



a Sandoz company

# Sustainability Report 2014

## Lek d.d.



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\* 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>   |
| Registration number:  | <b>District Court in Ljubljana under entry number: 1/36542/00</b>  |
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| <b>Contacts:</b>  |  |
| Legal representative<br>Vojmir Urlep, President of the Board of Management;<br><a href="mailto:vojmir.urlep@sandoz.com">vojmir.urlep@sandoz.com</a> | Contact person for reporting on sustainable development <sup>2</sup><br>Mojca Bernik, Environmental Manager;<br><a href="mailto:mojca.bernik@sandoz.com">mojca.bernik@sandoz.com</a> |
| Qualified person<br>Robert Hribar, Head HSE;<br><a href="mailto:robert.hribar@sandoz.com">robert.hribar@sandoz.com</a>                              |  |

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

## 1.1 Letter from the President of the Board of Management<sup>3</sup>



### Dear associates, partners and stakeholders!

Success comes in different forms. At Lek, a Sandoz company, it is based on exceptional knowledge and experience as well as an inclusive attitude towards our stakeholders. In year 2014, a strong spirit of cooperation and tight bonds between the associates at Lek, Sandoz and Novartis pervaded. With the same enthusiasm we were building on mutual cooperation with stakeholders in our external environment, especially with patient groups and local communities. Exceptional knowledge and experience have enabled us to consolidate the role of the largest development center within Sandoz.

In many areas we achieved record production volumes and continued investments in expansion and modernization of production capacity.

In Ljubljana we completed the Vials 2 project and doubled our annual production of lyophilized units. At Biopharmaceuticals Mengeš we opened new Quality Control laboratories in which the testing of biological activity for all Sandoz biosimilars will be performed. They will also support the release of products on the market for the entire Sandoz Biopharmaceuticals. In Lendava we started the construction of a high-bay warehouse and in Mengeš continued the construction of the facility for the manufac-

ture of everolimus which is the basic active ingredient for one of the key Novartis products.

Multiannual continuous investment enabled us to increase the production volume at all sites. The overall volume was 20% higher compared with the previous year. We realized net sales revenue in the amount of EUR 761.3 million, a 2% increase over the previous year. For the first time in its history, our Ljubljana Solids site exceeded its production total of 7 billion units. Continued growth of production volume is expected also in 2015.

Increased production also brings an increased consumption of natural resources and energy sources which is reflected in our absolute consumption the growth of which is, however, far behind the production growth.

At Lek, a Sandoz company, we are trying to limit the impact on the environment to the lowest possible level by installing the most advanced and environmentally least harmful equipment as well as by a number of environmental projects. We have invested EUR 2.9 million in several environment protection related projects. With implemented projects aimed at energy efficiency improvement we saved 34.2 TJ of energy.

At the forefront was the Prevalje site where with one major and several smaller projects we reduced energy consumption for this site for as much as 20.5 TJ per year. By introducing a system for exploiting waste gas from a steam boiler we generated major savings in natural gas consumption. In Mengeš, a new steam boiler with improved thermal efficiency was put in operation. At the Lendava site we continued the redirection of the outflow of used cooling water into the Mura river and we invested into technological equipment for the regeneration of waste reagent. In Ljubljana, we renovated and additionally isolated the facade of the tablet production facility.

Our efforts to reduce environmental impacts reflected also in the improvement of all Lek's key performance indicators. In one year, we reduced VOC emissions by 34% per tonne of product and improved energy efficiency by 15%. The water use efficiency is better than in the previous year by 10% and the efficiency of discarded waste also by 10% (t of waste/t of product).

Our consistent care for the environment and meeting high quality standards was also confirmed by numerous audits by customers and official government inspections among which the inspection by the American Food and Drug Agency (FDA) was particularly demanding and successful.

As I have already pointed out, all these would not have been possible without the exceptional knowledge, talent and experience of our associates. We are pleased to have once again extended the full Family Friendly Certificate that reflects our desire to create a work environment which contributes to a better work-life integration. We continued our targeted and systematic investment in development, education and training of our employees

<sup>3</sup> GRI Disclosure G4-1

and once again, for the thirteenth time in a row, received the TOP 10 Education Management Award.

We remain a stable employer. In 2014, we hired 249 new associates and finished the year with 3,124 employees, employed on a permanent basis, which is 5% more than the previous year.

However, in 2014 we unfortunately did not achieve the set objectives in the field of health and safety. After a long period of a decline in the number of work-related incidents and outstanding results, seven work-related accidents occurred resulting in the absence from work. One of the accidents had very serious and lasting consequences for the affected associate which we deeply regret. We adopted a number of additional measures to improve our culture of conduct and awareness of the

importance of safety. Today we already have 80 employees acting as promoters of safety across all Lek sites: they organize safety walkthrough inspections, inform and warn the personnel about safe conduct.

Our ambition and cooperation culture at Lek, a Sandoz company, goes beyond the level of financial performance. Caring for people, patients and employees remains at the core of our common aspiration for a long-term performance. It inspires us and sets new tasks.

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



## 1.2 Key data for 2014

### 1.2.1 Operations in 2014

Table 1: Key figures for 2014<sup>4</sup>

| Indicator                  | Unit                | 31. 12. 2014   | 31. 12. 2013   | Index 2014/2013 |
|----------------------------|---------------------|----------------|----------------|-----------------|
| <b>Number of employees</b> |                     | <b>3,124</b>   | <b>2,972</b>   | <b>105</b>      |
| - Ljubljana site           |                     | 1,801          | 1,762          | 102             |
| - Mengeš site              |                     | 817            | 739            | 111             |
| - Lendava site             |                     | 308            | 296            | 104             |
| - Prevalje site            |                     | 198            | 175            | 113             |
| <b>Production output*</b>  | <b>1,000 tonnes</b> | <b>4.69</b>    | <b>3.90**</b>  | <b>120</b>      |
| <b>Net sales revenue</b>   | <b>in EUR m</b>     | <b>761.338</b> | <b>745.334</b> | <b>102</b>      |
| <b>Liabilities</b>         | <b>in EUR m</b>     | <b>903.743</b> | <b>852.332</b> | <b>106</b>      |
| <b>Equity</b>              | <b>in EUR m</b>     | <b>500.362</b> | <b>524.287</b> | <b>95</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 annual data is difficult to compare. The comparison of production outputs between 2013 and 2014 is therefore not entirely relevant. 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 2013 is the result of adjustments made to the data on sterile product production output at the Ljubljana site. The change in the value also represents the change in the calculation of performance in all areas.

#### Economic performance<sup>5</sup>

In 2014, Lek realized net sales revenue in the amount of EUR 761.338 million, a 2% increase over the previous year. Revenue increased by 3% in foreign markets and decreased by 9% in the domestic market.

**Direct Economic Value Generated** amounted to EUR 776 million, of which **Economic Value Distributed** totalled EUR 743 million (96%), and **Economic Value Retained** amounted to EUR 90 million (12%).

**Operating Costs** amounting to EUR 490 million constituted the largest proportion in the structure of Economic Value Distributed or 66%. **Employee Costs** amounted to EUR

156 million (21%), **Payments to Providers of Capital** reached EUR 90 million or 12%, and **Payments to Government** totalled EUR 7 million or 1% of Economic Value Distributed.

In 2014, the tax relief value due to investment in research activity dropped to EUR 9.133 million (13.872 million in 2013). For investments, tax relief amounted to EUR 17.468 million (20.096 million in 2013). We also received public subsidies amounting to EUR 401,002 (EUR 454,000 in 2013).<sup>6</sup>

Graph 1: Structure of Economic Value Distributed

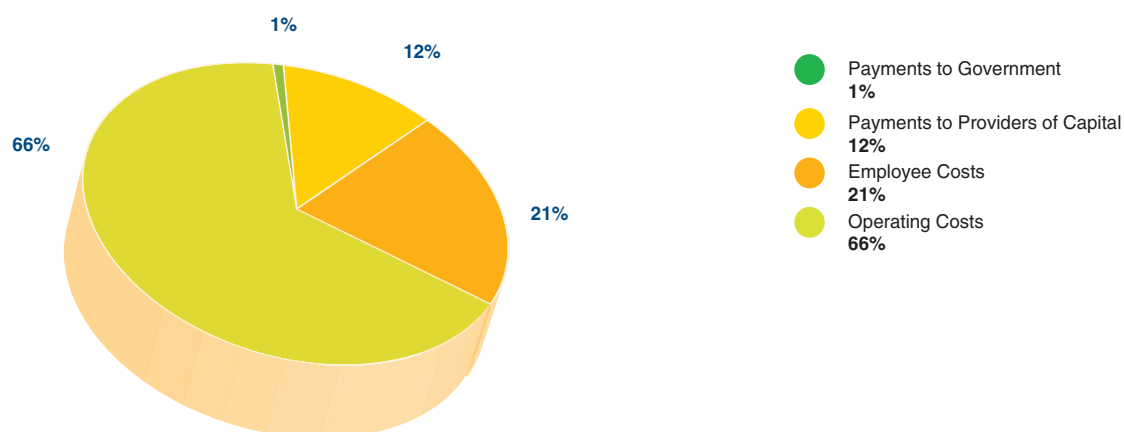




Table 2: Major environmental and social impacts<sup>7</sup>

| Indicator  | Unit              | 31. 12. 2014 | 31. 12. 2013 | Index 2014/2013 |
|--|-------------------|--------------|--------------|-----------------|
| Efficiency of energy resource use  | GJ/t              | 255          | 299*         | 85              |
| Water use efficiency***  | m <sup>3</sup> /t | 757          | 841*         | 90              |
| Waste volumes – efficiency   | t waste/t product | 7.40         | 8.25*        | 90              |
| VOC emission – efficiency  | t VOC/t product   | 0.021        | 0.032*       | 66              |
| LTIR** – work related injuries and illnesses involving days away from work (Lost Time Injury and Illness Rate) |                   | 0.22         | 0.04         | 550             |
| TRCR** – work-related injuries and illnesses requiring more than basic first aid (Total Recordable Case Rate)  |                   | 0.42         | 0.38         | 111             |

\* The figures differ from those published in the Sustainability Report 2013, as previously stated under the Notes of Table 1.

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

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

## 1.2.2 Health, safety and environment (HSE) objectives and their realization<sup>8</sup>

In the field of HSE, Lek, a Sandoz company, pursues 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 Data Management System (DMS).

We are committed to enhancing our environmental performance 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). By indicating impact management we present our annual objectives for 2015 by individual Lek sites together with the progress each site made towards the realization of our long-term objectives over the period up to 2015.

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

| HSE objectives by 2015   | Status 2014  |
|--|--|
| Improving water use efficiency by 10% over 2010.*                                  | <b>Realized.</b> Water use efficiency improved by <b>30%</b> .<br>Year 2010: 1,079 m <sup>3</sup> /t<br>Year 2014: 757 m <sup>3</sup> /t |
| Improving energy efficiency by 10% over 2010.                                      | <b>Realized.</b> Energy efficiency improved by <b>27%</b> .<br>Year 2010: 348 GJ/t<br>Year 2014: 255 GJ/t                                |
| Reducing VOC emissions (h-VOC and nh-VOC) to the air by 20% over the 2010 figures. | <b>Realized.</b> Emissions reduced by <b>61%</b> .<br>Year 2010: 258 t<br>Year 2014: 100 t   |
| Reducing waste volumes by 10% over 2010.   | <b>Realized.**</b> Year 2010: 13,125 t<br>Year 2014: 34,667 t or 9,263 t (excluding mycelium waste)                                      |
| Reducing LTIR to 0.1.  | <b>Not realized.***</b> 0.22 (0.16 for Lek associates)   |

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

\*\* Since 2011, in accordance with Novartis' reporting methodology, waste includes only the waste leaving the site and not that treated on the site. In 2012 mycelium waste generated by the fermentation production process at Lendava was redirected from the site's incinerator to a contractor biogas plant for treatment; therefore, the total mycelium waste volume is now reported as waste treated outside the site. Comparison of the volume of waste between 2010 and 2014 is realistic only if mycelium waste is subtracted from the total amount of waste. In 2014, the volume of mycelium waste amounted to 25,404 tonnes. Total waste in 2014 thus amounted to 9,263 tonnes, corresponding to a slightly less than 30% reduction in volume compared to 2010.

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

## Major impact of Lek within Sandoz



Alexander Lich, global Head HSE at Sandoz in 2014

Alexander Lich, global Head HSE at Sandoz in 2014, explains the importance of the health, safety and environment area and Lek's role within Sandoz.

### How would you tangibly illustrate the importance of corporate responsibility at Novartis?

Its importance is of course essential. It is the Sandoz objective to fulfil the mission to be "the main provider of high-quality affordable medicines, helping secure long-term access to healthcare for people around the world" by simultaneously striving to make efficient use of natural resources and minimizing our environmental impact.

In accordance with our mission we consider the full life cycle of our products. Sustainable operation begins already at the research and development stage by avoiding the use of environmentally hazardous starting materials and solvents. Potential emissions to water and air are reduced by introducing highly sophisticated abatement technologies into production. Last but not least we demonstrate our responsibility to the environment, neighbours and society also by adopting effective concepts to reduce waste, recycling and re-use of outgoing materials or generating energy by controlled thermal oxidation.

### How do you assess the importance of Lek's integrated reporting on its operations in the light of Sandoz policy and disclosure of sustainability development indicators?

It is extremely important for the development, manufacture and supply of our products. Patients and customers trust Lek and its people. Because of its size, Lek's capacity has a major impact on Sandoz' total environmental balance. We pride ourselves on openly disclosing the results of Lek's efforts in 2014. Lek's management team once again achieved a reduction of volatile organic compounds by 21% driven by technological improvements, e.g. at the Mengeš site. Moreover, the overall waste recycling rate has improved significantly.

Lek responsibly delivers on Novartis' commitment to health, safety and environment. Our goal is to be a leader in Health, Safety and Environment (HSE). We consider HSE implications in our healthcare activities, from research, through production and distribution, until our customers and patients use and dispose of the final product.

## HSE targets for 2014

| Objectives for 2014  | Realization in 2014 (for entire Lek, a Sandoz company)  |
|--|---|
| Ecotoxicity assessment of APIs   | <b>Realized.</b><br>Evaluation for all APIs (including new) for which ecotoxicity data is available in the literature.  |
| Non-halogenated VOC emissions to the air (nh-HOS); Target: ≤142 tonnes             | <b>Realized.</b><br>Emissions reached 99 tonnes.  |
| Halogenated VOC emissions to the air (h-HOS); Target: 1 tonne                      | <b>Realized.</b><br>Emissions reached 1.06 tonnes.  |
| Energy savings   | <b>Projects realized.</b><br>With implemented projects aimed at energy efficiency improvement we saved 34.2 TJ of energy, however, due to the increase in production the total energy consumption was 2% higher than in 2013. |
| Reducing hazardous waste volumes   | <b>Not realized.</b><br>Hazardous waste increased by 3.9%.  |
| Reducing non-hazardous waste volumes   | <b>Not realized.</b><br>Non-hazardous waste increased by 8.2%.  |
| LTIR* (own employees); Target: ≤0.14   | <b>Not realized.</b><br>The index reached 0.16.   |
| LTIR* (own employees + employees hired through employment agencies); Target: ≤0.16 | <b>Not realized.</b><br>The index reached 0.22.   |
| TRCR* (own employees + employees hired through employment agencies); Target: ≤0.46 | <b>Realized.</b><br>TRCR index reached 0.42.  |

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



### Comparison of energy use per product unit for the entire Lek (GJ/t of product)

Year 2010: 348

Year 2014: 255



- 27%

### Comparison of water consumption per product unit for the entire Lek (m³/t of product)

Year 2010: 1,079

Year 2014: 757



- 30%

### HSE targets for 2015

| Targets for 2015   | Unit                    | Mengeš   | Ljubljana   | Lendava                               | Prevalje                       |
|--|-------------------------|--|---|---------------------------------------|--------------------------------|
| Ecotoxicity assessment of APIs                                     | % of APIs in production | 100<br>Inclusion of results in PRORA*                        | 100<br>Inclusion of results in PRORA*                         | 100<br>Inclusion of results in PRORA* | Inclusion of results in PRORA* |
| Non-halogenated VOC emissions to the air (nh-HOS)                  | t                       | < 50 t   | < 20 t  | < 25 t                                | Maintaining the 2014 level     |
| Halogenated VOC emissions to the air (h-HOS)                       | 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<br>Cocineration of waste solvents                    | Maintaining the 2014 level                                    | Project Dipede recycling              | Maintaining the 2014 level     |
| Reducing non-hazardous waste volumes                               | t/t (efficiency)        | Project of increasing the proportion of waste to be recycled | Weighing waste at the site (setting up a scale)               | Maintaining the 2014 level            | Project Packaging              |
| Noise reduction  |                         | /  | Preparation of a study identifying the major sources of noise | /                                     | By 6 dBA at night              |
| LTIR (own employees + employees hired through employment agencies) |                         | 0.12   | 0.12  | 0.12                                  | 0.12                           |
| TRCR (own employees + employees hired through employment agencies) |                         | 0.46   | 0.46  | 0.46                                  | 0.46                           |

\* Process Risk Assessment

## 1.3 About us



**Lek**, a Sandoz company, is a joint-stock company, 100% owned by Novartis Pharma AG. It is based in Ljubljana, it has its development centers in Ljubljana and Mengeš and operates at four production sites: in Ljubljana, Mengeš, Prevalje and Lendava. In 2014, all the sites were included in the EMAS scheme and registered in the EMAS register.<sup>9</sup>

Lek, a Sandoz company, develops, manufactures and markets effective, safe and quality medicinal products, from standard generic drugs through to state-of-the-art biosimilars.<sup>10</sup>

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

**Sandoz**, a Novartis company, is a global leader in generics striving for sustainable access to high-quality healthcare. Sandoz employs over 26,000 associates and provides a broad range of affordable products for patients and customers worldwide.

Sandoz has a global portfolio of approximately 1,100 molecules, and holds the first position globally in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines. It also has a leading position in key therapeutic areas, from generic injectables, dermatology, respiratory, to cardiovascular, metabolism, the central nervous system, pain and gastrointestinal therapeutic areas. In 2014, Sandoz' sales amounted to USD 9.6 billion.

Sandoz develops, produces, and markets finished pharmaceutical products and intermediates, including 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.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has achieved consistent progress in certain regions and in different areas of differentiated products with a series of acquisitions, which include Hexal (Germany), EBEWE Pharma (Austria) and Fougera Pharmaceuticals (US).

Sandoz is on Twitter. Sign up to follow @Sandoz\_global at [http://twitter.com/Sandoz\\_Global](http://twitter.com/Sandoz_Global).

### Lek as part of Sandoz and Novartis

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

In recent years we have established ourselves as an important part of the entire Novartis Group. Among others, we manufacture active pharmaceutical ingredients for Novartis innovative medicines (Mengeš site), we are a center of excellence for ampoules (Ljubljana site) and take part in joint development projects.

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

**Novartis** headquartered in Basel, Switzerland, offers a diversified portfolio to best meet the increasing needs of patients and society at large: innovative medicines, eye care products and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58 billion, while R&D across the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). On 31 December 2014, Novartis Group companies employed approximately 133,000 people. Novartis products are available in more than 180 countries around the world.

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

## 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 Sandoz Corporate Responsibility program focuses on four key areas.

### Access to medicines.

We strive to increase access to health services, medicines and raising awareness about health.

### People and community.

We are a responsible and ethical employer and benefit our wider community.

### Sustainable Business operation.

We adopt a preventive approach, striving to make efficient use of natural resources and minimizing our environmental impact.

### Ethical business conduct.

We operate in accordance with the highest standards of ethical business conduct.

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 a **leading company in the industry**.

Through implementation of the corporate responsibility program:

- we further our business mission and
- develop programs, inclusive business models and other initiatives which increase accessibility, affordability and availability of high-quality medicines for patients around the world.

## Corporate volunteering – 10 years of Community Partnership Day

### A day that enriches all of us.

Lek, a Sandoz company, is one of the pioneers of corporate volunteering in Slovenia. There are a number of volunteers among Lek's associates who are dedicated to volunteering throughout the year. In early May, they join Novartis' associates around the world and give a helping hand to people in their home environment as part of the global Community Partnership Day initiative.

In 2014 we celebrated the tenth anniversary of this initiative which was launched a year after Novartis' acquisition of Lek. As across the entire Novartis, the Community Partnership Day has grown to become one of the most important activities to promote social responsibility.



We organised a fun day for residents of homes for the elderly in Mengeš and Prevalje.

In early May, more than 300 associates of Lek, a Sandoz company, Novartis Pharma, Novartis Animal Health and Alcon have dedicated their working day to volunteering. As **Katarina Klemenc**, Head Corporate Communication, owner and provider of corporate volunteering initiatives at Lek, said *"in volunteering, good will is typically repaid many times over as it provides valuable help and forges strong ties with the local community, and at the same time connects the associates and enhances their satisfaction."*

Novartis associates in Slovenia once again actively participated in the broad volunteering program in the local community.

- We took children with special needs to visit the House of Experiments and help them to participate in an exciting day of experiencing science.
- We landscaped the surroundings and painted and decorated the interiors of the holiday bungalows for children spending holidays in the Slovenian Friends of Youth resort in Pacug.
- We also landscaped the surroundings of the facility for rescue team training in Jezersko and helped children from socially handicapped families to landscape and refurbish the children's shelter Mala Hiša (Little House) in Pilštanj, managed by the Materina Dušica association.
- We organised a fun day on a boat on the Ljubljana river, including bingo and picnics for the residents of homes for the elderly Bokalce, Mengeš and Prevalje.
- We took part at a sports day for children at the Lendava Bilingual Primary School II, directing them at the orienteering run and athletics competition.



- We helped to paint the rooms at the Institute for the blind and visually impaired children Ljubljana, bringing some freshness into their environment.
- We prepared an exciting day for children with special needs in the swimming pool at Hotel Lek in Kranjska Gora.
- We donated blood.
- We helped raise donations for the humanitarian campaign Siti besed (Fed Up with Words) in a call center, as a part of the Stopimo skupaj (Let's Stand together) program, in collaboration with the Slovenian Friends of Youth and TV Slovenia.

### 10 years of Community Partnership Day in numbers

- 2,900 associates of Novartis Slovenia have contributed more than 23,000 hours of voluntary work.

- They have helped out more than 10,000 people and 40 organisations.
- They have donated more than 300 litres of blood.



We organised a sports day for the children at the Lendava Bilingual Primary School II

### 1.3.1 Key customers and markets<sup>11</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 2014, the leading three buyers accounted for 75%, 9% and 4% of net sales.

Lek sells its own products and the products of other Sandoz companies. Our major external direct sales markets include Central and Eastern Europe with 94% of products, and in Slovenia 5%. The majority of sales (87%) were realized by pharmaceutical products which is slightly more than in the previous year (2013: 84%), whereas APIs and biopharmaceuticals account for the remaining 13% (2013: 18%).

The total value of the Slovenian pharmaceutical market increased by 1.2% while a reduction in generic drug price levels resulted in a 3% 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 2014, the Health Insurance Institute of Slovenia introduced six therapeutic groups of medicines. In addition to the first therapeutic group of medicines which was introduced in October 2013 and included proton pump inhibitors, the Health Insurance Institute also introduced therapeutic groups of medicines for affecting the level of serum lipids, ACE inhibitors, medicines containing acetylsalicylic acid 100 mg, medicines containing imatinib, medicines containing triptanes and local action medicines for treatment of glaucoma. Reduced reference drug price levels, resulting in a lower sales volume of these drugs, affected both generic as well as innovative pharmaceutical companies. In 2014, the non-prescription drug market had negative growth of 2.4% by value and 5.5% by volume.

### 1.3.2 Major product groups and brands<sup>12</sup>

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

- cardiovascular drugs,

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

Our leading brands in Slovenia include Lekadol®, Amoksklav®, Linex®, Lekadol plus C®, Coupet®, Iroprem®, Tulip® and Operil, and in our export markets drugs with amoxicillin-clavulanic acid, omeprazol, atorvastatin and tacrolimus.

### 1.3.3 Development and production sites and processes<sup>13</sup>

#### 1.3.3.1 Ljubljana site



Verovškova road in Ljubljana is the location of Sandoz's leading and largest development center and one of Sandoz's major production plants, which is also the largest of all Lek's plants in Slovenia.

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

In Ljubljana, products for the entire Sandoz are developed, both standard and the technologically most demanding products such as formulations with modified release and nasal sprays. Many novel products are later also manufactured in Ljubljana.

On this location, manufacturing activities started in 1975 and are now carried out in two organizational units – Solids and Steriles. Since the outset, production has been continuously growing and modernizing. The biggest milestones were in 1992 and 2004 when we expanded the production plant, and in 2008 and 2014 when we set up new control laboratories and later expanded them. Investing in capacities and infrastructure continued also in 2014, by increasing the tableting capacity and packaging into plastic bottles. Once again we were successful in the area of quality, health and environmental safety. We successfully passed all inspections by state agencies and customer audits in both areas and thereby confirmed the high level of quality and safety of our manufacturing.

#### **Solid dosage forms (TDI)**

The solid dosage forms unit has a broad range of products as we manufacture more than 500 solid dosage forms for

which we use more than 90 molecules (active pharmaceutical ingredients). We package more than 3,000 finished pharmaceutical products for almost 90 markets around the world. The majority of our products are manufactured on multi-purpose production lines which are highly automated and centrally computer-controlled. This enables us reliable complexity management, with faster response to market needs and a reliable lead time from receiving raw materials to dispatching the finished product on the market.

In 2014, our tableting plant achieved a new production volume record with more than 7 billion pcs produced. We packaged more than 400 million primary packaging units in around 170 million packages. We remain the leading Sandoz location for launching new products. In 2014, we launched more than 360 finished products and more than 2,000 in the last three years.

### **On a path to becoming a leading Sandoz manufacture center for solid pharmaceutical forms**

*"In recent years, the production of solid pharmaceutical products at the Ljubljana site has been continuously increasing. At the same time we modernized production and infrastructure, increased our capacity and the number of employees.*

*Within Sandoz we have established ourselves through highly qualified associates with expertise in complex technologies who are able to quickly adapt to changing needs of the market while preserving the high quality of our products and ensuring the safety of the manufacturing process. In the area of solid pharmaceutical forms we act as a knowledge center for the Sandoz production network and have a leading position in introducing new technologies and processes, with our experts helping other production facilities.*

*The generic pharmaceutical industry is a dynamic business environment. Our customers expect high quality, responsiveness and a reliable supply at a competitive price. In the production of generics we can be successful only if we have knowledge that allows us to be able to manufacture demanding products, and with high productivity."*



Aleš Rokavec, site Head Solids, Ljubljana

### Sterile dosage forms

The Sterile Pharmaceutical Products unit continues to increase production output in all three areas: vials, ampules and liquid products.

This was mainly driven by:

- opening of a new facility for lyophilized vials (Vials 2) which doubled the existing capacity,
- production of a leading ampule product for Novartis Pharma,
- successful launching of a new nasal spray mometasone in the EU.

We reconfirmed the importance of the Steriles unit within the Sandoz global production network and our role as a center of excellence for production of lyophilized vials and ampules.

### Specifics of production in a sterile environment and new production of lyophilized vials



Ivo Aebischer, site Head Steriles in 2014, Ljubljana

*"The production of sterile products is very demanding, mainly due to the working conditions which must assure the sterility of the final product. The first and most important condition is proper training of the associates."*

*"At Lek, we have been building the knowledge about sterile production for over a decade and it has been continuously updated, mainly due to increasing requirements regarding quality. It was the knowledge of all employees at the Steriles production that placed us among the key technological production sites within Sandoz and the entire Novartis network."*

### Company headquarters

The Ljubljana site also features the company headquarters with a number of specialist services: Finance, Sales and Marketing, Procurement, Supply, Quality, Human Resources, Legal Affairs, HSE, Corporate Communication and others.

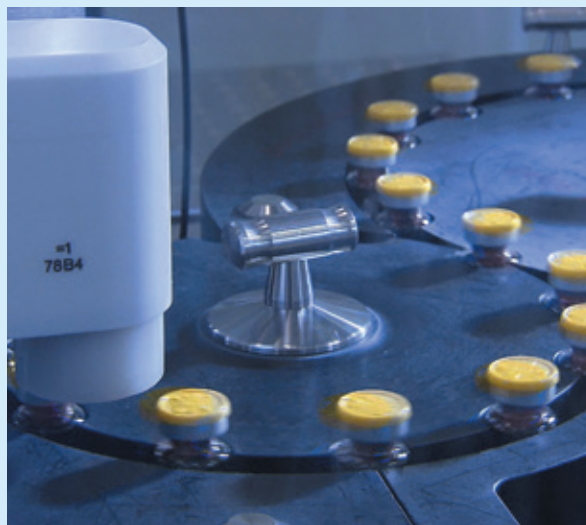
## Investment

### New facility for liquid products

After the successful completion of the Vials 2 investment project, we focused in 2014 on a key strategic project, a new plant for liquid products. More than 30 associates are involved in the project and regular production is planned in mid-2015.

The decision for this new investment is the result of a highly successful launching of mometasone nasal spray in the EU markets. The new facility will be an independent production unit, consisting of the preparation of solutions, new, state-of-the-art filling lines and related secondary packaging lines.

With this new plant for liquid products we will increase capacity by 18 million liquid products and gain a technological platform for nasal sprays for the global market, including the most demanding American market.



Vials 2 facility



### 1.3.3.2 Mengeš site



The Mengeš site comprises Active Pharmaceutical Ingredients (API) Mengeš, Biopharmaceuticals, Development of Pharmaceutical Ingredients, a part of Production of Solid Dosage Forms and development of Anti-infectives. The development and production of the active pharmaceutical ingredients at this site have been carried out since 1946. Its growth was driven by the expansion of the active pharmaceutical ingredient pipeline, both in processes of biosynthesis as well as organic synthesis. Since year 2000 it has witnessed a rapid ongoing development of biopharmaceuticals.

More than 20 active ingredients are included in the production program. In 2014, the API production volume and utilization of production capacities again grew by 15%. Increased growth of the existing production program and the introduction of new active ingredients was recorded, primarily for Novartis. The share of Novartis products in the entire Mengeš product pipeline is increasing and accounts for almost a quarter of production output.

In 2014, Biopharmaceuticals Mengeš fully realized all key development and production targets. The development part was enhanced by establishing the area Development of Pharmaceutical Products. Our production plant for recombinant technology (PORT) again produced record quantities of erythropoietin which is used for the treatment of anaemia, primarily in kidney patients and cancer patients. At the modified protein manufacturing facility (POMP), a production of pegylated filgrastim which is used for the management of chemotherapy- and bone marrow transplantation-induced neutropenia (low white blood cell count) is carried out. In June, new laboratories for Quality Control Bioanalytics were opened, in which the testing of biological activity for all Sandoz biosimilars will be performed. The new laboratories are an important addition to the site as they will support the release of products on the market for the entire Sandoz Biopharmaceuticals. Furthermore, new investments confirm that we are one of the key centers of Sandoz Biopharmaceuticals. In November we started the construction of a new facility with laboratories for protein analysis, development of finished biopharmaceutical forms and biophysics of proteins.

We successfully passed the JAZMP audit and extended the GMP certificate for the next three years.

## Construction of a new production plant in Mengeš



Egidij Capuder, site Head API production, Mengeš

*"In order to meet all the market needs for active ingredients, we decided to build a new production plant in Mengeš. The investment activities were very intense in 2014 and start-up of the new API production is planned for mid-2015."*

*"The rapid progress of this project is a result of the good cooperation between all stakeholders. Construction and installation works will be followed by complex technological equipment and all support system qualification processes."*

## Ambitious targets



Matjaž Oven, Head Biopharmaceuticals

*"In 2014, we strengthened our Biopharmaceuticals team with many new colleagues and are passionately pursuing ambitious targets that the unit has set. Together we contribute towards building a strong and sustainable quality culture and live our common mission."*

## Environmental improvements in Lendava



Gizela Štampar, Head Lendava Production (Anti-infectives)

*"We have improved a number of environmental aspects of manufacturing anti-infectives. With additional investment and modernization we successfully reduced the specific use of groundwater for the purpose of cooling of production processes. We also redirected the outflow of used cooling water from a small recipient into the Mura river and started to further exploit the waste flue gas heat from the incineration plant."*

## Investment in capacity expansion and packaging warehouse



Simon Rečnik, Head Packaging Center Lendava

*"In 2014, Sandoz adopted an important decision with regard to the future development of the Packaging Center Lendava. The almost EUR 25 million investment in the expansion of our plant is also one of the largest single investments at Lek, comprising the construction of a high-bay warehouse and auxiliary facilities."*

*The Lendava packaging center has since been considered within Technical Operations as one of the two key packaging facilities for the entire Sandoz."*

### 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 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 2014 we again achieved a 10% production growth as a result of modernization of technological equipment and process improvements. Accordingly, all market needs were met and the competitiveness of our products was enhanced. A further reduction in production cost and improvement of energy and environmental performance was driven by additional investment in production capacities, auxiliary infrastructure and other improvements in the technological processes. The site successfully passed all inspections.

At the Packaging Center Lendava (PCL), the filling and packaging of pharmaceuticals which are then supplied to more than 60 countries worldwide takes place. The Packaging Center Lendava is among the fastest growing Sandoz production plants. In 2014, we packaged more than 2.5 billion tablets and capsules and significantly increased our capacity with two new high-capacity packaging lines.

The Packaging Center Lendava is one of the youngest Sandoz plants within the entire global production network. The establishment of the plant reaches back to 2007 and the first batches for the market were dispatched at the end of 2008. In 2014, the Lendava packaging unit with 12 modern packaging lines for solid pharmaceutical forms became one of the largest packaging facilities within Sandoz and the number of employees exceeded 170. The Lendava facility continues to strengthen its position as one of the major economic entities in this part of Slovenia as the number of employees who come mainly from the local community, is growing constantly.

The vision of the facility is to become the best Sandoz packaging plant with a high level of customer service. The main objectives are efficient management of packaging complexity and supply of generic portfolio, high responsiveness to changing market needs and internal flexibility.



#### 1.3.3.4 Prevalje site



At the Prevalje site, 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, sold in more than 60 countries.

In 2014, the growth of production volumes continued. The tablet production grew by nearly 35%, in comparison with the previous year, and for the first time ever we exceeded the annual production of half a billion tablets. The production of finished products grew by 20%. The difference between the growth in the production of intermediates and finished products is primarily a result of contracts through public tenders for which we packaged a large part of the tablets manufactured in the form of the so called "hospital packs" that are typically five-times our normal packaging sizes. There was also a high growth in the production of mixtures and finished granulates while the production of powders for oral suspensions was slightly behind the results from the previous year. Energy consumption increased by 2.2%.

For 2015, we expect again high growth in production volumes.

Meeting high standards of quality and the awareness of the importance of safety at work and environmental protection was also confirmed by numerous audits by customers and official government inspections among which the inspection by the American Food and Drug Agency (FDA) was particularly successful.

**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 2014

For Lek, a Sandoz company, the year 2014 has been assessed as successful despite challenging business circumstances in the markets where we operate.

### A year of exceeding achievements

*"For the Prevalje site, year 2014 was a record year in all aspects. Good results were achieved with the awareness of the importance of quality, occupational safety and good customer service. The basis for our achievements are, however, excellent cooperation between organizational units at the site, support of other Lek sites, Kundl and Les Franqueses sites and Lek's central functions."*



Zlatko Ajd, site Head Prevalje

- We are **consolidating our position as the leading Sandoz Development Center**. We developed 27 novel products for the most demanding global markets, in total 80 new products over the last three years. The majority of the newly developed products were launched to markets in Europe, Canada, Australia, USA and Japan. At the end of the year, more than 280 development projects were under way in the Sandoz Development Center Slovenia. Their complexity is increasing in line with the company's strategy.
- We are a **key Sandoz location for introducing new products**. Nearly 700 new launches to global markets were executed from Slovenia, accounting for 33% of all Sandoz new launches.
- **The production volume has been increasing at all of our sites across Slovenia** (in Ljubljana, Mengeš, Lendava, Prevalje). Products manufactured in Slovenia, are marketed via the Sandoz global sales network in 160 countries across the world.
- Despite increasingly harsh economic conditions, Novartis also continued its investments in Slovenia and has **invested nearly EUR 1.6 billion in Slovenia over twelve years**. More than half of these funds were dedicated to development. We also invested in modernization and expansion of production capacity.
- In May, our Ljubljana Steriles unit achieved an important milestone. **Commencement of regular production of lyophilized vials** in the state-of-the-art facility Vials 2 enabled a doubling of the annual production of lyophilized vials.
- Also in May, **we opened two new packaging lines at the Lendava packaging center** and thereby considerably increased the capacity and responsiveness to market needs. In September we started to build a high-bay warehouse.
- In June we opened **new laboratories for quality control of products** with bioanalytical methods at Biopharmaceuticals Mengeš where biological activity of all Sandoz biosimilars will be tested. The new laboratories are a positive enhancement and recognition for the site as they will support the entire Sandoz Biopharmaceuticals in releasing products on the market.



- 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.
- In the domestic market we faced escalations in generating savings in healthcare which, due to administrative price cutting for some of our leading products, prevented the sales growth compared to the previous year. **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 hired 249 new associates** and ended the year with more than 3,100 associates. More than 45% of all our employees hold a university degree, of which nearly 370 hold a master's degree or a doctorate.
- For the fourth year in a row we enabled the most promising science students from the Alpe-Adria region to take part at the **regional BioCamp** offering them an insight into pharmaceutical industry guidelines. The winners Boris Brus and Janko Ignjatović participated at the Novartis global international BioCamp in Basel where Janko became one of the three winners.



At the 4<sup>th</sup> regional BioCamp 2014 we hosted young scientists from 10 countries.

### 1.3.5 Awards and acknowledgements

- We extended the full **Family Friendly Certificate** and proved our efforts to create a work environment which contributes to a better work-life integration.
- For the seventh 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 the environment and for transparent communication with stakeholders and the public. Our statements about the importance of responsibility to patients, employees, the environment and local communities are pursued in concrete objectives, about which we report transparently and comprehensively, in compliance with the RCI requirements for open communication with stakeholders and the public, using internationally renowned and comparable indicators (GRI) in our Sustainability Report 2014.
- We continued our targeted and systematic investment in **development, education and training** of our employees. Once again, for the thirteenth time in a row, we received the **TOP 10 Education Management Award**.
- We received an award for the **second place among the best HRM projects 2014** for our project "Monitoring

and promoting improvements and innovation among associates". It shows the building of company culture, stresses the importance of ideas and innovation and encourages all employees to improve their work.

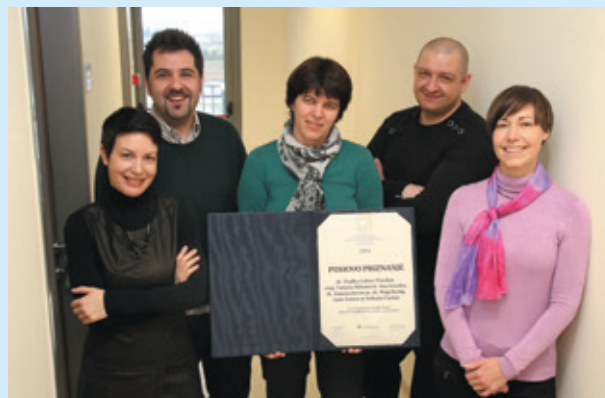
- We were recognized for the participation of students in the **practical training of students** of the Faculty of Chemistry and Chemical Technology.
- The project of thermal utilization of waste solvents at the Mengeš site placed us among the **finalists of the Siemens contest** for innovative and efficient use of resources.
- Our associate Gaj Stavber from the Development Center Slovenia became the **winner of the AmCham Top Potential of the Year 2014 contest**.
- A team of scientists at Biopharmaceuticals Mengeš and the National Institute of Chemistry Ljubljana received the **Puh Award 2014**.
- **Associate** Dr Tina Trdan Lušin from the Development Center Slovenia received the **Pregl Award 2014**.
- Dr Klemen Naveršnik, prototype analytics group head at the Development Center Slovenia, received the **Faculty of Pharmacy's Dean's Award 2014**.

## Development and manufacture of biosimilars

### The Puh award went to a team of researchers at Biopharmaceuticals Mengeš and the National Chemistry Institute Ljubljana

Lek experts Simona Jevševar, PhD; Maja Kenig, PhD; Nebojša Furlan and Sašo Tomše from Biopharmaceuticals Mengeš, together with their colleagues from the National Institute of Chemistry Ljubljana – Prof. Vladka Gaberc Porekar, PhD, Ana Jesenko and Tatjana Milunović, MSc, were the recipients of the Puh Award for the development and production of biosimilar medicinal products filgrastim and pegfilgrastim and the transfer thereof into production.

The Puh Award is one of the highest state recognitions in the area of scientific and research activities, given for outstanding achievements in the field of developmental activities, such as inventions, developmental achievements and the use of scientific findings when introducing innovations in economic practice.



Winners of the Puh Award: Simona Jevševar, PhD; Maja Kenig, PhD; Nebojša Furlan, Sašo Tomše and Tatjana Milunović, MSc

## 1.4 Development and reporting framework

In accordance with the Novartis Corporate Citizenship Policy, we strive for transparent and comparable public reporting. In addition to the economic impacts of our business operations, we also monitor and measure their societal and environmental impacts. Every year since 2010, we have compiled a comprehensive report on sustainable development, at the same time reporting in compliance with the requirements of the Responsible Care Initiative (RCI), EMAS Scheme and GRI Guidelines. The Sustainability Report was last published in September 2013. Even before 2010, we prepared environmental reports and reports within the 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.

The Sustainability Report which contains the EMAS Environmental Statement, is 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 2014 we report according to GRI G4 guidelines. We have not yet decided to seek external assurance for our sustainability reporting.<sup>15</sup> In the process of determining the content of the report on sustainable development, we also identified aspects that were exposed in different ways by our stakeholders: through questions raised on Community Partnership Days, interaction with the professional public at expert meetings, questions raised by employees (Workers' Council, Workers' Assembly and their representatives in the company's management bodies), contact with regulators (Agency for Medicinal products and Medical Devices) and through media questions. In this way we shaped the economic, environmental and social impacts of Lek d.d. operations.

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

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

|                             |   |   |  |   |
|-----------------------------|---|---|--|---|
| <b>Economic impact</b>      | <ul style="list-style-type: none"> <li>- Economic performance</li> <li>- Market presence</li> </ul>   |   |  |   |
| <b>Environmental impact</b> | <ul style="list-style-type: none"> <li>- Materials</li> <li>- Energy</li> <li>- Water</li> </ul>  | <ul style="list-style-type: none"> <li>- Emissions</li> <li>- Effluents 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> </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>- Consumers' health and safety</li> <li>- Labeling of products and services</li> <li>- Marketing communication</li> </ul> |

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

### Reporting in accordance with RCI requirements

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

### Reporting in accordance with EMAS Eco-Management Scheme requirements

The report meets the requirements of 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 2014 reporting characteristics<sup>17</sup>

- All the indicators and disclosures in the present report refer to the calendar year 2014.
- 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 51 and 52.
- 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>18</sup>
- The company Lek d.d. holds a 100% ownership stake in the following subsidiaries (as of 31 December 2014): Sandoz d.d., Hotel Lek d.o.o., and Lek Ljubljana Holding GmbH, Austria and 74.5% ownership stake in the Čistilna naprava Lendava d.o.o. Until 31. 12. 2014, Lek d.d. also held a 100% ownership stake in Novartis Animal Health d.o.o., in accordance with a contract on business share transfer, however, its new owner became Elanco – Eli Lilly company – on 1. 1. 2015.
- In 2014, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures.<sup>19</sup>
- To improve reporting accuracy, the following adjustments in the data collection were made for 2014, also impacting the comparability of previous years' data:<sup>20</sup>
  - On the basis of additional information, we improved the method of collecting data on the realization of the production plan for finished sterile products 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 including 2011 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.
  - As recommended by Novartis auditors, we added data on sewage sludge from the Lendava Wastewater Treatment Plant to other Lendava site waste also for all the previous years.

## 1.5 Governance, commitments, inclusion

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

At the end of 2014, the **Lek d.d. Board of Management** was composed of the following members:

**Vojmir Urlep**, President of the Board of Management,  
**Zvonko Bogdanovski**, Member of the Board of Management, Commercial Operations

**Ksenija Butenko Černe**, Member of the Board of Management, Legal Affairs

**Patrick Bernard Donnelly IV**, Member of the Board of Management, Finance (until 31. 10. 2014),

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

**Samo Roš**, Member of the Board of Management, Human Resources

**Bojan Dolenc**, Member of the Board of Management, Workers' Director (until 28. 2. 2014),

**Marjan Novak**, Member of the Board of Management, Workers' Director (from 7. 5. 2014).

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

**Francesco Balestrieri**, Chairman,

**Jeffrey Pilgram George**, Deputy Chairman (until 29. 5. 2014),

**Richard Francis**, Deputy Chairman (from 30. 5. 2014),

**Martin Jeffrey Rope**, Member,

**Knut Mager**, Member,

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

**Vesna Premovič**, Member – Workers' Representative.

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

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



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.
- Other matters in compliance with the law and according to the requirements of the Supervisory Board.

Management of the company business is overseen by the Supervisory Board, in accordance with its mandates and responsibilities. The Board can perform reviews and verification of the company's books and documentation, its treasury, securities and goods in stock, 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.

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 all relevant information related to environmental protection.

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

Appointment of the members of the Supervisory Board of Lek d.d. is confirmed by the Executive Committee of Novartis, the highest governance body, based on the skills and competencies of its members, with the aim of providing the best people, to cover all the company's functions, and to ensure their operational autonomy. Similarly to other levels of the company's functioning, supervisory bodies also operate in accordance with the Diversity & Inclusion initiative.

In their function, Supervisory Board members act to the benefit of the company and with due diligence, bound by an obligation of confidentiality. All members of the Supervisory Board avoid any conflict of interest. Upon their appointment, they have to sign a statement pursuant to Article 255 of ZGD-1, an obligation set for all Novartis Group employees in the Novartis internal Conflict of Interest Policy.

## For a better safety culture



Robert Hribar, Head HSE

*"To improve the safety culture and reduce the number of accidents at work, we designed a comprehensive plan in 2014, aimed at raising common awareness of the importance of safety."*

*Lek's management supported increased investments in solutions that will make our workplaces even safer. We have undertaken many projects. The beginning of 2015 was very encouraging as no accident resulting in sickness absence was recorded in the first two months, though in the first two months of 2014 there were two accidents resulting in sickness absence. In addition, two activities with a sustained contribution to safety were also of key importance in the previous year: the roll-out of the Safety Promoters initiative within which 80 associates are currently promoting safety among employees, and the implementation of the DuPont STOP program. The latter is based on enhancing observation and communication skills thereby reducing injuries and increasing the awareness about safety."*

*It is generally felt that the awareness about the importance of safety is growing in all areas and that we all want to contribute our share. This aspiration connects us all: the top management, trade union, worker's council, leaders and employees. We increasingly talk about safety and notice that the employees do not only take care for their own safety but often for the safety of their colleagues by encouraging awareness. Despite the progress, there is still room for improvement in each and every one of us."*

## 1.5.2 Employee participation in company management<sup>22</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' Council serves as a form of collective and indirect participation of employees in the management of the company. Two representatives of the employees are the Supervisory Board members, while the Workers' Director is also a member of the Board of Management.

A change of the president of the Worker's Council at the end of 2013 resulted also in a change of Supervisory Board member in 2014. Vesna Premovič, the president of the Workers' Council, became a new Supervisory Board member. Three new members of Euroforum (Novartis Workers' Council) were elected and in June they attended the annual meeting of this body. The Workers' Council elected Marjan Novak as the new Workers' Director and member of the Board of Management. In the next five-year term he will account for and represent the interests of workers in the HR and social area.

The Works Council has its own intranet site where monthly meeting records and other information useful for the employees are regularly published (Workers' Council activities, information with regard to labour law, tax policies, links to important laws, institutions ...).

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, the Workers' Director and HSE Director. Answers and/or any additional information are also provided after the meetings.

In 2014, the Workers' Council was regularly informed at meetings about organizational changes in individual units, topical issues which were subject to management decisions, establishment of Novartis Business Services, establishment of FCS (Finance Center Slovenia), amending certain internal acts, current events at Lek's trade union, change in access controls and devices for registering working hours at the Ljubljana site. It also took note of Lek's annual report for 2013 and other reports.

With its activities and initiatives the Workers' Council actively contributed to the implementation of legal rights and competences in the field of co-management. It informed the employees on a regular basis and responded to current issues in the company by submitting proposals and initiatives for the improvement of working life quality, working conditions and health and safety at work to the management.

Participation of employees in key projects to optimize business processes and improve environmental performance is described under item 2.1.5.

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

At Lek, a Sandoz company, we include diverse groups of stakeholders in our operations in order to understand their

needs and expectations and to improve access to health-care. 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.



Press conference on the occasion of the Children's Week (from left): Breda Krašna, Secretary General SAFY, Vlasta Nussdorfer, Slovenian Ombudsman, Darja Groznik, President of SAFY, Katarina Klemenc, Head of Corporate Communication at Lek, a Sandoz company, and Liana Kalčina, President of the national committee for children's rights at SAFY. (Photo: Barbara Zajc)

We focused our 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).

The well-branched network of our stakeholder relations is associated with their various interests and a wide spectrum of Lek's operations.



Red Noses in the Caravan Orchestra show, dedicated to children with developmental disabilities

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.

The Novartis/Sandoz model of stakeholder relationship management enables us to play an active role in the life of society at large 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 engagement<sup>24</sup>

In accordance with Novartis policy, we include stakeholders in different ways. For better understanding of patients' 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 healthcare. 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 endeavour 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 endeavour to be a respectable and successful healthcare company in Slovenia and abroad. It is maintained through a prompt response to the questions received, and by means of a responsive policy and practice of complaint handling.

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 2014, we received seven complaints from local residents<sup>25</sup>. The Ljubljana site received four complaints, two were noise-related, one referred to wrongly sorted waste in one of the containers and the other one to air emissions. In the first case, the complaint was filed by a local resident who also filed complaints in years 2011, 2012 and 2013. In previous years

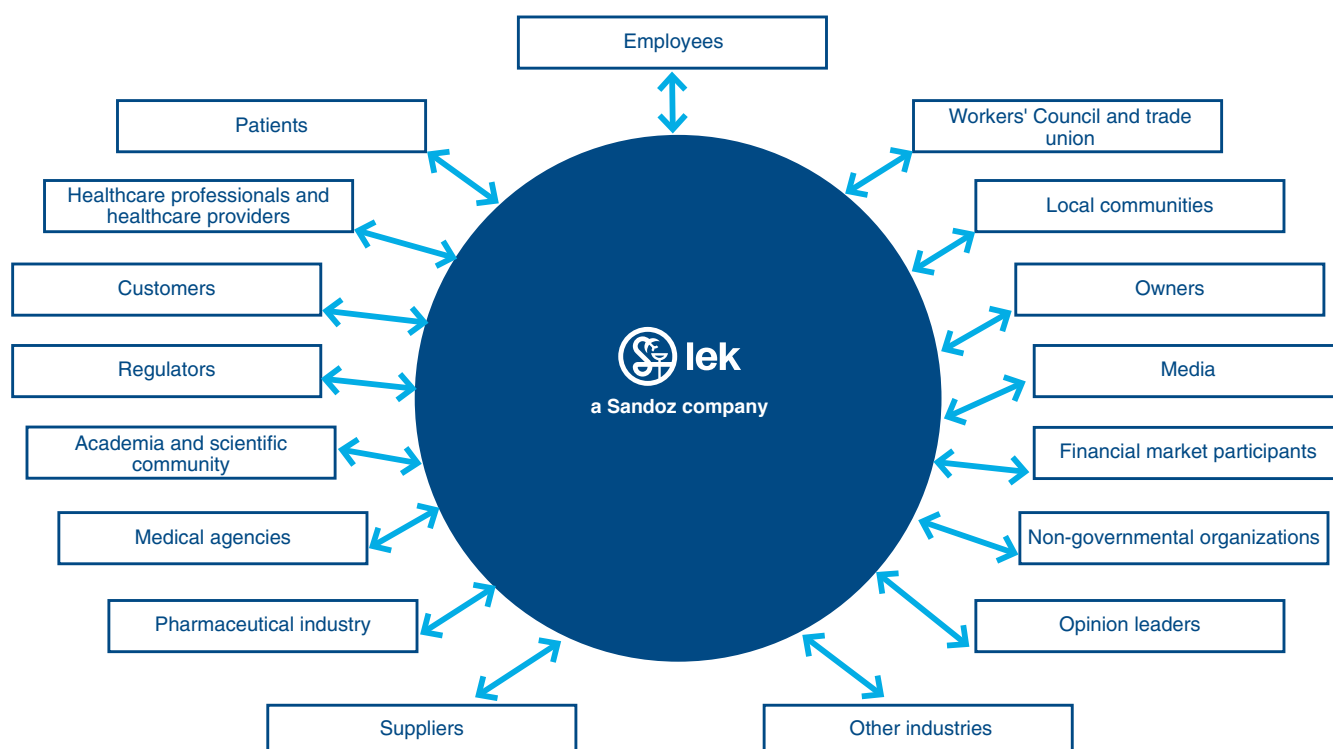
we installed silencers, whereby the noise level was considerably reduced significantly below limit values, therefore, no additional activities were carried out in 2014 with regard to this issue. Compliance with the law was confirmed by regular measurements of noise emissions. We also handled a complaint about the identified source of noise along the site border with Verovškova street. There we installed a sound barrier which was appropriately upgraded at the time of the overhaul. In the third case we tightened control over the appropriate separation of waste in production. The air-emission complaint was unjustified and related to steam coming from cooling towers along Verovškova street.

The Mengeš complaint referred to light pollution the source of which was an incorrect positioning of a flood light. The fault was remedied. At the Prevalje site we received two noise-related complaints. In one case, we examined the possibility of providing additional noise insulation for potential noise sources. The intrusive sound from the power station was prevented by meticulous closing of doors and windows. In 2015, some technical measures to reduce noise levels will be also conducted at the Prevalje site.

The inclusion of the local community is also carried out through Open House Days. In 2014, Biopharmaceuticals Mengeš organized an Open House Day for the families of the employees to show our loved ones where we work and what we do, to explain what the mission of our work is, and to visit the laboratories and other areas where we work. The response was excellent, with more than 300 people attending the event.

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

## Stakeholders we engage with



<sup>24</sup> GRI Disclosures G4-26, G4-27 | <sup>25</sup> GRI Indicators G4-EN34, G4-SO1



## Chronic kidney disease

### Personal stories and a patient's vital energy

Meeting a doctor, specialist nephrologist, and a kidney disease patient, deeply touched associates at Biopharmaceuticals Mengeš

Prof. Dr Marko Malovrh, specialist nephrologist, and a chronic kidney disease patient Dr Uroš Godnov spoke to the associates at Biopharmaceuticals Mengeš about the treatment of one of the most difficult diseases of our time, drawing on their own experience.

Prof. Dr Malovrh enlightened Lek associates at Mengeš on the subject of chronic kidney disease, the key risk factors and the course of treatment. Among treatment options mentioned was also erythropoietin, one of the most important medicines for the treatment of kidney diseases.

Uroš Godnov, doctor of Information Science, a patient with chronic kidney disease, dancer, cyclist, shared with the audience his personal experience of living with this severe and long-term condition. Despite his difficult diagnosis, Dr Godnov manages to function successfully in his working environment, moreover, he cycles, dances and lives life to

the full. His open and moving story as well as his courage and desire to live an active life, deeply touched all associates gathered in the packed lecture hall. He presented his views on the quality of life with the disease also at the Quality Day event in Lendava.



*Dr Godnov spoke about the treatment of one of the toughest diseases of our time, chronic kidney disease*

### 1.5.4 Lek's commitment to external initiatives and principles<sup>26</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 guidelines 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.

<sup>26</sup> GRI Disclosures G4-14, G4-15, G4-16, G4-56

## 2. Environment



### 2.1 Implementation of active environmental policy<sup>27</sup>

The key direct environmental aspects of our operations include the use of energy, water, emissions to the air, emission to water, waste, noise and, to a lesser extent, odour and the use of soil. Indirect environmental aspects mainly include impacts from suppliers/contractual service providers (Items 2.1.6 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 go beyond mere fulfilment of statutory provisions. The most important among them are the upgrading and improvements of existing measures and the introduction of new ones. 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.

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

In 2014 we were not charged with any penalties for non-compliance with environmental laws; however, we received seven external complaints, which are described under Item 1.5.3.1, together with action taken.

<sup>27</sup> GRI G4-DMA, GRI Indicators G4-EN29, G4-EN34

## Health, safety and environment systems

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

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

Priority is given to the following:

- The health and safety of our employees and all those affected by our operations, and
- 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 impact of our operations on the environment.

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

### HSE Policy guidelines

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

Our key guidelines are:

- Health, safety and protection of the environment constitute the basic responsibility of all our 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 the 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.**

### Compliance with HSE laws and standards<sup>29</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>30</sup> certified company, our Lendava and Mengeš sites operate in compliance with 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 2014, a total of 7 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 and health and safety at work. In the field of fire safety at the Lendava site we received a warning regarding identified deficiencies which were resolved within the prescribed period. In the field of health and safety at work we received a temporary ban for working with certain work equipment at the Mengeš site (certain deficiencies of work equipment) due to an injury of an associate. In 2014 we were involved in inspections covering the quality of operational processes and products related to the area of health checks and waste management.



## Health, safety and environment systems

### Environmental permits and related amendments issued to Lek

**All our sites implement the Novartis Environmental Management System (EMS).**

Environmental permits issued to Lek, a Sandoz company, by the Slovenian Environment Agency, specify the limit values for all atmospheric and water emissions, waste management, measures to reduce light pollution, methods for safe storage of raw materials and products for the company's sites. Our adherence to these values results in the safe operation of our production plants without excessive impact on the environment.

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

- Environmental permit for operation of a device with a high pollution potential (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
- Decision amending the environmental permit for the Lendava site, No. 35406-53/2014-8, dated 23. 1. 2015
- 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
- Decision amending the environmental permit for the Mengeš site, No. 35406-42/2014-4, dated 10. 9. 2014
- 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
- Decision amending the environmental permit with regard to emissions into waters for the Ljubljana site, Permit No. 35444-68/2014-2, dated 7. 10. 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
- Partial water use permit for direct use of water for industrial purposes from the public water supply network, for Lek d.d. (all sites), Permit No. 35536-19/2011, dated 15. 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
- Decision amending the partial water use permit for direct use of water for industrial purposes from the public water supply network for Lek d.d. (all sites), Permit No. 35536-90/2014-2 (concerning 35536-17/2013-2 and 35536-19/2011), dated 13. 1. 2015
- Water use permits for direct use of water No. 35536-20/2008, 35536-45/2012-5 and 35536-65/2013-8
- Greenhouse gas emission permits No. 35485-53/2014 dated 22. 10. 2014 and No. 35485-54/2014 dated 15. 12. 2014.

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

When identifying our environmental impacts, certain factors have to be taken into account. They primarily refer to the efficiency of the use of materials, energy resources, water, waste, atmospheric emissions and wastewater per tonne of product. Namely, there are considerable differences in product and API weight. 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 2014. The manufacturing structure therefore varies from year to year.

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

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

## 2.1.2 Major environment protection achievements

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

In 2014 we implemented the following measures:

- continued projects aimed at reducing atmospheric emissions and carried out additional redirection of emissions from production plants to a Regenerative Thermal Oxidizer – RTO) at the Mengeš site. Over the last seven years, we installed four such devices at Lek for more efficient and economic reduction of emissions on the basis of thermal oxidation of gasses: two in Ljubljana, one in Mengeš and one in Prevalje;
- restructured and partially repaired the sewage network at Ljubljana, Lendava and Mengeš sites and repaired or replaced old oil-traps with new ones that conform with the SIST EN 858-2 standard;
- completed the project of the redirection of the cooling water discharge outlet from the Kopica stream into the Mura river at the Lendava site;
- removed cooling devices that still contained R 22 gas at the Prevalje and Ljubljana sites and replaced them with new devices containing gas with lower global warming potential;
- continued the project of testing water-based coating of tablets at the Prevalje site;
- implemented measures to reduce the temperature of discharges of industrial waste water by installing a 6 m<sup>3</sup> tank for retention and cooling of waste water at the Ljubljana site;
- installed a new steam boiler for generating steam with better thermal efficiency (flue gas recovery) at the Mengeš site. The boiler has the option of co-incineration of non-halogenated waste solvents with a high calorific value (project in 2015);

- ensured technological equipment for the regeneration of waste reagents at the Lendava site;
- continued the project "packaging" at Lek level, reducing the use of raw materials. With smaller packaging sizes we also reduced the impact of transport on the environment (lower fuel consumption, lower CO<sub>2</sub> emissions).

## 2.1.3 Investments in environmental management<sup>32</sup>

We limit our environmental impacts by continuous environmental investments. In 2014 they amounted to EUR 2.9 million.

The major investment projects included the following:

- redirection of the cooling water discharge outlet into the Mura river,
- renovation of the sewage network and instalment of new oil-traps that conform to the SIST EN 858-2 standard at all Lek sites,
- technological equipment for the regeneration of waste reagent at the Lendava site,
- additional reconnections and amendments to the system of eliminating organic solvents from industrial exhausts at the Mengeš site,
- installation of cooling devices that contain gas with lower global warming potential at the Prevalje and Ljubljana site,
- new steam boiler with better thermal efficiency at the Mengeš site,
- restoration of the facade of the tablet production plant in Ljubljana, thereby improving the energy efficiency of the building.

## Innovative and efficient use of resources

### Lek among the finalists of the Siemens contest

The project of thermal utilization of waste solvents at the Mengeš site earned a position among the finalists of Siemens' contest for innovative and efficient use of resources.

A larger volume of waste solvents, suitable for energy recovery, is generated in the production process at the Mengeš site. By co-incineration of waste and natural gas we remove 20 to 30% of the annual volume of non-halogenated waste solvents with a high calorific value. The resulting energy is used for technological purposes for the generation of industrial steam. The basis for the co-incineration process is, in addition to being an appropriate device, also an appropriate monitoring platform. The device at Mengeš has obtained all necessary permits, including the integrated environmental permit.

The generated savings are equivalent to 1 million m<sup>3</sup> of natural gas per year or 2,000 t of CO<sub>2</sub> emissions. The cost of removal and incineration of waste solvents by the authorized waste disposal company is also lower.

The Werner von Siemens award recognizes projects aimed at increasing efficiency in the construction and management of facilities, manufacturing, electricity and water supply, sewage treatment and waste management and remediation of the negative effects on the environment. The most relevant factor in the assessment of quality of contesting projects is efficient use of energy sources, in addition, the jury also assesses the complexity and innovativeness of projects as well as their technological and business impacts.



From left to right: Andrej Brečko-Siemens, Egidij Capuder, Mojca Bernik and Jože Stopar from Lek, a Sandoz company, and Jurij Čretnik, Zoran Djurašinovič, Miran Oblak and Matej Šoberl from RACI d.o.o.

<sup>32</sup> GRI Indicator G4-EN31

## 2.1.4 Verification of compliance with implemented standards<sup>33</sup>

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 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 2013 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 2014. 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.



## 2.1.5 Optimization of business processes

Lek implements many projects for the optimization of business processes, which play a significant part in the improvement of the company's environmental performance. This is also integral to our business strategy and environmental policy. 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 2014, our associates from all four sites contributed 959 ideas (866 in 2013), of which around 500 were adopted. Over 260 ideas have already been applied in practice. Interesting suggestions and ideas were proposed by as many as 411 different associates, which represents 13% of employees. The implemented ideas resulted in direct measurable savings of over EUR 3.1 million.

### European Integrated Facilities Management (EIFM)

Also in 2014 we continued to roll-out the IFM project, that in May became a part of Novartis' biggest organizational change, the implementation of the new Novartis Business Services (NBS) division. This will enable Novartis to consolidate its activities across its key divisions and adding this fourth division will support the first three (Novartis Pharma, Sandoz and Alcon). The IFM project has therefore become a small part of the comprehensive functional organizational changes which are, through more direct corporate influence, orientated towards more intensive development, cost reduction and subsequently increased competitiveness. The new division is expected to be fully operational in 2015.

## Share at Th!nk Sandoz

### Lek's internal portal for equipment and chemicals exchange

Through the Th!nk Sandoz initiative designed for gathering interesting ideas from the employees, Lek's internal portal for laboratory equipment, other equipment and chemicals exchange was established. It is intended for exchanging the equipment that is no longer needed by the associates in one department but would be useful in another department or unit. The portal was successfully launched and came to life and soon contained over 50 pieces of different laboratory equipment and materials.



## Prime contest 2014

### Prime Solution, Prime Breakthrough and Prime Leader awards bestowed

Among 14 proposals received in the category Prime Breakthrough and 18 proposals in the category Prime Solution, the Prime Contest jury announce the winning proposals. The Prime Breakthrough award recognized the proposal Gastrointestinal Tract Simulators for a More Competitive Development of Finished Pharmaceutical Forms, submitted by the development Center Slovenia team (Uroš Klančar, Igor Legen, Barbara Kunič Tešović, Sandra Berglez, Alenka Bevc). The proposal – Similarity Factor – a Procedure to Compare Chromatograms, submitted by the proposers from the Development Center Slovenia (Miroslav Planinc Kovačević and Ivan Plantan) received the Prime Solution award. The Innovation Committee recognized with the title Prime Leader 2014 the leader who promoted an innovation most effectively in his/her department in the past year. The award in this category went to Luka Peternel, Head of the FT1 group, Pharmaceutical Development, Slovenia.

<sup>33</sup> GRI G4-DMA



## 2.1.6 Indirect environmental impacts<sup>34</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>35</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 recognized sources of indirect environmental impact of our operations. It is mitigated by more extensive use of teleconferencing and videoconferencing which replace long-distance business travel.

We regularly monitor fuel consumption, mileage and CO<sub>2</sub> emissions for all the fleet cars. This data is reported quarterly into the Novartis database.

For 124 company cars in 2014 (115 in 2013), a total traveling distance of 3,227,342 km (3,380,216 in 2013) was recorded, with fuel consumption of 231,360 litres (209 m<sup>3</sup> in 2013) and CO<sub>2</sub> emissions of 430 tonnes (465 in 2013).

The indirect impact of transport is also taken into account in the process of selecting suppliers in categories such as placing orders for packaging materials (see Item 2.2.4).

## 2.2 Raw materials and natural resources

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

Waste reuse and recycling are integral parts of our API production processes. We recycled and reused 91% of the total quantity of organic solvents which is the same as in 2013. 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 the previous three years), and to 76% in Mengeš. Currently, a project aiming to increase the proportion of regeneration at the Lendava site is being implemented. 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 light industrial fuel. In 2014, we replaced the existing steam boiler at the Mengeš site with a new boiler with better thermal efficiency. At the same time, we expect to obtain an environmental permit for co-incineration of non-halogenated waste solvents with high calorific potential in the new boiler in 2015.

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

### 2.2.2 Mass flow of materials

Changes in the structure and volume of pharmaceutical production cause an annual fluctuation of mass flow of materials at some of the Lek sites. There is no such fluctuation at the Lendava production and Prevalje sites, where one to two products are manufactured and as therein, the change in the volume of API production also means there is a comparable change in the use of raw materials. In 2014 we recorded an increased use of raw materials (by 11%), due to increased production volume at all sites.

**Table 3: Annual mass flow of various materials used\* in tonnes<sup>36</sup>**

| Year | Unit | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) |
|------|------|---------|-----------|--------|----------|-------------|
| 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      |
| 2014 | t    | 8,891   | 9,901     | 15,646 | 5,063    | 39,501      |

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

## 2.2.3 Efficiency of materials

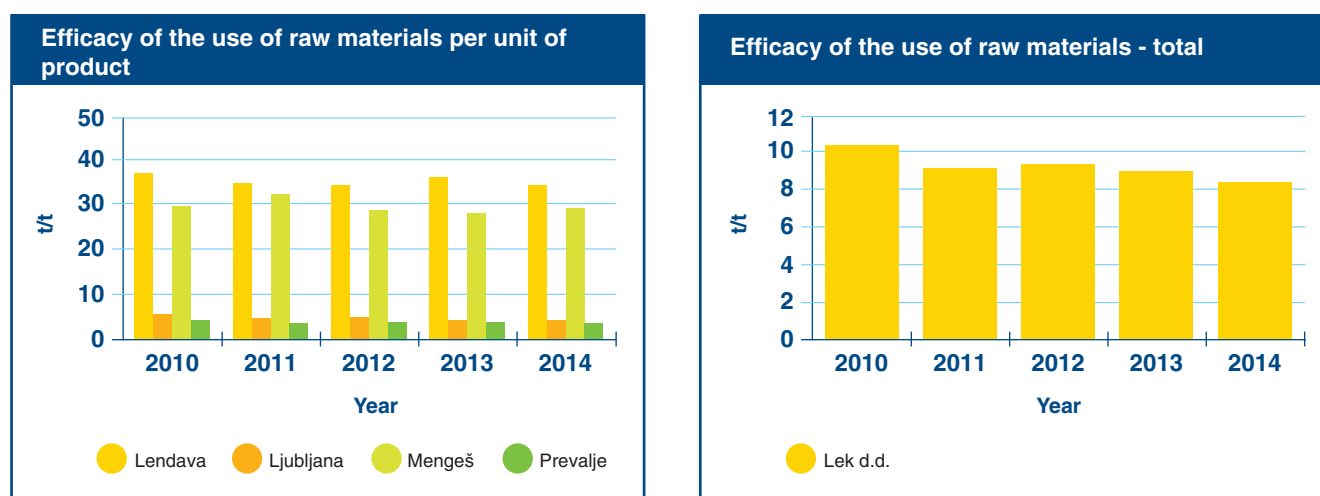
The graphic display of the efficiency of the use of all the raw materials at Lek d.d. reflects the intensive efforts to reduce the consumption of raw materials per unit of product. The quantity of raw materials used per tonne of API/product has been decreasing for a number of years. In 2014, we increased the efficiency of the use of materials by more than 7% compared to the previous year and in the 2010–2014 period by more than 17%. 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 is less obvious in the graph. For this purpose, an overview by product would be required. Efficiency of the use of raw materials strongly depends on the range of products manufactured at the Mengeš site, where the raw materials are integrated into the product only to a minor extent and are mostly used in the manufacture process of a finished product.

By reviewing the method for acquiring data on the realization of finished pharmaceutical products at the Ljubljana site, we improved the accuracy of the data on the efficiency of the use of raw materials in 2014.

**Graph 2: Efficacy of the use of various materials per unit of product<sup>37</sup> – by site and total**



## 2.2.4 Sustainable packaging approach<sup>38</sup>

The two production sites manufacturing finished dosage forms are the major consumers of packaging material: Ljubljana with 63% and Prevalje with 33%. At the Mengeš and Lendava sites packaging consumption accounts for less than 4% of the total packaging consumption of Lek, a Sandoz company.

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 2014

- By optimizing packaging of the product containing rabeprazol, rosuvastatin, ranital or candesartan we reduced the blister surface, volume and packaging weight.
- In the product containing levetiracetam we replaced blisters by plastic bottles thereby reducing the blister volume by 60%. The number of packs per pallet was increased by the same proportion, resulting in environmentally more optimal use of transport due to lower fuel consumption and less CO<sub>2</sub> emissions.
- We abolished patient information leaflets for products in the US market and hired contractors to inform pharmacists about the availability of package leaflets in electronic form. Patient information leaflets are now constantly updated while prior to that the updates reached the pharmacists only on receipt of the new shipment of medicines.

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

Old form of packaging



New form of packaging



• 60% reduction of blister surface

## 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 are 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 in 2014.

**Table 4: Efficiency of energy resource use per unit of product<sup>39</sup>**

| Year | Unit | Lendava | Ljubljana* | Mengeš | Prevalje | Lek (Total)* |
|------|------|---------|------------|--------|----------|--------------|
| 2010 | GJ/t | 2,240   | 197*       | 720    | 66       | 348*         |
| 2011 | GJ/t | 2,004   | 185*       | 677    | 53       | 307*         |
| 2012 | GJ/t | 1,697   | 190*       | 613    | 56       | 302          |
| 2013 | GJ/t | 1,577   | 191*       | 645    | 56       | 299*         |
| 2014 | GJ/t | 1,501   | 164        | 632    | 46       | 255          |

\* 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.

Lendava is still the best example of continuous reduction of energy consumption per unit of product due to the uniform production portfolio over a longer period of time. As shown in Table 4, energy consumption per tonne of product was reduced by 739 GJ or 33% at the Lendava site in the period 2010

– 2014. If realized production of the Lendava Packaging Center was also included, the reduction would be even greater. The efficient energy consumption per tonne of product at the entire Lek level increased by 93 GJ or 27% in the same period.

<sup>39</sup> EMAS Core Indicator, GRI G4-EN5



## 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. 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 replacing ethanol-based coating of one category of omeprazole with water-based coating. The regulatory approval of the change to the technological procedure was obtained in 2014. The Mengeš site also endeavours to replace more hazardous chemicals with less hazardous ones – in 2014, a modified production process of one of the active ingredients was successfully implemented and the use of dichloromethane was eliminated from the technological process.

## Interview

### Every planned activity should be performed safely

Uroš Uršič, Head of operational development at Mengeš explains that a series of successful optimization process examples also have a positive environmental impact, because development processes always include environmental aspects.

### Developing new products is key for all companies with a vision of growth. What is the role of the operational developments as part of API Mengeš in developing products and ensuring the growth of the company?

The operational development is based on three main pillars which are solving production issues, optimization of manufacturing of already launched products and transfer of new products into production. The objective of process optimization is to improve the price competitiveness of our products, while considering other aspects as well. When developing improved processes, our laboratory always considers environmental aspects as well. Accordingly, when developing a new process for the synthesis of one of our active ingredients – mycophenolate mofetil (MMF), we eliminated the use of dichloromethane and oxalyl chloride as reagent. Handling the latter namely requires special protective measures due to the formation of hydrogen chloride and carbon monoxide. Where possible, regeneration of waste solvent is being introduced into all our development processes, making an important contribution to sustainable growth. Together with our colleagues from Production, we reduced the use of dichloromethane to 10% of the original volume, by re-using it.

### What is particularly important for the successful transfer of products into production?

The transfer is successful, if the planned quantity of the product of adequate quality is manufactured during the transfer and the validity of the production process is confirmed. The path to achieving this is difficult. It is necessary to take into account a whole range of different and also indispensable aspects. Let me mention a few: a robust process with clearly developed and properly defined critical process points and critical material attributes, appropriate analytical methods, availability of raw materials, suitable processing equipment and also correctly evaluated aspects of safety,



*Uroš Uršič, Head of operational development at Mengeš*

health and the environment. The transfer is therefore successful only if care is taken that the process is carried out in a safe manner and without impacting human health and the environment. This is a difficult path to take, it is necessary to take into account a whole range of different and indispensable aspects.

### When making decisions on technological solutions, how important are their impacts on the environment?

My view is that our work is based on two pillars where there are no 'concessions'. The first one is quality assurance which in our industry goes beyond mere adequacy of products. The second, also important area, are aspects of health, safety and environment which are interconnected. In all our new projects, the safety concern is a key factor in decision-making. For each planned activity we have to ensure that it will be carried out safely in order to preserve the health of our employees as well as the sustainability of the environment.

## 2.3 Energy

### 2.3.1 Use of energy

**Table 5: Total consumption of energy<sup>40</sup>**

| Year | Unit | Lendava | Ljubljana | Mengeš  | Prevalje | Lek (Total) |
|------|------|---------|-----------|---------|----------|-------------|
| 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   |
| 2014 | GJ   | 387,500 | 412,023   | 330,623 | 64,043   | 1,194,189   |

At the Lek level, the overall energy consumption was by more than 2% higher than in the previous year. The largest increase was recorded at the Ljubljana site (by 6%), followed by the Prevalje (by 2%) and the Lendava site (slightly more than 1%). Less energy was used only at the Mengeš site, slightly more than 1%.

In terms of the total energy consumption, the Ljubljana and Lendava sites have the highest proportion with a 34% and 32% share, followed by Mengeš with 28% and Prevalje with nearly 6%.

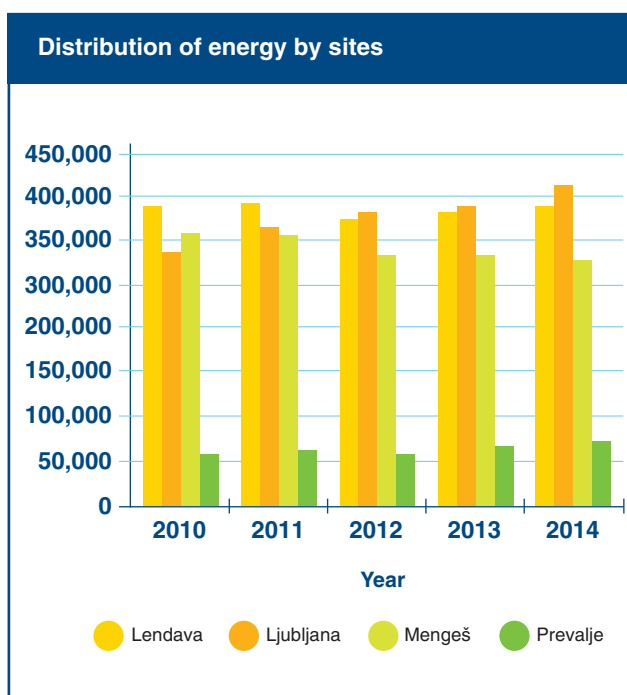
#### Measures to lower energy consumption



Luka Ušeničnik, Head of Energy at the Ljubljana site and Energy manager at Lek, a Sandoz company

*"Electricity presents the major part of the energy consumed at Lek. This amounts to 45 percent of all our energy consumption. As a result of last year's large increase in production volume, electricity consumption increased by 5% but the overall total energy consumption by only 2%. For such a result, a number of measures were necessary. With their help we saved 34.2 TJ of energy only in 2014, while reducing CO<sub>2</sub> emissions in the air by 1,408 tonnes."*

**Graph 3: Distribution of energy by sites in GJ**



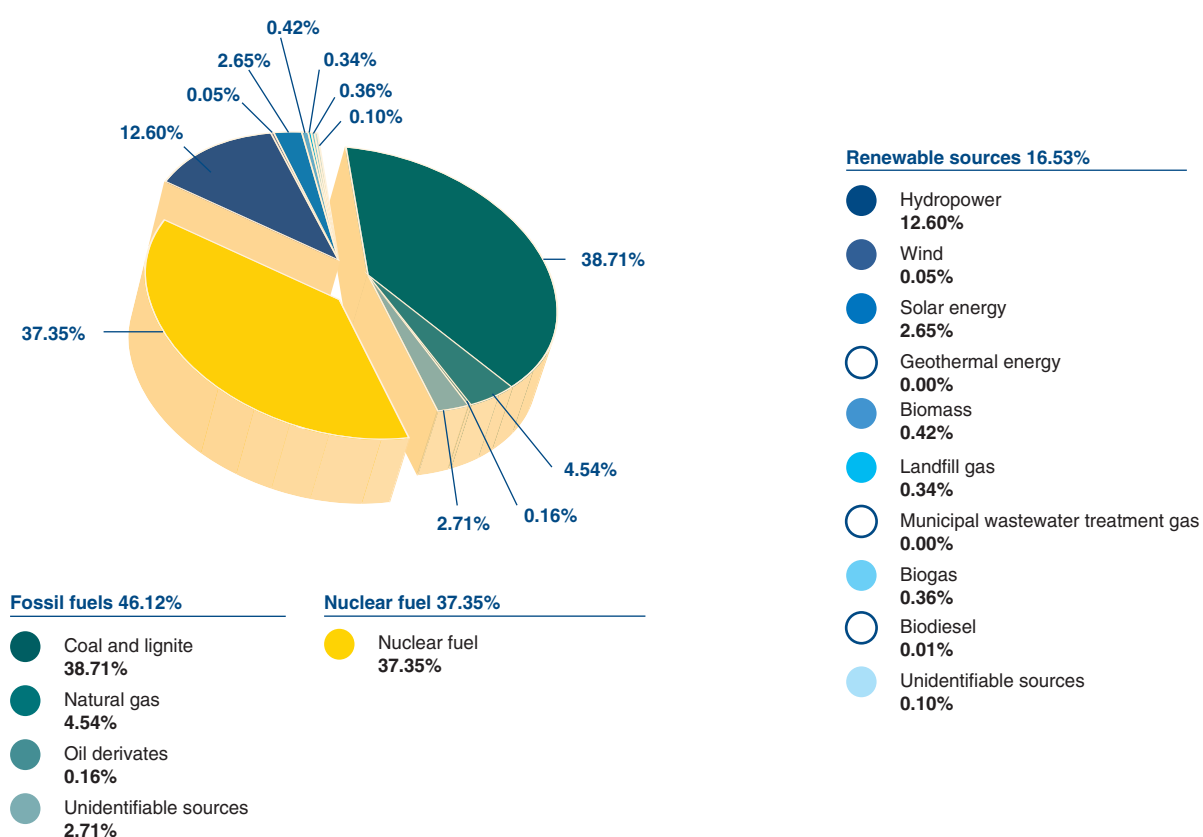
At the Mengeš site, we utilize waste solvents as secondary fuel for the operation of the steam boiler that generates heat and steam for technological purposes. At the Lendava site, the share of renewable energy amounts up to 1%. It is obtained from the incineration of organic waste generated in fermentation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

<sup>40</sup> GRI Indicator G4-EN3

Table 6: Structure of purchased electricity sources

|                                    | Year 2014      |
|------------------------------------|----------------|
| <b>Fossil fuels</b>                | <b>46.12%</b>  |
| Coal and lignite                   | 38.71%         |
| Natural gas                        | 4.54%          |
| Oil derivatives                    | 0.16%          |
| Unidentifiable sources             | 2.71%          |
| <b>Nuclear fuel</b>                | <b>37.35%</b>  |
| <b>Renewable sources</b>           | <b>16.53%</b>  |
| Hydropower                         | 12.60%         |
| Wind                               | 0.05%          |
| Solar energy                       | 2.65%          |
| Geothermal energy                  | 0.00%          |
| Biomass                            | 0.42%          |
| Landfill gas                       | 0.34%          |
| Municipal wastewater treatment gas | 0.00%          |
| Biogas                             | 0.36%          |
| Biodiesel                          | 0.01%          |
| Unidentifiable sources             | 0.10%          |
| <b>Total</b>                       | <b>100.00%</b> |

Graph 4: Structure of purchased electricity sources





**Table 7: Electricity consumption**

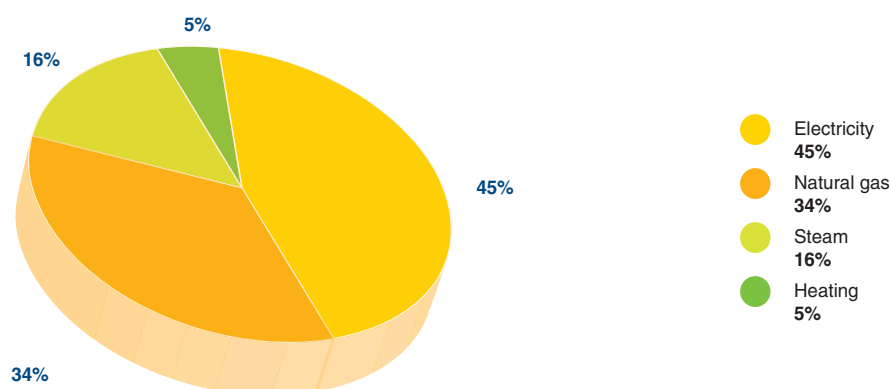
| Year | Unit | Lendava | Ljubljana | Mengeš  | Prevalje | Lek (Total) |
|------|------|---------|-----------|---------|----------|-------------|
| 2010 | GJ   | 154,082 | 134,083   | 115,320 | 23,376   | 426,861     |
| 2011 | GJ   | 155,551 | 140,221   | 115,898 | 24,111   | 435,781     |
| 2012 | GJ   | 167,994 | 152,638   | 116,215 | 24,551   | 461,398     |
| 2013 | GJ   | 189,032 | 155,394   | 116,498 | 25,686   | 486,610     |
| 2014 | GJ   | 198,955 | 169,269   | 117,140 | 26,601   | 511,965     |

In 2014, electricity consumption increased by 5% over the previous year.

### 2.3.2 Distribution of energy by energy sources

In the structure of purchased energy sources, electricity accounts for the largest proportion of used energy with

45% as well as natural gas with 34.5%. These two energy sources are the primary source for three sites. At the Ljubljana site specifically, in addition to these energy sources, we also purchase industrial steam that accounts for a 15% share and heating water for a mere 5% share of its energy sources.

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

### 2.3.3 Energy efficiency improvements<sup>41</sup>

We have been continuously increasing the production of difficult-to-make products which are manufactured in smaller quantities but have a higher added value. Complex production processes dictate the use of more complex production equipment which usually entails more demanding energy consumption. Our efforts to ensure energy efficiency are therefore a part of our production process management. We are also continuously building our employees' awareness of energy use.

In 2014, additional measures were taken to improve energy efficiency, that generated energy savings of 34.2 TJ in total and 1,408 tonnes lower emission of CO<sub>2</sub> into the air.

These results were achieved through the following projects:

- At the Mengeš site, several improvements to different energy systems were implemented, which resulted in energy savings of 3,996 GJ. By installing a more energy-efficient turbo compressor at the compressor station for the preparation of low-pressure air for fermentation we generated savings in electricity consumption. Significant savings were also generated in the

process of preparation of cooling water where a free cooling system was introduced improving the control of the entire system.

- At the Lendava site, a Girola boiler heating system was upgraded. The use of industrial steam was replaced by exploiting flue gases from the incinerator furnace. With this project, by installing a free cooling system and by some other smaller projects we reduced the use of energy by 6,694 GJ per year.
- At the Ljubljana site, we reduced energy consumption by 3,113 GJ per year through some smaller projects, especially the system for exploiting waste heat and improvement of air-conditioning control. At the same site, we also renewed the facade of the tablet production facility and improved the insulation and energy efficiency thereof.
- Lendava was the leading site in implementing energy projects. With one major and several smaller projects we reduced its energy consumption by as much as 20,459 GJ annually. Major natural gas savings were generated by introducing a system for exploiting waste gas from a steam boiler resulting from thermal oxidation of waste solvent emissions. Apart from some minor improvements we also upgraded air-conditioning systems and systems for the preparation of compressed air.

<sup>41</sup> GRI Indicator G4-EN6

## 2.4 Water

### 2.4.1 Water use efficiency

In the pharmaceutical industry, water is an indispensable natural resource. Efficiency of its use is therefore one of our major concerns. In 2014, water consumption per kg of product at the Lendava site was again reduced, despite the fact that the quantitative realization of the Lendava Packaging Center was not taken into account in the quantitative realization at the site level. Due to an improved system for reusing waste water, the consumption of fresh water dropped by 22,534 m<sup>3</sup> per year.

Water consumption per kg of product at the Lendava site:

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



**Table 8: Water consumption in 000 m<sup>3</sup> <sup>42</sup>**

| Year | Unit                  | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) |
|------|-----------------------|---------|-----------|--------|----------|-------------|
| 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       |
| 2014 | in 000 m <sup>3</sup> | 1,380   | 570       | 1,557  | 42       | 3,548       |

At the level of Lek, a Sandoz company, the efficiency of water use was improved by 15%. At the Mengeš site, water is used mainly for technological purposes. In 2014, only 5.4% of water was supplied from the public supply network,

and the rest (94.6%) came from our own pumping station (groundwater). The table only provides the data on water use efficiency for polluted waters (cooling waters excluded).

**Table 9: Efficiency of water use per unit of product<sup>43</sup>**

| Year | Unit              | Lendava | Ljubljana* | Mengeš | Prevalje | Lek (Total)* |
|------|-------------------|---------|------------|--------|----------|--------------|
| 2010 | m <sup>3</sup> /t | 962     | 198        | 548    | 31       | 246          |
| 2011 | m <sup>3</sup> /t | 833     | 214        | 500    | 22       | 227          |
| 2012 | m <sup>3</sup> /t | 745     | 216        | 496    | 29       | 236          |
| 2013 | m <sup>3</sup> /t | 772     | 218        | 570    | 31       | 246          |
| 2014 | m <sup>3</sup> /t | 650     | 196        | 532    | 24       | 208          |

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

### 2.4.2 Water supply sources<sup>44</sup>

Water from our own wells is used for technological purposes at the Lendava and Mengeš sites, for which we have obtained appropriate permits from the Ministry of Environment and Spatial Planning.<sup>45</sup> We regularly monitor groundwater levels, with pressure sensors every hour on a continuous basis all year around, and report the results to the respective Ministry. At the Mengeš site, the impact of the well on the level and direction of groundwater is also monitored simultaneously with this annual monitoring.

Monitoring of groundwater levels clearly showed that the dynamic groundwater supplies of Mengeško Polje are extensive. A longer time interval in monitoring the groundwater levels in the area of the Lek Mengeš facility shows an upward trend in groundwater levels (in the last decade). In January and February there was 3.5-times more precipitation than the average for the last 40 years (in the same time interval) and 36% more precipitation than the total average.

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

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

| Mengeš   | 2010  | 2011  | 2012  | 2013  | 2014  |
|--|-------|-------|-------|-------|-------|
| From our own pumping station (000 m <sup>3</sup> )         | 1,591 | 1,432 | 1,335 | 1,376 | 1,480 |
| From the public water supply network (000 m <sup>3</sup> ) | 94    | 77    | 80    | 81    | 83    |

| Lendava  | 2010  | 2011  | 2012  | 2013  | 2014  |
|--|-------|-------|-------|-------|-------|
| From our own pumping station (000 m <sup>3</sup> )         | 1,384 | 1,325 | 1,228 | 1,297 | 1,340 |
| From the public water supply network (000 m <sup>3</sup> ) | 46    | 39    | 61    | 58    | 58    |

### 2.4.3 Recycling and reuse<sup>46</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 a portion of water (spill) is discharged into the sewage system. The quantities of reused water vary greatly and depend on individual processes, so they cannot be accurately

calculated on the basis of the existing data capture method. 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 using the best available techniques (BAT). As the cooling cycles are of the closed-loop type, the consumption of well cooling water does not increase despite the increased production volume.

## 2.5 Waste

### 2.5.1 Waste management<sup>47</sup>

Due to a changed data collection methodology (see Item 1.4.1), changes in the volumes of waste for the previous year occurred in 2014. Consequently, a 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 accounts for more than 97% of all waste at the Lendava site and 73% 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). As recommended by Novartis, sewage sludge from the Lendava Wastewater Treatment Plant has been added to other Lendava site waste – the data was corrected also for all previous years.

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.

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

<sup>46</sup> GRI Indicator G4-EN10 | <sup>47</sup> EMAS Core Indicator, GRI Indicator G4-EN23, G4-DMA



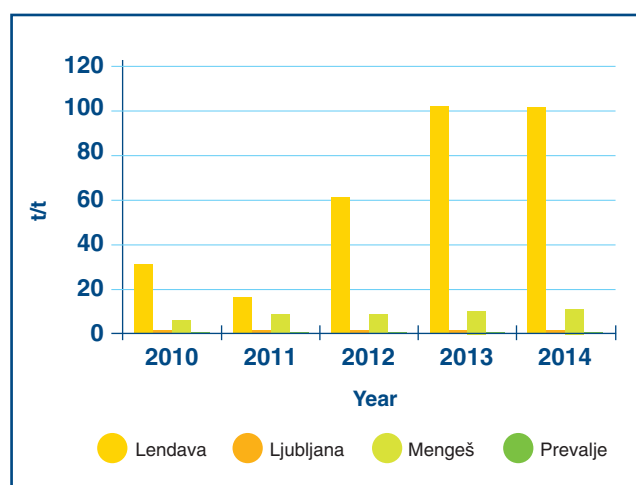
Table 11: Volumes of waste generated in tonnes

| Year | Unit | Lendava  | Ljubljana | Mengeš | Prevalje | Lek (Total) |
|------|------|----------|-----------|--------|----------|-------------|
| 2010 | t    | 5,936**  | 1,851     | 3,932* | 535      | 13,125**    |
| 2011 | t    | 3,550**  | 1,800     | 4,392  | 590      | 10,332**    |
| 2012 | t    | 13,572** | 2,210     | 4,904  | 676      | 21,363**    |
| 2013 | t    | 24,624** | 2,230     | 4,670  | 698      | 32,222**    |
| 2014 | t    | 26,147   | 2,739     | 5,146  | 636      | 34,667      |

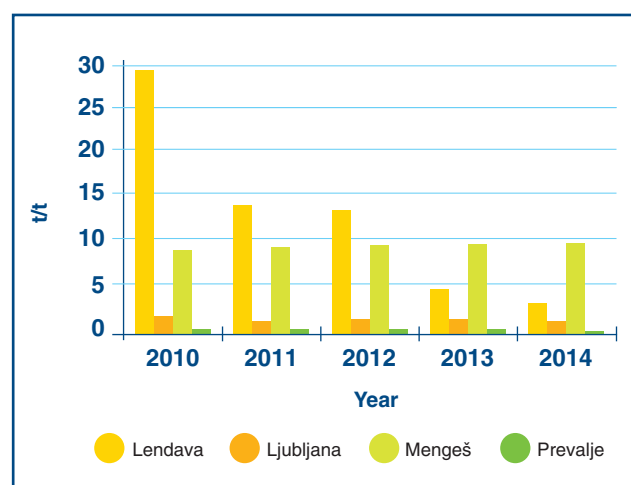
\* A correction, as waste was removed on the site and was not reported.

\*\* As recommended by Novartis, sewage sludge from the Lendava Wastewater Treatment Plant is added to other Lendava site waste.

Graph 6: Volume of waste per tonne of product – efficiency



Graph 7: Volume of waste per tonne of product – efficiency/disregarding mycelium waste



## 2.5.2 Disposal of hazardous waste<sup>48</sup>

Increasing production outputs and changes in the product range towards technologically more advanced products manufactured at the Mengeš site in smaller quantities by using complex techniques also result in increased absolute quantities of hazardous waste and quantities per unit

of product. We are limiting this growth by implementing environmentally advanced manufacturing solutions and measures to reduce the volume of waste of this type.

At the Mengeš site, non-halogenated waste solvents, being extremely pure and having a high calorific potential, account for 85 to 95% of total hazardous waste. The mixtures of halogenated waste solvents account for only 2 to 5% of total hazardous waste in Mengeš. By means of co-incineration with natural gas, 25 to 30% of the annual quantity of non-halogenated solvents is removed (no transport required, lower fuel consumption and CO<sub>2</sub> emissions). The energy obtained is utilized for manufacturing purposes to prepare industrial 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

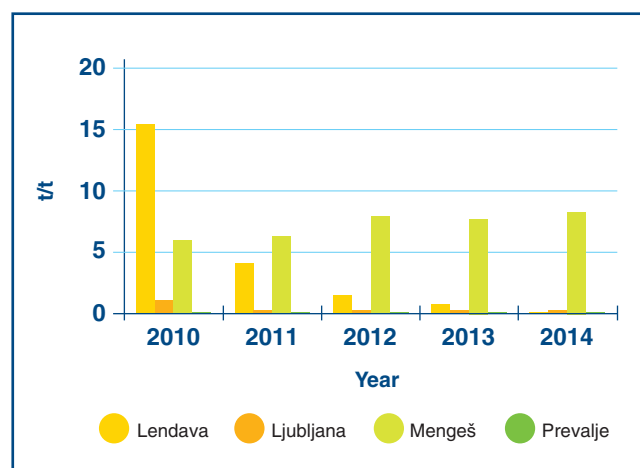
it impossible to reduce their volume. Since 2011, however, we have performed intensive segregation of the waste packaging of hazardous substances (also in case a hazardous substance is only present in traces) which we release for incineration with energy recovery.

In 2014 we considerably reduced volumes of hazardous waste at the Prevalje site by various measures. Reducing hazardous waste at the Lendava site was due to the result by the accredited laboratory showing that slag from the incinerator does not have hazardous properties. Waste was therefore diverted to non-hazardous waste.

<sup>48</sup> GRI Indicator G4-EN23 and RC KPI 5

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

| Year | Unit | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) |
|------|------|---------|-----------|--------|----------|-------------|
| 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       |
| 2014 | t    | 6       | 747       | 4,136  | 89       | 4,978       |

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

### 2.5.3 Disposal of non-hazardous waste<sup>49</sup>

Nearly 86% of total Lek waste volume is non-hazardous waste. At the Mengeš site, the biologically degradable waste generated by the manufacture of fennel and purple coneflower (*Echinacea*) juices is directed to a nearby biogas plant. Similarly, we direct the mycelium waste generated at the Lendava site, to a certified contractor biogas plant.

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

considerably compared to 2011. Municipal waste accounted for a mere 1%, whereas the share of waste packaging (paper, plastics, wood, metal, glass) amounted to just above 8%. Due to mycelium waste, biodegradable industrial waste accounted for as much as 74% of total waste or 87% of all non-hazardous waste across Lek in 2014.

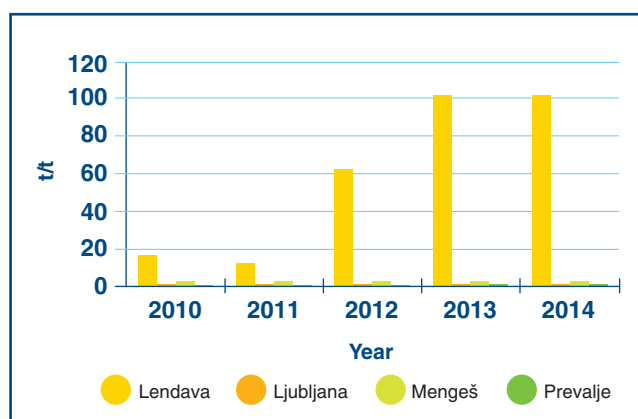
Municipal waste is disposed of, while waste packaging is mainly recycled (through the SLOPAK system), and the same applies to construction waste. Biodegradable waste is used for the manufacture of biogas, and other non-hazardous wastes are disposed of by certified companies by means of incineration.

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

| Year | Unit | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) | Lek (non-hazardous waste recyclable packaging not included)* |
|------|------|---------|-----------|--------|----------|-------------|--|
| 2010 | t    | 3,316*  | 1,322     | 921    | 324      | 5,883*      | 4,618*   |
| 2011 | t    | 2,767*  | 1,388     | 975    | 362      | 5,492*      | 3,933*   |
| 2012 | t    | 13,353* | 1,637     | 793    | 430      | 16,213*     | 14,393*  |
| 2013 | t    | 24,476* | 1,655     | 815    | 483      | 27,430*     | 25,493*  |
| 2014 | t    | 26,141  | 1,991     | 1,010  | 547      | 29,689      | 27,411   |

\* Data differs from that reported in the Sustainability Report 2013, as, on Novartis' recommendation, sewage sludge from the Lendava Wastewater Treatment Plant is added to other Lendava site waste.

**Graph 9: Non-hazardous waste volumes per tonne of product – efficiency**



*Strict waste segregation in laboratories*

## 2.6 Air emissions<sup>50</sup>



### 2.6.1 Abatement of air emission

We systematically measure and abate air emissions. We separately monitor greenhouse emissions and emissions from immobile devices, VOC and dust emissions being of key importance. Emission metering points are established on individual manufacturing devices and lines where the presence of emissions of VOCs, dust particles and other substances is expected in the exhaust air. 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>.

Lek, a Sandoz company, maintains its compliance with the limit value for total dust, amounting to 150 mg/m<sup>3</sup> and with the limit value for the mass flow of total gas in excess of 0.2 kg/h, which amounts to 20 mg/m<sup>3</sup>.

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

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

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

<sup>50</sup> EMAS Core Indicator, GRI Indicators G4-EN21, GRI G4-DMA, RC KPI 7, RC KPI 10



### 2.6.3 Sulphur dioxide (SO<sub>2</sub>)<sup>51</sup>

The volumes of SO<sub>2</sub> emissions at our sites have always been low, and were mainly generated by the devices for the thermal treatment of volatile organic compounds. In 2014 we recorded an increase in emissions as a result of occasional fluctuations in incineration of waste containing sulphur, mainly due to the inhomogeneity of the waste, primarily heavily polluted waste

waters and waste organic solvents. Despite the increase, such emissions were below limit values in 2014. The content of sulphur in natural gas is practically non-existent, as also confirmed by a supplier's statement.

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.

**Table 14: Sulphur dioxide emissions (SO<sub>2</sub>)<sup>52</sup>**

| Year | Unit | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) | Efficiency (Lek) (kg SO <sub>2</sub> /t product) |
|------|------|---------|-----------|--------|----------|-------------|--|
| 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      | 0.000  |
| 2013 | t    | 0.00    | 0.0004    | 0.0029 | 0,06     | 0.009       | 0.002  |
| 2014 | t    | 0.13    | 0.00      | 0.004  | 0.0105   | 0.145       | 0.031  |

### 2.6.4 Nitrogen oxides (NO<sub>x</sub>)<sup>53</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.

The total volume of these emissions increased by 48%, however it remains below statutory values and within the variability of the measurement process itself. A decline in nitrogen oxide emissions was recorded at the Ljubljana site, whereas at the Mengeš, Lendava and Prevalje sites a level similar to that in the previous year was maintained.

**Table 15: Emissions of nitrogen oxide (NO<sub>x</sub>)<sup>54</sup>**

| Year | Unit | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) | Efficiency (Lek) (t NO <sub>x</sub> /t product) |
|------|------|---------|-----------|--------|----------|-------------|---|
| 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   |
| 2014 | t    | 14.48   | 0.86      | 16.36  | 1.45     | 33.15       | 0.007   |

### 2.6.5 CO<sub>2</sub> and other greenhouse gasses<sup>55</sup>

The sources of direct CO<sub>2</sub> emissions (GHG1) at our sites remain as follows: burning of fuels and the incineration/treatment of flammable organic substances, production processes (e.g. fermentation) and the use of company cars.

Direct emission (GHG1)<sup>56</sup> data reported also includes:

- dinitrogen oxide (N<sub>2</sub>O) in CO<sub>2</sub> equivalents,<sup>57</sup>
- fluorinated hydrocarbons (hydrofluorocarbons – HFC) in CO<sub>2</sub> equivalents<sup>58</sup> and

- other greenhouse gasses (methane and others) in CO<sub>2</sub> equivalents<sup>59</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.

<sup>51</sup> EMAS Core Indicator, RC KPI 8, GRI Indicator G4-EN21 | <sup>52</sup> EMAS Core Indicator, RC KPI 7, GRI Indicator G4-EN21 | <sup>53</sup> EMAS Core Indicator, RC KPI 8, GRI Indicator G4-EN21 | <sup>54</sup> EMAS Core Indicator, RC KPI 7, GRI Indicator G4-EN21 | <sup>55</sup> GRI Indicators G4-EN15, G4-EN16, G4-EN19 | <sup>56</sup> RC KPI 10

<sup>57</sup> RC KPI 11 | <sup>58</sup> RC KPI 12 | <sup>59</sup> RC KPI 13

## Green roof on the new building in Mengeš

Before the end of the year we completely renovated the main entrance at our Mengeš site, together with the reception area, the classroom for new hires and bicycle shed. For the construction of the new complex, we used mainly wood. A special feature of the new building is its green roof which does not have a significant impact on reducing the building's energy requirements, however it has several favourable effects. Due to its location on a busy road it exerts a positive impact on reducing CO<sub>2</sub> emissions and other air pollutants (dust). The impact of the green roof with its pleasant shade will be significant particularly in the summer months with high outdoor temperatures.

The green roof in Mengeš is, beside the green roof above our canteen in Ljubljana the second construction project that reflects the sustainability of the company and outlines environmental, economic and sociological aspects.



Green roof on the newly renovated main entrance at the Mengeš site

**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 | 2010 | t CO <sub>2</sub> | 12,071  | 3,005     | 14,353 | 1,955    | 31,384      | 9.6  |
|      | 2011 | t CO <sub>2</sub> | 11,839  | 3,699     | 15,135 | 1,999    | 32,672      | 8.6  |
|      | 2012 | t CO <sub>2</sub> | 10,801  | 2,928     | 13,484 | 1,821    | 29,034      | 7.6  |
|      | 2013 | t CO <sub>2</sub> | 10,774  | 2,792     | 13,966 | 2,053    | 29,585      | 7.6  |
|      | 2014 | t CO <sub>2</sub> | 10,691  | 3,310     | 14,139 | 2,068    | 30,208      | 6.4  |
| GHG2 | 2010 | t CO <sub>2</sub> | 15,870  | 33,218    | 11,879 | 2,407    | 63,374      | 19.3   |
|      | 2011 | t CO <sub>2</sub> | 16,023  | 35,117    | 11,938 | 2,482    | 65,560      | 17.3   |
|      | 2012 | t CO <sub>2</sub> | 12,438  | 27,793    | 3,870  | 816      | 44,917      | 11.8   |
|      | 2013 | t CO <sub>2</sub> | 1,575** | 24,242**  | 970**  | 214**    | 27,001**    | 6.9  |
|      | 2014 | t CO <sub>2</sub> | 1,658   | 25,431    | 976    | 222      | 28,286      | 6.0  |

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

\*\* Quantities for 2013 were adjusted due to the change in the conversion factor introduced by the electricity supplier.

Due to the change in the conversion factor for the calculation of CO<sub>2</sub> from supplied electricity, total direct and indirect greenhouse gas emissions were reduced in 2012 and 2013 and increased in 2014. 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.

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.

At the Mengeš site, the main source of direct CO<sub>2</sub> emissions (GHG1) is natural gas combustion (>90%) in the burning

devices. One of the contributory factors is also the manufacture of technologically advanced products of higher energy complexity.

The Lendava and Mengeš sites participate in trading with CO<sub>2</sub> emission vouchers. According to the law, we have an obligation to report the emission to the Ministry of the Environment and Spatial Planning, and to pay an environmental fee for all four sites.

## 2.6.6 Volatile organic compounds (VOC)<sup>60</sup>

Novartis' recommendations on the use of alternative solvents in production are implemented through a systematic introduction of innovations in technological manufacture processes, where halogenated solvents are replaced with non-halogenated ones. In 2014, total VOC emissions saw a decrease of 21%. It decreased most significantly at the

Ljubljana site, by more than 50%, while the efficiency per tonne of product improved significantly along with production growth.

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

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

| Year | Unit | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) | Efficiency (Lek) (t VOC/t product) |
|------|------|---------|-----------|--------|----------|-------------|------------------------------------|
| 2010 | t    | 25      | 58        | 170    | 5,5      | 258         | 0.079*                             |
| 2011 | t    | 24      | 36        | 146    | 6,2      | 212         | 0.056*                             |
| 2012 | t    | 23      | 43        | 71     | 5,4      | 142         | 0.038*                             |
| 2013 | t    | 24      | 28        | 68     | 5,8      | 126         | 0.032*                             |
| 2014 | t    | 23      | 13        | 57     | 7,2      | 100         | 0.021                              |

\* Data differs from that reported in the Sustainability Report 2013 as result of changed data on production output for the Ljubljana site.

## 2.7 Water releases<sup>61</sup>

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

Only non-contact cooling water is released into the cooling sewage system. Unpolluted cooling water is discharged directly into a surface water course whenever possible. Roof precipitation wastewater is discharged into surface water courses directly or indirectly.

Reports on the Monitoring of Industrial Wastewaters Discharge for 2014 show that, with the exception of exceeding the Zn parameter in three out of the eight measurements at the Lendava site, no excessive pollution was identified at any of the other sites. In 2014, the manufacture of active pharmaceutical ingredients and related activities were carried out within the expected limits therefore we were not able to connect elevated concentrations with our operations. All the more so because we have so far not recorded any exceeding values during the monitoring implemented in 2015.

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 used. In 2014, their consumption increased slightly, as did the consumption of industrial water (in total by 7%).

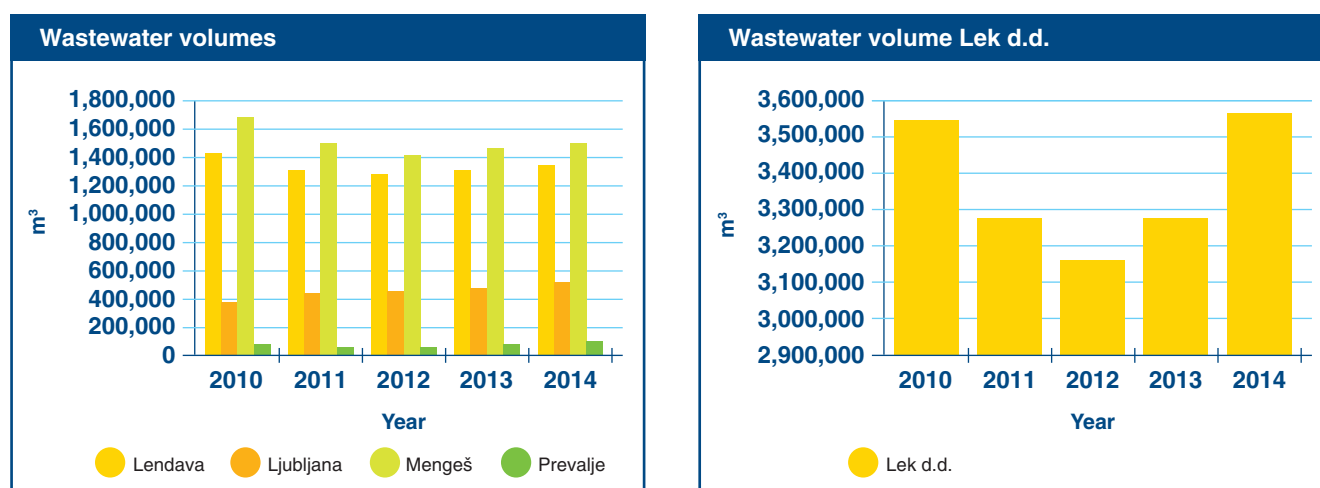
After use, unpolluted waste cooling waters are discharged into the surface water course, a procedure for which environmental permits have been obtained.

### 2.7.1 Waste waters

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



Graph 10: Wastewater volumes in cubic meters

Table 18: Wastewater volumes by discharge quality and destination<sup>62</sup>

|                                    | Year | Unit      | Lendava                             | Ljubljana                           | Mengeš                              | Prevalje           | Lek (Total) |
|------------------------------------|------|-----------|-------------------------------------|-------------------------------------|-------------------------------------|--------------------|-------------|
| Use of cooling water - unpolluted  |      |           |                                     |                                     |                                     |                    |             |
|                                    | 2010 | in 000 m³ | 1,260                               | 55                                  | 1,408                               | 11                 | 2,734       |
|                                    | 2011 | in 000 m³ | 1,170                               | 34                                  | 1,243                               | 10                 | 2,457       |
|                                    | 2012 | in 000 m³ | 1,109                               | 18                                  | 1,138                               | 5                  | 2,270       |
|                                    | 2013 | in 000 m³ | 1,129                               | 35                                  | 1,156                               | 5                  | 2,325       |
|                                    | 2014 | in 000 m³ | 1,212                               | 75                                  | 1,278                               | 8                  | 2,573       |
| 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 |      |           |                                     |                                     |                                     |                    |             |
|                                    | 2010 | in 000 m³ | 167                                 | 341                                 | 271                                 | 28                 | 807         |
|                                    | 2011 | in 000 m³ | 163                                 | 381                                 | 259                                 | 25                 | 828         |
|                                    | 2012 | in 000 m³ | 163                                 | 434                                 | 271                                 | 30                 | 898         |
|                                    | 2013 | in 000 m³ | 187                                 | 442                                 | 296                                 | 34                 | 959         |
|                                    | 2014 | in 000 m³ | 168                                 | 494                                 | 279                                 | 34                 | 975         |
| Discharge                          |      |           | into sewage system cleaning at WWTP | into sewage system cleaning at WWTP | into sewage system cleaning at WWTP | into sewage system |             |
|                                    |      |           |                                     |                                     |                                     |                    |             |
|                                    |      |           |                                     |                                     |                                     |                    |             |
|                                    |      |           |                                     |                                     |                                     |                    |             |
|                                    |      |           |                                     |                                     |                                     |                    |             |
|                                    |      |           |                                     |                                     |                                     |                    |             |

## 2.7.2 Phosphorus and nitrogen compounds, chemical oxygen demand

Nitrogen compound emissions mostly result from the fermentation production. The Mengeš site accounts for the largest share of these emissions, also at the expense of the 5-NOK production, followed by Lendava and Ljubljana, and, at a negligible level, the Prevalje site, as demonstrated in the graphic presentation of the emission trends by site. In 2014, the total volume of nitrogen compound emissions increased by 10%, however, it was still 21% lower than in 2010.

The Mengeš site is also the major generator of phosphorus compounds, their source being residual inorganic substances. As the annual amounts of phosphorus and nitrogen compounds are reported after treatment in the wastewater treatment plant, they largely depend on the efficiency of the wastewater treatment.

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

<sup>62</sup> EMAS Core Indicator, GRI Indicator G4-EN22

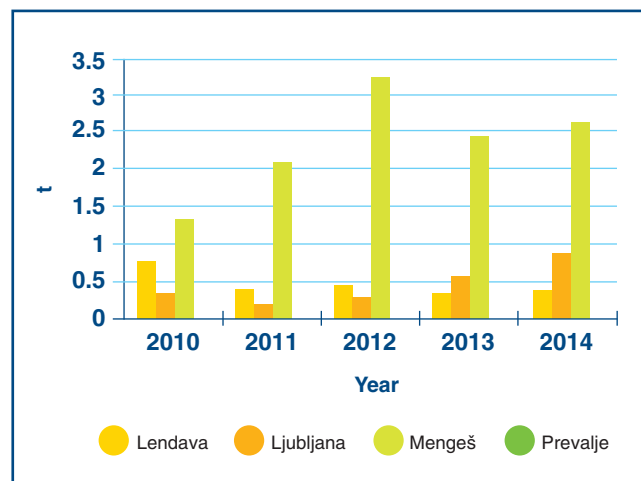
point of discharge of waste cooling waters into the sewage system. In 2014, we recorded a slight decrease in the chemical oxygen demand parameter (1%) on account of the Mengeš site. The Prevalje and Ljubljana sites together contribute to less than 3% of total wastewater pollution with organic impurities.

Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute parameters for the calculation of the environmental fee.

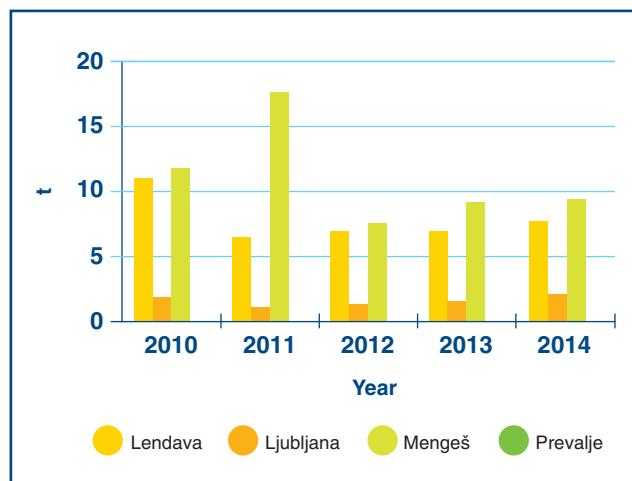
The highest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds each represent about 10% of the pollution.

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

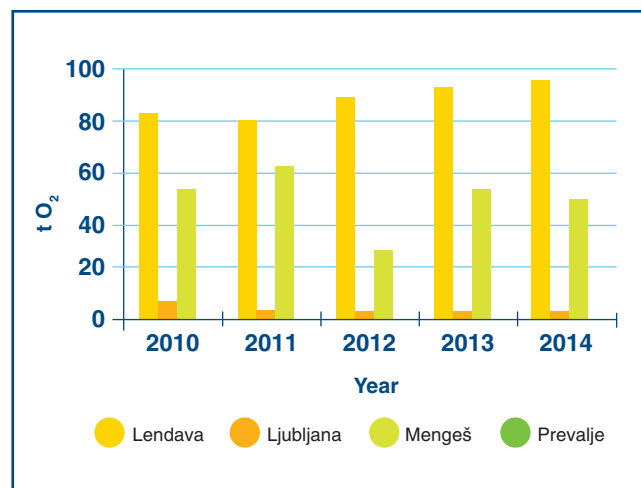
**Graph 11: Emissions of phosphorus compounds in wastewater<sup>63</sup>**



**Graph 12: Emissions of nitrogen compounds in wastewater<sup>64</sup>**



**Graph 13: Chemical oxygen demand (in tonnes O<sub>2</sub>)<sup>65</sup>**



Through increasing knowledge of chemical substances Lek started – even before the respective Slovenian and EU laws were implemented – to research the impact of active pharmaceutical ingredients potentially entering wastewaters as a result of our operations. From there, they pass through wastewater treatment plants into surface waters. However, 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.<sup>66</sup>

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

## 2.8 Other environmental impact

### 2.8.1 Odour

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

The monitoring of biofilters' operation and waste air loads is carried out by the National laboratory for health, environment and food from Maribor.

### 2.8.2 Soil

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

We consistently fulfil the requirements with regard to hazardous substance storage and transport, which are the major soil pollutants. We regularly check the leak-proof status of

sewage systems, particularly those carrying industrial wastewater. This is of particular importance at the Mengeš and Ljubljana sites which are situated in a water protection area. Furthermore, we introduce preventive measures in the production processes and the construction of facilities.

At the end of 2013, provisions from the European Industrial Emissions Directive (IED) from 2010 were transposed into the Slovenian legislation. This decision, among other things, introduces a requirement for operational monitoring of soil contamination at least once every 10 years, as well as remediation and return to its original state in case of an identified impact on the quality of soil after the termination of the industrial plant. Conditions and criteria for preparation of the report based on monitoring at the national level 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>                               | 36,878   | 102,822 | 20,140    | 1,946    | 161,786   |
| Building surfaces – aerial view (in m <sup>2</sup> )           | 37,087.5 | 15,703  | 39,930    | 7,324    | 100,044.5 |
| Asphalt surface – roads, courtyards (in m <sup>2</sup> )       | 43,608   | 18,138  | 46,269    | 9,257    | 117,272   |
| Total site surface area with parking lots (in m <sup>2</sup> ) | 129,742  | 136,663 | 121,500   | 18,527   | 406,432   |
| Production site surface area/product (in m <sup>2</sup> /t)    | 248      | 529     | 48        | 13       | 87        |

### 2.8.3 Noise

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 order to control any excessive environmental noise pollution, we perform regular monitoring and analyses. None of the measurement results indicates any noise overload at any of our sites during the day, evening and night time. An exception in 2014 was the Prevalje site, where excessive noise occurred during regular operation monitoring in the night time caused by an atmospheric emission control device (Regenerative Thermal Oxidizer - RTO). Remedial works are already underway.

In 2014, 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. Our policy and practice is to consistently adhere to statutory waste and industrial water

management requirements and take proactive measures. We thereby strive to mitigate any impact on the quality of the environment and consequently on the biodiversity of the areas surrounding our production sites. Lek facilities are located within industrial zones where there are no major environmentally critical habitat types or protected vegetation.

### 2.8.5 Light pollution

The existing legislative regulation on light pollution 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 had 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>67</sup> EMAS Core Indicator | <sup>68</sup> GRI Indicator G4-EN12, G4-DMA



## 2.9 Safety

### 2.9.1 Fire safety

Fire drills with intervention units that provide emergency assistance, were carried out at all our sites, along with evacuation drills.

The number of operative voluntary fire fighters has increased as 13 associates from the Prevalje and Mengeš site passed an advanced firefighting course and joined the operative Lek's volunteer industrial firefighting team. 14 fire fighters passed a basic course for carrying a self-contained breathing apparatus, 9 fire fighters took up a refresher course for carrying

a self-contained breathing apparatus and 4 fire fighters completed the "Interior Fire Extinguishing - Module A" training. The Ljubljana and Mengeš site organized a 71-hour course for First Interventions which was attended by 14 operational fire fighters.

There were no major interventions in 2014. In November, oil overheating occurred at the Prevalje site resulting in the manufacturing area being filled with smoke. Lek's volunteer industrial firefighting team and the fire brigade from Ravne in Carinthia intervened. The operation was successful.

## Commitment to safety at work

### Evacuation drill at Lek's production in Ljubljana

The evacuation drill took place on 25 July in the production facility at the Ljubljana site, in cooperation with the Ljubljana Fire Brigade. Lek's professional and voluntary firemen participated in the drill.



*Around 250 employees and external contractor were well prepared for the evacuation in case of emergency and exited the building in the shortest possible time.*

For the first time it was conducted so that all the employees and contractors were evacuated from the production facility. Normally, this kind of drill includes only individual buildings or departments.

At the time of the drill there were around 250 employees and external contractors in the two-storey facility. They exited at the marked escape routes and fire stairs and gathered at the designated assembly points.

**The purpose of the evacuation drill was:**

- to teach the participants about appropriate procedures and thereby assure maximum safety in the case of a real unexpected hazardous event,
- to check the functionality of all parts of Lek's safety system and the adequacy of procedures and instructions upon such a critical event,
- to check whether employees have all the required knowledge for proper action in the case of real danger.

The drill has shown that employees at Lek's production plant are well prepared for evacuation in case of emergency. It all went according to plan, and all employees left the building in the shortest possible time. The Ljubljana Fire Brigade arrived at the drill location in 7 minutes.

Evacuation drills are performed regularly in accordance with Slovenian legislation and also with Novartis internal rules as safe evacuation in the case of an emergency is a part of our commitment to safety at the workplace. The evacuation drill was prepared in accordance with Novartis internal rules about the readiness of employees in the event of an emergency and in line with Slovenian legislation.

## 2.9.2 Biological safety

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

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

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. Persons responsible for ensuring safety of work with GMOs are also appointed.

At the Mengeš site, we registered a new closed system for handling GMOs of Risk Group 1 in 2014. The purpose of the closed system is to test biological activity of biologicals for human use on a laboratory scale.

Lek, a Sandoz company, also has a 13-member Biological Safety Committee. Its tasks include checking the accuracy of biological agents' classification into risk groups and, consequently, the adequacy of proposed containment measures, and approving individual projects in accordance with the risk assessment.

Biological 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 biologics, making them accessible to the public by offering quality, safety and efficacy comparable to reference products, yet at a more affordable price. All Sandoz biosimilar drugs are also available to patients in Slovenia.

## 2.9.3 Providing storage and distribution safety

### 2.9.3.1 Storage

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

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

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

From our production sites, 7,164 consignments of finished products and APIs were dispatched to 100 countries in 2014. 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 21,218 tonnes (19,421 tonnes in 2013).

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. In 2014, we carried out transport validation for all types of transport (road, air, sea) in both critical periods (winter, summer) and on transport routes, selected on the basis of risk analyses.

In the organization of international road transport, we continued with the implementation of the "Control Tower" business model organized by DHL Belgium. In the organization of air transport, we successfully upgraded the cooperation with our partner DHL Global Forwarding. We focused primarily on setting up a common procedure for the implementation of activities in the quality of the executed transport service in line with new GDP guidelines.

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

In the area of sea transport we carried out a regular annual tender on a local basis. With this type of transportation we replaced air transportation for larger volumes of goods in 2014 and generated savings.

## 2.9.4 Chemical safety

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

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

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

## Lek HSE systems

### HSE organization, human resources and training

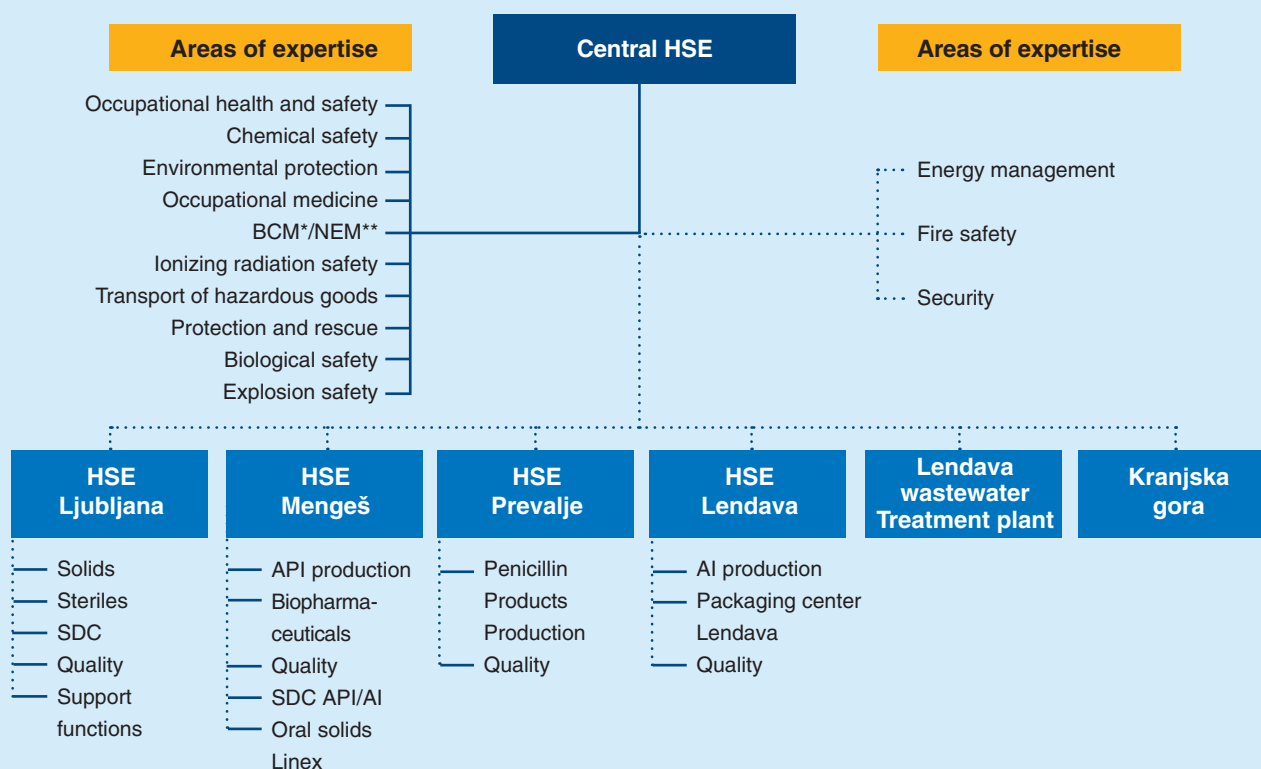
#### HSE function

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

#### HSE department

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

Figure 1: HSE organization scheme



By organizing appropriate training programs, we provide our employees with a level of HSE qualification sufficient for them to manage HSE aspects of their work. In cooperation with unit heads, the HSE unit prepares annual training plans and selects training topics for inclusion in the Training and Education Catalogue. Training programs are organized into three clusters: onboarding, continuing education, and training for promotion. We 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 first glance, to positively impact employee well-being, save valuable time and natural resources, and contribute to safety and quality.



HSE Team

\* BCM: Business Continuity Management

\*\* NEM: Novartis Emergency Management



## HSE Workshop

### Openly about HSE improvements

At a workshop that was held in February in Ljubljana, the HSE representatives from all sites of Lek, Sandoz company, presented their work and current issues in individual areas as well as the results of a global survey among the associates.

Progress is only possible with a sound knowledge of the situation, obstacles and opportunities on the journey to improvements. Preparing a strategy for achieving Novartis', Sandoz' and Lek's goals in the field of health, safety and environment opened a discussion on how to improve results. They looked deeper into issues and good practices of individual sites and the results on individual incident research. A great deal of attention was devoted to the analysis of incidents that occurred last year, root causes of occurrence of occupational accidents and

incidents in the current year. The participants were also updated on the 'Make the Safe Choice' campaign promoting safe practices in all Sandoz units and carefully listened to how to effectively create balance between professional and private goals.



*Workshop on improvements in the field of health, safety and environment*

## Lek HSE systems

### Environmental impact and risk assessment

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

When planning an intervention and its potential impact on the environment, an impact and stress admissibility assessment is made. The assessment is carried out in accordance with legal environmental guidelines, data from public sources, monitoring and studies carried out by authorized institutions, the current environment status and pollution, anticipated emissions resulting from the planned activities, and applicable environmental regulations. Impacts of the 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. At the beginning of 2015 we obtained an environmental permit for a minor environmental risk plant.

### Safety policy

Lek's safety policy is an integral part of our business policy with an established system for managing major accidents

involving hazardous substances in order to prevent any unforeseen events, and timely and effective emergency response. The [Safety policy](#) of the Mengeš facility that is classified as a minor environmental risk plant with regard to the type and quantity of hazardous substances, obliges us to do everything necessary to avoid major accidents involving hazardous substances.

<http://www.lek.si/media/storage/cms/attachments/2015/01/27/16/26/01/Varnostna-politika.pdf>

### Measures for risk prevention and mitigation

Risk assessment is carried out using various methods. The choice of an appropriate method depends on its suitability for the area subject to assessment and on the qualification level of the associates involved.

**Risk assessment is made for the following:**

- Risk Portfolio,
- Workplace Health Risk Assessment – WHRA,
- Capital expenditure projects: with priority use of the Zurich Hazard Analysis (ZHA) or the Hazard and Operability Study (HAZOP Study) in the project qualification phase,
- Facilities and production lines: the Zurich Hazard Analysis (ZHA) or the Process Risk Assessment (PRORA),
- 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 2014, 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.

## Lek HSE systems

### HSE aspects and system of achievement monitoring

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

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

Based on the findings in the Registry of HSE Aspects, corrective measures as well as business objectives and programs are defined. Revisions of the Registry of HSE Aspects are carried out at least once a year or in the case of major change to the internal or external environment. It serves as a basis for the preparation of the Risk Portfolio, business and activity plans and programs, and for the setting of personal goals for responsible persons.

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

In 2014, external auditing of the company's compliance with ISO 14001:2004 and BS OHSAS 18001:2007 was carried out and an audit according to the EMAS Directive.

Internal audits of the HSE service planned on an annual basis were performed. Concurrently, internal audits of the company's compliance with ISO 14001:2004 and OHSAS 18001:2007 requirements were carried out. Internal Novartis and Sandoz audits are more extensive, covering all areas of HSE on the part of the site being audited: environmental protection, occupational safety and health, chemical safety, fire safety, biological safety, explosion safety, 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. In 2014, we had Sandoz' HSE audit at Lendava and Novartis' HSE audit at Mengeš. The results of internal audits performed in 2014 showed the high level of the company's compliance with the statutory requirements as well as internal and external standards in all areas. Corrective action was taken on an ongoing basis.

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

In 2014 we met the basic EMAS requirement for verification of compliance with the provisions of the EMAS Directive. From the environmental verifier we obtained a statement that we operate in compliance with applicable legal requirements with regard to the environment and furthermore, that the data and information from the environmental statement provide a reliable, credible and true picture of the organization's operations at all Lek sites. In line with Novartis and Sandoz policy, Lek is committed to continuous improvement of environmental performance in compliance with local and national programs.

### Reporting methodology

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

HSE data is collected, recorded, verified and confirmed within a uniform Novartis reporting system in the Data Management System (DMS), whereby their transparency and comparability is ensured. Reporting frequency depends on the relevance of the reported data (monthly, quarterly or annually). Collected data serves as a basis for statutory reporting to ministries and other interested stakeholders, whereas once a year it is subject to review within the environmental management review performed by the organization's top management according to the EN ISO 14001:2004.

## 3. Labour

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

Lek's human resources policy places people at the heart of the entire business operation ("It's all about people"), along with three principles: "Cooperation. Development. Excellence." 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.

### The Minister of Labour, Family, Social Affairs and Equal Opportunities visited Lek

#### For more substantial cooperation

The themes of Lek's Management and the Minister of Labour, Family, Social Affairs and Equal Opportunities Dr Anja Kopač Mrak meeting were Lek's talent development, associated recognizing of human resources and cooperation with educational and research institutions. According to the Minister's opinion, the efforts of state institutions should be directed towards cooperation between academia and the economic sphere.

The competitive advantage of Lek, a Sandoz company, is the knowledge of all employees. In this knowledge and the high proportion of educated employees she sees the opportunity for Slovenia that should reflect in stimulating business and the tax environment. Creating new jobs and transfer of knowledge into business are common goals of the state and Lek, therefore the Minister called for more substantive mutual cooperation.



Guests from the Ministry of Labour, Family, Social Affairs and Equal Opportunities (from right to left): Peter Pogačar, Director General of the Directorate for Employment Relationships and Rights Deriving from Employment, Minister Dr Anja Kopač Mrak, Dejan Levanič, State Secretary and Petra Levstek, Head of Cabinet.

### 3.2 Employment

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

At the end of 2014, the proportion of women in Lek's total workforce was 45%, a level identical to that in the previous year. At year end, 91% of all employees (91.4% in 2013), worked on a full time permanent basis, and 6.7% were fixed-term employees (8.6% in 2013). 2.3% of all employees worked on a part-time basis, a level nearly identical to that in the previous year (2.2% in 2013).

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

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

#### 3.2.3 Coverage of the organization's defined benefit pension 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 2014, 85.57% (84.98% in 2013) of the workforce was included in the scheme. The premium is calculated on the basis of 5.844% of the employee's gross salary.

#### 3.2.4 Procedures for local hiring and proportion of senior management hired from the local community<sup>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%, the same as in the previous year.

### 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                | 110  | 115   | 225   |
| Number of employees returning to work after parental leave     | 110  | 111   | 221   |
| Percentage of employees returning to work after parental leave | 100% | 96.5% | 98.3% |

## 3.3 Occupational health and safety

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

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

In 2014 we recorded injuries of all associates (Lek's own employees and those employed through agencies). In previous years we evaluated the index only in cases when Lek's own associates were injured. We recorded 7 cases of workplace accidents requiring sickness absence and the 2014 LTIR rate amounted to 0.22. In one case, an associate sustained a serious injury resulting from an intervention in the working area of a drier during operation. The TRCR value in 2014 was 0.42 which means that there were in total 13 cases of

recorded injuries. All cases were investigated and effective corrective measures to prevent recurrence of such incidents were taken.

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

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

Among the primary causes of injuries in the first place is contact with the equipment/machinery (struck-by injury, tampering with a machine), followed by 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.

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

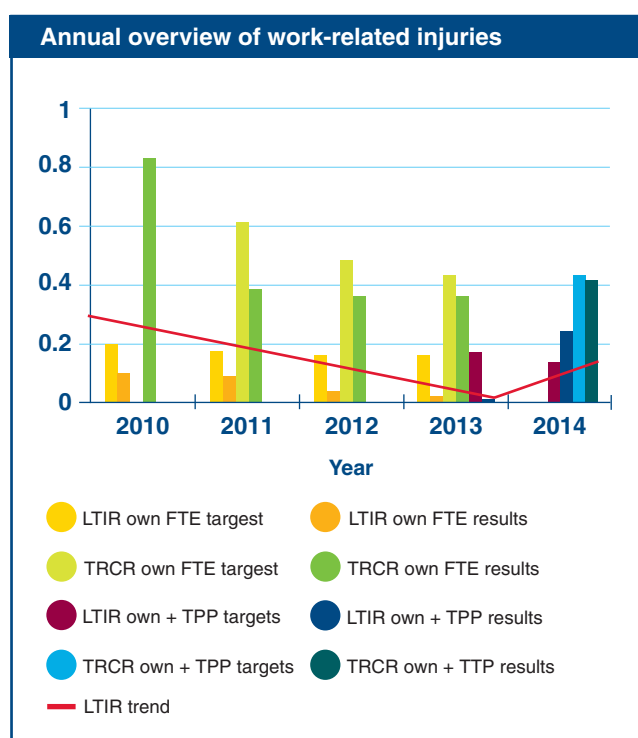
| Year | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) |
|------|---------|-----------|--------|----------|-------------|
| 2010 | 0.00    | 0.00      | 0.40   | 0.00     | 0.10        |
| 2011 | 0.52    | 0.00      | 0.00   | 0.00     | 0.05        |
| 2012 | 0.48    | 0.00      | 0.00   | 0.00     | 0.05        |
| 2013 | 0.00    | 0.00      | 0.17   | 0.00     | 0.04        |
| 2014 | 0.00    | 0.22      | 0.26   | 0.49     | 0.22        |

<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

Table 21: TRCR Index (Total Recordable Case Rate)

| Year | Lendava | Ljubljana | Mengeš | Prevalje | Lek (Total) |
|------|---------|-----------|--------|----------|-------------|
| 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        |
| 2014 | 0.69    | 0.43      | 0.26   | 0.49     | 0.42        |

Graph 14: Annual overview of work-related injuries LTIR and TRCR 2010–2014

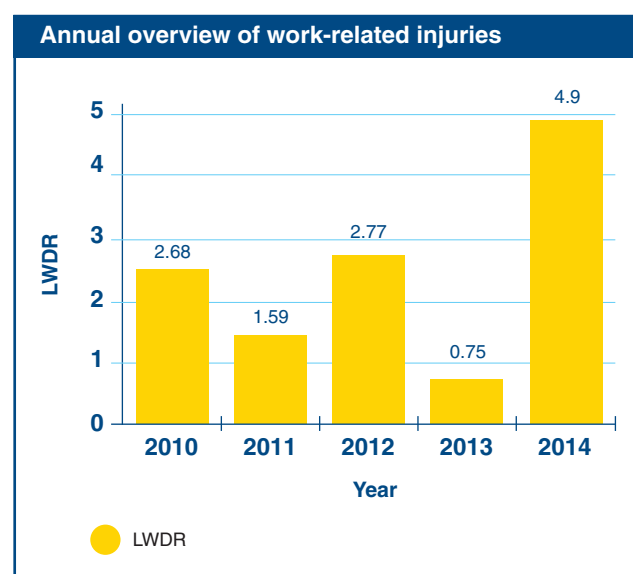


**LWDR – Lost Time Work-Day Rate** defines employee sickness absence due to work-related accidents.

It is calculated by using the following formula:  $LWDR = \text{number of lost days} \times 200,000 / \text{number of hours worked}$ .

For Lek d.d., the LWDR value for 2014 was 4.9. Compared with the previous year, it increased (0.75 in 2013) due to 7 cases of work-related injuries requiring sickness absence from work.

Graph 15: LWDR value (Lost Time Work-Day Rate) for Lek



### Incident rate (IR)

The incident rate for accidents with recorded sickness absence amounted to 1.3.

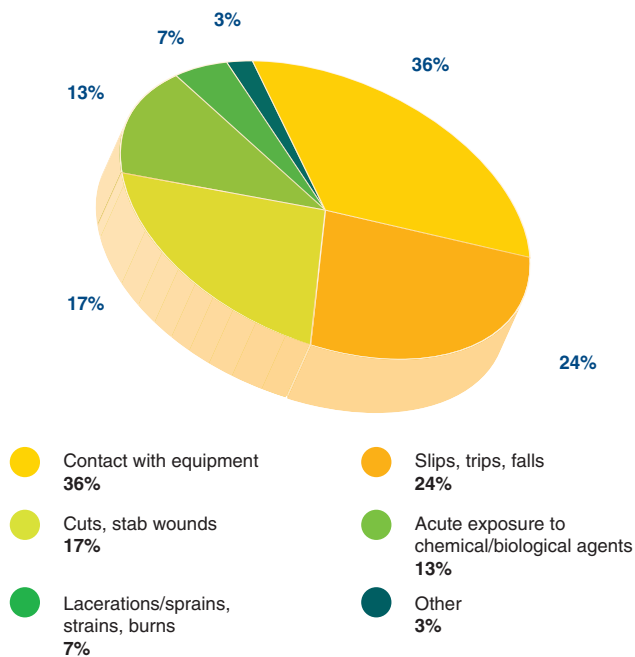
It is calculated using the following formula:

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

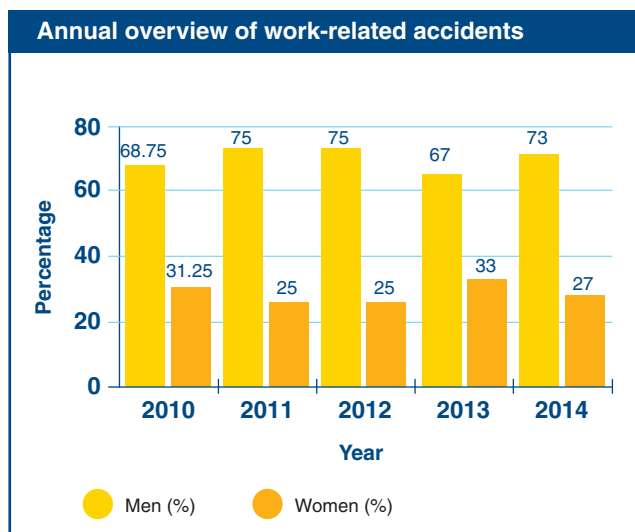
Great attention is paid to ensuring overall safety as this is the only way to continue the downward trend of work-related injuries.

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. 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 (>40) is high which can be attributed to intensified reporting and to the implementation of our guidelines to boost the safety culture, including employee activities to reduce the risk of accidents and other incidents; conduct of walkthrough inspections; safety meetings, and involvement of occupational medicine specialists in every workplace incident.

**Graph 16: Classification of causes of work-related incidents (LTIR and TRCR) for 2014**



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



### 3.3.3 Absenteeism<sup>79</sup>

The proportion of sickness absence was 3.8% recording a slight decrease compared to the previous year (2013: 3.97%). In men, the proportion was 2.96% and in women 4.65%. The rate is calculated on the basis of absence hours as follows: the number of lost working hours of an employee in the period is divided by the organizational unit's total number of working hours in the period.

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

In 2014, we recorded 10 injury cases among contracting providers which is more than in the previous years (2013: 4).

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>80</sup>

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

### 3.3.6 Occupational disease rate<sup>81</sup>

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

## Lek HSE systems

### Improving safety culture and health promotion

Enhancing safety culture is one of our key tasks. The health and safety at work board (Safety Board) ensures it stays at the core of the organization by regularly monitoring current events and taking initiatives for preventative activities. The support of the top management provides openness to such initiatives and confirms comprehensive involvement of the organization in reducing accidents.

Improved safety culture is reflected in continuous reduction in the number of work-related incidents. In 2014, we continued to disseminate information with regard to health and safety at work. We supported the analyses of incident and near-misses investigations by communicating causes and measures for prevention of occupational accidents in similar work environments. In units with increased risk we continued to carry out walkthrough inspections and safety meetings.

We have prepared a **program for the prevention of incidents and accidents and improvement of safety culture** and **selected**, in accordance with this program, over 80 employees to act as **safety promoters** at all Lek sites. The top management was actively involved in their selection and confirmation.

A **safety promoter** is employed in an organizational unit and dedicates 10 to 20% of his/her working time to safety, organizes walkthrough inspections, oversees the implementation of corrective measures in the unit, gathers information about near-misses, informs and reminds associates about safe conduct and behaviour and monitors safety indicators in his/her unit. All safety promoters at all sites are properly trained, as foreseen in the program.

In 2014, as we have done for a number of years, we again encouraged employees to embrace a more active and healthier lifestyle with the **Health promotion** programme and the Novartis initiative **Be Healthy**.

As a part of the health promotion programme we offered the associates preventative active recovery with special healthcare programmes, guided exercise and in a preventative vaccination program, e.g. against seasonal influenza and against tick-borne meningoencephalitis.

**In the field of health, safety and environment we carried out:**

- regular periodic training on health and safety at work and fire safety for the employees;
- regular training on establishing and maintaining the safety culture (Behaviour Based Safety – BBS) for new hires and managers;
- workshops on different areas of health and safety at work, such as industrial hygiene, incident investigations, process risks etc.;
- targeted education in the individual organizational units on health and safety at work, safety culture, chemical safety, fire safety and NEM (Novartis Emergency Management) as an integral part of the BCM (Business Continuity Management);



*Training of safety promoters in Ljubljana*

- tactical fire drills, in accordance with the risk portfolio, for checking the responsiveness of protection and rescue teams, their equipment and action in case of unforeseen events;
- evacuation drills with practical fire extinguishing training;
- regular annual training in first aid.

### Prevention of workplace accidents

By preventative behaviour we recognize and prevent inappropriate behaviour and hazardous situations. A rapid response reduces the severity of accidents and near-misses. On the basis of these basic guidelines we are improving the system of immediate reporting and in-depth analyses and include the relevant internal and external services, such as first-aid team, occupational medical doctors and others. We also strengthen preventative activities, including safety walkthrough inspections and meetings, counselling with regard to safety, analyses, communication and risk assessment.

### Six safety rules

On the basis of the analysis of incidents that occurred at Lek, we have established that the employee's safety largely depends on their hazardous behaviour, therefore we developed six basic safety rules.

## Basic safety rules

|  |  |   |  |   |   |
|--|--|---|--|---|---|
| <br><b>1.</b><br>Follow instructions and get trained. | <br><b>2.</b><br>Use proper tools / work equipment / personal protective equipment. | <br><b>3.</b><br>Ensure that energy has been isolated / prevent accidents. | <br><b>4.</b><br>Observe and correct unsafe conditions and at-risk behaviours. | <br><b>5.</b><br>Obtain an HSE permit before starting any work with an increased risk. | <br><b>6.</b><br>Safely on your way. |
| <br><small>a Sandoz company</small>                   | <br><small>a Sandoz company</small>   | <br><small>a Sandoz company</small>  | <br><small>a Sandoz company</small>   | <br><small>a Sandoz company</small>  | <br><small>a Sandoz company</small>  |



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

**MOVE** – increasing exercise.

**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** – knowing the values of key health indicators.

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

Workers who work in an improved working environment are healthier and more motivated. As a result, the following can be expected:

- ## Expected benefits
- Workers who work in an improved working environment are healthier and more motivated. As a result, the following can be expected:
- less absenteeism,
  - greater resistance of employees (the employees maintain and improve their health).
- satisfaction of employees,
  - education 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,
  - higher quality of products and services and
  - higher reputation of the organization.

## 16 weeks, 350 associates, countless new steps

Between 8 and 12 September we once again successfully carried out the Be Healthy Celebration Week. All Lek's sites participated in this global Be Healthy initiative and we all shared good practices across Novartis.

The Global Corporate Challenge, a health promotion program, is an international initiative calling on companies to encourage employees to embrace a healthy and active life. This time, 350 Lek associates participated in this program for 16 weeks, each of them received a pedometer for counting steps which were regularly recorded into a web or mobile application.



*The associates were spinning the health-wheel and carried out preventative activities.*

The associates, accompanied with the Olympians Petra Majdič and Žan Košir, took care of their health and well-being with a relaxing early morning workout. At a special workshop they learnt about balanced healthy diet. Checking key health indicators is a part of healthcare therefore Lek employees were also given an opportunity to check body mass index, blood pressure, intraocular pressure and blood sugar levels during the Be Healthy Celebration Week. The results of the preventative activities are positive and confirm their significant value. Two associates have successfully recovered after cancer had been detected at an early stage and having received early treatment. Based on the preventative examination, one associate successfully managed to take control of a severe disease with a help of specialist treatment. Measuring the ankle-brachial index resulted in two successful vascular



Lek's associates doing their morning exercise with Petra Majdič.

surgeries. By measuring intraocular pressure, 49 cases of marginal or elevated values were detected. Appropriate therapies and controls prevented permanent vision impairment in those associates at risk.

## 3.4 Training and education

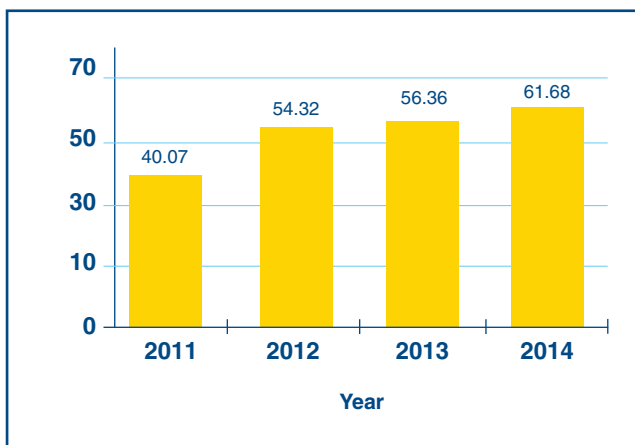
### 3.4.1 Average hours of training per year per employee by employee category<sup>83</sup>

In 2014 we once again increased the scope of training provided to our employees. Compared to the previous year, the average number of hours training per employee increased by nearly 9%. The average amount of time given to training per employee was 5.07 days per year, or 7.71 days if compulsory on-the-job-training is included.

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

| Year                     | 2011  | 2102  | 2013  | 2014  |
|--------------------------|-------|-------|-------|-------|
| Number of hours/employee | 40.07 | 54.32 | 56.36 | 61.68 |

**Graph 18: Average hours of training per year per employee**



Also in 2014 we provided employees the opportunity of part-time studies upgrading the level of their formal education. In total, 4.28% of the workforce was involved in part-time

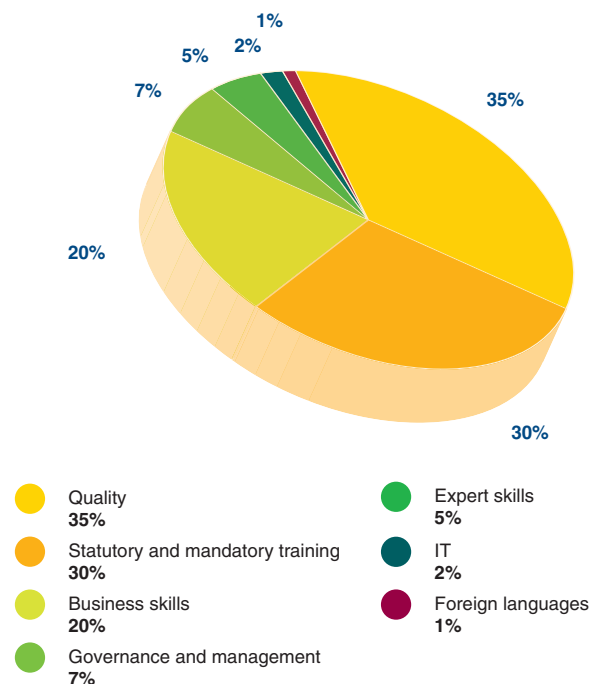
studies, which was nearly at the same level as in the previous year. With the company's support, 66 employees were involved in undergraduate studies, and 64 in post-graduate studies, mainly in biotechnology, biomedicine and chemistry.

### 3.4.2 Training by area

The largest number of training hours was dedicated to three areas: statutory and mandatory training (28%), business skills (22%) and quality (18%).

The highest participation rate was recorded in quality (35%), statutory and mandatory training (30%) and business skills (20%).

**Graph 19: Training in 2014 by area – participation rate**



<sup>83</sup> GRI Indicator G4-LA9

## 4. Products<sup>84</sup>



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. Communication of information related to pharmaceuticals<sup>85</sup> is regulated by the Medicinal Products Act.

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.

### Compliance with regulations concerning products<sup>86</sup>

The inspection authority at JAZMP instituted no offence procedure against Lek in 2014.



### Practices of measuring customer satisfaction<sup>87</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 2014.

### Adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship<sup>88</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 prior approval of all promotional activities.

In 2014, 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>89</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 Conduct regulates our corporate and environmental responsibility and our compliance with the regulations and Good Business Practice. It provides a basis for the trust of our key stakeholders (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 2014 we once again organized online training on the Code of Conduct for all our employees and achieved 99% participation. Nearly all employees refreshed their knowledge about the fully transparent and clear principles and to confirm their implementation in daily 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>90</sup>

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 the 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, forced or compulsory labour.

In 2014, there were no cases of discrimination and no requests to remedy any violation in this area in Slovenia.<sup>91</sup>

The company was also not involved in any antitrust procedure for any violation of antitrust regulations.<sup>92</sup>



## 6. Suppliers

### 6.1 Purchasing policy<sup>93</sup>

In mid-2014, a new service organization was established at Novartis – Novartis Business Services – a part of which is also Slovenia Purchasing (Direct and Indirect Purchasing). 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.

#### 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.

In 2014, we recorded substantial growth in the value of direct purchases which is largely due to the increased business volume of all Lek's sites. The internal system optimization resulted in a lower total value of purchases. The volatility of commodity markets and the raising of industry standards again tightened the pharmaceutical company's supply conditions thus additionally narrowing the range of suppliers. In

order to achieve more competitive prices and a more reliable supply chain we further increased the scope of active risk management and partnership with the Sandoz and Novartis global supply function.

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

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

#### 6.1.2 Supplier audit procedures

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

In selection processes, priority is given to third parties who share 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 and practices for selecting local suppliers<sup>94</sup>

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

Among individual countries, Slovenia maintains the largest share in the direct purchasing structure. In 2014, the level

of deliveries from the Slovenian market amounted to USD 47 million or 16% of total purchasing cost (2013: 18%). We mainly purchase packaging and raw materials from the Slovene chemical industry and merchandise from domestic distributors.

Also in the indirect purchasing structure among individual countries, Slovenia maintains the largest share with 77% (USD 178 million).

<sup>93</sup> GRI G4-DMA, Indicators G4-HR5, G4-HR6 | <sup>94</sup> GRI G4-DMA, Indicator G4-EC9

## GRI G4 Content Index - Core Option

| 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. | 1.1/4                      |
| <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.   | 1.2.1/6                    |
| G4-10   | Total number of employees by employment type, employment contract, region and gender.  | 3.2.1/53                   |
| G4-11   | Percentage of total employees covered by collective bargaining agreements.   | 3.2.2/53                   |
| G4-12   | Organization's supply chain.   | 6/62                       |
| G4-13   | Significant changes during the reporting period regarding the organization's size, structure, ownership, or its supply chain.  | 1.3.3/12, 1.4.1/20         |
| G4-14   | Explanation, whether and how the precautionary approach or principle is addressed by the organization.   | 1.5.4/24, 2/26             |
| G4-15   | Externally developed economic, environmental and social charters, principles or other initiatives to which the organization subscribes or which it endorses.                               | 1.5.4/24                   |
| G4-16   | Memberships of associations and national or international advocacy organizations.  | 1.5.4/24                   |
| <b>Identified Material Aspects and Boundaries</b> |  |                            |
| G4-17   | List of all entities included in the organization's consolidated financial statements or equivalent documents.   | 1.4.1/20                   |
| G4-18   | The process for defining the report content and the Aspect Boundaries.   | 1.4/19                     |
| G4-19   | Material Aspects identified in the process for defining report content.  | 1.4/19, 1.4.1/20           |
| G4-20   | Limitations regarding the Aspect Boundary within the organization.   | 1.4/19, 1.4.1/20           |
| G4-21   | Limitations regarding the Aspect Boundary outside the organization.  | 1.4/20                     |
| G4-22   | Effect of any restatements of information provided in previous reports and the reasons for such restatements.  | 1.4.1/20                   |
| G4-23   | Significant changes from previous reporting periods in the Scope and Aspect Boundaries.  | 1.4.1/20                   |
| <b>Stakeholder Engagement</b>                     |  |                            |
| G4-24   | List of stakeholder groups engaged by the organization.  | 1.5.3/22                   |
| G4-25   | Basis for identification and selection of stakeholders with whom to engage.  | 1.5.3/22                   |
| G4-26   | Approach to stakeholder engagement, including frequency by type and by stakeholder group.  | 1.5.3.1/23                 |
| 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.    | 1.5.3.1/23                 |
| <b>Report Profile</b>                             |  |                            |
| G4-28   | Reporting period.  | 1.4/19, 1.4.1/20           |
| G4-29   | Date of most recent previous report.   | 1.4/19, 1.4.1/20           |
| G4-30   | Reporting cycle.   | 1.4/19, 1.4.1/20           |
| G4-31   | Contact point for questions regarding the report or its contents.  | 1/3                        |
| G4-32   | GRI Content Index.   | p. 63                      |
| G4-33   | The organization's policy and current practice with regard to seeking external assurance for the report.   | 1.4/19                     |
| <b>Governance</b>                                 |  |                            |
| G4-34   | The governance structure of the organization, including committees of the highest governance body.   | 1.5.1/20                   |
| <b>Ethics and Integrity</b>                       |  |                            |
| G4-56   | Organization's values, principles, standards and norms of behavior such as codes of conduct and codes of ethics.   | 1.5.4/24, 5/61             |

## Specific standard disclosures

| Material Aspects                   | Disclosures on Management Approach (DMA) and Indicators |   | Chapter/Page  | Omission and/or Deviating Presentation  |
|------------------------------------|---|---|---|---|
| <b>ECONOMIC</b>                    | <b>DMA</b>  |   | 3.1/53<br>6.1/62, 6.2/62  |   |
| Economic Performance               | G4-EC1  | Direct economic value generated and distributed.  | 1.2.1/6   |   |
|                                    | G4-EC3  | Coverage of the organization's defined benefit plan obligations.  | 3.2.3/53  |   |
|                                    | G4-EC4  | Financial assistance received from government.  | 1.2.1/6   |   |
| Market Presence                    | G4-EC6  | Ratios of standard entry level wage by gender compared to local minimum wage at significant locations of operation.   | 3.2.4/53  |   |
| Procurement Practices              | G4-EC9  | Proportion of spending on local suppliers at significant locations of operation.  | 6.2/62  |   |
| <b>ENVIRONMENTAL</b>               | <b>DMA</b>  |   | 2.1/25-27, 2.2.4/31, 2.4.1/37, 2.5.1/38, 2.7/44, 2.7.1/44, 2.8.4/47, 2.9.3.2/49, 6.1/62 |   |
| Materials                          | G4-EN1  | Materials used by weight or volume.   | 2.2.2/30  |   |
| Energy                             | G4-EN3  | Energy consumption within the organization.   | 2.3.1/34  |   |
|                                    | G4-EN5  | Energy intensity.   | 1.2.1/7, 2.2.5/32   |   |
|                                    | G4-EN6  | Reduction of energy consumption.  | 2.3.3/36  |   |
| Water                              | G4-EN8  | Total water withdrawal by source.   | 2.4.1/37, 2.4.2/37  |   |
|                                    | G4-EN10   | Percentage and total volume of water recycled and reused.   | 2.4.3/38  |   |
| 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. | 2.8.4/47  |   |
| Emissions                          | G4-EN15   | Direct greenhouse gas (GHG) emissions (Scope 1).  | 2.6.5/42  |   |
|                                    | G4-EN16   | Energy indirect greenhouse gas (GHG) emissions (Scope 2).   | 2.6.5/42  |   |
|                                    | G4-EN19   | Reduction of greenhouse gas (GHG) emissions.  | 2.6.5/42  |   |
|                                    | G4-EN21   | NO <sub>x</sub> , SO <sub>x</sub> and other significant air emissions.  | 2.6/41, 2.6.3/42, 2.6.4/42  |   |
| Effluents and Waste                | G4-EN22   | Total water discharge by quality and destination.   | 2.7.1/45  |   |
|                                    | G4-EN23   | Total weight of waste by type and disposal method.  | 2.5.1/38–39   |   |
| Product and Services               | G4-EN27   | Extent of impact mitigation of environmental impacts of products and services.  | 2.7.2/46  |   |
| Compliance                         | G4-EN29   | Monetary value of significant fines and total number of non-monetary sanctions for non-compliance with environmental laws and regulations.                                | 2.1/25  |   |
| 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.    | 2.1.6/30, 2.9.3.2/49  |   |
| Overall                            | G4-EN31   | Total environmental protection expenditures investments by type.  | 2.1.3/28  |   |
| Supplier Environmental Assessment  | G4-EN33   | Significant actual and potential negative environmental impacts in the supply chain and actions taken.  | 2.1.6/30  | 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.  | 1.5.3.1/23, 2.1/25  |   |

| Material Aspects                         | Disclosures on Management Approach (DMA) and Indicators |   | Chapter/Page   | Omission and/or Deviating Presentation   |
|--|---|---|--|--|
| <b>SOCIAL</b>                            |   |   |  |  |
| <b>Labour practices and decent work</b>  | <b>DMA</b>  |   | 1.5.2/22, 3.1/53, 3.3.7/58, 5/61, 6.1/62                     |  |
| Employment                               | G4-LA1  | Total number and rates of new employee hires and employee turnover by age group, gender, and region.  | 1.2.1/6  |  |
|  | G4-LA3  | Return to work and retention rates after parental leave, by gender.   | 3.2.5/54   |  |
| Occupational Health and Safety           | G4-LA6  | Work-related injury rates.  | 1.2.1/7, 3.3.1/54, 3.3.2/54–56, 3.3.3/54, 3.3.5/54, 3.3.6/56 |  |
|  | G4-LA7  | Workers with high incidence or high risk of diseases related to their occupation.   | 3.3.6/56   |  |
| Training and Education                   | G4-LA9  | Average hours of training per year per employee by gender, and by employee category.  | 3.4.1/59   | Records of training by gender and by employee category are not yet kept.   |
| Equal Remuneration for Women and Men     | G4-LA13   | Ratio of basic salary and remuneration of women to men by employee category, by significant locations of operation.   | 3.2.4/54   |  |
| Supplier Assessment for Labour Practices | G4-LA15   | Significant actual and potential negative impacts for labor practices in the supply chain and actions taken.  | 2.1.6/30   | By signing a contractual agreement, the supplier undertakes to undertake to comply with all applicable laws and regulations related to fair labor practices. |
| <b>Human Rights</b>                      | <b>DMA</b>  |   | 5/61, 6.1/62   |  |
| 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.            | 5/61   |  |
| Non-discrimination                       | G4-HR3  | Total number of incidents of discrimination and corrective actions taken.   | 5/61   |  |
| Child labour                             | G4-HR5  | Operations and suppliers identified as having significant risk for incidents of child labor, and measures taken to contribute to the effective abolition of child labor.                              | 6.1/62   |  |
| Forced or Compulsory Labour              | G4-HR6  | Operations and suppliers identified as having significant risk for incidents of forced or compulsory labor, and measures to contribute to the elimination of all forms of forced or compulsory labor. | 6.1/62   |  |
| <b>Society</b>                           | <b>DMA</b>  |   | <b>5/61</b>  |  |
| Local Communities                        | G4-SO1  | Percentage of operations with implemented local community engagement, impact assessments, and development programs.   | 1.5.3.1/23   | 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 behavior, anti-trust, and monopoly practices and their outcomes.   | 5/61   |  |
| <b>Product Responsibility</b>            | <b>DMA</b>  |   | <b>4/60</b>  |  |
| Product and Service Labeling             | G4-PR3  | Type of product and service information required by the organization.   | 4/60   |  |
|  | 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.  | 4/60   |  |
|  | G4-PR5  | Results of surveys measuring customer satisfaction.   | 4/60   |  |
| Marketing Communications                 | G4-PR7  | Total number of incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship, by type of outcomes.         | 4/60   |  |



## Glossary of key terms

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

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

### GRI (Global Reporting Initiative)

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

GRI Guidelines provide a high degree of comparability, transparency and consistency of non-financial corporate reports, increasing stakeholder trust in corporate responsibility and sustainable development reports.

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

**Generics** are successors to pharmaceutical products whose patent protection has expired. A generic drug is a drug product that is comparable to a reference listed drug product in quality and quantity composition, active ingredient and dosage form, its bioequivalence being proven by means of respective bioavailability studies.<sup>95</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>96</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.

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

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

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

Lek started its own genetic technology development as early as the 1980's, creating a solid foundation for the manufac-

<sup>95</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>96</sup> Source: Humar M., Šmid-Korbar J., Obreza A. Dictionary of Pharmaceutical Terminology. Ljubljana 2011.

ture 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).

## About the Lavička Collection



The Lavička Collection is the most extensive pharmaceutical-medical collection in Slovenia and is of exceptional cultural, educational and scientific value. The Government of the Republic of Slovenia proclaimed the Lavička Collection a cultural monument of national importance.

Bohuslav Lavička (1879-1942), an apothecary, master of pharmacy, was collecting items that comprise this collection through the contacts he had established over several decades with all major European antique businesses and by doing so had created an almost complete collection of pharmaceutical and medical accessories, artefacts and books.

Due to the quality of its exhibits, the Lavička Collection is one of the richest in Europe. Since 1978 it has been owned by Lek. It consists of two parts, the library and the pharmaceutical-medical accessories collection. It contains more than 4,000 books and 500 items dating back to the period of early civilization up to the 20<sup>th</sup> century.

The collection that was first revealed and presented to the public in 1986 can be viewed on the first Thursday of every month at Lek's headquarters in Ljubljana.

Lek, a Sandoz company, significantly broadened access to this rich and unique source of knowledge by its digitization. The collection has been available in a digitalized form since march 2015 and nearly one thousand exhibits are now on view at <http://www.lek.si/en/about-us/lavicka-collection/>.





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