**Corporate Environment, Health, Safety and Energy Report 2014** 

LEO PHARMA MANUFACTURING SITES





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## STATEMENT

# Environment, Health, Safety and Energ

This report is a supplement to our CSR report and demonstrates our performance in 2014 in the areas of Environment, Health, Safety and Energy. During 2014 we have reached some important milestones and I would like to take this opportunity to thank all employees whose dedicated and hard work made this possible.

Firstly, three of our manufacturing sites achieved certification to the health and safety management system standard OHSAS 18001 which means that all of our manufacturing sites are now certified to this standard. Considerable work was required to achieve these certifications and a number of our employees were involved in the process. Constant focus on health and safety and implementation of a number of improvements was required, and I am proud that we have reached our goal to have all sites certified to this standard.

In the environmental area we have also seen some great results in 2014. In the spring, our two manufacturing sites in Denmark obtained certification to the environmental management system standard ISO 14001, and our site in Vernouillet was recertified to this standard in June. Now, only our two manufacturing sites in Cork and Southport remain to be certified to the ISO 14001 standard and I am confident that they will achieve this in 2015 according to schedule.

LEO Pharma's 2015 goal in relation to energy performance was achieved some years ago, but we have continued to focus on reducing our energy consumption. 14 new projects were initiated in 2014 which will result in an additional annual savings of approx. 2,255 MWh. Energy optimisation projects will have even higher focus in 2015 as EU legislation requires that all of our European sites submit energy audit reports before the end of 2015. As part of our continuous improvements of energy performance, new ambitious goals have also been set for 2020.

Even though we have had a very high focus on health and safety in recent years, we still have big challenges with our Lost Time Injury (LTI) rate and we have not yet succeeded in reducing the LTI rate to an acceptable level. The LEO Pharma goal is to achieve an LTI rate on a par with best in industry by the end of 2015. We achieved an LTI rate of 5.3 in 2014 for our manufacturing sites, and if we compare ourselves with the rest of the pharmaceutical industry, the best companies have an LTI rate close to 2.

To be able to improve our LTI rate, we need constant focus on health and safety and to identify possible hazards before they turn into injuries. I expect that the latest two OHSAS 18001 certifications in 2014 can contribute to keeping this focus and thereby bring down the number of injuries. While the focus in 2013 was about increasing safety awareness, 2014 focused on changing safety behaviours, and I am confident that the work we have done will further improve safety performance, An incident where an employee gets hurt is one incident too many.

I will do my utmost to support the EHSE strategy in the future.

#### Yours sincerely

Vice President, Finished Goods Manufacturing Ireland (Interim Head of GPS in parts of 2014 and 2015)

Atotachel

Brendan Fitzpatrick

## LEO Pharma Facts

LEO Pharma helps people achieve healthy skin. By offering care solutions to patients in more than 100 countries globally, LEO Pharma supports people in managing their skin conditions.

Founded in 1908 and owned by the LEO Foundation, the healthcare company has devoted decades of research and development to delivering products and solutions to people with skin conditions.

LEO Pharma is headquartered in Denmark and employs around to 4,800 people worldwide.

For more information, visit http://www.leo-pharma.com

This Environment, Health, Safety and Energy report covers the six LEO Pharma manufacturing sites:

Ballerup, Denmark (headquarters) Esbjerg, Denmark Cork, Ireland Dublin, Ireland Vernouillet, France Southport, Australia

"This Environment, Health, Safety and Energy report covers the six LEO Pharma manufacturing sites."

## CONTACT

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## **Manufacturing site descriptions**

#### **BALLERUP, DENMARK**

The history of LEO Pharma dates back to 1620 where the LEO Pharmacy in Copenhagen became royally privileged.

In 1908, the pharmacists August Kongsted and Anton Antons bought the LEO Pharmacy in Copenhagen. The same year, they founded Løvens kemiske Fabrik in the basement of the pharmacy. The factory expanded quickly and was moved to Brønshøj.

The first production in Ballerup (17 km northwest of Copenhagen) began in 1946 and in 1958 all activities were gathered there after relocation from the previous site in Brønshøj.

During the years, many companies have shown an interest in merging with or acquiring the successful company but Løvens kemiske Fabrik has never returned the interest, and in 1984 Knud Abildgaard created the LEO Foundation to ensure the development of Løvens kemiske Fabrik as an independent research-based pharmaceutical company. Thus, the LEO Foundation owns all shares in LEO Pharma.

In 2002, Løvens kemiske Fabrik changed its name to LEO Pharma.

The Ballerup site today has multiple corporate functions as well as API and Finished Goods Production. Most of the discovery, research and development departments are also located here.

The production on site can be divided into three main areas: Organic synthesis of active ingredients (vitamin D analogues), biological production of active ingredients (Fucidin<sup>®</sup>) and finished goods production. Finally, the company runs a secondary activity consisting of a small enzyme production.



Organic synthesis requires several synthesis steps and between the individual synthesis steps, it may be necessary to purify the intermediates. For both synthesis and purification, various kinds of organic solvents are used.

In the biological production, the active ingredients are produced from fungi. In many ways, this process is similar to the process of brewing beer. The production takes place in large tanks with water and culture media consisting of sugar and nutrient salts. When the fermentation is completed, the active ingredient is filtered out and the ingredient is purified a number of times. Organic solvents are used for the purification process.

The finished goods production manufactures and/ or packs tablets, capsules, liquid products and sterile products e.g. for injection. As finished goods often only require small amounts of active ingredients these ingredients must be mixed with substances whose only purpose is to function as fillers, carrying medium or flavour additive. The following finished products are manufactured in Ballerup:

Centyl<sup>®</sup> K mite, Centyl<sup>®</sup> K, Daivonex<sup>®</sup>/Dovonex<sup>®</sup> Scalp solution, Etalpha<sup>®</sup>/One-Alpha<sup>®</sup>, various products containing Fucidin<sup>®</sup>, Heparin LEO<sup>®</sup> and innohep<sup>®</sup>, Kaleorid<sup>®</sup> and Daivobet<sup>®</sup> Gel and Xamiol<sup>®</sup> Gel. The products are all for human use.

Daivonex<sup>®</sup>/Dovonex<sup>®</sup> Scalp solution, Daivobet<sup>®</sup> Gel and Xamiol<sup>®</sup> Gel are used to treat scalp psoriasis, Etalpha<sup>®</sup>/ One-Alpha<sup>®</sup> to treat calcium metabolism disorders and various Fucidin<sup>®</sup> products to treat infectious diseases.

The site area in Ballerup has grown over the years. Today the total site area is approximately  $150,000 \text{ m}^2$ .

The Ballerup site is situated in an area zoned for commercial use and for larger manufacturing enterprises. The Ballerup site holds a licence from the Danish Environmental Protection Agency (EPA).

In 2014, the number of employees in LEO Pharma Ballerup equalled 1,517.3 full time employees.

#### **ESBJERG, DENMARK**

The production in LEO Pharma A/S Esbjerg began in 1976 and the site area is about 34,000 m<sup>2</sup>. The Esbjerg site is situated in an area for enterprises with special requirements (heavy industry area) in the southern part of Jutland. LEO Pharma is one of the top manufacturers of the anticoagulant substance heparin, and Esbjerg is where crude heparin is manufactured.

When the crude heparin has been extracted from mucosa and bound on an ion exchanger, the crude heparin is shipped to LEO Pharma Cork in Ireland for further treatment. The production site holds a licence from the Danish EPA. In February 2013, the former licence was replaced with a new license to process 120,000 tonnes mucosa. In April 2014, a licence to establish facilities for handling the fertilizer Fertigro® was obtained, and so was as a licence to establish new administration building facilities and a workshop. An application for a new waste water discharge consent was sent to the local environmental authorities in February 2014. The authorities have not dealt with the application yet but plan to do so in the beginning of 2015.

In 2014, the number of employees in LEO Pharma A/S Esbjerg equalled 9.4 full time employees.





#### **VERNOUILLET, FRANCE**

The Vernouillet factory was built in 1964 and further expansion has taken place over the years. The latest expansion was carried out in 2012. The total site area is approximately 56,000 m<sup>2</sup>.

The Vernouillet Finished Goods Manufacturing site is located in the so-called Beauce plain about 80 km west of Paris. This is where active pharmaceutical ingredients (e.g. tinzaparin and fusidic acid) are received from LEO Pharma Cork and LEO Pharma Ballerup respectively, and further processed to pre-filled innohep® syringes and Fucidin® tablets. Burinex® tablets are also manufactured in Vernouillet.

In the process, the active pharmaceutical ingredients are mixed with excipients and filling agents and the finished goods are filled into syringes or made into tablets. Syringes are produced in two ways:

- 1. One method is where syringes are supplied from external suppliers. LEO then adds the API to the syringes and performs the control and packing.
- 2. Another method is production of syringes from assembling the syringe to filling in the API and to the subsequent control and packing. This is called Bulk Manufacturing.

In addition to syringes, the site produces Fucidin® tablets and Burinex® tablets in various doses.

LEO Pharma Vernouillet is declared to authorities as a declared installation with periodic control following the ICPE (Installation Classified for Environmental protection) regulation.

In 2014, the number of employees in Vernouillet equalled 346.5 full time employees.





#### CORK, IRELAND

LEO Pharma Cork is situated in Cork Harbour. In LEO Pharma Cork, two active pharmaceutical ingredients are produced from resin with heparin – Heparin Sodium and Tinzaparin Sodium.

The production in Cork began in 1987, and the site area is 79,000 m<sup>2</sup>. This site is dedicated to the production of active pharmaceutical ingredients for Heparin LEO<sup>®</sup> and innohep<sup>®</sup>. The site also has different support functions including a development department.

The active pharmaceutical ingredients are shipped to

LEO Pharma in Ballerup in Denmark or Vernouillet in France, where the heparin or tinzaparin finished products are manufactured. The trading name for tinzaparin is innohep<sup>®</sup> is an anticoagulant and is used for prevention and treatment of blood clots.

LEO Pharma Cork holds an IED license from the Irish Environmental Protection Agency (EPA).

In 2014, the number of employees in LEO Pharma Cork equalled 49.6 full time employees.

#### **DUBLIN, IRELAND**

The LEO Pharma Finished Goods Manufacturing site in Ireland is located near the centre of Dublin in close proximity to both residential and light industrial activities. The original building was constructed in 1954 and in 1960 LEO Pharma took ownership of it and commenced the manufacturing of pharmaceutical products there. From that time various adjacent land acquisitions have been made, bringing the total site area up to 42,000 m<sup>2</sup>.

The site has been used to manufacture many types of pharmaceutical products over the years including Active Pharmaceutical Ingredients (APIs). However, the manufacture of APIs ceased on site in 2007 and since these "licenced activities" are no longer carried out, the site surrendered its IPPC (Integrated Pollution Prevention Control) licence to the Irish EPA at the end of 2011. Now, the site has a licence from the Dublin City Council (DCC) regarding trade effluent discharge.

Manufacture on the site is now dedicated to the formulation, filling and packaging of LEO Pharma dermatology products for topical use such as ointments, creams and gels in different formats, but mainly tubes. Product ranges manufactured include Daivobet<sup>®</sup>, Dovonex<sup>®</sup>, Fucidin<sup>®</sup>, Xamiol<sup>®</sup> and Picato<sup>®</sup>. It is also a site for introduction of new topical products and topical applications/ solutions, from pilot scale to full scale commercial manufacture.

The bulk manufacturing facility has mixing and homogenising plants in clean rooms with batch volume capacity ranging from 10 litres to 4 m<sup>3</sup> along with all the associated support systems. Filling of the finished goods is also carried out in clean rooms. The facility has a total of seven tube filling and packing lines, one bottle filling line and one web process (bandage) line. There is also a sterile plant within the facility which is dedicated to the production of an ophthalmic eye gel product. This sterile plant also has a dedicated tube filling line.

In 2014, the number of employees in LEO Pharma Dublin equalled 410 full time employees.



#### PEPLIN OPERATIONS, API SOUTHPORT, AUSTRALIA

LEO Pharma's manufacturing site in Australia is situated in Southport in Queensland and is referred to as Peplin Operations or API Southport.

Peplin Operations PTY LTD (Peplin Operations) was acquired by LEO Pharma in November 2009. Peplin Operations' main function is to manufacture an Active Pharmaceutical Ingredient (API) from a plant called *Euphorbia peplus* (*E. peplus*) which contains ingenol mebutate which is used in the product Picato<sup>®</sup>. Picato<sup>®</sup> is used to treat Actinic Keratosis, a precancerous skin condition caused by sun damage.

In 2012-2013, Peplin Operations completed an upgrade of the manufacturing facility to support the transition from an R&D facility in 2011 to a full scale production plant facility in 2013. Since the upgrade, Peplin Operations has become a more lean and efficient site. The process commences with the delivery of fresh *E. peplus* plants to the site. The plants then go through a number of manufacturing process steps including drying and milling, extraction, purification and quality control. The final manufacturing process of the active pharmaceutical ingredient is purification where it is crystalized. Then, the API is packed and shipped overseas to Dublin and/or a contract manufacturer in the USA where it is used for manufacture of the finished product, Picato<sup>®</sup>.

Peplin Operations holds an environmental permit from the Department of Environment and Heritage Protection from the Queensland Government.

In 2014, the number of employees in Peplin Operations equalled 36 full time employees.



## **Environment, Health, Safety and Energy policies**

LEO Pharma has developed global policies concerning environmental affairs, energy performance and occupational health and safety. The policies which are presented here are reviewed every year but only updated when required:





LEO Pharma provides a safe and healthy working environment for all employees, contractors and visitors. LEO Pharma takes measures against Occupational Health and Safety problems in a professional and effective manner.

LEO employees follow applicable health and safety laws, regulations and policies. We conduct business in a manner that protects the health and safety at our workplace.

We strive to develop a proactive, continuous improvement working culture in which good health and safety practice is a natural part.

#### To demonstrate this commitment, LEO Pharma will:

- 1. Comply with current legislation on occupational health and safety (OHS) and any agreements made with organisations regarding OHS requirements.
- 2. Provide necessary human and financial resources to ensure that this policy is implemented and maintained and objectives and targets are achieved.
- **3.** At our manufacturing sites we will:
  - Implement an Occupational Health and Safety Management System in accordance with OHSAS international standards and continuously improve our health and safety performance.
  - Define specific health and safety goals and make all employees aware of these goals.

LEO Pharma will communicate this policy to all persons working for LEO and ensure that it is available to the public.

In order to ensure that this policy is effectively implemented and managed, it will be reviewed annually and updated where and when required.



Gitte Aabo President & CEO 24 September 2012

Anders B Spohr Executive Vice President 24 September 2012

Reference is made to GP\_000043 in eQuality

## Environment, Health, Safety and Energy goals

As a consequence of these policies, the following long term goals were set in 2011 by Group Management.

#### **ENVIRONMENT AND ENERGY GOALS**

Explanation of the energy goal:

of use.

LEO Pharma has the following global goals on environmental affairs and energy:

- 1. All existing manufacturing sites must be ISO 14001 certified by the end of 2015.
- 2. At the end of 2015, energy projects with a total saving of 15% of the energy consumed in 2010 will be implemented (equal to about 20,000 MWh).

If nothing changes (i.e. the activities at our manufacturing sites is the same as in 2010), the total energy con-

sumption in 2015 will be max 85% of the 2010 con-

sumption. However, the total energy consumption in

2015 may be higher if production rises, expands or new

facilities are built or taken into use. On the other hand,

the total energy consumption may fall if production goes down, part of it is outsourced or buildings are taken out

#### HEALTH AND SAFETY GOALS

LEO Pharma has the following global goals on health and safety:

- 1. All existing manufacturing sites must be OHSAS 18001 certified by the end of 2015.
- 2. The group LTI rate is on par with the best in industry at the end of 2015.

Explanation to the LTI rate goal:

LTI rate is calculated as:

## $LTI rate = \frac{(number of injuries with absence * 1000000 working hours)}{Total number of working hours}$

The injuries included in this calculation are injuries with absence beyond the day of the injury (note: other companies include only the injuries with more than three days of absence from work).

#### **STATUS ON 2015 GOALS**

In 2014, the manufacturing sites have been working on both the management system certification goals as well as the goals related to energy and occupational injuries.

The energy goal has been reached but not all of the other goals have been achieved yet. We are confident that our remaining certifications will be achieved before the end of 2015, but the goal regarding the LTI rate is still a challenge

#### MANAGEMENT SYSTEMS CERTIFICATION GOALS

The status and plans of the goals related to management systems are as follows:

Site	<b>ISO 14001</b> Environmental management system		OHSAS 18001 Occupational health & management system	safety
Ballerup	2014	<	2010 Re-certified 2013	<
Esbjerg	2014	< _	2010 Re-certified 2013	<
Vernouillet	2011 Re-certified 2014	< _	2014	<
Cork	2015		2013	<ul> <li>Image: A second s</li></ul>
Dublin	2012	<	2013 Obtained 2014	<
Southport	2015		2015 Obtained 2014	<

In March 2014 LEO Pharma's Danish sites in Ballerup and Esbjerg became certified to the ISO 14001 environmental management standard. The management system had previously been certified to the OHSAS 18001 standard for Health and Safety management and in the process leading up to the ISO 14001 certification, the existing management system was amended to become a combined EHS management system. This one system ensures continuous improvements within the EHS performance across the Danish sites. Integration of the systems has resulted in a minimum number of procedures and more efficient internal and external audits as they cover both systems at the same time.

Southport obtained the OHSAS 18001 certification in June, Dublin in October and Vernouillet in December. Southport even managed to get their certification one year ahead of schedule.

#### **ENERGY GOAL**

The purpose is:

- To build and execute efficient systems regarding energy savings in Global Product Supply (GPS) and R&D by the end of 2015
- To evaluate effective and coherent energy solutions across production sites to reduce our carbon emissions
- To establish a common understanding of where to invest in energy effective solutions in order to maximise return on investment

The status, as of today, is that energy saving projects implemented since 2011 have resulted in a total saving of 26,428 MWh/year. The projects in 2014 account for savings of approx. 2,255 MWh/year. The 2015 goal was already reached in 2012, but new energy saving projects will still be implemented each year.

Further information concerning the projects carried out can be seen in the section on "Environmental and Energy Projects".

#### LOST TIME INJURY RATE GOAL

The work to reach a group LTI on par with the best in industry at the end of 2015 is on-going. To achieve this goal, we increased our focus on Safety Awareness in 2013 and we will continue this focus in the years to come.

Our goal for 2014 was an LTI rate of 3.0 but we ended up with a total LTI rate of 5.3. Even though we did not reach the goal it was a reduction in the LTI rate from 6.5 in 2013.

More information on LTI is presented under "Health and Safety Performance".



## **Environmental and energy performance**

#### **ENVIRONMENTAL PERMITS AND LICENSES**

LEO Pharma's manufacturing sites have the required environmental permits for their operations and outlets according to local law and the permits and licenses are updated when needed. Please refer to the site descriptions for additional information.

#### OVERALL ENVIRONMENTAL AND ENERGY PERFORMANCE

Production takes place at six different sites and consists of various unit operations and syntheses. The environmental and energy performance of each site is described later in this section. The diagram below shows the overall environmental and energy performance across all sites in 2014:



\*Products incl. packaging (and intermediates sent for further processing at other plants)

## Input

#### **RAW MATERIAL AND CARRIERS**

The company's consumption of raw materials and carriers can be divided into the following categories (rounded off to whole tonnes):

Raw materials and carriers	2010	2011	2012	2013	2014
Organic solvents	1,247	1,633	2,064	1,531	1,553
Pharmaceutical products	34	41	40	38	29
Agricultural products	61,937	75,968	82,400	80,748	68,120
Acids/bases	331	469	370	383	287
Gels and filter material	1	50	20	19	16
Other organic compounds	1,274	1,313	1,294	1,226	1,568
Inorganic substances	4,604	5,485	5,322	5,444	4,536
Detergents	20	21	21	32	31
Total	69,448	84,980	91,531	89,421	76,141

Some of the pharmaceutical products used as raw materials are products from other LEO Pharma manufacturing sites.

Raw materials included in the grouping "agricultural products" include intestinal mucosa, sugar, corn-steep and *E. peplus* plants. Mucosa is a waste product from abattoirs and contains the important poly-saccharide, heparin. *E. peplus* is the plant from which the raw material for ingenol mebutate is extracted.

The total consumption has dropped from 2013 to 2014 because of a decline in the use of mucosa for crude heparin in Esbjerg. This also means a lower usage of salt, which is reflected in the decreased use of "Inorganic substances".

The increase in "other organic compounds" is mainly due to increased production in Dublin.

#### ENERGY

LEO Pharma has completed energy saving projects that will result in energy savings of 26,428 MWh per year. The projects have been implemented over the last three years. The energy consumption at the Dublin site has risen slightly due to increased production of finished goods. The energy consumption has fallen in Ballerup mainly because the weather in 2014 was not as cold as in a normal year. In Esbjerg it has also been less cold than normal and there has been less processing of mucosa compared to 2013.

The LEO Pharma 2015 energy goal has been achieved, but the energy saving projects will continue as energy projects make good business sense.

The consumption of energy in 2014 corresponded to the energy consumption (light, heating, cooking etc.) of 6,581 average single family households (Danish key figure).

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	MWh	76,764	71,030	70,172	66,898	63,122
DK - Esbjerg	MWh	7,098	8,225	8,337	6,236	5,395
FR - Vernouillet	MWh	14,280	15,862	17,812	16,786	16,705
IE - Cork	MWh	6,728	6,275	6,664	6,917	7,012
IE - Dublin	MWh	23,002	23,386	28,175	30,260	30,296
AUS - Southport	MWh	917	1,215	1,904	1,608	2,508
Total	MWh	128,789	125,993	133,064	128,705	125,038

Total consumption of energy over the last five years has been:

The energy consumed, divided into the different types being used at LEO Pharma:



Note: Diesel and petrol only covers the amount used for internal transportation.

In 2014, the use in per cent of Oil (0.002%), Forklift gas (0.125%) and Diesel and Petrol (0.025%) is so low that the figures do not show on the graph.

#### WATER

LEO Pharma uses water for production processes, in the composition of products and for cleaning and sanitary purposes. All water comes from a municipal water supply.

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	m <sup>3</sup>	165,622	152,898	150,106	174,454	146,698
DK - Esbjerg	m <sup>3</sup>	16,220	21,954	25,266	22,589	19,905
FR - Vernouillet	m <sup>3</sup>	21,653	20,507	26,094	36,719	44,328
IE - Cork	m <sup>3</sup>	41,922	35,406	47,266	55,114	49,402
IE - Dublin	m <sup>3</sup>	43,416	41,692	49,746	53,890	52,539
AUS - Southport*	m <sup>3</sup>	1,308	1,308	2,554	4,186	4,439
Total	m <sup>3</sup>	290,141	273,765	301,032	346,952	317,311

\*Water consumption for Southport in 2010 was unknown and was set as equal to 2011.

The total consumption of water in 2014 corresponded to the consumption of 2,555 average single family households (Danish key figures).

#### Ballerup

We have seen a decrease in the use of water in 2014 at the Ballerup site. The main reason is that we have had fewer incidents with contamination of the condensate for the boilers compared to 2013 so more water can be reused. Furthermore, the production of Fucidin<sup>®</sup> API has been a little lower in 2014 than in 2013.

#### Esbjerg

The decline in use of water in Esbjerg from 2013 to 2014 was due to a decrease in production volumes.

#### Vernouillet

The increased water consumption in Vernouillet was caused by increased production.

#### Cork

The decline in use of water in Cork from 2013 to 2014 was due to a decrease in production volumes.

#### Dublin

Water consumption decreased in Dublin in 2014 despite increased production volumes and activity. This was due to an artificially high usage in 2013 associated with the validation and commissioning of a new water purification plant.

Furthermore, with the introduction of domestic water metering and charges for households in Ireland in 2014, water consumption has assumed a higher focus and priority in general in Ireland at present. LEO has commenced testing of water from a well drilled on site, and is currently evaluating the quality to assess whether it can be used as a possible source of raw water for purification and process use next year, thereby reducing dependence on the municipal supply in future years.

#### Southport

The increase in water was due to some issues with the process water which required wash outs of the RO tanks and CIP tanks. Tanks are still washed out and a cleaning routine in some production areas has been implemented which requires a hose out to remove chemical residue and also dust from production.



## Output

#### PRODUCTS

LEO Pharma production divided into the six manufacturing sites:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	1,825	1,640	1,630	1,259	1,208
DK - Esbjerg	tonnes	8	10	11	11	9
FR - Vernouillet	tonnes	54	60	90	92	101
IE - Cork	tonnes	11	15	16	15	13
IE - Dublin	tonnes	2,650	2,655	2,378	2,504	2,850
AUS - Southport	tonnes	*	*	*	*	*
Total	tonnes	4,548	4,380	4,125	3,881	4,181

\*Means production amount is confidential.

The production volume includes packaging.

#### Ballerup

Most of the production in Ballerup is finished goods. The decrease in production of sterile products is due to the fact that parts of this finished goods production has been moved to other sites. On the other hand, larger volumes of liquid products including suspensions and gels are produced in Ballerup. There has also been a small decrease in the Fucidin<sup>®</sup> API production but an increase in the chemical API production.

#### Dublin

The increase in production tonnage in Dublin in 2014 reflects a 21% increase in unit product output in 2014 compared to 2013.

#### Vernouillet

There has been an increased demand for innohep<sup>®</sup> syringes in 2014 which is reflected in figure for Vernouillet.

The production volume from Esbjerg is intermediate for the Cork site. Cork produces intermediates for Vernouillet and Ballerup. All products from Vernouillet and Dublin are finished goods. Southport only produces intermediates for Dublin and for a contract manufacturer in the USA.

#### WASTE

The total amount of waste generated by LEO Pharma:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	2,612	2,718	2,567	2,326	2,149
DK - Esbjerg	tonnes	67,905	83,981	93,806	94,149	82,117
FR - Vernouillet	tonnes	397	521	588	581	542
IE - Cork	tonnes	304	678	144	151	97
IE - Dublin	tonnes	708	692	697	743	793
AUS - Southport	tonnes	37	37	1,836	811	1,649
Total*	tonnes	71,963	88,627	99,638	98,761	87,347

\*Construction and project related waste is excluded.

#### **Ballerup and Esbjerg**

In Ballerup, the decrease in waste volumes is due to decreased production.

#### Esbjerg

Most of the waste from LEO Pharma comes from the Esbjerg site and consists of intestinal mucosa from which the heparin is extracted.

The Esbjerg site extracts the polysaccharide heparin from intestinal mucosa from pigs. The concentration of heparin in mucosa is low which means that an input of approximately 67,000 tonnes mucosa results in approximately 9 tonnes of extracted crude heparin. The large amount of residual waste is primarily recycled as farm land fertilizer (under the trade name Fertigro<sup>®</sup>) with a smaller amount used as an energy source in biogas producing plants.

#### Cork

The drop in waste volumes from 2013 to 2014 in Cork can be explained by the fact that in 2013, 32 tonnes of Ethanol mother liquor was sent for waste incineration. This happens every few years but not every year. Also the landfill waste was 18 tonnes lower in 2014 due to lower production volumes meaning less filter material being used.

#### Dublin

While the overall amount of waste increased in Dublin in 2014 due to increased production, the relative waste amount compared to production volume has decreased in 2014 compared to 2013.

#### Southport

The waste volume in Southport seems to have increased considerably in 2014. However, an investigation is on-going since irregularities have been discovered in the waste reports from the waste removal company. It seems that the waste report information is not reliable.

As a consequence of the above, the recycling percentage is high, as the following chart shows.

Waste divided into kinds of treatment:



In 2014, special treatment accounted for 2.1%, incineration with recycling of energy 0.7%, incineration without recycling of energy 0.3% and landfill 0.2%.

Waste for recycling (recycle or reuse) - excluding mucosa waste - consists of: cardboard, paper, glass (clear and coloured), plastic (soft and hard), iron, aluminium, stainless steel, cable scrap, electronic scrap, fluorescent tubes and batteries.

Other kinds of waste that are sorted out for different kinds of treatment or re-use are: combustible waste, construction waste for recycling, waste deposit and incineration, pharmaceutical waste, clinical risk waste, chemical waste for recycling, chemical waste for special treatment, and PVC.

Waste for landfill consists of fractions that cannot be reused e.g. rockwool and some other building materials.

The reason why LEO Pharma sorts so many different fractions is that – for some fractions – it is a local legal requirement. Other fractions are sorted out because there is a financial benefit in sorting out the fraction.

On a regular basis, LEO Pharma investigates the options for implementing additional sorting or minimising waste generation.

#### WASTE WATER

Waste water is water from the production, cleaning and sanitary waste water. The waste water is sent to municipal treatment for purification before it is let out to sea or rivers.

Amounts of waste water being discharged:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	m <sup>3</sup>	158,246	145,315	138,000	153,816	107,952
DK - Esbjerg	m³	5,190	7,025	9,231	10,167	9,995
FR - Vernouillet	m <sup>3</sup>	16,596	15,906	19,713	44,718	44,260
IE - Cork	m³	19,077	18,042	28,845	35,119	23,369
IE - Dublin	m³	37,756	45,759	45,544	47,524	41,968
AUS - Southport	m <sup>3</sup>	n/a	n/a	n/a	622	413
Total*	m <sup>3</sup>	236,865	232,047	241,333	291,966	227,957

\*Only sanitary waste is led to the sewage. The amount is not measured.

#### Ballerup

In Ballerup, the decrease in waste water is due to fewer incidents with contamination of the condensate for the boilers compared to 2013 thus water can be reused. Other reasons are less production of Fucidin® API and sterile products and less validation activities compared to 2013.

#### Esbjerg

In Esbjerg less processing of mucosa resulted in a reduction in waste water.

#### Cork

The decline in use of waste water is linked to the decrease in production volumes.

#### Dublin

As stated in the section on water, the figure in 2013 was artificially high and therefore the table reflects a decline in waste water despite increased production volumes.



The overall Chemical Oxygen Demand (COD) from the different sites:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	363	385	290	349	182
DK - Esbjerg	tonnes	4	5	43	76	70
FR - Vernouillet	tonnes	2	2	1	6	6
IE - Cork	tonnes	4	5	5	9	7
IE - Dublin	tonnes	15	18	16	19	22
AUS - Southport	tonnes	n/a	n/a	n/a	n/a	n/a
Total	tonnes	388	415	355	459	287

The overall Total Organic Carbon (TOC) from the different sites:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	121	128	97	116	61
DK - Esbjerg	tonnes	1	2	14	25	23
FR - Vernouillet	tonnes	1	1	0	2	2
IE - Cork	tonnes	1	1	2	3	2
IE - Dublin	tonnes	5	6	6	3	7
AUS - Southport	tonnes	n/a	n/a	n/a	n/a	n/a
Total	tonnes	129	138	119	149	95

#### Ballerup

The major contributor to COD in the waste water effluent in Ballerup stems from the production of Fucidin<sup>®</sup> API. The reduction in COD is due to less organic solvents in the waste water in 2014 compared to previous years.

#### Esbjerg

At the Esbjerg site, the amount of COD in the waste water stems from activities in the production area which was taken into use in 2013. The waste water contains residues of mucosa which is easily biodegradable in the waste water treatment plant. There has been an increased focus on water consumption compared to the waste water discharge after a flow meter has been mounted on the waste water discharge pipe from the manufacturing process. To limit the flush water volume for cleaning of process tanks is difficult as this is subject to GMP requirements. Other possibilities for reduction in water usage are considered with a focus on water consumption in the steam boiler and the adjoining water treatment facility.

#### Vernouillet

The measurements of COD in the waste water from the site in Vernouillet show considerably increased concentrations in the last two years. The reason is a change in the method of collecting and analysing the waste water. The changes have been made to display a more representative image of the activities on site.

#### Cork

The COD in the waste water from Cork stems from washing of raw material. This washing is due to higher phosphorus levels in the raw material. The decrease in 2014 is a result of a decrease in the waste water discharged from the site.

#### **AIR EMISSIONS**

The activities of the company resulted in a number of solvents, acid gases and greenhouse gases being emitted into the air.

Emission of organic solvents to the atmosphere from the production:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	9.5	13.7	11.6	11.4	10.7
DK - Esbjerg	tonnes	0	0	0	0	0
FR - Vernouillet	tonnes	0.6	0.2	1.5	1.8	2.5
IE - Cork	tonnes	n/a	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	n/a	n/a	n/a	n/a	n/a
AUS - Southport	tonnes	n/a	n/a	0.2	0.6	1.2
Total	tonnes	10.1	13.9	13.3	13.8	14.4

The majority of emitted solvents are: from the biological production and purification and from the organic synthesis - both in Ballerup. The figures have not changed much.

The emission of the greenhouse gas carbon dioxide  $(CO_{2})$  on site:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	7,078	6,331	6,342	6,128	5,667
DK - Esbjerg	tonnes	1,319	1,531	1,492	1,107	965
FR - Vernouillet	tonnes	1,501	1,444	2,019	1,633	1,641
IE - Cork	tonnes	n/a	839	756	770	790
IE - Dublin	tonnes	2,364	2,816	5,014	6,107	6,100
AUS - Southport	tonnes	133	133	146	470	440
Total	tonnes	12,395	13,094	15,769	16,215	15,603

The amount of  $CO_2$  for DK is only from direct emissions from the site (e.g. emission from on-site boilers or forklift gas emissions). The reduction in  $CO_2$  is due to the lower energy consumption. For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from www.key2green.dk.

Emission of NO<sub>x</sub>:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	5.5	4.9	4.9	4.7	4.4
DK - Esbjerg	tonnes	1.0	1.1	1.1	0.8	0.7
FR - Vernouillet	tonnes	1.2	1.2	2.1	0.0	1.8
IE - Cork	tonnes	n/a	1.2	1.3	0.4	1.4
IE - Dublin	tonnes	4.0	5.0	8.8	10.7	10.8
AUS - Southport	tonnes	1	1	0.2	0.4	0.4
Total	tonnes	13	14	18	17	19.5

The amount of  $NO_x$  is only from direct emissions from the site (e.g. emission from on-site boilers or forklift gas emissions).

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from www.key2green.dk.

In Dublin the higher emissions of  $\mathrm{NO}_{\rm x}$  is due to the generation of on-site electricity from gas.

Emission of SO<sub>2</sub>:

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	0.04	0.04	0.04	0.03	0.03
DK - Esbjerg	tonnes	0.01	0.01	0.01	0.01	0.01
FR - Vernouillet	tonnes	0	0	0.02	0.02	0.02
IE - Cork	tonnes	n/a	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	n/a	n/a	n/a	n/a	n/a
AUS - Southport	tonnes	~0	~0	~0	0.08	0.09
Total	tonnes	0.05	0.05	0.07	0.14	0.15

The amount of  $SO_2$  is only from direct emissions from the site (e.g. emission from on-site boilers or forklift gas emissions).

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from www.key2green.dk.

Emission of ozone-depleting substances (ODS) (CFC, HCFC, halon and methyl bromide):

Site	Unit	2010	2011	2012	2013	2014
DK - Ballerup	tonnes	0	0.0690	0.0600	0.1050	0.0390
DK - Esbjerg	tonnes	0	0	0	0	0
FR - Vernouillet	tonnes	0	0	0.0150	0	0
IE - Cork	tonnes	n/a	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	0.067	0.1750	0.0125	0.0503	0.0020
AUS - Southport	tonnes	n/a	n/a	n/a	n/a	n/a
Total	tonnes	0.0670	0.2440	0.0875	0.1553	0.0410

In Ballerup and Dublin, HCFC was used for topping up the old cooling systems.



## Environmental and energy projects

#### **ENVIRONMENTAL PROJECTS**

During 2014, a new facility for handling Fertigro® has been constructed in Esbjerg and was operational at the end of ultimo 2014. The facility reduces the risk of accidental spills of Fertigro® as the old facility was run down and leaks had arisen which were captured by the bunding. The new facility also reduces the odour from the plant to the neighbours although LEO Pharma was already within the odour limits. Fertigro® is now stored in big, closed slurry tanks after cooling which reduces the odour.

#### **ENERGY PROJECTS**

#### Ballerup

Two major projects and one minor project were implemented in 2014. In the fermentation area, a cooling unit has been replaced. This will result in an annual saving of183 MWh/year. In the development area, the HVAC (ventilation) system has been optimised resulting in savings of 1,109 MWh/year. Finally, 7 HEPA filters were removed in our galenic production which resulted in annual savings of 3.5 MWh.

#### Esbjerg

No energy projects have been prioritised in 2014.

#### Vernouillet

In 2014, 5 energy projects have been implemented. Two of the projects were about optimisation of operations on secondary hot and chilled water resulting in savings of 36 MWh/year. Two projects were about modulation of burners on the boilers and optimisation of flow temperatures to promote the condensation resulting in annual savings of 259 MWh. The last project was about management of speed variation of the pumps which resulted in savings of 46 MWh/year.

#### Cork

A project to replace an existing skid for processing Heparin Sodium with a new unit has been implemented.

The overall objective was to replace the existing unit with a new one suitable to accommodate a full batch. This reduces the operation time almost by a factor of 4. The installed power on the new unit is approx. 50% greater but with the lower running time there is an overall saving annually of approximately 54.5 MWh.

#### Dublin

A number of significant energy saving projects related to upgrade and replacement of air handling units were implemented during the year which resulted in average energy savings of over 326 MWh. Installation of LED lighting on the main production packing floor (with automatic 'on/off' switching based on motion, and auto dimming depending on natural light) commenced and will lead to significant energy and cost savings when completed.

Increased energy metering will be introduced in 2015 as part of a global initiative to identify other possible energy saving projects that can be pursued in future years.

#### Southport

Three projects were implemented in 2014. One project was about managing the usage of a smaller chiller instead of using a much larger chiller. This results in energy savings of 146 MWh/year. The second project was about better temperature and humidity control settings for the HVAC (ventilation) systems. This results in energy savings of 62 MWh/year.

Finally, one of the dryers has a heat recovery system on the exhaust so the exhaust air is used for pre-heating the incoming air. This is expected to result in an estimated saving of approx. 30 MWh/year.

## Other environmental issues

#### **GROUND AND GROUNDWATER PROTECTION**

Today, the company prevents contamination of ground and groundwater by handling chemical substances and products in such a way that the risk of spills and environmental incidents is minimised.

If possible, it is LEO Pharma's policy to seal or remove existing ground contamination by excavation. If this is not possible, investigations are made to determine whether the ground contamination has caused any contamination of the groundwater, and whether the contamination is within company premises. If not, counter-pumping is initiated.

If the contamination is within our own area, the groundwater is monitored in order to discover any possible contamination risks.

A prerequisite for the above is that the contamination is caused by the company itself.



#### ENVIRONMENTAL ACCIDENTS/INCIDENTS

The number of environmental accidents/incidents reported to the authorities:

Site	2010	2011	2012	2013	2014
DK - Ballerup	2	3	3	18	5
DK - Esbjerg	0	0	2	0	56
FR - Vernouillet	0	0	0	3	4
IE - Cork	10	15	5	10	5
IE - Dublin	2	2	2	6	8
AUS - Southport	0	0	0	1	0
Total	14	20	12	38	78

#### **Ballerup**:

Ballerup had two major environmental incidents. One incident involved too much acetone (approx. 1.000 litres) being added to a tank resulting in a spill through piping out over the roof and some ended up in rain water system. The local environmental authorities were contacted and parts of the spill were sucked up. The other major incident was during a cleaning procedure in a laboratory, where HNO<sub>3</sub> and HCI were accidentally mixed causing generation of hazardous fumes. Two other incidents were small incidents where the BOD/COD level was too high (4.2, limit is 3) in one waste water well and there was too much suspended solids in another. Another small incident was that the concentration of dichloromethane in the exhaust of the active coal filter in the synthesis area was too high.

In 2013, a goal was set for 2014 to find the reasons for non-compliance with the waste water permit. Focus was on the Fucidin<sup>®</sup> API production and a water ring pump was found to be the source of discharge of acetone. The aim is to decrease this discharge in the future and a goal for 2015 is to lower the amount of organic solvents in the waste water by 10% compared to 2013 as the base year.

#### Esbjerg

All incidents are related to waste water. In all measurements, the site is above the limit for COD, suspended solids, total N, oil & fat. At 2 measurements pH was too low. The authorities are aware of the problems and LEO Pharma applied for a new waste water consent in February 2014. The authorities will start processing the application in the beginning of 2015. The local waste water treatment plant is able to handle the waste water from LEO Pharma and therefore our waste water does not have a negative effect on the water downstream from the treatment plant despite the high number of incidents.

#### Vernouillet:

One of the incidents reported to the authorities in 2014 was high pH value on waste water and another one was high flow values also for waste water. One incident was where the water consumption on site has exceeded the permitted level. A new application has been submitted and official authorization to use more water is expected. Another incident was a spill of one litre of fuel on the ground.

#### Cork:

Four of the incidents were breaches of conductivity limit value on surface water. One being caused by water from the plant hot water loop being drained which entered a surface drain, one was a leak from hosing on a brine unit feeding the reverse osmosis water unit in the Utilities building, one was caused by oil from car engine in car park which entered surface water drains and the final one was caused by flush water from WFI entering surface water drains. The last incident was the daily effluent allowance (200 m<sup>3</sup>) exceeded. 362 m<sup>2</sup> was released. The EPA has been informed of all incidents.

#### **Dublin:**

There were eight incidents notified to the licensing authorities, Dublin County Council, in 2014. Five were COD exceeding limits, one was a neutralisation chamber pump-out temperature reading which was 43-44°C (limit 42°C) on one reading, one was accidental discharge from neutralisation chamber to foul sewer via high level overflow and the last one was an effluent meter recording incorrectly. None of the incidents caused damage to the environment.

#### Southport:

No environmental incidents were reported to the authorities in 2014.

#### COMPLAINTS

Complaints received by LEO Pharma:

Site	2010	2011	2012	2013	2014
DK - Ballerup	0	1	1	0	0
DK - Esbjerg	0	0	0	0	0
FR - Vernouillet	0	0	0	0	0
IE - Cork	0	0	0	0	0
IE - Dublin	0	2	0	2	0
AUS - Southport	0	0	0	0	0
Total	0	3	1	2	0

In Ballerup, the sterilisation of raw materials in the Fucidin<sup>®</sup> area sometimes causes odour nuisance to neighbours and people passing by the site which has led to complaints in 2011-2012. Various possibilities have been investigated for reduction of this odour. The best possible solution was implementation of condensers on the fermentation tanks during the sterilisation. The solution has been implemented during 2014. This has given a reduction of the odour by 50-55% compared to what it has been previously. Unfortunately, the temperature of the sterilisation has been raised since the project design of the condensers and although the odour has been reduced it has not been reduced enough compared to what was desired. However, no new complaints have been received.





## **Health and Safety**

#### **OCCUPATIONAL INJURIES**

Efforts continue to ensure we reach a group LTI rate on par with the best in industry at the end of 2015. Even though LEO Pharma has had extra focus on Safety Awareness in the previous years, this goal will be very difficult to achieve. LEO Pharma has worked hard to provide employees and managers with tools and information needed in order to improve LEO Pharma's safety culture. However, it has proven to be a longer journey than originally planned and the goal of an LTI rate of approximately 2 by the end of 2015 will probably not be reached.

The goal for 2014 was to have fewer injuries with absence than in 2013 and to reach an LTI rate of 3.0. As can be seen from the tables below, the goal of fewer injuries with absence was achieved but the LTI rate goal was not.

In connection with the work on OHSAS 18001 certifications, we have seen a positive effect on injuries. The Ballerup site which was the first site to obtain an OHSAS 18001 certification has experienced a drop both in the number of LTIs and in the days lost due to an injury as can be seen below. And even though there are still injuries it seems that the consequences of the injuries are not as severe as previously. It is our hope that the latest two OHSAS 18001 certifications in Dublin and Vernouillet will have a positive effect on the number of injuries on these sites as well.

The number of lost time injuries in 2010-2014 wa	as:
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	LOST TIME INJURIES				
Site	2010	2011	2012	2013	2014
DK - Ballerup	16	16	12	11	6
DK - Esbjerg	0	0	1	0	0
FR - Vernouillet	8	8	4	9	9
IE - Cork	0	1	0	0	0
IE - Dublin	3	2	4	4	6
AUS - Southport	0	2	1	2	0
Total	27	29	22	26	21

The Lost Time Injuries rate is stated below and is calculated

I TI rato —	(number of injuries with absence * 1000000 working hours)
LIIIate –	Total number of working hours

Lost Time Injury Rate:

as:

Cite	LTI RATE						
Sife	2010	2011	2012	2013	2014		
DK - Ballerup	7.0	6.5	4.7	4.3	2.4		
DK - Esbjerg	0.0	0.0	54.6	0.0	0.0		
FR - Vernouillet	20.9	16.6	7.7	15.9	15.8		
IE - Cork	0.0	9.5	0.0	0.0	0.0		
IE - Dublin	5.1	3.3	6.1	6.0	8.3		
AUS - Southport	0.0	24.9	9.0	21.7	0.0		
Total	7.9	7.7	5.5	6.5	5.3		

The number of days lost due to an injury is also calculated. This number says something about the severity of the injury. All in all the number of days away from work due to an occupational injury has been higher in 2014 than in 2013. This is mainly due to injuries in Vernouillet which have been more severe than last year. On the other hand the severity of the injuries has been less in Dublin. While the Dublin site had more injuries in 2014 than in 2013, the number of days lost has been reduced by more than half.

In Ballerup, both the number of LTIs and lost days have been reduced in 2014. This is a fantastic result.

#### Number of Lost Days:

Cite	NUMBER OF LOST DAYS						
Site	2010	2011	2012	2013	2014		
DK - Ballerup	241	72	25	64	36		
DK - Esbjerg	0	0	1	0	0		
FR - Vernouillet	373	337	324	182	310		
IE - Cork	0	4	0	0	0		
IE - Dublin	244	22	86	97	42		
AUS - Southport	0	2	1	5	0		
Total	858	437	437	348	388		

In the table below the Lost Day Rates for the previous five years are calculated.

According to GRI (Global Reporting Initiative), the Lost Day Rate (LDR) is calculated as:

 $LDR = \frac{(number of days lost * 200000)}{total working hours}$ 

Lost Day Rate (LDR):

Site	LDR						
She	2010	2011	2012	2013	2014		
DK - Ballerup	21.07	5.86	1.95	5.00	7.18		
DK - Esbjerg	0.00	0.00	8.58	0.00	0.00		
FR - Vernouillet	194.63	139.63	48.01	64.14	108.76		
IE - Cork	0.00	7.60	0.00	0.00	0.00		
IE - Dublin	83.75	7.33	26.03	29.00	11.67		
AUS - Southport	0.00	4.98	1.36	10.83	0.00		
Total	50.10	23.31	11.84	17.40	19.48		

The number of lost days may not all originate from injuries in the same year as the number of lost days are summarised by calendar year. This means that some

lost days may originate from injuries from the previous year, and other lost days may be counted in the year following the injury.

#### Ballerup:

As can be seen from the above tables, the site in Ballerup has managed to bring down the number of LTIs to almost half of the number in 2013. Furthermore, four of the six injuries with absence did not result in more than a maximum of 3 days' absence, so the consequences of an LTI were not very severe. This is an amazing achievement and Ballerup will continue its focus on injury prevention.

One of the focus areas in 2014 was ergonomics, including heavy lifting both in offices and in the production areas. Additional technical aids for transport and lifting of equipment (pallet jacks) were purchased after sharing of accident information from the Vernouillet site. The global campaign on ergonomics was supported by local workshops, leaflets and sharing of good solutions on the intranet. Another of the focus areas was focus on chemical handling and risk assessments. The result was a very limited number of associated injuries both with and without absence. About half of the injuries both with and without absence were due to slips, trips and falls.

As of 31 December 2014, the Ballerup site had 21 days without a Lost Time Injury.

#### Esbjerg:

In Esbjerg, one-way traffic has been introduced at the site to reduce the risk of hitting pedestrians as trucks and tank wagons will no longer be reversing.

Furthermore, the acoustics have been improved in several areas after acoustic problems were identified at a health and safety audit in 2013.

As of 31 December 2014, the Esbjerg site had 755 days without a Lost Time Injury.

#### Vernouillet:

Many improvements have been made in Vernouillet during the year. One of the most significant improvements is an improvement in the dry form manufacturing area. In this area there was a high risk of falling. Every time an operator had to clean, assemble or disassemble the equipment, he had to use a step ladder and even step on the equipment sometimes. At the same time he had to carry heavy parts of equipment. Therefore a solution had to be found to improve the workplace. The result is the implementation of a new platform. Now people in the area can do the job in a safe way.



#### Cork:

Due to the excellent and diligent work of all onsite, the manufacturing plant in Cork ended the year 2014 with no injuries resulting in more than 1 day of absence. As of 31 December 2014, Cork reached 1324 days without a Lost Time Injury.

The last LTI in Cork was recorded in 2011, just prior to the commencement of work on OHSAS 18001 certification. Certification was achieved in October 2012. Of course a certificate on the wall does not make a plant safe overnight but the process of certification has raised safety awareness on site to new levels and has driven the improvements in safety procedures and activities on site. This new level of awareness on site amongst personnel has generated many more reported near misses and continuous improvement opportunities, which in turn has led to hazards being identified and control measures put in place before accidents happen. Safety is the first item at all operations meeting each day.

As in all organisations, the safety systems are continuously reviewed with a view to improvement. It is vital that occupational health and safety are managed with the same degree of expertise and to the same standards as other core business areas such as QA and production if they are to effectively manage risk and prevent harm to people.

#### Dublin:

While 2013 focused on increasing safety awareness on the site, 2014 focused on changing behaviours to further improve the safety culture.

The level of safety training was increased substantially with over 1700 hours of training received by staff and contractors including training in performing risk assessments; manual handling; chemical awareness; VDU work-place assessments; as well as continuation of combined EHS and GMP refresher training. The wider Health & Safety Organisation consisting of Safety Delegates and Management Representatives were very active in promoting safety and reporting on safety performance, and there is less reliance on the EHS Department as a result, which is a good indicator of improved safety culture.

"Safety First" has become the standard at departmental meetings from the Senior Management team right through the organisation, as well as in company-wide monthly briefings. Constant communication of safety issues and safety improvements has encouraged all departments to report on near misses and safety hazards and to focus on addressing these to prevent more serious incidents and accidents.

Occupational Health initiatives continued in 2014 with a major focus on employee wellness, particularly in relation to stress and mental health.

The overall improvement in safety culture on site was reflected in the site achieving certification to OHSAS 18001. Hopefully, all of the above and the recent certification will help reduce the number of injuries.

As of 31 December 2014, the Dublin site had 146 days without a Lost Time Injury.

#### Southport:

As of 31 December 2014, the Southport site had 498 days without a Lost Time Injury. Previously, the longest period without an LTI was 280 days.

The site managed to receive an OHSAS 18001 certification one year ahead of schedule - this was a major achievement for Peplin Operations. The safety culture has improved in all areas and the safety focus has been increased. This shows by a reduced the amount of safety incidents occurring due to increased safety reporting and workplace inspections. Compared to 2013, the number of injuries without absence in 2014 has been reduced by 50%.

— we help people achieve healthy skin



# It's not about being safe **IT'S ABOUT STAYING** SAFE





## Significant environmental parameters

The most significant environmental impacts have been selected based on the following criteria.

#### Substances and products

The substances and products used in production in LEO Pharma are divided according to their origin or what characterises them.

#### **Energy and water**

Energy and water are included in the accounts as both are scarce resources.

#### Waste

To avoid any unnecessary waste of resources, minimisation of the waste volume is important. In addition, it is important that as much waste as possible is recycled in order to exploit all resources of the waste. Consequently, waste is considered a significant environmental parameter and is included in the accounts.

#### Air pollution

Emission of solvents,  $CO_2$  and  $NO_x$  to the air contributes to e.g. photochemical ozone formation, greenhouse effect and acidification. The emission of these substances is therefore considered a significant environmental parameter and is included in the accounts. Filters have been mounted at the exhausts which emit dust. The filters are regularly maintained and replaced. Consequently, the emission of dust to the air is insignificant and this environmental parameter is therefore not dealt with further in the accounts.

#### Waste water

The waste water contains residues of pharmaceutical products, raw materials and carriers. The content of these substances may impact on the degree of purification and efficiency of the waste water treatment works, and finally, non-retained substances may affect the marine environment. Therefore, waste water is considered a significant environmental parameter and is dealt with in the accounts.

#### Contamination of ground and groundwater

Emission of environmentally problematic substances to the ground may contaminate the ground and groundwater. This may have consequences for any extraction of groundwater in the locality. Therefore, this environmental parameter is significant and is dealt with in the accounts.

## **Accounting policy**

#### **REGISTRATION OF DATA**

Data has been registered for the corporate report for 2010-2014. However, some data is missing from Southport as it has gone from being an R&D facility to manufacturing site during this period.

The registration of data has been made by key persons in the company.

The registration has been made regularly in connection with the daily operation of the company (e.g. readings), extract of data from the production control system or in connection with payment of invoices (purchase of raw materials and dispatch of waste).

Registrations have been made for internal transportation but not for external transportation.

#### **USE OF ENVIRONMENTAL KEY FIGURES**

#### Energy

Key figures from Key2Green's website (www.key2green. dk) have been used for the calculation of the energy consumption and the emissions of  $CO_2$ ,  $SO_2$  and  $NO_x$  from the Ballerup, Esbjerg and Southport consumption of natural gas and forklift gas. The heating value of natural gas has been based on information from DONG Energy's website.

The conversion from company energy consumption to energy consumption per average household (130m<sup>3</sup>, 3 persons) has been made on the basis of energy data from the Danish Building Research Institute, 2010 in year 2010-2012. At that time each household consumed 19.4 MWh equal to 69.84 GJ. For 2013 and 2014, energy data from the Danish Building Research Institute, 2014 has been used, where each household consumes 19.0 MWh, equal to 68.4 GJ.

Conversion of energy: 1 MWh equals 3.6 GJ 1 m3 of natural gas equals 0.0396 GJ 1 litre of truck gas equals 0.02486 GJ 1 m3 of oil equals 0.03023 GJ

#### Water

The conversion from the company water consumption to water consumption per average household is calculated based on: one household is defined as three persons with a water consumption of 41.4 m<sup>3</sup>/year per person. (Source used for water consumption per person: the Danish Building Research Institute, 2010 in the years 2010-2012). For the year 2013 and 2014, one household is defined as three persons with a water consumption of 40.1 m<sup>3</sup>/year per person (Danish Building Research Institute, 2014)

#### Waste water

For Ballerup, Esbjerg and Vernouillet, the TOC is calculated as COD divided by 3 as there are no measurements of TOC at these facilities.

#### Working hours

For the calculation of working hours, the following figures have been used:

Denmark: 18.75 business days per month x 12 months/ year x 7.4 hours per day = 1,665 working hours/year *Ireland*: 45 work weeks/year x 39 hours per week = 1,755 working hours/year

France: 47 work weeks/year x 35 hours per week = 1,645 working hours/year

Australia: 48 work weeks/year x 38 hours per week = 1,824 working hour/year

The total working hours are the sum of full time employees x working hours for each site. In total this was 3,424,949 working hours in 2010. In 2011, the total working hours were 3,745,271 and in 2012 the total working hours were 3,967,602. In 2013, the total working hours were 3,982,855. In 2014, the total working hours were 3,984,359.

#### Number of days lost

This is the number of working days lost due to a work related injury. (Saturdays, Sundays and public holidays are omitted.)

# Clarification of terminology in the EHSE report

#### API

Active Pharmaceutical Ingredient

#### Average household in Denmark

130m<sup>2</sup> house and 3 persons using 19.4 MWh (69.84 GJ) in energy for heating, heating of water and electricity and 124.2 m<sup>3</sup> water according to the Danish Building Research Institute, 2010. For 2014, energy data from the Danish Building Research Institute, 2014 has been used, where each household of 3 people consumes 19.0 MWh, equal to 68.4 GJ and 120.3 m<sup>3</sup> water.

#### BOD (Biological Oxygen Demand)

BOD is an abbreviation for biochemical oxygen consumption after five days. A biological method for determining the content of biologically degradable organic substance in e.g. waste water.

#### СНР

Combined Heat and Power, integrates the production of usable heat and power (electricity), in one single, highly efficient process.

#### COD (Chemical Oxygen Demand)

COD is an expression of the amount of oxygen necessary for a chemical decomposition of the present organic substance. Thus, COD is a measuring unit for the content of the organic substance.

#### EHSE

Environment, Health, Safety and Energy

#### EPA

Environmental Protection Agency

#### FTE (Full Time Employees)

Recalculation of number of employees to full time employees meaning part time employees count by the number of hours they work

#### GPS

Global Product Supply, part of LEO Pharma organisation covering API Manufacturing, Finished Goods Manufacturing, Quality Control, Quality Assurance and Supply Chain Support

#### GRI

Global Reporting Initiative.

#### IPL

A Danish IT system for identification, prioritisation and solution of EHS issues.

#### LTI rate

The definition of Lost Time Injury Rate is the number of Lost Time Injuries multiplied by 1 million divided by the number of working hours worked in the reporting period. A Lost Time Injury is a work injury where the injured party has at least 1 complete day or shift off work.

#### Manufacturing sites

Sites where production takes place. The figures in the EHSE report cover all activities at the manufacturing site whether it is production, R&D, sales, finance, engineering (or something else), and other support facilities on-site.

#### MAI

An IT management system which helps companies keep track of their EHS performance.

#### R&D

Research and Development

#### тос

Total organic carbon. The total amount of organic carbon in a water sample.

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