje	Lek (Total)*
2009	GJ/t	2,450	174	631	73	315
2010	GJ/t	2,240	213*	720	66	363*
2011	GJ/t	2,004	195*	677	53	315*
2012	GJ/t	1,697	191*	613	56	302*
2013	GJ/t	1,577	197	645	56	303

\* 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.

## 2.2.6 Abandoning the use of hazardous volatile organic compounds

By replacing hazardous VOCs with less hazardous substances, Lek has significantly improved the tablet film-coating process. With continuous measures we are reducing the level of environmental pollution with hazardous waste and additionally lowering the VOC emissions into the air. The new measures are aimed at reducing the level of environment pollution

with hazardous waste through elimination of halogenated air emissions to the air. 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 we have successfully completed the project of ethanol-based coating of omeprazole with water-based coating. The regulatory approval of the change to the technological procedure is expected in 2014.

## 2.3 Energy

### 2.3.1 Use of energy

**Table 5: Total consumption of energy<sup>38</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	GJ	373,855	347,466	314,520	60,314	1,096,155
2010	GJ	388,834	340,136	355,266	58,551	1,142,787
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

\* In the data reported for 2012 in the Data Management System, an error was identified that was subsequently corrected.

In 2013, the total consumption of energy was at all sites a mere 2% higher compared to the previous year. The level of consumption lags considerably behind the increase recorded in the production output in Lendava where, through improvements and efficient use of energy, we achieved more than a 7% improvement, as evident from the energy efficiency calculation (Table 4). The use of energy at the Prevalje site was higher due to the increase in production capacity; however, in terms of efficient use per tonne of production it remains at the same level as in 2012. For reasons already mentioned (versatility of the sites' portfolios),

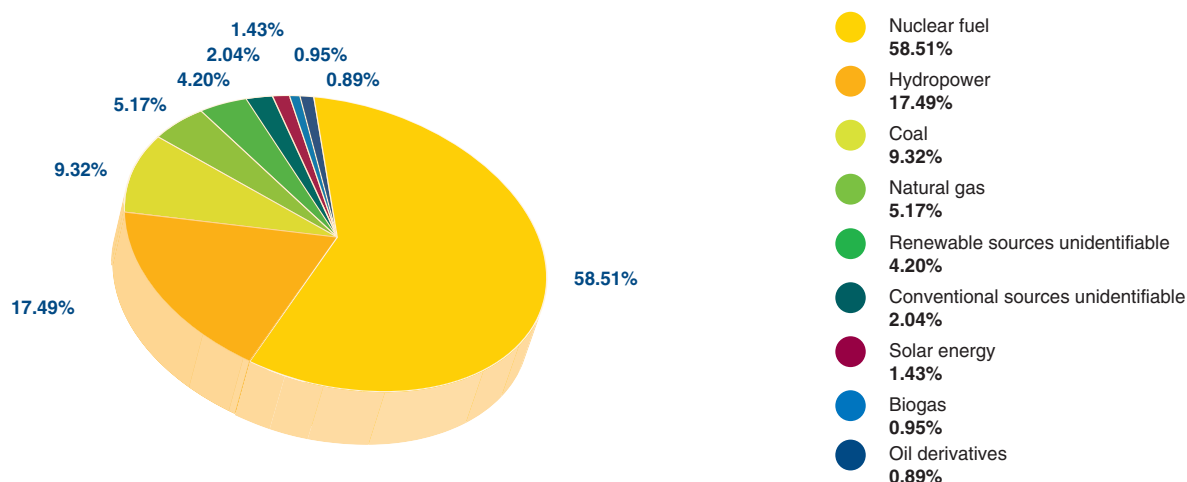
making a year-to-year efficiency comparison between the Ljubljana and Mengeš site difficult.

Of the total energy consumed, electricity accounts for 42% which is obtained entirely from the power supply network. In the structure of purchased electricity sources, the largest proportion of energy for production is obtained from the nuclear power station; compared to 2012 the proportion of renewable sources also increased by a good 2%.

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

	Year 2013
<b>Conventional sources</b>	<b>75.93%</b>
Coal and lignite	9.32%
Natural gas	5.17%
Oil derivatives	0.89%
Unidentifiable	2.04%
Nuclear fuel	58.51%
<b>Renewable sources</b>	<b>24.07%</b>
Hydropower	17.49%
Wind	0.00%
Solar energy	1.43%
Biomass	0.00%
Geothermal energy	0.00%
Landfill gas	0.00%
Municipal wastewater treatment gas	0.00%
Biogas	0.95%
Unidentifiable	4.20%
<b>Total</b>	<b>100.00%</b>

**Structure of purchased electricity sources**



At the Mengeš site, waste solvents are used as secondary fuel for the operation of a boiler producing 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.

In 2013, electricity consumption increased by almost 5% over the previous year.



**Table 7: Electricity consumption**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	GJ	147,061	132,126	104,032	24,743	407,962
2010	GJ	154,082	134,083	115,320	23,376	426,861
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

### 2.3.2 Energy efficiency improvements<sup>39</sup>

Lek, a Sandoz company, has been continuously boosting the production of higher-complexity products dictating the use of specific techniques and being of higher energy complexity. They are manufactured in lower quantities and have a higher added value. Our efforts to ensure energy efficiency are a part of our production processes. We are also building our employees' awareness of energy use.

In 2013, additional measures were taken to improve energy efficiency:

- At the Mengeš site, several improvements to different energy systems were implemented, which resulted in energy savings of 5,000 GJ. By implementing the system for exploiting the waste heat from the air compressor on the steam boiler we generated savings in natural gas consumption. Several old and energy inefficient cooling systems were replaced and optimization of a cold water preparation was carried out. By installing a water gasifier of nitrogen we eliminated the problem of the accumulation of ice on the nitrogen station, while saving some electrical energy for the preparation of water. Lighting in non-production facilities was replaced with a more energy efficient system.

- At the Prevalje site, adsorbers for filtering organic solvents from waste process air were replaced with the thermal oxidation (RTO) system. Energy savings of 10,040 GJ are expected to be fully reflected in 2014. We also successfully completed the project of rational use of external lighting, achieving annual energy savings of 200 GJ.
- On the office building in Ljubljana, the existing absorption cooling aggregate was replaced by two water-cooled chillers that are more energy efficient and have a considerably lower greenhouse gas emission potential. At the same site, we also renewed the roof on the production facility and improved the energy efficiency thereof.
- At the Lendava site, a number of energy projects were implemented. By replacing burning devices on the stationary incinerator furnace, the consumption of natural gas was reduced. By exploiting the waste heat from air compressors and its integration in the distillation process we reduced the use of steam. Annual savings in the site's total energy consumption amounted to 9%.

The listed projects resulted in energy savings totalling 57,600 GJ, the savings are also reflected in a 3,455 tonnes lower emission of CO<sub>2</sub> into the air.

## 2.4 Water

### 2.4.1 Water use efficiency<sup>40</sup>

In the pharmaceutical industry, water is an indispensable natural resource. Efficiency of its use is therefore one of our major concerns. At the Lendava site, water consumption per kg of product was reduced despite the increased production volume in two newly installed fermentors. By installing a system for reusing waste water for the purpose of cooling, the consumption of fresh water dropped considerably in 2013, by nearly 55 m<sup>3</sup> per day.

Water consumption per kg of product at the Lendava site:

- 2011: 6.8 m<sup>3</sup> of total water consumption/kg of product
- 2012: 5.8 m<sup>3</sup> of total water consumption/kg of product
- 2013: 5.4 m<sup>3</sup> of total water consumption/kg of product



**Table 8: Water consumption in 000 m<sup>3</sup> <sup>41</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	in 000 m <sup>3</sup>	1,304	406	1,648	36	3,394
2010	in 000 m <sup>3</sup>	1,427	396	1,679	39	3,541
2011	in 000 m <sup>3</sup>	1,333	415	1,502	34	3,284
2012	in 000 m <sup>3</sup>	1,272	452	1,409	35	3,168
2013	in 000 m <sup>3</sup>	1,316	477	1,452	39	3,284

On the level of Lek, a Sandoz company, the efficiency of water use dropped by 5%, particularly due to previously described factors (increase in capacity at the Lendava Packaging Center the quantitative realization of which is not taken into account, the product portfolio change in Mengeš and one incident in Prevalje).

At the Mengeš site, water is used mainly for technological purposes. From the public supply network, only 4 to 6% of the water is supplied, and the rest (at least 94%) comes from our own pumping station (groundwater). As shown in the table, the table only provides the data on water use efficiency for polluted waters (cooling waters exclusive).

**Table 9: Efficiency of water use\* per unit of product<sup>42</sup>**

Year	Unit	Lendava	Ljubljana*	Mengeš	Prevalje	Lek (Total)*
2009	m <sup>3</sup> /t	1,177	151	536	28	219
2010	m <sup>3</sup> /t	962	214	548	31	256
2011	m <sup>3</sup> /t	833	225	500	22	233
2012	m <sup>3</sup> /t	745	217	496	29	237
2013	m <sup>3</sup> /t	772	224	570	31	249

\* Changes to the previous years' data were due to the improved method of acquiring data on production realization at the Ljubljana site.

## 2.4.2 Water supply sources<sup>43</sup>

From the Ministry of Agriculture, we have obtained appropriate permits for the use of water for technological purposes supplied from the Lendava and Mengeš sites' own wells.<sup>44</sup> Regular monitoring of groundwater levels is performed as well, and the results are reported to the respective Ministry. Simultaneously with this annual monitoring, the impact of the well on the level and direction of groundwater is also monitored at the site.

In the first half of year 2013, precipitation levels were by as much as 57% above the average for this period, whereas from June onwards, it was the opposite case. Monitoring of groundwater levels clearly showed that the dynamic groundwater supplies of Mengeško Polje are extensive. Despite of the below-average precipitation from June onwards there was no sharp decline in groundwater levels; they were declining fairly steadily and continuously.

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

Mengeš	2009	2010	2011	2012	2013
from own pumping station (000 m <sup>3</sup> )	1,591	1,591	1,432	1,335	1,376
from public supply network (000 m <sup>3</sup> )	64	94	77	80	81

Lendava	2009	2010	2011	2012	2013
from own pumping station (000 m <sup>3</sup> )	1,262	1,384	1,325	1,228	1,297
from public supply network (000 m <sup>3</sup> )	42	46	39	61	58

<sup>41</sup> EMAS Core Indicator, RC KPI 21, GRI Indicator G4-EN8 | <sup>42</sup> EMAS Core Indicator | <sup>43</sup> GRI Indicator G4-EN8 | <sup>44</sup> Water use permits No. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8

### 2.4.3 Recycling and reuse<sup>45</sup>

Recycled water is mostly reused for the cooling of processes, mainly at the Mengeš site. The share of recycled water, however, is on the increase at other sites as well.

At the Mengeš site, a three-level cooling water system operating at different temperature regimes enables the water from one system to be fed into a higher-temperature system, while one portion of water (spill) is discharged into the sewage system. The quantities of reused water vary greatly and depend on individual processes, so they cannot be

accurately calculated on the basis of the existing data capture method. Based on relevant calculations, it has been assessed that almost 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 with the best available techniques (BAT). As the cooling cycles are of the closed-loop type, the consumption of well cooling water will not rise despite the increased production volume.

## 2.5 Waste

### 2.5.1 Waste management<sup>46</sup>

Due to a changed data collection methodology (see Item 1.4.1) changes in the volumes of waste for the previous year occurred. Consequently, a direct comparison of waste volumes generated in 2011 and 2012 with the volumes in the previous years is not entirely appropriate. The data for 2011 and 2012, however, is comparable in consideration of the fact that mycelium waste is no longer incinerated in our incineration plant, and consequently became the subject of reporting in 2012 and 2013. Mycelium waste, however, accounts for more than 97% of all waste at the Lendava site and nearly 74% of the total waste from the entire operation of Lek, a Sandoz company. 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).

In 2013, disregarding biodegradable waste (mycelium, waste fennel plant, waste Echinacea plant, green garden waste) the effective waste management was improved by nearly 5%.

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, particularly liquid waste solvents and solid hazardous waste. One portion of this waste is reused as an energy source. The remaining quantity is released to authorized companies for environmentally acceptable disposal.

Despite increasing production outputs, changes in the production structure and the rising number of employees, the relative quantities of non-hazardous waste have remained at almost the same level over the past 5 years.

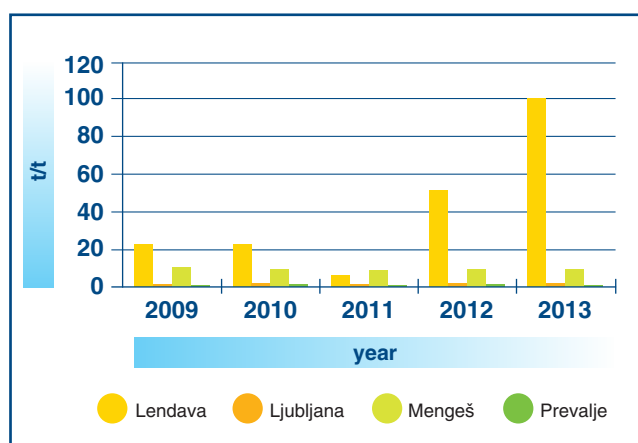
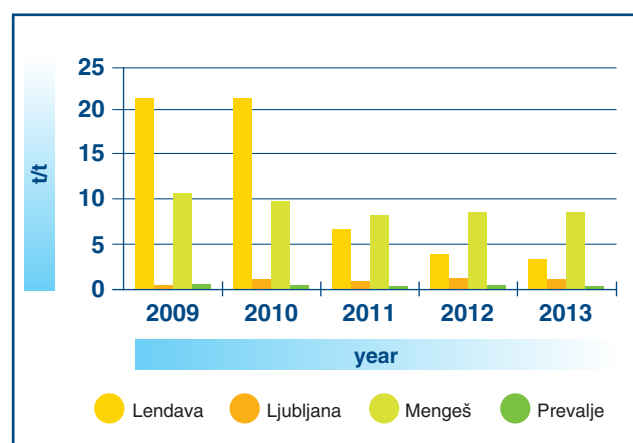
As already mentioned, it applies for all quantitative data presented below that since 2011, only data for the volume of waste released for treatment outside the production site, has been reported.

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	t	3,343	1,646	5,234	573	10,796
2010	t	3,801	1,851	4,907	535	11,094
2011	t	1,432	1,800	4,392	590	8,214
2012	t	11,374	2,210	4,904	676	19,164
2013	t	24,258	2,230	4,670	698	31,856

<sup>45</sup> GRI Indicator G4-EN10 | <sup>46</sup> EMAS Core Indicator, GRI Indicator G4-EN23, G4-DMA



**Graph 3: Volume of waste per tonne of product – efficiency****Graph 4: Volume of waste per tonne of product – efficiency / disregarding mycelium waste**

## 2.5.2 Disposal of hazardous waste<sup>47</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 specific 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.

At the Mengeš site, non-halogenated waste solvents, being extremely pure and having a high caloric 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. By means of co-incineration with natural gas, 20 to 30% of the annual quantity of non-

halogenated solvents is removed. The energy obtained is utilized for manufacturing purposes to prepare technical steam.

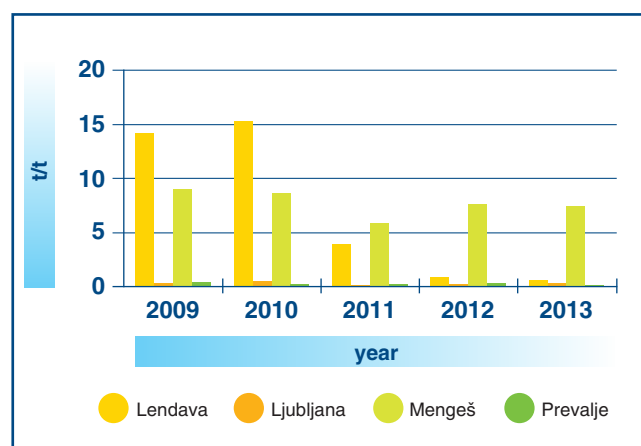
At the Ljubljana site, out-of-date products account for a considerable portion of the generated hazardous waste. The inventory management method in place, however, makes it impossible to reduce their volume. Since 2011, however, we have performed intensive segregation of the waste packaging of hazardous substances (also in case a hazardous substance is only present in traces) which we release for incineration with energy recovery.

In 2013, we introduced measures to reduce the volume of hazardous waste at all sites, except in Ljubljana. At the level of Lek, the volume was smaller by 7% compared to 2012.

**Table 12: Volume of hazardous waste in tonnes**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	t	2,173	423	4,380	253	7,229
2010	t	2,619	529	3,987	211	7,346
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

<sup>47</sup> GRI Indicator G4-EN23 and RC KPI 5

**Graph 5: Volume of hazardous waste per tonne of product – efficiency**

### 2.5.3 Disposal of non-hazardous waste<sup>48</sup>

In 2013, the volume of mixed municipal waste was reduced by nearly 5% compared to the year before and by as much as 41% compared to 2010. The reduction was achieved mostly by stricter segregation and sorting. For the same reasons, the volumes of waste packaging collected continue to increase.

At the Mengeš site, the biologically degradable waste generated by the manufacture of fennel and purple coneflower (Echinacea) juices is directed to a nearby biogas plant. Similarly, we direct the mycelium waste generated at the Lendava site, to a certified contractor biogas plant.

As a result of redirecting the mycelium waste for treatment to a 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 9%. Due to mycelium waste, biodegradable industrial waste accounted for as much as 88% in 2013 (mycelium waste volume was not reported in 2011 as it was disposed of through incineration at the production site, and in 2012 we started directing it to the biogas plant only in the middle of the year, therefore the annual volume was almost half as much than in 2013.). The remaining 2% accounted for other non-hazardous waste.

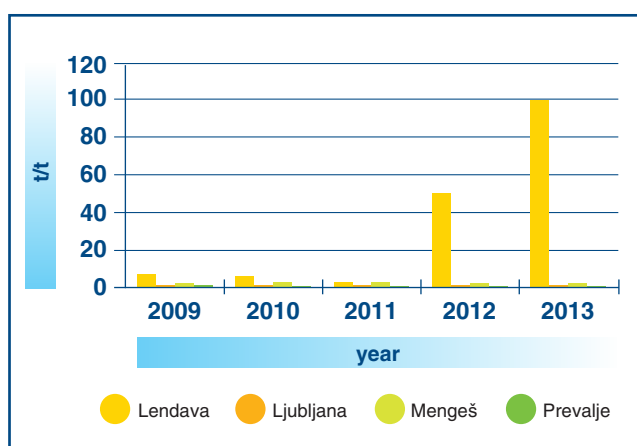
Municipal waste is disposed of, while waste packaging is mainly recycled (through the SLOPAK system), and the same applies to construction waste. Biodegradable waste is used for the manufacture of biogas, and other non-hazardous wastes are disposed of by certified companies by means of incineration.

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Lek (non-hazardous waste without recyclable packaging)*
2009	t	1,170	1,223	855	320	3,568	2,549
2010	t	1,181	1,322	921	324	3,748	2,483
2011	t	649	1,388	975	362	3,374	1,815
2012	t	11,154	1,637	793	430	14,014	12,194
2013	t	24,110	1,655	815	483	27,063	25,126

<sup>48</sup> GRI Indicator G4-EN23

**Graph 6: Non-hazardous waste volumes per tonne of product – efficiency**



*Strict waste segregation in laboratories*

## 2.6 Air emissions<sup>49</sup>

### 2.6.1 Abatement of air emission

Lek, a Sandoz company, has been systematically measuring and abating air emissions. We separately monitor greenhouse emissions and emissions from immobile devices. Of the latter emissions, VOCs and dust are the most important. 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. At these points, the content of a specific substance and/ or dust in the air is measured, and samples for analysis are collected. For all the outlet ducts measured, assessments of substance and/or dust emissions have been made as prescribed.

To reduce organic substance emissions, we use devices for thermal oxidation of waste gas, adsorbers, gas washers, and others.

Air emissions from devices for the production of finished dosage forms and APIs are divided into VOC emissions evaluated in accordance with the VOC Directive, and emissions of substances evaluated on the basis of the Industrial Emissions Directive. 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 <5%, for existing devices it is <15%, whereas VOC emissions in captured waste gases do not exceed the limit concentrations of 20 mg C/m<sup>3</sup>. For the the existing device, equipped with a device for waste gas removal, the limit values of 50 mg C/Nm<sup>3</sup> for thermal oxidation of waste gas and 150 mg C/Nm<sup>3</sup> for other methods of waste gas removal applied until the end of year 2013.

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.

## Investments in environment technologies

### A new device for treatment of atmospheric emissions at the Prevalje site

We monitor the expansion of production with systematic efforts for simultaneous introduction of the state-of-the-art and most environmentally friendly technology available. At the Prevalje site, the existing air emission treatment devices (adsorbers) were replaced in 2013 with a more efficient and economical device for treatment of waste air from coating drums. This system for regenerative thermal waste air oxidation (RTO) operates without adding any natural gas into the combustion chamber already at concentrations between 1.2 to 1.5 g of solvents per m<sup>3</sup> of waste air.



*RTO device in Prevalje*

<sup>49</sup> EMAS Core Indicator, GRI Indicator G4-EN21, RC KPI 7, RC KPI 10



## 2.6.2 Emissions from waste incinerators and co-incinerators

At the Lendava site, the waste incinerator operates, mainly treating industrial waste generated at the site. Due to the release of mycelium waste to a biogas plant for treatment, its scope of operation has diminished. During the incineration process, controlled via a control system, 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, technical 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, technical 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>50</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 2011 and 2012 the emission monitoring performed at all of our sites showed a level of almost zero, also in 2013, the total SO<sub>2</sub> emissions was below 10 kg. This was confirmed by a supplier's statement that the content of sulphur in natural gas is practically non-existent.

**Table 14: Sulphur dioxide emissions (SO<sub>2</sub>)<sup>51</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (skupaj)	Efficiency (Lek) kg of SO <sub>2</sub> /t product)
2009	t	0.11	0.03	0.03	0.00	0.17	0.05
2010	t	0.12	0.01	0.00	0.00	0.13	0.04*
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	0.0000
2013	t	0.00	0.0004	0.0029	0.006	0.009	0.002

\* Changed efficiency data for SO<sub>2</sub> for Lek as a result of changed data on production output for the Ljubljana site.

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.

## 2.6.4 Nitrogen oxides (NO<sub>x</sub>)<sup>52</sup>

At Lek, a Sandoz company, 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 2013, the total volume of nitrogen oxide emissions increased slightly (by 6%), compared to 2012, however it remains below statutory values. A decline in nitrogen oxide emissions was recorded at the Ljubljana site, whereas the Mengeš and Prevalje site a level similar to that in the previous year was maintained. The Lendava site recorded a 39% increase in emissions which is however, within the variability of the measurement process itself.

**Table 15: Emissions of nitrogen oxides (NO<sub>x</sub>)<sup>53</sup>**

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) t NO <sub>x</sub> /t product)
2009	t	10.14	0.78	8.72	1.38	21.02	0.007*
2010	t	9.14	1.30	16.36	1.36	28.16	0.009*
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

\* Changed efficiency data for NO for Lek as a result of changed data on production output for the Ljubljana site.

<sup>50</sup> EMAS Core Indicator, RC KPI 8, GRI Indicator G4-EN21

<sup>51</sup> EMAS Core Indicator, RC KPI 7, GRI Indicator G4-EN21

<sup>52</sup> EMAS Core Indicator, RC KPI 8, GRI Indicator G4-EN21

<sup>53</sup> EMAS Core Indicator, RC KPI 7, GRI Indicator G4-EN21

## 2.6.5 CO<sub>2</sub> and other gases contributing to the greenhouse effect<sup>54</sup>

The sources of direct CO<sub>2</sub> emissions (GHG1) at our sites remain as the following: 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>55</sup> data also includes:

- dinitrogen monoxide (N<sub>2</sub>O) in the equivalents of CO<sub>2</sub>,<sup>56</sup>
- fluorinated hydrocarbons (hydrofluorocarbons - HFC) in the equivalents of CO<sub>2</sub><sup>57</sup> and

- other greenhouse gases (methane and other) in the equivalents of CO<sub>2</sub>.<sup>58</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	2009	t CO <sub>2</sub>	11,636	2,371	12,310	2,027	28,344	7.8
	2010	t CO <sub>2</sub>	12,071	3,005	14,353	1,955	31,384	9.9
	2011	t CO <sub>2</sub>	11,839	3,699	15,135	1,999	32,672	8.8
	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	7.7
GHG2	2009	t CO <sub>2</sub>	15,153	34,105	10,715	2,548	62,521	17.2
	2010	t CO <sub>2</sub>	15,870	33,218	11,879	2,407	63,374	20.1
	2011	t CO <sub>2</sub>	16,023	35,117	11,938	2,482	65,560	17.7
	2012	t CO <sub>2</sub>	12,438	27,793**	3,870**	816**	44,917**	11.8
	2013	t CO <sub>2</sub>	5,856	28,122	3,382	855	38,215	9.9

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

\*\* Quantities for 2012 were adjusted due to the change in the conversion factor introduced by the electricity supplier.

\*\*\* The data differs from the data in the 2012 report due to an error identified in the entry into the DMS (Data Management System).

Due to changes in legislation, the Lendava and Mengeš sites participated in trading with CO<sub>2</sub> emission vouchers in 2013 for the last time. According to the law, we now have the obligation to report to the Ministry of the Environment and Spatial Planning, and to pay an environmental fee for all four sites.

In 2012 and 2013, total direct and indirect greenhouse gas emissions were reduced, mainly due to the change in the conversion factor for the calculation of CO<sub>2</sub> from supplied electricity. This factor depends on the structure of electricity purchased and is calculated by the supplier. The total volume of direct greenhouse gas emissions, however, was slightly increased compared to the previous year.

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 cutting-edge technology products of higher energy complexity.

The increasing 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.

## 2.6.6 Volatile organic compounds (VOC)<sup>59</sup>

In accordance with Novartis' recommendations on the use of alternative solvents in production, a systematic process of replacing halogenated solvents with non-halogenated ones in technological manufacture processes is underway. In 2013, total VOC emissions again saw a decrease (by slightly more than 11%), whereas the efficiency per tonne of product improved significantly.

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 quantity of halogenated solvents at the Prevalje site was reduced even prior to that.

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

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) † VOC/t product)
2009	t	24	70	203	2.7	300	0.083*
2010	t	25	58	170	5.5	258	0.082*
2011	t	24	36	146	6.2	212	0.057*
2012	t	23	43	71	5.4	142	0.038*
2013	t	24	28	68	5.8	126	0.033

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

## 2.7 Water releases<sup>60</sup>

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 the release duct, whereas at the Prevalje site, industrial wastewater is also technologically neutralized.

Into the cooling sewage system we only release non-contact cooling water. Unpolluted cooling water is discharged directly into the 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 2013 show that, with the exception of exceeding the temperature in one of the three measurements at the Ljubljana site, no excessive pollution was identified at any of the four sites. In the case of this deviation it is necessary to take into account that the maximum temperature measured over a period of 24 hours was 41.3 °C and that the water flow from the equalization basin later joins with water flows from other waste waters from the site which also means cooling the temperature of the water flow under consideration. The statutory prescribed limit value for the parameter temperature upon discharge into the sewer system is 40 °C.

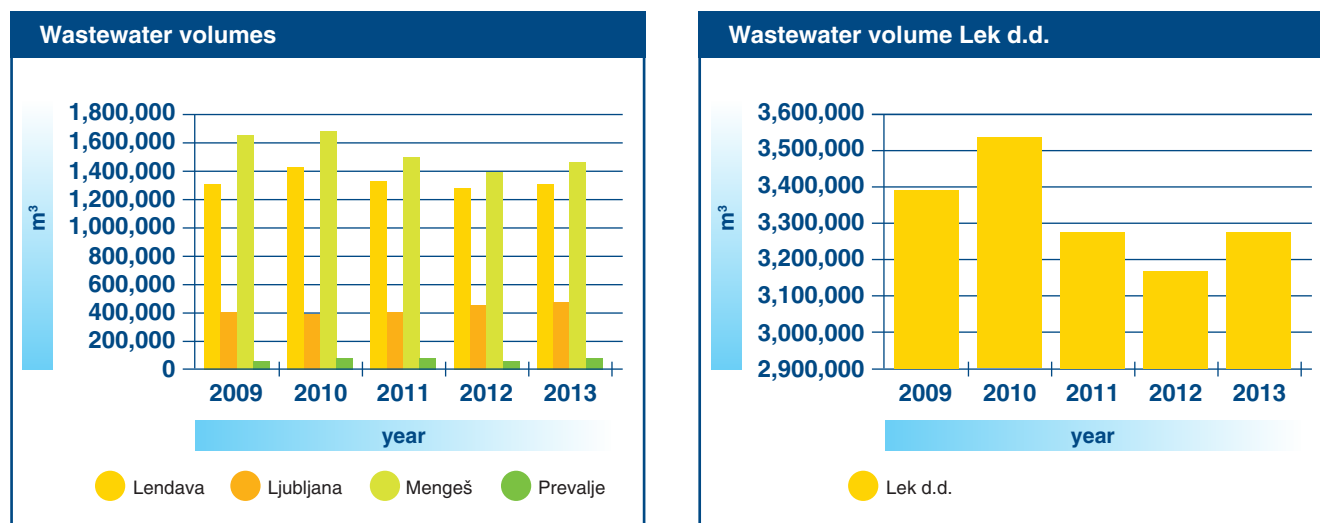
### 2.7.1 Wastewaters

Protection of waters from pollution is one of the most complex areas of environmental protection and an important aspect of a comprehensive water management. We are aware that pollutants pose a risk to human health and the environment therefore we are 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 more than 80% of the total water quantity. In 2013, their consumption increased slightly, as did the consumption of industrial water (in total slightly less than 4%).

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



Graph 7: Wastewater volumes (in m<sup>3</sup>)Table 18: Wastewater volumes by discharge quality and destination<sup>61</sup>

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Use of cooling water - unpolluted							
	2009	in 000 m <sup>3</sup>	1,125	79	1,381	13	2,598
	2010	in 000 m <sup>3</sup>	1,260	55	1,408	11	2,734
	2011	in 000 m <sup>3</sup>	1,170	34	1,243	10	2,457
	2012	in 000 m <sup>3</sup>	1,109	18	1,138	5	2,270
	2013	in 000 m <sup>3</sup>	1,129	35	1,156	5	2,325
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							
	2009	in 000 m <sup>3</sup>	180	327	267	23	797
	2010	in 000 m <sup>3</sup>	167	341	271	28	807
	2011	in 000 m <sup>3</sup>	163	381	259	25	828
	2012	in 000 m <sup>3</sup>	163	434	271	30	898
	2013	in 000 m <sup>3</sup>	187	442	296	34	959
Discharge			into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system	into sewage system cleaning at WWTP

<sup>61</sup> EMAS Core Indicator, GRI Indicator G4-EN22

## Wastewater

### Redirection from the Kopica stream to the Mura river

The Lendava production site uses groundwater for the cooling of technological processes. Its rational use is achieved so that it is carried through cooling systems at several temperature levels. The generated waste cooling waters are not contaminated; therefore we release them back to the environment after use taking into account that the maximum statutory released temperature is 30 °C.

In 2013, after obtaining all permits, we started relocating the outlet of non-contaminated waste cooling waters from the Kopica stream into the Mura river. We assessed that the current outlet into the Kopica stream was not appropriate any longer due to the increased quantities of cooling waters. With this investment, we organized the discharge outlet into the Mura river through a pressure pipe and at the same time separated the discharge of precipitation waters from that of waste cooling waters. The latter are still discharged into the Kopica stream through oil-traps.

For industrial wastewaters we have a special, independent, closed-loop sewage system. Industrial wastewaters are filtered at the wastewater treatment plant build in 2001 together with the municipality of Lendava. Only Lek's sanitary wastewaters are discharged into the public sewage system.



Redirection of cooling water discharge outlet into the Mura river

## New cleaning technology

### With ozone to cleaner wastewaters

By investing into a technically advanced wastewater treatment in Mengeš we pursued Sandoz' active environmental policy, one of the pillars of our corporate responsibility. Once again we proved that we often do more to protect the environment than required by law. We started to investigate the impacts of pharmaceutical ingredients in wastewaters even before we were required to do so by national or European legislation.

As explained by Egidij Capuder, Head of API Production Mengeš, upon starting up a new wastewater treatment plant in December, our in-depth knowledge of chemical substances enabled us to investigate the effects of pharmaceutical ingredients that can come into wastewaters during the production process. In doing so, we reviewed and evaluated ecotoxicity data for hundreds of substances that are produced at Lek, a Sandoz company.

The new environmental acquisition at the Mengeš site is a modern treatment plant for removing pharmaceutical substances from wastewaters using ozone. With a simple technology for treating wastewaters with ozone, pharmaceutical substances and other micro-pollutants are efficiently and permanently eliminated with a minimum impact on the environment. Ozone is namely one of the most powerful oxidants that proved to be, due to its properties, a highly efficient agent for wastewater treatment. This technology features a high degree of automation and flexibility. Its additional advantage is that it does not require the storing of harmful chemicals as ozone breaks back down into oxygen.

No hazardous by-products are generated in the treatment process, and residual oxygen from the production of ozone can be used also in other production processes.



Ozonizer in Mengeš. Production engineering and the project manager Gorazd Bergant, technical coordinator from Mengeš Production, Marijan Resnik and Jože Stopar as a representative for ecology and HSE, played a key role in starting up the wastewater treatment plant. In the picture (from left): Jože Stopar, Ana Šarec (Head HSE Mengeš) and Marijan Resnik.

## 2.7.2 Phosphorus and nitrogen compounds, chemical oxygen demand

Nitrogen compound emissions mostly result from the fermentation production, particularly at the Mengeš site followed by Lendava and Ljubljana, and, at a negligible level, the Prevalje site, which is demonstrated in the graphic presentation of the emission trends by site. In 2013, the total volume of nitrogen compound emissions increased by 7.5%, however, it was still lower by 30% than in 2011.

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. In 2013, they dropped by nearly 18% and are at the same level as in 2009.

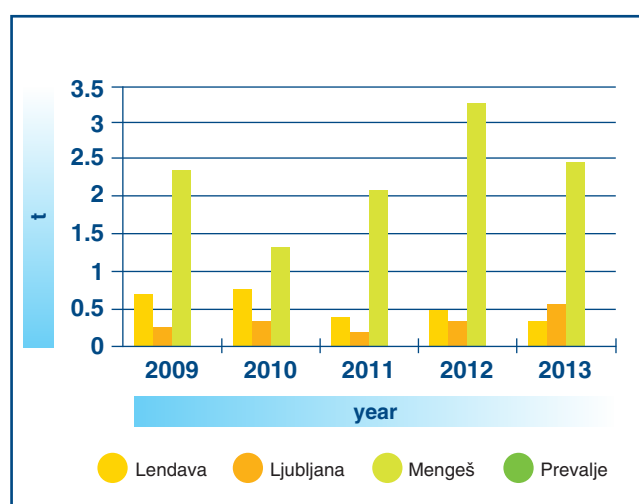
To provide an assessment of the level of pollution with organic impurities, chemical oxygen demand is an important parameter, providing the quantity of oxygen needed for

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 2013, we recorded a slight increase in the chemical oxygen demand parameter on account of the Mengeš location. The Prevalje and Ljubljana sites together contribute to less than 2% of total wastewater pollution with organic impurities.

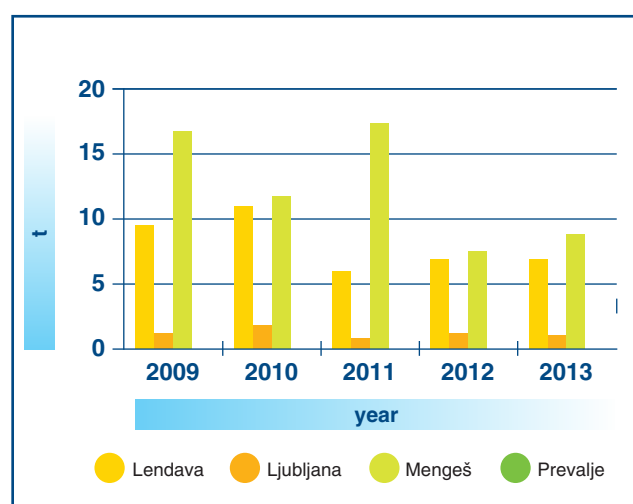
Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute parameters for the calculation of the environmental fee. The highest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds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

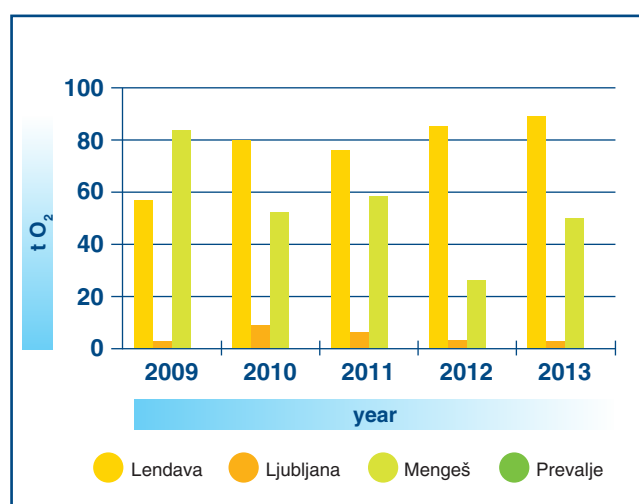
**Graph 8: Emissions of phosphorus compounds in wastewater<sup>62</sup>**



**Graph 9: Emissions of nitrogen compounds in wastewater<sup>63</sup>**



**Graph 10: Chemical oxygen demand (in t O<sub>2</sub>)<sup>64</sup>**



Through increasing knowledge of chemical substances and the significance of biotic diversity for human beings, 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. Even though it has been established that only a small percentage 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 ecotoxicity data of APIs are regularly reviewed and evaluated, and proper action is taken (see the article on "With ozone to cleaner wastewaters" under Item 2.7.1).<sup>65</sup>



## 2.8 Other environmental impact

### 2.8.1 Odour

At all the sites, we have installed biofilters wherever odour from industrial processes is expected, thus preventing it from affecting the local population (e.g. above wastewater equalization ponds). The monitoring of biofilters' operation and waste air loads is carried out by the Public Health Institute Maribor. Slovenia's environmental regulations do not cover environmental odour pollution.

In 2013, we received a question from a Preserje resident with regard to an unpleasant odour spreading from the equalization basin in Mengeš. The investigation showed that the source was the cultivation of agricultural land and not Lek, a Sandoz company (also reported under Item 1.5.3.1).<sup>66</sup>

### 2.8.2 Soil

As the environmental impact on soil pollution is usually irreversible, this area is of special concern to Lek.

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 have not yet been adopted; however, based on good international practices, we have already launched activities to meet requirements for the Mengeš site.

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

**Table 19: Land use by site<sup>67</sup>**

	Mengeš	Lendava	Ljubljana	Prevalje	Lek
Green surfaces in m <sup>2</sup>	35,141,5	104,478	25,504	1,946	167,707
Building surfaces – aerial view (in m <sup>2</sup> )	37,087,5	15,703	41,099	7,324	101,213.5
Asphalt surface – roads, courtyards (in m <sup>2</sup> )	45,470	16,482	40,185	9,257	111,340
Total site surface area with parking lots (in m <sup>2</sup> )	129,742	136,663	121,245	18,527	405,907
Production site surface area/product in (m <sup>2</sup> /t)	250	564.1	61.5	16.6	105.4

### 2.8.3 Noise

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. The main identified source of noise is manufacturing activity, particularly the operation of fermentors, compressor stations, as well as ventilation and cooling devices. The noise-emission levels are largely due to the immediate vicinity of busy roads, especially at the Ljubljana site.

In 2013, we received two noise-related complaints. They are described under Item 1.5.3.1.

### 2.8.4 Biodiversity<sup>68</sup>

At Lek, a Sandoz company, we are aware of the significance of environmental protection and that is reflected in our consistent adherence to statutory waste and industrial water management requirements and proactive measures taken.

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

With the existing legislative regulation on light pollution we are facing a big challenge. It stipulates the reduction of external illumination of production and parking areas, while on the other hand meeting minimum standards for working conditions dictates sufficient illumination. Taking into account the results of studies that research the well-being of people exposed to warmer colour shades of outdoor lighting, we are confronted with requirements that we hardly meet in practice. For this reason, Lek, a Sandoz company, has designed comprehensive expert studies for its sites. The outdoor lighting was remedied using modern technologies; however at the same time we compromised by reducing its operation in the limited period of time when labour needs are reduced.

<sup>66</sup> GRI Indicator G4-EN34 | <sup>67</sup> EMAS Core Indicator | <sup>68</sup> GRI Indicator G4-EN12, G4-DMA

## 2.9 Safety

### 2.9.1 Fire safety

In the last three years, fire safety arrangements for buildings were carried out at all our sites, on the basis of Novartis and Slovenian legislation. The arrangements included the installation of fireproof doors, sealing of installation through-penetrations with fire-resistant materials, covering grey zones with an automated fire alarm system, emergency and safety lighting, installation of fire dampers, organizing intervention accesses, construction of the hydrant network and stable fire fighting systems. The conclusion of all arrangements with regard to fire protection is scheduled for within the next two years.

In the Fire Prevention Month (October), tactical fire drills with intervention units that provide emergency assistance, were carried out at our sites. The number of voluntary fire fighters has increased at all sites. A basic fire fighting course was organized as a part of the operation of Lek's volunteer industrial firefighting team. At the Mengeš site, we replaced a 20-year old fire engine with a new fire engine and a trailer for transportation of firefighting equipment.



*With an extensive tactical fire drill at the Mengeš site we checked our overall emergency preparedness.*

Last year we had two events (Ljubljana, Mengeš) resulting in production of smoke on the premises. In the first case, the smoke was due to overheating of insulation on the equipment and in the second case due a fault in a fork-lift's electrical system. There were no injuries to personnel or objects, only damage to equipment occurred.

On 17 September, a container deflagration occurred at the Prevalje site. There were no injuries to personnel, only material damage occurred. After the event, an investigation was carried out showing that chemical reaction was the most likely cause of the event. There was an increased volume of waste, but no major negative impacts on the environment. Potassium clavulanate, which was in the container, is easily biodegradable and the resulting emissions into the air were in the form of CO<sub>2</sub>, CO and NO<sub>x</sub>. Technical measures and revised operating procedures were implemented to prevent a recurrence of the event.

### 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:**

- Risk Group 1: Biological agents /genetically modified organisms with minimum risk of causing disease in humans, and negligible risk of spreading into the environment ;
- Risk Group 2: Biological agents /genetically modified organisms with a potential to cause disease in humans, and potentially hazardous to workers; the risk of spreading into the environment is minimal; in most cases, effective prevention or treatment is available.

Lek's manufacture involves exclusively biological agents of Risk Group 1 for which risk assessments were made. The risk assessment includes the risk that biological material poses to a worker and containment measures to reduce the risks and potential exposure of workers. We provide them additional preventative measures and biological monitoring for early detection of potential problems.

To ensure adherence to biological safety, we appointed a Biological Safety Officer at the corporate level, with deputy 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. Appointed are also persons responsible for ensuring safety of work with GMOs.

Lek, a Sandoz company, also has a 12-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.

In 2013, an expansion of the closed microbiological control system in Ljubljana was implemented. The Ljubljana site also successfully passed an inspection.

Biological drugs 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 biologicals, 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.

## The first Lek independent biological safety officer, Katarina Rajapakse

### Biological agents are the basis of our development and drug production

#### In 2013, you became Lek's first independent Biological Safety Officer. Have the requirements with regard to biological safety in Slovenia changed in recent years?

Biological safety in Slovenia has been regulated since 2002, and two years later regulation came into force for persons responsible for biological safety in companies.

At Lek, a Sandoz company, the independence of the position and the field of biological safety became inevitable due to a rapid development of the Biopharmaceuticals unit. The unit has been operating since 2002 at the Mengeš site, where the development, manufacture and analyses of biological substances are carried out. Within Biopharmaceuticals, as many as 8 out of 10 of Lek's closed system for work with genetically modified organisms have been registered so far. The production facility PORT1 is one of them, the others are all laboratories. In these closed systems the development, optimization, pilot processes and analyses of genetically modified cell lines and their products are carried out.

The system of biological safety provides us with the necessary infrastructure and decision-making processes with regard to human and environmental safety when handling biological materials. My primary tasks are to raise the awareness of associates about safe work and offer help in understanding the basic principles of biological safety when handling biological materials. Preventative action is also of key importance here.

#### Which other areas of expertise does Lek's Biological Safety Officer cover?

I am responsible for following new developments and information about potential risks of working with recombinant technologies. I advise in the preparation of risk assessments and other documents with regard to biological safety, such as contingency plans in the event of an accident or incident when using recombinant technologies. I co-create written guidelines for working with biological material in a closed system and ensure that the associates who come in contact with biological material are sufficiently qualified. I regularly check containment measures and equipment and report to laboratory heads about identified problems or faults.

I am accountable for the cooperation with the regional information center and for informing the public about using recombinant technologies. There are also external inspections and internal audits, communication with the Ministry of Agriculture and Environment which is responsible for approval of the use of GMOs, as well as reporting, registration and modifications to closed systems for work with GMOs.

#### Which of Lek's processes require the need for concern for biological safety?

At Lek, a Sandoz company, in the development and drug manufacture we almost exclusively make use of the classical biotechnological production of substances the basis of which are biological factors. Microorganisms in



Katarina Rajapakse, PhD., Biological Safety Officer at Lek d.d.

bioreactors produce antibiotics, they biotransform molecules and form many secondary metabolites, called active ingredients. The increase in the efficiency of strains can be significantly influenced by optimizing the conditions, for example nutrients, temperature and pH, by the use of recombinant technologies and selection of strains, and by purification processes, we influence the yield of the produced active ingredient.

All these activities require measures to prevent infections, allergies or intoxication of workers and the release of biological agents in the environment.

With the establishment of Biopharmaceuticals, Lek has entered an area of new-generation medicines also known as modern recombinant biological drugs.

Biologicals in comparison with conventional medicines have practically no side effects and are extremely effective. All the manufacture processes for recombinant biologics that include live cells, i.e. the development of mammal cell lines, the use of recombinant technology and production are inevitably included in the biological safety system.

#### How does the experience that you have gained in research work help you?

Ten years of research in biomedicine and biotechnology at home and abroad gave me a broadness and oversight of a number of techniques, their weaknesses or alternative approaches which are used in Lek's closed systems. The laboratory is a very homely and familiar environment for me. This enables me to understand and be able to ask researchers the right questions when it is necessary to evaluate the working process and anticipate potential hazards and possibilities of exposure to biological material. And on this basis I also propose and adopt effective measures for the safety of our associates.



## 2.9.3 Providing storage and distribution safety

### 2.9.3.1 Storage

At Lek, a Sandoz company, 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 place in accordance with the legal requirements.

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). The system was further upgraded in 2013.

### 2.9.3.2 Distribution<sup>69</sup>

From our production sites in Slovenia, 6,720 consignments of finished products and APIs were dispatched to 93 countries in 2013. During the transport of both non-hazardous and hazardous goods, no accidents occurred. Compared to the previous year, the volume of distributed goods increased slightly and amounted to 19,421 t (17,816 in 2012).

In September 2013, new EU guidelines on Good Distribution Practice of medicinal products for human use (GDP) entered into force. We implemented these guidelines in our distribution processes for all transport methods.

In the organization of international road transport, we continued with the implementation of the "Control Tower" business model organized by DHL Belgium. With the optimization of transport cost, especially with a good planning of shipments and utilization of vehicles, target savings were achieved.

In the organization of air transport, we successfully upgraded the cooperation with our partner DHL Global Forwarding, and carried out two workshops where we focused on the quality of the executed transport service in line with new GDP guidelines.

A regular local call for bids was put out for sea freight forwarding services, bringing us some savings.

The trend of transition from air to sea transport will also continue in 2014 in order to reduce cost and provide better quality service in terms of GDP.

## 2.9.4 Chemical safety

With its chemical safety system, Lek, a Sandoz company, ensures safe handling of chemicals in laboratories as well as in the API and finished products manufacturing process. In accordance with the legal requirements for the handling of chemicals and the Novartis' guidelines, we keep our employees informed of their hazardous properties. 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 (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.

## Lek HSE systems

### HSE organization, human resources and training

#### HSE function

The HSE function employs the 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.

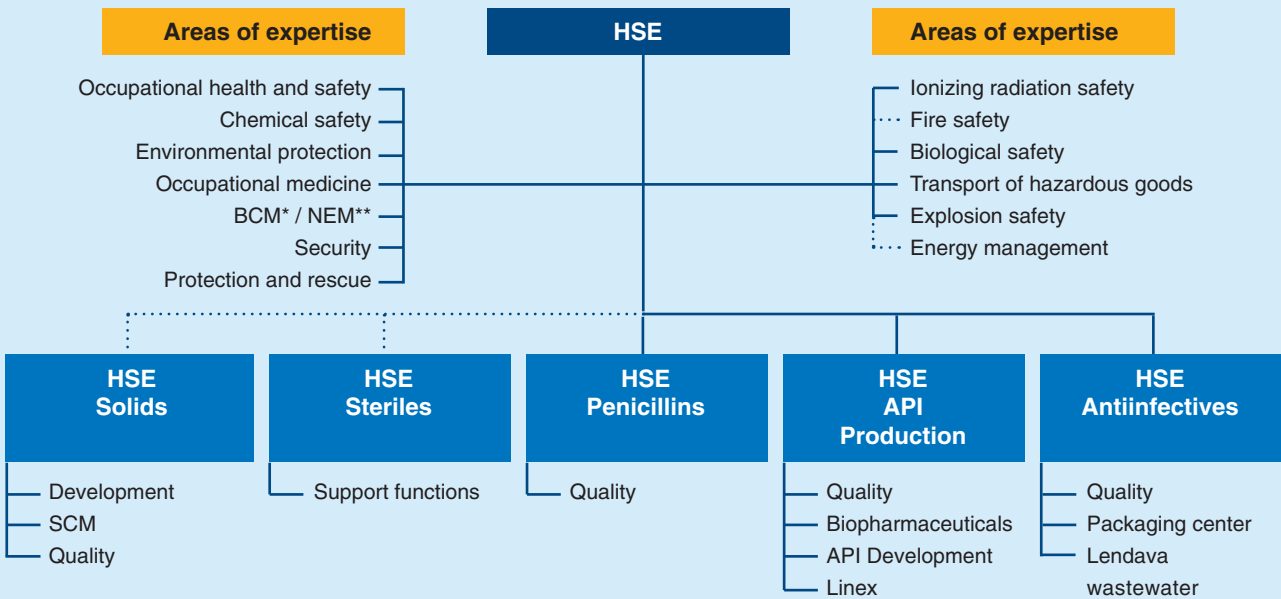
#### HSE department

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>69</sup> RC KPI 22, GRI Indicator G4-EN30, G4-DMA

Lek HSE 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 the following clusters: onboarding, continuing education, and training for promotion.

We also encourage direct interaction of employees in different roles, functions and units beyond the formal HSE function organization. For this purpose, the Re:act Initiative was launched, creating opportunities for the employees to provide ideas, regardless of how insignificant they might appear at a first glance, to positively impact employee well-being, save valuable time and natural resources, and contribute to safety and quality.



HSE team Ljubljana



HSE team Mengeš



HSE team Prevalje



HSE team Lendava

## Lek HSE systems

### Environmental impact and risk assessment

In accordance with legal requirements, all Lek sites have acquired environmental permits for operation (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 anticipated intervention are evaluated according to individual 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, Nos. 71/08 and 105/10) Lek, with the exception of the Mengeš production plant, 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. Being a minor environmental risk plant, we filed an application for an environmental permit with the relevant Ministry. The permit is due by the end of 2015, as major risk sources are given priority.

### 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)
- Introduction of new products and production processes: 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 2013, 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.

In 2013, we had one HSE emergency event in Prevalje as reported under Item 2.9.1.

### 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 the case of major change to the internal or external environment. It serves as a basis for the preparation of the Risk Portfolio, business and activity plans and programs, and for the setting of personal goals for responsible persons.

In our operations, our compliance with legal and other requirements reflects in successfully completed internal and external audits, inspections, water, air and noise monitoring, and with applicable environmental permits.

In 2013, audits of an external customer were carried out as well as an internal energy audit and external auditing of the company's compliance with ISO 14001:2004 and BS OHSAS 18001:2007 and an audit according to the EMAS Directive.



## Lek HSE systems

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, and 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, and the EMAS Directive. The results of internal audits performed in 2013 showed the high level of the company's compliance with the statutory requirements as well as internal and external standards in all the 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 2013 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 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

## 3.1 Human resource policy<sup>70</sup>

"It is all about people. Cooperation. Development. Excellence" is the slogan of our human resources policy. Its 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 policy supports the basic business orientations, aiming to achieve a high level of innovation, growth and better productivity in the reporting year.

Lek, a Sandoz company, is 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.

In 2013 there were 8 labour court proceedings against Lek, 4 new lawsuits were filed, other proceedings continue from 2012.

<sup>70</sup> GRI G4-DMA, GRI Indicator G4-LA16

## Employment

### Lek, the most reputable employer in 2013

Lek, a Sandoz company, received the awards The Most Reputable Employer Among Pharmaceutical Companies in Slovenia and The Most Reputable Slovenian Company 2013. The latter has a special meaning, because the reputation of our company and its eligibility as an employer of choice was confirmed by job seekers themselves. The MojeDelo.com recruitment portal, that gives the award, conducted, for the fourth time in a row, an extensive survey among more than one thousand candidates in the labour market. Also in previous years Lek, a Sandoz company, ranked among the most reputable employees.

Vojmir Urlep, President of the Board of Management of Lek, a Sandoz company, emphasized the importance of this acknowledgement because being recognized as the most reputable employer also means to be a responsible one, and reputable organisations attract top talents, which is of crucial importance in a very competitive and knowledge-based pharmaceutical industry.

**Samo Roš**, Head of Human Resources and Member of the Board of Management at Lek, a Sandoz company, pointed out: *"The award represents a confirmation of creating a motivating and challenging working environment for employees. As a part of one of the biggest global pharmaceutical companies our employees have the chance to develop their careers internationally, we invest a lot in their personal and professional development."*

As is evident from this Sustainability Report of Lek, a Sandoz company, we also encourage a healthy way of life among our employees, an inclusive and diverse working environment, we pay particular attention to career development of women, and improvement of work-life balance among employees.



Vojmir Urlep, President of the Lek Board of Management, and Samo Roš, Head of Human Resources, attending the The Most Reputable Employer award ceremony

## Regional BioCamp 2013

### Contemporary Technologies for Affordable Therapies

How to broaden access to medicines is a question that inspires Sandoz associates in their daily work. 35 top and most promising science students from the Alpe-Adria region were trying to find an answer to this question at the third Regional BioCamp 2013 that we organized in Ljubljana.

The participants of this unique international event in Slovenia developed a case study, transferring their acquired knowledge into practical work and thereby connecting science and business. The teams had to prove themselves not only as science experts but also had to show a great deal of business knowledge. The principal theme of the third Regional BioCamp was Contemporary Technologies for Affordable Therapies.

The winners in the competitive part were Patricia Wildberger from the Institute of Biotechnology and Biochemical Engineering at Graz University and Gašper Pustovrh from the Biotechnical Faculty at the University of Ljubljana. They were awarded with the participation in the Novartis global BioCamp 2013 in Basel, Switzerland. Patricia Wildberger really enjoyed those two days in Ljubljana. *"The Regional BioCamp was a wonderful experience. The lectures and viewings were very interesting, we had the opportunity to get a first-hand view of how the pharmaceutical industry works and we also learned about challenges pharmaceutical companies face nowadays and in the future. I also had the pleasure to be part of a really*

*great team, each of our team members brought in their own competence and expertise, so we were able to take on the challenge and prepare a successful business case,"* explained Patricia. The second winner, Gašper Pustovrh, loved the Regional BioCamp and was pleased with his achievement. The participants of the event that opens doors to new knowledge and innovative thinking were also addressed by Jernej Pikalo, the Minister of education, science and sports.



Participants of the Regional BioCamp 2013

## 3.2 Employment

### 3.2.1 Total workforce by employment type and employment contract<sup>71</sup>

At the end of 2013, the proportion of women in Lek's total workforce was 45%, the level identical to that in the previous year. At year end, 91.4% of employees (86.8% in 2012) worked on a permanent full-time basis, and 64 employees or 8.6 % were fixed-term employees (10.9% in 2012). 2.2% of all employees worked on a part-time basis, the level identical to that in the previous year (2.3%).

### 3.2.2 Percentage of employees covered by collective bargaining agreements<sup>72</sup>

The Collective Bargaining Agreement covers 99% of total workforce, a level identical to that in the previous years.

### 3.2.3 Coverage of the organization's defined benefit plan obligations<sup>73</sup>

Lek provides 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 2013, 84.98% of the workforce was included in the scheme. The premium is calculated on the basis of 5.844% of the employee gross salary.

### 3.2.4 Procedures for local hiring and proportion of senior management hired from the local community<sup>74</sup>

At Lek, the process of hiring foreign employees is compliant with established corporate practice following EU recommendations. 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.<sup>75</sup> The proportion of local human resources in the senior management team (consisting of unit heads and board of management members) is 91% and slightly higher than in the previous year (90% in 2012).

### 3.2.5 Parental leave<sup>76</sup>

Parental leave is granted to every employee fulfilling the criteria laid down in the Parental Protection and Family Benefits Act.

	Men	Women	Total
Number of employees having taken parental leave	93	108	201
Number of employees returning to work after parental leave	90	98	188
Percentage of employees returning to work after parental leave	97%	91%	94%
Number of employees returning after parental leave to work in the same position	90	98	188
Percentage of employees returning after parental leave to work in the same position	97%	91%	94%

## 3.3 Occupational health and safety

### 3.3.1 Standard injury, lost day, and absentee rates<sup>77</sup>

One employee accident resulting in sickness absence was recorded. In 15 workplace accidents, the injury required medical attention beyond first aid. 9 such accidents occurred to Lek associates, 4 to workers working through employment agencies and in two cases students were injured. In 2013, a total of two workplace accidents occurred resulting in sickness absence from work. Apart from one Lek employee, one contractual worker also suffered such injury. The total number of workplace accidents (including both internal and external associates) requiring sickness absence, declined (in the previous year, 4 workplace accidents were recorded).

### 3.3.2 Standard injury rate<sup>78</sup>

Across Novartis Group, including Lek, a Sandoz member, occupational health and safety are long-term objectives, aiming for preventative action and promotion of safe conduct. 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) indicator and the TRCR (total recordable case rate) indicator (including sick leave cases and the cases where medical attention beyond first aid is required but the employee is able to return to his working environment without sick leave). The two indicators are calculated according to the number of cases per 200,000 hours worked.

<sup>71</sup> GRI Disclosure G4-10, Indicator G4-LA1 | <sup>72</sup> GRI Disclosure G4-11 | <sup>73</sup> GRI Indicator G4-EC3 | <sup>74</sup> GRI Indicator G4-EC6 | <sup>75</sup> GRI Indicator G4-LA13 | <sup>76</sup> GRI Indicator G4-LA3

<sup>77</sup> RC KPI 2, GRI Indicator G4-LA6 | <sup>78</sup> GRI Indicator G4-LA6



## Calculation formulas:

**LTIR** = number of lost-time injuries (work-related injury/illness resulting in the use of sick leave) x 200,000 / number hours worked.

**TRCR** = total recordable case rate (beyond first-aid criteria) x 200,000 / total hours worked.

Additional recording of hazardous occurrences and near misses is also performed. 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. The most frequent causes of injury were slips, trips and falls. Through incident investigation using the TapRoot analysis we note that the number of incidents could be reduced with an improved safety culture and more care taken by the employees.

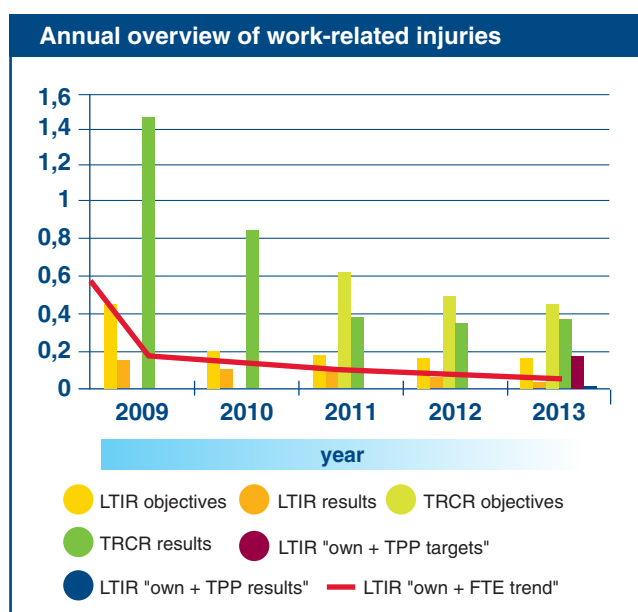
Table 20: LTIR Index (Lost Time Injury and Illness Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	0.00	0.09	0.40	0.00	0.15
2010	0.00	0.00	0.40	0.00	0.10
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

Table 21: TRCR Index (Total Recordable Case Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2009	0.62	1.86	3.03	0.65	1.47
2010	0.00	0.51	1.99	0.69	0.86
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

Graph 11: Annual overview of work-related injuries LTIR and TRCR 2009–2013 for Lek

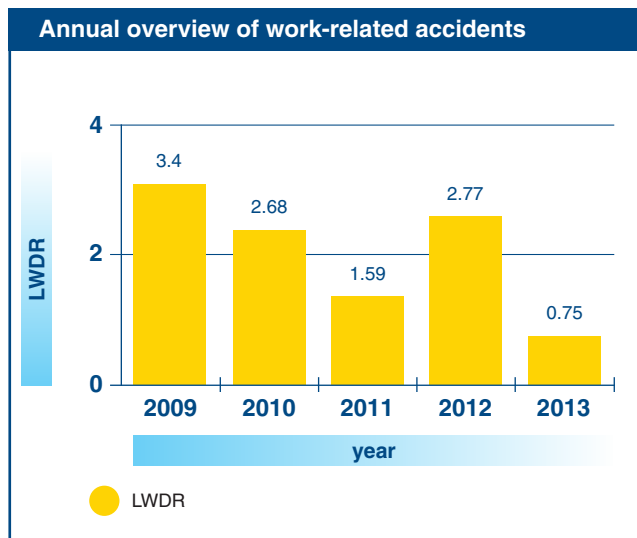


Workplace safety

**LWDR – Lost Time Work-Day Rate**<sup>79</sup> is an indicator defining 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.

For Lek d.d., the LWDR value for 2013 was 0.75, which is the lowest value of all time. The downward trend of the LWDR value was recorded continuously since 2008, except in 2012, when the value was 2.77 as a result of a severe work-related accident that required prolonged sick leave.

<sup>79</sup> GRI Indicator G4-LA6

**Graph 12: LWDR value (Lost Time Work-Day Rate) for Lek**

### Incident rate (IR)

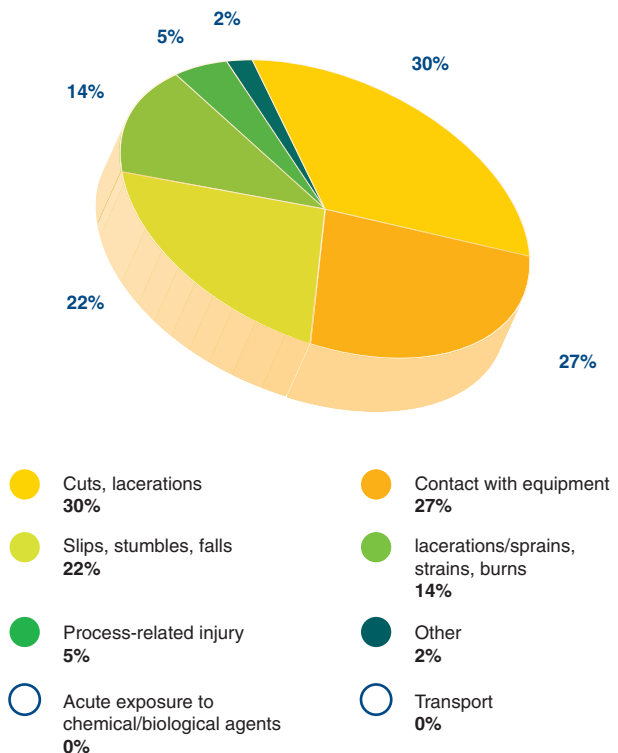
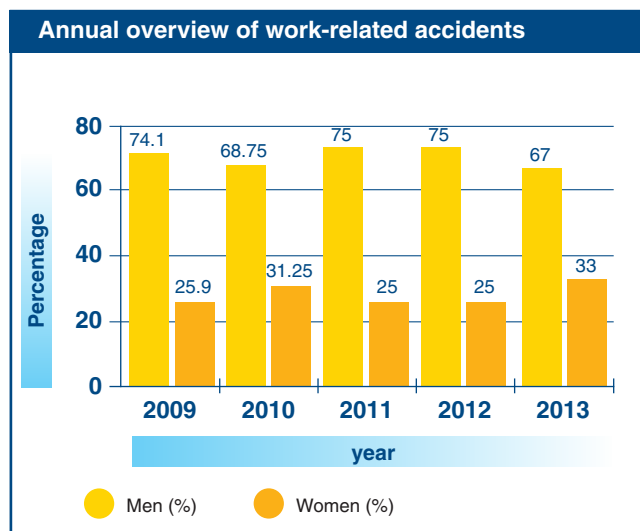
The incident rate for accidents with recorded sickness absence amounted to 0.2.

It is calculated using the following formula:

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

Great attention is paid to ensuring overall safety as this is the only way to continue the downward trend of work-related injuries.

To be able to provide a more comprehensive picture, we also monitor the cases where first aid was administered and the employee was able to return to his/her working environment without sick leave. Less severe incidents constitute an encouragement for further preventive action, and a reminder of the presence of hazardous behaviour in our working environment. The number of first aid cases is high (> 40) 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.

**Graph 13: Classification of reasons for work-related incidents (LTIR and TRCR) for 2013****Graph 14: Classification of work-related incidents (LTIR, TRCR) by gender**

### 3.3.3 Absenteesm<sup>80</sup>

The proportion of sickness absence in 2013 was 3.97%, recording a slight increase compared to the previous year (3.6% in 2012). In men, the proportion was 2.86% and in women 4.83%. The rate is calculated on the basis of absence hours as follows: the total number of lost working hours due to absenteeism in the period is divided by the organizational unit's total number of working hours in the period.

<sup>80</sup> GRI Indicator G4-LA6

### 3.3.4 Absenteeism rate due to work-related injuries for contracting providers

In 2013, we recorded 4 injuries among contracting providers, a level identical to that the year before and lower than the level in 2010 (7 cases).

Contracting providers perform construction and maintenance activities. Injuries result from insufficient measures to prevent falling from a height and careless handling of tools. By means of walkthrough inspections, training for contracting providers, and building awareness, we strive to improve their conduct and strengthen their preventive attitude.

### 3.3.5 Number of work-related fatalities<sup>81</sup>

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

### 3.3.6 Rate of occupational disease<sup>82</sup>

At Lek, a Sandoz company, no occupational illness has been identified and confirmed to date. In the process of de-

tecting occupational illness, we closely cooperate with occupational medicine specialists, both in the field of risk assessment and workplace stress identification.

### 3.3.7 Health promotion program<sup>83</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. Health promotion is at Lek, a Sandoz company, 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.

The "Be Healthy" program that we implement is an initiative aiming to improve the health of our employees and is implemented across the entire Novartis group around the world. It is designed to promote healthy lifestyle, share knowledge and experience and prevent injuries and illnesses which could affect associates' private and professional life. It is designed on the basis of risk assessments for individual jobs, reports from periodic medical examinations and individual medical reports.

## The Be Healthy program is based on four pillars:



#### MOVE

**MOVE** – increasing exercise.



#### CHOOSE

**CHOOSE** – choosing healthy food options and appropriate diet for staying in good shape at home as well as at work / lectures on balanced diet.



#### KNOW

**KNOW** – knowing the numbers of key health indicators.



#### MANAGE

**MANAGE** – ongoing support for employees / lectures on stress management.

## Expected benefits

Workers who work in an improved working environment are healthier and more motivated.

As a result, the following can be expected:

- greater resistance of employees (the employees maintain and improve their health)
- satisfaction of employees
- reduction and easier management of negative impacts of stress
- reduction of risk factors such as high blood pressure, high blood sugar and cholesterol, which lead to a greater prevalence of cardiovascular disease, obesity and diabetes;
- less absenteeism
- higher quality of products and services
- higher reputation of the organization

Several activities were carried out as a part of the "Be Healthy" initiative. In the period 2011– 2013, 198 employees were included in healthcare programs while 686 participated in guided exercise. Of these, 651 employees underwent medical tests such as examination of the cardiovascular system (cycloergometry), spirometry, ECG, analysis of bodily structure, blood pressure and cholesterol levels, triglyceride and blood sugar levels.

In the context of the preventative vaccination program, 518 or 17% of all Lek employees (308 Ljubljana, 95 Mengeš, 28 Prevalje and 87 Lendava) were vaccinated against tick-borne meningoencephalitis in 2013, and against seasonal influenza 168 or 5.6% of all Lek employees (72 Ljubljana, 76 Mengeš, 12 Prevalje and 7 Lendava).



In 2013, all Lek sites took part in the global GCC (Global Corporate Challenge) project. The project encourages the employees to walk using a pedometer. All participating employees together made 127,329 km or 198,965,605 steps (a daily average of 14,033 in Ljubljana, 20,914 in Lendava, 17,118 in Mengeš and 19,397 in Prevalje).

77% GCC participants reported that the project changed their attitude to taking the care of their health in their own hands in a positive sense.

## Be healthy celebration week

### Small steps can often lead to greater well-being

Novartis puts great emphasis on the promotion of healthy living among the employees, in order to attract as many associates as possible with a variety of opportunities and initiatives. In 2013, up to 95% of employees joined the global Be Healthy initiative. A part of the initiative is also the annual Be Healthy Celebration Week, in which 2,400 associates from all sites participated.

An ally in our efforts to spread the notion of a healthy lifestyle, a former top biathlon athlete Petra Majdič, prepared a Nordic walking course in cooperation with two professional instructors for the associates at all sites. Also important for the preservation of health are preventative health checks. The employees had a chance to measure the ankle-brachial index for preventive detection of arterial diseases in the legs and the test with tumour markers for the detection of cancerous changes in the prostate. The response was significant, as at the Ljubljana, Mengeš and Lendava site 203 ankle-brachial indexes were measured and 124 blood samples were tested for PSA markers.



Our associates learned the technique of Nordic walking as a part of the Be Healthy Celebration Week



Measurements of ankle-brachial index were carried out.

We also focused on another two visible factors of caring for health, together with a doctor and athlete Nada Rotovnik Kozjek, MD. In presentations that have been met with strong interest by employees, she advised on a diverse and balanced diet.

*"Everybody takes care of his/her own health; however it is the responsibility of an employer to encourage the employees to embrace healthy lifestyles. Healthy and relaxed employees can cope more easily with challenges both at the workplace and in their private lives," said Robert Hribar, Head HSE at Lek, a Sandoz company, on the occasion of the Be Healthy Celebration Week "I am pleased that this year, movement, healthy eating and well-being activities have once again taken over Lek's premises for a few days. The program was designed so as to enable a comprehensive approach to maintaining a healthy lifestyle of the associates. We focused particular attention on our associates in production and therefore adjusted the program of activities during the Be Health Celebration Week to their work schedule."*

## Lek HSE systems

Enhancing the company's safety culture is one of our key responsibilities. These efforts are supported by the work of the Safety Board keeping track of current events and receiving proposals for preventive action. Senior management shows its support by being open towards new initiatives, confirming the organization's overall commitment to reducing the work-related accident rate.

The improved safety culture is reflected in a considerable decline in the LTIR rate and the number of work-related accidents.

In 2013, we continued to spread HSE information. Our process of investigating accidents and near misses has been supported by communication about the underlying reasons and measures to prevent incidents in similar working environments. In high-risk units, we continued walkthrough inspections on site by senior managers and safety meetings.

In 2013, we continued to promote an active and healthy lifestyle of our employees through the Health Promotion Program and the Novartis Be Healthy initiative.

Within the health promotion program, we provided our employees with an opportunity to attend preventive health programs which include specific health sustaining programs, guided workouts, and participation in vaccination campaigns, e.g. seasonal flu and tick-borne encephalitis vaccination. The program was enriched with measurements of key health indicators, such as the ankle-brachial index and measurements of tumour marker PSA in men.

In 2013, the following HSE activities were organized:

- Regular periodic training for employees in occupational health and safety, and fire safety;
- Regular training on Behavior Based Safety for newly recruited employees and managers;
- Workshops covering various occupational health and safety areas, e.g. industrial hygiene, investigation of incidents, process risks, etc.;
- Targeted training programs on HSE, safety culture, chemical safety, fire safety and NEM (Novartis Emergency Management) as an integral part of the BCM (Business Continuity Management) in individual organizational units;
- Tactical fire drills in accordance with the Risk Portfolio to check the level of protection and rescue teams' response, equipment availability, and their conduct in case of emergency;
- Evacuation drills with real-life fire-extinguishing tests;
- Regular first aid training.

## Prevention of workplace accidents

Preventive action aims to identify and prevent inappropriate behaviour and hazardous practices. For this purpose we are upgrading the system of immediate reporting and comprehensive analyses as well as the involvement of competent internal and external services such as a first-aid team, an occupational medicine specialist, and others. We continue to intensify preventive activities, including walkthrough inspections and safety meetings, safety consulting, analyses of work-related accidents, communication, and risk assessment.

## 3.4 Training and education

### Employee education and training

#### TOP 10 Award for the 11<sup>th</sup> time in a row

The TOP 10 Education Management 2013 award proves the quality of our education system. The award is dedicated to the ten most successful companies and organisations in Slovenia which in 2013 invested in education and training of employees the most. It is given by Planet GV in cooperation with the Education Management Institute Sofos.

Upon receiving the award, Jasna Kos, Head of Learning&Training at Lek, a Sandoz company, highlighted: *"This year we have been ranked, for the eleventh time in a row, among the ten most successful companies in Slovenia which invest most intensely and systematically in the development of human resources. The award confirms that continuous and systematic investment in education and training of employees is of the utmost importance for our company. The culture of knowledge and learning is embedded in all the pores of our company."*

At Lek, a Sandoz company, we give priority to quality and regulation, governance and management and expert skills. In recent times we have focused more intensely on education on compliance and integrity as well as the education of leaders with in-house programs. We also encourage the development of advanced learning forms, including self-education and e-learning.



Jasna Kos, Head Learning&Training at Lek, a Sandoz company

#### 3.4.1 Average hours of training per year per employee by employee category<sup>84</sup>

The scope of training provided to our employees has been increasing for the past few years. Compared to the previous year, the average number of hours training per employee increased by nearly 4%. The average amount of time given to training per employee was 4.63 days per year or 6.99 days if compulsory on-the-job-training is included.

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

Year	2011	2102	2013
Number of hours / employee	40.07	54.32	56.36

Also in 2013, Lek, a Sandoz company provided employees the opportunity of part-time studies. In total, 5% of the workforce was involved in part-time studies, which was at the same level as in the previous year. With the company's support, 71 employees were involved in undergraduate studies, and 82 in post-graduate studies, mainly in biotechnology, biomedicine and chemistry.

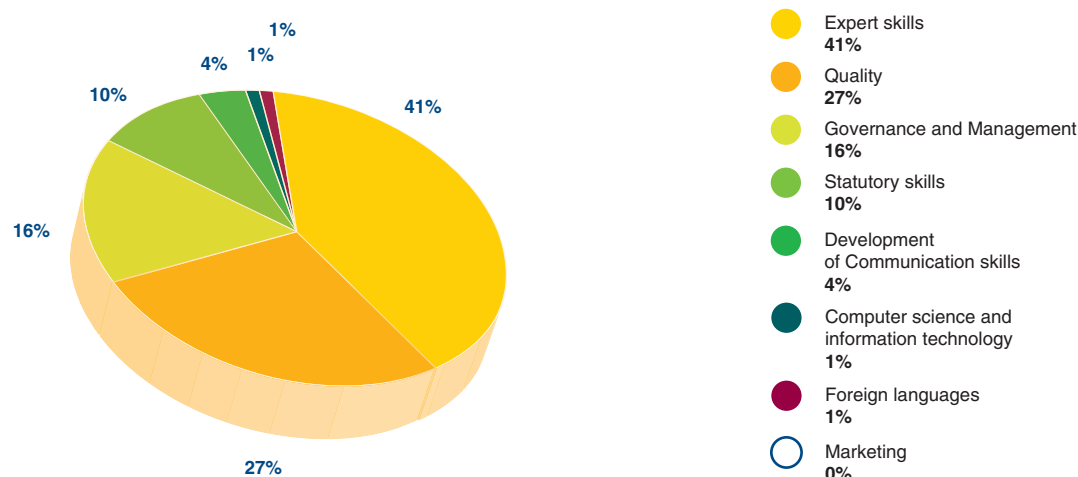
#### 3.4.2 Training by area

In 2013, the largest number of training hours was dedicated to quality (22%), governance and management (18%) and foreign languages (18%). The highest participation rate was recorded in expert skills (41%), followed by quality (27%), governance and management (16%).

<sup>84</sup> GRI Indicator G4-LA9



Graph 15: Training in 2013 by area – participation rate



## 4. Products<sup>85</sup>

Communication of information related to pharmaceuticals<sup>86</sup> is regulated by the Medicinal Products Act. Lek provides the professional public in Slovenia with information on the properties and action of medicines on the basis of the Summary Product Characteristics approved by the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). With patient information leaflets, we openly and transparently communicate all the relevant information regarding the safety and efficacy of medicinal products, as well as posology and administrative information, to the final consumer. Similar practice applies to non-prescription drugs.

With regard to communication we ensure compliance with the Novartis Promotional Practices Policy which, in several

cases, is even more restrictive than the above Act. 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 at [www.lek.si/en](http://www.lek.si/en).

The key therapeutic groups of medicines that we develop, produce and market, are listed under item 1.3.2.

### Business development

#### Leading in the introduction of new products

Lek, a Sandoz company, is a leading Sandoz site in the introduction of new products. In 2013, more than 1,300 launches of new products were carried out in global markets. This represents 36% of all Sandoz' new launches. Among them there are as many as 20 demanding patent launches to different countries across the world.



One of the products launched in 2013.

#### Compliance with regulations concerning products<sup>87</sup>

In 2013, the inspection authority at JAZMP introduced an offence procedure against Lek which was however, halted due to the lack of evidence supporting the alleged offence.

#### Practices of measuring customer satisfaction<sup>88</sup>

To gain an insight into the satisfaction of the professional

public, a series of expert meetings were held. Based on participants' feed-back, 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. No opinion survey about pharmaceutical companies was conducted in 2013.

<sup>85</sup> GRI G4-DMA | <sup>86</sup> GRI Indicator G4-PR3 | <sup>87</sup> GRI Indicator G4-PR4 | <sup>88</sup> GRI Indicator G4-PR5

### Adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship<sup>89</sup>

In drug advertising we act in accordance with the Rules on Advertising of Medicines (OG., RS 105/ 2008, 105/ 2010, consolidated text, effective from 8 January 2011) and with the internal SP3 – Promotional Practices Policy. Conformity of conduct is verified on a daily basis by previous approval of all promotional activities.

In 2013, 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 the Promotional Practices Rules. There was no sponsorship involving drug promotion. In corporate sponsorship, there were no non-compliance cases.

## 5. Human rights and antitrust compliance<sup>90</sup>

The business operations of Lek, a Sandoz company, are significantly characterized by the Code of Conduct, which defines the principles of ethical and accountable decision-making. The Code of Conducts 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 (patients, employees, shareholders, healthcare partners and society at large).

In the area of compliance of our operations, much attention is paid to regular and ongoing training of our employees. In 2013 we once again organized online training on the Code of Conduct for all our employees and achieved 99.7% participation. Nearly all employees refreshed their knowledge about fully transparent and clear principles and to confirm their implementation in every-day operations. 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>91</sup>

### Lek stars

#### Associates who are an example to others, awarded

Also in 2013 we selected the best associates who in the previous year stood out due to their values, conduct, knowledge transfer and driving diversity and inclusion. 17 individuals received this acknowledgement this year, 6 awards were given for outstanding business achievements and innovation, leading breakthrough, leading solution and for the first time also for the leading manager.

The community of Lek's Stars has increased by 40 exceptional associates.



*The supply launching team was awarded in the Outstanding Business Achievements category.*

In order to prevent corruption and to ensure legal compliance, we follow Novartis' global policy regulating this area, and our internal rules. Standards apply also in relations with Third Parties. Based on the Third-Party Guidelines, we establish and maintain business relations with our business partners who comply with and implement the same ethical business standards and compliance principles that are binding on the Novartis employees.

We treat our employees equally, with integrity and respect, thereby creating an inclusive working environment to which every employee can fully contribute regardless of their ethnic origin. 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. The individual diversity and

personal characteristics of our employees constitute an asset and strength of our company, and are the source of our teams' creativity. The highly inclusive working environment is also created through the implementation of the Diversity and Inclusion initiative which has significantly outgrown Novartis' original female inclusion initiative.

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

In 2013, there were no cases of discrimination and no requests to remedy any violation in this area in Slovenia.<sup>92</sup>

In 2013, the company was not involved in any antitrust procedure for any violation of antitrust regulations.<sup>93</sup>

## 6. Suppliers<sup>94</sup>

### 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 not allowed to use the business relations between the Group and its suppliers for private purposes.

In the period 2010 – 2013, the purchasing processes underwent no modifications.

#### 6.1.1 Purchasing system

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. Roles and responsibilities within purchasing activities (customer need identification, supplier selection, conclusion of agreements, and purchase orders) are clearly defined. The strategic purchasing function is a separate organizational unit specializing in direct and indirect purchasing.

Continued recession in the EU and restrained global economic growth has strongly affected the purchasing result in 2013 also. The internal system optimization also had a significant resulting 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 purchasing markets were: Slovenia, Germany, Switzerland, Italy, China, India and Austria.

#### 6.1.2 Supplier audit procedures<sup>95</sup>

Supplier audits are performed in accordance with the Sandoz and Novartis quality standards and guidelines. Selection criteria are documented. Uniform selection criteria include prices, quality, delivery deadlines, reliability, compliance with regulatory requirements and Sandoz' guidelines, as well as suppliers' corporate responsibility policies.

In selection processes, priority is given to third parties who share its societal and environmental values, and who undertake to 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 also 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, practices, and proportion of spending on locally-based suppliers at significant locations of operation<sup>96</sup>

Supplier selection is based on predetermined selection criteria. In this process, priority is given to suppliers having the best quality - price - service triangle. In certain categories of items where the delivery date is one of the key elements, we strive to obtain local suppliers.

Among individual countries, Slovenia maintains the largest share in the purchasing structure. In 2013, the level of

deliveries from the Slovenian market amounted to USD 211 million or 41% of total purchasing cost (16% in 2012). On the domestic market, we mainly purchase merchandise of domestic production. We mainly purchase packaging and raw materials from the Slovene chemical industry and merchandise from domestic distributors.

<sup>94</sup> Disclosure G4-12 | <sup>95</sup> GRI G4-DMA, Indicators G4-HR5, G4-HR6 | <sup>96</sup> GRI G4-DMA, Indicator G4-EC9



## Table of contents according to GRI G4 - reporting guidelines

General standard Disclosures		
Disclosure		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.	1.2/8
<b>Organizational Profile</b>		
G4-3	Name of the organization.	1./3
G4-4	Primary brands, products, and/or services.	1.3./10, 1.3.2/12, 1.3.3/12
G4-5	Location of organization's headquarters.	1./3, 1.3./10
G4-7	Nature of ownership and legal form.	1./3, 1.3./10
G4-8	Markets served.	1.3.1/12
G4-9	Scale of the organization.	1.1.1/4
G4-10	Total number of employees by employment type, employment contract, region and gender.	1.1.1/4, 3.2.1/50
G4-11	Percentage of total employees covered by collective bargaining agreements.	3.2.2/50
G4-12	Organization's supply chain.	6./59
G4-13	Significant changes during the reporting period regarding the organization's size, structure, ownership, or its supply chain.	1.3.3/12, 1.4.1/18
G4-14	Explanation, whether and how the precautionary approach or principle is addressed by the organization.	1.5.4/22, 2./22, 2.1/24
G4-15	Externally developed economic, environmental and social charters, principles, or other initiatives to which the organization subscribes or which it endorses.	1.5.4/22
G4-16	Memberships of associations and national or international advocacy organizations.	1.5.4/22
<b>Identified Material Aspects and Boundaries</b>		
G4-17	List of all entities included in the organization's consolidated financial statements or equivalent documents.	1.4.1/18
G4-18	The process for defining the report content and the Aspect Boundaries.	1.4./17
G4-19	Material Aspects identified in the process for defining report content.	1.4./17
G4-20	Limitations regarding the Aspect Boundary within the organization.	1.4./17
G4-21	Limitations regarding the Aspect Boundary outside the organization.	1.4./17
G4-22	Effect of any restatements of information provided in previous reports, and the reasons for such restatements.	1.4.1/18
G4-23	Significant changes from previous reporting periods in the Scope and Aspect Boundaries.	1.4.1/18
<b>Stakeholder Engagement</b>		
G4-24	List of stakeholder groups engaged by the organization.	1.5.3/20
G4-25	Basis for identification and selection of stakeholders with whom to engage.	1.5.3/20
G4-26	Approach to stakeholder engagement, including frequency by type and by stakeholder group.	1.5.3.1/21
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.	1.5.3.1/21
<b>Report Profile</b>		
G4-28	Reporting period.	1.4./17, 1.4.1/18
G4-29	Date of most recent previous report.	1.4./17, 1.4.1/18
G4-30	Reporting cycle.	1.4./17, 1.4.1/18
G4-31	Contact point for questions regarding the report or its contents.	1./3
<b>Governance</b>		
G4-34	Report the governance structure of the organization, including committees of the highest governance body.	1.5.1/18
<b>Ethics and Integrity</b>		
G4-56	Organization's values, principles, standards and norms of behaviour such as codes of conduct and codes of ethics.	1.5.4/22, 5./58

## Specific standard disclosures

Material Aspects	Disclosures on Management Approach (DMA) and Indicators		Chapter/page	Omissions and/or deviating presentation
<b>ECONOMIC</b>	<b>DMA</b>		3.1/48 6.1.2/59, 6.2/59	
Economic Performance	G4-EC1	Direct economic value generated and distributed.	1.1.1/4	
	G4-EC3	Coverage of the organization's defined benefit plan obligations.	3.2.3/50	
	G4-EC4	Financial assistance received from government.	1.1.1/4	
Market Presence	G4-EC6	Ratios of standard entry level wage by gender compared to local minimum wage at significant locations of operation.	3.2.4/50	
Procurement Practices	G4-EC9	Proportion of spending on local suppliers at significant locations of operation.	6.2/59	
<b>ENVIRONMENTAL</b>	<b>DMA</b>		2./22-24, 2.2.4/27, 2.4.1/30, 2.5.1/32, 2.7/38, 2.7.2/41, 2.8.4/42, 2.9.3.2/45, 6.1.2/59	
Materials	G4-EN1	Materials used by weight or volume.	2.2.2/26	
Energy	G4-EN3	Energy consumption within the organization.	2.3.1/28	
	G4-EN6	Reduction of energy consumption.	2.3.2/30	
Water	G4-EN8	Total water withdrawal by source.	2.4.1/31, 2.4.2/31	
	G4-EN10	Percentage and total volume of water recycled and reused.	2.4.3/32	
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.	2.8.4/42	
Emissions	G4-EN15	Direct greenhouse gas (GHG) emissions (Scope 1).	2.6.5/37	
	G4-EN16	Energy indirect greenhouse gas (GHG) emissions (Scope 2).	2.6.5/37	
	G4-EN19	Reduction of greenhouse gas (GHG) emissions.	2.6.5/37	
	G4-EN21	NO <sub>x</sub> , SO <sub>x</sub> and other significant air emissions.	2.6/35, 2.6.3/36, 2.6.4/36	
Effluents and Waste	G4-EN22	Total water discharge by quality and destination.	2.7.1/39	
	G4-EN23	Total weight of waste by type and disposal method.	2.5/32–34	
Product and Services	G4-EN27	Extent of impact mitigation of environmental impacts of products and services.	2.7.2/41	
Compliance	G4-EN29	Monetary value of significant fines and total number of non-monetary sanctions for non-compliance environmental laws and regulations.	2.1/24	
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.	2.1.6/25, 2.9.3.2/45	
Overall	G4-EN31	Total environmental protection expenditures and investments by type.	2.1.3/24	
Supplier Environmental Assessment	G4-EN33	Significant actual and potential negative environmental impacts in the supply chain and actions taken.	2.1.6/25	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 filed, addressed, and resolved through formal grievance mechanisms.	1.5.3.1/21, 2.1/24, 2.8.1/42	

Material Aspects	Disclosures on Management Approach (DMA) and Indicators		Chapter/page	Omissions and/or deviating presentation
<b>SOCIAL</b>				
<b>Labour practices and decent work</b>	<b>DMA</b>		1.5.2/19, 3.1/48, 3.3.7/53, 6./58, 6.1.2/59	
Employment	G4-LA1	Total number and rates of new employee hires and employee turnover by age group, gender, and region.	1.1.1/5, 3.2.1/50	
	G4-LA3	Return to work and retention rates after parental leave, by gender.	3.2.5/50	
Occupational Health and Safety	G4-LA6	Work-related injury rates.	1.1.1/5, 3.3.1/50, 3.3.2/50–52, 3.3.5/53, 3.3.6/53	
Training and Education	G4-LA9	Average hours of training per year per employee by gender, and by employee category.	4.1/56	Records of training by gender and by employee category are not yet kept.
Equal Remuneration for Men and Women	G4-LA13	Ratio of basic salary and remuneration of women to men by employee category, by significant locations of operation.	3.2.4/50	
Supplier Assessment for Labour	G4-LA15	Significant actual and potential negative impacts for labour practices in the supply chain and actions taken.	2.1.6/25	By signing a contractual agreement, the supplier undertakes to comply with all applicable laws and regulations related to fair labour practices.
Labour Practices Grievance Mechanisms	G4-LA16	Number of grievances about labour practices filed, addressed, and resolved through formal grievance mechanisms.	3.1/48	
<b>Human Rights</b>	<b>DMA</b>		5./58, 6.1.2/59	
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.	5./58	
Non-discrimination	G4-HR3	Total number of incidents of discrimination and corrective actions taken.	5./58	
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.	6.1.2/59	
Forced or compulsory Labour	G4-HR6	Operations and suppliers identified as having significant risk for incidents of forced or compulsory labour, and measures to contribute to the elimination of all forms of forced or compulsory labour.	6.1.2/59	
<b>Society</b>	<b>DMA</b>		5./58	
Local Communities	G4-SO1	Percentage of operations with implemented local community engagement, impact assessments, and development programs disadvantaged areas by type.	1.5.3.1/21	Currently, the data acquisition system does not allow the calculation of the proportion, however we do report on the number of activities.
Anti-competitive Behaviour	G4-SO7	Total number of legal actions for anti-competitive behaviour, anti-trust, and monopoly practices and their outcomes.	5./58	
<b>Product Responsibility</b>	<b>DMA</b>		4./57	
Product and Service Labeling	G4-PR3	Type of product and service information required by the organization.	4./57	
	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.	4./57	
	G4-PR5	Results of surveys measuring customer satisfaction.	4./57	
Marketing Communication	G4-PR7	Total number of incidents of non-compliance with communications, including advertising, promotion, and sponsorship, by type of outcomes.	4./58	



## 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 economic, social and environmental impact of an organization. Depending on the scope of disclosures and measurable indicators, reports are classified into three application levels from C to A). A "plus" (e.g. A+) signifies that the report was reviewed by an independent third party.

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 ones 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>97</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>98</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** is frequently referred to as gene cloning or genetic engineering. 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.

**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).

<sup>97</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>98</sup> Source: Humar M., Šmid-Korbar J., Obreza A. Dictionary of Pharmaceutical Terminology. Ljubljana 2011.



*a Sandoz company*

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