




lek

a Sandoz company

A young child with a joyful expression is holding a large white board. The child is positioned in front of a wall made of reddish-brown mud bricks. The board they are holding features a photograph of a blue sky with white clouds. The child is wearing a blue garment with a white geometric pattern. The background shows a rural landscape with a dirt field and some trees under a clear sky.

Sustainability Report 2010 Lek d.d.



Sustainability Report 2010 – Lek d.d.

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* Blue Angel products are made from 100% post-consumer waste without any chlorine bleaching.

** EU Flower products meet criteria for responsible use of forest resources as well as standards for the entire production process.



Lek Sustainability Report for 2010

The 2010 report on sustainable operations by Lek Pharmaceuticals, a Sandoz company, uses for the first time the reporting requirements of the Responsible Care Initiative (RCI) and the EMAS Eco-Management Scheme, complementing them with the GRI Guidelines at a “C” application level.

As a Sandoz company, Lek Pharmaceuticals is also a member of the Novartis Group, one of the global leaders in corporate citizenship and sustainable development reporting. Lek reports regularly and comprehensively to Novartis, which in turn performs internal controls and assesses the conformity of the indicators. Lek's data for a broader set of indicators is

thus included in the aggregate data of the Novartis corporate reports. (Please visit www.novartis.com, www.corporatecitizenship.novartis.com and www.novartisfoundation.org).

Lek was inspired by both the Novartis Corporate Citizenship Policy and by its search for application solutions of optimum rationality to prepare an expanded report fulfilling the reporting requirements of the RCI, EMAS Scheme and GRI Guidelines. Lek thereby wishes to implement the Novartis policy in Slovenia, the country where it operates, as a visible and accountable member of local and national communities.

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 the “C” application level (self-declared).



a Sandoz company

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia • [/www.lek.si](http://www.lek.si)

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LETTER FROM THE PRESIDENT OF THE BOARD OF MANAGEMENT



Letter from the President of the Board of Management

Dear Reader,



The present Report is an upgrade, in both scope and substance, to all the previous reports compiled by Lek Pharmaceuticals to provide its key stakeholders an overview of environmental, economical and societal impacts of its operations. When compiling the report, we followed the Novartis' common strategy of the four corporate citizenship pillars, which are comprehensive sets of our sustainable development concept: patients, business management, people and community as well as concern for natural environment. At Lek, a Sandoz company, these are viewed as the pillars supporting all of the company's plans and their implementation.

Reporting of measurable results first requires strategic planning and day-to-day implementation of the set objectives. In addition to comprehensive and strictly controlled internal reporting in accordance with the Responsible Care requirements, Lek has decided to publicly disclose the basic performance indicators in compliance with the EMAS Eco-Management Scheme and the GRI Guidelines. The company thereby enhances comparability between the impact of its operations and its corporate performance, while meeting Novartis' and Sandoz' firm commitment to sustainable development.

In many aspects, Lek's economic sustainability is a result of development capabilities, vertical organizational structure, and competencies. Despite the economic crisis, Lek has not recorded any significant drop in its sales revenues in the past two years. In 2010, sales revenues lagged by 2% behind the figure posted the year before. In 2009, developments in the global market caused the volume of orders to decline. However a gradual economic recovery and rebound could be seen in 2010. A number of production lines operated to their full capacity. The production of potassium clavulanate at the Lendava site posted record results, the high growth in API production continued, while growth was recorded in the manufacture of sterile products. According to selected key indicators, our production facilities are among the highest-ranking at Sandoz, while the Prevalje site ranks at the very top. We introduced a number of new products and formulations, mainly for the highly developed markets of EU, Canada, USA, Japan, Brazil and others. In Slovenia, our domestic market, we increased our market share and consolidated our position in some of the major therapeutic groups.

We manifest our responsibility towards patients by providing novel, high quality and innovative generic and biosimilar medicinal products. In Lek's two development centers, Ljubljana and Mengeš, approximately one quarter of all Sandoz' global development activities in the field of standard generics and biopharmaceuticals take place. In terms of development, the year 2010 was a highly intensive one: we produced the first API of our own development for a biosimilar, launched 36 new products on some of the most demanding markets, while the number of development projects under way in our development centers exceeded 200. In addition to the research and development activities, we actively worked at raising awareness of certain patient groups, in particular the young population. To mention just one: on 5th May, World Asthma Day, in cooperation with contracting experts, we organized a training program on the significance of asthma management and held several breathing workshops.

Business Ethics Principles, defined in the Novartis Code of Conduct, are integrated in our organizational culture. Knowledge of the Code of Conduct is consolidated through refresher courses. We are proud to recognize that the e-courses organized in 2010 were successfully completed by a great majority of Lek employees.

In many aspects, employee satisfaction depends on work-life balance, which should be based on long-term solutions and a flexible system. Our endeavors to create an optimum working environment for our employees were strongly supported by the permanent Family Friendly Enterprise certificate we were among the first Slovenian companies to receive.

The certification represented the final step in a series of initiatives and activities aimed at upgrading the foundations laid in 2007, the year when Lek was one of the first Slovenian companies to receive the basic Family Friendly Enterprise certificate. Our responsibility towards people and the community materialized in the form of numerous campaigns attended by many Lek employees. Lek Family Days, the Community Partnership Day, and the campaign of assembling bicycles for a children's holiday home were just a few.

Our business achievements also reflect our implementation of the HSE policy (Health, Safety and Environment) characterized by the fulfillment of legal requirements and corporate orientations, overall concern for the employees, production optimization by improving economic, energy and environmental efficiency and openness to the public. Implementation is monitored through HSE reporting, and through adherence to the international OHSAS 18001 occupational safety and health standard and the Responsible Care Initiative coupled with the EMAS Eco-Management Scheme.

We have been systematically reducing our impacts on the natural environment, which remain within the legal limits. In 2010 alone, EUR 2.2 million were invested in environmental protection. The key environmental measures are carried out within the HSE system for which the 5-year implementation period expired in 2010. The full or partial fulfillment of the set targets is thoroughly reported in the final section of the present Report. Suitable raw materials and considerable quantities of energy and water are essential for pharmaceutical production. We mainly improved water consumption and energy efficiency, thus confirming the success of several years' implementation of the measures aimed at reducing exploitation of natural resources. Our endeavors were recognized at the corporate level as we were honored with the Novartis' Energy Excellence Award and the Extraordinary Environmental Achievements award. By improving energy use efficiency, we also cut CO₂ emissions.

Some of the targets will remain in the focus of our attention and endeavors. Emissions of volatile organic compounds have been significantly reduced; however, we are still working on further reduction.

While we have achieved a decrease in waste volume, changes in the products manufactured over the years do not always result in a clear picture and data comparability over the years.

We strongly believe that the present time, characterized by economic decline and a growing lack of trust in global financial markets, requires above all long-term thinking as well as adherence to sustainable business orientations and business ethics principles.

We are convinced that in these highly challenging times, the link between corporate performance and legal compliance, continuous trust building and a fair attitude towards the employees, business partners, government institutions and the public is growing stronger than ever.

Consequently, our objectives set for the period until 2015 are highly demanding, following our general orientation of constant improvement of process efficiency: we have planned for 10 – 20% improvement in the HSE Key Performance Indicators. This will be achieved through production processes improvement, measures aimed at reducing environmental impact, and through an open relationship with all the key stakeholders. When developing new products intended to preserve and restore health, and when creating added value, we remain true to our one and only basic principle: responsible business.

Vojmir Urlep
President of the Board of Management





I. LEK, A SANDOZ COMPANY – COMPANY IDENTITY CARD



The Four Pillars of Novartis Corporate Citizenship

1.

At Lek, a Sandoz company, social responsibility and commitment to sustainable development are important elements of business operations and a key to success.

2.

As a member of Sandoz, the generic division of Novartis, Lek is building its operations on the four pillars of corporate citizenship: responsibility towards patients, accountable business management, responsibility towards people and communities, and concern for natural environment.

3.

Through responsible business operations, we wish to create value for the community. Considerable attention is dedicated to regular monitoring of ethical, social and environmental responsibility towards the society and the environment in which we operate, and to ensuring adherence of our business conduct with applicable laws, the Novartis Code of Conduct, policies and internal acts.

4.

The Novartis Code of Conduct is the basic act regulating since the year 2003 our responsibility towards the society and environment, as well as the conduct of our operations in accordance with Good Business Practice and applicable laws. Within its framework, training of employees is one of the key areas of monitoring and implementation of compliance with the basic rules of Novartis' operation and social responsibility. By providing our employees with regular training on the company's policies and objectives in the field of business compliance and ethics, we create an encouraging, healthy and safe working environment, enhance accountability for health, and endeavor to ensure better access to treatment by manufacturing generic drugs.



1. Lek, a Sandoz Company – Company Identity Card

Lek at a glance

Company name:	Lek farmacevtska družba d.d.
Abbreviated name:	Lek d.d.
Registered office:	Ljubljana
Business address:	Verovškova 57, 1526 Ljubljana, Slovenija
Registration number:	1732811000
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-pošta:	info@lek.si
Website:	http://www.lek.si

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¹ Disclosure GRI 3.4

1.1 How we operate²

Lek is a pharmaceutical company, an integral part of Sandoz, the generic division of the Novartis Group. We develop, manufacture and market effective, safe and quality medicinal products, from standard generic drugs through to state-of-the-art biosimilars.

Legal form and ownership structure

Lek is a joint-stock company, 100% owned by Novartis Pharma AG.

Registered office

Registered office is in Ljubljana, whereas the production facilities are located in Ljubljana, Mengeš, Prevalje and Lenjane. All the company's sites are in the process of EMAS certification.

Lek

Lek, a Sandoz company, is one of the pillars of this second-largest global generics manufacturer. We operate as a global development center for products and technologies, a global manufacturing center for active pharmaceutical ingredients and medicinal products, a competence center for the development of vertically integrated products, and a Sandoz competence center in the field of development and manufacturing of biopharmaceutical products. We also act as a supply centre for the markets of CEE, SEE and CIS, and we market and sell Sandoz products in Slovenia. For more information, please visit <http://www.lek.si>.

Sandoz

Sandoz, a division of the Novartis Group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by patents. Sandoz has a portfolio of approximately 1000 active pharmaceutical ingredients and sells its products in about 130 countries. Key product groups include cardiovascular medicines, anti-infectives, treatments for central nervous system and alimentary tract disorders, oncology and respiratory therapies, as well as medications for blood and blood forming organ disorders. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWEPharma (Austria), and Oriel Therapeutics (US). In 2010, Sandoz employed more than 23,000 people (full-time equivalents) worldwide and achieved annual net sales of USD 8.5 billion. For more information, please visit www.sandoz.com.

Novartis

Novartis provides healthcare solutions that address the growing needs of patients and societies. Focused only on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas.

In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group.

With its headquarters in Basel, Switzerland, Novartis Group companies employ approximately 119,000 associates and operate in more than 140 countries around the world. For more information, please visit www.novartis.com.

Key customers and markets³

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 2010, the shares in the company's net sales held by the leading three buyers amounted to 53.3, 10.5 and 4.6%, respectively.

Central and Eastern Europe with a 79% share, and Slovenia with a 9% share are Lek's major external direct sales markets for its own products and the products by other Sandoz companies. The majority of sales were once again realized by pharmaceutical products, whereas APIs and biopharmaceuticals account for the remaining 15%.

Major groups of Lek products and brands⁴

We are focused on the following leading indication groups:

- Anti-infectives,
- Cardiovascular drugs,
- Gastrointestinal drugs,
- Self-medication drugs and
- On individual markets, drugs from other indication areas.

Lek leading brands:

- Amoksiklav®, the most globalized leading product of Sandoz Group
- Tulip®, Coupet®, Acipan®, Nillar®, Voxin®, Candea®, Linex®, Fluimukan®, Lekadol®, Operil® and Persen®.

² Disclosure GRI 2.1, GRI 2.3, GRI 2.4, GRI 2.5, GRI 2.6

³ Disclosure GRI 2.7

⁴ Disclosure GRI 2.2

1.2 Highlights and milestones of Lek's operations 2010

- Lek was the first to offer the Slovenian market generic Rosuvastatin.
- The Biopharmaceuticals Development Center in Mengeš produced the first API of its own development for a biosimilar.
- We developed 36 new products for the world's most demanding markets.
- The production facility for solid dosage forms at the Ljubljana site achieved a record production output of 4.5 billion tablets and capsules.
- Novartis' investments in Slovenia exceeded EUR 1 billion.
- The major portion of investments went into development, modernization and expansion of production capacities, and further reduction of the company's environmental impact.
- Strong investments were made into employee training and development.
- The beginning of 2011 saw more than 200 development projects going on.

Major sustainability events and awards⁵

Family Friendly Enterprise Certificate

Lek was among the first Slovenian companies to have received in 2007 the Family Friendly Enterprise Certificate. Our strict adherence to the guidelines and requirements won us a full Family Friendly Enterprise Certificate in 2010.

We wish to make the work atmosphere as friendly and pleasant as possible. This includes:

- Flexible working time with a choice of arrival and departure times,
- Organizing associates' meetings,
- Communications with employees,
- Performing employee opinion surveys,
- Information and communications policy,
- Appointment of a work-life balance officer,
- Company Open House Day,
- Promotion of equal opportunities,
- Supervision and additional activities for school children during holidays,
- Assistance with family member care etc.



Rebuilt in 2008, Lek kindergarten has operated for over 35 years, providing daily care for children of Lek employees.

TOP 10 Education Management 2010

Professionally planned operations and investments in employee education, training and personal development won us another TOP 10 Education Management award. The award confirms our development orientation which we are maintaining even in these tough economic times.

Award for the contributions to the development of pharmacy in Slovenia

On 2 December 2010, the Faculty of Pharmacy of the University of Ljubljana celebrated the 50th anniversary of the introduction of pharmacy as a field of academic study in Slovenia. Special awards were presented for contributions to the development of pharmaceutical science. Lek, a Sandoz company, which has cooperated with the Faculty of Pharmacy since its foundation in 1960 in numerous areas of development, in the teaching process, in the creation of academic curriculum, and by providing financial support in order to create material conditions needed for the Faculty's development, was one of the award recipients.

Sandoz and Novartis Outstanding Achievement Award

In 2010, Lek employees received a number of awards for outstanding achievements and contributions to the excellent business results of Sandoz and Novartis.

The awards included BioNext, ExCEED, Novartis HR Diversity and Inclusion Award, Novartis Energy Excellence Award, three Sandoz technical operations awards (for successful FDA inspection, supply chain management excellence, outstanding cost savings in purchasing), global technical operations award for inventory management excellence, global human resources excellence award to the technical operations HR team, three Competitive Edge Awards, and Sandoz award for top communication.

The HSE achievement award was granted to the Solid Dosage Forms and Sterile Products manufacture unit at the Ljubljana site for achieving more than 2.5 million lost-time accident-free working hours.

More details on established business standards and awards granted for improvements in the field of environmental impact reduction are provided in the Environmental Aspects of Business Operations section.



Family Friendly Enterprise Certificate

⁵ Disclosure GRI 2.10

Operations in 2010

Table 1: Key figures in 2010⁶

Indicator	Unit	31. 12. 2010	31. 12. 2009	Index 2010/2009
Number of associates		2,487	2,564	97
- Ljubljana site		1,490	1,421	105
- Mengeš site		601	593	101
- Lendava site		209	180	116
- Prevalje site		170	184	92
- Representative offices		17	186	9
* Production output	000 tonnes	5,86	3,05	
Net sales revenues	in EUR m	552,515	562,600	98
Liabilities	in EUR m	829,067	897,596	92
Equity	in EUR m	675,661	707,752	95

**Due to extremely big differences in the weight of various types of products, e.g. biological drugs and drugs such as Immunal®, and due to the manufacturing structure being adjusted to the changed demand, the data is difficult to compare.*

In 2010, Lek d.d. realized net sales revenues to the amount of EUR 552.515 million, a 2% drop over the year 2009 (8% in the domestic market, 2% in foreign markets).

Major changes⁷

At the time of reporting, no major changes took place either in the company's size, organizational structure or ownership structure. No merging activities or joint ventures were underway.

2010 reporting characteristics⁸

- The reporting period for all the indicators and disclosures in the present document refers to the calendar year 2010.
- Some of the data (data on associates, key data on financial operations and economic impacts of business operations) were acquired in the financial reporting process for the purpose of 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 in sub-sections 2.8 and 2.9.
- As a socially responsible company, Lek, a Sandoz company, voluntarily issued its first public environmental report for the year 2009 (to see the full report, please visit <http://www.lek.si/media/storage/cms/attachments/2010/12/13/22/17/40/Okoljsko-porocilo-2009.pdf>).
- Before that, Lek reports were mainly compiled to meet the reporting requirement of the Responsible Care Initiative. For the year 2010, we received an initiative to voluntarily include in the report, in addition to environmental disclosures, a selection of qualitative and quantitative indicators of economic and social impacts. Consequently, the basic EMAS and GRI indicators essential to Lek were included. The indicators are based on the key characteristics of Lek's business activity and situation. We are aware of the fact that a company's performance does not only depend on the financial business indicators but also on the quality of relations with key stakeholders. We are proud of the good business practice of Novartis and at the same time we wish to become part of the good business practice of the companies operating in Slovenia.
- Reports in the above described form are to be compiled annually and should contain the key information 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 conformity of 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.
- The company Lek d.d. holds a 100% ownership stake in the following subsidiaries (as of 31 December 2010): Sandoz, d.d., Hotel Lek d.o.o., Novartis Animal Health d.o.o., Lek Skopje doel and Lek Ljubljana Holding GmbH, Austria. In the Wastewater Treatment Plant Lendava d.o.o., Lek holds a 74.5% ownership stake. In 2010, Lek d.d. performed no activities that might impair the comparability of data for the previous year.
- The year 2010 saw no events that might require adjustment of information from previous reports.

⁶ Disclosure GRI 2.8

⁷ Disclosure GRI 2.9

⁸ Disclosures GRI 3.1 – 3.3, GRI 3.5 – 3.8, GRI 3.10 – 3.11

Governance and management⁹

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
- **Markus Peter Delfosse**, Member of the Board of Management, Technical Operations
- **Daniel Karrer**, Member of the Board of Management, Finance
- **Darija Brečević**, Member of the Board of Management till 18 April 2010, Human Resources
- **Samo Roš**, Member of the Board of Management since 1 June 2010, Human Resources
- **Bojan Dolenc**, Member of the Board of Management, Workers' Director

Lek Supervisory Board:

- **Peter Goldschmidt**, Supervisory Board Chairman
- **Andreas Rummelt**, Member of the Supervisory Board, Deputy Chairman till 5 July 2010
- **Jeffrey George**, Member of the Supervisory Board since 5 July 2010, Deputy Chairman since 4 November 2010
- **Peter Ruprecht**, Member of the Supervisory Board
- **Peter Kraljič**, Member of the Supervisory Board (independent associate member)
- **Aleksander Koren**, Member of the Supervisory Board, Workers' Representative
- **Uroš Urleb**, Member of the Supervisory Board, Workers' Representative

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 enforce 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 Management Board member.

In 2010, 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.

The Workers' Council constitutes a form of collective and indirect employee participation in the company management. 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 (innovation, occupational safety, diversity and inclusion, supervisory committee of Lek Trade Union). The Workers' Council meetings are attended by the President of the Management Board, Workers' Director and HR Director who respond to the questions and initiatives launched by the employees or provide the necessary additional information subsequently. In 2010, the issues raised most frequently in-

cluded working hours, working conditions, business results and plans, holiday facilities, organizational changes and additional pension insurance. A report on the Supervisory Board meetings held in 2010 was also presented.

The Workers' Council member serving on the Occupational Safety Board took active part in the auditing procedure for workplace risk assessment. The Committee for Economic, Status-related, HR and Social Issues met to take a position with regard to the issues discussed, and presented its views at a Workers' Council meeting (additional health insurance, selling apartments from the company's housing fund).

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 Management Board, Management Board members and respective departments' representatives.

1.3 Overview of key stakeholders¹⁰

Lek's key stakeholders include the employees, company owners, patients, patient groups, government authorities, regulators, local communities, non-governmental institutions, professional associations, members of the Academy of Arts and Sciences, healthcare professionals, buyers, suppliers and media. We build our relationships with stakeholders on the basis of corporate citizenship principles. We endeavor to maintain an open dialogue with them, seeking for most appropriate forms of cooperation.

The stakeholder structure complexity results from the diversity of stakeholders' interests and the 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. This serves us as a basis for our participation 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.

Communications with key stakeholders

Lek has an open dialogue with the public and other interested parties, identifying the reasons for their concerns on the Lek Open House Day, promptly settling stakeholder complaints, and responding on a regular basis to the questions received. The company is open and proactive in building its relations with the media which serve as the voice of the public interest.

The Lek Environmental Performance Report 2009, along with the contacts for additional information, was published at our website <http://www.lek.si>. We received no requests for additional disclosures of environmental impacts.

⁹ Disclosures GRI 4.1 - 4.4

¹⁰ Disclosures GRI 4.14 and 4.15

1.4 Overview of Lek's commitment to external initiatives and principles¹¹

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.

Lek implements a number of initiatives which form part of its commitment as a Novartis and Sandoz organization. These include the UN Universal Declaration of Human Rights, the ILO Declaration on Fundamental Principles and Rights at Work, the Rio Declaration on Environment and Development, the UN Convention against Corruption, the OECD Guidelines for Multinational Enterprises, the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, and a voluntary commitment to reduce greenhouse gas emissions in accordance with the Kyoto Protocol.

1.5 Lek production sites and processes

Ljubljana production site

Located in the industrial zone of north-western part of Ljubljana, Lek is the largest Slovenian and one of larger Sandoz units. 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 2008, the manufacturing was split into solid dosage forms production and steriles production.

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. In 2010, 127 million packages of different products were delivered from Ljubljana.



Ljubljana production site

Company headquarters, marketing and sales

The Ljubljana site also features the company headquarters, administrative services, the HSE head office, the Patent Head Office, the Quality and Quality Management units, and the Sandoz Development Center Slovenia.

Mengeš production site

At the Mengeš site, the manufacture of active pharmaceutical ingredients and solid dosage forms takes place. Other facilities include the Antiinfectives – Genetics development unit and the Quality unit. Furthermore, the site comprises one of the Sandoz' main biopharmaceuticals development and production centers.

At the Mengeš site, spreading over two local communities, Domžale and Mengeš, the manufacturing activity has been carried out for over 60 years (since 1946).

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. In 2010, Tacrolimus and Omeprazole were the best selling products. Several new products were also launched, ensuring further growth of the site.

Since 2000, the year when a new development laboratory for recombinant DNA technology was set up, the Mengeš site has made considerable progress by implementing and developing this type of technology. The Biopharmaceuticals unit grew into a production facility through the inauguration of Slovenia's first production plant for recombinant DNA technologies – PORT 1. It is complemented by the Biopharmaceuticals development center which employs 150 experts and joins all the major development functions in one place.



Mengeš production site

Lendava production site

At the Lendava site, the Antiinfectives unit and the Packaging center operate.

In 1985, the API production started with Gentamycin, and in 1992, Potassium clavulanate followed. Based on standard biotechnology which is the result of the company's own

¹¹ Disclosures GRI 4.12 and GRI 4.13

Glossary of key terms

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.

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.

RCI (Responsible Care Initiative), a global, voluntary initiative developed autonomously by the chemical industry

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

Generics

Generics are successors to pharmaceutical products whose patent protection has expired. Generic medications are just as effective, safe and quality as the original branded equivalents but they are sold at more affordable prices. The Bioequivalence Study has to prove that generic medicinal products are identical to the previously patented original. The clinical comparative study guarantees that generic medicines contain the identical active ingredient, dosage, effect and patient tolerance. In addition, the manufacturer has to prove that each step in the manufacturing process complies with the highest quality standards. This begins with API manufacture, continues with the control of the entire manufacturing process, and ends with the finished product analysis. Approval for the sales of a generic drug is granted only if all the criteria have been met. Although no basic research is needed, generic products necessitate many years of extensive research work.

know-how, the manufacture of Potassium clavulanate by using standard fermentation is currently performed along with the production of Gentamycin sulphate. Lendava is the leading location for the manufacturing of Potassium clavulanate in the Sandoz Group, and its demand continues to increase. Gentamycin is a wide-spectrum aminoglycoside antibiotic for hospital use in severe bacterial infections. Lek is an important manufacturer of Gentamycin outside China and South Korea.

Since 2009, a packaging center has operated at the Lendava site. The center supplies EU markets with finished products from Sandoz plants all over the world.



Lendava production site

Prevalje production site

At the Prevalje site, a single-purpose production plant for penicillin products operates.

In 1978, the present plant for pharmaceutical and dental production became an integral part of Lek. A decade later, the Prevalje plant started the manufacture of a broad-spectrum antibiotic from the group of beta-lactame antibiotics, i.e. a combination of potassium clavulanate and amoxicillin with a broad spectrum of antimicrobial action. Potassium clavulanate is produced at the Lendava site, whereas amoxicillin is obtained from a Sandoz location outside Slovenia. The broad-spectrum antibiotic is one of Lek's and Sandoz' major products, its sales having doubled in the 2003-2009 period. It is manufactured in the form of tablets or powders for peroral suspensions. The process of packaging these into finished products and in the form of mixtures and granules, intermediate products for further processing, is also carried at this site.



Prevalje production site

1.6 Lek's responsibility in everyday operations

For an active life of asthma patients

As a partner of the Slovenian Asthma and Sports Association, Lek provides children with education opportunities, encourages them to engage in sports, and offers them holidays at the seaside as well as indoor swimming.

One event with an educational purpose is the Lek cycling marathon named "For Better Breathing", in which for the fourth year running the members of Lek cycling team joined Marko Baloh, a Slovenian ultra marathon cyclist.



In the overall campaign, special emphasis was put on the high incidence of asthma and allergies. The participants were encouraged to engage in regular exercise and their attention was drawn to the impact of the increasing environmental pollution.

Sweet-o-biking in the House of Experiments

By simulating type-1 diabetes, a new experiment named Sweet-o-Bike is making visitors to the House of Experiments familiar with this disease, as well as health food principles and the obesity issue. A special day under the professional leadership of Karin Kanc, a diabetes specialist, was dedicated to raising awareness and acquiring knowledge about the disease. As a sponsor, Lek enabled participants to visit the House of Experiments for free.



Lek Red Nose Family Days

Lek Family Days are held at all sites across Slovenia to enable families of Lek employees to get to know the workplaces and jobs of their close family members, as well as the significance of Lek as part of a global pharmaceutical company. To the great pleasure of all the children, the Red Nose Clown-doctors attended the Family Days. Lek has closely cooperated with them since they first appeared in Slovenia almost six years ago. Now, we support their worthy mission as a general sponsor.



Knowing and adhering to the Novartis Code of Conduct

We adhere to our Code of Ethics -- the Novartis Code of Conduct -- because we believe that continuous good performance is necessarily associated with ethical business. The Code of Conduct covers topics such as individual employee responsibilities, discrimination, conflict of interest, bribery, business gifts and entertainment, insider trading, restriction of competition, compliance with laws, and the use and protection of the company's assets and information. The Novartis Code of Conduct is well known to all the employees, and its individual sections are dealt with in regular employee e-training programs.

In 2010, Novartis organized e-training on compliance for the majority of its employees, mostly related to the Code of Conduct, conflict of interest, quality performance management, and Good Promotional Practices. Online training has become a must and forms part of our everyday working activities. Novartis expects its employees in each of the countries where it operates to successfully complete at least 90% of the training programs. In Slovenia, a total of 4,112 employees were invited to take part in e-training, meaning that each may have completed several courses on compliance. The completion rate exceeded Sandoz's 90% target.

Glossary of key terms

Biotechnology

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.

Recombinant DNA technology

It 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 the protein still having a human structure.

Biopharmaceutics

Biopharmaceutics is the latest and the fastest growing branch of pharmaceutical science. In Slovenia and globally, 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 1980's, creating a solid foundation for the manufacture of recombinant proteins and/or biopharmaceuticals for human use.

Similar biological drugs

The concept of biological similarity as defined by the European Medicinal Products Act requires a higher level of expertise in science, technology and logistics. The term "similar biological drug" denotes a biological drug of quality, safety and efficacy identical to that of the original drug, yet more affordable to the patients. They are complex, naturally produced protein components which the human organism contains in extremely small quantities, yet their lack may cause various diseases and abnormal development. Chemically, biosimilars are protein drugs or glycoproteins.

GMO (genetically modified organisms)

A GMO 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.

Antibiotics

Antibiotics are active pharmaceutical ingredients interfering with bacterial metabolism or killing bacteria. 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.

Community Partnership Day

We encourage our employees to engage in charity work, and we therefore organize an annual Community Partnership Day which is held every May. This day dedicated to employees helping other people constitutes regular working time. On Community Partnership Day, the management team and the employees donate blood and engage in volunteer activities to help those in need. We offer help to the homeless, elderly, socially deprived, various non-governmental and charity institutions, and others.



Open House Day

At the Mengeš production site, an Open House Day was held on 22 June 2010 for local fire brigades, which represents a new step in the tradition of this event (at the Prevalje site in June 2009, at the Lendava site in September 2009).

Drug information folders in Braille

For our customers, we have included texts in Braille in the information folders for all our drug products, including Lek self-medication drugs.

Team support for children's bicycles

As part of a Team Communication and Team Games education program, Lek employees working in Biomedicine assembled children's bicycles which they donated to the Kranjska Gora holiday home of the Ljubljana Moste – Polje Friends of Youth Association.

1.7 Economic performance

Direct Economic Value Generated¹²

In 2010, the company's Direct Economic Value Generated amounted to EUR 581 million, of which Economic Value Distributed totalled EUR 560 million (96%), and Economic Value Retained EUR 21 million.

Operating Costs reached EUR 350 million (62.5%), Employee Costs amounted to EUR 122 million (21.8%), Payments to Providers of Capital reached 14.3% (EUR 80 million), and Payments to Government totalled EUR 8 million (1.4% of Direct Economic Value Distributed).

Major forms of State aid received¹³

Income tax relief amounted to EUR 16,560 for research activity and EUR 38,000 for investments.

We also received public subsidies amounting to EUR 629,000.

1.8 Labor relations and decent work

Total workforce by employment type and employment contract¹⁴

- At the end of 2010, the proportion of women in Lek's total workforce was 46% (47% the year before).
- At year end, more than 90% of Lek employees worked on a permanent full-time basis. 7.7% were fixed-term employees (in 2009, the proportion was below 2%), and 2.4% worked on a part-time basis (less than 2% in 2009).

Percentage of employees covered by collective bargaining agreements¹⁵

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

Coverage of the organization's defined benefit plan obligations¹⁶

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 2010, 88.81% of the workforce was included in the scheme. The premium equals 5.844% of the gross salary of the employee.

Each insured employee is allowed to make his/her own decisions on the use of the accumulated assets after retirement, whereas the law provides insured employees with a possibility to withdraw from the additional pension scheme prematurely.

Procedures for local hiring and proportion of senior management hired from the local community at significant locations of operation¹⁷

As a Sandoz company and as part of an international organization, Lek d.d. hires foreign employees according to an established corporate practice pursuant to EU recommendations. In accordance with the corporate principles, 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. Lek senior management consists of unit heads and Management Board members. Local representatives account for 90% of the senior management team.

Average hours of training per year per employee by employee category¹⁸

The average time of training per employee was 3.6 days (29 hours). If compulsory on-the-job training is included, the average time of training was 5 days (41 hours). For the time being, training data records are not kept by employee category.

Average training hours/employee

As of 31 December 2010	41.1
As of 31 December 2009	44.8

In 2010, the most frequently acquired skills were foreign languages (26%), statutory training (22%) and governance and management skills (19%). The highest participation rate was recorded in statutory training (37%) followed by quality (22%), and governance and management (15%).

¹² Indicator GRI EC1

¹³ Indicator GRI EC4

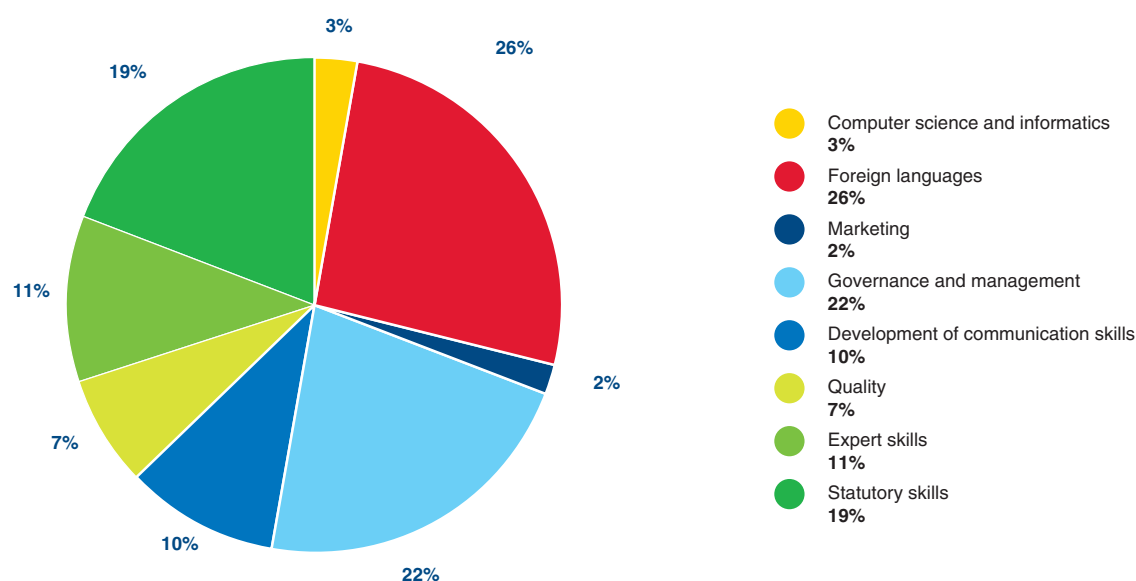
¹⁴ Indicator GRI LA1 - partly

¹⁵ Indicator GRI LA4

¹⁶ Indicator GRI EC3

¹⁷ Indicator GRI EC7

¹⁸ Indicator GRI LA10 - partly

Graph 1: Training in 2010 by area (in hours)

Occupational safety of Lek associates and third-party employees

Number of work-related fatalities¹⁹

In 2010, there were no work-related fatalities.

Standard injury, lost day, and absentee rates²⁰

In 2010, we recorded two employee accidents which resulted in sickness absence, one injury among workers working through employment agencies, and one student accident. A total of 5 minor accidents at work resulting in sickness absence were recorded.

Standard injury rate

Detailed records of work-related incidents in the employees working on a permanent basis have been kept for several years by means of the LTIR (lost time injury and illness rate) indicator (sick leave) and the TRCR (total recordable case

rate) indicator (including sick leave cases and the cases where the basic first aid criteria is 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.

The most frequent causes of injury were slips, falls and cuts. No severe injuries were recorded. The investigation and recording of occupational injuries were upgraded by additional recording of hazardous occurrences and near-accidents. We implement the alternative work system, whereas in the high-risk organizational units, walkthrough inspections with senior managers on site are performed and safety meetings are held. We maintain our long-term objective of preserving the positive trends achieved.

Table 2: LTIR (lost time injury and illness rate) indicator – rate of sickness absence due to work-related injuries and disease by site (number of cases per 200,000 hours)

LTIR Indicator – 200,000 hours	Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek
	2006	0.00	0.97	0.58	0.68	0.77
	2007	0.00	0.59	0.62	2.05	0.65
	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

¹⁹ POR OI1

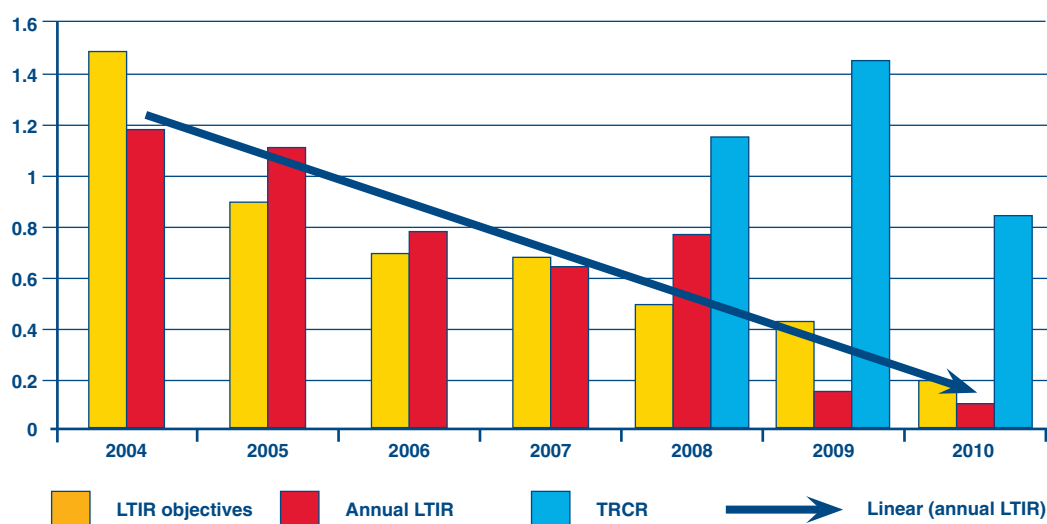
²⁰ POR OI2, Indicator GRI LA7

Table 3: TRCR (total recordable case rate) Indicator* – rate of work-related injuries by site (number of cases per 200,000 hours)

TRCR Indicator – 200,000 hours	Year	Lendava	Ljubljana	Mengeš	Prevalje	Lek
	2006	0.00	1.13	0.58	0.69	0.87
	2007	0.61	1.17	0.62	2.05	1.06
	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

* Data is comparable for the period since 2008 – the previous years' data are for orientation purpose only.

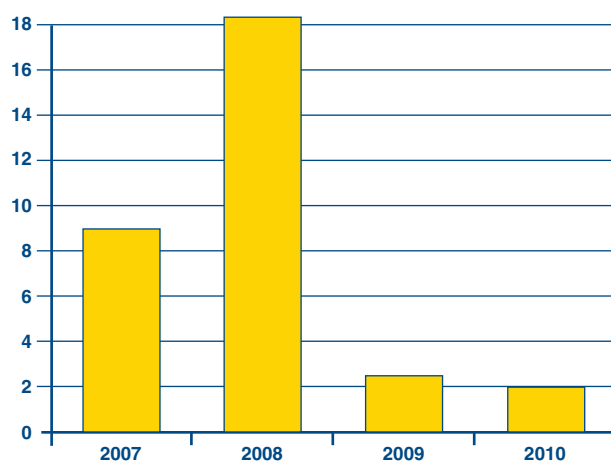
Graph 2: Annual overview of work-related accidents LTIR 2004 - 2010 and TRCR 2008 – 2010 for Lek d.d.



Lost time work-day rate (LWDR)²¹ is an indicator defining employee sickness absence due to work-related accidents. It is calculated by using the following formula: $LWDR = \text{number of lost days} \times 200,000 / \text{number of worked hours}$.

For Lek d.d., the LWDR value for 2010 was 2.68, confirming the absence of incidents requiring prolonged sick leave.

Graph 3: Value of LWDR (lost time work-day rate) Indicator for Lek d.d.



In 2006, the LWDR value of 35.68 stood out due to the incidents requiring prolonged sickness absence.

²¹ GRI Indicator LA7

Absenteeism rate²²

At Lek d.d., the proportion of sickness absence in the 2010 period was 5.1%, compared to 4.5% in 2009. 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.

Absenteeism rate due to work-related injuries for contracting providers

With the aim of enhancing safe behaviour also among contracting providers, we introduced close monitoring of the indicators for this group of associates in 2010. We recorded only 7 injury cases, mainly in construction and maintenance where the risk of accident is highest.

Number of fatal accidents in contracting providers²³

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

Rate of occupational disease²⁴

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.

1.9 Responsibility for products and services²⁵

As a pharmaceutical company, Lek manufactures and sells active pharmaceutical ingredients and finished prescription and over-the-counter (non-prescription) medicines, providing related information to the professional public through registration dossiers, and to the final consumer in the form of patient information leaflets. Communication of information related to pharmaceuticals is strictly regulated by the Medicinal Products Act.

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. The scope of their application is increasing, while some of the more potent prescription drugs were switched to non-prescription status.

Compliance with regulations concerning product information²⁶

In 2010, we received no penalty for non-compliance with regulations and voluntary codes concerning product and service information and labelling.

Practices of measuring customer satisfaction²⁷

No measurements of customer (i.e. final buyer) satisfaction with prescription drugs are performed. Every two years, however, we measure the reputation of Lek Pharmaceuticals with the professional public (medical doctors and pharmacists) which is also an indirect indicator of the professional public's satisfaction with our services. In 2010, no survey of this type was carried out.

Programs for adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship²⁸

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 Drug Advertising 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 sponsorship²⁹

In the field of prescription drug promotion, no non-compliance cases were recorded in 2010. In the area of non-prescription drugs and food supplements, we received a warning with regard to one food supplement, which was duly noted and the necessary action was taken. Furthermore, a warning was issued for two non-prescription drugs where the advertising campaign was adjusted to the updated standards and requirements. In corporate sponsorship, there were no non-compliance cases. There was no sponsorship involving drug promotion.

²² GRI Indicator LA7²³ POR OI3²⁴ POR OI4, Indicator GRI LA7²⁵ Indicator GRI PR3²⁶ Indicator GRI PR4²⁷ Indicator GRI PR5 - partly²⁸ Indicator GRI PR6²⁹ Indicator GRI PR7

II. LEK HEALTH, SAFETY AND ENVIRONMENT SYSTEMS



2. Lek Health, Safety and Environment Systems

2.1 Lek HSE policy

In the present section we summarize the major elements of the Lek Health, Safety and Environment Policy (see Item 3: Active environmental policy), which is integrated into our operations. We are committed to sustainable development as a basis of our business thinking, and to the Responsible Care Initiative for the chemical industry.

- Implementation of legal regulations and corporate guidelines is the basis of our Environmental Management System (EMS). We constantly check conformity of our operations with the relevant acts, regulations and guidelines.
- We play an active role in protecting health, providing safety and protecting the environment.
- Of prime importance in our activities are the health and safety of our employees and other people impacted by our operations, and protection of the environment.
- We made protection of the environment a topic of continuous employee training, and we thereby achieved a high level of familiarity with the company's environmental objectives and environmental awareness among our employees.
- Health, safety and protection of the environment constitute the basic responsibility of our managerial staff, and they are thus role models for other employees.
- By introducing the best performing 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, HSE risks are well defined, monitored, managed and regularly documented.
- To improve efficacy and accountability in HSE, we set measurable goals.
- To achieve risk management goals, we propose and implement preventive and corrective measures whenever necessary.
- Lek is a company, open to the public. We actively cooperate with the external public, particularly with the local population. We respond to their initiatives, seeking common solutions for further improvements.

2.2 Compliance with laws and standards

In our operations, we strictly fulfill legal and other requirements, focusing in particular on effective application of new legal and other requirements in our work processes and practice. The individuals authorized in specific areas of expertise keep track of and identify new legal and other require-

ments in the public publication system, ensuring appropriate internal publication after a GAP analysis. Responsibility for effective application in practice lies with the site heads / representatives of HSE units.

All our sites implement the Novartis Environmental Management System within a broader HSE system.

Our fulfillment of legal requirements is reflected in the following environmental permits and licences acquired:

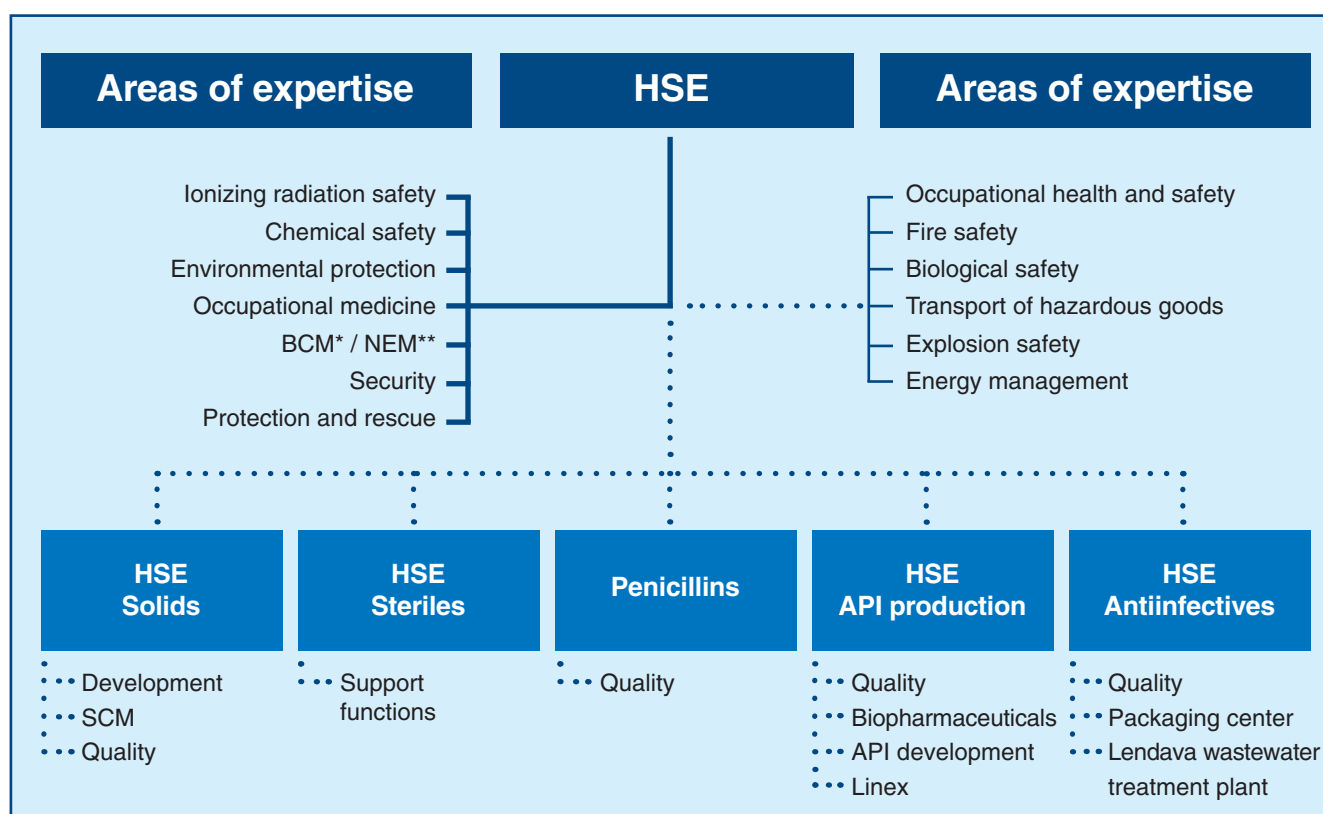
- Environmental permit for operation of a device with a high pollution potential (IPPC), for Lendava site, Permit No. 35407-172/2006, dated 15 April 2010
- Environmental permit for operation of a device with a high pollution potential (IPPC), for Mengeš site, Permit No. 35407-171/2006, dated 14 May 2010
- Environmental permit for operation of a device using VOCs, for Ljubljana site, Permit No. 35430-19/2006, dated 30 January 2008
- Environmental permit for operation of a device with regard to emissions into waters, for Ljubljana site, Permit No. 35441-339/2006, dated 8 November 2010
- Environmental permit for operation of a device using VOCs, for Prevalje site, Permit No. 35413-23/2007, dated 26 December 2007
- Environmental permit for operation of a device with regard to emissions into waters, for Prevalje site, Permit No. 35441-338/2006, dated 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 the sites), Permit No. 35536-5/2007, dated 1 June 2007
- Water use permits for direct use of water (Nos.: 35507-248/2003, 35504-143/2003, 35536-20/2008 and 35536-34/2007)

2.3 Human resources and training

HSE service

The HSE service consists of a HSE representative from the management team (director) and persons authorized for individual professional areas. As authorized by the Management Board, they are responsible for compliance of the respective area with the legislation of the Republic of Slovenia and with the standards of Novartis/Sandoz, for acting as Lek's representative in the area of expertise, for conducting inspections, performing periodic internal audits, and monitoring the implementation of corrective measures, consulting and providing professional assistance in the implementation of corrective measures by sites, and for notifying the management team about identified risks.

Figure 1: HSE organization



* BCM: Business Continuity Management

** NEM: Novartis Emergency Management

HSE unit

The HSE system has been applied to activities at all the Slovenian sites of Lek d.d.: Ljubljana, Verovškova 57, Mengeš, Kolodvorska 27, Prevalje, Perzonalni 47, and Lendava, Trimlini 2d.

The roles, responsibilities and authorizations in the area of HSE have been defined according to the company and function organizational structure. 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 all of our contracting partners. The largest unit having a suitable HSE organization in place is the Host which sets internal standards for individual sites that also apply to the Guests.

By identifying HSE training needs and by organizing suitable 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: induction courses, continuing education, and training for promotion.

The formal organization of the HSE function should not prevent employees working in different roles, functions and units from interacting. 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. Each employee contributing an idea is awarded an attractive prize.

2.4 HSE research and development

Extensive measures and activities bring results. A continuing process of recording and assessing workplace risk and stress levels, detailed analyses of work-related accidents and severe near-accidents as well as numerous endeavors to improve workplace behavior undoubtedly contributed to a rise in the level of safety culture and a reduction in the number of work-related accidents. This is reflected in the LTIR indicator value (Lost Time Injury and illness Rate; number of injuries suffered by Lek employees/ 200,000 worked hours) and in a reduced number of injuries among contracting providers and student workers.

In order to curb the number of work-related accidents, near-misses and hazardous behavior cases, we continue activities aimed at enhancing the company's safety culture.

Our process of investigating accidents and near-misses has been upgraded by the introduction of intensified, large-scale communication with regard to the underlying reasons and preventive measures to be implemented in similar working environments. In high-risk units, we continued walkthrough

inspections on site by senior managers and safety meetings. The topics to be dealt with were selected on the basis of accidents, reported near-misses and identified risk analysis. In cooperation with an occupational medicine specialist, we provided our employees with an opportunity to attend preventive health programs, which include specific health sustaining programs, guided workouts, and participation in seasonal flu vaccination campaigns. Our preventative approach to employee health is undergoing significant change, and will be further adjusted, upgraded and supported in the years to come.

Progressive implementation of a comprehensive safety system is of key importance to the company's growth and development. It is associated with promoting due diligence, continuous learning, and employee training and promotion. In 2010, 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 hired employees and managers;
- Periodic HSE training for managerial staff: internal HSE topics were upgraded in cooperation with the Labor Inspectorate of the Republic of Slovenia;
- Targeted training on Explosion Safety (ATEX);
- Training on Process Safety performed by two lecturers from the Swiss Institute of Safety and Security; the training program is essential for ensuring safety of manufacturing processes;
- Training on NEM (Novartis Emergency Management) as an integral part of BCM (Business Continuity Management);
- Tactical fire drills in conformity with the risk portfolio, to check the response of protection and rescue teams and the status of firefighting equipment, and to test alertness in case of emergency;
- Evacuation drills with fire extinguishing tests;
- Open House Day (Mengeš) for local firefighter clubs, and a workshop dealing with the fire safety awareness of employees in the domestic environment.

2.5 Environmental impact and risk assessment

In accordance with legal requirements, all Lek sites have acquired environmental permits for operation (see Item 2.2. 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. Environmental impact evaluation is performed by using a 6-level scale (negligible, minor, moderate, major, massive or catastrophic exceeding the regulatory limits).

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 Ministry of the Environment and Spatial Planning. The permit is due by the end of 2015, as major risk sources are given priority.

2.6 Risk prevention and mitigation measures

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

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

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

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

2.7 HSE objectives

For 2010, the following measurable HSE objectives were set (see Item 4.2. Realization of HSE objectives for 2010):

- Improving water use efficiency,
- Improving energy efficiency,

- Reducing emissions of volatile organic compounds (VOC),
- Reducing waste volumes,
- Reducing the number of work-related injuries.

2.8 HSE aspects and system of achievement monitoring

When identifying and assessing environmental aspects associated with the company's activity, pharmaceutical products and services, Lek takes into account the following:




- Direct impacts which are within the company's direct control, and
- Indirect impacts resulting from the company's cooperation with third parties, i.e. suppliers, buyers, service providers (see Item 3.9. Indirect environmental impacts)

At Lek, environmental aspects have been upgraded into so-called HSE aspects. For a specific area of expertise, they are created at the proposal of the qualified 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 qualified HSE person evaluates them in consideration of the following:

- GAP analysis,
- Audit (internal, by Novartis),
- Inspections,
- Complaints / internally identified deviations,
- Risk analyses,
- Accidents / hazardous occurrences (near-misses).

According to the risk methodology, aspects are evaluated in the following manner:

-  Corrective measures needed
-  Special caution needed
-  Risks managed appropriately

In the evaluation process, compliance in the following areas is taken into account:

- legislation,
- business efficiency, and
- company reputation.

Based on the findings in the Registry of HSE Aspects, corrective measures as well as business objectives and programs are defined.

Within the environmental aspects identified in 2010, the following areas were evaluated: raw materials and ancillary materials (water, energy, raw materials entering the production process,.....), air and water emissions, waste (generation, management, treatment), noise, transport, lighting, and some other specific areas (ionizing radiation, electromagnetic radiation.....).

Based on the evaluation of environmental aspects, the following aspects were attributed major significance at the company level: use of water and energy, emissions of volatile organic compounds, and the level of environmental pollution with waste. Objectives for 2010 were set in consideration of the major environmental aspects 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.

The Register of HSE Aspects is managed by the HSE site teams. 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 qualified persons.

In our operations, our compliance with legal and other requirements is reflected in successfully completed internal and external audits, inspections, water and noise monitoring, and with the environmental permits in effect. Internal audits of the HSE service are planned on an annual basis and performed according to individual HSE areas. 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.

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.

Internal audits according to EN ISO 14001:2004 standard are carried out periodically.

The planning, launching, implementation and maintenance of the auditing program are carried out in accordance with the requirements of EN ISO 14001:2004 standard and the EMAS system.

2.9 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 mandatory regulatory 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.

For the year 2010, the Management Review was carried out in April 2011. In addition to the discussion of items of the above standard, special emphasis was placed on the presentation / provision of risk mitigation measures at individual sites.

2.10 Emergency preparedness

For Lek d.d., emergency management is of great importance. Emergencies include any physical and chemical incident, product-related emergencies, and any other critical situation that might adversely impact the company's employees, environment, assets and/or reputation.

Whenever an emergency / incident occurs, an internal organizational network of responsible and professional individuals assigned to study and monitor such events as well as to adopt remedial measures to be taken in emergency cases, is established by means of the NEM (Novartis Emergency Management) system.

The basic purpose of NEM is to:

- Establish an organizational network of responsible and professional individuals assigned to study and monitor emergency events / incidents and to take decisions with pre-determined roles and responsibilities;
- Provide prompt access to professional and technical assistance;
- Establish efficient internal and external communication;
- Ensure continuity of business operations throughout the duration of an emergency event / incident.

Prevention of major environmental accidents

It is based on the environmental policy, Good Manufacturing Practice, fulfillment of all legal requirements for equipment and safe work, the use of the Best Available Technology (BAT), and on the level of employee qualification and awareness.

Prevention of workplace accidents

To enable prompt action and mitigation of accident and near-miss consequences, we established a system of immediate reporting and inclusion of authorized internal and external services such as a first-aid team, an occupational medicine specialist, and others. Extensive support is dedicated to preventive activities such as walkthrough inspections, safety meetings, safety consultations, analyses of work-related accidents, communication and risk assessment. These are aimed to detect work-related accidents and occupational diseases, to prevent their occurrence, or reduce their influence. All the levels of the organization are involved in these activities.

III. ACTIVE ENVIRONMENTAL POLICY



3. Active Environmental Policy

Environmental accountability is an integral part of Lek business strategy. Numerous environmental protection activities are integrated into our operations, often exceeding legal requirements. Special emphasis is put on upgrading and improving existing measures, and introducing new ones.

We promote effective and careful exploitation of natural resources, and, in particular, control over greenhouse gas emissions and energy efficiency. Our HSE policy is based on the achievement of measurable objectives. We implement global goals set by Novartis on the basis of Good Practice guidelines and the use of BAT.

We identified water and energy use, VOC emissions, and environmental pollution with waste as being major potential sources of environmental impact. Through systemic long-term projects and measures such as the project of gradually replacing volatile organic compounds with less hazardous substances, or by recycling of raw materials, we significantly reduce potential risk of any type of environmental impact.

The methods for potential risk identification, preventive measures and response in case of emergencies, and the process of analyzing any such event are defined in the following documents: Novartis-Lek Emergency Management Manual, Concept of Environmental Risk Mitigation, Fire Safety Rules, and other.

One of our major goals is limiting the use of raw materials and energy. Systematic and consistent monitoring of their realization is performed at the company and site level.

3.1 Established standards, and awards granted for accountable environment and natural resource management³⁰

ISO 14001, OHSAS 18001 and RCI

The successfully completed audits in 2010 confirm that we operate in accordance with ISO 14001 Environmental



Management Standard, OHSAS 18001 Occupational Health and Safety Standard, and Responsible Care Initiative.

Novartis Energy Excellence Award

For the seventh year running, Novartis granted awards for projects aimed to improve energy efficiency (Energy Excellence Award), thereby realizing one of its major environmental objectives pursued in all of its operations – reducing the use of energy and, consequently, cutting CO2 emissions. Out of a record 124 energy-saving projects and ideas, the expert panel selected 5 winners, and honored 11 projects with special awards for solution importance, quality or innovation. Among the special award winners was the project performed by a Lek team to improve energy efficiency of the cooling towers, the largest energy consumers of the Ljubljana site. Despite the relatively small amount invested in the project (EUR 15,000), the savings made in the first year exceeded EUR 90,000.



The team rewarded for energy efficiency (from left to right): Luka Ušeničnik, Metod Koncilija, Aleš Dolenc, Ivan Emil Hribar and Peter Toni.

Awards for outstanding environmental management achievements at the Mengeš site

At the Mengeš site, Novartis awards for special initiatives and outstanding achievements were presented. Awards were granted to two associates working in Environmental Management area. Marijan Resnik received an environmental care management award, and Jože Stopar was granted a compliance award for the acquisition of IPPC permit.



Award winners Marijan Resnik and Jože Stopar receiving congratulations from Hansjuerg Wetter, Head of API Unit.

³⁰ Disclosure GRI 2.10

3.2 Environmental protection expenditures³¹

We make continuous investments in environmental management and environmental impact mitigation. At the Ljubljana site, we continued with the process of reconnecting the ducts for discharge of VOC emissions to a new device for thermal treatment of gases. Values of emissions discharged from the device are below the prescribed limit values. Under specific conditions, the device also operates in the so-called autothermal mode. Consequently, no gas addition into the combustion chamber burner is required during the oxidation of solvents.

In October 2010, a device for removal of halogenated VOC air emissions by means of cryocondensation (condensation with liquid nitrogen as the refrigerant) started to operate at the Mengeš site. An amount of EUR 0.7 million was invested in the project. In addition to existing plants, new plants which represent a source of halogenated solvent discharges will be connected to the device. Minor projects were underway at other sites. Total environmental protection expenditure amounted to EUR 2.2 million.

3.3 Strategic projects

The principles of our environmental policy and accountability are integrated into the key strategic projects for improving and optimization of business processes.

Connect project

As the purpose of Novartis Connect project is to identify and use the opportunities for rationalization and economy of business operations, it was carried over into the year 2010. Within the project, Novartis companies compare the supply, demand and processes in several business categories in the same country or in the same area, thus mutually replacing existing solutions with more rational ones if found during benchmarking. This also applies to environmental issues. With the cooperation of Sandoz Austria, this project represents one of the major partnerships at the Novartis corporate level.

Explosion safety – ATEX

At Lek, the process of harmonizing all the production sites, lines and systems with explosion safety laws and regulations has been underway since 2006. After the completion of ATEX certification of installations for buildings, lines and systems at our production sites, we resumed in 2010 the process of maintenance certification which should be completed within 5 years of the initial installation certification, confirming the company's adherence to changes, and an appropriate level of Ex equipment maintenance.

LEAN – Lean Production Initiative

At all our production sites, the Lean Production Initiative is in progress, aimed to increase the efficiency of production in all of its aspects. Within the initiative, various projects are underway to boost productivity and to cut the use of raw materials, packaging, energy and other natural resources in individual production process phases. Their purpose is to raise our competitive position and to reduce the level of environmental pollution per product unit.

The projects performed in 2010 in the solid dosage forms production as part of the initiative, saved us more than EUR 3 million. The major part of the savings was accounted for by improved production yields and, consequently, by reduced waste volumes and improved production efficiency, all of which resulted in lower specific use of energy.

3.4 Reuse of raw materials

In API manufacturing, the recycling and reuse of organic solvents are integrated into the process of manufacturing procedure development wherever feasible. In 2010, as much as 88% of all the organic solvents used were recycled and reused in the manufacture. The highest level of reuse was achieved at the Lendava site where almost 97% of the solvents used underwent recycling. 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, and released to authorized providers for further treatment or disposal.

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, additional activities were performed for systemic segregation, collection and preparation of waste for recycling. Several sorting tests of municipal waste were carried out to reduce the waste volumes intended for disposal, and to increase the waste volume for reuse.

³¹ GRI Indicator EN30 - partly

Efficiency of materials

Table 4: Annual mass flow of various materials used* by site (in t)³²

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek
2006	t	5,389.85	2,171.19	6,538.87	792.62	14,892.52
2007	t	5,265.46	8,039.93	8,414.12	3,066.68	24,786.20
2008	t	6,102.20	8,432.80	10,642.35	3,514.66	28,692.02
2009	t	6,079.99	5,867.95	11,467.48	3,472.68	26,888.11
2010	t	6,455.76	8,436.04	14,403.98	3,513.38	32,809.12

* 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).

At the Mengeš site, the major part of the flow of starting materials is accounted for by organic solvents and technological gas (liquid nitrogen). Multiple reuse of organic solvents is possible within the same production process, whereas the average share of recovered solvents accounts for about two thirds of total consumption at all the production

plants. Liquid nitrogen is primarily used for finalizing operations and inertization. It is not returned into the process. The increase in the mass flow recorded in 2010 was due to the lower production volume achieved the year before, particularly at the Ljubljana site.

Table 5: Efficiency of various materials used* per unit of product by site

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek
2006	t/t	44.0	0.9	18.2	1.1	4.2
2007	t/t	40.2	2.7	15.3	4.9	5.8
2008	t/t	44.6	2.7	17.5	4.6	6.2
2009	t/t	39.8	3.7	23.0	4.2	8.8
2010	t/t	37.2	2.0	29.2	4.0	5.6

* 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).

3.5 Replacing hazardous volatile organic compounds with less hazardous substances

At Lek, a project of gradual replacement of hazardous VOCs with less hazardous substances in the tablet film-coating process has been successfully underway for several years now. The project was first launched at the Prevalje site where the use of methylene chloride in the tablet film-coating process for a broad-spectrum antibiotic, a combination of potassium clavulanate and amoxicillin, will be entirely replaced with ethanol by the end of 2011. Despite the fact that solvent replacement requires a regulatory approval, the process is running successfully.

This good practice will also be applied at the Ljubljana site where activities to replace the ethanol production phase with the water phase on individual products are already underway.

3.6 Fire safety

In the field of fire safety, three tactical fire drills were organized in accordance with the Risk Portfolio. 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. At the Mengeš site, an Open House Day was organized for all the local fire brigades, and a workshop on the fire-safety awareness raising for employees in their domestic environment was held.

At the Ljubljana and Mengeš sites, we updated the fire reporting and alerting systems, and upgraded the stable fire-fighting systems as part of our capital expenditure projects. In 2010, there were no major interventions.

³² EMAS Core Indicator

3.7 Storage

Storage of hazardous chemicals, including chemical waste, complies with the legal requirements and Novartis guidelines. Storage compatibility is considered in view of individual chemicals' properties.

In 2010, the Globally Harmonized System (GHS) of classification and labelling of chemicals for manufacture and storage purposes was implemented in accordance with the legal requirements.

3.8 Distribution

Accidents related to product distribution³³

From Lek, 4731 consignments of finished products and APIs were dispatched to 85 countries around the world either by road, air or sea. During the transport of both non-hazardous and hazardous goods, no accidents occurred and neither did in the dispatching process (fatality - injury, spill - discharge, damage to property, civil commotion, or media coverage).

Table 6: Abstract from the report on hazardous goods transport issued by the Safety Advisor

Class	Quantity in kg
3	3,144,171
4.1	256,764
4.2	405
4.3	12
5.2	16
6.1	5,550
6.2	987
8	4,710
9	1,555
TOTAL	3,414,170

3.9 Indirect environmental impacts

As most of the indirect environmental impact is potentially caused by suppliers, these are bound by Novartis to commit to the Novartis Corporate Citizenship Policy. By signing a supply agreement, the supplier guarantees to execute the contractual obligations in accordance with all applicable laws and regulations associated with HSE, 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.

Environmental impact of transport is limited by more extensive use of teleconferencing and videoconferencing which replace long-distance business travel.

3.10 Biological safety

Lek deals exclusively with biological agents from Risk Groups 1 and 2 which are defined as follows:

- 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.

The basic task of those responsible for biological safety is to diminish potential risk in the handling of biological agents, and to ensure compliance with the Slovenian legislation and Novartis guidelines.

The persons responsible for biological safety at Lek include:

- Person authorized for biological safety of Lek d.d., and persons authorized for biological safety at the Mengeš, Ljubljana and Lendava sites;
- Persons responsible for control and safety of the areas where work with GMOs is performed;
- Persons responsible for the implementation of measures planned for accidents associated with GMOs, and
- Heads of projects related to working with GMOs.

At Lek, a nine-member Biological Safety Committee has been operating since 2005. Its tasks include:

- Reviewing the lists of biological agents of Lek d.d.;
- Checking the accuracy of biological agents' classification into risk groups and, consequently, the adequacy of proposed containment measures;
- Approving individual projects in accordance with the risk assessment, taking into account workplace safety and potential risk to the environment and to human health.

3.11 Efficiency of water and energy resource use

In 2010, 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 implementation of measures aimed at decreasing the use of natural resources.

A comparison of efficiency by year provides a true picture of trends at the sites where a single product or a small number of products are manufactured (Lendava, Prevalje). At the

³³ POR OI22

sites with versatile portfolios (Ljubljana, Mengeš), where the production of individual products is subject to major market fluctuations, major variations are observed also in the specific use of water and energy resources. The absolute and

relative use of energy and water by site fluctuates mostly as a result of the changes in production volumes.

Energy

Total use of energy

Table 7: Use of energy³⁴

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2006	GJ	348,476	251,715	291,665	60,605	952,460
2007	GJ	347,971	295,720	291,825	59,872	995,387
2008	GJ	352,418	319,995	288,974	61,017	1,022,403
2009	GJ	384,367	347,466	314,520	60,314	1,106,667
2010	GJ	399,679	340,136	355,266	58,551	1,153,633

Indirect use of energy from primary sources³⁵

The increase in energy use resulting from a higher production output was compensated by electricity savings; consequently, the total increase trend is insignificant. The highest growth in use was recorded in natural gas (+ 8%), since the Mengeš and Lendava sites using natural gas mainly in the production of process steam increased their production outputs by 10%.

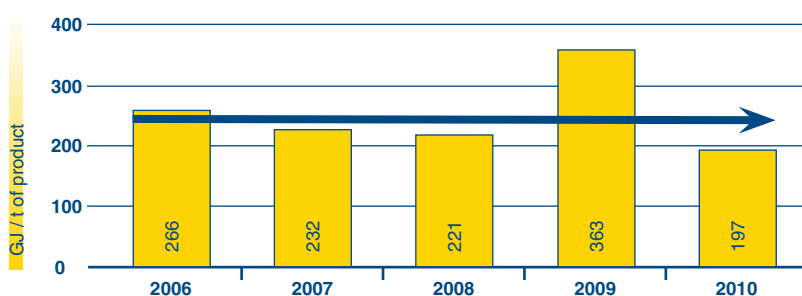
Lek does not have its own electricity production.

In the structure of purchased electricity, the ratio of conventional to renewable resources is 3 to 2. Renewable sources of electricity account for 40%, hydropower being in the leading position with 38% of total use. Of the conventional resources, coal and lignite rank first, with a 47% share in the total structure of purchased electricity resources.

Table 8: Efficiency of energy resource use per unit of product by site³⁶

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2006	GJ/t	2,848	106	811	82	266
2007	GJ/t	2,658	99	531	95	232
2008	GJ/t	2,573	102	476	80	221
2009	GJ/t	2,427	196	631	73	363
2010	GJ/t	2,199	67	720	66	197

Graph 4: Efficiency of energy use per unit of product at the level of Lek d.d.*



* The blue line indicates the trend between 2006 and 2010

³⁴ EMAS Core Indicator, POR OI19

³⁵ GRI Indicator EN4

³⁶ EMAS Core Indicator

At the Mengeš site, waste solvents are used as secondary fuel for the operation of a device producing heat and steam for manufacturing purposes. We have obtained an environmental protection permit for its operation.

At the Lendava site there is a fixed share of renewable energy amounting to 2-3%; it is obtained from incineration of organic waste generated in fermentation production.

Owing to an increase in production volume at the Lendava site, the use of energy in the past five years has been slightly increasing in absolute terms. However, a higher production profitability and more efficient energy use in relative terms caused the energy use trend to decrease. The measures contributing to this situation in 2010 include the use of waste heat for pre-heating of batch feeding water and closing of cooling cycles.

At the Mengeš site, around 2/3 of total energy use is accounted for by natural gas and 1/3 by electricity. Natural gas is used by steam boilers for the production of industrial steam and purified water, and for the heating of premises in winter time. 5-10% of the energy used for steam production is obtained also by waste solvent incineration. Electricity use has increased, mainly due to newly built facilities (production plant, laboratories) requiring more specific HVAC (Heating, Ventilating, Air Conditioning) conditions (GMP requirements) and, consequently, more electricity for their fulfillment.

At the Prevalje site, many years of systematic implementation of measures aimed at reducing usage resulted in improved efficiency of electricity use. With approximately identical or slightly lower use of energy resources, a larger amount of products is produced every year. Due to the small size of the site, the use of energy and gas is largely influenced by differences in the production volume, whereas external air temperatures influence the use of electricity, due to the operation of cooling towers. In 2010, the use of electricity was lower also because of a different accounting method.

At certain sites, the production of higher-complexity products is growing in line with the respective site's strategy. For such production, specific techniques are used, and the products are lesser in quantity but have a higher added value (MMF,

S-OMP, ATV, ...). As these products are more demanding in terms of energy use, the requirement for energy efficiency will be increasingly important in the years to come.

At the Ljubljana site too, an upward trend of energy efficiency can be observed, even though the relevant data vary a lot. A more significant deviation was recorded in 2009, when the need for prompt adjustments to market requirements due to the economic crisis dictated production of multiple different products in smaller-scale batches. Given the specific nature of pharmaceutical production, this also resulted in slightly higher use of raw materials and energy resources per unit of product.

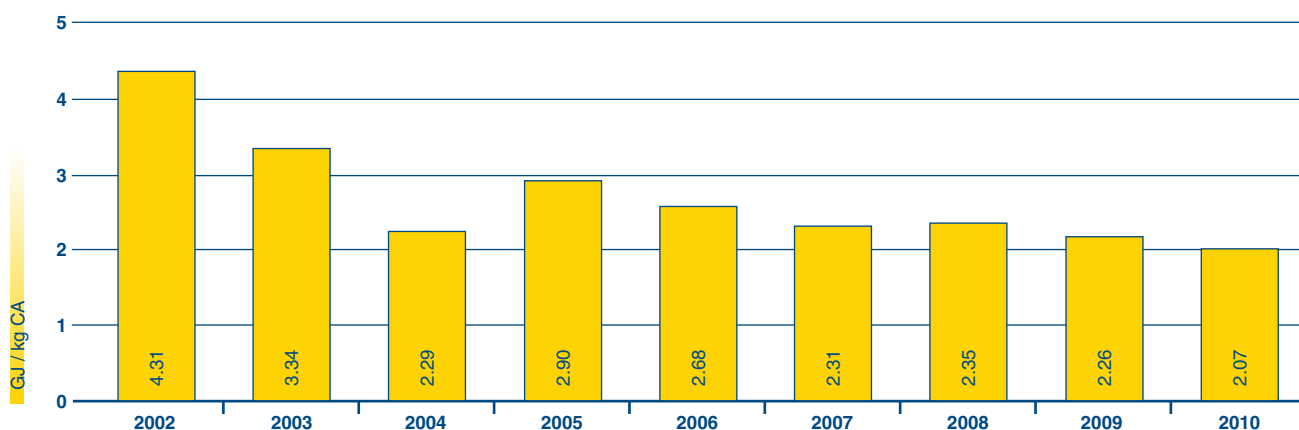
Energy savings resulting from improved energy efficiency³⁷

The employees were kept up to date with the methods and possibilities for energy resource economy, while providing their own respective initiatives. Furthermore, measurable savings were made through efficient energy use in manufacturing processes and distribution systems of secondary energy resources. The measures aimed at achieving efficient energy use also caused CO₂ emissions to decrease as follows:

- by 512 t of CO₂ / l due to optimization of cooling tower operation at Lek Ljubljana,
- by 329 t of CO₂ / l due to optimization of compressed air production at Lek Lendava,
- by 612 t of CO₂ / l due to optimization of an air handling unit at Lek Ljubljana,
- by 204 t of CO₂ / l due to optimization of an air handling unit at Lek Mengeš,
- by 300 t of CO₂ / l due to minor maintenance works on compressed air branching at Lek as a whole.

In 2010, the energy resource use was higher due to increased production outputs at all of Lek sites, i.e. by 4.2%. Specific use of energy per unit of product, being defined in different ways depending on the production type at a specific site, was lower by an average of 2%.

Graph 5: Downward trend of specific energy use – example of potassium clavulanate in Lendava



³⁷ GRI Indicator EN5

Water

Water use

Water is the main natural resource used in our activities, which is why we strive to use it efficiently. Water use efficiency per unit of product is being improved by reuse of

cooling water, production optimization, improved efficiency, and other measures. This will be further reported under Item 4.2

Graph 6: Total water use* (in 000 m³)³⁸

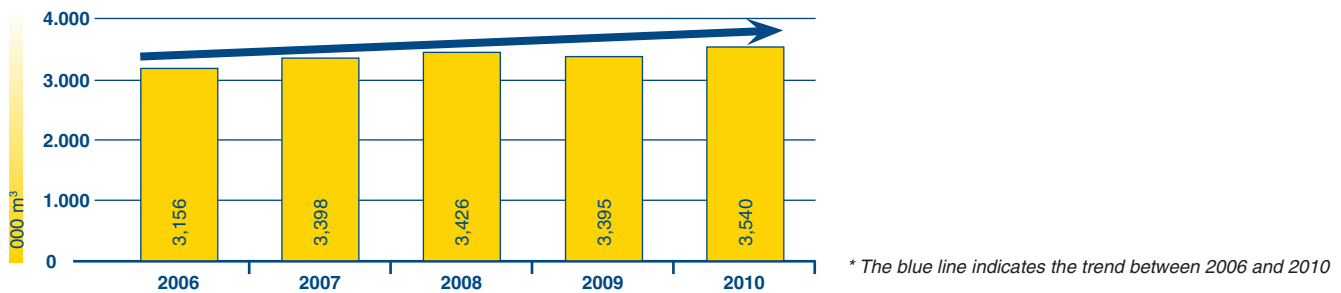


Table 9: Total water use by site (in 000 m³)³⁹

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje
2006	in 000 m ³	1,492	238	1,391	36
2007	in 000 m ³	1,460	322	1,574	41
2008	in 000 m ³	1,468	450	1,470	38
2009	in 000 m ³	1,304	406	1,648	36
2010	in 000 m ³	1,427	396	1,679	39

Total quantity of pumped water by source⁴⁰

All the sites are supplied with water from the public supply network, while the Lendava and Mengeš sites pump water used for manufacturing purposes also from their own wells (drill holes). The Mengeš site has two wells, and the Len-

dava site has six. Relevant water use permits have been obtained from the Ministry of the Environment and Spatial Planning (Nos. 35507-248/2003, 35504-143/2003, 35536-20/2008 and 35536-34/2007). Regular monitoring of ground-water levels is performed as well. The results are reported to the respective Ministry.

Table10: Water supply quantities and sources at the Mengeš and Lendava sites (in 000 m³)

Mengeš	2006	2007	2008	2009	2010
From own pumping station (000 m ³)	1,316	1,483	1,392	1,591	1,590
From public supply network (000 m ³)	74	91	76	64	94
Lendava	2006	2007	2008	2009	2010
From own pumping station (000 m ³)	1,450	14,52	1,455	1,262	1,384
From public supply network (000 m ³)	41	24	43	42	40

³⁸ POR OI21

³⁹ EMAS Core Indicator, POR OI21

⁴⁰ GRI Indicator EN8 – partly

Total quantity of recycled and reused water⁴¹

Mainly reused water is used for cooling processes. This is mostly the case at the Mengeš site. There is a three-level cooling water system operating in different temperature regimes, so that the water from one system can 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.

Owing to a more efficient water use, the trend of its use at the Lendava location has not changed in the past five years in absolute terms. However, in relative terms, the trend has been falling, mainly resulting from the reuse of cooling water for batch feeding water after the sterilization of fermentors. According to our estimates, this trend will continue in 2011.

At the Mengeš site, water is used mainly for manufacturing purposes. 4-6% is supplied from the public supply network, while the major part is pumped from the well (groundwater). Until 2008, the indicator of efficient water use per unit of product had been falling due to production optimization, improved efficiency and other measures, while in 2009 the trend reversed. This was due to the start of production of higher-added value product (tacrolimus) requiring considerable water quantities. This trend continued into 2010, when

water use was slightly higher than the year before. This was a result of greater production volume and, to a lesser extent, of water mains leakage which, however, has been successfully remedied.

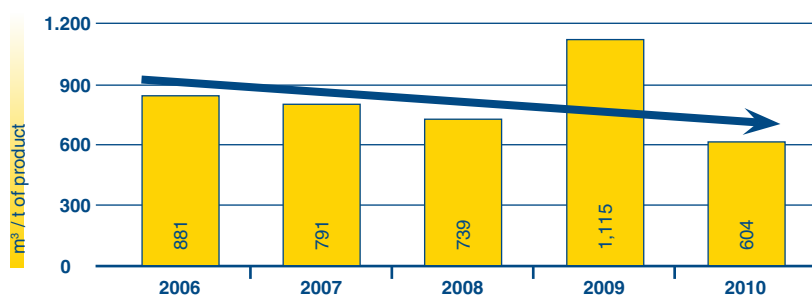
At the Ljubljana site, the trend towards increasing energy use efficiency is also reflected in increased water use efficiency. There are considerable fluctuations on the year-to-year level; nevertheless, a higher deviation observed in 2009 (the same as in case of energy use) is a result of prompt adjustments to market requirements by the production of several different products in small-scale batches. In order to provide production cleanliness with respect to smaller batches, the said adjustments also required higher water use.

The environmental indicator trend for Lek water use in 2010 proves the efficacy of the measures taken in the water management area.

Table 11: Water use efficiency per unit of product and by site⁴²

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek (total)
2006	m ³ /t	1,383	64	1,048	33	881
2007	m ³ /t	1,203	63	690	45	791
2008	m ³ /t	1,154	125	468	33	739
2009	m ³ /t	1,139	201	536	28	1,115
2010	m ³ /t	956	76	548	31	604

Graph 7: Efficiency of water use per unit of product - Lek d.d.*



* The blue line indicates the trend between 2006 and 2010

⁴¹ GRI Indicator EN10 - partly

⁴² EMAS Core Indicator

3.12 Measurable indicators

All the data given in this report, arranged according to individual indicators, form part of the Novartis Environmental Report.

The report refers to the data of a specific site, whenever this is required for the purpose of EMAS certification. The column »Lek« summarizes the data of all the four sites. In graphs, the blue line indicates the waste volume trend for the period between 2006 and 2010.

Waste management⁴³

Over the past 5 years, the relative volumes of waste generated have been diminishing as a result of manufacturing process optimization and improvements. On the other hand, increased production outputs resulted in a considerable in-

crease in the absolute volumes of waste generated, particularly at the Lendava and Mengeš sites.

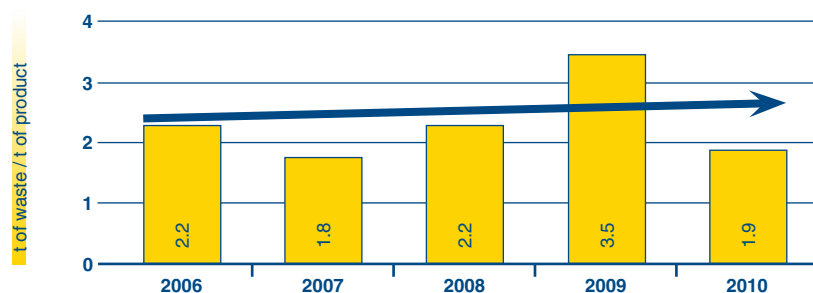
When identifying waste volume trends at the Lendava site, we should take into account that two technologically different production processes take place at the site: process bio-fermentation production of APIs, and non-process production – packaging of finished dosage forms. Consequently, the waste generated differs both in type and volume. The packaging process is characterized by considerable quantity oscillations depending on product changeover. The goal of achieving a 5% reduction in the relative waste volumes will be realized in 2011 through further process optimization.

At the Mengeš site, more than 80% of total waste is accounted for by hazardous waste, particularly liquid waste solvents and solid hazardous waste. All hazardous waste is released to the companies authorized by the Ministry responsible for

Table 12: Amounts of waste generated by site (in t)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek
2006	t	1,774	1,246	4,390	421	7,831
2007	t	1,677	1,599	4,039	458	7,774
2008	t	3,663	1,457	4,474	535	10,130
2009	t	3,343	1,646	5,234	573	10,797
2010	t	3,801	1,851	4,907	535	11,094

Graph 8: Waste amount per tonne of product – efficiency (t of waste/ t of product)



* The blue line indicates the trend between 2006 and 2010

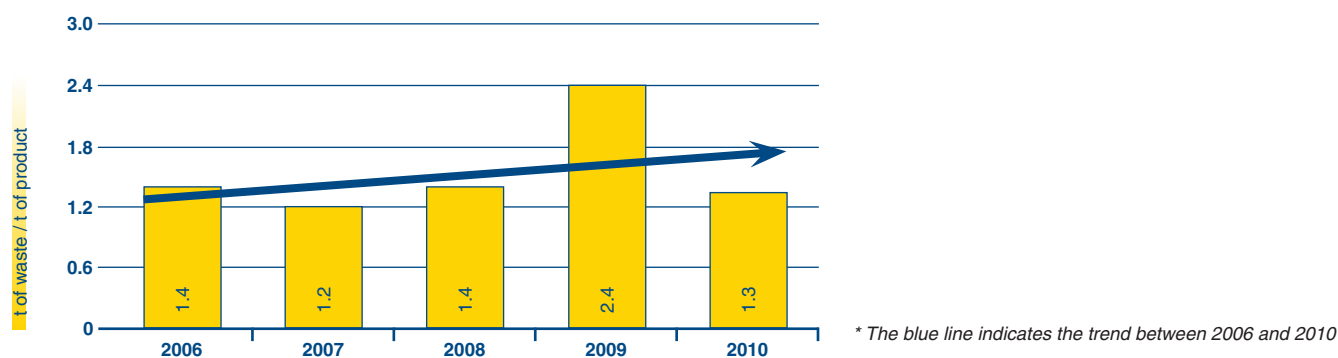
Disposal of hazardous waste⁴⁴

Table 13: Hazardous waste volumes by site (in t)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek
2006	t	775	122	3,753	207	4,856
2007	t	1,268	338	3,145	201	4,953
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	7,345

⁴³ EMAS Core Indicator and GRI Indicator EN22

⁴⁴ GRI Indicator EN22, POR O15

Graph 9: Hazardous waste amounts per tonne of product – efficiency (t of waste/ t of product)

environmentally acceptable disposal. Specific clean waste is reused as an energy resource in an environmentally friendly manner, for which we have obtained an environmental permit (see Item 2.2. Compliance with laws and standards).

Over the past 5 years, the increase in the volume of hazardous waste generated was mainly due to the changes in the production program. This was mostly accounted for by the Mengeš site, where our strategic focus was placed on the manufacture of higher-complexity products by using special techniques with higher added value but greater energy complexity. This is the reason why the index of hazardous waste generation intensity per tonne of product grew significantly in 2009. However, we simultaneously launched measures to reduce the volume of this type of waste. By improving the process of industrial waste treatment (stripping) in 2010 we reduced the volume of waste generated in the product of the highest complexity in terms of quantity by more than 70%, thus reducing total relative quantities of hazardous waste by 0.6 t per tonne of product.

Among the hazardous waste generated at the Mengeš site, non-halogenated waste solvents prevail, accounting for 85–95% of total hazardous waste. The mixtures of halogenated waste solvents account for 3–11%. In 2010, the use of halogenated solvents in the manufacture started to decline as a result of improvements implemented in accordance with Novartis' recommendations on the use of alternative solvents in production (replacing halogenated solvents with non-halogenated ones) and due to the introduction of environmentally advanced technological solutions (a cryo-condensation unit at the air exhaust, a distillation column for solvent recovery). At the Mengeš site, 15–30% of the annual volume of non-halogenated waste solvents of extreme purity and with a high calorific potential is removed in a burning device through co-incineration of natural gas, this practice having been introduced as early as in 2007. The acquired energy is utilized for technological purposes to prepare technical steam. The permit for the operation of the device for the processing of waste solvents by means of co-incineration is covered within the integral environmental permit for the Mengeš site (see Item 2.2. Compliance with laws and standards).

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. The increase recorded in 2010 is attributable to 137.45 additional tonnes of waste resulting from the decontamination of rooms and the equipment of the dry injection plant (cefalosporins). In accordance with Novartis' requirement, the process of grinding filled capsules and vials was abolished in 2009 and 2010. This resulted in reclassification of this type of waste from non-hazardous to hazardous waste, which is one of the reasons for increased volumes of the latter.

Disposal of non-hazardous waste⁴⁵

Despite increasing production outputs, changes in the production structure and the rising number of employees, the relative quantities of waste (t of waste / t of product) have remained at almost the same level over the past 5 years. The structure of waste, however, has been subject to considerable change. The highest level of change is recorded in waste packaging, mainly due to more consistent waste segregation and sorting. This type of waste accounts for 20%. The highest growth is posted at the Ljubljana and Mengeš sites where an annual increase of up to 30% was recorded on all the segregated waste fractions. This result was largely due to additional employee training and awareness-raising at all the sites. Intensive waste segregation also resulted in reduced volumes of mixed municipal waste.

At the Mengeš site, relatively large volumes of biologically degradable waste are generated by the manufacture of fenel and Echinacea juices, the volume depending on the production outputs. The waste is collected by certified waste treatment companies for further composting.

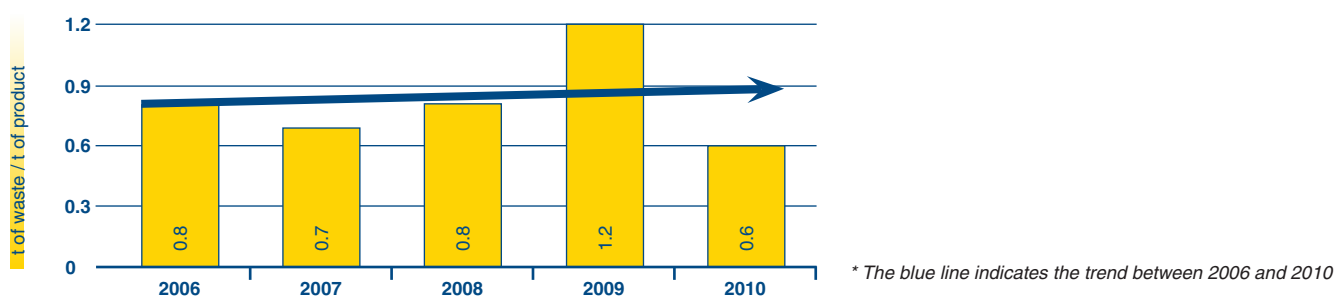
The structure of non-hazardous waste is the following: up to 30% of municipal waste, up to 30% of waste packaging by fraction (paper, plastics, wood, metal, glass), up to 20% of biodegradable industrial waste, while the remaining share is accounted for by other non-hazardous wastes. Municipal waste is disposed of, waste packaging is mainly recycled (through the SLOPAK system), biodegradable waste is used as a compost-like material, whereas other non-hazardous wastes are disposed of by certified companies by means of incineration.

⁴⁵ GRI Indicator EN22, POR OI6

Table 14: Non-hazardous waste amounts by site (in t)

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Lek non-hazardous waste without recyclable packaging
2006	t	999	1,125	637	215	2,975	2,254
2007	t	409	1,261	894	257	2,821	1,808
2008	t	1,449	1,159	917	285	3,811	2,802
2009	t	1,170	1,223	855	320	3,568	2,549
2010	t	1,181	1,322	921	324	3,749	2,483

Graph 10: Non-hazardous waste amounts per tonne of product - efficiency (t of waste / t of product)



Air emissions⁴⁶

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, measurements of the substance and/or dust content in the air are made, and samples for analysis are taken. For all the outlet ducts measured, assessments of substance and/or dust emissions have been made as prescribed. We distinguish between greenhouse emissions and emissions from immobile devices; of the latter emissions, VOCs and dust are the most important. Organic substance emissions are effectively reduced by means of devices for exhaust air cleaning such as thermal gas incinerators, adsorbers, gas washers, and other.

Emissions from waste incinerator

Emissions from this source are generated at the Lendava site, where a waste incinerator operates, and at the Mengeš site, where co-incineration of natural gas and waste non-halogenated solvents is carried out. For the operation of the devices, environmental permits have been obtained.

At the Lendava site incinerator, mainly incineration of waste from production on the site is carried out. Waste waters generated in the incineration process are discharged into the industrial sewage system, whereas flue gases are directed through the flue gas purification section into the atmosphere. 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. In case of any

deviation from the prescribed temperature, the waste dispensing system is halted automatically.

At the Mengeš site, most of the air emissions are generated by four burning devices which utilize natural gas as the primary source of energy. In one of these devices, thermal oxidation of fumes originating from the manufacturing process is performed. For the production of industrial steam, natural gas and non-halogenated waste solvents of extreme purity and high calorific value are burnt simultaneously. Emission monitoring is regularly performed at all the emission release points. 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).

Sulphur dioxide (SO₂)

SO₂ emissions originate from burning devices and devices for the thermal treatment of volatile organic compounds. Emission volumes are small, and the emission trend shows no major oscillations.

At the Lendava site, waste incineration is the major source of this type of emissions, which also contain sulphur due to their organic nature. At the Mengeš and Ljubljana sites, SO₂ emission results from the presence of sulphur in the natural gas used in the burning devices (Mengeš) and/or in the devices for thermal treatment of waste gases (Ljubljana). The values of SO₂ emission volumes by year are based on the data on their concentration at individual measuring points and at the time of device operation. Emission monitoring is carried out at all sites.

⁴⁶ EMAS Core Indicator, GRI Indicator EN20, POR OI7, POR OI10

Table 15: Sulphur dioxide (SO₂) emissions by site⁴⁷

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek
2006	t	0.00	0.08	0.03	0.00	0.11
2007	t	0.11	0.03	0.03	0.00	0.17
2008	t	0.10	0.04	0.02	0.00	0.16
2009	t	0.11	0.03	0.03	0.00	0.16
2010	t	0.12	0.01	0.00	0.00	0.13

Table 16: Sulphur dioxide (SO₂) emissions – efficiency in kg per tonne of product at Lek

Year	Efficiency (kg SO ₂ / t of product)
2006	0.03
2007	0.04
2008	0.03
2009	0.05
2010	0.02

Nitrogen oxides (NO_x)⁴⁸

At all sites, nitrogen oxide (NO_x) emissions arise from incinerators or co-incinerators, burning devices and to a lesser extent the manufacture of nitrooxine at the Mengeš site. Variations in emission volumes recorded in Mengeš between 2008 and 2010 are due to the operation of the device for co-incine-

ration/treatment of waste for energy generation purposes and, to a lesser extent, to the above product's manufacturing volume. Nitrous gases produced in the manufacturing process are purified by neutralization in a nitrous gas washer. At all sites, regular emission monitoring is performed.

Table 17: Nitrogen oxide (NO_x) emissions by site⁴⁹

Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (per t of product)
2006	t	7.00	1.00	14.93	1.45	24.38	0.007
2007	t	9.05	0.65	7.81	1.42	18.93	0.005
2008	t	9.30	1.14	10.82	1.36	22.62	0.006
2009	t	10.14	0.78	8.72	1.38	21.02	0.006
2010	t	9.14	1.30	16.36	1.36	28.15	0.008

Carbon dioxide and other gases contributing to the greenhouse effect

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. GHG1 also include some other gases (CO₂ equivalents) used in or arising from Lek processes, e.g. HFC, N₂O and methane.

CO₂ which is generated at the sites producing electricity, heat and steam as an equivalent to the purchased electricity, heat and steam, is considered an indirect greenhouse gas (GHG2).

⁴⁷ EMAS Core Indicator, POR OI7, GRI Indicator EN20

⁴⁸ EMAS Core Indicator, POR OI8, GRI Indicator EN20

⁴⁹ EMAS Core Indicator, POR OI7, GRI Indicator EN20

Table 18: CO₂ and other gases contributing to the greenhouse effect – total quantity, and quantity by site⁵⁰

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek	Efficiency (per t of product)
GHG1	2006	t of CO ₂	15,870	1,300	11,296	2,072	30,538	8.5
	2007	t of CO ₂	12,189	1,741	11,058	2,039	27,027	6.3
	2008	t of CO ₂	12,492	1,953	11,523	1,954	27,923	6.0
	2009	t of CO ₂	11,740	2,371	12,310	1,966	28,388	9.3
	2010	t of CO ₂	12,667	3,005	14,353	1,958	31,983	5.5
GHG2	2006	t of CO ₂	13,780	18,472	9,638	2,384	44,275	12.3
	2007	t of CO ₂	13,705	29,110	9,642	2,411	54,868	12.8
	2008	t of CO ₂	14,364	31,721	10,134	2,661	58,879	12.7
	2009	t of CO ₂	15,153	34,105	10,715	2,548	62,522	20.5
	2010	t of CO ₂	15,870	33,218	11,879	2,407	63,375	10.8

The table of GHG1⁵¹ includes:

- dinitrogen monoxide (N₂O) in the equivalents of CO₂⁵²,
- fluorinated hydrocarbons (hydrofluorocarbons - HFC) in the equivalents of CO₂⁵³ and
- other greenhouse gases (methane and others) in the equivalents of CO₂⁵⁴.

The increasing volumes of direct and indirect greenhouse gas emissions result from a manufacture using specific techniques with higher added value, which, however, require a higher use of energy, water, specific chemicals and other raw materials⁵⁵.

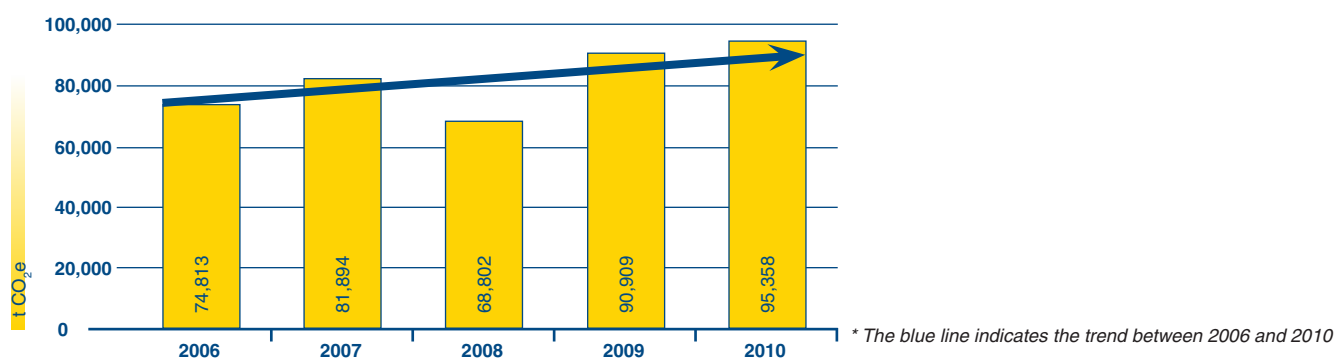
To contain the increase in the volume of this type of emissions, we use devices for purification of air emissions, and implement various environmental measures. The sites' energy management teams implement alternative solutions to reduce energy use in manufacturing and non-manufacturing facilities by installing energy-efficient devices, and by regulating and insulating the rooms. The savings are documented, accounting for a minor percentage of total CO₂ emission⁵⁶.

The Lendava and Mengeš sites participate in trading with CO₂ emissions vouchers. According to the legislation, we

have the obligation to report to the Ministry of the Environment and Spatial Planning, and to pay an environmental fee. At the Lendava site, direct emissions (GHG1) mainly result from organic waste incineration. After a sharp decline in 2007 due to some of the waste from other Lek sites being submitted to other disposal facilities for different methods of disposal, the annual quantity of CO₂ has not changed considerably over the past few years. Purchased electricity represents a major source of indirect emissions (GHG2). In the past 5 years, GHG2 emissions have shown only a slightly upward trend.

At the Mengeš site, the main causes of CO₂ emissions (GHG1) are natural gas combustion (> 90%) in gas burners, and the manufacturing structure putting special emphasis on products of higher complexity in terms of energy. Indirect CO₂ emissions (GHG2) result from electricity use. Consequently, the rising trend is identical to the trend of the site's electricity use, which is on the increase due to the construction of new facilities.

The decrease in the amounts of greenhouse gas emissions at the Prevalje site is mainly due to a reduced number of fleet cars.

Graph 11: Total CO₂ emissions (GHG1 and GHG2)

⁵⁰ POR OI10

⁵¹ POR OI11

⁵² POR OI12

⁵³ POR OI13

⁵⁴ GRI Indicator EN16

⁵⁵ GRI Indicator EN18

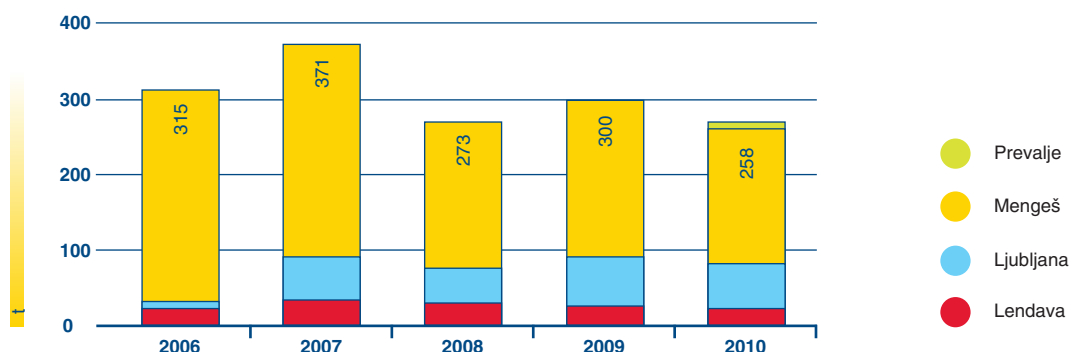
⁵⁶ POR OI9

Volatile organic compounds (VOC)⁵⁷

The reduction of emissions of halogenated volatile organic compounds recorded in 2010 was largely due to the new device installed at the Mengeš site, using state-of-the-art cryogenic condensation technology for removal of halogenated solvents from exhaust air. The gaseous nitrogen evaporated on the device is reused in the manufacturing process for device inertization. Thermal treatment of non-halogenated

solvent emissions with natural gas causes their air emission level to diminish steadily. At the Ljubljana site, the changes in the exploitation of current capacities and the introduction of new production lines resulted in a slight increase in the use of volatile organic solvents (acetone, ethanol ...) emissions, which are collected and purified by means of thermal treatment.

Graph 12: Total emissions of volatile organic compounds



Water releases

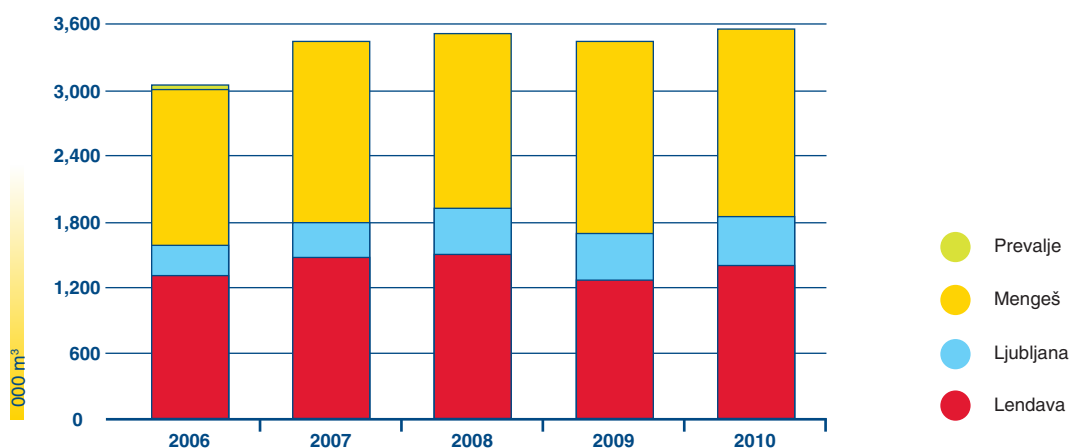
Industrial, cooling and municipal wastewaters directly or indirectly resulting from manufacturing processes are directed into the public sewage system through separate three-channel ducts. Unpolluted waters are discharged directly into the water stream whenever possible.

Wastewaters

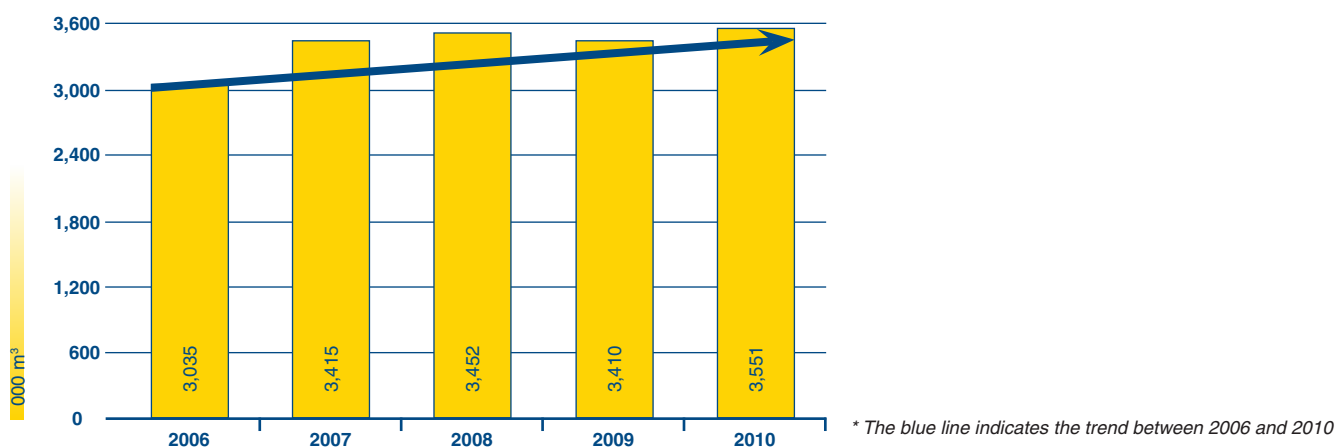
Over the past 5 years, the Lendava site has recorded a slightly downward trend of relative wastewater volumes, which corresponds to the diminishing water use. In 2011, no changes in the trend are anticipated.

At the Mengeš site, more than 80% of the total water amount is used for process cooling. Waste cooling waters are discharged into the water stream, while the remaining wastewaters resulting from the manufacturing process are directed into the Domžale municipal wastewater treatment plant together with municipal waters. The amounts of both used and waste waters are directly linked to the manufacture and introduction of new products, the reduction of raw material and energy resource costs being a constant goal. This means a reduced water use and, consequently, diminishing amounts of waste industrial waters. Since 2006, the absolute volume of waste industrial process waters has been decreasing, and the intensity of water use per unit has been diminishing as well.

Graph 13: Wastewater volumes by site (in 000 m³)



⁵⁷ POR OI9

Graph 14: Total wastewaters (in 000 m³)Table 19: Wastewater volumes by discharge quality and destination, by site⁵⁸

	Year	Unit	Lendava	Ljubljana	Mengeš	Prevalje	Lek
Cooling water (unpolluted)	2006	in 000 m ³	1,323	86	1,014	12	2,435
	2007	in 000 m ³	1,303	134	1,195	12	2,644
	2008	in 000 m ³	1,310	57	1,186	13	2,566
	2009	in 000 m ³	1,125	79	1,381	13	2,598
	2010	in 000 m ³	1,260	55	1,408	11	2,734
Discharge			into water stream	into sewage system	into water stream	into sewage system	
				cleaning at the WWTP*			
Industrial water use (polluted)	2006	in 000 m ³	169	152	377	24	722
	2007	in 000 m ³	157	188	379	29	753
	2008	in 000 m ³	158	393	284	25	860
	2009	in 000 m ³	180	327	267	23	797
	2010	in 000 m ³	167	341	271	28	806
Discharge			into sewage system	into sewage system	into sewage system	into sewage system	into sewage system
			cleaning at the WWTP*	cleaning at the WWTP*	cleaning at the WWTP*		cleaning at the WWTP*

* WWTP - wastewater treatment plant

For the release of wastewater into the sewage system / water streams, environmental permits have been obtained (see Item 2.2. Compliance with laws and standards)

Phosphorus and nitrogen compounds, chemical oxygen demand

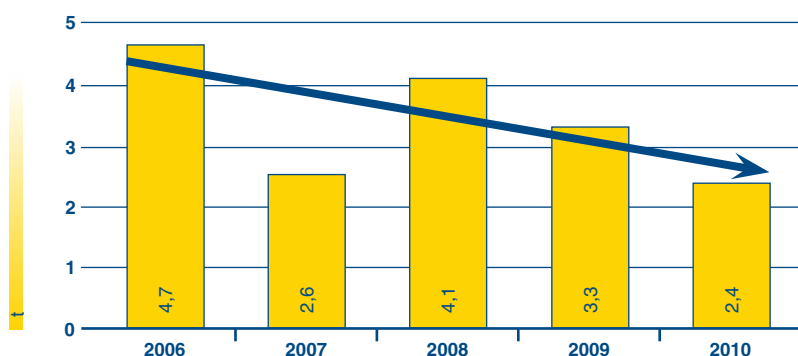
The annual level of phosphorus and nitrogen compound pollution as well as the level of pollution due to chemical oxygen demand (COD), have been diminishing for several years. The main reason for this trend is the termination of the manufacture of some older products such as cimetidine in 2006. The increasing nitrogen compound emissions and the level of pollution due to chemical oxygen demand in 2009

are linked to the launching of production of higher-complexity products at the Mengeš site. Environmental measures implemented in 2010 contributed to a decline in the value of both parameters.

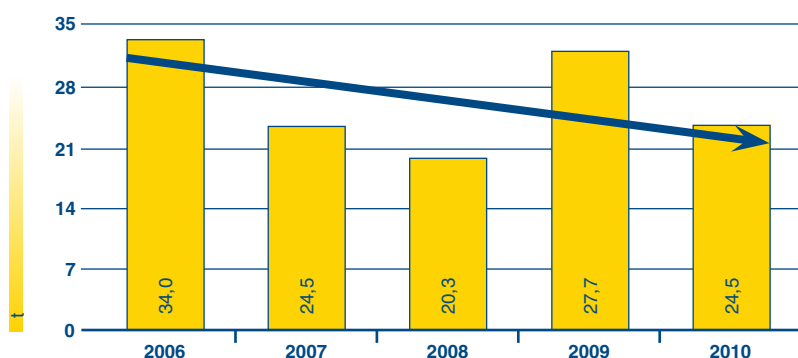
Chemical oxygen demand, total phosphorus compounds and total nitrogen compounds in wastewaters also constitute taxation parameters. The largest impact, accounting for more than 80%, is associated with chemical oxygen demand, whereas phosphorus and nitrogen compounds each represent about 10% of the pollution.

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. Most of the phosphorus compounds are

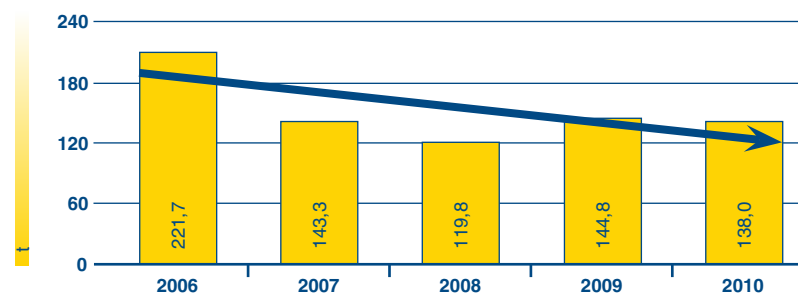
⁵⁸ EMAS Core Indicator, GRI Indicator EN21

Graph 15: Phosphorus compound emissions⁵⁹

* The blue line indicates the trend between 2006 and 2010

Graph 16: Nitrogen compound emissions⁶⁰

* The blue line indicates the trend between 2006 and 2010

Graph 17: Chemical oxygen demand (in t of O₂)⁶¹

* The blue line indicates the trend between 2006 and 2010

formed at the Mengeš site, the reason for their presence in wastewater being residual inorganic substances.

As the annual amounts of phosphorus and nitrogen compounds are reported after the treatment in the wastewater treatment plant, they largely depend on the efficiency of the wastewater treatment. The levels of pollution due to chemical oxygen demand are measured 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. Wastewaters and the content of all three parameters are regularly monitored by the respective monitoring authorities. Monitoring is performed three to six times per year, depending on the site's wastewater volume.

Other environmental impacts

Odor

At all the sites, biofilters have been installed wherever odor is expected in the air (above the flotation tanks). In this way, the odor resulting from the industrial process is prevented from affecting the local population. As Slovenia's environmental regulations do not cover environmental odor loads, the requirements for odor load reduction were not integrated in the environmental permitting procedure. The monitoring of biofilters' operation and waste air loads is carried out by the Public Health Institute Maribor.

In 2010, Lek received no odor-related complaints.

⁵⁹ POR OI15

⁶⁰ POR OI16

⁶¹ POR OI14

Soil

In all the phases of manufacturing processes and projects aimed at expanding production capacity, Lek is active in preventing soil pollution. 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. No remedial action due to soil pollution has been needed at Lek so far.

Table 20: Land use by site⁶²

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

Noise

In order to prevent any environmental noise pollution, we perform regular monitoring and analyses. 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.

⁶² EMAS Core Indicator

IV. ENVIRONMENTAL POLICY AND TARGET ACHIEVEMENT



4.1 Policy

Our concern for the environment, targeted minimization of the environmental impact of our activities, and adherence to the environmental policy are our key guidelines forming the basis of our social responsibility.

Our environmental impacts are being constantly reduced through regular assessment of system performance, open communication with internal and external publics, and through every employee's participation in our environmental management efforts. The progress is monitored annually for individual sites and for the company as a whole. Data for reporting requirements are collected and confirmed in the Novartis DMS system.

At the end of the previous 5-year period, we set ourselves the following HSE objectives for the next 5-year period:

- Improving water use efficiency by 10% compared with the year 2010,
- Improving energy efficiency by 10% over 2010,
- Reducing VOC emissions into the air (h-VOC and nh-VOC) by 20% over the 2010 figures,
- Reducing waste volumes by 10% over 2010, and
- Reducing the LTIR to 0.1 by 2015.

4.2 HSE target achievement in 2010

For the period up to 2010, Lek set itself the following HSE targets:

- Improving water use efficiency by 10% compared with the year 2005,
- Improving energy efficiency,
- Reducing VOC emissions into the air to 240 t,
- Reducing waste volumes,
- Reducing the LTIR to 1 in 2010.

The objectives set were fully or partly met. This was largely due to positive changes in the employee culture and awareness that every individual can contribute to better working conditions and reduced environmental impact. As the objectives are set for each individual site separately and for Lek as a whole, site management teams actively participate in all the environmental projects and support their implementation. Major achievements of 2010 include the acquisition of Integrated Pollution Prevention and Control (IPPC) permits for the Mengeš and Lendava sites, which was the result of team effort and support from all respective departments.

Improving water use efficiency

Water use efficiency per unit of product is improving on a year-by-year basis, which is confirmed by the trend presented in Graph 6. In absolute terms, water use increased by 3.7% over the year 2009. Nevertheless, the savings made, and the changes in the manufacture structure and volume resulted in a decline from 1,115 to 604 m³/t of product. The tentative objective of a 10% improvement in water use efficiency set for the year 2010 was not only achieved but even exceeded.

Improving energy efficiency⁶³

We achieved the objective set due to the upward trend of energy efficiency resulting from systematic implementation of measures aimed at reducing the use of natural resources. Compared to 2009, the use of energy per unit produced fell from 363 GJ/t to 197 GJ/t. The main factors were the increase in production profitability and the measures aimed at improving energy efficiency at the Lendava site.

Reducing VOC emissions into the air

Despite a downward trend of VOC emissions into the air recorded in the period between 2005 and 2010, the 2010 objective of 240 t of emissions was not met. In 2010, VOC emissions amounted to 257.9 t, a 14% decline over the year 2009.

Reducing waste volumes

Due to business process optimization and improvements, a slightly downward trend of waste management efficiency, measured as the amount of waste per tonne of product, has been observed over the past 5 years. Given the increasing production volumes of high added-value products (e.g. biological medicines), in which higher volumes of waste result from lower production outputs, the annual efficiency indicator fails to provide a truthful picture, however.

Our waste management goals were not fully met, the reason being the increasing production outputs (at the Lendava site, production output rose by 82% in the period 2005 – 2010) and larger quantities of out-of-date and expired products (including past inventories).

Reducing the number of accidents resulting in sickness absence (measured as the Lost Time Incident Rate LTIR/ 200,000 worked hours).

We perform systematic monitoring and implementation of objectives set to reduce the number of accidents resulting in sickness absence. This is achieved by means of preventative solutions regardless of the risk level in the company as a whole, while additional measures were implemented for higher-risk units. Maintaining the positive trends established continues to be the company's long-term goal.

4.3 Objectives for 2011

Objectives for the year 2011:

- Reducing VOC emissions into the air: <210t
- Improving water use efficiency (m³/USD of sales) by 2%
- Reducing energy use by 1.6%
- Reducing waste volumes by 5% (t/t of production output)
- Maintaining the LTIR at 0.18

The Lek Sustainability Report 2011 will be published in mid-2012.

⁶³ EMAS Core Indicator

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GRI application levels

		C	C+	B	B+	A	A+
Mandatory	Self-declared	x					
Optional	Third-party checked						



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