lek

a Sandoz company

Sustainability Report 2012 Lek d.d.

Table of Contents

Sustainability Report 2012 – Lek d.d.
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*The Ecolabel reflects the manufacturer's commitment to continual environment management improvements.

1. Company Profile

1.1 Key Data for 2012

1.1.1 Operations in 2012

Table 1: Key figures for 2012[1]

Indicator	Unit	31. 12. 2012	31. 12. 2011	Index 2012/2011
Number of employees		**2,780**	**2,571**	**108**
- Ljubljana site		1,713	1,557	110
- Mengeš site		655	629	104
- Lendava site		245	218	112
- Prevalje site		167	167	100
Production output*	**000 tonnes**	**5.94**	**5.22****	**114**
Net sales revenues	**in EUR m**	**660.435**	**623.084**	**106**
Liabilities	**in EUR m**	**869.540**	**873.378**	**99.6**
Equity	**in EUR m**	**505.451**	**499.521**	**101**

* *Due to extremely big differences in the weight of various types of products, and due to the manufacturing structure being adjusted to the changed demand, the data is difficult to compare. We therefore believe that the comparison of production outputs is irrelevant. Differences in product weight should also be taken into account when reading data on the efficiency per tonne of product. Example: the weight of similar biologicals 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.*

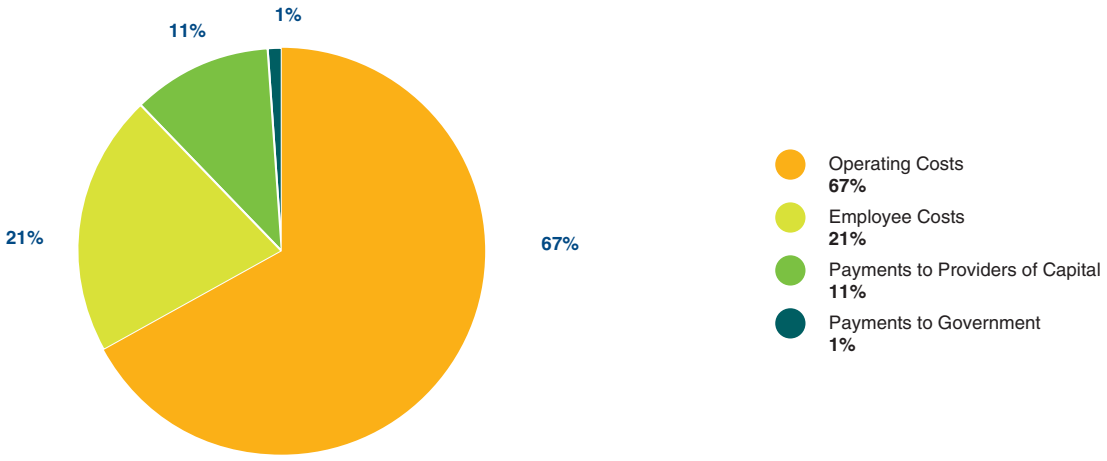
** *The change in the value over that reported for 2011 results from adjustments made to the data on production output and use of raw materials. The changes occurred due to an improved methodology for collecting data on production output for various finished pharmaceuticals and mass flows of raw materials at the Ljubljana site, the improvement being made on the basis of additional information obtained.*

Economic performance[2]
In 2012, Lek d.d. realized net sales revenues to the amount of EUR 660.435 million, a 6% increase over the year 2011, In foreign markets, they increased by 8%, whereas in the domestic market, they dropped by 8%.

Direct Economic Value Generated amounted to EUR 680 million. Of this, **Economic Value Distributed** totalled EUR 629 million (92.5%), and **Economic Value Retained** EUR 51 million (7.5%).

Within Economic Value Distributed, **Operating Costs** amounted to EUR 420 million (67%), **Employee Costs** amounted to EUR 134 million (21%), **Payments to Providers of Capital** reached EUR 70 million (11%), and **Payments to Government** totalled EUR 5 million (1% of Economic Value Distributed). Due to increased volume of investment in research activity, the related tax relief doubled against the year before, amounting to EUR 23.811 million. For investments, income tax amounted to EUR 19.44 million. We also received public subsidies amounting to EUR 263,000.[3]

Graph 1: Structure of Economic Value Distributed



[1] Disclosure GRI 2.8, GRI Indicator EC1, GRI Indicator LA1 | [2] GRI Indicator EC1 | [3] GRI Indicator EC4

Table 2: Major environmental and social impacts[4]

Indicator	Unit	31. 12. 2012	31. 12. 2011	Index 2012/2011
Efficiency of energy resource use	GJ/t	193	222*	87
Water use efficiency	m^3/t	151	165*	92
Waste volumes – efficiency	t of waste/t product	3.23	1.57*	206
VOC emissions - efficiency	t of VOC/t of product	0.024	0.041*	59
LTIR** - work-related injuries and illnesses involving days away from work		0.05	0.05	100
TRCR** - work-related injuries and illnesses requiring more than basic first aid		0.35	0.39	90

* *The figures differ from those published in the Sustainability Report 2011, due to adjustments made to the data on production output and use of raw materials previously stated under the Notes of Table 1. These result in changes in the calculation of efficiency in all the areas.*
** *The definition of LTIR and TRCR indicators as well as the formula for their calculation are indicated under Item 3.3.2 Monitoring work-related accidents.*

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

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

Our environmental performance is being improved through:
- Regular assessment of the HSE system performance,
- Open communication with internal and external publics, and
- Every employee's participation in our environmental management efforts.

Production processes for pharmaceuticals and active pharmaceutical ingredients differ greatly from site to site, and so do their impacts, particularly environmental ones (waste, emissions into the air, and other). To ensure better transparency of our efforts to manage the relevant environmental impacts, in this year's report we present our annual objectives by site, thereby enabling us to track the realization of long-term objectives at the level of Lek over the period up to 2015 calculated according to the role of each site.

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

Objectives by 2015	Status 2012
Improving water use efficiency by 10% over 2010.	**Realized.** Water use efficiency improved by **32%.** Year 2010: 786 m^3/t Year 2012: 534 m^3/t
Improving energy efficiency by 10% over 2010.	**Realized.** Energy efficiency improved by almost **24%.** Year 2010: 254 GJ/t Year 2012: 193 GJ/t
Reducing VOC emissions into the air (h-VOC and nh-VOC) by 20% over the 2010 figures.	**Realized.** Emissions reduced by **45%.** Year 2010: 258 t Year 2012: 143 t
Reducing waste volumes by 10% over 2010.	**Partly realized.*** Year 2010: 11,000 t Year 2012: 19,000 t
Reducing LTIR to 0.1.	**Realized.** 0.05

* *Since 2011, in accordance with the Novartis' reporting methodology, waste includes only the waste leaving the site, and not that treated on site. Due to the fact that in 2012 mycelium waste generated by the Lendava fermentation production process was redirected from the site's incinerator to a contractor biogas plant for treatment, the total mycelium waste volume is now reported as waste treated within the site.*

[4] Disclosure GRI 1.2

Lek, a Sandoz company[5]

Company name:	**Lek farmacevtska družba d.d.**
Abbreviated name:	**Lek d.d.**
Registered office:	**Ljubljana**
Business address:	**Verovškova 57, 1526 Ljubljana, Slovenia**
Registration number:	**1732811000**
Standard Classification of Economic Activities in the European Community (NACE):	**21.200 Manufacture of pharmaceuticals**
Registered at:	**District Court in Ljubljana under the registry number: 1/36542/00**
Telephone:	**+ 386 1 580 21 11**
Fax.:	**+ 386 1 568 35 17**
E-mail:	**info.lek@sandoz.com**
Website:	**http://www.lek.si/en**

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[5] Disclosure GRI 2.1, Disclosure GRI 2.4 | [6] Disclosure GRI 3.4

HSE targets for 2012

Objectives for 2012	Realization in 2012
Projects to improve water use efficiency.	**Prevalje:** Project for the use of wastewater generated during the process of water treatment for cooling purposes. Use of fresh water for cooling purposes reduced by 30%. **Lendava:** Reduced water use as a result of the installation of a cooling system with a passive cooling option (fermentation).
Projects to improve energy efficiency.	**Lek:** Improving energy efficiency by 13%. **Lendava:** - Redirecting mycelium waste from the site incinerator to a biogas plant – annual energy savings. 34,627 GJ and 2,055 t CO_2, compressed air system optimization before pre-fermentation filters – annual energy savings: 800 GJ and 82 t CO_2, - Passive cooling on the fermentation cooling system – annual energy savings: 983 GJ in 101 t CO_2. **Mengeš:** - Improving energy efficiency of waste heat recovery device in the process of sludge-removing and desalting of steam boilers, - Lamp replacement project. **Prevalje:** Lighting optimization in non-production facilities. **Ljubljana:** - Replacing the cooling system of the administration building, - Replacing an air-conditioning unit in the production area by a system of higher energy efficiency.
Reducing atmospheric VOC emissions < 147 t*.	VOC emissions to the air: 143 t. **Prevalje:** kick-off of the project for replacing adsorbers by an air emission control device (Regenerative Thermal Oxidizer – RTO) of higher performance and improved energy efficiency. **Mengeš:** Introduction of a new air emission control device (Regenerative Thermal Oxidizer – RTO). **Ljubljana:** Introduction of a new air emission control device (RTO). **Lendava:** Improvement of the efficiency of treatment of emissions from the neutralization tank by redirecting the source of emissions to a higher-efficiency VOC treatment.
Projects to reduce waste volumes	**Lendava:** Removal of mycelium in a biogas plant (previously incinerated). **Prevalje:** Release of waste ethanol for reuse (previously incinerated). **Lek:** packaging project.
Lost time injury and illness rate LTIR 0.15.	LTIR Indicator amounted to 0.05.

* *Interim changes in the total target value amounts of individual sites resulted in adjustment of the Lek target to < 147 t.*

HSE targets for 2013

		Mengeš	Ljubljana	Lendava	Prevalje
Ecotoxicity assessment of APIs	% of APIs in production	100	100	Gentamicin – calculation and pilot project	100
Non-halogenated VOC emissions to the air (nh-VOC)	t	71	Maintaining the 2012 level	Maintaining the 2012 levels - Making a study to reduce pollution at sources of VOC	Maintaining the 2012 levels
Halogenated VOC emissions to the air (h-VOC)	t	1	No emissions	No emissions	No emissions
Energy savings	J	3 projects	3 projects	5 projects	3 projects
Reducing hazardous waste volumes	t/t (efficiency)	3 projects	Maintaining the 2012 level	Maintaining the the 2012 level	Reuse of solvents
Reducing non–hazardous waste volumes	t/t (efficiency)	0.31	Maintaining the 2012 level	Maintaining the 2012 level	Maintaining the 2012 level
LTIR (permanent employees)		0.14	0.14	0.14	0.14
LTIR (permanent employees + employees hired through employment agencies)		0.16	0.16	0.16	0.16
TRCR (permanent employees)		0.43	0.43	0.43	0.43

1.2 Letter from the President of the Board of Management

Dear Reader,

Changes in demand on the market and increasingly difficult operating conditions have become realities, leaving a strong mark on the year 2012. But according to an old saying, no one can ever take away your knowledge. Lek, a Sandoz company, has therefore focused all of its efforts on enhancing the development, quality and flexibility of its product mix.

We reached several milestones of long-term significance. At all of the Slovenia-based sites of Sandoz, we again recorded strong growth in our production output, which was accompanied by intensive development activities and extremely active launching of new products. Net sales revenues were increased by 6%, whereas our production output rose by 14%. With a record total of 1,300 new products, our product launch volume achieved a 40% share of that of Sandoz. We completed the process of developing 26 novel products for some of the world's most demanding markets, managing as many as 260 development projects at year end.

Our investments and a number of future-oriented steps made us the holder of one third of Sandoz' total development projects and the leading development center in the Group. This accomplishment, along with the many achievements, findings and initiatives taken by our associates, are a source of great pride for Lek.

It goes without saying that knowledge alone is not enough. The purpose and method of its application are equally important. Our intention to operate in a responsible manner is proven by the company's Eco-Management and Audit Scheme certification and the registration in the EMAS Register. We are the first EMAS-certified Slovenian pharmaceutical company, and we implemented EMAS requirements at all of our sites.

The present report provides a detailed description of several significant achievements that made the year 2012 extremely successful for Lek also in terms of the company's operational sustainability. The outstanding achievements include massive innovation efforts: the Slovenian Chamber of Commerce and Industry gave its Golden Innovation Award to two Lek associates, whose work was also recognized by the international scientific community through the publication of an article in several renowned scientific journals. Worth noting are Lek Open House Days organized at the Mengeš and Lendava sites, and the Family Day held at all our sites: in Ljubljana, Mengeš, Lendava and Prevalje.

Our business achievements were accompanied by thorough management of our economic, societal and environmental impacts. Due to expanding production capacities, we were able to employ 300 new associates, thereby increasing our workforce by 8%. In view of the unfavorable economic situation in Slovenia, hiring new people is particularly important. Furthermore, the proportion of labor costs in the Economic Value Distributed remained at 21%, its value increasing by a little over 10%.

When reviewing Lek's environmental impacts, we wish to emphasize significant growth in parallel with a fluctuating production output and the introduction of numerous new products at the Mengeš and Ljubljana sites. Improved environmental efficiency, the core of our environmental objectives, was the common thread of our endeavors, even in the situation described above. At this point, it should once again be emphasized that with our operations we have always striven to go beyond mere fulfillment of statutory requirements and regulations. We endeavor to propagate the best international corporate practice in the field of responsible environment management.

Lek, a member of the Sandoz and Novartis Group, strives to minimize its impact on the natural environment, while maintaining focus on the key influences of our business. Through investments, implementation of various measures, and a constant concern for improving production processes, in 2012 we cut back the use of water by 32%, and the use of energy by 24% over 2010, the baseline year. Compared to that same year, emissions of volatile halogenated and non-halogenated compounds into the air were reduced by as much as 45%. Numerous activities were aimed at ensuring safety at work, which is also reflected in the low rate of sickness absence due to work-related injuries and illness maintained at a low level of 0.05. All the above-stated results constitute considerable improvements over the plan.

The progress achieved results from the efforts of numerous teams, introduction of new technologies, and adjustments made to the production processes at all of the sites: Ljubljana, Mengeš, Lendava and Prevalje. Investments and process-related novelties introduced at the Lendava site not only increased production output but also

improved water and energy use efficiency, while reducing emissions of volatile organic compounds. With these improvements, the site appropriately marked its 30th anniversary in a town that has above all become a place for people to live.

The use of water was also diminished at the Prevalje site where, similarly to the Mengeš site, we also improved energy consumption and started replacing absorbers to achieve a decrease in the emissions of volatile organic compounds into the air. By completing capital projects and introducing thermal oxidizers used to control emissions, we have already achieved a significant reduction in the emissions of volatile organic compounds into the air at the Ljubljana and Mengeš sites.

Deviations from the set objectives were only recorded for waste volumes, where growth was observed. At the Lendava site, we permanently discontinued the process of mycelium waste incineration conducted in 2010, the baseline year. The waste was redirected to a biogas plant for reprocessing, which was the main factor of the waste volume growth recorded. Even though the project itself is dedicated to reducing waste volumes, the use of the Novartis reporting methodology resulted in increased figures.

Such fluctuations and the product mix vary from site to site. For the year 2013, short-term objectives by individual site were therefore given priority, which enabled additional transparency of our business operations.

It is to be expected that constant changes in the market situation will further dictate dynamic adjustments of our production portfolio. As satisfactory as our achievements in the environment protection may be, they can by no means be generalized. Through continuing efforts in each of the forthcoming years, we will strive to reach the same level of achievement.

Our firm commitment to being a responsible corporate citizen and a family-friendly company will be maintained and further consolidated, regardless of any economic issue we are facing in our environment. This is reflected in the significant role that corporate responsibility plays in adopting business decisions and plans. In our endeavors, we receive considerable support and motivation from our enthusiastic and committed associates who participate in Sandoz' and Novartis' initiatives promoting a healthy lifestyle, safe work and volunteerism in their respective local communities.

Vojmir Urlep, MSc
President of the Board of Management

1.3 About us

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

Within Sandoz, Lek has the following functions:

- Global development center for products and technologies,
- One of the key global manufacturing center for APIs and medicines,
- Competence center for the development of vertically-integrated products,
- Sandoz' competence center for the development and manufacture of biopharmaceuticals,
- Supply center for the markets of CEE, SEE and CIS, and
- Responsibility for the marketing and sales of Sandoz products in Slovenia.

Lek,[7] 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: Ljubljana, Mengeš, Prevalje and Lendava. In 2012, all the sites became EMAS certified, and registered in the EMAS Register.

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

For more information about Lek, please visit www.lek.si/en.

Sandoz, the generic division of the Novartis Group, is a global leader in the fast-growing industry of generic pharmaceuticals, offering a wide array of approximately 1,100 high-quality, affordable products that are no longer protected by patents. With nearly 26,000 employees in approximately 140 countries, Sandoz holds the leading position globally in biosimilars, injectables, ophthalmics and dermatology as well as a strong global No.5 position in inhalables. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments, and hormone therapies. Sandoz develops, produces, and markets these medicines along with pharmaceutical and biotechnological active substances and anti-infectives.

In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWE Pharma (Austria), Oriel Therapeutics (US), and Fougera Pharmaceuticals (US). In 2012, Sandoz posted sales of USD 8.7 billion.

For more information, please visit www.sandoz.com.

** Sandoz is on Twitter. Follow @Sandoz_global at: twitter.com/sandoz.*

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a highly diversified drug portfolio: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas.

In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 128,000 full-time-equivalent associates and operate in more than 140 countries around the world.

For more information, please visit www.novartis.com.

** Novartis is on Twitter. Follow @Novartis at: twitter.com/novartis.*

[7] Disclosures GRI 2.3 and 2.6

The Four Pillars of Novartis Corporate Citizenship

As an integral part of Novartis and Sandoz, Lek in 2012 again strengthened and developed the Four Pillars of Novartis Corporate Citizenship:

Patients

According to our perception of corporate citizenship, patients come first.

Business management

We believe that continuous good performance is associated with business ethics.

People and community

We strive to be an employee- and family-friendly company, actively involved in the community, and showing great concern for children in distress.

Concern for the environment

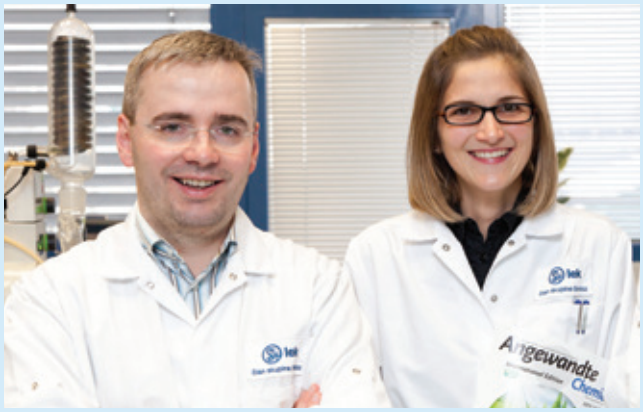
We are building employee awareness about safety and health at work to minimize environmental impacts.

Patients

Golden Innovation Award for two researchers from Lek

On the occasion of the 10th Innovation Day, the Chamber of Commerce and Industry of Slovenia (CCIS) made awards to the most innovative companies and best innovators in the year 2011. Among 230 participating innovations, Lek Pharmaceuticals, a Sandoz company, received the highest acknowledgment – the Golden Innovation Award.

The award was presented to Dr Ivana Gazić Smilović, expert researcher at the Department of Organic Synthesis, and Dr Zdenko Časar, global Head of API Portfolio Management at Sandoz, for the development of a new method for the preparation of an active ingredient for the treatment of plasma cell cancer. The innovation is protected by two patent applications for which the most advanced knowledge was used.



The publication of a selected summary in some scientific journals such as Chemistry & Industry and Synfacts confirmed the significance of the achievement in scientific circles.

Business management

Manager of the Year 2012 Title Awarded to Vojmir Urlep

The management board of the Managers Association selected Vojmir Urlep, President of the Board of Management of Lek, a Sandoz company, as Manager of the Year 2012. According to the opinion of the management board of the Managers Association, Lek d.d. under the leadership of Vojmir Urlep delivers above-average business results, above-average customer and employee satisfaction, and high added value, and plays a leading development role within the Sandoz Group. All this augurs well for the further global development of Lek, Slovenia's oldest pharmaceutical company.

Presentation of the award to Vojmir Urlep at the Managers Association congress.

People and community

Community Partnership Day

For the eighth year running, Lek employees took part in the Community Partnership Day, the Novartis global volunteering initiative. Over 200 volunteers from the sites across Slovenia offered help to individuals and different organizations. Throughout Novartis, more than 25,000 volunteers from 54 countries joined this year's event, a 25% increase over the year before.

As is their tradition, employees from the Lek sites in Ljubljana, Mengeš, Lendava and Prevalje, on this occasion again donated blood. They also paid particular attention was again to children, youth and the elderly. Several educational workshops and excursions were organized for school children, while the elderly were entertained through a social event, and introduced to the world of computers.

A natural science day was organized for the pupils of the Lendava bilingual primary school.

Wink at the Sun 2012 – Lek Sunshine Games entertain children in Kranjska Gora

To entertain children vacationing in its Villa in Kranjska Gora, Lek once again organized the Sunshine Games held as part of the Wink at the Sun campaign. The Slovenian Friends of Youth Association and Lek d.d, a Sandoz company, its long-term partner, were co-organizing the Wink at the Sun campaign for the 14th time in a row. At the national level, this year's campaign provided free holidays for around 300 children. As the campaign is very strong also at the level of local associations and societies of the Friends of Youth, around 1,000 children in total will enjoy a free holiday with the Friends of Youth at the PanSlovenian level.

For the 14th time in a row, Lek Sunshine Games brought joy to children during their summer holidays.

Concern for the environment

Lek, the first Slovenian company to obtain EMAS certification

Lek, a Sandoz company, became the first Slovenian pharmaceutical company to join EMAS, the EU Eco-Management and Audit Scheme. EMAS reporting became part of Lek's Sustainability Report. The combined information about the company's economic, social and all environmental impacts provided in the report contributes to reporting transparency. The EMAS Scheme was implemented at all the four sites of Lek d.d.: Ljubljana, Mengeš, Lendava and Prevalje.

EMAS registration, performed by the Slovenian Environment Agency, was marked with a special ceremony.

1.3.1 Key customers and markets[8]

In accordance with the Group's strategic orientations and organizational structure, Sandoz Group companies are the key buyers of Lek products and active pharmaceutical ingredients. In 2012, the shares in the company's net sale held by the leading three buyers amounted to 24.56%, 7.93% and 4.93%.

Lek sells its own products and the products of other Sandoz companies. Our major external direct sales markets for Lek and Sandoz products include Central and Eastern Europe with 84%, and Slovenia with 6%. The majority of sales (86%, v 2011 85%) are realized by pharmaceutical products, whereas APIs and biopharmaceuticals account for the remaining 14% (15% in 2011).

The drop in the proportion of sales realized in Slovenia was mainly due to a 4% decrease in the total value of the Slovenian pharmaceutical market. The market for generic pharmaceutical manufacturers such as Lek shrunk by 6%. The main contributors to the market shrinkage were measures taken by the Ministry of Health to curb spending on medicinal products reimbursed by health insurance. Reduced reference drug price levels, resulting in a lower drug sales value affected both generic and originator pharmaceutical companies. The non-prescription drug market recorded no growth either, as a consequence of the country's deteriorating economic situation and the impaired purchasing power of the population.

As an amendment to the Consolidation of Public Finance Act, the foundations were laid for introducing reference drug prices at the level of therapeutic groups. Rules providing a new regulatory basis for drug classification are to be adopted in the first half of 2013.

1.3.2 Major groups of products and brands[9]

The key therapeutic groups of medicinal products developed, manufactured and marketed by Lek include:

- Cardiovascular drugs,
- Antiinfectives,
- Gastrointestinal drugs,
- Other prescription drugs dispensed in pharmacies, and covering a broad spectrum of therapeutic groups for the treatment of various diseases, and
- Self-medication drugs.

Our leading brands in Slovenia include Lekadol®, Amoksiklav®, Tulip®, Linex®, Coupet®, and in our export markets omeprazol, tacrolimus and Ketonal®.

1.3.3 Lek production sites and processes[10]

1.3.3.1 Ljubljana production site

The industrial zone of north-western part of Ljubljana is the location of the Sandoz' leading development center and one of the Sandoz' major global production plants, and the largest in Slovenia.

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

The production function consists of the production units for solid and sterile dosage forms. On this location, manufacturing activities started in 1975 and expanded significantly in 1992 by the opening of a new tablet production plant which was further expanded in 2004. In the years that followed, the growth and modernization of the manufacturing processes continued. The same trend could also be observed in 2012. The year 2012 was marked by a number of activities in the field of quality and investments. We successfully passed several inspections, and completed a significant number of capital projects aimed at upgrading production capacities.

Solid dosage forms

With about 80 APIs and more than 200 formulations manufactured and packaged, Lek Ljubljana is the leading Sandoz organization in terms of product range size. Manufacturing which is mostly highly automated and centrally computer-controlled, takes place on multi-purpose production lines. In 2012, we posted a record production volume for the third year running. For the first time in the company's history, our tablet plant manufactured more than 6 billion units of solid dosage forms. The highest growth was recorded for film-coated tablets where above 30% growth was achieved over the year before. Growth was recorded both with existing products and novel ones the number of which rose by 40. With more than 340 million units packaged in 2012, the Packaging Center posted a record as well. The 855 new product launches rank us to the top of all the Sandoz companies.

Sterile dosage forms

The main contribution to sterile production growth comes from ampoules for which we are the Novartis center of excellence. This means that we obtain products from other Novartis production plants as well. Our sterile production output in 2012 was 15% higher than the year before.

At the start of the year, we renovated and modernized the Steriles Packaging unit, thereby increasing its capacity.

Company headquarters

The Ljubljana site also features the company headquarters with administrative services, the Health, Safety and Environment head office, the Patent head office, the Quality and Quality Management units, and others.

[8] Disclosure GRI 2.7 | [9] Disclosure GRI 2.2 | [10] Disclosure GRI 2.6

1.3.3.2 Mengeš production site

The Mengeš site features the development and manufacture of active pharmaceutical ingredients, the production of solid dosage forms, the Antiinfectives - Genetics development department, and the Quality unit. Furthermore, the site comprises one of the main biopharmaceuticals development and production centers of Sandoz, which is the global leader of biosimilars production.

APIs are manufactured by means of biological (fermentation) and chemical procedures (organic syntheses) followed by physical and chemical procedures for isolation and purification of active ingredients. At the Mengeš site, the manufacturing has been carried out since 1946, and since 2000 it has witnessed fast development of biopharmaceuticals.

In 2012, the API production volume grew again. Of great importance is the production of tacrolimus where we maintain a competitive advantage through continuous technological improvements. One of the key achievements of the Mengeš site was the opening of new cell and molecular biology laboratories in the Biopharmaceuticals Development Center.

The Mengeš site successfully passed all the inspections.

1.3.3.3 Lendava site

The Lendava site comprises the Antiinfectives production unit and a packaging center.

At the Lendava site, we manufacture Potassium clavulanate, the key ingredient of a broad-spectrum antibiotic, one of Lek's and Sandoz' leading products, and Gentamycin sulphate. The manufacture is based on standard biotechnology which is the result of the company's own know-how. Lendava is the leading location for the manufacturing of Potassium clavulanate in the Sandoz Group, and demand for it continues to be high. Similarly to the previous years, the production of Potassium clavulanate, the leading product, posted record results, a combination of physical growth and improved technologies. By eliminating the bottlenecks, we increased our production capacities and were able to meet all the market requirements.

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

The Packaging Center Lendava (PCL) where the filling and packaging of pharmaceuticals takes place, supplies the markets of more than 60 countries in Europe and worldwide. It is one of the fastest growing Sandoz locations. In 2012, 1.4 billion tablets and capsules were packaged in the PCL, the result due to constant productivity growth. At the same time, the center focuses on its key objective of providing a high level of customer service with a high level of response to the changing market requirements, and with internal flexibility.

The total capital investment value exceeds EUR 30 million. According to the 2013 plan, a production capacity of as many as 10 packaging lines is anticipated, which will be further expanded in order to consolidate our position of a strategic manufacturing site within the Sandoz global production network.

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

1.3.3.4 Prevalje production site

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

For the Prevalje site, 2012 was one of the most successful years ever. According to the Sandoz guidelines, special emphasis was placed on quality. We successfully passed all the inspections performed at the site, while assuring also the quality of our incoming materials. We manufactured a record 393 million tablets and 13 million oral suspensions, a 30% increase over the plan. In 2013, even a higher growth rate is expected due to the installation of a new tablet-coating pan which will improve the production capacity for coated tablets by almost 50%. We reorganized the dispensing room to provide more space and to improve the flow of materials. In addition, we renovated the parking area to meet our employees' requirements.

1.3.4 Highlights and milestones of Lek's operations in 2012

The year 2012 was marked by **production growth** at all the Sandoz sites in Slovenia, **successful development projets, a high percentage of new launches of Sandoz products produced by Lek,** and **new investments.**

Highlights of the year:

- Continued strong growth of production volumes at all the Sandoz production sites in Slovenia.
- All the sites successfully passed the most demanding audits carried out by the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), the US Food and Drug Agency (FDA), and several other audits, thus **proving the high level of our quality management system** to ensure patient safety. Through outstanding performance, we consolidated our position as one of Sandoz' key entities.
- We **launched more than 1,300 new products** across the world. This record level represented an 80% increase over the year before, and 40% of all Sandoz' new product launches. We launched a patented anticholesterol medication, which was one of our major, highest--complexity launches.
- We developed 26 novel products for the world's most demanding markets. At the end of 2012, more than 260 development projects were under way. This made us **Sandoz' leading development center.**
- As the large increase in the production volume required creation of new job positions, we hired **300 new employees,** mostly in the production area, in the Quality unit, and in the Biopharmaceuticals unit.
- At the **Sandoz Biopharmaceuticals Development Center,** an upgrade of the production plant for recombinant erythropoietin resulted in record production output. This contributed considerably to continued high growth in biosimilars sales volumes, which consequently consolidated Sandoz' leading position among the world's biopharmaceutical manufacturers.
- In **Slovenia,** we maintained the leading position in non-prescription drugs, and further strengthened our position as the second-largest generics supplier.
- We celebrated the 30th anniversary of our Lendava site. In these three decades, the site has developed into an important part of Sandoz, while maintaining its role as the region's major employer.

Packaging Center Lendava.

- At the **Regional BioCamp AlpeAdria,** a 3-day event held for the second year running, some of the most promising students of the Alps-Adriatic region were given an insight into pharmaceutical industry trends.

The best team at the Regional BioCamp Alpe Adria 2012.

- The management board of the Managers Association selected Vojmir Urlep, President of the Board of Management of Lek, a Sandoz company, as **Manager of the Year 2012,** which enhanced Lek's reputation as a leading development center of Sandoz.
- The value of Novartis' investments in development activities, modernization and expansion of production capacities in Slovenia over the past ten years exceeded **EUR 1.3 billion.**
- At the Mengeš site, we opened a state-of-the art **cell and molecular biology laboratory** in the Sandoz' Biopharmaceuticals Center. At the Ljubljana site, the construction of a new control center was started, and investments were continued to increase the capacity of the key production programs.

Opening a new laboratory at the Mengeš site.

- We invested in the development, education and training of our employees.
- By fulfilling the EMAS requirements, we were the first Slovenian pharmaceutical company and the sixth Slovenian company to receive EMAS registration for all the four sites.
- A routine environmental management system audit in accordance with ISO 14001:2004, and a renewal audit according to OHSAS BS 18001:2007 were performed.
- The Association of Chemical Industries of the Slovenian Chamber of Commerce and Industry awarded Lek a certificate for their **Responsible Care Initiative® - RCI,** and granted the company the right to use in 2013 the RCI logo for sustainable improvement of its health, safety and environment performance, and for transparent sustainability reporting.

1.3.5 Awards and acknowledgements[11]

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

Major recognitions include:
- The Golden Innovation Award awarded by the Chamber of Commerce and Industry of Slovenia, and
- Publication of an article by the researchers of the Sandoz Development Center Slovenia in Angewandte Chemie, a renowned general chemistry journal.

Awards granted at the level of Sandoz and Novartis:
- The highest Sandoz scientific award for special achievements of our scientists,
- Sandoz' annual Technical Operations Award,
- Sandoz annual Human Resources Award,
- Sandoz annual award in the Occupational Health and Environment Management category for the Ljubljana Solids and Steriles Production site (for the 3rd year running),
- Sandoz annual Anti-infectives Award,
- Sandoz quarterly awards for best leaders development, sense of urgency, and operational excellence,
- Sandoz ExCEEd Award in the Rx segment,
- Global Novartis IT excellence award "Global Excellence – Winning Culture Award",
- Global Novartis Finance for People Development award,
- Sandoz and Novartis Quality annual Excellence Award to the Slovenian Quality team.

In addition to the above, Lek received the following awards:
- The Lendava Packaging Center won an award for Outstanding Economic Achievements presented by the Lendava municipality.
- For the 10th year in a row, Lek won the TOP 10 Education Management Award, thereby consolidating its position among the 10 Slovenian companies with the highest level of professionally planned and systematic investments in knowledge and training of their employees.

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 economical 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 RCI, EMAS Scheme and GRI Guidelines. Even before 2010, we prepared environmental reports and reports within the Responsible Care Initiative (RCI).

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

All the reports, also containing the EMAS Environmental Statement, are available at 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, www.corporatecitizenship.novartis.com in www.novartisfoundation.org). Their collection is performed in compliance with the improvement guidelines provided by Novartis internal HSE audits. We have not yet decided to seek external assurance for our sustainability reporting, but we are considering this possibility.[13]

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), disclosing them also at the site level.

Reporting in accordance with GRI Guidelines

Lek's reporting in compliance with the GRI Guidelines uses reporting guidelines at Application Level B.

[11] Disclosure GRI 2.10 | [12] Disclosures GRI 3.2 and 3.5 | [13] Disclosure GRI 3.13

1.4.1 2012 reporting characteristics[14]

- All the indicators and disclosures in the present report refer to the calendar year 2012.
- Employee data, key data on financial operations, and economic impacts of business operations were acquired in the financial reporting process for the purpose of the company's annual report compilation in accordance with International Accounting Standards and the Slovenian legislation.
- The objective of Lek's HSE reporting is compliant with Novartis' and Sandoz' objectives to provide a fair and well-balanced picture in the field of health, safety and environmental impacts (HSE). The system of monitoring HSE achievements and the reporting methodology are described on page 44.
- 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 Lek sites 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 the members of the pharmaceutical associations.
- The report covers the major economical, environmental and social impacts of the organization.
- Reporting refers to the company Lek d.d. and to all of its manufacturing locations in Slovenia.[15]
- The company Lek d.d. holds a 100% ownership stake in the following subsidiaries (as of 31 December 2012): Sandoz, d.d., Hotel Lek, d.o.o., Novartis Animal Health, d.o.o. and Lek Ljubljana Holding GmbH, Austria. In the USA (through Lek Ljubljana Holding GmbH), Lek d.d. indirectly owns the company Lek Pharmaceuticals, Inc., whereas in the Čistilna naprava Lendava d.o.o. (Lendava Wastewater Treatment Plant) it holds a 74.5% ownership stake.
- In 2012, there were no changes in the size, structure and ownership of Lek d.d. There were no merger activities or joint ventures. The company Lek Skopje d.o.o., Macedonia, had already been divested in 2012.[16]
- To improve the reporting accuracy, the following adjustments in the data collection process were made for 2012[17], also impacting the comparability of previous years' data:
  - On the basis of additional information, we improved the method of collecting data on the realization of the production plan for various finished dosage forms and mass flows of starting materials at the Ljubljana site. Following some minor corrections to the production plan realization / use of starting materials in 2008, the calculations of resource use efficiency changed as well.
  - When reporting on wastes, we followed Novartis' request that reporting since 2011 inclusive should only cover wastes leaving the site. Consequently, the waste thermally treated at the site was no longer reported in 2011. We reported however on the ashes and slags resulting from such thermal treatment. In 2012, mycelium waste generated by the fermentation process at the Lendava site was redirected from the site incinerator to a contracting biogas plant for processing. As a result, the total volume of mycelium waste is now reported as waste treated outside the site.

1.5 Governance, commitments, inclusion

1.5.1 Governance and management[18]

The **Board of Management** of Lek d.d. worked with 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
Daniel Karrer, Member of the Board of Management, Finance (until 30 September 2012)
Aleš Rokavec, Member of the Board of Management, Technical Operations (since 1 August 2012)
Samo Roš, Human Resources
Bojan Dolenc, Member of the Board of Management, Workers' Director

Supervisory Board:
Peter Goldschmidt, Chairman
Jeffrey George, Deputy Chairman
Peter Rupprecht, Member (until 1 October 2012)
Cesare Frontini, Member
Knut Mager, Member (since 2 October 2012)
Peter Svete, Member, Workers' Representative (since 1 October 2012)
Aleksander Koren, Member, Workers' Representative
Uroš Urleb, Member, Workers' Representative (until 1 October 2012)

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. Furthermore, the Board of Management represents and acts on behalf of the company. 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.

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

[14] Disclosure GRI 3.1, 3.3, 3.7, 3.8 and GRI 3.10–3.11 | [15] Disclosures GRI 2.6 and 3.6 | [16] Disclosure GRI 2.9 | [17] Disclosures GRI 3.9–3.11 | [18] Disclosures GRI 4.1 and 4.4–4.7

The primary function of the Supervisory Board is to oversee the policy pursued by management. The Board can perform reviews and verification of the company's books and documentation, its treasury, securities and goods in stock, and other matters. The Supervisory Board can request the Board of Management to provide any information needed for the Board to perform its supervisory role.

The main responsibilities of the Supervisory Board include the following:

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

In accordance with its competencies and responsibilites, the Supervisory Board performs due supervision of the company's management, monitoring it through the reports provided by the Board of Management on a regular basis at Supervisory Board meetings, and on the basis of other notifications the Board of Management assesses as significant in accordance with statutory and internal regulations. In this way, the Board performs comprehensive control of the company's economic, environmental and social impacts. Information on these impacts is also provided to the Supervisory Board as part of its competency of approving the company's annual report which also encompasses the business report which contains, inter alia, all the major environmental protection information.

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

Appointment of the members of the Supervisory Board of Lek d.d. is confirmed by the Executive Committee of Novartis, the highest governance body, with the aim of providing the best people, based on their skills and competencies, to cover all the company's functions, and to ensure their operational autonomy. Similarly to other levels of the company's functioning, supervisory bodies operate in accordance also 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. On their appointment, they have to sign a statement pursuant to Article 255 of ZGD-1, an obligation set for all the Novartis Group employees in the Novartis internal Conflict of Interest Policy.

1.5.2 Employee participation in company management [19]

The company Lek d.d. adheres to the methods and conditions for worker participation in management as provided by the Slovenian Worker Participation in Management Act. The employees exercise their rights to participation in management individually and collectively through the Workers' Council, Workers' Assembly and their representatives in the company's management bodies.

The workers' representatives also act as Supervisory Board members, while the Workers' Director also performs the function of Board of Management member.

It consists of several committees (for general issues, for economical, status-related, human resources and social issues), while its members serve on various boards of the company (innova tion, occupational safety, diversity and inclusion, supervisory committee of Lek Trade Union).

In 2012, the employees proposed no initiatives to the Supervisory Board. However, they maintained direct contacts with the Workers' Director who provided them with answers and assistance in finding suitable solutions with regard to job changes and working conditions, and gave them additional information.

At Workers' Council meeting, questions and initiatives provided by employees are answered and responded to immediately by the President of the Board of Management, Workers' Director and HSE Director. Answers and/or any additional information is also provided after the meetings. The issues raised most frequently included working hours, working conditions, business results and plans, holiday facilities, organizational changes, and additional pension insurance.

At all the sites, the Workers' Council members, jointly with the HSE function, participated in the review of risk assessment. At **employee meetings** held at each of the sites, employees actively participated and put forward their questions which were answered on the spot by the President of the Board of Management, Board of Management members and respective services' representatives. A member of the **Diversity and Inclusion committee (D&I)** took active part in the Committee's work, presenting the "Project 50+" initiative dealing with opportunities for better utilization of the skills and knowledge of employees older than 50 years who would share their knowledge and expertise with younger co-workers through mentorship. Furthermore, the Committee member participated in the "aging workforce" initiative, seeking solutions for the elderly employee population.

A member of the Innovation Committee participated in the process of improving the model of quality and transparent identification of the most successful innovators at Lek. Criteria for assessing the impacts of proposed solutions in the Leading Solution and Leading Breakthrough categories were redefined and improved. The selected innovators were honored with awards within the Lek Stars campaign. After the implementation of the Th!nk Sandoz initiative for online idea management, the Committee member took part in the process of assessing ideas filed in the web-based application.

1.5.3 Shareholder overview and inclusion [20]

Lek, a Sandoz company, focused its activities on five key groups of stakeholders: patients, employees, shareholders, healthcare partners (healthcare professionals, regulators, professional associations, buyers, suppliers) and the society (local commu nities, non-governmental institutions, members of the Academy

[19] Disclosures GRI 4.4 and 4.17 | [20] Disclosures GRI 4.14, 4.15, 4.16 and 4.17

of Arts and Sciences, and the media. On the basis of corporate citizenship principles, we endeavor to maintain an open dialogue, seeking for most appropriate forms of cooperation.

The well-branched network of our stakeholder relations is associated with their various interests and a wide spectrum of Lek's operations. Our understanding of and dialogue with the stakeholders are based on the following Novartis' principles: commitment to patients, Lek people and local communities, respect of 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 the society and to upgrade the knowledge of our activity and stakeholders' expectations. We participate in social discussions where we present our views, being open for other people's opinions, and improving the company's performance through strategic adjustments of our corporate practice.

1.5.3.1 Stakeholder participation

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

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

Referring to the anticipated expansion of the production capacities at the Lendava site in 2012, we received from the local population, via the local community and civil initiative, questions about the environmental impacts of the new project, operation of the new incineration plant, and an unpleasant odor allegedly spreading from a section of the municipal sewage system in the close vicinity of the Lek site. Answers were provided on an ongoing basis, and the local population was given the opportunity to become familair with our operations on the Open House Day organized on the occasion of the 30th anniversary of the Lendava site.

The Ljubljana site received two noise-related complaints. Despite the fact that our noise emission levels had already been below the statutory threshold, silencers were installed in the first case, whereby the noise level was reduced further. In the second case, several additional noise measurements were performed by a certified external provider. The measurements revealed that in none of the cases the noise resulting from our operations exceeded the statutory limits.

We are open and proactive in building our relations with the media which serve as the voice of the public interest.

A glimpse of the Open House Day at the Mengeš site.

We cooperate with the groups of patients organized in associations and initiatives, with professional organizations, training and education institutions, and researchers in the field of chemistry, biology and healthcare.

Cooperation with the local community is reflected in our Open House Days organized on a regular basis. In 2012, they were held at the Mengeš and Lendava sites. The people interested in the company and its operations are shown round our production plants, presented with production-related activities, and provided with answers to their questions. Their response to these events has always been favorable.

To enable families of Lek employees to get to know the workplaces and jobs of their close family members, we organize Lek Family Days. We also wish to present our employees the company's social responsibility reflected in its cooperation with various organizations. Within the first Family Day campaign, we invited Red Nose Clowndoctors, our long-term partners in this campaign. This time we received a visit from the House of Experiments, our sponsoree since 2008. The Family Days were held at all of the Lek Slovenia-based sites on four consecutive Saturdays in November and December. More than 1,100 employees and their family members took part in the pleasant gatherings organized as part of the campaign.

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

1.5.4 Overview of Lek's commitment to external initiatives and principles[21]

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

- UN Universal Declaration of Human Rights,
- LO 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.

Furthermore, Novartis is a member of the Workplace Wellness Alliance of the World Economic Forum (WEF) (www.weforum.org/issues/workplace-wellness-alliance), Their orientations were also embraced by Lek.

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

[21] Disclosures GRI 4.9, 4.12 and 4.13

2. Environment

2.1 Implementation of active environmental policy

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

Lek's active environmental policy encompasses a number of environmental protection activities frequently exceeding legal requirements. Emphasis is placed on upgrading and improving current measures and implementing new ones. Business decisions are made in consideration of direct and indirect environmental impacts.

2.1.1 Specifics of business operations, and disparities in data collected

When identifying Lek's environmental impacts, certain specific features have to be taken into account. They mostly refer to the efficiency of the use of materials, energy resources, water, waste, atmospheric emissions, and wastewaters per tonne of product. Consequently, there are considerable differences in product and API weight. Compared to some self-medication drugs, similar biological drugs, for example, have low weight, yet their manufacture requires larger quantities of water and energy resources, and their financial value is higher as well. These disparities become particularly noticeable in seeking a common basis for the preparation of data for Lek, and they are also apparent at the Ljubljana and Mengeš sites which have an extensive, versatile product portfolio.

Lek's operations are also characterized by interim adjustments of the production program to changes in demand which could again be observed in 2012. The manufacturing structure therefore varies from year to year.

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

2.1.2 Major environment protection achievements

By implementing our environmental policy, we aim to improve the environmental performance of our processes. In 2012, we noted the following achievements in this area:

- We continued projects aimed at reducing atmospheric emissions:
  - At the Mengeš site, additional reconnections for discharge of halogenated solvent emissions into a cryocondensation device were executed,
  - At the Mengeš site, a thermal oxidizer for the control of air emissions was replaced by a regenerative thermal oxidizer (RTO), a device of higher performance and better cost efficiency. An identical device (the second in the last five years) was installed at the Ljubljana site;
- With intensified segregation, we reduced the volume of non-hazardous waste for disposal;
- Biodegradable mycelium resulting from the manufacture of clavulanic acid at the Lendava site was redirected to a bio-gasworks for reprocessing, which was mainly due to the alignment of our waste management practice with the statutory hierarchy, our objective to save energy and to reduce CO_2 emissions, to reduce the volume of ashes for disposal, and last but not least, to raise the level of cost efficiency.
- At the Prevalje site, we increased the use of wastewater generated in the process of water preparation for cooling purposes, whereby the use of fresh water for cooling purposes fell by 30%;
- A packaging project performed at the level of Lek d.d. brought about decreased use of raw materials, whereas the decrease in the packaging unit size diminished the impact on transport (reduced CO_2 emissions).

2.1.3 Investments in environmental management[22]

Environmental investments are part of our everyday business operations. In 2012, they amounted to EUR 2.4 million.

Environment protection investments

Treatment of air emissions with devices of higher energy efficiency

At the Ljubljana and Mengeš sites, we completed an extensive project of replacing the device for thermal oxidation of VOC emissions with new regenerative thermal oxidizer (RTO) with improved operational performance and better energy efficiency. Without any natural gas added, the new devices operate already at concentrations between 1.2 and 1.5 g of solvents per m^3 of waste air. The RTO operating at the Mengeš site has also a central condensation system fitted before the inlet of waste process gases.

RTO device in Ljubljana.

The major investment projects included:

- Completion of investment in two new, state-of-the-art thermal oxidizers installed at the Ljubljana and Mengeš sites to further reduce VOC emissions to the air;

[22] GRI Indicator EN30

- Installing an additional silencer at the Ljubljana site to further reduce environmental noise, despite the fact that our noise emission levels had already been below the statutory threshold;
- Additional upgrading of the software for collection and processing of data obtained from ongoing measurements of atmospheric emissions from the Lendava incineration plant which also encompassed the replacement of the mechanical platform and operation system to meet the quality requirements for the automated system for the collection and evaluation of data from stationary sources of emissions);
- Proceeding with upgrading of air-conditioning systems and with replacing of lights at individual sites to improve energy effciency (preparation of projects for the Ljubljana and Mengeš sites).

2.1.4 Verification of compliance with implemented standards

Lek, with all its four production sites, in 2012 became the first Slovenian pharmaceutical company to join the EMAS scheme, the EU Eco-Management Audit System. The EMAS environmental verifier (the Slovenian Institute of Quality and Metrology (Accreditation Number SI-V-0001)) confirmed the Sustainability Report of Lek d.d. for the year 2011. The report fulfilled all expectations regarding open communication and periodic publishing of verified environmental information. Following a successful environmental audit and verification of legal compliance, we received on 16 November 2012 the EMAS certificate from the Slovenian Environment Agency.

We also successfully passed other external verifications which confirmed the compliance of our operations with the requirements of ISO 14001, OHSAS 18001 and the Responsible Care Initiative.

External verifications re-affirmed our compliance with ISO 14001, OHSAS 18001, and RCI requirements. We received our first EMAS registration certificate.

Lek HSE systems

Lek HSE Policy

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

Priority is given to:
- 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 legal requirements. Our operations are based on the four pillars of the Novartis Corporate Citizenship policy. We focus on the 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 ourselves measurable goals.

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

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

Lek HSE Policy guidelines

We implement the HSE system on the basis of clear guidelines integrated into our operations. Fulfillment of legal requirements and corporate orientations constitutes a platform for our HSE risk management system.

We adhere to the ISO 14001 standard, the international OHSAS 18001 occupational safety and health standard, and the Responsible Care Initiative for the chemical industry, coupled with the EMAS Eco-Management Scheme.

Our key guidelines[23] include:
- Health, safety and protection of the environment constitute the basic responsibility of all our associates.
- We play an active 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 safe working environment and knowledge of risks.
- By introducing the best performing and cost-effective technologies available, we strive to become one of the leading environmentally-committed companies.
- We strive to make continuous progress in our use of raw materials and energy resources, and in reduction of environmental impact, which is constantly monitored through regular measurements and data follow-up.
- At our production sites, we regularly define, monitor and document HSE risks.
- To achieve risk management goals, we propose and implement preventive and corrective measures whenever necessary.

We provide our stakeholders with well-balanced information on our corporate responsibility, which forms a solid basis for dialogue and formation of views and decisions.

[23] Disclosure GRI 4.11

Lek HSE systems

Compliance with HSE laws and standards

We operate in adherence with the 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, emissions to the air, 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 applies particularly to the pharmaceutical industry.

Being an IPPC certified company, our Lendava and Mengeš sites operate in compliance with the Decree on the Type of Activities and Installations with a High Large-Scale Pollution Potential. The two IPPC permits also cover greenhouse gas emissions from the two cooling devices, whereas this type of emissions at the Ljubljana and Prevalje sites are included in the 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 practice. The individuals authorized for specific areas keep track of and identify them, ensuring appropriate internal publication after a GAP analysis. Responsibility for effective application in practice lies with the site heads / representatives of HSE units.

In 2012, a total of 13 inspections were carried out at all of the four sites, revealing our overall compliance with the applicable regulations. The majority of the inspections covered the environmental aspect of our operations, and one focused on the company's fire safety and occupational safety.

All our sites implement the Novartis Environmental Management System.

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

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

- Environmental permit for operation of a device with a high pollution potential (IPPC) for the Lendava site, Permit No. 35407-172/2006 dated 15 April 2010
- Decision amending the environmental permit for the Lendava site, No. 35407-37/2011-33, dated 12 July 2012
- Decision amending the environmental permit for the Lendava site, No. 35406-33/2012-4, dated 15 March 2013
- Environmental permit for operation of a device with a high pollution potential (IPPC), for Mengeš site, Permit No. 35407-171/2006, dated 14 May 2010
- Decision amending the environmental permit for the Mengeš site, No. 35407-22/2010, dated 28 December 2010
- Decision amending the environmental permit for the Mengeš site, No. 35407-54/2011, dated 16 May 2012
- Decision amending the environmental permit for the Mengeš site, No. 35406-24/2012-3, dated 23 August 2012
- Environmental permit for operation of a device using VOCs, for Ljubljana site, Permit No. 35430-19/2006, dated 30 January 2008
- Decision amending the environmental permit for operation of a device using VOCs, for the Ljubljana site, No. 35430-6/2010, dated 4 March 2011
- Decision amending the environmental permit for the Ljubljana site, No. 35430-9/2012-4, dated 11 September 2012
- Decision amending the environmental permit for the Ljubljana site, No. 35431-15/2012-2, dated 20 November 2012 – permit extension
- Environmental permit for operation of a device with regard to emissions into waters for the Ljubljana site, Permit No. 35441-339/2006, dated 8 November 2010
- Environmental permit for operation of a device using VOCs, for the Prevalje site, Permit No. 35413-23/2007, dated 26 October 2007
- Decision amending the environmental permit for operation of a device using VOCs, for the Prevalje site, No. 35412-17/2012-2, dated 4 October 2012 – permit extension
- Environmental permit for operation of a device with regard to emissions into waters for the Prevalje site, Permit No. 35441-338/2006, issued on 2 February 2011
- • 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, issued on 15 July 2011
- Water use permits for direct use of water (Nos. 35507-248/2003, 35504-143/2003, 35536-20/2008 and 35536-45/2012-5)
- Greenhouse gas emission permits No. 35433-88/2009 dated 19 August 2009, and No. 35433-87/2009 dated 18 August 2009
- Decision extending the permit granting the status of a manufacturer exempt from pollution charge for the CO_2 emissions resulting from the burning of fuels at the Mengeš and Lendava sites, No.DT 4231-77/2011 dated 30 November 2011

2.1.5 Optimization of business processes

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

TH!NK SANDOZ Initiative
TH!NK SANDOZ, a web-based idea management program, was launched as a pilot project in April 2012. In its first year, the TH!NK SANDOZ initiative recorded excellent results. At all Lek sites, employees contributed more than 600 interesting ideas to improve work procedures and processes, of which more than 150 were applied in practice. The ideas adopted in 2012 are expected to deliver savings of EUR 4.4 million, whereas those implemented in practice so far have resulted in EUR 2.2 million savings. Although searching in the database can be carried out according to several criteria, the searching tool does not enable segregation by content. Consequently, we cannot provide the information on the exact number of HSE improvements, even though a number of improvements are directly related to this area. According to our estimates, more than 10% of improvements are directly HSE-related, and at least 5% are environment-related.

The management staff has already recognized the significance of identifying creative and innovative associates. Their innovation-oriented thinking brings the company additional quality, enabling it to achieve and exceed its business goals faster. They therefore deserve our full support.

European Integrated Facilities Management (EIFM)
We continued the EIFM project aimed at improving business transparency and cutting the costs.

Project-related activities are performed simultaneously in several European regions. Slovenian sites are comprised in the region that includes Novartis organizational units in Germany, Austria and Switzerland. We create a uniform basis for effective facility and equipment maintenance, waste management, landscaping, and other factors. The new working method will be supported by appropriate information technology solutions, and will improve the business transparency, contributing to long-term savings.

In 2012, we completed the activities planned, including the selection of potential providers and the final selection of EIFM categories. The Help Desk assumed an important role in the process of receiving bids for contractual services. For the project and online portal launching, several communication materials were prepared. A management model was established, and an operational team was appointed for Slovenia, consisting of representatives of the major business functions.

Explosion safety– ATEX
By obtaining ATEX certificates for installations for buildings, lines and system at our production sites, we fulfilled the criteria for maintenance certification. The project complies with explosion safety regulations. Maintenance certification proves an appropriate level of compliance with the changes implemented, and a proper level of Ex equipment maintenance.

Activities related to explosion safety such as building maintenance, upgrading of equipment, and employee training, certainly contributed to reducing the number of incidents recorded in the company over the past years.

We are Sandoz Initiative
Performance is the key factor of our winning culture implemented through the "We are Sandoz" initiative. The initiative is instrumental in developing the organization and an excellent working environment. It gives every employee the opportunity of contributing to the company's future and expressing their opinions.

It is based on the following elements of our success:

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

Leading Solution, Leading Breakthrough, and Leading Manager Project
The Leading Solution project encompasses any minor improvement, either visible or invisible, contributing to the quality of the work process. Initiatives received are collected on a monthly basis, and assessed by a special committee. If the committee finds a particular idea suitable for implementation and upgrading, the idea is then classified into the next awarding category, the Leading Breakthrough category. As part of this project, Lek presented the Leading Solution, Leading Breakthrough and Leading Manager awards. The Lek Leading Solution award 2012 was given to the BCS-biowaiver project, a novel approach to the registration of fast-release solid dosage forms.

2.1.6 Indirect environmental impacts

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.

For waste management, we only select suppliers having all authorizations needed, and those recorded as contracting providers with the respective Ministry.

Transport is one of the major sources of indirect environmental impact. It is mitigated by more extensive use of teleconferencing and videoconferencing which replace long-distance business travel. For all the fleet cars used by Lek employees, fuel consumption, mileage and CO_2 emissions are monitored on a regular basis [24]. These data is reported quarterly into the Novartis database. For the 96 fleet cars Lek had in 2012, a total traveling distance of 3,231,854 km was recorded, with fuel consumption of 453 m^3, and CO_2 emissions of 1,204 tonnes.

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.).

[24] GRI Indicator EN7

2.2 Raw materials and natural resources

2.2.1 Recycling of hazardous and non-hazardous waste

Waste reuse and recycling are integral parts of our API production processes. In 2012, we recycled and reused 89% of the total quantity of organic solvents, an increase of 3 percentage points over the year before. In Lendava, the leading site in terms of waste reuse in recycling, the percentage of reused organic solvents amounted to as much as 97% (the figure identical to that recorded in 2011). 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 vapor for manufacturing purposes. Since adequate combustion conditions are provided, emissions generated in the process are comparable to those resulting from the combustion of environment-friendly energy resources such as natural gas and possibly industrial fuel.

In the field of non-hazardous waste, systemic segregation, collection and preparation of waste for recycling are continuously performed. In 2012, biodegradable mycelium waste from the Lendava production process was redirected from the incineration plant to a bio-gas works for reprocessing.

2.2.2 Mass flow of materials

Changes in the structure and volume of pharmaceutical production cause the annual mass flow of materials at the corporate level to grow. In 2012, the greatest contributor to this increase was the manufacturing process at the Ljubljana and Lendava sites where the change in the volume and structure of pharmaceuticals and API production was the most notable. On the other hand, the consumption of raw materials at the Menge site fell by 7% due to the structure of the API product range.

Table 3: Annual mass flow of various materials used* (in t)[25]

Year	Unit	Lendava**	Ljubljana***	Mengeš	Prevalje	Lek (Total)
2008	t	6,102	9,714	10,642	3,515	29,973
2009	t	6,080	7,232	11,467	3,473	28,252
2010	t	6,456	9,015	14,404	3,513	33,388
2011	t	6,811	8,804	16,898	3,858	36,371
2012	t	7,548	9,861	15,707	3,979	37,095

* *Total quantity of materials purchased within the reporting period to ensure smooth progress of manufacturing process to the finished product phase (including packaging but exclusive of fuels, water and manufacturing equipment).*
** *The data for 2009, 2010 and 2011 differs from the data published in the previous report due to elimination of decimal rounding-off errors.*
*** *The method of acquiring data on the use of materials was upgraded in 2012, which was also reflected in changed data for the previous years.*

2.2.3 Efficiency of materials

Graphic display of the efficiency of the use of all the raw materials at Lek d.d. reflects intensive efforts to reduce the consumption of raw materials per unit of product. The quantity of raw materials used per tonne of API / product started to fall in 2010. In the 2010 – 2012 period, the reduction achieved was as much as a 23%.

At the Lendava and Prevalje sites, single-purpose production plants and/or plants with one to two products operate in comparable years. The increasing efficiency of the use of materials is demonstrated in Graph 2.

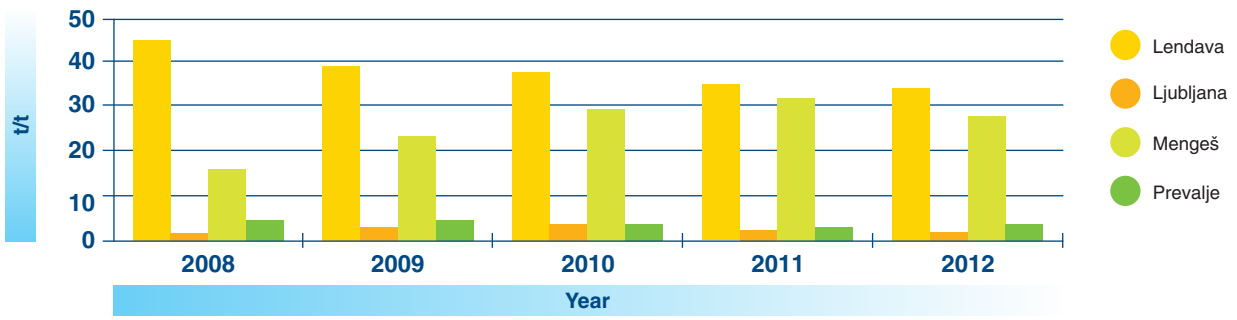
Due to the extensive range of active ingredients and products, and as a result of changes to the product portfolio, the efficiency of the use of raw materials cannot be seen from the graph. For this purpose, an overview by product would be required since their production output varied significantly.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

By upgrading the method for acquiring data on the realization of finished pharmaceutical products at the Ljubljana site, the accuracy of the data on the efficiency of the use of raw materials improved further in 2012.

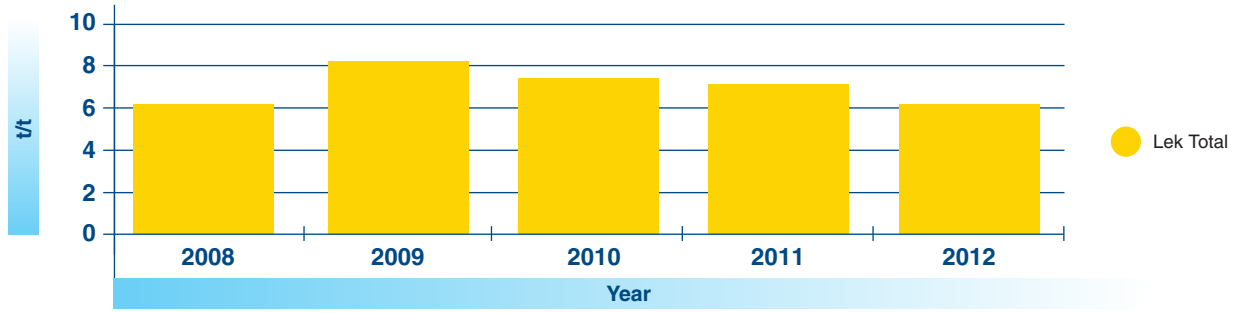
[25] EMAS Core Indicator, GRI Indicator EN1

Efficiency of the use of various materials per unit of product[26] - by site and total

Efficiency of the use of various materials per unit of product



Efficiency of the use of various materials per unit of product – Lek Total



2.2.4 Sustainable packaging approach

The two production sites manufacturing finished dosage forms are the major consumers of packaging material: Ljubljana with 68%, and Prevalje with 28%. At the Mengeš and Lendava sites packaging consumption accounts for less than 4% of total packaging consumption of Lek d.d.

In accordance with our commitment to waste management hierarchy, we defined in 2012 the basic principles of packaging design and production in order to improve packaging sustainability.

- 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 recycable.
- 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 made in 2012:

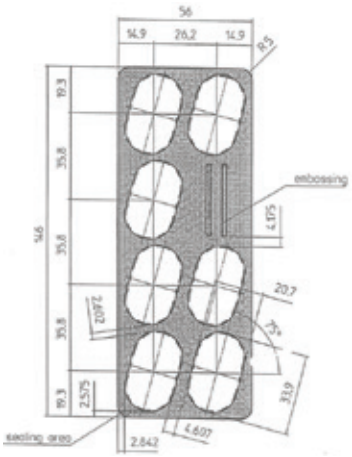
- By changing the blister size for omeprazole active ingredient, we reduced its surface by 17%, the shaping foil weight by 20%, and the covering foil weight by 15%.
- By optimizing the packaging for pantoprazole active ingredient, we reduced the blister surface by 50%, and the box volume and packaging weight by 20%. The number of packs per pallet was increased by 20% which also results in improved environmental efficiency of transport.
- By introducing a new wrapping foil, we reduced its consumption.
- Plastic strapping was replaced by non-slip paper for covering pallets.
- Transport cartons were standardized.

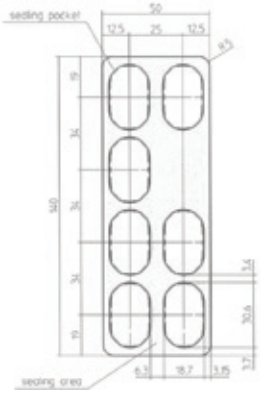
[26] EMAS Core Indicator

Changing the blister dimension for omeprazole active ingredient

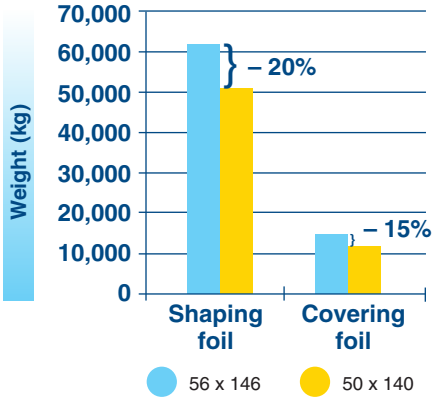
Previous blister dimension:
56 x 146 mm²

New blister dimension:
50 x 140 mm²





Shaping and covering foil consumption compared (FP manufacture in 2012)



Reduction:

- Blister surface – **17%**
- Shaping foil weight – **20%**
- Covering foil weight – **15%**

2.2.5 Water consumption and energy efficiency

In 2012, the efficiency of water, electricity and natural gas use per unit of product was improved once again, which was the result of many years of systematic endeavors in this area. At the level of Lek, the energency efficiency per tonne of product improved by 13%.

We have often mentioned fluctuations resulting from the changes in production volume and structure which 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.

Table 4: Efficiency of energy resource use per unit of product[27]

Year	Unit	Lendava	Ljubljana*	Mengeš	Prevalje	Lek (Total)*
2008	GJ/t	2,573	97	476	80	213
2009	GJ/t	2,450	174	631	73	315
2010	GJ/t	2,240	115	720	66	254
2011	GJ/t	2,004	106	677	53	222
2012	GJ/t	1,697	92	613	56	193

** 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.*

[27] EMAS Core Indicator

Responsibility towards the environment and employees

Multi-dimensional improvements at the Prevalje site

By implementing a specific project, the Prevalje site reduced water consumption by as much as 30%. Upgrading of the parking area reduced the risk of soil contamination.

The investment in a central weighing room was also beneficial in terms of HSE, since the modern weighing booths meet the latest HSE standards. In the weighing room, an upgraded ventilation system is installed, and separate weighing booths are provided.

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. The new measures are aimed at reducing the level of environment pollution with hazardous waste through elimination of halogenated air emissions to the air. At the Prevalje site, the studies for replacing the ethanol phase by the water phase in the film-coating process were continued after methylene chloride had been fully replaced with ethanol in 2011. Although the project of replacing the ethanol-based coating of omeprazole with water-based coating at the Ljubljana site has already been completed, regulatory approval is still pending due to the long duration of the procedure.

Abatement of emissions

Iceland and Thailand joined the group of countries replacing methylene chloride with ethanol

Action to replace methylene chloride with ethanol at the Prevalje site started in 2004. Despite our wish to obtain approval for the replacement as soon as possible, the approval process was slower than anticipated, mostly due to regulatory restrictions. Approvals for individual markets were granted over a period of six years. For Iceland and Thailand, the last two markets, we received approvals at the beginning of 2012. The last batch of film-coated tablets using methylene chloride was manufactured in July 2011.

2.3 Energy

2.3.1 Use of energy

Table 5: Total consumption of energy[28]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2008	GJ	352,417	319,995	288,974	61,017	1,022,403
2009	GJ	373,855	347,466	314,520	60,314	1,096,155
2010	GJ	388,834	340,136	355,266	58,551	1,142,787
2011	GJ	391,965	358,339*	350,825	60,253	1,161,382*
2012	GJ	371,988	381,552	335,382	57,434	1,146,356

** In the data reported for 2011 in the Data Management System, an error was identified that was subsequently corrected. The value indicated in the above table is the correct one, whereas the Sustainability Report 2011 contains the wrong value.*

By means of a comprehensive program of improvements mainly encompassing well thought-out rationalization of production management and planning we achieved a reduction of a little more than 1% in the total consumption of energy at all of our sites compared to the year before. The level of consumption lags behind the increase recorded in the production output, the result being achieved through improvements and efficient use of energy.

This outstanding achievement and a favorable ratio between the two results are reflected in the energy efficiency calculation (see Table 2).

Measures to improve energy efficiency undertaken in 2011 and 2012 were mainly reflected in the use of natural gas. The real dimensions of the achievement can be understood in the light of the fact that the production volume was increased significantly and that a record 1,316 new products were launched. Both factors are usually major contributors to energy consumption.

In the total energy consumed, electricity[29] accounts for 40%. It is obtained entirely from the power supply network. In the structure of purchased electricity sources, the share of energy for production obtained from nuclear power increased considerably, as we switched to another supplier of electricity.

Table 6: Structure of purchased electricity sources

	Year 2012
Conventional sources	**78.26%**
Coal and lignite	13.20%
Natural gas	6.42%
Oil derivatives	1.29%
Unidentifiable	4.86%
Nuclear fuel	52.49%
Renewable sources	**21.74%**
Hydropower	15.81%
Wind	2.73%
Solar energy	1.60%
Biomass	0.00%
Geothermal energy	0.00%
Landfill gas	0.00%
Municipal wastewater treatment gas	0.00%
Biogas	1.21%
Unidentifiable	0.39%
Total	**100.00%**

[28] EMAS Core Indicator, RC KPI 19 | [29] GRI Indicator EN4

At the Mengeš site, waste solvents are used as secondary fuel for the operation of a boiler producing heat and steam for manufacturing purposes. At the Lendava site, the share of renewable energy amounts to 1 – 2%. It is obtained from incineration of organic waste generated in fermentation production.

Table 7: Electricity consumption

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2008	GJ	139,452	131,382	98,389	25,838	395,061
2009	GJ	147,061	132,126	104,032	24,743	407,962
2010	GJ	154,082	134,083	115,320	23,376	426,861
2011	GJ	155,551	140,221	115,898	24,111	435,781
2012	GJ	167,994	152,638	116,215	24,551	461,398

In 2012, electricity consumption increased by almost 6% over the year before.

2.3.2 Energy efficiency improvements[30]

Lek has been boosting the production of higher-complexity products dictating the use of specific techniques and being of higher energy complexity. They are manufactured in lower quantities and have a higher added value. This is the reason why we have further intensified our efforts to ensure energy efficiency which already forms part of our production processes. We are also building our employees' awareness of energy use.

In 2012, several measures were taken to improve energy efficiency:

- At the Mengeš site, several energy projects were under way. By replacing the system for incineration of organic solvents from waste process air, we significantly reduced the consumption of natural gas for incineration, as well as solvent vapors in exhaust air. The changes implemented to the cooling system, and in the use of waste heat for removal of sludge from steam boilers increased the energy efficiency of the above devices.
- At the Prevalje site, a decrease in water and electricity consumption resulted from the upgrading of the cooling system and of the lighting installation in the non-production facilities.
- At the Ljubljana site, the air-conditioning system in the production facilities was replaced by a system of higher energy efficiency. A new thermal oxidizer for removal of organic solvent vapors from process air was added, and the cooling system in the administration building was replaced by a new one.
- At the Lendava site, we reduced the consumption of vapor for the treatment of mycelium currently transported to the biogas plant for reprocessing. We switched to a solution of higher energy and environmental performance. By changing the waste treatment method, we reduced electricity and natural gas consumption, thus achieving 10% annual savings in the site's total energy consumption. By exploiting the waste heat from the air compressor, we improved the energy efficiency of the steam boiler.
- Effective measures to reduce energy consumption indirectly resulted in reduced CO_2 emissions at the Lendava and Mengeš sites which participate in the EU Emissions Trading Scheme. Compared to 2011, emissions diminished by a total of 7.5%, i.e. 2,042 tonnes of CO_2.

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 Lek's major concerns. Water use efficiency was particularly improved at the Lendava and Mengeš sites, significantly contributing to the overall result. With multiple improvements, we again achieved significant progress, and confirmed the forecasts made in 2011 by reducing water consumption by 7%. The anticipation that the downward trend in water consumption can also be maintained in 2012 was fulfilled by achieving a 4% decline in total water consumption.

At the Lendava site, water consumption per kg of product was reduced despite the increased production volume in two newly installed fermentors. The trend has been downward both in relative and absolute terms, mainly resulting from the reuse of cooling water for batch feeding water after the sterilization of fermentors.

In the new Fermentation 2 facility, higher efficiency was achieved through installation of a closed-loop cooling system. For the purpose of cooling the old fermentors, an additional heat exchanger was installed to cool deferrized water. In 2013, new solutions will be implemented, and therefore further improvement can be expected. We are planning to introduce a system of reusing water from devices for purified water production, and to upgrade the system of cooling the oil in two-bar compressors.

Water consumption per kg of product at the Lendava site:

- 2011: 6.79 m^3 of total water consumption / kg of product
- 2012: 5.76 m^3 of total water consumption / kg of product

[30] GRI Indicators EN5 and EN7

Table 8: Water consumption in 000 m³ [31]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2008	in 000 m³	1.468	450	1.470	38	3.426
2009	in 000 m³	1.304	406	1.648	36	3.394
2010	in 000 m³	1.427	396	1.679	39	3.541*
2011	in 000 m³	1.333	415	1.502	34	3.284*
2012	in 000 m³	1.272	452	1.409	35	3.168

**The data for 2010 and 2011 differs from the data reported in the previous report due to the reconciliation of decimal rounding off.*

At the Mengeš site, water is used mainly for manufacturing purposes. At least 94% is pumped from the well (groundwater), and only 4-6% is supplied from the public supply network. As shown in the table 9, water consumption at the Mengeš site diminished. The table only provides the data on water use efficiency for polluted waters (cooling waters exclusive).

Table 9: Efficiency of water use* per unit of product[32]

Year	Unit	Lendava	Ljubljana*	Mengeš	Prevalje	Lek (Total)*
2008	m³/t	1,154	119	468	33	179
2009	m³/t	1,177	163	536	28	229
2010	m³/t	962	115	548	31	179
2011	m³/t	833	123	500	22	165
2012	m³/t	745	105	496	29	151

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

2.4.2 Water supply sources[33]

From the Ministry of Agriculture, we have obtained appropriate permits for the use of water for manufacturing purposes supplied from the Lendava and Mengeš sites' own wells.[34] Regular monitoring of groundwater levels is performed as well, and the results are reported to the respective Ministry. Simultaneously with this annual monitoring, the impact of the well on the level and direction of groundwaters is also monitored at the site.

In 2012, precipitation levels were below the multi-year average until October, whereas in October and November more than double the average level was recorded. Such broad variations confirmed the abundance of dynamic supplies in the Mengeš field. Despite the above-average precipitation levels, no sudden drop in the groundwater levels was recorded. Abundant rainfall in October caused their increase in less than a month.

Table 10: Water supply quantities and sources at the Mengeš and Lendava sites (in 000 m³)

Mengeš	2008	2009	2010	2011	2012
From own pumping stations (000 m³)	1,392	1,591	1,591	1,432	1,335
From public supply network (000 m³)	77	64	94	77	80

Lendava	2008	2009	2010	2011	2012
From own pumping station (000 m³)	1,455	1,262	1,384	1,325	1,228
From public supply network (000 m³)	43	42	46	39	61

[31] EMAS Core Indicator, RC KPI 21 | [32] EMAS Core Indicator | [33] GRI Indicator EN8 | [34] Water use permits nos. 35507-248/2003, 35504-143/2003, 35536-20/2008 and 35536-34/2007

2.4.3 Recycling and reuse[35]

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 poured into a higher-temperature system, while one portion of water (spill) is discharged into the sewage system. The quantities of reused water vary greatly and depend on individual processes, so they cannot be accurately calculated on the basis of the existing data capture method. Based on relevant calculations, it has been assessed that almost the entire cooling water quantity is reused at least twice.

At the Lendava site, the project of fermentation production expansion by installing two additional fermentation vessels was performed with the best techniques available. As the cooling cycles are of the closed-loop type, the consumption of well cooling water will not rise despite the increased production volume.

At the Prevalje site, we used the wastewater generated in the process of water preparation for cooling purposes, thereby reducing the fresh water consumption in the cooling towers by 30%.

2.5 Waste

2.5.1 Waste management[36]

Over the past 5 years, the relative volumes of generated waste (t of waste / t of product) have been diminishing due to manufacturing process optimizations, whereas the increasing production volumes have resulted in an increase in the absolute waste volumes.

Due to a changed data collection methodology (see Item 1.4.1), changes in the volumes for previous years occurred. Consequently, a direct comparison of waste volumes generated in 2011 and 2012 with the volumes in the previous years is not entirely appropriate. The data for 2011 and 2012, however, is comparable in consideration of the fact that mycelium waste is no longer incinerated in our incineration plant, and consequently became the subject of reporting in 2012.

At the Lendava site, the types and volumes of waste differ as a result of two different production processes (biofermentation production of APIs, and packaging of finished dosage forms). The packaging process is characterized by major variations in quantity that depend on the product changeover.

At the Mengeš site, more than 80% of total waste is accounted for by 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.

In 2011, the reporting methodology for waste changed (see Item 1.4.1) due to the fact that the waste disposed of at the Lendava site by incineration, and at the Mengeš site by co-incineration with energy utilization, is no longer taken into account. Reports only cover the volume of waste released for treatment outside the production site. Given the change in the final waste disposal destination, the new method of data recording based on the Novartis' methodology is the major cause for the increase in the total waste figures for 2012. According to the methodology, mycelium waste previously incinerated in the site's own incineration plant was not included in the report. Since 2012 when it was first released to a nearby biogas plant for treatment, it has been covered by the report, and strongly impacts the waste figures reported.

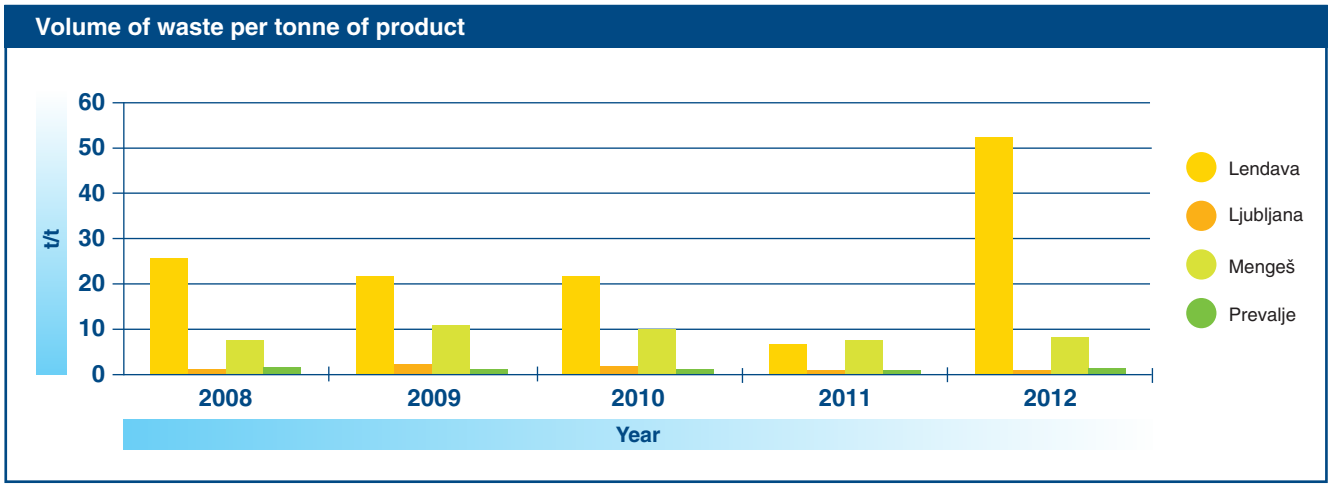
Table 11: Volumes of waste generated (in t)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)*
2008	t	3,663	1,457	4,474	535	10,129
2009	t	3,343	1,646	5,234	573	10,796
2010	t	3,801	1,851	4,907	535	11,094
2011	t	1,432	1,800	4,392	590	8,214**
2012	t	11,374	2,210	4,904	676	19,164**

** The data for 2010 and 2011 differs from the data reported in the previous report due to the reconciliation of decimal rounding off.*
*** Volume of waste released for treatment outside the production site.*

[35] GRI Indicator EN10 | [36] EMAS Core Indicator, GRI Indicator EN22

Graph 3: Volume of waste per tonne of product* – efficiency



** Volume of waste released for treatment outside the production site.*

2.5.2 Disposal of hazardous waste[37]

Increasing production outputs and changes in the product range towards technologically more advanced products manufactured in smaller quantities by using specific techniques (Mengeš) 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. By improving the manufacturing waste at the Mengeš site, we lowered the total relative volume of hazardous waste by 0.6 t per tonne of product already in 2010.

At the Mengeš site, non-halogenated waste solvents, being extremely pure and having a high calorific potential, account for 85–95% of total hazardous waste. The mixtures of halogenated waste solvents account for 3–11%. By means of co-incineration with natural gas, 15– 30% of the annual quantity of non-halogenated solvents is removed. The energy obtained is utilized for manufacturing purposes to prepare technical steam.

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

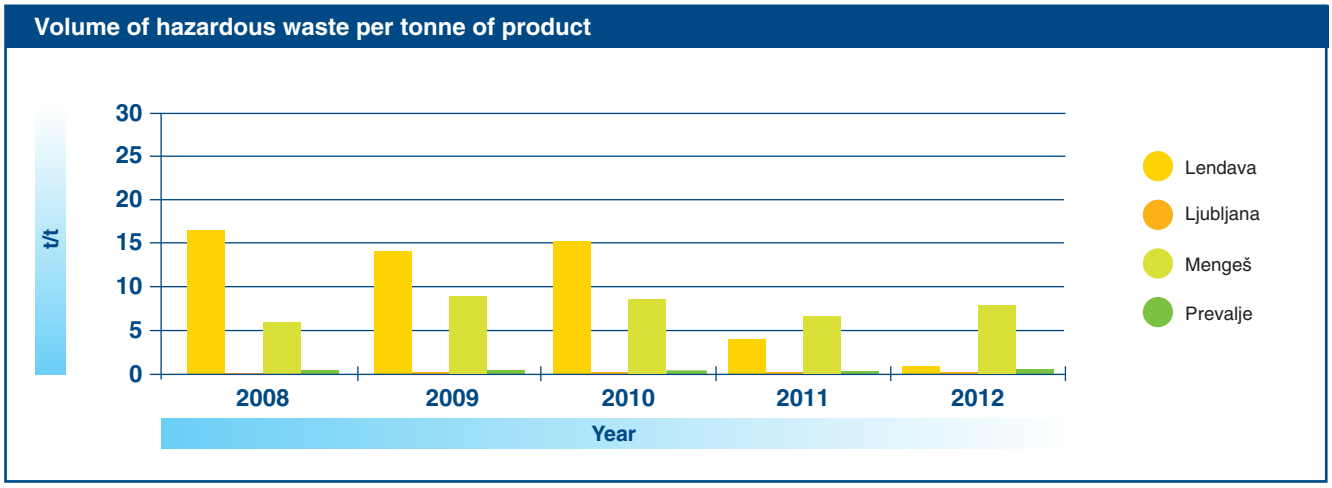
Table 12: Hazardous waste volumes (in t)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2008	t	2,214	298	3,557	250	6,319
2009	t	2,173	423	4,380	253	7,229
2010	t	2,619	529	3,987	211	7,346**
2011	t	783*	412	3,416	228	4,839**
2012	t	220*	572	4,111	247	5,150

** The data for 2010 and 2011 differs from the data reported in the previous report due to the reconciliation of decimal rounding off.*
*** Volume of waste released for treatment outside the production site.*

[37] GRI Indicator EN22 and RC KPI 5

Graph 4: Volume* of hazardous waste per tonne of product - efficiency



** Volume of waste released for treatment outside the production site.*

2.5.3 Disposal of non-hazardous waste[38]

A more consistent approach to waste segregation and sorting as well as better employee awareness resulted in a 5% decrease in the volume of mixed municipal waste in 2012. For the same reasons, the volumes of waste packaging collected continue to increase.

At the Mengeš site, the biologically degradable waste generated by the manufacture of fennel and purple coneflower juices was redirected in 2011 from the composting plant to a nearby biogas plant. In 2012, we similarly redirected the mycelium waste generated at the Lendava site for treatment from the site's own incineration plant to a certified contractor biogas plant, thus adhering to the statutory requirement of waste management hierarchy. The exhausted mycelium is a by-product of fermentation broth filtration. According to the Waste Assessment (Regional Institute of Public Health Kranj, January 2012), it constitutes non-hazardous waste, and is therefore suitable for further treatment in a biogas plant. Changing the treatment method resulted in 10% annual savings in the site's total energy consumption. Atmospheric CO_2 emissions dropped significantly as well.

As a result of redirecting the mycelium waste for treatment to a biogas plant, the structure of non-hazardous waste changed considerably compared to 2011. Municipal waste accounted for a mere 2%, whereas the share of waste packaging (paper, plastics, wood, metal, glass) amounted to 17%. Due to mycelium waste which was not reported in 2011 as it was disposed of through incineration at the production site, biodegradable industrial waste accounted for 77%, while the remaining 4% is accounted for by other non-hazardous waste.

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

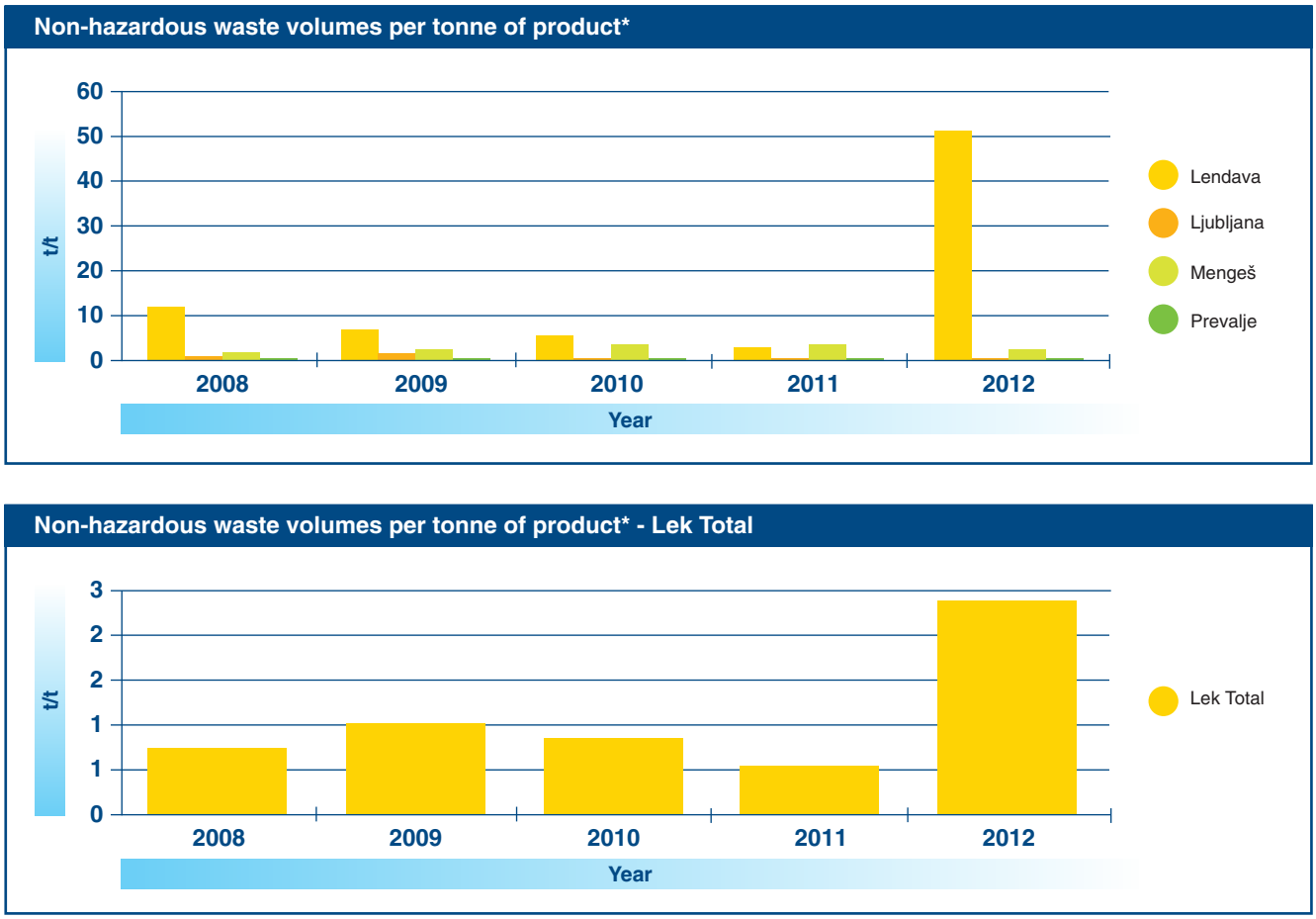
Table 13: Non-hazardous waste volumes by site (in t)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)*	Lek (non-hazardous waste without recyclable packaging)*
2008	t	1,449	1,159	917	285	3,810	2,802
2009	t	1,170	1,223	855	320	3,568	2,549
2010	t	1,181	1,322	921	324	3,748	2,483
2011	t	649**	1,388	975	362	3,374**	1,815**
2012	t	11,154**	1,637	793	430	14,014**	12,194**

** The data for 2008, 2010 and 2011 differs from the data published in the previous report as a result of the adjustment made due to incorrect decimal rounding off.*
*** Volume of waste released for treatment outside the production site.*

[38] GRI Indicator EN22

Graph 5: Non-hazardous waste volumes per tonne of product* - efficiency



** Volume of waste released for treatment outside the production site.*

2.6 Air emissions[39]

2.6.1 Abatement of air emissions

Lek has been systematically measuring and abating air emissions. We separately monitor greenhouse emissions and emissions from immobile devices. Of the latter emissions, VOCs and dust are the most important. Emission metering points are established on individual manufacturing devices and lines where the presence of emissions of VOCs, dust particles and other substances is expected in the exhaust air. At these points, the content of a specific substance and/or dust in the air is measured, and samples for analysis are collected. For all the outlet ducts measured, assessments of substance and/or dust emissions have been made as prescribed.

To reduce organic substance emissions, we use devices for exhaust air cleaning such as thermal gas incinerators, adsorbers, gas washers, and other. In 2012, the Ljubljana and Mengeš sites witnessed the conclusion of a major project of replacing the existing thermal gas incinerators with two devices of higher energy efficiency, which are able to operate without additional fuel (natural gas) within a specific range of solvent concentration in the waste air. To remove dust particles before the exhaust air outlet, two H.E.T. filter units are installed, capable of trapping 99.95% of dust particles ranging from 0.1 – 0.3 μm in diameter.

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. Lek complies with all relevant regulations in this area. 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 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^3. For the existing device, furnished with a device for waste gas removal, the limit values of 50 mg C/Nm^3 for incineration of waste gas, and 150 mg C/Nm^3 for other methods of waste gas removal will become effective as of 31 December 2013.

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

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

[39] EMAS Core Indicator, GRI Indicator EN20, RC KPI 7, RC KPI 10

2.6.2 Emissions from waste incinerators and co-incinerators

At the Lendava site, the waste incinerator operates, mainly treating industrial waste generated at the site. Due to the release of mycelium waste to a biogas plant for treatment, its scope of operation diminished. During the incineration process, controlled via a control system, flue gas parameters are regularly measured. The set limit/alarm values prevent the waste incineration process from running outside the permissible limits. By incineration of waste and natural gas as supporting fuel, technical steam is obtained.

At the Mengeš site, thermal oxidation of industrial fumes is carried out in one of the four combustion plants using natural gas as a primary source of energy. By co-incineration of natural gas and non-halogenated solvents of high purity and calorific potential, technical steam is obtained. Emission monitoring is regularly performed at all the emission release points. In 2011, permanent emission measurements were provided on the waste solvent co-incinerator for the parameters prescribed in the environmental permit.

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

2.6.3 Sulphur dioxide (SO_2)[40]

The volumes of SO_2 emissions at Lek sites have always been low, and were mainly generated by the devices for the thermal treatment of volatile organic compounds.

Table 14: Sulphur dioxide emissions (SO_2)[41]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) (kg of SO_2/t of product)
2008	t	0.10	0.04	0.02	0.00	0.16	0.03
2009	t	0.11	0.03	0.03	0.00	0.17*	0.05
2010	t	0.12	0.01	0.00	0.00	0.13	0.02
2011	t	0.00	0.01	0.00	0.00	0.01	0.002
2012	t	0.00	0.0001	0.00	0.00	0.0001	0.0000

** The data differs from the data in the 2011 report due to the reconciliation of the sum total of decimals rounded off.*

In 2011 and 2012 the emission monitoring performed at all of our sites showed a level of almost zero. This was confirmed by a supplier's statement that the content of sulphur in natural gas is practically non-existent. The values of SO_2 emission volumes by year are based on the data on their concentration at individual measuring points and on the time of device operation.

2.6.4 Nitrogen oxides (NO_x)[42]

Nitrogen oxide emissions mainly arise from incinerators and co-incinerators, burning devices and to a lesser extent the manufacture of nitrooxine at the Mengeš site. At all the sites, regular emission monitoring is carried out.

In 2012, the total volume of nitrogen oxide emissions decreased further, remaining below the statutory values. A decline in nitrogen oxide emissions was recorded at the Prevalje and Mengeš sites, whereas the other two sites maintained a level similar to that in the year before.

Table 15: Emissions of nitrogen oxides (NO_x)[43]

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficiency (Lek) (t of NO_x/t of product)
2008	t	9.30	1.14	10.82	1.36	22.62	0.005**
2009	t	10.14	0.78	8.72	1.38	21.02	0.006
2010	t	9.14	1.30	16.36	1.36	28.16*	0.006**
2011	t	7.17	1.33	15.06	1.40	24.96	0.005
2012	t	7.58	2.33	9.94	1.27	21.12	0.004

** The data differs from the data in the 2011 report as a result of the adjustment made due to incorrect decimal rounding off.*
*** Changed efficiency data for NO_x for Lek as a result of changed data on production output for the Ljubljana site.*

[40] EMAS Core Indicator, RC KPI 8, GRI Indicator EN20 | [41] EMAS Core Indicator, RC KPI 7, GRI Indicator EN20 | [42] EMAS Core Indicator, RC KPI 8, GRI Indicator EN20
[43] EMAS Core Indicator, RC KPI 7, GRI Indicator EN20

2.6.5 CO_2 and other greenhouse gases

At Lek, direct emissions (GHG1) result from the burning of fuels and the incineration/treatment of flammable organic substances, production processes (e.g. fermentation) and the use of company cars. The group of GHG1 also includes some other gases used in or arising from Lek processes, e.g. HFC, N_2O and methane.

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

Carbon dioxide and other gases contributing to the greenhouse effect[44]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficency (Lek) (t of CO_2/t of product)**
GHG1	2008	t CO_2	12,492	1,953	11,523	2,027	27,995	5.8
	2009	t CO_2	11,636	2,371	12,310	2,027	28,344**	8.2
	2010	t CO_2	12,071	3,005	14,353	1,955	31,384**	7.0
	2011	t CO_2	11,839	3,699*	15,135	1,999	32,673*	6.3
	2012	t CO_2	10,801	2,928	13,469	1,821	29,019	4.9
GHG2	2008	t CO_2	14,364	31,721	10,134	2,661	58,880**	12.2
	2009	t CO_2	15,153	34,105	10,715	2,548	62,521**	18.0
	2010	t CO_2	15,870	33,218	11,879	2,407	63,374**	14.1
	2011	t CO_2	16,023	35,117	11,938	2,482	65,560**	12.6
	2012	t CO_2	12,438	38,434	11,970	2,530	65,372	11.0

* *Changes of data as a result of changed data on production output for the Ljubljana site.*
** *The data differs from the data in the 2011 report due to reconciliation of the sum total of decimals rounded off.*

Direct emissions (GHG1)[45] data include:

- Dinitrogen monoxide (N_2O) in the equivalents of CO_2[46],
- Fluorinated hydrocarbons (hidrofluorocarbons - HFC) in the equivalents of CO_2[47] and
- Other greenhouse gases (methane and other) in the equivalents of CO_2.[48]

The Lendava and Mengeš sites participate in trading with CO_2 emission vouchers. According to the law, we have the obligation to report to the Ministry of the Environment and Spatial Planning, and to pay an environmental fee.

In 2012, total direct and indirect greenhouse gas emissions were reduced at the Lendava, Mengeš and Prevalje sites. The quantities of direct and indirect emissions at the level of Lek diminished.

Until recently, direct emissions (GHG1) at the Lendava site mainly resulted from organic waste incineration. As a result of the mycelium waste released to a biogas plant for treatment, their volumes diminished in 2012.

Indirect emissions (GHG2) mainly result from purchased electricity, their volumes in 2012 showing a drop following the slight upward trend in the previous years. The savings are documented, still accounting for a minor percentage of total CO_2 emissions.[49]

At the Mengeš site, the main causes of CO_2 (GHG1) emissions are natural gas combustion (> 90%) in the burning devices. One of the contributory factors was the manufacture of cutting-edge technology products of higher energy complexity. The increasing emission volumes recorded in the 2009 – 2011 period were also due to new products of high complexity. Consequently, emission abatement is our top-priority task. It was mainly achieved through systemic energy management, process changes, implementation of new technological solutions, and installation of energy- and environmentally efficient devices.

2.6.6 Volatile organic compounds (VOC)[50]

In accordance with Novartis' recommendations on the use of alternative solvents in production, a systematic process of replacing halogenated solvents with non-halogenated ones is underway at Lek. In 2012, total VOC emissions saw a considerable decrease, whereas the efficiency per tonne of product improved significantly.

At Mengeš, a device for removal of halogenated solvents from exhaust air using state-of-the-art cryogenic condensation is used. Due to the final replacement of methylene chloride with ethanol at the Prevalje site, halogenated solvents are no longer used.

[44] GRI Indicator EN16 | [45] RC KPI 10 | [46] RC KPI 11 | [47] RC KPI 12 | [48] RC KPI 13 | [49] GRI Indicator EN18 | [50] RC KPI 9

Table 17: Total emissions of volatile organic compounds

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)	Efficency (Lek) (t of VOC/t of product)
2008	t	25	52	195	1.7	274	0.057
2009	t	24	70	203	2.7	300	0.086
2010	t	25	58	170	5.5	258	0.057
2011	t	24	36	146*	6.2	212	0.041
2012	t	23	43	71	5.4	142**	0.024

* *The change to the data from the previous report results from the change in the data for omeprazole manufacture reporting. The manufacture of Omeprazol was terminated in December 2011, however, due to our record keeping system, one part of the plan realization was presented in January 2012. When reporting for 2011, we took into account emissions with regard to the realization. In 2012, however, this practice was changed, and emissions data was transferred from January 2012 to December 2011 (5.678 t of nH-VOC).*

** *The data differs from the data reported in 2011 due to the reconciliation of decimal rounding off.*

2.7 Water releases

Wastewaters are directed into the public sewage system through separate three-channel ducts: manufacturing, cooling and municipal. For industrial wastewaters, all the sites have equalization ponds installed before the release duct, whereas at the Prevalje site, industrial wastewater is also technologically neutralized.

Into the cooling sewage system we only release non-contact cooling water. Unpolluted water are discharged directly into the water stream whenever possible. Roof precipitation wastewater is discharged into the waters directly or indirectly.

In 2012, the Lendava site started the process of obtaining permits and other documents for the planned intervention of redirecting the existing outlet for the discharge of cooling (unpolluted) waters into the Kopica stream to the discharge outlet into the Mura river. Due to high volumes of wastewaters, Lek will not be able to discharge the cooling waters into the Kopica stream after 31 December 2014. Consequently, the discharge outlet relocation is the only solution. As part of this relocation, the discharge of precipitation waters will be separated from that of waste cooling waters. Precipitation waters will still be discharged into the Kopica stream through oil traps. The decision on amending the environmental permit for the said intervention was issued at the beginning of 2013.

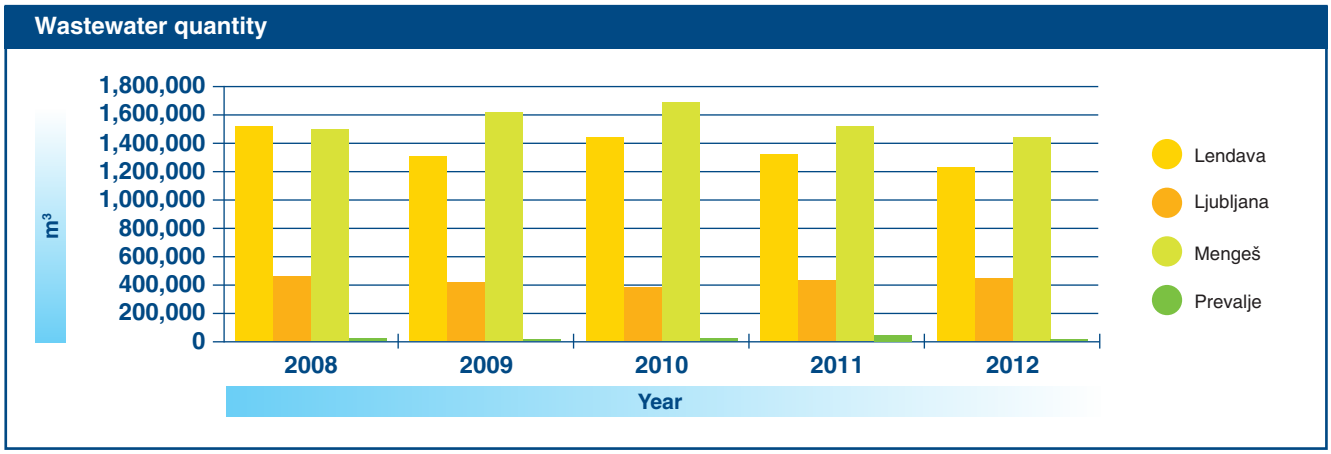
Reports on the Monitoring of Industrial Wastewaters Discharge for 2012 (Excessive Pollution Levels section) show that no excessive pollution was identified at any of the four sites.

2.7.1 Wastewaters

The quantity of wastewaters generated by Lek dropped for the second time in a row. The decline, amounting to slightly over 4%, was mainly due to reduced volumes of wastewaters at the Lendava, Mengeš and Prevalje sites. At the Lendava site, this reduction is mainly the result of further optimization of water use for the cooling of fermentors, while at Mengeš it is due to several minor measures taken in the manufacturing process.

At the Mengeš and Lendava sites, waste cooling waters account for more than 80% of the total water quantity. In 2012, their consumption slightly declined, whereas the consumption of industrial water recorded a slight increase.
After use, unpolluted waste cooling waters are discharged into the water stream, a procedure for which environmental permits have been obtained. Due to additional closed-loop systems of water use, the quantity of unpolluted industrial water diminished in 2012, whereas the increased production volume resulted in a slightly increased polluted water quantity. The total volume of waste industrial waters dropped by slightly more than 4%.

Graph 6: Wastewater quantity (in 000 m³)



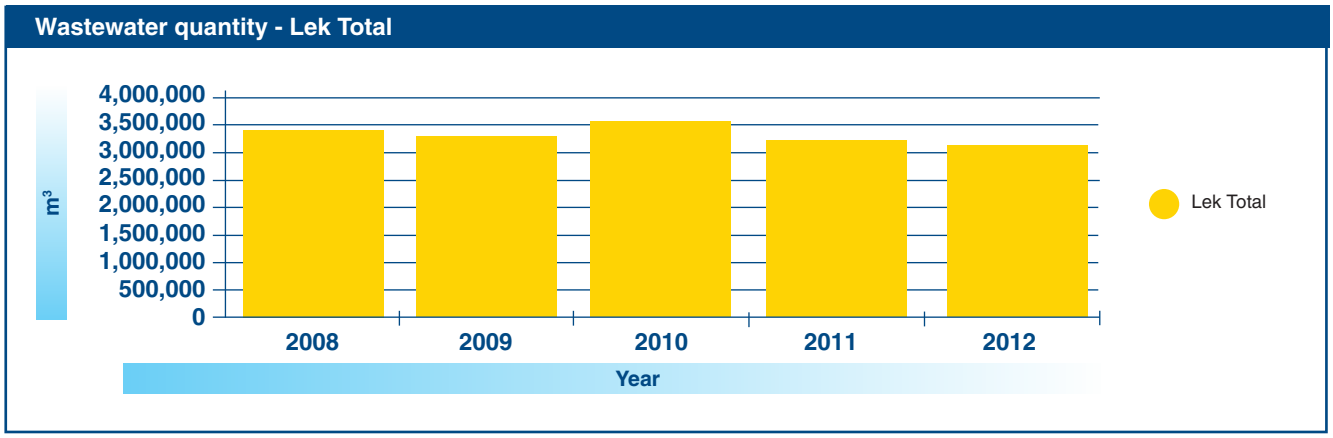


Table 18: Wastewater volumes by discharge quality and destination[51]

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
Use of cooling water - unpolluted							
	2008	in 000 m³	1,310	57	1,186	13	2,566
	2009	in 000 m³	1,125	79	1,381	13	2,598
	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
Discharge			into water system	into sewage system cleaning at WWTP	into water system	into sewage system	
Use of industrial - polluted							
	2008	in 000 m³	158	393	284	25	860
	2009	in 000 m³	180	327	267	23	797
	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
Discharge			into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system cleaning at WWTP	into sewage system	into sewage system cleaning at WWTP

** The data differs from the data reported in 2011 due to reconciliation of the sum total of decimals rounded off.*

[51] EMAS Core Indicator, GRI Indicator EN21

2.7.2 Phosphorus and nitrogen compounds, chemical oxygen demand

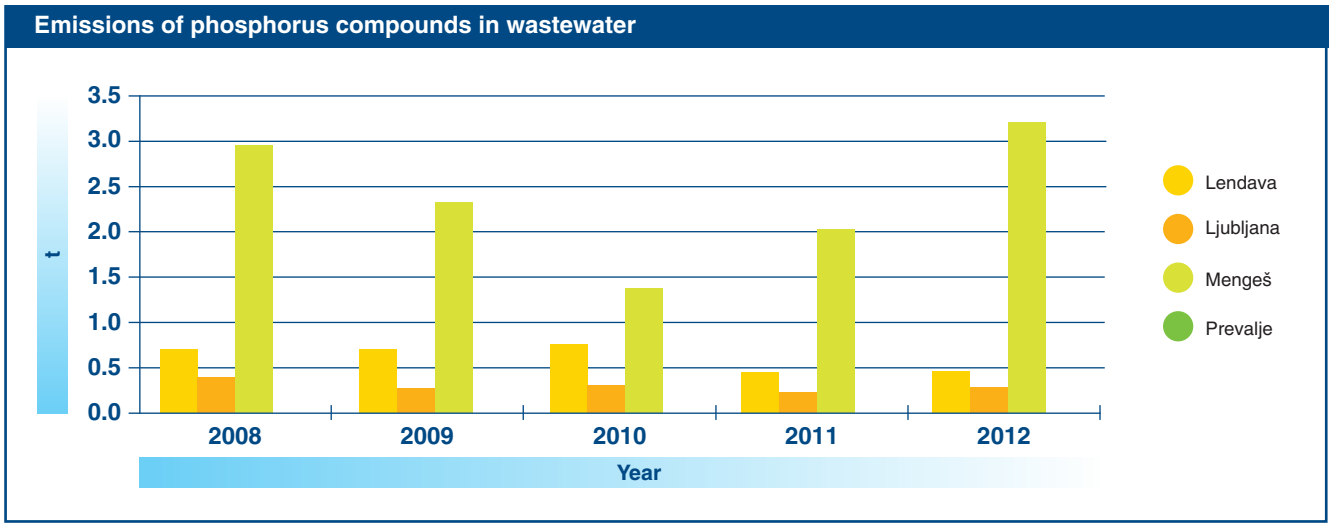
Nitrogen compound emissions mostly result from the fermentation production, particularly at the Mengeš site followed by Lendava and Ljubljana, and, at a negligible level, the Prevalje site, which is demonstrated in the graphic presentation of the emission trends by site. In 2012, the total volume of nitrogen compound emissions at Lek declined.

The Mengeš site is also the major generator of phosphorus compounds, their source being residual inorganic substances. As the annual amounts of phosphorus and nitrogen compounds are reported after treatment in the wastewater treatment plant, they largely depend on the efficiency of the wastewater treatment. In 2012, they rose to the level of 2008.

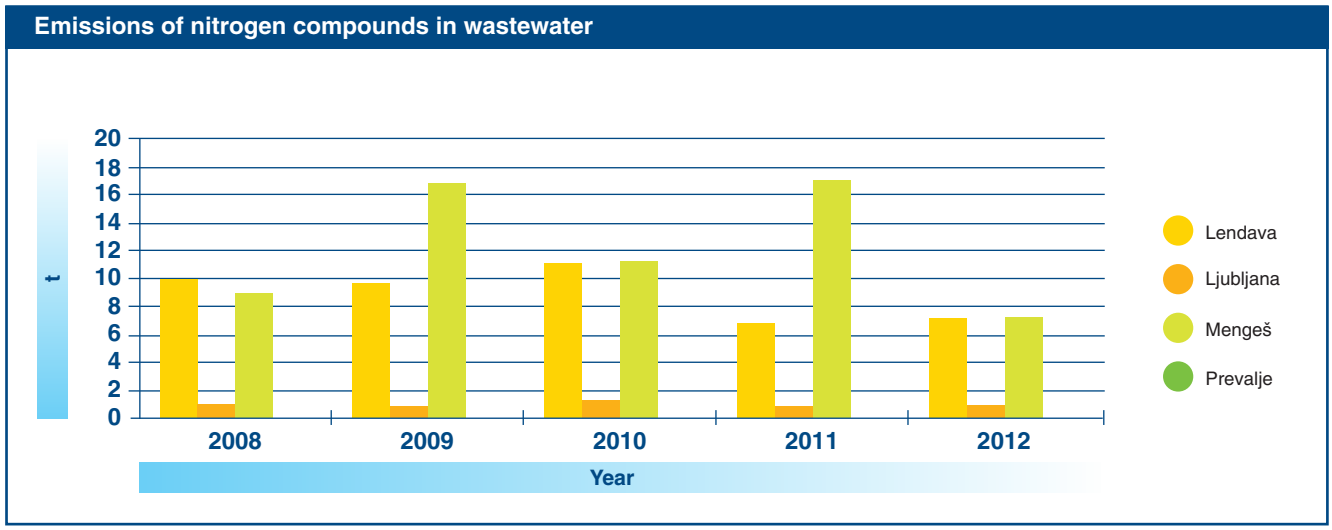
To provide an assessment of the level of pollution with organic impurities, chemical oxygen demand is an important parameter, providing the quantity of oxygen needed for chemical oxidation of organic pollution in wastewater. Chemical oxygen demand measurements aimed at assessing the pollution level are carried out at the point of discharge of waste cooling waters into the water stream, and at the point of discharge of industrial wastewater into the treatment plant collector. The level of chemical oxygen demand declined in 2012.

Lek's 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. 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.

Graph 7: Emissions of phosphorus compounds in wastewater[52]

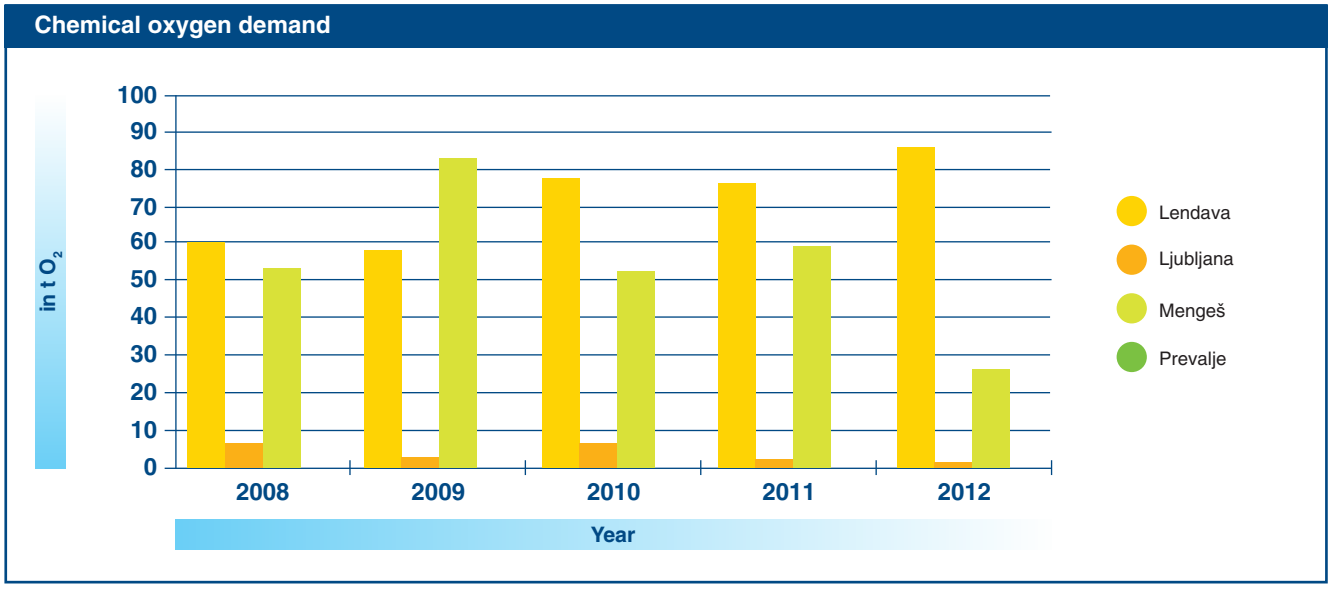


Graph 8: Emissions of nitrogen compounds in wastewater[53]



[52] RC KPI 15 | [53] RC KPI 16

Graph 9: Chemical oxygen demand (in t of O_2)[54]



Through increasing knowledge of chemical substances and the significance of biotic diversity for human beings, Lek started – even before the respective Slovenian and EU laws were implemented - to research the impact of active pharmaceutical ingredients potentially entering wastewaters as a result of our operations. From there, they pass through wastewater treatment plants into surface waters. Even though it has been established that only a small percentage of APIs present in the wastewaters are generated by the manufacturing process (the major part results from the final users of pharmaceutical products), ecotoxicity data of APIs are regularly reviewed and evaluated, and proper action is taken.

2.8 Other environmental impacts

2.8.1 Odor

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

In 2012, we received a letter from the civil initiative / Lendava community, complaining about an unpleasant odor occasionally spreading from the public sewer pipeline duct bordering the Lek facility. As the duct is an integral part of the municipal sanitary wastewater system, the odor is the result of insufficient flow rate within the duct, particularly in summer.

2.8.2 Soil

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

We consistently fulfill the requirements for hazardous substance storage and transport, which are the major soil pollutants. We regularly check the leak tightness 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.

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

Table 19: Land use by site[55]

	Mengeš	Lendava	Ljubljana	Prevalje	Lek
Green surfaces (in m^2)	45,748	104,478	28,780	6,698	185,704
Building surfaces – aerial view (in m^2)	32,145	12,963	38,003	6,658	89,769
Asphalt surface – roads, courtyards (in m^2)	39,023	19,222	43,315	5,171	106,731
Total site surface area with parking lots (in m^2)	126,537	136,663	121,015	18,527	402,742
Production site surface area/product (in m^2/t)	231.5	623.5	29.2	18.1	67.9

[54] RC KPI 14 | [55] EMAS Core Indicator

2.8.3 Noise

In order to control any excessive environmental noise pollution, we perform regular monitoring and analyses, while implementing appropriate preventive measures as early as in the production technology design stage. None of the measurement results indicates any noise overload at any of the four Lek sites, which applies to both day and night shifts. 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.

A project designed for the Prevalje site in 2012 is aimed at mitigating noise emissions through installation of the fan of the RTO inside the energy facility. The standard RTO design with an external fan could be environmentally problematic due to proximity of residential buildings.

In 2012, Lek received two noise-related complaints.

2.8.4 Biodiversity[56]

Lek's awareness of the significance of environmental protection is reflected in its consistent adherence to statutory waste and industrial water management requirements and proactive measures taken. We thereby strive to mitigate any impact on the quality of the environment and consequently on the biodiversity of the areas surrounding our production sites. Lek facilities are located within industrial zones where there are no major environmentally critical habitat types or protected vegetation.

2.9 Safety

2.9.1 Fire safety

Within our routine fire-safety activities, we performed four tactical fire drills in 2012. At the Mengeš site, the drill was carried out on a larger scale, involving 8 fire intervention teams, a cave rescue team, a mountain rescue unit, emergency medical service, a police unit, the Slovenian rescue dog handlers' association, and the Ljubljana Regional Notification Center. The drill covered the following aspects: training of fire intervention teams, employee evacuation, verification of active fire safety system functionality, and verification of the compliance of emergency management procedures and guidance. We checked the level of protection and rescue teams' response, equipment availability, and their conduct in case of emergency. For all the employees, we organized theoretical training programs and evacuation drills with real-life fire-extinguishing tests.

Within the Fire-Safety Month campaign, workshops on the local fire-safety awareness raising were held for the employees at all of the Lek sites. Investments were made to upgrade the active and passive firefighting systems. In 2012, there were no major fire-safety interventions.

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

2.9.2 Biological safety

Lek deals exclusively with biological agents from Risk Groups 1 and 2:

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

Lek's manufacture involves exclusively biological agents of Risk Group 1. All the genetically modified organisms (GMO) belong to this group as well. For the biological agents, risk assessments were made.

Responsibilities for biological safety assurance have been clearly defined. Each of the Mengeš, Ljubljana and Lendava sites employs a Biological Safety Officer, which is also the case at the Lek corporate level. Furthermore, certain employees are responsible for GMO management safety. The basic task of Biological Safety Officers is to reduce potential risk of biological factors management and to ensure compliance with the Slovenian laws and Novartis' guidelines.

At Lek, a nine-member Biological Safety Committee operates. 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.

The programs for risk management in working processes featuring biological factors in contained areas, prepared in 2012, were implemented in the new laboratory of cellular and molecular biology established in the Biopharmaceuticals Development Center at the Mengeš site in 2012.

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

[56] GRI Indicator EN14

2.9.3 Providing storage and distribution safety

2.9.3.1 Storage

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

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

In 2012, we further upgraded the classification and labelling of chemicals according to the GHS (Globally Harmonized System) for manufacture and storage purposes, and in the field of waste management.

2.9.3.2 Distribution[57]

From Lek production sites, 5857 consignments of finished products and APIs were dispatched to 93 countries. During the transport of both non-hazardous and hazardous goods, no accidents occurred.

In the organization of international road transport, we continued with the implementation of the "Control Tower" business model organized by DHL Belgium. The project proved to be successful and cost efficient.

A global tender was launched for the selection of an air freight forwarder, and a local call for bids was put out for sea freight forwarding services.

In 2012, the volume of distributed goods remained at the level of 2011, amounting to 17,816 tons. Major changes took place in the distribution of goods for the Russian Federation, where the goods in stock at the Ljubljana site intended for that market were relocated to the Hoče location, freeing the capacity of the Ljubljana site, and increasing the volume of operation in Hoče. In the distribution of goods to Asian countries, the model of dispatch and transport organization was changed, which also resulted in cost savings.

2.9.4 Chemical safety

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

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

Lek HSE systems

HSE organization, human resources and training

HSE function

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

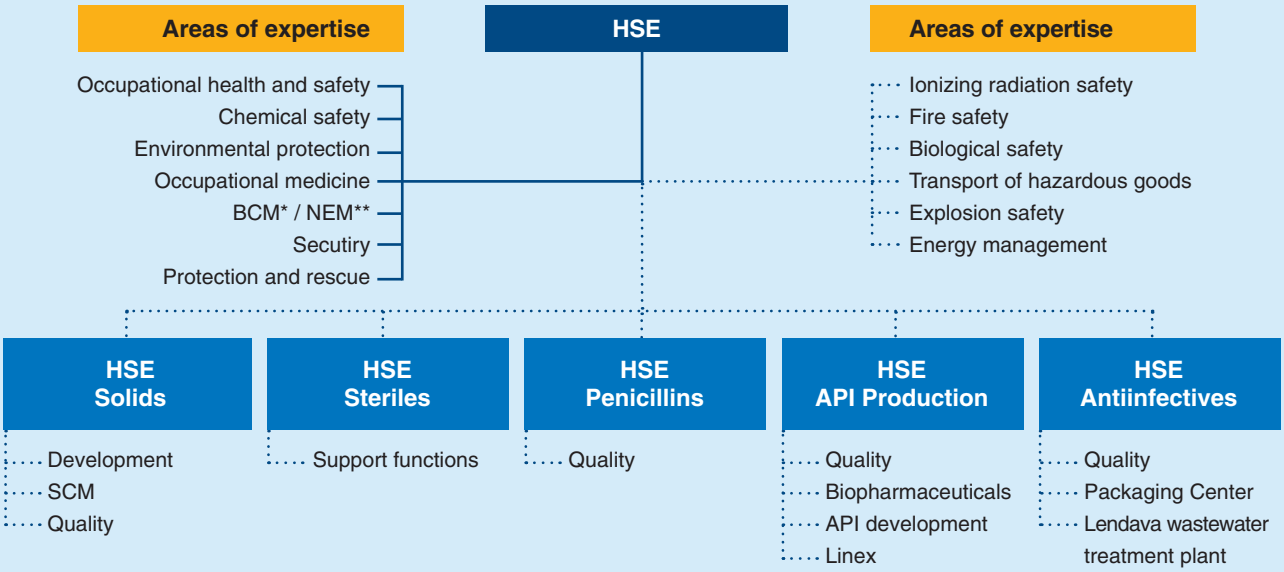
HSE department

The HSE system has been established at all the 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. Host sets internal standards for individual sites that also apply to the Guests.

[57] RC KPI 22

Lek HSE systems

Figure 1: HSE organization



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

By organizing appropriate training programs, we provide our employees with a level of HSE qualification sufficient for them to manage HSE aspects of their work. In cooperation with unit heads, the HSE unit prepares annual training plans and selects training topics for inclusion in the Training and Education Catalogue. Training programs are organized into the following clusters: onboarding, continuing education, and training for promotion.

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

Environmental impact and risk assessment

In accordance with legal requirements, all Lek sites have acquired environmental permits for operation (see Compliance with laws and standards).

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

Pursuant to the Decree on the Prevention of Major Accidents and Mitigation of their Consequences (OG of RS, Nos. 71/08 and 105/10) Lek, with the exception of the Mengeš production plant, is characterized as a negligible source of risk. At the Mengeš production plant, classified as a source of minor environmental risk (mainly due to the presence of flammable substances at the site), hazardous substances were detected as anticipated. By applying the measures planned for emergency cases which may result in large-scale emissions, fire or explosion, and by means of response measures, the necessary action was taken to prevent major incidents. Being a minor environmental risk plant, we filed an application for an environmental permit with the relevant Ministry. The permit is due by the end of 2015, as major risk sources are given priority.

Measures for risk prevention and mitigation

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

Risk assessment is made for:

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

Lek HSE systems

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 2012, 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.

At the Lendava site, additional measures were taken to mitigate process-related risks in the process of final potassium clavulanate drying.

In 2012, there were no HSE emergency events.

HSE aspects and system of achievement monitoring

Pursuant to the Novartis guidelines, environmental aspects at Lek 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 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 successfully completed internal and external audits, inspections, water, air and noise monitoring, and with the environmental permits in effect.

In 2012, audits of an external customer were carried out as well as an internal energy audit and external auditing of the company's compliance with ISO 14001:2004 and BS OHSAS 18001:2007.

Internal audits of the HSE service planned on an annual basis were performed according to individual HSE areas. 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 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 EMAS Directive. The results of internal audits performed in 2012 showe a high level of the company's compliance with the statutory requirements as well as internal and external standards in all the areas. Corrective action was taken on an ongoing basis.

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

All Lek sites meet all the basic EMAS requirements, including environmental performance improvement. In line with Novartis and Sandoz policy, Lek is committed to continuous improvement of environmental performance in compliance with local and national programs. Following the EMAS registration in 2012, internal audits will be initiated in 2013 pursuant to the Directive's requirements.

Reporting methodology

The reporting methodology used at Lek 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 system.

3. Labor

3.1 Human resources policy

"It is all about people. Cooperation. Development. Excellence" is the motto of our human resources policy. Its priority task is to design processes, tools and systems in the field of human resource management. Considerable emphasis is placed on talent development, succession planning, compensation of achievements, appropriate organizational development and training. Our HR team continually strives to ensure that all the processes are performed professionally and in accordance with applicable standards. The policy supports the basic business orientations, aiming to achieve a high level of innovation, growth and better productivity in the reporting year.

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

Concern for employees

Working out and cooking with Petra Majdič for a healthy life

For the second year in a row, Lek employees had an opportunity of dedicating one week to healthy living and well-being in the company of Petra Majdič, our Olympic medalist. This year, the Be Healthy Celebration Week, held within the Novartis' global Be Healthy initiative, was complemented with new activities raising employee awareness of the significance of a healthy lifestyle and physical activity. In addition to the relaxing morning workout, cooking was another opportunity to meet Petra. The cooking challenge participants learnt how to prepare tasty dishes from spelt wheat, and found out that the preparation of a dish does not require large amounts of salt.

Beside the opportunity to meet the renowned athlete, the employees were taught how to use the defibrilators installed at all of the four Lek sites. During the Be Healthy Celebration Week, free measurements of key health indicators such as blood pressure, blood sugar and cholesterol levels were carried out. The week ended with several hiking trips to the neighboring countryside.

3.2 Employment

3.2.1 Total workforce by employment type and employment contract[58]

At the end of 2012, the proportion of women in Lek's total workforce was 45%, the level 1% below that in 2011. At year end, 86.8% of Lek employees worked on a permanent full-time basis (91% in 2011). Almost 11% were fixed-term employees (10.9%), whereas in 2011, their share amounted to 9%. 2.3% of employees worked on a part-time basis, the level approximately identical to that in 2011 (2.4%).

3.2.2 Percentage of employees covered by collective bargaining agreements[59]

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

[58] GRI Indicator LA1 | [59] GRI Indicator LA4

3.2.3 Coverage of the organization's defined benefit plan obligations[60]

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 2012, 85.59% of the workforce was included in the scheme. The premium is calculated on the basis of 5.844% of the employee gross salary.

3.2.4 Procedures for local hiring and proportion of senior management hired from the local community[61]

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. Local representatives account for 90% of the senior management team (consisting of unit heads and Management Board members), the level of 2011.

3.2.5 Parental leave[62]

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	95	93	188
Number of employees returning to work after parental leave	95	90	185
Percentage of employees returning to work after parental leave	100%	97%	98%
Number of employees returning after parental leave to work in the same position	91	90	181
Percentage of employees returning after parental leave to work in the same position	96%	97%	96%

3.3 Occupational health and safety

3.3.1 Standard injury, lost day, and absentee rates[63]

In 2012, we recorded one severe employee accident resulting in prolonged sickness absence, two accidents of workers working through employment agencies, and one student accident. A total of 4 accidents at work resulting in sickness absence were recorded. Consequently, the total number of accidents at work (including both internal and external associates) requiring sickness absence declined (compared to 7 in 2011).

3.3.2 Standard injury rate[64]

Preventive action and promotion of safe conduct at work are long-term objectives in the process of providing workplace safety and health across Novartis. Detailed records of work-related incidents in our employees have been kept for several years by means of the LTIR (lost time injury and illness rate) indicator and the TRCR (total recordable case rate) indicator (including sick leave cases and the cases where the basic first aid criteria are exceeded but the employee is able to return to his working environment without sick leave). The two indicators are calculated as a number of cases per 200,000 hours worked.

[60] GRI Indicator EC3 | [61] GRI Indicator EC7, Disclosure GRI 4.1 | [62] GRI Indicator LA15 | [63] RC KPI 2, GRI Indicator LA7 | [64] GRI Indicator LA7

Calculation formulas:

LTIR = number of lost-time injuries (work related injury or illness resulting in unfitness for work) x 200.000 / total hours worked.

TRCR = total recordable case rate (first-aid criteria exceeded) x 200.000 / total hours worked.

Additional recording of hazardous occurrences and near misses is also performed. In high-risk organizational units, walkthrough inspections with senior managers on site are performed and safety meetings are held. In case of minor accidents, we implement the alternative work system, a decision on such work being on the part of the individual employee. Work-related injuries were mainly due to employees' inattention and carelessness. The most frequent causes of injury were cuts, injuries caused by tools and equipment, stumbles and falls.

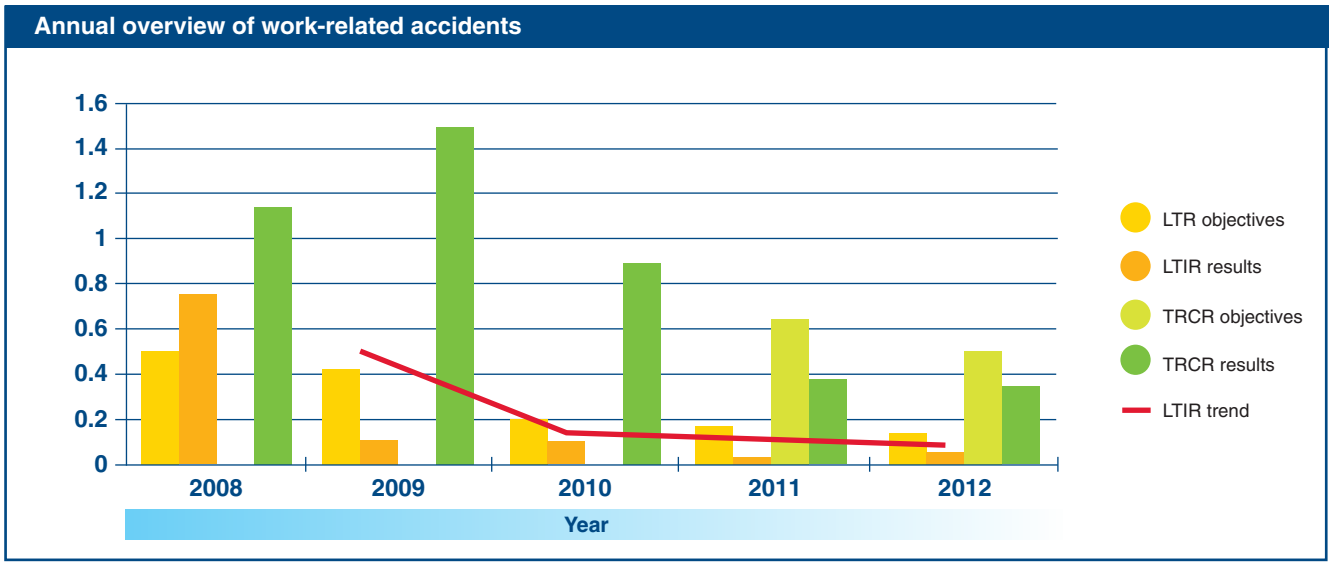
Table 20: LTIR Indicator (Lost Time Injury and Illness Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2008	0.62	0.77	0.80	0.68	0.76
2009	0.00	0.09	0.40	0.00	0.15
2010	0.00	0.00	0.40	0.00	0.10
2011	0.52	0.00	0.00	0.00	0.05
2012	0.48	0.00	0.00	0.00	0.05

Table 21: TRCR Indicator (Total Recordable Case Rate)

Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek (Total)
2008	1.24	1.36	0.80	0.68	1.16
2009	0.62	1.86	3.03	0.65	1.47
2010	0.00	0.51	1.99	0.69	0.86
2011	1.04	0.16	0.39	1.49	0.39
2012	0.97	0.14	0.74	0.00	0.35

Graph 10: Annual overview of work-related accidents LTIR and TRCR 2008–2012 for Lek

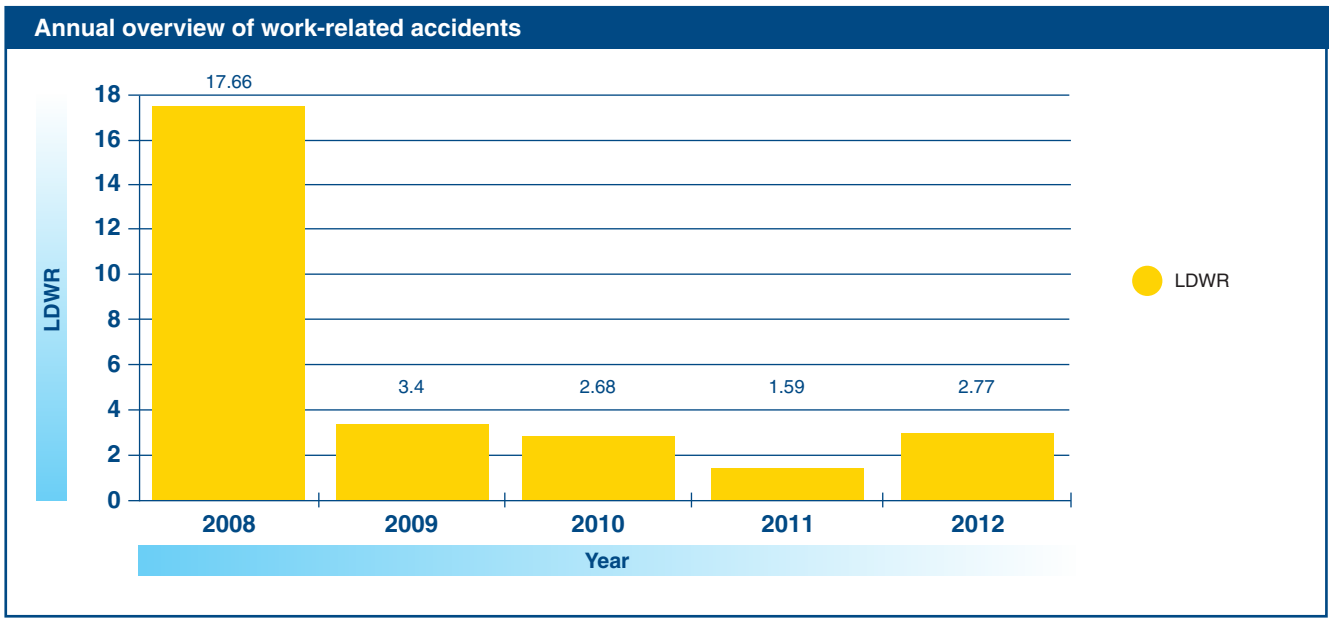


LWDR Lost Time Work-Day Rate[65] is an indicator defining employee sickness absence due to work-related accidents. It is calculated by using the following formula: LWDR = number of lost days x 200,000 / number of worked hours.

For Lek d.d., the LWDR value for 2012 reached 2.77, an increase over the year before (an all-time low of 1.59), mainly reflecting a severe work-related accident requiring prolonged sick leave.

[65] Indicator GRI LA7

Graph 11: LWDR value (Lost Time Work-Day Rate) for Lek



Incident rate (IR)

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

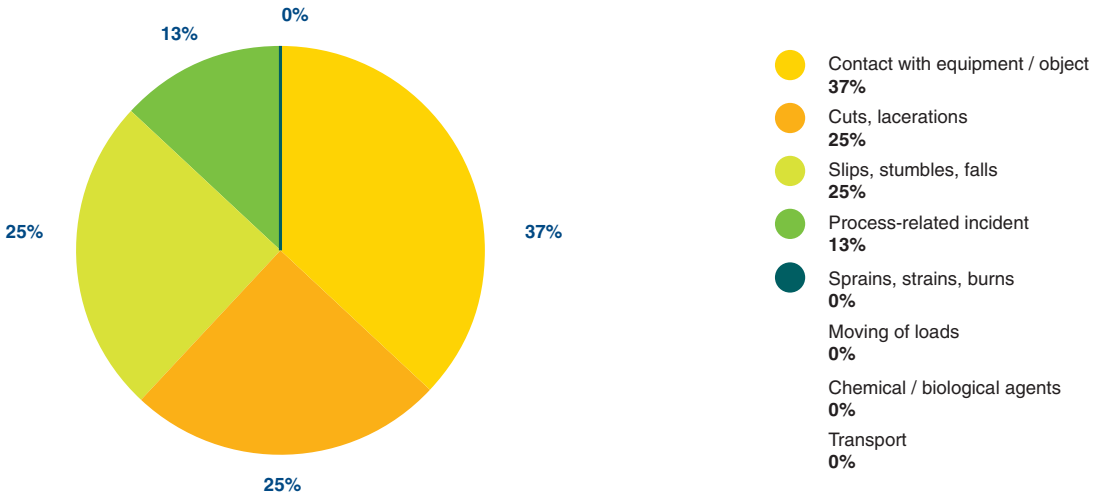
It is calculated using the following formula:

$$\text{Incident rate: IR} = \frac{\text{No. of work-related injuries* x 1.000.000}}{\text{Number of hours worked}}$$

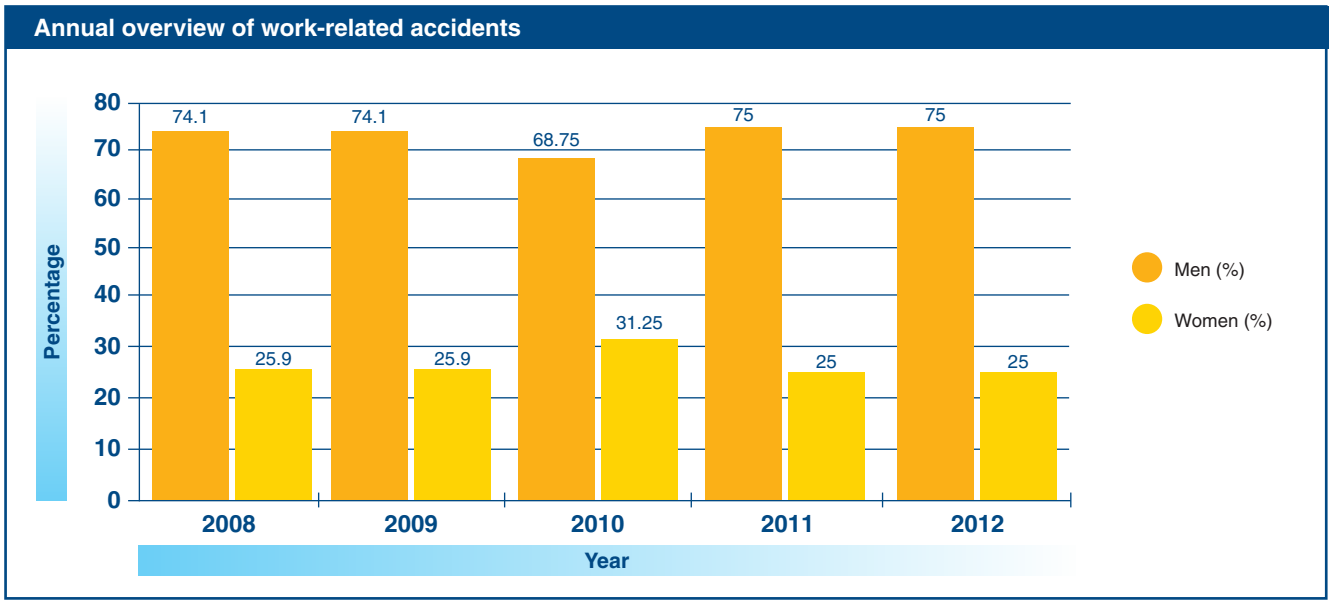
Great attention is paid to ensuring overall safety as this is the only way to continue the downward trend of work-related injuries. Work-related incidents are still mainly attributable to risky conduct, particularly in working with equipment and accessories. This type of incident accounted for the highest proportion of employee accidents.

To be able to provide a more comprehensive picture, we also monitor the cases where first aid was administered and the employee was able to return to his/her working environment without sick leave. Lower-severity incidents constitute an encouragement for further preventive action, and a reminder of the presence of hazardous behavior in our working environment. The number of first aid cases is high (> 40) which can be attributed to intensified reporting and to the implementation of our guidelines to boost the safety culture, including employee activities to reduce the risk of accidents and other incidents, conduct of walkthrough inspections, safety meetings, and involvement of an occupational medicine specialist in every workplace incident.

Graph 12: Classification of reasons for work-related incidents (LTIR and TRCR) for 2012



Graph 13: Classification of work-related incidents (LTIR, TRCR) by gender for Lek



3.3.3 Absenteeism[66]

At Lek d.d., the proportion of sickness absence in 2012 was 3.6% (2.9% in men, and 4.5% in women), recording a slight decline. In 2011, it amounted to about 4%. The rate is calculated on the basis of absence hours as follows: the total number of lost working hours due to absenteeism in the period is divided by the organizational unit's total number of working hours in the period.

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

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

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

3.3.5 Number of work-related fatalities[67]

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

3.3.6 Rate of occupational disease[68]

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. No occupational illness has been identified and confirmed to date.

[66] GRI Indicator LA7 | [67] RC KPI 1 and RC KPI 3, GRI Indicator LA7 | [68] RC KPI 4, GRI Indicator LA7

Lek HSE systems

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

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

In 2012, we continued to spread HSE information. Our process of investigating accidents and near misses has been supported by communication about the underlying reasons and measures to prevent incidents in similar working environments. In high-risk units, we continued walkthrough inspections on site by senior managers and safety meetings.

Similarly to several previous years, we promoted an active and healthy lifestyle of our employees through the Health Promotion Program and the Novartis Be Healthy initiative.

Within the health promotion program, we provided our employees with an opportunity to attend preventive health programs which include specific health sustaining programs, guided workouts, and participation in vaccination campaigns, e.g. seasonal flu and tick-borne encephalitis vaccination. The program was complemented with counselling on the prevention of chronic pulmonary diseases provided in cooperation with specialists from the Golnik Clinic of Respiratory and Allergic Diseases.

In 2012, the following HSE activities were organized:

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

Prevention of workplace accidents

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

3.4 Training and education

The quality of our learning and training program was confirmed by the TOP 10 Award we received again in 2012 (see Item 1.3.5), which ranks us among the top ten Slovenian companies in terms of investments made in employee learning, and employee development through learning and training programs.

3.4.1 Average hours of training per year per employee by employee category[69]

Compared to the year before, the scope of training provided to our employees increased significantly as shown in the table below. The average time of training per employee was 4.44 days. If compulsory on-the-job training is included, the average time of training was 6.79 days. The fact that our learning and training system was successfully tested at all of the inspections conducted is a good indicator of its performance. No amendment or improvement of the system was needed.

Average training hours/employee

As of 31 December 2011	40.07
As of 31 December 2012	54.32

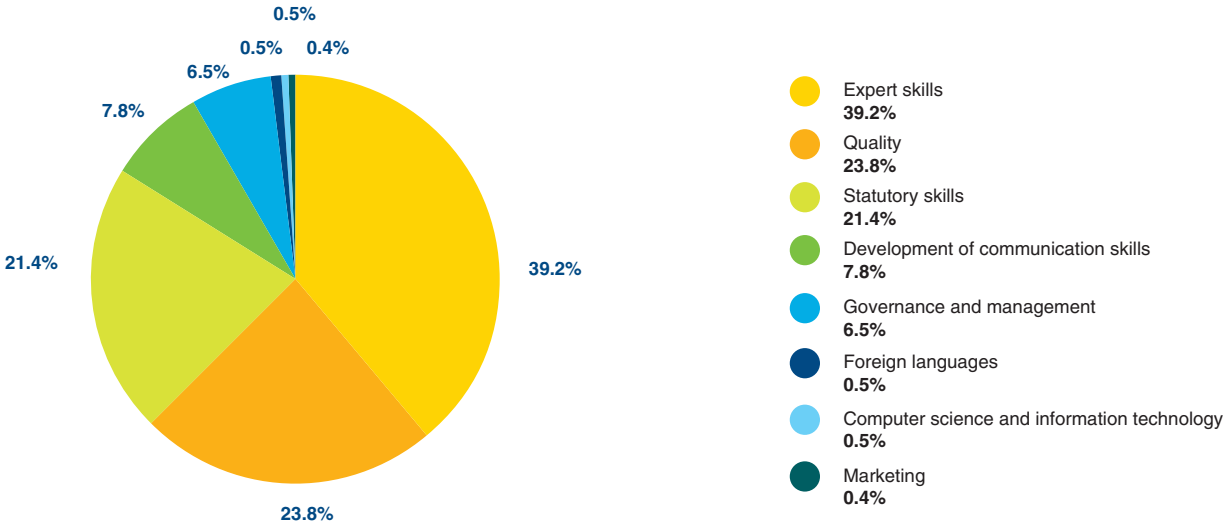
Employees were again provided the opportunity of part-time studies. In 2012, 5% of total workforce was involved in part-time studies. 63 employees were involved in undergraduate studies, and 78 in post-graduate studies, mainly in biotechnology, biomedicine and chemistry.

3.4.2 Training by area

In 2012, the most frequently (in hours) acquired skills were quality (24%), governance and management skills (19%), and expert skills (16%). The highest participation rate was recorded in expert skills (39%), quality (24%), and statutory skills (21%).

[69] GRI Indicator LA10

Graph 13: Training in 2012 by area (participation rate)



4. Products

Lek provides the professional public in Slovenia with product information in accordance with marketing authorizations issued by the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). Product-related communication with the professional public is based on Summary Product Characteristics approved by JAZMP and performed in accordance with the Medicinal Products Act. The key therapeutic groups of medicinal products developed, produced and marketed by Lek are listed under Item 1.3.2.

Communication of information related to pharmaceuticals[70] is regulated by the Medicinal Products Act. Product-related information to the final consumer is provided in the form of patient information leaflets. 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. Pursuant to the Novartis Policy, we communicate every information supported by reasonable scientific evidence, particularly those related to safety such as contraindications, warnings, interactions etc.

Similar practice applies to non-prescription drugs, where there is a growing need for clear and intelligible information.

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.

For non-prescription self-medication drugs, practice similar to that for prescription drugs applies. 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. In 2012, the use of non-prescription drugs recorded a decrease, which is the result of the overall economic situation and of the decline in our customers' purchasing power.

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.

Compliance with regulations concerning product information[71]
In 2012, the Public Agency for Medicinal Products and Medical Devices (JAZMP) initiated no offence procedure.

Practices of measuring customer satisfaction[72]
In 2012, no opinion survey about pharmaceutical companies was conducted. To gain an insight into the satisfaction of the professional public, a series of meetings were held. At workshops, we presented the company's achievements, and asked the professional public about their view of Lek, and their satisfaction with our interactions and prescription- and non-prescription drug portfolio. We asked for proposals for improvement. Once again, Lek proved to be enjoying a good reputation with the professional public which manifests a high degree of satisfaction with our product range.

Programs for adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship[73]
In the field of 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 Promotional Practices Policy. Conformity of conduct is verified on a daily basis by previous approval of all promotional activities.

Adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship[74]
In 2012, 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.

[70] GRI Indicator PR3 | [71] GRI Indicator PR4 | [72] GRI Indicator PR5 – partlially | [73] GRI Indicator PR6 | [74] GRI Indicator PR7

5. Human rights and antitrust compliance

The business operations of Lek, a Sandoz company, are significantly marked by the company's commitment to ethical and accountable decision making as stated in our Code of Conduct, our key document regulating our social and environmental responsibility and our compliance with the regulations and Good Business Practice.[75] It provides a basis for the trust of our key stakeholders (patients, employees, shareholders, healthcare partners and society at large). In 2012, we organized for all our employees online training on the Code of Conduct which had been upgraded the year before to meet employees' requirements better. They were given the opportunity to refresh their knowledge of fully transparent and clear principles and to confirm their implementation in everyday 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.

In order to prevent corruption and to ensure legal compliance, we follow Novartis' global initiative regulating this area. In 2012, we adopted a new global anti-bribery policy, updating the Third-Party Guidelines requiring our business partners to comply with and to implement the ethical business standards and compliance principles binding on the Novartis employees and its companies.

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. We expect our employees to demonstrate respect towards each other and to avoid any form of harassment or discriminatory behavior. Individual diversity and personal characteristics of our employees constitute an asset and strength of our company, and are s source of our teams' creativity. They serve as a link between the company, patients and customers. We firmly believe that they are a basis for mutual understanding and successful business performance. 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 highly inclusive working environment is also created through the implementation of the Diversity and Inclusion initiative which significantly outgrew Novartis' original female inclusion initiative.

Lek d.d. refuses any form of child, bonded or forced labor.

In 2012, there were no cases of discrimination and no requests to remedy any violation in this area in Slovenia.[76]

In 2012, the company was not involved in any antitrust procedure for any violation of antitrust regulations.[77]

[75] Disclosure GRI 4.8 | [76] GRI Indicator HR4 | [77] GRI Indicator SO7

6. Suppliers

6.1 Purchasing policy

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

In the 2010 – 2012 period, the purchasing processes underwent no modifications.

6.1.1 Purchasing system

According to the internal rules regulating the 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 specialized for direct and indirect purchasing.

Restrained global economic growth and recession in the EU strongly affected the purchasing result in 2012. Purchasing conditions in the pharmaceutical industry were worsened by fluctuating and unpredictable trends in the markets of raw materials, and by tighter pharmaceutical standards, which resulted in a shrinking selection of suppliers. In 2012, we further increased the scope of active risk management activities. In these times of uncertain trends, our association with Sandoz' and Novartis' global function was even more important in the process of negotiating competitive prices and a more reliable supply chain.

Our leading purchasing markets include Slovenia, Switzerland, China, Germany, India, Austria and Belgium.

6.1.2 Supplier audit procedures

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

Sandoz gives priority 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, Fair Labor Practices and unlawful discrimination.

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

6.2 Policy, practices, and proportion of spending on locally-based suppliers at significant locations of operation[78]

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

Among individual countries, Slovenia maintains the largest share in the purchasing structure. In terms of value, the level of deliveries to the Slovenian market increased in 2012, amounting to USD 45 million (16% of total purchasing costs).

Since the value of total purchases increased by 36%, the share of the domestic market slightly dropped over the year before (18% in 2011). On the domestic market, we mainly pucha-se merchandise of domestic production. We mainly purchase packaging and raw materials of the Slovene chemical industry and merchandise from domestic distributors.

[78] GRI Indicator EC6

Table of Contents according to GRI G3.1 Reporting guidelines

Contents according to GRI G3.1[79] – Application level B

Disclosure	Description	Reported	Page (Section)
Standard disclosures Part 1: Profile Disclosures			
	1. Strategy and Analysis		
1.1	Statement from the most senior decision-maker of the organization.		8–9 (1.2)
1.2	Description of key impacts, risks, and opportunities.		4 (1.1.1)
	2. Organizational Profile		
2.1 – 2.5	Name of the organization, primary brands, products, and/or services, location of organization's headquarters, operational structure of organization.		5, 10 (1.3), 13 (1.3.1)
2.6 – 2.8	Nature of ownership, markets served, key data.		3 (1.1.1), 10 (1.3), 13 (1.3.1), 17 (1.4.1)
2.9	Significant changes during the reporting period regarding size, structure, or ownership.		17 (1.4.1)
2.10	Awards received.		16 (1.3.5)
	3. Report Parameters		
3.1 – 3.4	Reporting period for information provided, date of most recent previous report, reporting cycle, contact point for questions regarding the report or its contents.		5, 16 (1.4), 17 (1.4.1)
3.5 – 3.7	Process for defining report content, boundary of the report, specific limitations on the scope or boundary of the report.		16 (1.4), 17 (1.4.1)
3.8	Basis for reporting on joint ventures, subsidiaries, leased facilities, outsourced operations, and other entities that can significantly affect comparability from period to period and/or between organizations.		17 (1.4.1)
3.9	Data measurement techniques and the bases for calculations.		17 (1.4.1)
3.10	Explanation of the effect of any re-statements of information provided in earlier reports, and the reasons for such restatement.		17 (1.4.1)
3.11	Significant changes from previous reporting periods.		17 (1.4.1)
3.12	Table identifying the location of the Standard Disclosures in the report.		
3.13	Policy and current practice with regard to seeking external assurance for the report.		16 (1.4)
	4. Governance, Commitments and Engagement		
4.1	Governance structure of the organization.		17 (1.5.1), AR 2012*
4.2 – 4.3	Indicate whether the Chair of the highest governance body is also an executive officer. For organizations that have a unitary board structure, state the number and gender of members of the highest governance body that are independent and/or non-executive members.		Not relevant. Lek d.d. has a two-tier management system.
4.4	Mechanisms for shareholders and employees to provide recommendations or direction to the highest governance body.		18 (1.5.2)
4.5 – 4.7	Linkage between compensation for members of the highest governance bodies and the organization's performance (including social and environmental performance). Conflicts of interest, process for determining composition...		18 (1.5.1)
4.8	Mission, vision, codes of conduct and principles.		19 (1.5.4); AR 2012
4.9	Procedures of governance body for overseeing organization's management, including relevant risks and opportunities; compliance with internationally agreed standards and codes of conduct.		19 (1.5.4); AR 2012
4.10 – 4.11	Processes for evaluating governance body's own performance; precautionary approach.		21, AR 2012
4.12 – 4.13	External initiatives to which the organization subscribes or endorses; memberships in associations.		19 (1.5.4)
4.14 – 4.17	Stakeholder engagement; basis for identification and selection of stakeholders; frequency of engagement; key topics and concerns raised through stakeholder engagement.		18 (1.5.3), 18 (1.5.2)
Standard disclosures Part 2: Disclosures of Management Approach (DMAs)			
DMA EC	Economic performance		8 (1.2), 10 (1.3), AR 2012
DMA EN	Environment		20 (2.1)
DMA LA	Labor		45 (3.1)
DMA HR	Human rights		53 (5.)
DMA SO	Society		53 (5.), 54 (6.1)
DMA PR	Products		51 (4.)

** Annual Report of Lek d.d for the year 2012, Source: www.ajpes.si*

[79] Disclosure GRI 3.12

Contents according to GRI G3.1 – Application level B

Disclosure	Description	Reported	Page (Section)
Standard disclosures Part 3: Performance Indicators			
	Economic		
EC1	Direct economic value generated and distributed, including revenues, operating costs, employee compensation, donations and other community investments, retained earnings, and payments to capital providers and governments.	fully	3 (1.1.1)
EC3	Coverage of the organization's defined benefit plan obligations.	fully	46 (3.2.3)
EC4	Significant financial assistance received from government.	fully	3 (1.1.1)
EC6	Policy, practices, and proportion of spending on locally-based suppliers.	fully	54 (6.2)
EC7	Procedures for local hiring and proportion of senior management hired from the local community.	fully	46 (3.2.4)
	Environment performance indicators		
EN1	Materials used by weight or volume.	partially	24 (2.2.2)
EN4	Indirect energy consumption by primary source.	fully	28 (2.3.1)
EN5	Energy saved due to conservation and efficiency improvements.	fully	29 (2.3.2)
EN7	Initiatives to reduce indirect energy consumption and reductions achieved.	partially	23 (2.1.6), 29 (2.3.2)
EN8	Total water withdrawal by source.	fully	30 (2.4.2)
EN10	Percentage and total volume of water recycled and reused.	fully	31 (2.4.3)
EN14	Strategies, current actions, and future plans for managing impacts on biodiversity.	fully	41 (2.8.4)
EN16	Total direct and indirect greenhouse gas emissions by weight.	fully	36 (2.6.5)
EN18	Initiatives to reduce greenhouse gas emissions and reductions achieved.	fully	36 (2.6.5)
EN20	NO_x, SO_x, and other significant air emissions by type and weight.	fully	34–35 (2.6)
EN21	Total water discharge by quality and destination.	fully	38 (2.7.1)
EN22	Total weight of waste by type and disposal method.	fully	31 (2.5.1), 32 (2.5.2), 33 (2.5.3)
EN30	Total environmental protection expenditures and investments by type.	fully	20 (2.1.3)
	Social indicators: labor practices and decent work		
LA1	Total workforce by employment type, employment contract, and region, broken down by gender.	partially	3 (1.1.1), 45 (3.2.1)
LA4	Percentage of employees covered by collective bargaining agreements.	fully	45 (3.2.2)
LA7	Rates of injury, occupational diseases, lost days, and absenteeism, and total number of work-related accidents, by region and by gender.	partially	46–49 (3.3)
LA10	Average hours of training per year per employee by gender, and by employee category.	partially	50 (3.4.1)
LA15	Return to work and retention rates after parental leave, by gender.	fully	46 (3.2.5)
	Social indicators: human rights		
HR4	Total number of incidents of discrimination and actions taken.	fully	53 (5.)
	Social indicators: society		
SO7	Total number of legal actions for anti-competitive behavior, anti-trust, and monopoly practices and their outcomes.	fully	53 (5.)
	Social indicators: responsibility for products		
PR3	Type of product and service information required by procedures, and percentage of significant products and services subject to such information requirements.	fully	51 (4.)
PR4	Total number of incidents of non-compliance with regulations and voluntary codes concerning product and service information and labeling, by type of outcomes.	fully	51 (4.)
PR5	Practices related to customer satisfaction, including results of surveys measuring customer satisfaction.	partially	51 (4.)
PR6	Programs for adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship.	fully	51 (4.)
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.	fully	51 (4.)

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

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

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

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.[80] 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 infections.

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. Similar biological drugs, however, are more cost effective and affordable to a larger group of people.

Lek started its own genetic technology development as early as in the 80's of the 20th century, creating a solid foundation for the manufacture of recombinant proteins and/or biopharmaceuticals for human use.

Biological drugs (active ingredients) are large, complex molecules generated by recombinant molecular biology or hybridoma techniques and are produced from cultured genetically modified cells. 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 patient lives. They provide a more efficient therapeutic approach to cancer, AIDS, anemia, rheumatic, cardiovascular and some other types of diseases. Over the past years, biologics have saved lives, prolonged survival and improved the quality of life for patients with severe and often chronic diseases.

Biotechnology combines all the technological applications using biological systems, living organisms or their derivatives with a 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.

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.[81]

GMO (genetically modified organism) is an organism (with the exception of humans) or microorganism whose genetic material has been altered using techniques which change the genetic material in ways different from crossbreeding or natural recombination under natural conditions.

Similar biological drugs 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.

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.

[80] Source: Humar M., Šmid-Korbar J., Obreza A. Dictionary of Pharmaceutical Terminology. Ljubljana 2011.
[81] 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).

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