

— we help people  
achieve healthy skin



# Corporate Environment, Health, Safety and Energy Report 2015

LEO Pharma manufacturing sites

**LEO**<sup>®</sup>



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# Statement from Senior Vice President

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This report is a supplement to our CSR report and demonstrates our performance in 2015 in the areas of Environment, Health, Safety and Energy.

During 2015 we have reached some important milestones. Our greatest achievements were reached in May and July, respectively when the remaining 2 of our 6 manufacturing sites (in Southport and Cork) obtained the certification to the environmental management standard ISO 14001. This means that we reached our goal set in 2010 that all manufacturing sites must be ISO 14001 and OHSAS 18001 certified by the end of 2015. I would like to take this opportunity to thank all employees whose dedicated and hard work made this possible.

However, having reached these certifications does not mean that we can rest on our laurels and we need to constantly improve and do more.

In terms of Environmental and Energy performance a number of additional improvement projects have been identified and scoped in 2015. These will be developed and executed going forward as we strive to deliver on our 2020 goals.

In recent years, we have had a very high focus on health and safety but we still have challenges with our Lost Time Injury (LTI) rate. That being said, we have managed to decrease the number of injuries and the number of days lost to injuries has also decreased so the injuries are not as severe as earlier. Whilst acknowledging the improvements made, it is clear that we must improve even further to be comparable or better than 'best in class'. To do so we must do more to embed the right safety culture and behaviours across LEO.

I have seen great initiatives around our sites in the last year and I will encourage sharing of best practice and proactive implementation of these. We have great opportunities to become best in class and I will do my utmost to support and strengthen the EHSE strategy in the future.

Yours sincerely  
Senior Vice President, Global Product Supply



Jim McPherson



# 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 5,000 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

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Our manufacturing sites in Ballerup, Cork, Dublin, Esbjerg, Southport and Vernouillet are all certified:

LEO



**Environment & Safety**  
ISO 14001



**People & Health**  
OHSAS 18001

# Environment, Health, Safety and Energy Policies

The Environment, Health, Safety and Energy (EHSE) performance of LEO Pharma is linked to our EHSE policies which were first drafted in 2011. The present ones valid since 2012 and displayed below were still in force in

2015 but will be obsolete from the beginning of 2016 where a new LEO Code of Conduct is implemented. The new Code of Conduct will cover EHSE policies as well:



## LEO Pharma Corporate Environment and Energy Policy

**LEO Pharma is committed to the protection of the environment, the prevention of pollution and the continual improvement in energy performance.**

**LEO employees follow applicable environmental laws, regulations and policies. We conduct business in a manner that protects the environment.**

**We strive to develop a proactive, continuous improvement working culture in which good environment practice is a natural part.**

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

1. Comply with all applicable legislation, regulations and obligations related to environmental performance and energy consumption, efficiency and performance.
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 Environment and Energy Management System in accordance with ISO international standards in order to continuously reduce our environmental impact.
  - Define specific environmental and energy goals and make all employees aware of these goals.
  - Ensure that all new projects are designed and built using best available technology for environmental and energy performance

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.



*Anders B. Spohr*  
 Anders B. Spohr  
 Executive Vice President  
 24 September 2012

*Gilte Aabo*  
 Gilte Aabo  
 President & CEO  
 24 September 2012



*Anders B. Spohr*  
 Anders B. Spohr  
 Executive Vice President  
 24 September 2012

*Gilte Aabo*  
 Gilte Aabo  
 President & CEO  
 24 September 2012

Reference is made to GP\_000042 in eQuality

Reference is made to GP\_000043 in eQuality

# Global Environment, Health, Safety and Energy Goals

LEO Pharma's EHSE goals are closely connected to these policies and in 2011, Group Management set the 2015 goals which will be dealt with below. New 2020 goals have also been established and will set the direction in the following years. These are displayed at the end of the report before the appendices.

## ENVIRONMENT AND ENERGY GOALS

LEO Pharma had the following global goals in relation to 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).

## HEALTH AND SAFETY GOALS

LEO Pharma had the following global goals in relation to 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.

## STATUS ON 2015 GOALS

In 2015, the manufacturing sites were working on achieving both the management system certification goals as well as the goals related to energy and occupational injuries.

All goals have been achieved except for the goal regarding the LTI rate which is still a challenge.

The Global EHS goal set in 2011, that all sites would have the dual certifications by the end of 2015, was achieved 6 months ahead of schedule and the success was celebrated at an event held in September across all sites.

This milestone could not have been reached without the close collaboration of all manufacturing sites. One of the ways this collaboration was facilitated was through the interaction of empowered individuals at EHS global summits, where representatives from EHS departments and other EHS representatives in the organisation met to discuss the platform for such collaboration, to share best practice and to find synergies for cross-site alignment. The second of these summits was held in September 2015 and at this summit the seeds for the work with LEO Pharma's EHSE 2020 goals were planted. (See more in the section on Environment, Health, Safety and Energy goals 2020).

Details of the performance are displayed in the following sections.



# Environmental and energy performance

## ENVIRONMENTAL GOAL

The goal that all existing manufacturing sites would be ISO 14001 certified by the end of 2015 has been achieved.

In March 2015, the Dublin site was re-certified to the ISO 14001 environmental management standard with high praise from auditors. The Southport site obtained their ISO 14001 certificate in May and the site in Cork became certified to the ISO 14001 standard in July.

## 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 in Appendix 1 for additional information.

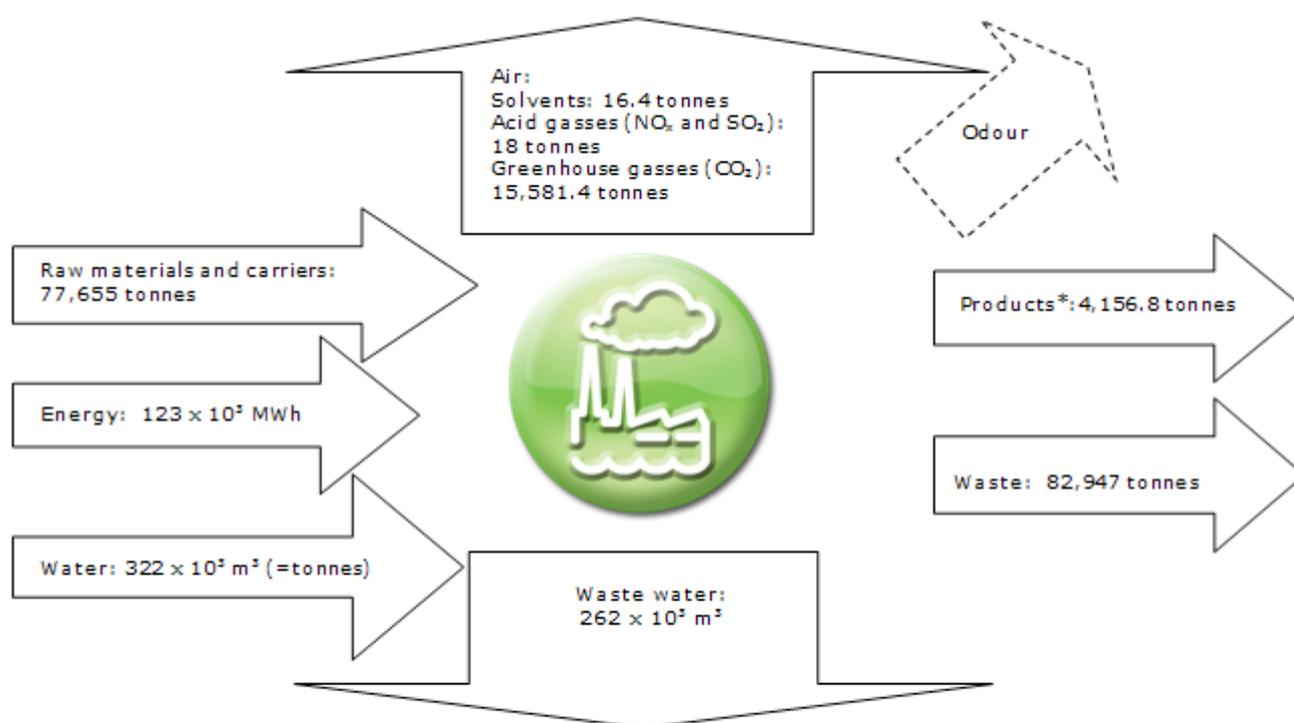
## ENERGY GOAL

The energy goal, that energy projects with a total saving of 15% of the energy consumed in 2010 will be implemented at the end of 2015, was achieved in 2012. As stated above new energy goals 2020 have been established.

ISO 14001 certifications					
	2011	2012	2013	2014	2015
<b>Ballerup</b>				X	
<b>Esbjerg</b>				X	
<b>Vernouillet</b>	X (Initial certification)			X (re-certification)	
<b>Cork</b>					X
<b>Dublin</b>		X (Initial certification)			X (re-certification)
<b>Southport</b>					X

## 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 2015:



\*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	2015
Organic solvents	1,247	1,633	2,064	1,531	1,553	1,857
Pharmaceutical products	34	41	40	38	29	44
Agricultural products	61,937	75,968	82,400	80,748	68,120	69,013
Acids/bases	331	469	370	383	287	329
Gels and filter material	1	50	20	19	16	16
Other organic compounds	1,274	1,313	1,294	1,226	1,568	1,680
Inorganic substances	4,604	5,485	5,322	5,444	4,536	4,680
Detergents	20	21	21	32	31	36
<b>Total</b>	<b>69,448</b>	<b>84,980</b>	<b>91,531</b>	<b>89,421</b>	<b>76,141</b>	<b>77,655</b>

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.

In Ballerup, the API production has been increased resulting in more use of organic solvents. Southport has also had more production in 2015 than 2014 which thereby contributes to the increased amount of organic solvents used.

The main contributor to the increased use of agricultural products is the increased API production in Ballerup, which resulted in increased use of corn steep and sugar. The increase in "other organic compounds" is mainly due to increased production in Dublin.

### ENERGY

Due to EU legislation, all European manufacturing sites, which do not hold an ISO 50001 energy standard certificate, have been audited in 2015 by an external company who looked at the energy savings potential. The Dublin site which is already certified to ISO 50001 was exempt

from the EU requirement, and so was the Southport site. However, the audits resulted in suggestions from the auditing body on where to invest in energy saving projects and the suggestions have been put together in a LEO Energy Efficiency Programme. The programme also covers the non-audited sites and includes more than 30 potential energy efficient projects identified across the manufacturing sites.

One of the suggestions was to run campaigns and in November, a global campaign on energy and CO2 reduction was held. This did not only support our ambition to lower the energy consumption and reduce CO2 but did also fit perfectly with the COP 21 Climate Summit which was held in Paris at the time.

Another suggestion was changing to LED lighting. This is already in progress as a project was launched in 2015 to change existing lights to LED lights, primarily in production areas. The project is ongoing in Vernouillet (FR), Dublin (IE), Cork (IE) and Southport (AU) and will continue in 2016. In Ballerup (DK) the lights will be changed to LED when lights need to be replaced. Other suggestions from the programme will be evaluated and prioritised in 2016.

In 2015, energy monitoring systems were installed at the French and the Irish sites giving the energy managers enhanced opportunities to improve and validate the energy efficiency at the sites. The energy monitoring system in Ballerup will be upgraded in 2016 allowing us to differentiate between the different site operations as well as pinpointing the large energy users within cooling, air handling units and other large energy end users. Esbjerg site is also expected to establish an energy monitoring system in 2016 using the same software platform as the French and Irish sites.

The consumption of energy in 2015 corresponded to the energy consumption (light, heating, cooking etc.) of 6,457 average single family households (Danish key figure).

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

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	MWh	76,764	71,030	70,172	66,898	63,122	63,468
DK - Esbjerg	MWh	7,098	8,225	8,337	6,236	5,395	5,149
FR - Vernouillet	MWh	14,280	15,862	17,812	16,786	16,705	16,227
IE - Cork	MWh	6,728	6,275	6,664	6,917	7,012	7,318
IE - Dublin	MWh	23,002	23,386	28,175	30,260	30,296	28,960
AUS - Southport	MWh	917	1,215	1,904	1,608	2,508	1,567
<b>Total</b>	<b>MWh</b>	<b>128,789</b>	<b>125,993</b>	<b>133,064</b>	<b>128,705</b>	<b>125,038</b>	<b>122,689</b>

\*the figure has been changed compared to the 2014 report due to a calculation error.

**Ballerup**

Most of the energy used in Ballerup is for production where API production has gone up but tablet production gone down.

**Esbjerg**

For the Esbjerg site less energy has been used partially due to production in bigger batches. Furthermore, the raw material received has not been as cold as earlier and thus the site has not spent as much energy on warming it up.

**Cork**

The Cork site has installed meters on all large end users and it has already turned out to be a good investment. The meters have among other things disclosed that by shutting down production ventilation and air conditioning during Christmas holiday period can save around 800 kWh per week, The Christmas shutdown was approx. 2 weeks.

However, the energy consumption in Cork has increased slightly. This could be explained by the small increase in production.

**Dublin**

Even though the output from the Dublin site has increased, the energy consumption has been reduced due to several energy saving projects such as e.g. the LED lighting project mentioned above. Other projects to be

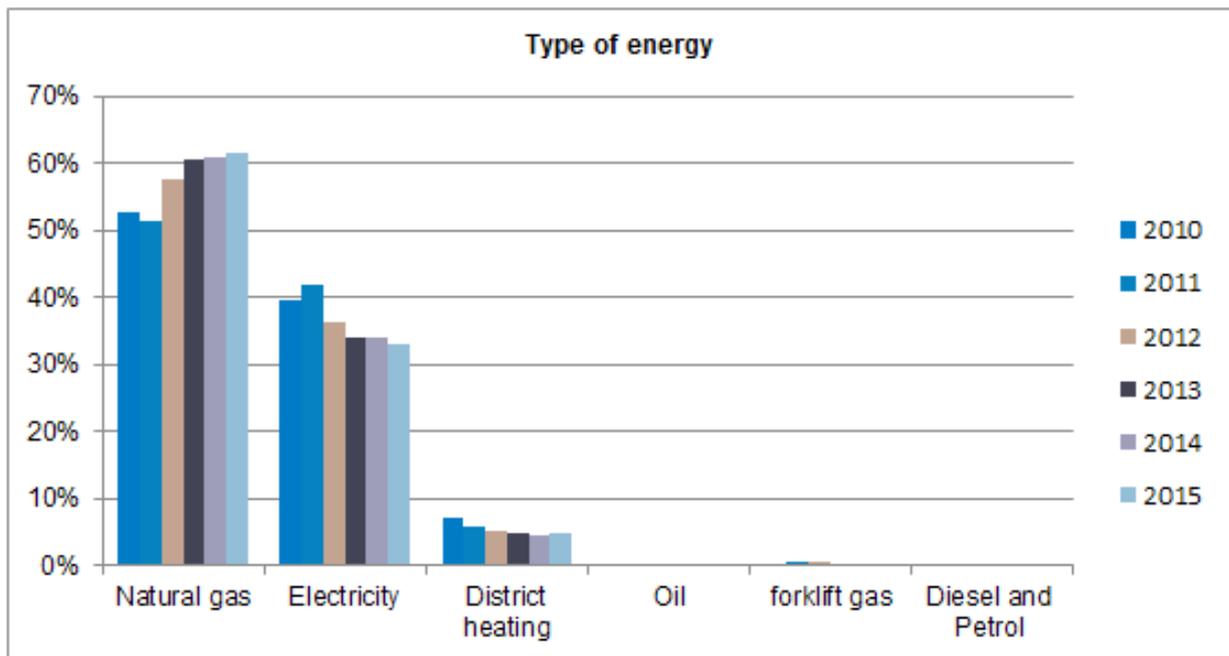
mentioned are a heat tracing control project in one area where heat tracing is only used when required and lagging of boilers in another area which at the same time improves safety by eliminating accidental skin burns.

To engage the employees and as a part of improving energy and environmental awareness on-site, an art competition for children of employees was held in Dublin in October. Themes for entries were in the areas of Energy Saving, Protecting the Environment, Renewable Energy, Water Conservation and Reducing Waste. The winning 12 entries were used to produce a 2016 desk calendar which was given to all employees in Dublin at year-end and helped to raise the awareness on this subject site-wide.

**Southport**

The energy consumption in Southport has not changed much. However, they have almost doubled their output. In 2014 a project regarding usage of a smaller chiller instead of much larger chiller was initiated. The effect of the optimised usage of chillers is beginning to shine through in 2015 and the large chiller is only used when absolutely necessary. Another project which has been implemented is the replacement of an old dryer with a new one which is much more energy efficient.

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 the last couple of years, the amount of Oil, Forklift gas, Diesel and Petrol used 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. We expect this to change in 2016 where Dublin will take a well on-site into use.

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	m <sup>3</sup>	165,622	152,898	150,106	174,454	146,698	159,524
DK - Esbjerg	m <sup>3</sup>	16,220	21,954	25,266	22,589	19,905	17,122
FR - Vernouillet	m <sup>3</sup>	21,653	20,507	26,094	36,719	44,328	41,990
IE - Cork	m <sup>3</sup>	41,922	35,406	47,266	55,114	49,402	46,020
IE - Dublin	m <sup>3</sup>	43,416	41,692	49,746	53,890	52,539	56,237
AUS - Southport*	m <sup>3</sup>	1,308	1,308	2,554	4,186	4,439	1,303
<b>Total</b>	<b>m<sup>3</sup></b>	<b>290,141</b>	<b>273,765</b>	<b>301,032</b>	<b>346,952</b>	<b>317,311</b>	<b>322,196</b>

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

The total consumption of water in 2015 corresponded to the consumption of 2,594 average single family households (Danish key figures).

### **Ballerup**

Increased production of API requires more use of water, which explains the increase in 2015

### **Esbjerg**

The decline in use of water in Esbjerg from 2014 to 2015 was due to production in larger batches thus less water is used to flush out product and for cleaning between batches. A small amount of the water used in 2014 was used for construction work. This has not been the case in 2015.

### **Vernouillet**

The Vernouillet site has focused on reduction of water usage and modifications have been made to the purified water system in laboratories where flush time interval has been changed. The changes are expected to save 6660 litres/year.

### **Cork**

At the Cork site, washroom facilities were reviewed for water saving opportunities in March 2015. It was found that most of the taps on sinks were old and leaking with very high flow rates which explains some of the decline in water usage..

It was decided to replace all of the taps with water saving models. The taps that have been installed use approximately half of the water that the old taps use and turn off automatically after use.

This will reduce water usage from approx. 80,000 litres/year for sinks to approx. 40,000 litres/year. Further saving opportunities will be undertaken on showers and toilets around site as these have been identified as further water saving opportunities.

Due to the introduction of a new filtration unit in production, a reduction in the number of Clean-In-Place (CIP)

cycles required has also reduced water usage. The old filtration unit required 4 CIPs as each product batch was split into 4 parts. Now each batch is processed in one part and only 1 CIP is required. This results in an approximate water saving of 60% over the old filtration units CIP.

### **Dublin**

A significant unexplained increase in water usage led to full review of the water systems to identify the cause. It turned out to be a leaking underground pipe on the sprinkler system, which was subsequently repaired. This leak, combined with the increased production activity, explains the increase in water usage in 2015.

Testing of water quality and volumes from a well drilled on the Dublin site was completed in 2015, and there is sufficient capacity of suitable quality water to meet the immediate and future raw water needs on-site. An investment application was approved to bring the well into full production in 2016. Use of LEO Pharma's own well has a considerable CSR benefit as it makes the site independent of the Dublin municipal water supply which is close to capacity and is often rationed in times of drought.

### **Southport**

The water usage in Southport has dropped significantly. This is due to the *E.peplus* being sucked directly from extraction tank instead of being flushed out. This results in a reduction of water consumption.



## Output

### PRODUCTS

LEO Pharma production divided into the six manufacturing sites:

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	1,825	1,640	1,630	1,259	1,208	1,037
DK - Esbjerg	tonnes	8	10	11	11	9	9
FR - Vernouillet	tonnes	54	60	90	92	101	101
IE - Cork	tonnes	11	15	16	15	13	13
IE - Dublin	tonnes	2,650	2,655	2,378	2,504	2,850	2,997
AUS - Southport	tonnes	*	*	*	*	*	*
<b>Total</b>	<b>tonnes</b>	<b>4,548</b>	<b>4,380</b>	<b>4,125</b>	<b>3,881</b>	<b>4,181</b>	<b>4,157</b>

\*Means production amount is confidential.

The production volume includes packaging.

Most of the production in Ballerup is finished goods. Even though the API and sterile production have increased, the tablet production has been significantly lower in 2015 than in 2014. As stated earlier, the production in Dublin has also risen but the production output on the other the sites have not changed much.

The production volume from Esbjerg is starting material of the API produced in Cork. Cork produces API (tinzaparin and heparin) 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	2015
DK - Ballerup	tonnes	2,612	2,718	2,567	2,326	2,149	2,407
DK - Esbjerg	tonnes	67,905	83,981	93,806	94,149	82,117	77,797
FR - Vernouillet	tonnes	397	521	588	581	542	735
IE - Cork	tonnes	304	678	144	151	97	90
IE - Dublin	tonnes	708	692	697	743	793	908
AUS - Southport	tonnes	37	37	1,836	811	833**	1,009
<b>Total*</b>	<b>tonnes</b>	<b>71,963</b>	<b>88,627</b>	<b>99,638</b>	<b>98,761</b>	<b>87,347</b>	<b>82,947</b>

\*Construction and project related waste is excluded.

\*\* The figure has been changed since the data received from the company collecting the waste was not correct.

### **Ballerup**

In Ballerup, the growth in waste volumes is primarily due to increased volume of solvents for recycling, and also due to considerable increases in pharmaceutical waste and waste plastics.

In 2015, a waste disposal unit was installed in the kitchen of the staff restaurant. This means that the organic waste from the staff restaurant is now sent to a biogas plant instead of for incineration. Therefore, 49 tonnes of organic waste from kitchen has gone to biogas and lowered the amount of waste for incineration with energy recovery.

Following identification of a non-conformance related to sorting of hazardous waste in Ballerup, there has been a renewed focus on training, guidance and performing additional checks of this waste fraction to ensure proper sorting in future.

### **Esbjerg**

Production output has not changed from 2014 to 2015 but the figures display a major reduction in waste volumes

Most of the waste generated in 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®) with a smaller amount used as an energy source in biogas producing plants.

The reduction in waste from Esbjerg is due to a reduction in Fertigro® and partially due to a lower amount of water being used where some of it ends up in the waste

### **Cork**

As for Esbjerg the waste volumes have been reduced. During Q2 2015 all landfill was diverted to Refuse Derived Fuel where energy is recovered as heat. This changes the classification from disposal to recovery.

### **Dublin**

The production output in Dublin has increased in 2015 compared to 2014, and this has also resulted in an increase in the volumes of waste.

A Green Business site assessment was performed in 2015, and a number of waste reduction and recycling initiatives will be progressed in 2016 following a review of a number of opportunities identified, particularly in relation to packaging waste

### **Vernouillet**

The figures show a significant increase in waste volumes in Vernouillet. The majority of the waste comes from the production area. There has been an increase in production and some of the waste comes from quality rejections which have resulted in destruction of large volumes of product. As a result, although the product output is the same as last year, the production has increased.

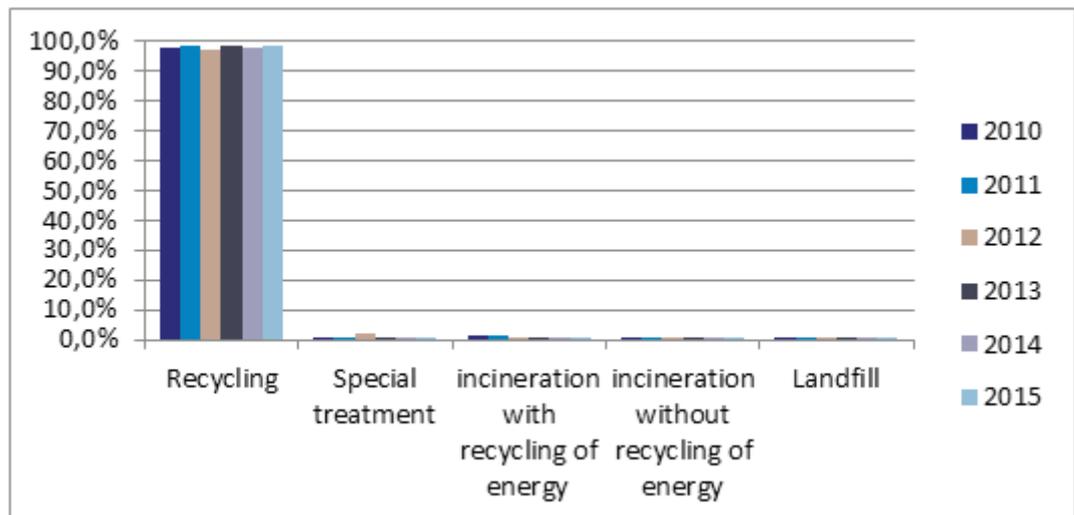
### **Southport**

The waste volume in Southport has increased as a natural consequence of the production volume being almost twice as high in 2015 as in 2014.

A waste project has also been conducted in Southport where glass items are now sorted and recycled instead of being sent to landfill.

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

Waste divided into kinds of treatment:



In 2015, special treatment accounted for 0.3%, incineration with recycling of energy 0.8%, incineration without recycling of energy 0.3% and landfill 0.1%.

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 re-used 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	2015
DK - Ballerup	m <sup>3</sup>	158,246	145,315	138,000	153,816	107,952	131,953
DK - Esbjerg	m <sup>3</sup>	5,190	7,025	9,231	10,167	9,995	9,339
FR - Vernouillet	m <sup>3</sup>	16,596	15,906	19,713	44,718	44,260	51,989**
IE - Cork	m <sup>3</sup>	19,077	18,042	28,845	35,119	23,369	22,231
IE - Dublin	m <sup>3</sup>	37,756	45,759	45,544	47,524	41,968	45,843
AUS - Southport*	m <sup>3</sup>	n/a	n/a	n/a	622	413	380
<b>Total</b>	<b>m<sup>3</sup></b>	<b>236,865</b>	<b>232,047</b>	<b>241,333</b>	<b>291,966</b>	<b>227,957</b>	<b>261,735</b>

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

\*\*The flow meter shows a false reading because the waste water pipes are sometimes blocked causing the water to rise.

**Ballerup**

The increase is due to the increased API production.

**Esbjerg**

In Esbjerg production in larger batches has resulted in a reduction in waste water as less water is used for flushing out product and between batches. A small amount of waste water in 2014 may have been due to construction work which has not been the case in 2015.

**Vernouillet**

The water consumption is much lower than the water outlet. As stated in the notes to the table above, this could be due the waste water figures being inaccurate because of blocked pipes. The flow meter is checked and calibrated every year and found to be working correctly. An investigation is being conducted to find the root cause of the problem.

**Cork**

Due to the introduction of the new filtration unit as mentioned above, the water usage has been reduced which in turn reduces the water going to effluent.

**Dublin**

Again the increase in figures is linked to increased production in Dublin in 2015 compared to 2014.

**Southport**

The drop in waste water being discharged is link to the decrease in water usage due to the new process where weed is being sucked directly from extraction tank instead of being flushed out.

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

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	363	385	290	349	182	276
DK - Esbjerg	tonnes	4	5	43	76	70	67
FR - Vernouillet	tonnes	2	2	1	6	6	10
IE - Cork	tonnes	4	5	5	9	7	9
IE - Dublin	tonnes	15	18	16	19	22	21
AUS - Southport	tonnes	n/a	n/a	n/a	n/a	n/a	n/a
<b>Total</b>	<b>tonnes</b>	<b>388</b>	<b>415</b>	<b>355</b>	<b>459</b>	<b>287</b>	<b>383</b>

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

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	121	128	97	116	61	92
DK - Esbjerg	tonnes	1	2	14	25	23	23
FR - Vernouillet	tonnes	1	1	0	2	2	3
IE - Cork	tonnes	1	1	2	3	2	3
IE - Dublin	tonnes	5	6	6	3	7	7
AUS - Southport	tonnes	n/a	n/a	n/a	n/a	n/a	n/a
<b>Total</b>	<b>tonnes</b>	<b>129</b>	<b>138</b>	<b>119</b>	<b>149</b>	<b>95</b>	<b>128</b>

#### Ballerup

The major contributor to COD in the waste water effluent in Ballerup stems from the production of Fucidin® API. The waste water contains sugar, corn steep and some organic solvents. Most of this is very easily biodegradable and the COD/BOD ratio is around 2. The COD and TOC calculations are based on 6 measurements of 24 hours resulting in some uncertainties as production varies a bit and sometimes a fermentation tank may be emptied to the waste water stream during 24 hours if it has been infected.

#### 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. An application regarding a new waste water discharge permit was submitted to the local environmental authorities in February 2014. The authorities have not dealt with the application yet.

#### Vernouillet

The measurements of COD in the waste water from the site in Vernouillet show considerably increased concentrations in the last three years. As stated last year, 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. The increase in 2015 is due to new cleaning procedures implemented to prevent contamination in the sterile area. This involves more use of solvents and consequently more COD in the wastewater.

#### Cork

The COD in the waste water from Cork stems from washing of raw material and CIP of production equipment.

**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	2015
DK - Ballerup	tonnes	9.5	13.7	11.6	11.4	10.7	7.7
DK - Esbjerg	tonnes	0	0	0	0	0	0
FR - Vernouillet	tonnes	0.6	0.2	1.5	1.8	2.5	8.2
IE - Cork	tonnes	n/a	n/a	n/a	n/a	n/a	0
IE - Dublin	tonnes	n/a	n/a	n/a	n/a	n/a	n/a
AUS - Southport	tonnes	n/a	n/a	0.2	0.6	1.2	0.5
<b>Total</b>	<b>tonnes</b>	<b>10.1</b>	<b>13.9</b>	<b>13.3</b>	<b>13.8</b>	<b>14.4</b>	<b>16.4</b>

The majority of emissions are from Ballerup and Vernouillet.

The figure for Vernouillet is also due to the new cleaning procedures mentioned above. This also results in more emission to the air.

The emitted solvents in Ballerup are primarily from the biological production and purification and from the organic synthesis. Even though the use of organic solvents has increased in Ballerup, the amount of organic solvents emitted to the air has decreased. The calculations may differ over the years as the data are based on short term measurements.

The emission of the greenhouse gas carbon dioxide (CO<sub>2</sub>) on site:

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	7,078	6,331	6,342	6,128	5,667	5,798
DK - Esbjerg	tonnes	1,319	1,531	1,492	1,107	965	939
FR - Vernouillet	tonnes	1,501	1,444	2,019	1,633	1,641	1,778
IE - Cork	tonnes	n/a	839	756	770	790	851
IE - Dublin	tonnes	2,364	2,816	5,014	6,107	6,100	5,758
AUS - Southport	tonnes	133	133	146	470	440	457
<b>Total</b>	<b>tonnes</b>	<b>12,395</b>	<b>13,094</b>	<b>15,769</b>	<b>16,215</b>	<b>15,603</b>	<b>15,581</b>

The amount of CO<sub>2</sub> reported for DK is only from direct emissions from the site (e.g. emission from on-site boilers or forklift gas emissions). Except for Dublin, there are no significant changes in the CO<sub>2</sub> emission from 2014 to 2015 and the changes for Dublin is due to less use of energy.

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from [www.key2green.dk](http://www.key2green.dk).

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

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	5.5	4.9	4.9	4.7	4.4	4.5
DK - Esbjerg	tonnes	1.0	1.1	1.1	0.8	0.7	0.7
FR - Vernouillet	tonnes	1.2	1.2	2.1	0.0	1.8	0.7
IE - Cork	tonnes	n/a	1.2	1.3	0.4	1.4	1.5
IE - Dublin	tonnes	4.0	5.0	8.8	10.7	10.8	10.2
AUS - Southport	tonnes	1	1	0.2	0.4	0.4	0.4
<b>Total</b>	<b>tonnes</b>	<b>13</b>	<b>14</b>	<b>18</b>	<b>17</b>	<b>19.5</b>	<b>18.0</b>

The amount of NO<sub>x</sub> is only from direct emissions from the site (e.g. emission from on-site boilers or forklift gas emissions).

The emission of NO<sub>x</sub> has decreased due to less emission in Vernouillet and Dublin as a direct consequence of the

drop in energy consumption.

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from [www.key2green.dk](http://www.key2green.dk).

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

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	0.04	0.04	0.04	0.03	0.03	0.03
DK - Esbjerg	tonnes	0.01	0.01	0.01	0.01	0.01	0.01
FR - Vernouillet	tonnes	0	0	0.02	0.02	0.02	0.02
IE - Cork	tonnes	n/a	n/a	n/a	n/a	n/a	n/a
IE - Dublin	tonnes	n/a	n/a	n/a	n/a	n/a	n/a
AUS - Southport	tonnes	~0	~0	~0	0.08	0.09	0.09
<b>Total</b>	<b>tonnes</b>	<b>0.05</b>	<b>0.05</b>	<b>0.07</b>	<b>0.14</b>	<b>0.15</b>	<b>0.15</b>

The amount of SO<sub>2</sub> is only from direct emissions from the site (e.g. emission from on-site boilers or forklift gas emissions). There are no changes from 2014 to 2015.

For Ballerup, Esbjerg and Southport, the amounts are calculated using key performance indicators from [www.key2green.dk](http://www.key2green.dk).

Emission of ozone-depleting substances (ODS)  
(Combination of R407c, R134a, R404a, R410a):

Site	Unit	2010	2011	2012	2013	2014	2015
DK - Ballerup	tonnes	0	0.0690	0.0600	0.1050	0.0390	0.0450
DK - Esbjerg	tonnes	0	0	0	0	0	0.0000
FR - Vernouillet	tonnes	0	0	0.0150	0	0	0.0042
IE - Cork	tonnes	n/a	n/a	n/a	n/a	n/a	0.0000
IE - Dublin	tonnes	0.067	0.1750	0.0125	0.0503	0.0020	0.0605
AUS - Southport	tonnes	n/a	n/a	n/a	n/a	n/a	n/a
<b>Total</b>	<b>tonnes</b>	<b>0.0670</b>	<b>0.2440</b>	<b>0.0875</b>	<b>0.1553</b>	<b>0.0410</b>	<b>0.1097</b>

In Ballerup and Dublin, HCFC was previously used for topping up the old cooling systems but is not used any longer. On the Vernouillet site there has been a leak in the air conditioning system which explains the increase.

For Ballerup it has been necessary to top up old cooling systems. Most of the cooling systems today at the Ballerup site are running on NH<sub>3</sub>. The increase in Dublin is also HFC gasses.

## 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.

Where 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.

One of the initiatives to prevent contamination is in Cork, where new chemical storage bunds have been installed to replace old storage. This will now allow segregation of acids and bases used for effluent treatment. The new storage has built-in bunds to prevent spills leaking to the environment.



**NOISE**

In Dublin, a site-wide noise and vibration survey commissioned by EHS was conducted which identified vibration issues that needed to be addressed relating to warehouse vehicles and their use.

**ENVIRONMENTAL ACCIDENTS/INCIDENTS**

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

Site	2010	2011	2012	2013	2014	2015
DK - Ballerup	2	3	3	18	5	5
DK - Esbjerg	0	0	2	0	56	40
FR - Vernouillet	0	0	0	3	4	3
IE - Cork	10	15	5	10	5	4
IE - Dublin	2	2	2	6	8	6
AUS - Southport	0	0	0	1	0	0
<b>Total</b>	<b>14</b>	<b>20</b>	<b>12</b>	<b>38</b>	<b>78</b>	<b>58</b>

**Ballerup:**

3 of the reportable accidents were about oils or fluids entering the waste water drain. One was due to a defect which has now been repaired and improved to contain leaks in future. The other two accidents were because of open valves and employees have been retrained. The two remaining incidents were about exceeding the waste water permit; one was the sulphate content in the waste water drain being too high and the other was the COD/BOD content being too high due to organic solvents.

**Esbjerg**

All incidents in Esbjerg are related to waste water as the waste water contains too much suspended solids and fat resulting in too high COD and also too much Total-N. Application for new permit sent to authorities in February 2014 however they have still not handled the application. The waste water treatment plant has no problem in dealing with the waste water and it does not affect the environment downstream from the waste water treatment plant.

**Vernouillet:**

The three incidents in Vernouillet was due to one incident of too high pH in the waste water and two incidents regarding too high flow. The flow issue has been solved as the site is now allowed to emit more wastewater per day.

**Cork:**

The four reportable environmental incidents in Cork were all about breach of Exposure Limit Value of the surface water conductivity. Following these non-conformities, a project was initiated to monitor the conductivity using an online conductivity instrument and in case of high conductivity, the surface water will be diverted automatically to the waste water. If the conductivity is within specification, it will go to the surface water system. This online monitoring will also raise an alarm through the building management system (BMS) to alert utilities personnel to the issue. For an interim period, the surface water is now drained to the waste water effluent.

**Dublin:**

There were six incidents notified to the licensing authorities in 2015. Two were COD exceeding limits, two were effluent discharge below the pH limit of 6.0, one incident was an accidental discharge of process effluent to foul sewer and the last one was accidental contamination of surface water with foul water due to a blocked drain and subsequent overflow. This has now been addressed by increasing the frequency of drain inspections.

**Southport:**

No environmental incidents were reported to the authorities in 2015.

## COMPLAINTS

Complaints received by LEO Pharma:

Site	2010	2011	2012	2013	2014	2015
DK - Ballerup	0	1	1	0	0	1
DK - Esbjerg	0	0	0	0	0	0
FR - Vernouillet	0	0	0	0	0	0
IE - Cork	0	0	0	0	0	0
IE - Dublin	0	2	0	2	0	0
AUS - Southport	0	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>1</b>

In Ballerup, the sterilisation of raw materials in the Fucidin® area sometimes causes odour nuisance to neighbours and people passing by the site which led to complaints in 2011-2012. Various possibilities were investigated for reduction of this odour. The best possible solution was implementation of condensers on the fermentation tanks during the sterilisation. The solution was 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 process 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. Therefore, the Ballerup site received another complaint about odour in 2015. It has not been possible to identify any unusual conditions but wind direction may have caused the nuisance. The sterilisation process odour does not constitute any health risk.





# Health and safety performance

## HEALTH AND SAFETY GOALS

The goal that all existing manufacturing sites must be OHSAS 18801 certified by the end of 2015 was achieved in 2014 ahead of schedule. In December, the Cork site

was recertified to the OHSAS 18001 standard for Health and Safety management.

### OHSAS 18001 certifications

	2010	2011	2012	2013	2014	2015
<b>Ballerup</b>	X (Initial certification)			X (Re-certification)		
<b>Esbjerg</b>	X (Initial certification)			X (Re-certification)		
<b>Vernouillet</b>					X	
<b>Cork</b>				X (Initial certification)		X (Re-certification)
<b>Dublin</b>					X	
<b>Southport</b>					X	

The other goal that the group LTI rate is on par with the best in industry at the end of 2015 has proven to be more ambitious than expected and the goal has not been achieved. The LTI rate 2015 ended up at a total LTI rate of 4.3 compared to an LTI rate in 2014 of 5.3.

We have also seen a reduction in the number of injuries and the number of lost days as a consequence of an injury has also been improved. These are also indicators that we are improving.

As can be seen, the Dublin site has really managed to bring down their number of

lost time injuries, and also the number of lost days due to an injury has been significantly improved.

We have continued to increase our focus on Safety Awareness in 2015 but to change the culture is a long journey. We have established a number of sub-goals to achieve this and we are heading in the right direction but we still have room for improvement.

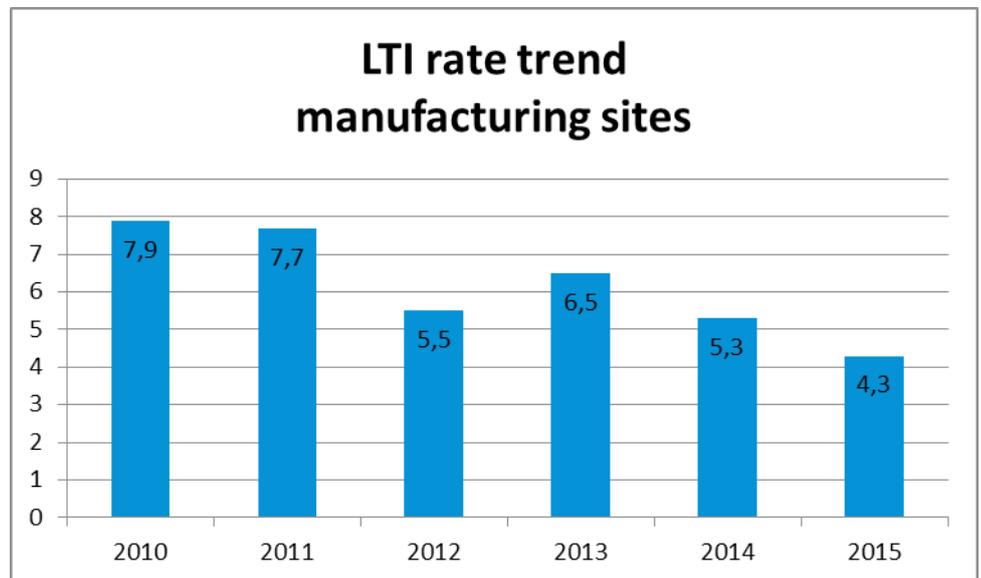
The Lost Time Injuries rate is stated below and is calculated as:

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

The number of lost time injuries in 2010-2015 was:

LOST TIME INJURIES						
Site	2010	2011	2012	2013	2014	2015
DK - Ballerup	16	16	12	11	6	8
DK - Esbjerg	0	0	1	0	0	0
FR - Vernouillet	8	8	4	9	9	7
IE - Cork	0	1	0	0	0	0
IE - Dublin	3	2	4	4	6	3
AUS - Southport	0	2	1	2	0	0
<b>Total</b>	<b>27</b>	<b>29</b>	<b>22</b>	<b>26</b>	<b>21</b>	<b>18</b>

These figures result in the following LTI rate trend:



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 lower in 2015 than in 2014. This is mainly due to injuries in Vernouillet being less severe than last year, but they still account for many lost days. The two injuries in Vernouillet with the most lost days were: a fall on stairs which resulting in a broken finger and 82 lost days. The other one was a manual handling injury where the injured party tried to remove a chair which was stuck under a table. The injured party hurt her shoulder and had 103 lost days.

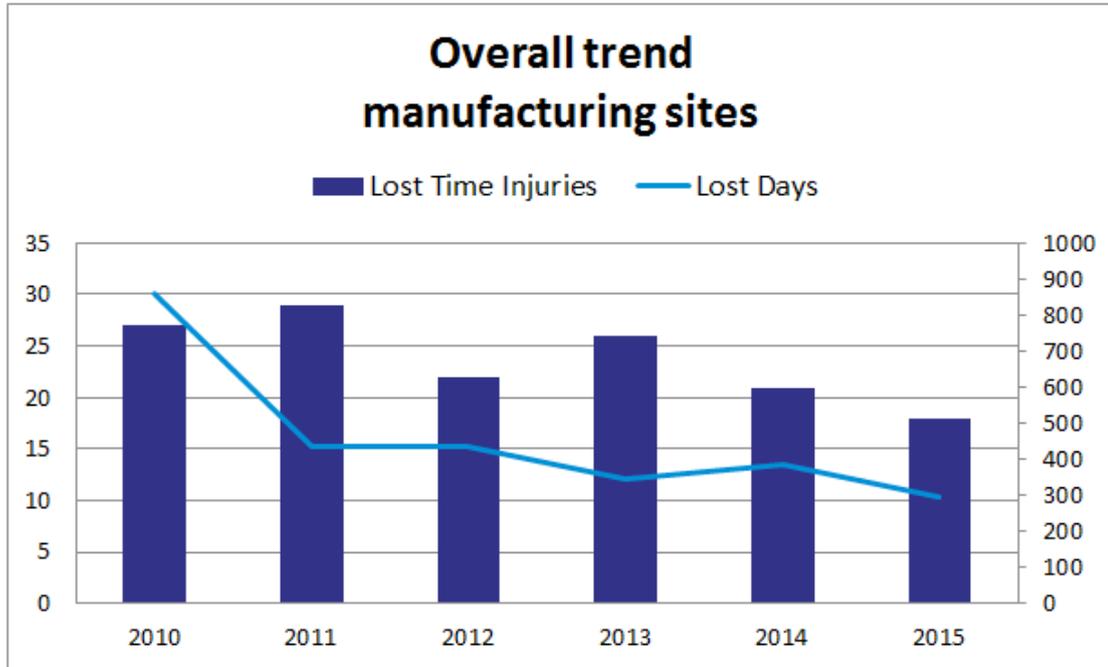
The number of lost days in Ballerup has increased, primarily due to two injuries which resulted in 10 and 35 days, respectively. The first one was an employee who suffered a concussion in a car accident in Romania and the other was a strain of the shoulder in connection with a raw material being lumpy and employee trying to loosen these during suction of raw material with metal lance. Corrective action is ensuring the raw material is with the normal loose texture. The Dublin site has really improved and their injuries are not very severe as can be seen from the fact that 3 injuries result in only 5 lost days, the lowest level of absence in many years in Dublin.

Number of Lost Days:

Site	NUMBER OF LOST DAYS					
	2010	2011	2012	2013	2014	2015
DK - Ballerup	241	72	25	64	36	56
DK - Esbjerg	0	0	1	0	0	0
FR - Vernouillet	373	337	324	182	310	237
IE - Cork	0	4	0	0	0	0
IE - Dublin	244	22	86	97	42	5
AUS - Southport	0	2	1	5	0	0
<b>Total</b>	<b>858</b>	<b>437</b>	<b>437</b>	<b>348</b>	<b>388</b>	<b>298</b>

As can be seen three sites are doing really good. Heading the field is the Cork site which had reached 1689 days without a Lost Time Injury as of 31 December 2015. This is more than 4 and a half year. The Cork site is followed by the Esbjerg and the Southport site which have had 1120 and 863 days,

respectively, without an injury. The three remaining sites all had lost time injuries in 2015 and at the end of the year the time passed since the last LTI was 92 days for Dublin, 63 for Vernouillet and 38 days for Ballerup.



# Health and safety projects and initiatives

LEO Pharma continuously works to decrease the number of injuries. Some of the initiatives to achieve this are listed below.

The 10 GOOD ATTITUDES, which is a set of good behaviours to be followed by all employees, were rolled out in 2014 and embedded in the business in 2015 where the GPS area in particular was encouraged to take the e-learning training. The 10 GOOD ATTITUDES are part of our journey to change behaviour and establish a safe workplace for all.

The 10 GOOD ATTITUDES are supported by global campaigns within various areas. In 2015, campaigns on slips, trips and falls, road safety, ergonomics and manual handling were rolled out across all sites. All subjects have been covered before but the campaigns were updated with new campaign material.

Another initiative which helps us monitor our health and safety performance is the use of Colour Coding where each department or area is colour coded according to certain parameters to reflect its safety rating. This tool is not only suitable for creating awareness but also good indicators of where to put our future efforts to drive safety improvements.

A lot of training has been conducted locally on e.g. confined space training and ATEX training which highlighted the dangers, protective measures and employee requirements when working in these areas.

All sites have conducted emergency and evacuation training according to local legislation and both practical and theory training have also been given in fire awareness. The fire training soon turned out to be a good investment since the Dublin site had a fire in an IT room which set off the alarm. The response was prompt from the newly trained emergency response team and the fire did not cause much damage. In addition, emergency response training has been offered to a group of employ-

ees with focus on saving lives in case of an injury.

In addition to the global EHS campaigns run on all sites, the sites have their own local campaigns and quizzes to create awareness about other EHS issues. Below, you will find detailed information on local projects and initiatives.

## **Ballerup:**

One of the focus areas in 2015 has been to improve the working environment in the API production areas where the conditions for handling raw materials have been improved. This means that high potency substances are now weighed out in isolated environments which then prevent emission of high potency substances when the product is transferred to the reactor. Less potent substances are weighed out in a room where access requires passing through a personnel sluice with fogging shower. Upon termination of the task, the fogging shower is used to tighten the particles to the suit and other PPE before the protection is taken off. The production laboratory facilities have also been improved with new fumehoods, safety cabinets class 2 and HPLC cupboards and upgrade of both personnel sluice and ventilation automations.

A selected group of managers have been trained in stress management and after evaluation of the courses it has been decided to offer the course to all managers in Ballerup during 2016.



**Esbjerg:**

In October 2013, the certifying body made a suggestion to gather the employees in one building to ease the cooperation between the employees on site. In 2015, an extra floor was built on top of the existing production building. It will be ready for use in the beginning of 2016 and the employees are very pleased with this solution.

With the implementation of the new Fertigro® plant, the traffic layout has been changed to prevent injuries involving reversing tank wagons. The tank wagons enter the site from the South and exit through the new North gate.

**Vernouillet:**

The Vernouillet site has had some near-misses in the past regarding pallets being pushed down from the racks. As a consequence thereof, all racks have now been protected with grids between the racks and pallets cannot be pushed down from the racks.

**Cork:**

The level of safety awareness at the site in Cork has improved significantly since OHSAS 18001 certification in 2012. Near-misses and continuous improvement opportunities are reported which leads to hazards being identified and control measures put in place before accidents happen.

One of the actions taken in 2015 was based on a gap analysis in 2014 which identified deficiencies in the confined space entry system. The solution was to work with a local expert company in confined space entry to



design a portable, adjustable confined space entry system, which is suitable for use on all vessels on site. Having more than 100 planned confined space entries conducted each year in LEO Pharma Cork, this makes good sense and now a portable, adjustable davit retrieval assembly, coupled with a practical supporting system has been developed for use to keep our colleagues safe.



This is one of the solutions which LEO Pharma is looking at implementing at more of the sites.

Another initiative which will also be implemented at other sites in 2016 is the lone worker system which has been installed on the Cork site in 2015. This involves units which are intended to be used by personnel that may need to work alone or in an isolated area for an extended period of time where they will not be in contact with other personnel.

The unit work in a similar way to a mobile phone. There is a large Red "Panic" button which will directly contact security. It also comes with tilt alarm which activates in the event of a person falling over due to an incident and this will also alert security. The units can also be called into from any phone as they have a normal mobile number printed on each unit. Finally, the unit are Ex rated so can be used in all areas.

One of the examples which shows that reportings and continuous improvement suggestions are taken seriously is the installation of Diphoterine® Chemical burn emergency wash stations which was suggested by an analyst who had experience with the product from another employer's facility. The treatment neutralises almost all chemicals that can cause chemical burns as it quickly eliminates the residual chemical product on the skin or in the eye.

Other examples are installation of a new ATEX tanker unloading earth rite system to ensure correct earthing of solvent tankers being unloaded and introduction of Easy Grip anti-slip overshoes on site to address a slippery floor surface.

### **Dublin:**

While 2013 focused on increasing safety awareness on the site, and 2014 focused on changing safety behaviours, the focus in 2015 was on improving the safety culture. The roles and responsibilities of the EHS Department were reviewed along with that of the wider Health and Safety Organisation (HSO). A stronger, restructured Emergency Response Team (ERT) was also developed. These initiatives were undertaken to ensure adequate support and cover as the site now produces greater volumes and a wider range of products, and has added additional shift-working arrangements. As can be read from the tables above, the benefits of these investments in safety were felt at year-end where an increased level of safety hazard reporting for the second year in a row contributed to the lowest ever lost days due to workplace injuries since records began.

A number of capital investments in safety equipment also took place in 2015 including site security upgrades, Closed circuits television (CCTV), and building access control. Emergency lighting and fire alarm upgrades were also implemented. Emergency phones and new Emergency Response Team radios were introduced.

A submission was entered for the Pharmachem Ireland Responsible Care Awards under the Occupational Health category. Titled "Health and Wellbeing - Essential Life Skills and Emergency Response", the submission highlighted the high level of interest shown by our employees in coming forward for training as Cardiac First Responders (CFR), with others volunteering to become members of the Emergency Response Team. Over 160 personnel have completed the CFR training, and as well as benefiting colleagues in LEO, these volunteers bring these valuable life skills with them into their local communities.

Occupational Health initiatives in 2015 continued to focus on employee wellness. The LEO Dublin campaign in 2014 of "Speak Up" which encouraged employees to talk about psychosocial issues was followed by a "Reach Out" campaign in 2015, which encouraged employees to seek help for stress and psychosocial issues if required.

### **Southport:**

The great results in Southport is owing to an increased safety awareness on site where employees are reporting hazards/ incidents which is clear evidence that the safety culture is heading in the right direction. This has been improving since the introduction of the safety data management system used in Southport, employee training and clear and concise communication across the site. The site has worked tirelessly in recording and completing housekeeping inspections which help the site maintain a safe site which is always audit ready.

# Global Environment, Health, Safety and Energy Goals 2020

LEO Pharma has the following 2020 global goals on environmental affairs and energy:

1. New ISO 14001 certifications for all manufacturing sites (A new ISO 14001 standard will come into force in the middle of 2015)
2. Update and implement Energy & Environmental policy
3. Aiming for a water reduction of 5% by end of 2020 compared to the water usage in 2013
4. Aiming for no waste to landfill
5. Identify and implement waste reduction projects in order to sustain that more than 97% of our generated waste is recycled
6. ISO 50001 certifications for all manufacturing sites in EU
7. Reduce CO2 emissions
8. Implement energy saving projects equal to 10% of the energy consumption in 2013.

## Health and Safety 2020 goals

LEO Pharma has the following 2020 global goals on health and safety:

1. LTI rate 2020 LEO Group  $\leq 2$  and LTI rate 2020 in Global Product Supply  $< 1$
2. ISO 45001 certifications for all manufacturing sites (ISO 45001 replaces OHSAS 18001 in 2016)
3. Update and implement Health and Safety Policy
4. Registration of chemicals according to REACH legislation
5. Monitor chemicals on the REACH Authorisation and restriction lists up against LEO use of these chemicals and communicate it to relevant part of the business

To support the goals, LEO Pharma has selected mai™ as its global EHS management software system. mai™ will be used as the solutions in our European manufacturing sites to improve the reporting and management of our EHS performance, better manage our risks, and regulatory compliance and streamline our EHS processes based on the international standards OHSAS18001 and ISO14001. The Southport site uses another EHS management system tool.

A working group with members from the European manufacturing sites and Global EHS was formed in 2015. This group are working on the customisation of the system and deployment to the European manufacturing sites. The mai™ system is expected to be rolled out in Q2 2016.

As mentioned in the overall Global Environment, Health, Safety and Energy goals section, a summit was held in September 2015. The purpose of this summit was among other things to initiate the 2020 goals on alignment of management systems and safety awareness. The alignment of systems is an on-going process over the next years and we expect the collaboration to result in global management system certification before 2020.

# Appendices

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## Appendix 1 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®) 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® K mite, Centyl® K, Daivonex®/Dovonex® Scalp solution, Etalpa®/One-Alpha®, various products containing Fucidin®, Heparin LEO® and innohep®, Kaleorid® and Daivobet® Gel and Xamiol® Gel. The products are all for human use.

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

The site area in Ballerup has grown over the years. Today the total site area is approximately 150,000 m<sup>2</sup>.

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 2015, the number of employees in LEO Pharma Ballerup equalled 1,632.3 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 as well as a licence to establish new administration building and workshop. An application regarding a new waste water discharge permit was submitted to the local environmental authorities in February 2014. The authorities have not dealt with the application yet.

In 2015, the number of employees in LEO Pharma A/S Esbjerg equalled 10 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<sup>®</sup> syringes and Fucidin<sup>®</sup> tablets. Burinex<sup>®</sup> 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<sup>®</sup> tablets and Burinex<sup>®</sup> 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 2015, 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>. 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 2015, the number of employees in LEO Pharma Cork equalled 46.3 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>.

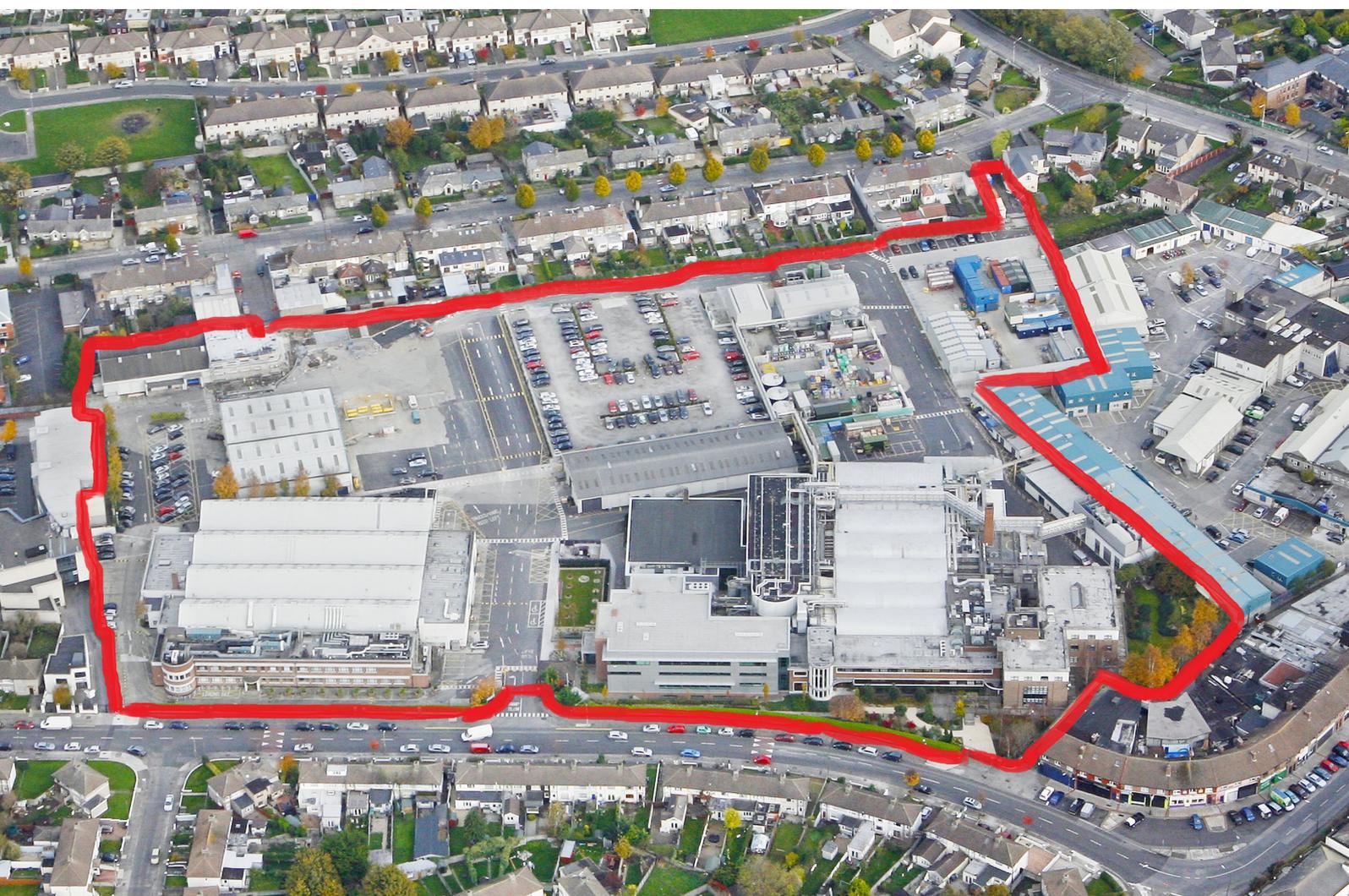
The site has been used to manufacture many types of pharmaceutical products over the years including Active Pharmaceutical Ingredients (APIs). However, the manufacture of APIs ceased on site in 2007 and since these “licenced activities” are no longer carried out, the site surrendered its IPPC (Integrated 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 2015, the number of employees in LEO Pharma Dublin equalled 440 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®. Picato® 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®.

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

In 2015, the number of employees in Peplin Operations equalled 40.4 full time employees.



## Appendix 2

### 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<sub>2</sub> and NO<sub>x</sub> 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.

## Appendix 3

### 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](http://www.key2green.dk)) have been used for the calculation of the energy consumption and the emissions of CO<sub>2</sub>, SO<sub>2</sub> and NO<sub>x</sub> 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 (130 m<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 2013-2015, 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 m<sup>3</sup> of natural gas equals 0.0396 GJ

1 litre of truck gas equals 0.02486 GJ

1 m<sup>3</sup> 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 2013-2015, 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.)

\* <http://www.sbi.dk/miljo-og-energi/gronne-regnskaber/gront-regnskab-for-boliger/energi-benchmark-fra-sbi>

## Appendix 4

### Clarification of terminology in the report

#### *API*

Active Pharmaceutical Ingredient

#### *Average household in Denmark*

130 m<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 2014-2015, 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.

#### *CHP*

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

#### *TOC*

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

\* <http://www.sbi.dk/miljo-og-energi/gronne-regnskaber/gront-regnskab-for-boliger/energi-benchmark-fra-sbi>



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