

# Sustainability Report 2018



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# We are builders of well-being as manufacturers of pharmaceuticals and active pharmaceutical ingredients

Orion is a globally operating Finnish pharmaceutical company – a builder of well-being. We innovate, develop, manufacture, sell and market human and veterinary pharmaceuticals as well as active pharmaceutical ingredients. We also serve as a contract manufacturer to other pharmaceutical companies. We are continuously developing new drugs and treatment methods. The core therapy areas of our pharmaceutical R&D are central nervous system (CNS) disorders, oncology and respiratory diseases, for which we develop inhaled Easyhaler® pulmonary drugs.

Our mission is to build well-being by providing high-quality pharmaceuticals and self-care products that help people take good care of themselves every day. Pharmaceuticals give patients help and effective treatment for their illnesses. An effective drug also creates added value for patients by improving their quality of life.

Orion has developed from a shop founded by three pharmacists more than a century ago into an international company that carries out medical research at the top international level. We are now the leading pharmaceutical company and one of the oldest and most financially sound companies in Finland.

Our corporate website provides plenty of up-to-date information about us, our operations and our products and services at www.orion.fi/en. Our Code of Conduct, Group policies and information about sustainability and corporate governance are also available on our website.

The Group consists of the following businesses:



Our production plants and pharmaceutical research centres are located in Finland, and in addition to this we have a research unit in Nottingham, England. The largest of our sites is Mankkaa, Espoo, where the Group and its parent company Orion Corporation are headquartered. Our own sales and marketing organisations cover almost all European countries. In markets outside Europe, we work in partnerships with other companies.

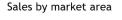


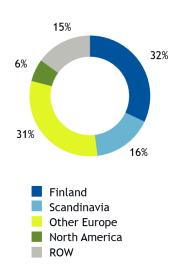
#### Operations and sites of the Orion Group

Finland	Headquarters and administration in Espoo
	Pharmaceutical manufacturing in Espoo, Turku, Kuopio and Salo
	Active pharmaceutical ingredient R&D in Espoo, manufacturing in Hanko and Oulu (Fermion)
	Pharmaceutical research centres in Espoo and Turku
	Marketing: Espoo, Turku, Kuopio, Oulu and Tampere
UK	Sales unit in Newbury, England
	Research & development in Nottingham, England
Europe	Orion Pharma subsidiaries with sales and marketing operations in 26 countries
India	Support functions, Subsidiary FinOrion Pharma India Pvt. Ltd. in Mumbai
Rest of the World	Global partner network for sales

Orion's products are available in pharmacies and hospitals in more than a hundred countries. The Group's net sales in 2018 were about EUR 977 million. Finland contributed 32% of the net sales. Scandinavia and the rest of Europe accounted for 47%, and North America and the rest of the world accounted for 21%. Our customers include healthcare providers and professionals, consumers and other pharmaceutical companies. In healthcare, our customers primarily include specialist doctors and general practitioners, vets, nurses, pharmacies, hospitals, healthcare centres, clinics and laboratories and their respective procurement organisations.

Orion Corporation, the parent company of the Group, is a public company whose shares are listed on Nasdaq Helsinki. Orion had ~73,000 registered shareholders at the end of 2018, of which 95% were households. Households held 42% of the entire stock. We publish quarterly information about the financial performance of the Orion Group. Our news releases and publications as well as information about our ownership base are shared in the Investors section of our corporate website.





# Statement by CEO Timo Lappalainen

Orion is a globally operating Finnish developer of pharmaceuticals and self-care products - a builder of well-being. For us, responsible business is a prerequisite and a firm foundation for building a successful business. Managing, reporting and developing corporate responsibility and sustainability are an integral part of the continuous development of our company.

Sustainability is not a separate project from Orion's other activities, but should be well integrated and part of our everyday work. It is a common theme for all Orionees and everyone must be engaged. In the coming few years, we will put even more effort into ensuring that sustainability is better integrated across the Company.



Integrating sustainability into operations is a journey. The subject changes its shape and the goal is constantly moving forward. Therefore, the project will never be finished but our aim is that in a few years sustainability will be even more deeply integrated into operations and Orion will be more agile and able to respond to the sustainability challenges, seize opportunities, and respond to stakeholder requirements.

Last year, Orion conducted a wide materiality assessment to highlight the most material sustainability topics. Dialogue with our stakeholders is essential, and we wanted to ask our important stakeholders for their views on the materiality of corporate responsibility topics. We received more than 1440 replies to the survey from our key stakeholders. We are grateful to those who took the time to share their perspectives, and we received valuable insights into corporate responsibility topics that in our stakeholders' eyes are particularly relevant for Orion and our business, today and in the future.

Based on the analysis, we have identified the most important themes of corporate responsibility. The key focus of all Orion's operations and corporate responsibility is patient safety and ensuring a reliable supply of medications. Another important theme is business ethics and transparency, doing business in a responsible manner. Thirdly, it is about manufacturing medications and other products in an environmentally sustainable way, and fourthly it is about responsibility for our employees, Orionees. Under these four themes, we will set goals, targets and concrete measures to ensure continuous improvement. For Orion economic responsibility, which is strongly linked to these themes, is very important as well. We take care of our profitability and competitiveness and are committed to creating a positive impact throughout the value chain.

As a pharmaceutical company, our ultimate goal is to help patients to treat their diseases and improve well-being effectively and safely. We are continuously working to ensure this, and we are seeing good results. During the last 5 years, the number of product recalls has been declining. In addition to this, we have been preparing for the serialisation and anti-tampering feature requirements for several years, and implementation is proceeding as planned. This preventative action against falsified medicines will further improve patient safety.

In 2018, we have also made progress internally in raising awareness, developing competences and updating our processes to even better integrate sustainability into the day-to-day activities of our procurement organisation. During the course of the year, we have also trained suppliers, adjusted our sustainability audit program and widened the scope from environment, health and safety to sustainability, i.e. also paying more attention to topics such as labour and ethics. We work continuously to ensure a responsible supply chain.

The themes of sustainability and the principles of continuous improvement towards meeting our targets are deeply embedded in Orion's day-to-day work and corporate culture. To us, responsibility is a principle built into our common values. It reflects a caring attitude towards everything we do.

Timo Lappalainen President and CEO

# The Group values and principles are the cornerstones of our operations and corporate responsibility

Our corporate values characterise our way of working within the Orion Group: Appreciate each other, Strive for excellence and Build the future.



These are Orion's renewed values, which were approved by the Board of Directors outside the reporting period in February 2019. In 2018, we conducted a value survey and engaged Orionees to revise the Group values. 2073 Orionees, 65% of the personnel, answered the survey. Based on the survey and workshops, we formulated renewed Group values. Values form the basis of Orion's operations and are evident in everything we do. These values are rooted in the DNA of every Orion employee and guide the strategic choices which we will make in the future.

Orion is committed to operating in a responsible and sustainable manner and to enhancing ethical working practices. Our Code of Conduct determines the basic principles which our employees are expected to follow and to observe in their interactions with each other and with the stakeholders of our company, as well as with the society and environment. Every Orion employee is committed to following the high ethical standards and business practices as outlined in the Group's Code of Conduct.

In addition to the above, Orion's operations and ways of working are subject to specifically determined company policies and numerous mandatory guidelines concerning our practices. All our policies have been approved by the Group's executive management, and they are applied Groupwide. Especially important are the Good Practices required to be followed by healthcare industries worldwide in the development and manufacturing of pharmaceuticals. Standard Operating Procedures (SOPs) are detailed internal guidelines, based on the Good Practices, providing details of the procedures to be applied in work phases as well as the related requirements and responsibilities.

In addition to the regulatory requirements by healthcare authorities, pharmaceutical companies are bound by numerous commonly agreed industry rules and codes concerning marketing, R&D, and collaboration with healthcare professionals and patient organisations. Orion is committed to the codes of practice of EFPIA (European Federation of Pharmaceutical Industry Association) that are accessible on the EFPIA website at www.efpia.eu. Fermion is also a member of Cefic (The European Chemical industry Council, www.cefic.org) and its sector group APIC (Active Pharmaceuticals Ingredients Committee, www.apic.cefic.org) respectively.

Our corporate strategy emphasises a strong culture of working together, based on work that is significant and creates value for our customers. We want to be an excellent workplace and a responsible and attractive employer, which takes care of continuously developing the well-being and skills of our staff.

We are committed to continuously improving our performance in sustainability. We strive to achieve the high targets we have set for managing matters related to the environment, occupational health and safety, human resources, and ensuring our operations are ethical. Patient safety is the guiding value in all Orion's operations. The Company ensures that the pharmaceutical products developed, manufactured, sold and marketed are proven to be safe for their users when used correctly and effective for the indications for which they are approved, and consistent with the quality standards set for them.

Orion's corporate responsibility governance model provides a solid foundation for managing and developing sustainability throughout the Company. Board of Directors oversee all matters concerning sustainability and approve the statutory reporting. Sustainability is led by the CEO and Orion Executive Management Board and all Orionees have a role to play in ensuring that sustainability is embedded into the business. Key responsibilities and internal stakeholders are presented in the chart below.

The corporate responsibility function, which belongs to the Corporate Functions organisation, is managed and coordinated by the Head of Corporate Responsibility. She reports to Senior Vice President, Corporate Functions, who is a member of the Orion Group's Executive Management Board and he reports to President and CEO.



The following statement by the Executive Management Board of the Orion Group confirms our commitment to responsible operations and continuous development:

### Orion is committed to responsibility and continuous improvement

The operations and activities in the Orion Group are based on compliance with laws and regulations, as well as with ethically acceptable operating practices. These principles, together with Orion's values and our dedication to 'Building well-being', are the key drivers for us in our approach to corporate responsibility in our daily work, in whatever we do.

With our strong commitment towards promoting health, we aim to enhance trust in Orion as a company that cares for and contributes towards the welfare of humankind. We are committed to sustainable development and constantly improving performance, aiming for the highest standards in the industry with respect to the environment, health, safety, business ethics and integrity.

We aim to be a trustworthy partner in terms of economic, social and environmental criteria. We also aim to be an attractive and solid workplace, respecting human rights and equality. Our commitment to responsibility allows us to expect the same from our business partners.

# Our principles of reporting on sustainability

# The Report content is based on materiality

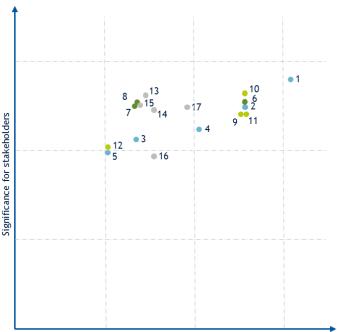
This Report is the 10th sustainability report of the Orion Group, the focus being on calendar year 2018. In the report, our focus is on the most relevant matters to our operations, using the GRI (Global Reporting Initiative) framework as a guideline.

Materiality analysis is a tool that we use to highlight the most material sustainability topics. It helps to identify corporate responsibility topics that affect our stakeholders and are particularly relevant for Orion and our business, today and in the future.

The materiality of Orion's sustainability topics was re-assessed during autumn 2018, with support from external consultants. The assessment consisted of four parts: defining sustainability topics, stakeholder survey, determining significance of impacts and analysis of results.

Dialogue with our stakeholders is essential, and we wanted to ask our important stakeholders for their viewpoints on the materiality of corporate responsibility topics. We received more than 1440 replies to the survey from our key stakeholders i.e. personnel, health care professionals, decisionmakers, partners, investors and consumers.

Material topics are essentially the same as previous years. The assessment confirmed our view that patient safety, ensuring a reliable supply of medications and manufacturing medications in an environmentally sustainable way are the most material issues for us. All the issues in the matrix are material but the priority of the topics differ. In the matrix, the vertical axis shows the significance for stakeholders and the horizontal axis the significance of Orion's economic, environmental and social impacts.



#### Significance of economic, environmental and social impacts

#### **Research and development**

- 1. Patient safety is the cornerstone of Orion's corporate responsibility
- We invest in the early research and development of new medicines
  In addition to developing medicines, we take part in developing new treatments
- 4. We develop medicines specifically for national chronic diseases
- 5. We actively develop products and solutions for self-care

#### Production and subcontracting

6. We manufacture medicines in an environmentally sustainable way, taking care of material and energy efficiency and wastewater treatment 7. We take care of occupational health and safety and human rights in the whole supply chain 8. Our supply chain is transparent and we are open about it: we communicate consistently about both positive and negative matters 9. We bring cost-effective medicines to the Finnish market 10. We ensure the availability of medicines in unexpected situations 11. We educate healthcare professionals about the effects of medicines 12. We produce information and take part in social dialogue 13. We are a responsible employer and taxpayer 14. We invest in the well-being and constant development of our staff 15. Our marketing and communications are ethical and they are based on facts and research 16. Our management systems and our corporate responsibility reports are verified by a third party (e.g. ISO14001, ISO45001, GRI)

17. We act to reduce environmental impacts caused by the use of medicine (e.g. packaging, production, logistics, wastewater)

In addition to the issues, we have identified and chosen the most relevant indicators for us, largely relying on the GRI framework. Additionally, supporting the material issues we have established some Orion-specific indicators that reflect our practices and processes to ensure the quality of our products and their safety to patients.

The prioritising, principles and boundaries used in this Report, as well as the key stakeholder groups have been confirmed by Orion's Executive Management Board, which also approves the Report for publication.

## Scope of our reporting

Our sustainability report principally covers Group-wide operations. The data represents all our operational locations and is reported according to the Group structure. As our operations' environmental impact mainly comes from our manufacturing operations and because all our manufacturing units are located in Finland, we only include our Finnish sites in the data concerning environmental management.

The foreign operational units of the Orion Group are primarily marketing or liaison offices that market our pharmaceutical products, mainly in leased premises and with operations in the country that they are located in. Almost all of their employees are engaged in marketing except for a few employees working in support functions. Some reported personnel data only covers Finland due to the lack of data for the foreign subsidiaries. As the foreign units are relatively small however, their impact on the Group figures is minor.

The following organisational groupings are used in the data collection and reporting:

#### Orion Group

#### **Orion Corporation**

- Pharmaceutical operations and Head Office functions in Espoo
- Pharmaceutical operations in Turku
- Pharmaceutical operations in Kuopio
- Pharmaceutical operations in Salo
- Foreign Orion Pharma marketing subsidiaries and FinOrion Pharma India Pvt. Ltd.

#### Fermion Oy

- API manufacturing in Hanko
- API manufacturing in Oulu
- API R&D unit in Espoo

Due to the sale of the Orion Diagnostica in 2018, in the Sustainability Report the Orion Diagnostica segment is reported as a discontinued operation; the review only covers continuing operations for 2018. The comparison figures for 2016-2017 include the Orion Diagnostica segment that affects the comparability of the data reported for the preceding years. Additionally, no material changes have been made to the scope, boundary or measurement methods in comparison with the previous Report.

The Report has not been assured by a third party.

# Our stakeholder groups



In doing business and performing our work we are involved with a number of stakeholder groups which our Group and its representatives interact with, and which are both affected by our activities and can directly or indirectly affect our performance and operating conditions.

The key stakeholders have been defined based on the criteria, which included reasonable expectations of the stakeholder groups towards us and their importance in relation to our business.

# Our memberships in industry associations and advocacy organisations

The following industry associations and advocacy organisations are the most relevant to the Group, and the Orion Corporation and/or its subsidiaries are members thereof:

- Chemical Industry Federation of Finland / Confederation of Finnish Industries, EK
- EFPIA, European Federation of Pharmaceutical Industry Associations
- International Chamber of Commerce, Finnish Section
- Helsinki Region Chamber of Commerce
- Turku Chamber of Commerce
- Finnish Health Technology Association (FiHTA) / The Federation of Finnish Technology Industries
- The Association for Finnish Work
- Excellence Finland
- CEFIC (European Chemical Industry Council) and its sub-organisation APIC (Active Pharmaceutical Ingredients Committee Cefic)
- FIBS, sustainability network in Finland
- Pharmaceutical Supply Chain Initiative, PSCI

# Our commitments to external initiatives

Orion is a member of the international **Responsible Care** programme, which is a voluntary environment, health and safety initiative of the chemical industry. The objective of the programme is to promote operations that are in line with sustainable development, from both social and environmental points of view. All participating companies are committed to continuously improving their health, safety and environmental performance and to developing their products and operations in a way that increases social well-being. The programme has participants in over 50 countries. The Chemical Industry Federation of Finland coordinates the membership of Finnish companies in Responsible Care, which reports on the performance on an annual basis at www.kemianteollisuus.fi/en.

We are also members of the Finnish **Energy Efficiency Agreement for Industries 2017–2025**. This is an extension period of the joint programme for the members of the Confederation of Finnish Industries (EK) that ended in 2016, with a goal of ensuring that the national energy efficiency improvement targets derived for Finland based on the EU Energy Efficiency Directive are reached. The programme also aims to significantly increase Finland's contribution towards achieving the EU-wide energy efficiency target set for 2030. Under the new programme, the savings target for 2025 is 7.5% of energy consumption in 2016, and the intermediate target is 4% for 2020.

Orion is a member of the **Pharmaceutical Supply Chain Initiative (PSCI)** and endorses the PSCI Principles, which set standards for suppliers in the areas of ethics, labour, health and safety and environment. PSCI is a group of pharmaceutical and healthcare companies who share a vision to establish and promote responsible practices that will continuously improve social, health, safety and environmental sustainable outcomes across the industry.

# We are a member of the FTSE4Good index

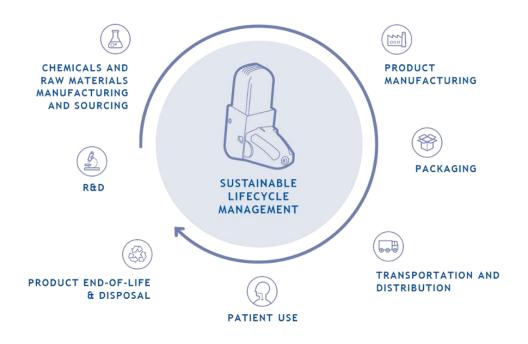
For a long time, the Orion Corporation has been included in sustainability indexes of companies listed on the Nasdaq Helsinki stock exchange (OMX Sustainability Finland GI, OMX Sustainability Finland PI, OMX Sustainability Finland Cap GI and OMX Sustainability Finland Cap PI).

We have been a member of the globally recognised FTSE4Good Index since 2016. The companies included in the index have been independently assessed to meet the FTSE4Good criteria. The FTSE4Good Index Series is designed to measure the performance of companies demonstrating strong environmental, social and governance (ESG) practices.



# Sustainable pharmaceutical product lifecycle management

Sustainability at Orion means balancing social, economical and environmental factors and is a principle built into our common values. We consider these aspects during the entire life cycle of a product - from research and development through to manufacturing to patient use and product end-of-life disposal.



## R&D

In our R&D activities, our commitment to building well-being means that we develop efficacious and safe medicinal treatments for unmet medical needs, representing innovation and the highest quality standards. We are committed to high ethical standards concerning pharmaceutical research and development.

We conduct environmental, health and safety risk assessments for all new products before manufacturing starts.

## Chemicals and raw materials manufacturing and sourcing

Suppliers are required to comply with Good Practices (GxP) requirements, and in addition to this, according to our Third Party Code of Conduct and Supplier Sustainability Requirements we expect our suppliers to demonstrate their commitment to sustainable and ethical practices. We only purchase our materials from suppliers whose qualifications we have confirmed. We conduct GxP audits into the operations of our GxP-critical business partners and suppliers. We always take and analyse samples of raw materials before approving them for production.

We manage and monitor our suppliers' environmental, health and safety (EHS) and ethical compliance as well. Our risk-based sustainability programme conducted 12 sustainability on-site audits in 2018. In 2018, we have made progress in further integrating sustainability into the processes and day-to-day activity in our procurement department. We also joined Pharmaceutical Supply Chain Initiative (PSCI) in 2018 to promote responsible practices and to share and learn best practices across the industry.

## Product manufacturing / own factories

We have identified the most significant environmental aspects for the Orion Group, and continuously improve our performance in this regard. Among other things, particular emphasis has been placed on continuously improving our wastewater handling and focusing on occupational health and safety at our own factories. We are also committed to reaching the energy savings target for 2025, which is 7.5% of energy consumption in 2016. This means a saving of slightly over 12 GWh,

40% of which was achieved in 2018. In 2018, we made the commitment to cut our scope 1 and 2 greenhouse gas emissions according to IPCC recommendations. This means reductions of 75% by the year 2025, using 2016 as the reference year.

Our products are manufactured using qualified production equipment in a controlled production environment using validated production and quality control methods to ensure that each batch fulfils predetermined quality specifications. The data integrity of all manufacturing and quality control activities is reviewed in detail before a batch is released to market. We take immediate action if any deficiency concerning product quality is detected.

## Packaging

We minimise waste through package design and optimise shelf life, package sizes and material flows. Optimising shelf life is of particular importance to ensure that all the resources needed in manufacturing, packaging and transportation are not wasted.

Safety is also an important aspect in packaging. Packaging plays an important role in protecting our products. We are implementing new safety measures, serialisation and anti-tampering features, to improve safety and traceability even further.

## Transportation and distribution

In logistics, we use specialist service providers to meet our strict quality and reliability requirements. Our partners have measures in place to reduce their own environmental impact.

### Patient use

We conduct continuous safety monitoring, collect customer feedback and carry out benefit-risk evaluations throughout the entire lifespan of a product.

We also provide healthcare professionals with clear information on the appropriate use of our medicinal products.

#### Case Easyhaler, dry powder inhaler

One example of our efforts for the environment is Easyhaler. For our dry powder inhaler, Easyhaler, one of the original development objectives was to create a propellant-free inhaler for environmental reasons. The Montreal Protocol in 1987 prohibited the use of ozone-depleting chlorofluorocarbon (CFC) propellants for inhaled products as in metered dose inhalers (MDIs). Since the Montreal Protocol came into force, the use of most ozone-depleting substances has either ceased or at least declined. CFCs were replaced by hydrofluoroalkane (HFA/HFC) propellants, and their use is still permitted in asthma medications. In MDIs, propellants are discharged during use and released after product disposal. HFCs are potent greenhouse gases with around 1300 times more global warming potential than carbon dioxide. And, the carbon footprint of single MDI products is still 10-20 times higher than dry powder inhalers. <sup>1</sup>Therefore, propellant-free inhalers have been a tool in the fight against ozone layer depletion but also in reducing the impact of climate change when in use.

## Product end of life & disposal

We make sure that waste materials from our own operations are appropriately treated. Medicines which have expired or which are no longer needed should be returned to pharmacies to be disposed of appropriately, and packaging materials should be taken to dedicated collection points for recycling. Guidance on the proper disposal of pharmaceutical waste may be accessed on our webpages at www.orion.fi/sustainability. For additional and local information it is advisable to consult your pharmacy, as medication disposal schemes, in order to prevent pharmaceuticals from ending up in the environment, may vary from country to country.

<sup>&</sup>lt;sup>1</sup> Montreal Protocol on Substances that Deplete the Ozone Layer, Medical and Chemicals Technical Options Committee, 2018 Assessment Report, UN Environment

# Pharmaceuticals in the environment

While we treat our industrial wastewater in a highly developed process, we also invest in environmental responsibility throughout the products' life cycle in many other ways. The goal is to keep nature free from pharmaceutical residues.

Pharmaceuticals may end up in the environment in various ways, due to effluents from manufacturing facilities, medicines consumed by patients and then excreted, and the improper disposal of unused and expired medicines.

#### Pharmaceutical residues in the environment

It is estimated that 88% of pharmaceutical residues result from the general use of pharmaceutical products. 10% of pharmaceutical residues result from the improper disposal of expired and leftover products.

Just 2% of pharmaceutical residues result from production.

Evaluating the potential environmental impact of our products starts in the product development stage. We conduct an environmental risk assessment on all new products to identify any risks that the substances included in the products could cause if released into nature, and ways to prevent these risks in our own operations. We are constantly assessing the environmental impacts of our manufacturing activities, and green chemistry is the aim when manufacturing active pharmaceutical ingredients, for example. Shortening and lightening the various stages of work also reduces the amount of chemicals used.

Reducing the environmental impact from the production of pharmaceuticals and controlling risks at the original source is also important. Orion has succeeded in reducing its pharmaceutical residues from production significantly by developing its wastewater management system. The process is currently based on a separate drainage system. In the system, wastewater containing compounds unsuitable for a biological treatment plant or which are otherwise hazardous to the environment is separated from the rest of the wastewater. A new wastewater classification system is the key, and the high-risk wastewater is directed into special tanks and treated as appropriate. The extra water is evaporated as energy-efficiently as possible, and the residues are incinerated in the same furnace as other hazardous waste. Only the ashes remain.

Being responsible does not just mean continuously improving our own operational site processes but also being committed to rigorously managing and monitoring the sustainability of our global supply chain. We ensure that materials are only purchased from responsible suppliers with strict requirements set by us. Pharmaceuticals in the environment is one of the criteria which is considered in the procurement process. We do this through assessment questionnaires, by undertaking risk-based sustainability audits, and by ensuring that necessary corrective action is agreed upon with suppliers and followed up afterwards. Further information about our responsible supply chain management is available in the *Managing the sustainability of our suppliers* section, and the results of the sustainability audits conducted in 2018 is available in the *Performance indicators of Product Responsibility* section.

In addition, packaging matters, those working with package design take the size of packages and the shelf life of products into consideration to reduce the amount of unused or expired medicines. The packaging also contains instructions for the proper disposal of medicines.

Our top priority is to provide patients with the right and safe medicines in the right way when they need them. Our sales staff and other personnel advise health care professionals to ensure that products are used correctly, but also to advise them, for example, to start new medicines with smaller packages. We can use our influence to encourage the responsible use of medicines and reduce the amount of drug waste.

Expired or leftover products should be returned to the pharmacy to be disposed of properly. Improper disposal will create a major environmental load, which is why Orion also wants to have an impact on this phase of a product's life cycle as well. Orion tries to increase consumer awareness on the matter in a number of ways. In terms of consumer awareness, Orion cooperates with pharmacies and other health care professionals, and in 2018 we added a detailed guide to proper disposal to our webpages. In addition, Orion is the main partner of John Nurminen Foundation's Clean Baltic Sea projects in 2018-2019.

#### Our efforts in the fight against antimicrobial resistance

Antibiotics are life-saving medicines and the cornerstone of managing bacterial infections. Unfortunately, antibiotics are widely overused and misused in both people and animals. Inappropriate use of antibiotics leads to antimicrobial resistance (AMR). As a result, antibiotics become ineffective and curing previously treatable infections becomes difficult. The World Health Organisation characterises AMR as one of the biggest threats to public health in the world today.

Antibiotics are widely overprescribed in primary healthcare in particular, where more than half of all patients with acute respiratory tract infections are treated with antibiotics. Most acute respiratory tract infections are caused by viruses and antibiotics are not needed to cure them. Antibiotics should only be prescribed when a bacterial infection is suspected. Limiting unnecessary antibiotic prescriptions in primary healthcare settings is an important step in reducing bacterial resistance to antibiotics.

Our goal to keep nature free from pharmaceutical residues and our efforts to achieve this also naturally apply to antibiotics as well. In addition to our efforts to keep pharmaceutical ingredients out of the environment, we also have an interesting product on the market.

For poultry, Orion's portfolio includes Broilact®, a unique Competitive Exclusion (CE) product providing a refined selection of bacteria that establish and develop a healthy adult-type microflora in the intestines of chickens, turkeys, geese, pheasants, quails and partridges. Increased awareness and the restrictions on antibiotic use in poultry have increased the interest in this commercially available CE product.

# Product responsibility - ensuring patient safety and product availability

Patient safety is the guiding value in all Orion's operations and the essence of our corporate responsibility. Responsibility and caring are an integral, uncompromised and natural part of everything we do at Orion. The responsibility of the manufacturer for the safety, quality and uncompromised compliance with requirements extends through all the phases and functions included in research and development, procurement, manufacturing, marketing and communications. The legal and regulatory requirements of healthcare authorities, the primary purpose of which is to ensure patient safety, guide our activities in everything we do. In addition to this, we also follow the commonly agreed codes of harmonised practices applied by our industry internationally.

Our basic mission is to build sustained well-being by providing efficient, safe and competitive products for the prevention and treatment of illnesses and their symptoms. We promote health and quality of life with our products and by sharing guidance to consumers and healthcare professionals on the correct and proper use and storage of the products. The complementary education and training we offer to healthcare professionals, in particular to doctors and nurses as well as to pharmacy staff, also falls within the scope of product responsibility, as does our support given to patient organisations.

As a pharmaceutical company, we must ensure that the drugs and active pharmaceutical ingredients developed, manufactured and marketed by us are proven to be safe for their users, effective for the indications for which they are approved, and that they meet the quality requirements set for them as well as the needs of the customers and patients.

It is important from the point of view of our product responsibility that the information about a medicinal product we share to doctors, pharmacies and patients is in accordance with the product characteristics confirmed for it by regulatory medicinal authorities on the basis of the results of the research and the data collected in clinical use. It is also important that we provide the necessary guidelines for taking and storing the product correctly.

The guiding principles of the quality standards of our entire supply chain are based on full compliance with the EU-regulated good operating practices in manufacturing, laboratories, and R&D, and the efficiency and fluency of processes and product safety and the consistent quality and high reliability of delivery. As our products are also sold outside the EU, we make sure that our operations are compliant with the good practices applicable in those countries.

In our pharmaceutical research and development operations we follow the relevant legislation, the relevant regulatory authorities' instructions and guidelines and the principles determined in our <u>Pharmaceutical R&D Ethics Policy</u>, which conforms to the Helsinki Declaration, and the common, internationally adopted codes of our industry.

As the manufacturer and the marketing authorisation holder, we are responsible for the quality and safety of our products. The Finnish Medicines Agency Fimea is the authority that inspects pharmaceutical and active pharmaceutical ingredient (API) plants and contract manufacturers in Finland according to the Pharmaceutical Products Act, also on behalf of the authorities of other EU member states. The recent Mutual Recognition Agreement (MRA) between the USA and the EU provides a possibility for the FDA in the USA to also rely on inspections performed by Fimea. Moreover, healthcare authorities from many other countries continuously supervise our operations. The supervision and inspections also cover the pharmacovigilance and the operational premises, the R&D operations, as well as those products for which we act as a distributor when the marketing authorisation is held by another pharmaceutical company.

## Management of product responsibility

The basics of the management of our product responsibility are determined in the Quality Management System to ensure that each product batch released for sale is in accordance with the marketing authorisation, and based on this we continually monitor safety throughout each product's life cycle. We systematically follow the outcomes of the quality and safety monitoring, and in events which cause concern we instantly carry out the necessary procedures to ensure patient safety.

#### Management of pharmaceutical product responsibility

The management of product responsibility concerning pharmaceuticals is arranged as follows:

- Chief Medical Officer (CMO) is an experienced senior physician carrying the primary responsibility for the Company's medical governance and medical ethics. The CMO is responsible for the safety of our study programmes, the assessment of medicinal benefit/risk balance and activities related to them. The CMO shall always prioritise the benefit for the patient. The CMO reports to the Senior Vice President, R&D, who is a member of the Orion Group's Executive Management Board.
- The Global Medical Affairs, headed by the Vice President, CMO, Medical Affairs & Pharmacovigilance, in collaboration with the global marketing and sales organisations, is responsible for our compliance with the legal requirements concerning the marketing of pharmaceuticals in all those countries where Orion is present. The Global Medical Affairs reports to the Chief Medical Officer.
- Qualified Person responsible for pharmacovigilance (QPPV) is responsible for the establishment and the maintenance of the pharmacovigilance system of the marketing authorisation holder, as provided in EU Directives 2001/83/EU and 2001/82/EU and, accordingly, in Section 30 of the Finnish Medicines Act. The QPPV shall act as a contact point for the regulatory authorities on a 24-hour basis for safety related issues. The QPPV in Orion is Director, Global Drug Safety, who reports to the Chief Medical Officer. The duties of the QPPV include the responsibility of our operational compliance with the international regulatory requirements concerning the monitoring the safety of medicines, regulatory reporting and actions related to the management of patient safety risks.
- The Accountable Director is, as provided in Section 9 of the Medicines Act, primarily responsible for ensuring that our medicinal products are manufactured in the correct way and that the quality requirements are met. The Medicines Act requires that the pharmaceutical company's quality organisation must be independent of production. This independence has been organised in the Orion Group in such a way that the Vice President, Quality Management, holds the position of the Accountable Director and reports directly to the President and CEO. The VP, Quality Management, is responsible for the compliance of our Quality Management System with the requirements of international regulatory authorities as well for the quality assurance and control of our products. In compliance with the Medicines Act, Fermion also has an accountable director who reports to the President of Fermion.
- Before any batches of medicines produced are released for sale or for clinical trials, the socalled **Qualified Person** (QP) in our Quality Assurance organisation checks the documentation and analytical results of all batches. The produced batch can only be checked by QP, who is legally qualified as determined in EU Directive 2001/83/EU and in the Finnish Medicines Act. QP's commonly have a Master's degree in pharmacy and they are required to have experience in the pharmaceutical industry. QP ensures and confirms that a batch of medicine has been manufactured in accordance with the marketing authorisation and that Good Practices has been complied with in manufacturing (GMP). Active pharmaceutical ingredient (API) batches are released for sale by independent Quality Assurance departments at each of Fermion's production sites.

Tasks related to product responsibility are performed in cross-organisational working groups consisting of persons with a broad range of skills and competences necessary both in the product development phases and in commercial manufacturing.

The basis for the quality of a medicinal product and an API is built into the course of the research and development phases. The manufacturing methods and equipment are determined during these phases, as are the requirements for the raw materials and the product. Industrialisation is included as an elementary part in the product development phase, the purpose of which is to make sure that the manufacturing methods are applicable on an industrial production scale and that each production batch corresponds to the product described in the marketing application.

In terms of quality, it is irrelevant where the product is manufactured under Orion's marketing authorisation, as Orion is equally responsible for all products. We purchase our materials from suppliers whose qualifications we have confirmed. Audits of their manufacturing sites are important steps in the process of selecting and monitoring our raw material suppliers, as well as in ensuring the continued availability and consistent quality of the raw materials and the traceability of the documentation. In the qualification process for API suppliers, we also audit the manufacturers of the intermediate materials used in the manufacturing process of the API.

Each batch of raw material is sampled, analysed and released for use by our Quality organisation before use in production. Packaging materials and the printed packaging information are also checked accordingly. In-process samples are taken during the manufacturing process to ensure the consistent quality of the product. Samples are taken and analysed of each manufactured batch, and the documentation of the batch is checked before it is approved for sale. In the approval process, we check that the batch has been manufactured in accordance with the marketing authorisations granted for the product by the authorities in different countries and that all the results of the analysis meet the requirements confirmed in the authorisations. When releasing products for sale, we use even stricter internal quality criteria in order to ensure the required quality throughout the entire shelf-life of the product. With the help of the batch documentation, all the materials and the phases of manufacturing, quality control, transportation and distribution can be traced without gaps. This traceability is important if there is reason to find out if a potential manufacturing deviation from the specification has occurred. We also follow the stability of each product in stability studies through the labelled expiry date of the product.

The quality management procedures for APIs are described in the control strategy. The quality control methods are established at an early stage when the multi-staged manufacturing process is being developed, whereby the purity profile and the corresponding quality requirements for the ingredient are determined. The quality of the active ingredient is monitored throughout the manufacturing process, and all batches are analysed before they are released for sale.

Patient safety is a fundamental priority and a core value at Orion. We work to ensure the safety and the optimal benefit/risk balance of our products throughout their lifecycles. We maintain a pharmacovigilance system required by legislation and regulatory requirements to monitor the safety of our medicines and to implement timely and effective risk mitigation actions when appropriate to ensure the safe use of our products and patient safety.

All customer complaints concerning our products are assessed, and the root causes are investigated. Centralised handling of the complaints enables us to form an overall picture based on the complaints concerning a single product over its entire life cycle, covering all phases from R&D until the end of its sales. This procedure also facilitates the assessment and follow-up of the impacts of corrective and preventive action.

#### Pharmacovigilance

Pharmacovigilance is a science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other drug-related problems. Our duty is to monitor the safety of our medicinal products throughout their lifecycles right from the early phases of R&D until the product is no longer available on the market. Several functions of the Company are involved in the pharmacovigilance processes coordinated by the Global Drug Safety organisation, which is a headquarter function. Appropriately qualified and trained experts are responsible for assessing and carrying out the activities related to managing the benefit/risk balance of the products. Our pharmacovigilance operations and Quality Management System are compliant with international regulatory requirements and guidelines. All data concerning the safety of our products is collected into a single point for assessment, continuous monitoring and reporting. In addition to the data collected from clinical trials, the information which is monitored includes spontaneous reports and feedback from healthcare professionals, literature, regulatory authorities and patients about any adverse effects, medication errors, interactions and overdoses, for example. The core activities in the pharmacovigilance operations also include risk management plans, safety reporting to healthcare authorities, various periodic safety reviews and internal audits of pharmacovigilance activities. Orion prepares a Risk Management Plan (RMP) for all new medicines, which describes what is known and not known about the medicine's safety and states what measures will be taken to prevent or minimise its risks. The authorities approve the RMP, and the measures agreed in the RMP are implemented when the product is placed on the market. The measures are product-specific and can include e.g. additional materials or educational programmes for health care professionals to ensure the safe and correct use of the product or e.g. Post Authorisation Safety Studies (PASS) to obtain further information on a medicine's safety, or to measure the effectiveness of risk management measures. RMP is continuously maintained throughout the life cycle of the product.

Orion collects safety information on e.g. adverse effects worldwide and reports it to the relevant regulatory authorities. Both Orion and the regulatory authorities continuously evaluate the information to detect safety signals that might affect the benefit-risk balance of the products to identify any emerging safety issues at an early stage. In addition to continuous signal detection procedures, Orion periodically reviews the cumulative data. Periodic Safety Update Reports (PSURs) are prepared and submitted to the regulatory authorities. In the PSUR, all available safety information and the benefit-risk profile of the product are thoroughly evaluated and e.g. changes to the measures described in the RMPs or other risk minimisation measures will be proposed if necessary.

We work in continuous collaboration with authorities in evaluating the safety of our products and on the balance between risks and benefits. When necessary, we take action to ensure patient safety and to ensure that our medicines are used correctly and safely. Such action may include, for example, updating the information provided in the Summary of Product Characteristics and the Package Leaflet, communicating information to healthcare professionals or providing training, adding, e.g., contraindications or precautions and warnings to the medicines, or discontinuing sales. The possible action is always taken in a controlled manner in collaboration with healthcare authorities.

#### Audits help to ensure operational quality

Manufacturing and sales of medicines and APIs are subject to certain regulatory permissions. During the authorisation procedure, the regulatory authorities have ensured that Orion has the appropriate qualities for the operations and that each drug released by Orion meets the specified requirements. The regulatory authorities for pharmaceuticals (Fimea in Finland) monitor and assess our research, supply chain and pharmacovigilance operations by means of regular inspections. In these inspections they also assess the effectiveness of the procedures we have in place for the follow-up and processing of adverse effects and complaints, and our readiness to withdraw a product from the market.

The inspections are conducted in the name of the medicinal authorities of the EU and other countries in the so-called PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Scheme) collaboration, which covers 49 countries. In addition, our operations are regularly monitored and inspected by authorities representing non-PIC/S countries. The recent Mutual Recognition Agreement between the EU and the USA enables the FDA to rely on inspections performed by EU authorities.

First, however, we take our own initiative to proactively ensure and monitor the adequacy and compliance of our operations and facilities by means of internal control. We carry out systematic audits and management reviews of our own operations and we continuously develop our internal procedures.

In addition to the authorities, our customers, partners and contract manufacturing principals also assess our ability to operate in compliance with the regulations and the commitments agreed in the contracts. In their inspections and audits they check the adequacy and regulatory compliance of our operations and facilities for our supply chain and R&D of pharmaceuticals and APIs.

Correspondingly, we in turn monitor the adequacy and regulatory compliance of our subcontractors, suppliers and other collaboration partners. In addition to assessments based on written enquiries, we carry out on-site audits of their facilities to make sure that the external parties involved in our supply chain, R&D and distribution meet the regulatory requirements and obligations mutually agreed upon in the collaboration contracts. We also follow up and monitor the fulfilment of the action to correct the shortcomings identified in the audits.

#### We withdraw the product in the event of defects

Sometimes we need to recall product from sales. A signal of a quality defect may come from many parties, but in all cases, the Orionees in different functions and organisations come together immediately to take prompt action to investigate the case and find out the root cause. Recalls and withdrawals are always agreed together with the authorities. Medicinal products and APIs which do not comply with their specifications and which may cause harm to their users will immediately be recalled from sale and distribution, and from consumption if necessary. Depending on the seriousness of the case, the product is either withdrawn just from the wholesalers and retailers or also from the patients as well. Similar measures are taken if there are deficiencies in the integrity of the data in the manufacturing documentation. We instantly report the events to the relevant regulatory authorities in all countries where the product is sold.

We have internal processes in place to support the prompt and proper initiation of recalls, prompt and accurate communication and efficient processing in such cases. The recall can be initiated at any time of the day if necessary. We also regularly test the efficiency and functionality of our recall procedures. All employees of the Orion Group are obliged to inform the local person responsible for pharmacovigilance about any adverse effect events they have become aware of. In addition, our phone operators have been trained to forward any queries requiring urgent action to the attention of our experts even outside office hours.

In 2018, our call center activities were further developed to increase flexibility and to meet various customer needs. Since January 2018, customers have also been able to contact the Orion call center and talk about their products with experts at the weekends and outside office hours, and ask about Orion's products or report any adverse events or make a complaint about products when needed. The call center is open every day of the year between 8 am and 10 pm. 24-hour reporting is also made possible using easily accessible reporting and contact forms on our web pages. Web pages and forms have been further developed to ensure easy use and to comply with GDPR related requirements.

#### Product availability - ensuring a reliable supply of medications

Orion aims to maintain a high level of service at all times. During autumn 2017, Oriola, our pharmaceutical warehousing and distribution service provider, faced challenges with implementing SAP. In an unexpected and exceptional situation, the Orionees at all levels of the organisation worked seamlessly to secure the distribution of medicines. Domesticity was an advantage, being able to deliver the products directly from our own warehouses. Orion also appointed alternative distribution channels in Finland in order to secure the availability of Orion products on the Finnish market. We continued the multichannel distribution in Finland throughout 2018 and will continue in 2019.

#### Serialisation and anti-tampering features improve patient safety

Falsified medicines are often disguised as authentic medicines, but may contain ingredients of substandard quality or may be in the wrong dosage. As the falsified medicines have not been checked for quality, safety or efficacy, they can pose a risk to public health. Falsified medicines are an immense global challenge. In Europe and Finland, falsified medicines are not a significant problem yet, but with the EU Directive, preventative action is being taken ahead of time.

To prevent the entry of falsified medicinal products into the legal supply chain and thus improve patient safety, the EU Falsified Medicines Directive will take effect on 9 February 2019 across Europe. Regulation requires that medicines released for sale after 9 February 2019 contain certain mandatory safety features - serialisation and anti-tampering features on the pharmaceutical packaging. Serialisation requirements are already in force in many countries, for example in China, the USA, South Korea, Saudi Arabia and Turkey.

Serialisation across the European pharmaceutical market means that all individual prescription medicines must be traceable throughout the chain. In practice, all pharmaceutical packaging must include a unique identifier so that a sales package can be traced all the way back to the production

plant and production line. The EU Directive concerns all prescription medicines for human use, therefore non-prescription medicinal products and veterinary medication do not come under the Directive. In addition to including a serial number and a product code, prescription medicine packaging is sealed, so that the customer can be sure that the packaging has not been opened.

Orion has been preparing for the serialisation requirements for several years. All Orion packaging lines have been updated in order to comply with the Directive, and the whole supply chain has been successfully verified. New serialised products are being manufactured continuously, and in order to test the system gradually Orion started delivering serialised products to pharmacies well before the end of 2018. We will continue to implement this regulation, and ensure our products comply with it and similar existing and upcoming requirements in other markets.

# Information about a medicine can only be shared based on the product's marketing authorisation

Pharmaceutical products may only be sold and used under a product-specific marketing authorisation granted by a pharmaceutical regulatory authority, and using the facts provided in the Summary of Product Characteristics (SPC) confirmed for the product as part of the marketing authorisation. A marketing authorisation is granted and maintained valid for products which are safe to use for their indicated purpose, are proven to be therapeutically effective, appropriate for use as drugs, meet quality requirements and are appropriately manufactured and labelled. The authorisation also defines the product's indication, i.e. the purposes for which the medicine can be used.

The product-specific Package Leaflet (PL) must be found in every single retail package. Pharmaceutical legislation and regulatory authorities require that for products classified as drugs, the pharmaceutical company may only provide information which is contained in the SPC. The product information leaflet in the package contains the main facts about the drug and its use as approved by authorities. The drug and health authorities maintain national and international drug databases, which contain up-to-date information for every product with a valid marketing authorisation. The information and arguments presented by the manufacturer and/or the marketer in any communication about the product Information for the valid marketing authorisation.

In the EU, pharmaceutical companies are not allowed to communicate information about prescription drugs directly to consumers. Instead, this is the responsibility of healthcare professionals such as doctors and pharmacies, as well as healthcare authorities. Marketing self-medication products directly to consumers is allowed under strictly regulated conditions.

We also aim to look after patient safety by sharing accurate and up-to-date information about the use, storage and safety of our products via our own marketing and corporate communications channels to the extent permitted by law and the commonly adopted industry codes.

For the sale of an API, Fermion shall provide its customers with registration materials (DMF, AFMF, CEP<sup>2</sup>) approved by regulatory authorities which form part of the marketing authorisation documentation concerning the medicine in which the API acts. For each batch, the customer shall receive the related supply documents, an analysis certificate and a safety data sheet concerning the substance. All packages are labelled with warning signs and information allowing it to be traced.

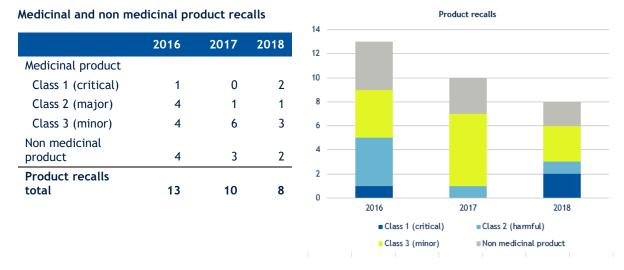
#### Complementary references in the Sustainability section of our corporate website:

<u>Code of Conduct</u> <u>Supplier requirements</u> <u>Our practices in approving suppliers</u> <u>Quality Policy</u> <u>Anti-corruption Policy</u> <u>Pharmaceutical R&D Ethics Policy</u>

<sup>2</sup> DMF Drug master file AFMF Active substance master file CEP Certificate of suitability

## Performance indicators for product responsibility

The units of the Orion Group have determined objectives for the quality levels of their products. Our main metrics are product recalls due to quality defects and critical observations reported by third parties in their inspections and audits of our operations. We want to demonstrate an uncompromised level of quality and performance in our operations as standard. We also actively follow up and process the feedback from customers and consumers and use it as a basis for managing our operations, although we have not included it in our sustainability reporting.



Defects identified in medicinal products are classified as critical, major or minor, depending on the degree of severity.

**Class 1 (critical):** product defects that are or may be life-threatening or pose a serious health hazard to users.

**Class 2 (major):** product defects which may be harmful to the users or may affect medical treatment but which are not included in Class 1.

**Class 3 (minor):** product defects which are not likely to pose a significant health hazard to the users, but where the removal of the defective product from the market is otherwise justified.

The trend for recalls has been declining over the past five years. Some years ago, the main reasons for recalls were related to product stability; several actions have been taken to ensure that each product batch released to market will fulfil all their requirements until the expiry date.

Two class 1 recalls were performed. The first concerned particles in the vials, batches of which were recalled from pharmacies and hospitals. The second recall was due to an API (active pharmaceutical ingredient) manufacturer, who detected a previously unknown impurity generated during the chemical synthesis of the API. This initiated a global process between regulatory authorities and pharmaceutical companies in order to evaluate chemical synthetic ways of manufacturing similar substances. Orion recalled the product from pharmacies and hospitals, and has taken further action to eliminate the root cause.

One class 2 "major" recall of a medicinal product concerned one batch. The product defect was due to a damaged filling needle that caused a deviation during the filling of the product. Three medicinal product class 3 "minor" recalls were either due to an error in the text in the leaflet or secondary packaging. The third recall was due to an error in the SAP system that was instantly fixed.

In addition to the medicinal products, two non-medicinal products were also recalled. Two recalls were due to an error in the text in the secondary packaging.

In the operations and functions of our Supply Chain organisation, major development programmes are underway to prevent product defects. Improvement measures taken in the different phases of

the pharmaceutical manufacturing processes have shown good results, which are already reflected in our indicator listing the number and severity of product defects. They also result in an improved reliability of deliveries and customer satisfaction, as well as a lower number of rejected production batches and thus a reduced amount of hazardous waste and lower manufacturing costs.

The purpose of the Top Supply Chain project, the reason behind our improved performance, is to analyse the root causes of non-conformities, to implement corrective and preventive action on a large scale, and to perform all tasks right first time, which improves both product quality and productivity. Our purpose is to achieve a straightforward process, in which unnecessary work is minimised and people are aware of their role and responsibility for the outcome.

	2016	2017	2018
GxP and other audits by authorities	12	16	12
EHS audits by authorities	0	3	1
GxP and other audits by partners	43	59	46
EHS audits by customers and partners	0	3	2
Audits total	55	81	61
Critical observations	0	0	0





In the inspections conducted into our sites and operations by medicinal authorities and our business partners, the investigators primarily check our compliance with the Good Practices (GxP) requirements, i.e. manufacturing (GMP), distribution (GDP), laboratory (GLP), clinical (GCP) and pharmacovigilance (GVP). Partners in particular are also paying increasing attention to the management of EHS affairs, i.e. the level of environmental protection and occupational health and safety. Some are also paying attention to issues on labour and ethics.

The observations made in inspections and audits related to the Good Practices requirements are classified as either critical, major or minor based on their level of severity. The investigator may also recommend better procedures, instead of ones already adopted that may still be acceptable.

**Critical:** The practice involves a high risk to drug safety and/or drug quality. An essential violation of Good Practices.

Major: The practice may incur a risk to the safety or quality of a drug. Incompliant with Good Practices.

Minor: Drug safety is not compromised. A minor non-conformity with Good Practices.

Recommendation: The practice is compliant, but an improvement is recommended.

In the sustainability (i.e. environmental, occupational health and safety, labour and ethics) audits, observations are also classified as critical, major or minor based on their severity.

**Critical:** The observation is currently causing serious and immediate risks in terms of sustainability performance, or the observation violates essential laws and regulations.

**Major:** Unless managed properly, the observation may cause a serious risk in terms of sustainability performance.

Minor: Minor issues with no serious risks in terms of sustainability performance.

Authorities conducting GxP inspections mostly represent healthcare authorities, such as Fimea in Finland and the FDA in the USA. The inspections of our pharmaceutical formulation and active pharmaceutical ingredient sites focus on the regulatory GMP, GDP, GCP and GVP compliance. In 2018, a total of 12 (16) inspections were made and no critical observations were recorded in the inspections.

Our business partners, mainly customers, marketing partners and contract manufacturing principals, made a total of 46 (59) GMP audits, both at pharmaceutical formulation and active pharmaceutical ingredient production sites. No critical observations were recorded in the audits.

Inspections by third parties are a part of daily life at pharmaceutical companies, and as a matter of principle we are ready to welcome an auditor into our premises at any time. Every inspection is different depending on the kind of criteria the inspecting organisation works with. The inspectors also have different ways of working. It is quite normal for minor defects to be observed. After the inspection, the auditor is especially interested to see how the shortcomings that have been observed are amended and how they are prevented from recurring. As a rule, we take immediate action to correct even the most minor defects straight after each inspection. When planning corrective action, we also check to see if a corresponding defect can also be identified at other locations, regardless of where it was detected. The corrective action is documented in detail and reported to the organisation which carried out the audit.

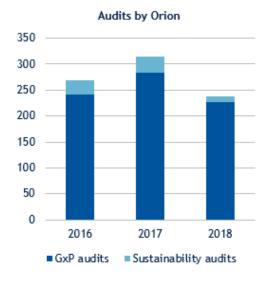
The observations made by inspectors may take some time to amend, which may cause delays to our production programmes. In the estimates concerning short-term risks and uncertainties, Orion's management points out accordingly that our broad product range may pose risks to the reliability of deliveries and make it challenging to maintain the high quality standards required in production. Any remedial action that may be required may at least temporarily have effects that reduce the reliability of deliveries and increase costs. Our product range also includes products manufactured by other pharmaceutical companies. Possible problems related to the delivery reliability of the products originating from those manufacturers may cause a risk to our reliability of deliveries.

In addition to the GxP audits made by authorities and our partners, we also conduct regular internal audits at all our manufacturing sites in accordance with annual plans. The purpose of these audits is to make sure that operations are compliant with the regulatory requirements and meet the levels defined in the Quality Handbooks. In the internal audits, we evaluate our operational quality with the eyes of an independent external auditor. Similarly, we conduct also internal EHS (environmental, occupational health & safety) audits on an annual basis.

#### conducted by Orion 2016 2017 2018 GxP audits 241 284 226 19 Critical observations 16 9 Rejections 5 4 1 Sustainability audits 28 30 12 Critical observations 13 7 1 Rejections 0 1 0

Audits of the operations and sites of material and

service suppliers and contract manufacturers



In our own GxP audits into our suppliers and other business partners, we apply the same severity classification as is used by authorities and our partners when evaluating the results of their GxP inspections into our operations.

Although we have selected our business partners using strict GMP and sustainability criteria, and regulatory authorities have audited them to confirm their compliance with GMP, we consider it important to check the eligibility and approvability of our existing partners and supplier candidates by carrying out regular surveys and audits.

Like in previous years, most of the 226 GxP audits we conducted in total in 2018 were carried out into operations of our GxP-critical business partners and suppliers, such as API manufacturers, suppliers of raw materials and other materials, contract manufacturers and organisations providing clinical research services to us. Although the number of critical observations has been declining over the years, the importance and necessity of on-site audits remains.

From time to time, GxP audits result in a rejection due to severe observations recorded in audits. Strong justifications for a rejection would be, for example, the risk of cross-contamination and severe defects in the quality management systems, validation, documentation and data systems.

Sustainability audits are a tool that we use to manage and monitor a supplier's EHS and sustainability compliance. We also ensure that any necessary corrective action is agreed with the supplier and monitor that the action is implemented.

During the course of the year, we widened the scope of our sustainability audit program from EHS to sustainability. In the on-site audits, we also pay more attention to topics such as labour and ethics. In 2018, we conducted sustainability audits at 12 sites in India and China, and recorded one critical observation. Typical critical observations would be, for example, fire and explosion safety, issues with permits and licences as required by local authorities, as well as findings related to employee working hours. Although the amount of critical observations have decreased over the years, the results of our sustainability audits of the sites of Indian and Chinese suppliers in particular still suggest a need to further develop environmental and occupational health and safety at workplaces in these countries, where the suppliers for the pharmaceutical industry are increasingly located. Over the years we have also developed our system of categorising audit findings, therefore it is to be noted that the years under report are not directly comparable.

# Environment - manufacturing products on an environmentally sustainable way

# Management of environmental affairs

Our responsibility as a company is to recognise and manage our impact on the environment and drive the reduction of our business's environmental burden. Orion's environmental, health and safety (EHS) policy defines the Group-level commitment on how we manage environmental matters and promote the well-being of our workforce. Our EHS Management System for managing, monitoring and developing environmental matters also comprises energy efficiency, process safety and occupational health and safety. The EHS Management System ensures effective management and compliance with valid legislation and with other regulations and requirements concerning our operations. The environmental management system is built upon the principles set out in the ISO 14001 environmental standard. In the development of energy efficiency, we apply the principles of the ETJ+ energy management system and practices consistent with the ISO 50001 standard. In the management of occupational health and safety, we apply OHSAS 18001 guidelines and the ISO 45001 standard that will replace the former one. The management of EHS matters is monitored through annual internal audits. We are committed to continuously improving our performance in environmental, health and safety matters and strive to achieve the high objective we have set for managing them.

### Environmental aspects, impacts and continuous improvement

We are committed to manufacturing our products in an environmentally sustainable way. We have identified the most significant environmental aspects for the Orion Group and its businesses. These relate to the consumption of raw materials, energy and water, emissions into the air and wastewater, and the amounts of waste arising from the operations. Orion's most significant environmental aspects and the related approaches to continually improve our performance in them are as follows:

Environmental aspect	Our approach	Target	Achievements in 2018
Material efficiency	We know the most central material flows in our production operations.	Less hazardous waste per total	Share of hazardous of total waste
	We identify the items in need of development in order to minimise our waste flows. We forward our recyclable surplus materials for further recovery. We manufacture our products right the first time. We reduce the proportion of hazardous waste in our total waste.	waste	Orion Group: 81% Progress against 2016 baseline: increased 4 p.p. to 81% (inc. wastewater collection) Turku factory (exc. wastewater collection): decreased 8 p.p. to 22% Kuopio factory: decreased 10 p.p. to 27%
Wastewater management	We know the quality of our wastewater. We reduce the environmental burden on waterways caused by our operational sites by minimising the residues of harmful chemicals in our wastewater.	Reducing the environmental burden on waterways by reducing the residues of harmful chemicals in our wastewater	In 2017, new pre-rinse water collection systems were set up at our production sites. Continuous work based on risk assessments to ensure the separation of wastewater streams that include non- biodegradable or otherwise environmentally harmful substances and to treat them following BAT reference documents.

Environmental aspect	Our approach	Target	Achievements in 2018
Energy efficiency	Our target is to improve the efficient use of energy and reduce our energy consumption by applying practices determined in our Energy Management System. We are committed to the extension period of the joint Energy Efficiency Programme for the members of the Confederation of Finnish Industries (EK).	Energy savings target for 2025 of 7.5% and the intermediate target for 2020 of 4% of energy consumption in 2016 For Orion, this means a saving target of slightly over 12 GWh.	Energy savings achieved by saving measures and efficiency improvements of 1,074 MWh 40% of Energy Efficiency Programme's energy savings achieved
Emissions into air and climate change	We contribute towards the prevention of climate change by reducing our greenhouse gases, CO <sub>2</sub> e and volatile organic compound (VOC) emissions.	Greenhouse gas (GHG) reduction target for 2025 -75% against our 2016 baseline (scope 1 & 2 emissions)	Set and agreed upon Orion's GHG target. Emission reductions made through energy efficiency program. GHG reduction of -11% against 2016 baseline <sup>1</sup>

<sup>1</sup> Some of the GHG reduction in 2018 is due to the sale of Orion Diagnostica. In 2017, energy consumption in Orion Diagnostica constituted 5% of the Orion Group's total energy consumption.

We continuously monitor matters related to the environment, among other things by measuring emissions, monitoring the amount of waste and compiling statistics on the use of resources.

Measuring our performance is vital in managing sustainability and in monitoring the development. Monitoring and reporting our environmental performance for some items is obligatory based on requirements specified in the local and site-specific environmental permits. More importantly however, gathering data and assessing indicators is a tool for us to monitor and improve our own performance.

We aim to reduce the burden on the environment caused by our operations by implementing programmes and measures. We plan, choose, buy and invest while predicting and considering the environmental risks and impacts of our solutions. The core principle behind this is material and resource efficiency: achieving more with less. To be successful, we manufacture our products right first time and use our resources – materials, labour, energy, water, time and money – as wisely as possible. In doing so, we also create a substantial economic benefit.

In addition to our activity programmes, we encourage the achievement of good results by keeping our processes up to date, investing in improved process technology and methods, and a more efficient use and handling of chemicals and other manufacturing materials.

Environmental investments are made at our operational sites on an annual basis, either with the primary purpose of reducing our environmental burden or as part of major upgrading and replacement investments carried out in accordance with the Group's long-term investment plans. In 2018, a significant milestone was reached, as a new production unit of over EUR 30 million was completed for the factory in Hanko. An investment in a new API manufacturing facility was made to meet both increasing global demand and the tightening requirements on quality, safety, the environment, and occupational health in the pharmaceutical industry. In this new efficient production unit, active pharmaceutical ingredients (APIs) can be made in very highly automated and closed process with state-of-the-art technology. The new, modern factory unit meets the

increasingly strict quality and regulatory requirements including safety and purity requirements. Primarily, the facility is dedicated for manufacturing the APIs for our proprietary medicinal products and increases the total API production capacity of our Hanko site to about 300 tonnes.

#### Legal and other environmental requirements

Elementary legislation to be attended to in the management of environmental affairs includes that concerning environmental protection, waste, chemicals and energy.

We produce pharmaceuticals and active pharmaceutical ingredients (APIs). All of the Group's production plants are in Finland, and the manufacturing plants have the valid environmental permits required for operations as required by the Finnish Environmental Protection Act. The prerequisites for granting an environmental permit include, among others, that the plant shall neither cause harm to health nor significant environmental degradation or the risk thereof. The environmental regulations and permits are location-specific. They provide the acceptable maximum levels of emissions into air, soil and water, as well as the methods and scopes for the measurement, monitoring and reporting of the items detailed in the permits to authorities. All production sites of the Orion Group have **contracts on the handling of industrial wastewaters** with their local wastewater treatment operator. The acceptable limits for the wastewaters are determined in the contracts. We regularly monitor and analyse the quality of our wastewaters.

All our sites are required to have **permits to store and handle hazardous chemicals**, with the exception of the pharmaceutical manufacturing sites in Kuopio and Salo, as they do not handle hazardous chemicals on a broad scale.

In accordance with Finnish **waste legislation**, we aim to reduce waste, avoid producing waste and deliver usable fragments for re-use and recovery.

The Orion Group is subject to the provisions of the Finnish **Energy Efficiency Law**, which obliges us to continuously improve energy efficiency and to report on our activities and performance to the Finnish Energy Authority. Our Energy Management System helps us fulfil the requirements and the purpose of this legislation.

Fermion is the part of the Orion Group that is subject to the provisions of the **REACH Regulation** concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, which require Fermion to register all solvents and intermediate products imported or produced by the Company amounting to at least one tonne per year.

The **CLP legislation** (Classification, Labelling and Packaging of Substances and Mixtures) concerns the entire supply chain of Orion to a considerable extent. The purpose of CLP is to harmonise the classification and labelling system of chemicals within the EU.

We aim for the highest standards in the industry with respect to the environment. The minimum levels set in legislation, regulations and the environmental permits are usually not satisfactory targets for Orion in the management of environmental responsibility. We aim to be significantly better, and a higher target can often prove to be more meaningful economically.

#### Environmental management responsibilities

In the Orion Group, the conformity of operations with the environmental management, which is an elementary component in the EHS Management System, is coordinated by the Director for EHS and Facility Management, and by the EHS organisation with its EHS Specialists reporting to him. He reports to the Senior Vice President, Supply Chain, who is a member of the Group's Executive Management Board. In Fermion, EHS activities are coordinated by a safety manager who reports to the President of Fermion. Fermion's safety manager and EHS Specialists are members of the groupwide EHS network. The core tasks of the EHS organisation in environmental management include, among other things, taking part in the preparation of continuous improvement programmes, external and internal EHS audits, guidelines and training sessions, following up of safety observations and the resulting corrective action, risk assessments, investigations of events causing injury, EHS reporting and internal communications about EHS affairs.

The local site managers are responsible for arranging operations at the operational site in accordance with the EHS Management System. Each supervisor shall see to it that their subordinates

are familiar with the guidelines concerning the reduction of our environmental impact. They shall also promote employees' commitment to our development goals and motivate them to take corrective action to prevent damage to the environment.

The management teams of the business divisions and line functions are primarily in charge of environmental affairs within their operational units, observing the nature of the unit's operations, the regulatory and legal requirements, and the related environmental risks.

The units of the Group are also responsible for identifying the main environmental impact of their operations and developing their operations and activities in an environmentally friendly manner. They also determine division and location-specific procedures for environmental damage and accidents, and document the main tasks and activities that have an impact on environmental safety. They also issue guidelines for them as well as establishing and maintaining operating procedures for the collection, processing and archiving of information related to environmental safety. Acting according to our environmental principles in our daily work is the responsibility of each Orion employee.

#### **Emergency preparedness and response**

In the event of an emergency, pre-determined procedures have been put in place by the Group management for taking control of the event and its consequences and for normalising the situation. Depending on the severity and the nature of the situation, predefined procedures are in place. Preparedness plans in case of different kinds of accidents and other exceptional events are based on continuously following up and monitoring our operational environment.

Emergencies classified as the most serious category pose an imminent threat towards our Company and, in the worst case, they could jeopardise our operations or people's health or safety and cause great damage and harm. The model of action established for the severest kind of emergencies stipulates that the Team for the Management of Exceptional Circumstances, chaired by the President and CEO and consisting of certain pre-defined persons, starts working in accordance with the Team's charter and shares tasks and guidelines applicable in the event of an emergency. The basic composition of the Team is complemented with other persons depending on the type of event.

In less critical events, i.e., in which the consequences and damages are assessed to be clearly minor compared to those in the most severe category, the most suitable operational model is used from the selection of models established.

In the Rescue Plans established for each operational site, potential accidents and exceptional events involving the risks of environmental hazard or workplace safety are described, together with related instructions as well as matters and responsibilities concerning preparedness, rehearsals, training and communications.

In case of emergency, we eliminate the threat and the hazard as soon as possible based on our procedures to limit the damage to people and property, and we appoint appropriate persons to take care of the situation. We take care of internal and external communications to ensure that up-to-date and reliable information is available quickly and transparently. We also observe the role of the relevant public authorities in managing the event. In addition to this, we also take care of continued operations, staff arrangements and alternative or temporary operational arrangements.

In February 2018, there was a chemical accident at Fermion's factory in Hanko. The accident was due to a technical failure in the heating system. In March at the same factory there was a deflagration caused by the ignition of a solvent, which caused a fire alarm. Neither of these events caused personal injury or environmental damage. Corrective action has either been completed or is under way to prevent similar events from occurring in the future.

#### Operating the EHS management system

The following procedures are elementary in operating our EHS Management System and for predicting, preventing and observing exceptional events and situations and for taking corrective action:

- Regular EHS risk assessments for the identification of potential shortcomings and nonconformities
- Development programmes with objectives, action plans and progress monitoring
- Systematic data collection and evaluation of items within the scope of the EHS and Energy Management Systems
- Regular internal EHS audits in departments
- Audits conducted by regulatory authorities and our collaboration partners at our sites
- Overall assessment of the EHS and Energy Management Systems by the Group management in annual management reviews
- Safety observation system for reporting on acute and possible hazardous situations as well as for monitoring the progress of the corrective action taken
- Notifications of and concerns regarding environmental harm and safety received from instances outside our Company, such as collaboration partners or neighbours

A team of EHS experts investigates the observations recognised in risk assessments and audits or in the safety observation system, as well as the notifications received from external instances in collaboration with management and relevant experts. In this process, the causes and the degree of severity are also assessed, and the necessary action is planned to eliminate the defect or to mitigate the harm and to prevent a similar event from recurring.

We follow up the implementation, applicability and efficiency of our EHS Management System by means of regular internal site audits and in the annual management reviews. The audits and management reviews help us identify needs to develop and improve our operations and the management system. In addition, we make sure that the system and our operations follow the principles set out in the ISO 14001 standard.

In its annual management review, the Group's executive management evaluates the applicability, sufficiency and efficiency of our EHS Management System. In the review, the management assesses things like the outcomes of the EHS audits, the results and the level of improvement of the EHS activities, the progress of the corrective and preventive action taken, as well as the recent and upcoming changes in circumstances, requirements and obligations. In addition, the management evaluates our EHS Management System, policy and targets, and considers possibilities for improvement and necessary changes.

#### New EHS information system - supports our ambition towards a safer workplace

Some 3000 safety and environmental observations are made each year at Orion, and we have become more and more active over the years. A new EHS information system was launched in 2018 that improved system accessibility and the usability of information across the organisation. The safety and environmental observations and incident reports can now be made on the move using a mobile phone. Ease of access and the possibility to enter observations on the spot ensures higher quality reporting.

The information system gathers information on safety and environmental observations, injuries, audits and inspections as well as on corrective action related to these notifications. The system enables valuable safety information to be found conveniently in one place, which is available and used by all Orionees. The system aims to bring forth a consistent EHS operating model for the whole of Orion. The information system supports our ambition towards achieving a safer workplace and helps in improving safety culture.

#### **Training and awareness**

Training is part of our active EHS culture and plays an important role. We maintain and promote our staff's awareness of environmental, health and safety affairs as well as of our energy efficiency improvement programmes by providing information in our internal communication channels and by means of guidelines and various training events.

Supervisors have a special responsibility for ensuring that existing staff and new employees receive sufficient training on the safety procedures and environmental matters of the department and division they work in.

### Indicators of environmental performance

#### Production output and use of materials

Production volumes by type of product<sup>1</sup>

Tonnes	2016	2017	2018
Tablets	1,047	1,561	1,753
Injection products	49	47	45
Gels and ointments	796	902	1,544
Liquid preparations	279	260	254
Active pharmaceutical ingredients, API	209	181	182





<sup>1</sup> The total production volume of the Orion Group cannot be converted into a commensurate unit of measure, because the product portfolio consists of various forms of products. Tablets in various forms are the most common pharmaceutical preparations produced. The table representatively indicates total production volumes of our typical product types in tonnes, which have been calculated using average conversion factors. In 2017, conversion factors have been adjusted, especially when related to tablets. The primary and secondary packages of the products are not included in the figures. Production volumes of inhalers are not disclosed due to company confidentiality.

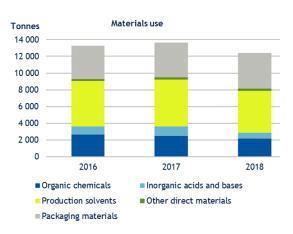
Using the number of retail packages as a measure, our output of medicinal products in 2018 came to 60 (58) million retail packages of pharmaceutical preparations produced. Our tablet packaging operations have been centralised into our packaging and logistics centre in Salo, where 37 million sales packages were produced.

The combined production of active pharmaceutical ingredients (API) at Fermion's sites in Hanko and Oulu came to 182 tonnes. The annual API production quantities depend on what APIs are included in the production programmes, as well as the phases ongoing in the manufacturing processes and their duration, with wide API-specific variations.

The pharmaceutical industry operates in global networks. As a result, it is not economically feasible to establish and maintain in-house manufacturing technologies for all the different types of products that we offer. Such as is the case with other pharmaceutical companies, we also allocate our capacity and resources efficiently, sub-contracting some of our own products to other manufacturers.

#### Use of materials

Tonnes	2016	2017	2018
Manufacturing materials: <sup>1</sup>			
Organic chemicals	2,610	2,485	2,127
Inorganic chemicals	193	167	167
Inorganic acids and bases	1,002	1,106	700
Detergents	NA	NA	74
Production solvents	5,422	5,648	5,052
Laboratory solvents	10	17	19
Gases	28	34	16
Biological materials	5	4	0
Direct materials total	9,271	9,462	8,155
Packaging materials:			
Corrugated cardboard	462	627	666
Wooden packaging	589	597	790
Plastic packaging	1,500	1,498	1,419
Paper fibre-based consumer packaging	1,055	1,055	966
Glass packaging	289	289	314
Aluminium packaging	79	99	73
Other packaging materials	51	29	13
Packaging materials total	4,024	4,194	4,241
Use of materials total	13,296	13,656	12,395
Recycled solvents, tonnes	1,815	2,000	1,805
Share of total materials, %	14%	15%	15%



<sup>1</sup> Manufacturing material classifications have been adjusted in 2018 for inorganic chemicals, inorganic acids and bases and production solvents. Detergents are reported separately first time in 2018. These changes affect the comparability for 2016-2018.

#### Use of materials by reporting unit 2018

Tonnes	Orion Group	Orion Corporation	Fermion Oy
Inorganic acids and bases	700	7	693
Organic chemicals	2,127	1,284	844
Inorganic chemicals	167	115	52
Production solvents	5,052	193	4,858
Other direct materials	109	91	18
Direct materials total	8,155	1,691	6,464
Consumer packaging/wrapping	966	966	0
Corrugated cardboard packaging	666	666	0
Glass packaging	314	314	0
Wooden packaging	790	717	72
Plastic packaging	1,419	1,408	11
Other packaging materials	86	86	0
Packaging materials total	4,241	4,157	83
Materials total	12,395	5,848	6,547

The reported use of materials includes the substances and materials used by the Company's own operations for pharmaceuticals and active pharmaceutical ingredients (APIs), and part of the materials used in R&D. The use of materials is primarily dependent on the production volumes of finished products, but it is also affected by improvements in the manufacturing process and the amount of semi-finished products and intermediates sourced from external suppliers. Fermion, which manufactures active pharmaceutical ingredients in chemical processes, uses most of the **direct manufacturing raw materials** in our Group. Fermion accounted for 79% of the Group's total consumption of direct materials in 2018. Solvents account for the largest share, 41%, of the total volume of materials used in the Group's production operations.

In the process of manufacturing medicines in Espoo and Turku the main solvent is ethanol, and most of it is used in tablet-coating processes and in the production of tablet masses. Additionally, several tonnes of isopropanol is used in Turku. A considerable proportion of solvents is used in the manufacturing of hormonal products.

The use of packaging materials has slightly increased year on year compared to 2016. The majority of the packaging materials were used for the packaging of medicines for retail and wholesale, and Fermion only accounted for about two percent of the Group total. Fermion's products are in the form of powder and are delivered to customers in large sacks and fibre or plastic barrels, whereas products from Orion Corporation are distributed in wholesale and retail packages.

The materials used in 2018 for the many different types of packaging accounted for 34% of our Group's total material consumption. The most commonly used packaging materials include plastics, cardboard and other wood fibre-based materials, glass and aluminium. Plastics and glass are mostly used as primary packaging materials, which come into direct contact with the medicine. Aluminium is mostly used in blister packages, but is also used in the collars of injection bottles and some cream tubes. A very thin layer of aluminium film is contained in the bag protecting the Easyhaler inhaler in its retail packaging.

Cardboard and liner are the most common materials of secondary packaging, which the primary packages are packed into. Cardboard and plastic film as well as bubble and cell plastics are the most common materials used in wholesale packaging.

#### Some solvents can be recycled at our own production sites

Regenerated solvents comprise the only relevant reusable materials in the Orion Group. Solvents are regenerated and reused by Fermion. Both Fermion's Hanko and Oulu plants retain some of their solvents and regenerate them in their distilleries. The Oulu plant reuses the regenerated solvents in its production processes, whereas in Hanko part of the distillate is used as fuel in the plant's VOC combustion facility and thereby as an energy source for API processes. In 2018, regenerated solvents accounted for 36% of the Orion Group's total solvent consumption.

Our ability to use recycled auxiliary and excess materials in our own manufacturing processes is practically limited to Fermion's solvents, due to strict requirements concerning the quality, composition and purity of the materials used in the manufacturing of medicines. The purity and safety requirements also concern packaging. Usable materials that definitely do not contain residues of active ingredients are recycled.

#### **Reducing waste**

Waste in all forms is an important aspect of our efforts to reduce our environmental impact. Our aims are aligned with the priority targets specified in the EU waste strategy, which are included in the Finnish Waste Act. These priorities include reducing the amounts of waste generated and recycling waste materials. Waste that cannot be re-used as material in our own operations is delivered to an appropriate third party to be used in another way whenever possible, such as for energy recovery. The amount of waste sent to landfill is kept to a minimum.

In the manufacture of pharmaceuticals, the tolerance for errors and defects is zero. A batch which fails to meet the specified requirements concerning quality and standard operating procedures is hazardous waste, and all input resources consumed in its production - materials, energy, time and labour - are lost. Therefore, it is essential to manufacture our products right the first time.

#### Fortum Waste Solutions takes care of our waste

Fortum Waste Solutions Oy, specialist provider of environmental management services, is our partner providing almost all the services we need for managing our waste. With practices established in collaboration with Fortum Waste Solutions, we make sure that waste is correctly sorted and handled at the source. With its efficient logistics infrastructure, our partner collects and transports our waste and treats the fractions in its advanced processes. Via Fortum Waste Solution's comprehensive recycling, recovery and reuse networks, all our reusable and recoverable surplus materials are forwarded to third parties for further use.

Most of the Orion Group's waste is hazardous, and most of it comes from Fermion, which produces active pharmaceutical ingredients at its plants in Hanko and Oulu using synthetic methods of organic chemistry and handling great amounts of raw materials. Almost all waste from Fermion's processes is hazardous because it contains active pharmaceutical ingredients or other chemicals.

Hazardous waste also results from the manufacture of medicines, because those materials that contain or may contain active pharmaceutical ingredients or other chemical substances classified as hazardous shall be treated as hazardous. Typical materials treated as hazardous waste include drug waste, organic and inorganic chemicals and mixtures classified as hazardous or harmful, cytostatic, and carcinogenic among others. We make sure that our hazardous waste materials are given appropriate further treatment, during which process they are made safe for both people and the environment.

In the pre-treatment processes, our partner sorts out those fractions of our hazardous waste that can be recycled for further use. Such materials include for example accumulators, batteries, refrigerating equipment and electronic equipment. Fortum Waste Solutions incinerates our hazardous waste at its Riihimäki treatment facility, which is specialised in the destruction of hazardous waste at extremely high temperatures. Most of our hazardous waste generates heat in the incineration process that is utilised as energy for district heating system in the Riihimäki region. The exact distribution of the heat value is hard to determine, but it is estimated that at least more than a quarter is pure solvents with a high heat value. From reporting perspective, these fractions, however, are reported in the category of "incineration, mass burn" as they are hazardous waste. Some of our hazardous waste, especially waste fractions with a high water content, is sent to physical-chemical pre-treatment. These fractions are pre-treated by evaporation or drying before incineration.

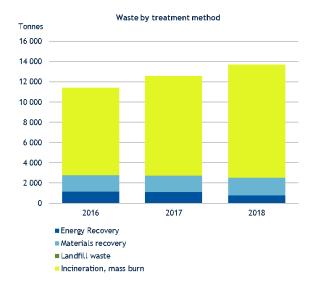
The manufacturing processes of pharmaceutical products and APIs differ very much from each other, and the waste amount and types generated also differs accordingly. Our pharmaceutical product manufacturing sites in Espoo, Turku, Kuopio and Salo mainly generate non-hazardous fractions that are recovered either as materials or as energy. A considerable part of all our non-hazardous waste consists of different kinds of packaging materials.

#### Hazardous and non-hazardous waste

Tonnes	2016	2017	2018
Hazardous waste	8,772	10,006	11,182
Non-hazardous waste	2,634	2,592	2,543
Tatal	44.404	40.500	10 705
Total	11,406	12,598	13,725

#### Waste by treatment method<sup>1</sup>

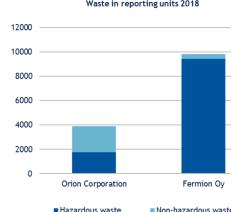
Tonnes	2016	2017	2018
Energy recovery	1,143	1,101	751
Materials recovery	1,612	1,614	1,768
Landfill waste	4	0	4
Incineration, mass burn	8,646	9,882	11,202
Waste total	11,406	12,598	13,725



<sup>1</sup> The waste treatment category "incineration, mass burn" was added in 2018 and data adjusted accordingly for 2016 and 2017.

#### Waste by reporting unit 2018

Tonnes	Orion Group	Orion Corpo- ration	Fermion Oy
Hazardous waste	11,182	1,762	9,420
Non-hazardous waste	2,543	2,150	393
Waste total	13,725	3,912	9,813



One of the indicators included in the KPIs for monitoring the implementation of the Orion Group's strategy monitors the share of hazardous waste of our total waste. Our aim is to reduce hazardous waste in particular, but also total waste as well. The share of hazardous waste has increased by 4 percentage points to 81% against the 2016 baseline despite the efforts made. The main reason has been our efforts in our target of reducing the environmental burden on waterways by reducing the residues of harmful chemicals in our wastewaters. Based on environmental risk assessments, we differentiate the wastewater fractions that are unsuitable for biological wastewater treatment or pose a risk to the environment. Since 2017, most of the active pharmaceutical ingredients containing wastewater have been collected and sent to treatment as hazardous waste, with a 100% reduction. Our efforts to achieve our wastewater management target therefore affect our progress towards reaching our target for material efficiency.

Nevertheless, we are moving in the right direction and our efforts are yielding positive results. At our factories in Turku, when excluding the wastewater collection, the share of hazardous waste of total waste has decreased by 8 percentage points from 30% to 22%, and in Kuopio by 10 percentage points against the 2016 baseline from 37% to 27%. The focus has been on the separation of waste at

Waste in reporting units 2018

the source, and these achievements are the results of continuous co-operation and knowledgesharing between waste management and production personnel. In 2018, our operations in Finland generated about 13,500 tonnes of waste, which was 7% more than in 2017. The increase was due to the increased amount of hazardous waste from both the production of pharmaceuticals and APIs. The increase came from the recovery of waters from the processes containing APIs and increased production of one product that has large waste streams. API water collection systems were built at our sites in Hanko, Oulu, Espoo and Turku during the course of 2017, so 2018 represents the first full reporting period where the advanced wastewater management effects can be seen as an increase in hazardous waste. This method of recovering and treating API waters has increased the amounts of hazardous waste, but on the positive side, considerably lower amounts of chemical substances are ending up in municipal effluent treatment plants and the environment. The API water collection systems also enabled a more accurate separation of water-based waste streams from solvent waste at Fermion's production facilities. This does not decrease the amounts of hazardous waste, but makes its treatment more energy efficient when water-based streams can be pre-treated by evaporation and solvent-based waste fractions can be incinerated straight with high fuel value without water.

In 2018, we evaluated the hazardous waste material flows and different kind of optimisation and project ideas were thought up. The focus of these upcoming projects is to pilot new processes and technologies that could help us to reduce generated waste and improve the quality of waste fractions in a way that could make them recyclable, in other words elevating the waste streams according to the EU's waste strategy hierarchy. One example is an acquisition of a completely new kind of hazardous waste compactor by one of our production plants, which will reduce the packaging needs of drug waste from production and reduce the total number of transportation kilometers driven.

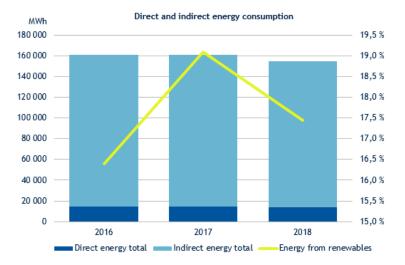
**Fermion's** direct manufacturing material flows are many times higher than those involved in the manufacture of pharmaceutical preparations. Fermion's total waste increased by 8% and its share of the Group's total waste in 2018 was about 73%. Overall, Fermion generated 8% more hazardous waste than in 2017. Fermion's share of the entire Group's hazardous waste was about 84%. Only 4% of Fermion's total waste was handled as non-hazardous. Fermion was able to recycle 1,805 tonnes of used solvents back to production, which accounted for 36% of the Orion Group's total solvent consumption and 15% of total material usage.

**Orion Corporation**, comprising the pharmaceutical preparations business, accounted for about 27% of the Group's overall waste, with almost the same amount of total waste as in the previous year. The amount of hazardous fractions increased by 39% due to the installation of API water collection systems. Other fractions in the hazardous waste consisted of drug waste, halogenated solutions and organic chemicals.

# Improved energy efficiency in production and reducing emissions

MWh	2016	2017	2018
Heavy fuel oil	0	0	0
Light fuel oil	451	402	1,189
Natural gas	14,347	14,399	12,404
Direct energy total	14,797	14,801	13,593
District heat	50,298	48,512	42,917
Steam	26,825	27,787	29,714
Electricity	69,520	69,719	68,974
Indirect energy total	146,643	146,017	141,605
Energy total	161,440	160,818	155,198
Energy from renewables	16%	19%	17%

#### Direct and indirect energy consumption by primary energy source



#### Energy consumption by reporting unit 2016-2018

	MWh 2016	Share 2016	MWh 2017	Share 2017	MWh 2018	Share 2018
Orion Corporation	107,507	<b>67</b> %	106,889	<b>66</b> %	106,171	<b>68</b> %
Fermion Oy	45,081	<b>28</b> %	46,097	<b>29</b> %	49,028	32%
Orion Diag- nostica Oy	8,852	5%	7,833	5%	NA	NA
Total	161,440	100%	160,818	100%	155,198	100%



MWh	Orion Corporation	Share <sup>1</sup>	Fermion Oy	Share <sup>1</sup>	Group total	Share <sup>2</sup>
Light fuel oil	1,153	1%	36	0%	1,189	1%
Natural gas	11,813	11%	591	1%	12,404	8%
Direct energy total	12,967	12%	626	1%	13,593	<b>9</b> %
District heat	40,345	38%	2,572	5%	42,917	<b>28</b> %
Electricity	48,429	<b>46</b> %	20,545	42%	68,974	44%
Steam	4,430	4%	25,284	52%	29,714	1 <b>9</b> %
Indirect energy total	93,204	<b>88</b> %	48,401	<b>99</b> %	141,605	<b>9</b> 1%
Total	106,171	100%	49,028	100%	155,198	100%

# Energy consumption in the reporting units by type of energy in 2018

<sup>1</sup> Share of total consumption by energy type

<sup>2</sup> Proportion of the Group's total energy consumption

The reported energy consumption covers the Orion Group's properties in Finland, except for those that do not contribute significantly to the total and have no production operations. The Group has no production plants outside Finland. Rented offices abroad are excluded from this report.

Our total absolute energy consumption in 2018, including electricity, heating and fuels consumed was 155,198 MWh. The 3% decrease in total energy consumption was mainly due to the sale of Orion Diagnostica business division.

Energy saved due to conservation and efficiency improvements

Energy saved MWh	2016	2017	2018
Electricity	33	-1,841	-346
Heating energy	2,035	4,992	1,420
Fuels	0	574	0
Total energy saved	2,068	3,725	1,074

2018 Energy saved MWh <sup>1</sup>	Electricity	Heating energy	Fuels	Total energy saved
Orion Corporation	-346	1,420	0	1,074
Fermion Oy	0	0	0	0
Total energy saved	-346	1,420	0	1,074

<sup>1</sup> Energy savings are estimates and are calculated in compliance with the guidelines of the Energy Authority.

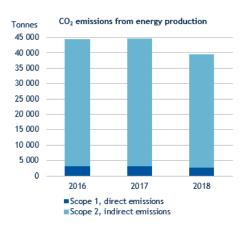
Orion is committed to the extension period of the joint Energy Efficiency Programme for the members of the Confederation of Finnish Industries (EK). In Finland, the programme's primary means is to fulfil the strict requirements based on the EU Energy Efficiency Directive. Under the

new programme, the savings target for 2025 is 7.5% of energy consumption in 2016, and the intermediate target is 4% for 2020. For Orion, this means a saving of slightly over 12 GWh, 40% of which was achieved in 2018. The energy savings of 1,074 MWh were achieved through the savings measures and by improving energy efficiency at the Salo and Turku sites. At the Turku pharmaceutical plant, a cooling machine was renewed into a heat pump that reduces the need of district heat in a building. New LED lighting was also installed at both the Salo and Turku sites.

Our aim is to improve the efficient use of energy and reduce our energy consumption by applying the practices determined in our Energy Management System. We share best practices from across the group, and aim to take the advantages of excellent solutions by applying them at other locations where applicable.

Tonnes CO <sub>2</sub>	2016	2017	2018
Scope 1, direct emissions	3,065	3,089	2,788
Scope 2 indirect emissions	41,394	41,500	36,793
CO <sub>2</sub> emissions total	44,459	44,589	39,581





Direct and indirect  $CO_2$  emissions by type of energy

Tonnes CO <sub>2</sub>	Type of energy	2016	2017	2018
All sites <sup>1</sup>	electricity	19,311	20,065	18,212
Fermion & Orion Corporation Turku	steam	5,281	6,879	7,454
All sites	district heat	16,802	14,556	11,127
Espoo	natural gas	2,945	2,982	2,474
Espoo and Kuopio	light fuel oil	120	107	315
CO <sub>2</sub> emissions total		44,459	44,589	39,581

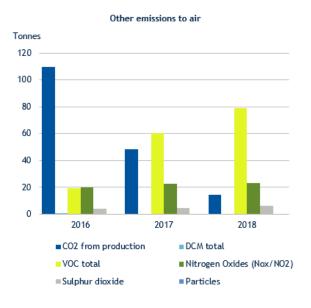
<sup>1</sup> The proportion of different sources of energy used to generate the purchased electricity is based on the socalled residual mix, the most recent one of which is published by the Energy Authority of Finland.

Direct and indirect  $CO_2$  emissions have been calculated for our Finnish locations. At our Kuopio site, the steam-generating boiler uses light fuel oil. The  $CO_2$  emissions due to the use of light fuel oil increased compared to 2017, as in Espoo a boiler facility used light fuel oil as a standby power during factory maintenance work.

The  $CO_2$  emissions have been calculated based on the emission factors of the fuel. The  $CO_2$  emissions from electricity, purchased natural gas and district heating energy have been calculated using emission factors provided by our energy suppliers.

## Other emissions to air

Tonnes	2016	2017	2018
CO <sub>2</sub> from production	110	49	15
Methylene chloride (DMC)	1	0	0
VOC total	19	60	79
Nitrogen oxides (NOx/NO <sub>2</sub> )	20	23	23
Sulphur dioxide, SO <sub>2</sub>	4	5	6
Particles	0.1	0.1	0.1



Strict limits concerning volatile organic compound (VOC) emissions from the use of solvents are set in the local environmental permits for our manufacturing plants.

Very stringent emission limits apply to methylene chloride, perchlorethylene, dimethylformamide and N-methylpyrrolidone. Fermion, which accounts for about 96% of the Group's total consumption of solvents, successfully controls its emissions.

In Oulu, VOC emissions are treated in the facility operating according to cryogenic principles, in which the vaporised solvents are recondensed into liquid form by means of liquid nitrogen. The increase in reported emissions is due to the replacement of Fermion's old VOC combustion facility, which was based on catalytic oxidation, and the upgrading of the entire exhaust system at the Oulu site in 2016. The VOC emissions from the pharmaceutical manufacturing operations in Espoo and Turku mainly originate from ethanol, which is used as the primary solvent in tablet-coating processes and in the manufacture of tablet masses. In 2018, we started using gas scrubbers instead of an incinerator to control the VOC emissions as well as causing direct  $CO_2$  emissions from the VOC compounds being incinerated. Our gas scrubbers, however, proved to be less efficient than anticipated, causing our VOC emissions to increase. We are investigating the cause of poor efficiency and aim to improve it in 2019. The majority the 63 tonnes of VOC emissions come from Fermion's sites and Oulu in particular. The nitrogen oxides were emissions from the boiler facility in Espoo that uses natural gas, and from the VOC combustion facility at Fermion's Hanko plant. In addition, the sulphur dioxide came from the VOC facility in Hanko.

# Environmental impact of transporting products and business travel

Specialist service providers meeting our strict quality and reliability requirements provide practically all the services we need for the transportation of materials and goods. Currently, we do not monitor or assess the environmental impact of the transportation of our goods, but we use responsible partners that have measures in place to reduce their own environmental impact.

Travelling for work is part of life for many Orion employees. We have centralised the travel arrangements in Finland and a few other European countries to one travel agency. The reported carbon dioxide emissions from the business flights taken by the Orion Group cover at least 83% of the employees. The business flights arranged by other travel agencies for employees at our foreign locations cannot be reported.

1,000 miles	2016	2017	2018
Flights in Finland	644	726	521
International flights	9,322	8,993	8,567
Flights total	9,967	9,719	9,088

#### CO<sub>2</sub> emissions from business flights

CO <sub>2</sub> emissions, tonnes	2016	2017	2018
Flights in Finland	156	175	126
International flights	1,702	1,637	1,565
CO <sub>2</sub> emissions from business flights total	1,858	1,812	1,691

#### Calculation of the CO<sub>2</sub> emissions:

In 2018, Orion's employees flew 6% fewer miles on business trips than in 2017.

#### $CO_2$ emissions of new company cars came to an average of 126 g/km

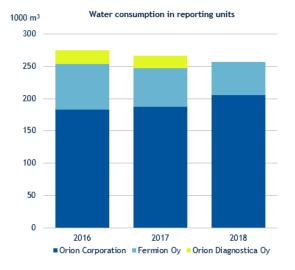
About 140 employees belonging to the Orion Group in Finland had a company car as an employment benefit in 2018. Our company car policy emphasises low emissions, fuel economy and traffic safety. Our  $CO_2$  emission target for new company cars is 120 g/km by 2020. As the average length of time a company car remains in service is three years, the average  $CO_2$  emissions of the entire fleet in 2018 was 122 g/km and this figure is decreasing year on year.

At Espoo, we also provide our employees with the option of charging electric and hybrid cars at our car park. In 2018, 97,200 kilometers were charged and 14 tonnes of  $CO_2$  emissions avoided.

#### Water and wastewater programs

# Withdrawal and consumption of water by reporting unit

1,000 m <sup>3</sup>	2016	2017	2018
Orion Corporation	183	188	205
Fermion Oy	71	59	51
Orion Diagnostica	21	19	NA
Total water from municipal supply	275	266	256



All water consumed by Orion is taken from local municipal water supply systems. There are significant differences in the volumes of water consumed between our units and locations, and in the purpose behind this consumption, due to the differing characteristics of their facilities and operations. Total consumption of water in 2018 increased by about 4% from the previous year.

**In Orion Corporation**, water consumption increased by about 9%. The largest share of the water at Orion Corporation is consumed at the pharmaceutical manufacturing plant in Espoo. This came to about 125,000 m<sup>3</sup> and represents 61% of the Orion Corporation's total.

Medicines are manufactured in batches, and all process steps must meet very strict purity requirements throughout the supply chain. To prevent cross-contamination, the process equipment, accessories and lines are thoroughly cleaned with water after the all the batches of the product have been completed so that no residues remain of any substances used in the product. The more that separate batches of different medicines are produced in low quantities, the more washing must be done. Considerable amounts of water are also used by gas scrubbers, whose function is to capture evaporated solvents, mainly ethanol, and to decrease the emissions of volatile organic compounds (VOC) into the air. In finished products, water is a substance in the composition of liquid solutions such as cough medicines and injections.

**Fermion's** water consumption showed a further decreasing trend, with 14% lower consumption than in the previous year, accounting for 20% of the Orion Group total. Water consumption decreased most in Hanko, namely by about 24%, and the site represents about 49% of Fermion's total water use. Fermion's annual water consumption varies depending on which active ingredients are manufactured during the course of the year as well as on the type and phase of the substances' manufacturing processes.

#### Wastewater quality is monitored as required in our environmental permits

Our production sites generate practically as much wastewater as they consume fresh water. The wastewater is led to municipal water treatment plants either directly or after neutralisation, where solids and substances with biochemical oxygen demand (BOD) or chemical oxygen demand (COD) are removed. No wastewaters from our sites are directly conducted to natural waterways. The exiting process waters of Fermion's Hanko plant are pre-treated in the adjacent biological treatment plant of Hangon Puhdistamo Oy, from which the treated water is conducted to the sea via the local municipal discharge pipe.

The burdening impact of our effluents is monitored in the ways specified in the site-specific environmental permits. The total annual loads are the averages of the results from samples taken a few times during the year. Therefore the results may be distorted, because the emissions from production vary from one day to another. The levels of solids contained in our wastewaters are low, whereas the values of biological and chemical oxygen demand, BOD and COD, are higher than the corresponding ones in community wastewaters. This is mainly due to the high carbon content of the wastewaters, which at the sites where pharmaceuticals are manufactured originate from the ethanol escaping into the exiting waters via gas scrubbers.

The total Group BOD in 2018 was about 149 tonnes, against 200 tonnes in 2017. COD came to about 254 tonnes (391), down by 35%. The nutrient loads in the Orion Group's wastewaters are relatively low. The total nitrogen load of 10,800 kg/year corresponds to the annual emissions of about 2,000-3,000 people (10-15 g/person/day) and the phosphorous load of 800 kg/year is equivalent to the nutrient emissions of about 1,000 people (3 g/person/day).

# Significant progress on wastewater management and the reduction of pharmaceutical residue emissions

One of the most significant environmental aspects of Orion Group's own production is wastewater. We have set targets to reduce the environmental burden on waterways caused by our operational sites by minimising the residues of harmful chemicals in our wastewaters even further. In 2017, the Orion Group took a significant step forward regarding that aim as we finished the long project of improving the wastewater management, and got the new pre-rinse water collection systems running at our production sites. As a result of the project, most of the wastewaters from production and equipment washings that contain API residues are now being collected and sent to treatment with a 100% reduction. Before, these were discharged to municipal wastewater treatment plants and after treating then discharged in the Baltic Sea. In 2018, we have gained experience with these new systems and carried out wastewater toxicity and pharmaceutical ingredient residue assessments in Hanko to verify successful process implementation.

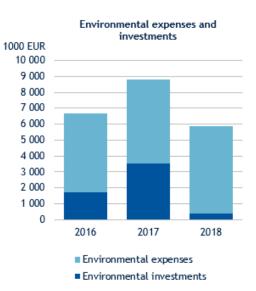
Based on environmental risk assessments, we differentiate the wastewater fractions that are unsuitable for biological wastewater treatment or which pose a risk to the environment. Our new wastewater management model with new internal classification criteria for wastewaters was set in 2016 and was stricter than those required by authorities. During the course of 2017, we installed and started new wastewater collection systems at our sites at Turku, Espoo, Hanko and Oulu.

The energy needed to transport and treat the collected wastewater is related to the amounts of the collected streams and the level of precision of the separations. Optimising our wastewater management based on the experiences with the new systems, and ensuring that our operations continue to abide by the principles of the industry's Best Available Techniques is a continuous process. With these systems, most of the harmful substances are eliminated from the wastewaters led from our sites into municipal treatment plants. This recovery and treatment method however increases the volume of our hazardous waste.

# **Environmental expenditures and investments**

# Total environmental protection expenses and investments

EUR 1,000	2016	2017	2018
Environmental investments	1,710	3,550	396
Environmental protection expenses	4,957	5,238	5,500
Environmental expenditures total	6,667	8,788	5,896



# Total environmental protection expenditure and investments by reporting organisational unit in 2018

EUR 1,000	Orion Group	Orion Corpo- ration	Fermion Oy
Environmental investments	396	396	0
Environmental protection expenses	5,500	1,665	3,835
Environmental expenditures total	5,896	2,061	3,835

**Environmental investments** consist of projects for improving energy efficiency, the efficient and safe use of materials, consumption of water, and management of effluents, waste and emissions. Our environmental investments in 2018 came to about EUR 0.4 million (EUR 3.6 million in 2017). In 2018, investments were especially related to improvements to energy efficiency in Salo and Turku.

**Environmental protection expenses** consist of items relating to waste, wastewater, and the prevention of emissions into the air and ground, noise abatement, energy efficiency, environmental permits as well as improving of the environmental management in our operations in Finland. The greatest single cost item in 2018 was once again waste, at EUR 4.5 (4.3) million. Our annual waste bill is largely affected by the amount of hazardous waste, because it is notably more expensive to treat than non-hazardous fractions.

Wastewater treatment also makes up a considerable share of our annual environmental expenditures. In 2018, our effluent treatment costs were about EUR 0.6 million.

# Responsibility for Orionees - building well-being at work

As an organisation of highly educated professionals, it is important for us to ensure that employees are committed to Orion as an employer and that they are highly inspired professionals. We encourage our employees to continuously develop themselves, and to feel that they are doing meaningful work that corresponds to their skills in a well-managed and safe working environment in which people are treated equally and fairly.

# Management of labour practices and decent work

# Success by working together, with common values and harmonised practices

Orion is Finland's largest pharmaceutical employer and an international working environment for multi-talented people. Our workforce is made up of many nationalities and cultural backgrounds, but is unified by the common Orion business culture of succeeding together and our shared values and practices. We offer the opportunity to work in an international environment and provide varied and challenging career opportunities for experts in different fields. We are a responsible employer, and constantly develop well-being at work and motivate our employees to continually develop their competences. We offer our employees a healthy and safe working environment and a smoothly-operating working community. We also make sure that our employees have the necessary skills and mindset to implement the Group's strategy. We want every Orion employee to share our attitude of continuous renewal and to feel that his or her work is meaningful. Healthy and competent staff is a key factor in our success and the foundation of our corporate responsibility, which enables us to bring value to our customers and to meet the strict requirements of the pharmaceutical industry.

To our staff, our "Building well-being" mission means purposeful and responsible work, whereby we succeed by working together and which we are proud of together. Our staff are building Orion's future as a team, in the spirit of the Group's values and by implementing the Group strategy.

#### Succeeding Together!

- Our work is valuable and significant for the customer.
- We are a responsible employer.
- We want to be an excellent place to work and an attractive employer.
- We take responsibility for the continuous development of our occupational well-being and competence.

In human resources management, we operate according to effective legislation, collective agreements, security regulations and other obligations. We ensure responsible operations in relation to our employees and their working conditions by adhering to the Group's shared values, the procedures and responsibilities specified in our Corporate Governance Manual, as well as the joint ethical principles and policies.

The core principles in human resources are outlined in the <u>Human Resources Policy</u>, which is based on our Group values. The ethical principles concerning our working community are outlined in the <u>Code of Conduct</u> of the Orion Group. The Code of Conduct applies to all our employees and businesses, and every individual employee is expected to follow it. All employees are also obliged to abide by the topic-specific corporate policies, which determine our main principles for ensuring responsible operations.

Our leadership principles, *Working together – the Orion way*, outline the Orion way of leading people and acting as a member of a working community. The following four themes are the most important: Leader as a Coach, Skills of Working Together and Personal Leadership, Customer-Focused Leadership, and Leadership in Collaborative Partnership.

Working together with staff, we are building a value-based corporate culture of succeeding together, which is characterised by open and constructive interaction and continual renewal.

Interaction between employees and management is respectful, transparent and unobstructed. Issues are handled quickly and constructively. Collaboration is forthright and takes place as part of the normal daily work and at meetings based on labour-related legislation.

#### Management responsibilities in human resources affairs and services

Human resources affairs and services are managed and coordinated by the Human Resources Department, which belongs to the Corporate Functions organisation. The Vice President, Human Resources, reports to the Senior Vice President, Corporate Functions, who is a member of the Orion Group Executive Management Board. The core tasks of the Human Resources Department include employment affairs and collaboration, payroll and rewarding, personnel data management, talent and competence management, recruitment and organisational renewal, and occupational well-being and healthcare.

#### Human Resources Policy emphasises equality and fairness

Our Code of Conduct emphasises respectful and courteous behaviour at the workplace. As it is outlined in our Code of Conduct, every Orion employee is entitled to good, courteous and respectful treatment by his or her supervisors, subordinates and fellow employees.

Each employee in the Orion Group shall have equal possibilities to succeed and develop in his/her own work. Age, gender, sexual orientation, religion or ethnic background may never, at any stage of the employment relationship, be considered a discriminating factor.

Members of our working community are responsible for treating everyone equally and fairly in daily operations and decision-making. Everyone is responsible for maintaining and promoting a good working atmosphere, behaving appropriately and respecting others.

The Human Resources Policy provides the framework for establishing equal opportunities plans in all countries where we have operations, observing the local country-specific legislation. Our sites in Finland follow an *Equality Plan* drawn up to broadly support and promote equality at the workplace in recruitment, payroll systems, in adapting people's working and private lives, and in educational opportunities. By equality, we also mean equality of the sexes. When developing working conditions and operational practices, we observe the aspects of equality. The working group for the development of equality at our Finnish sites consists of representatives of all employee groups and the employer. Both the supervisors and the employee representatives are obliged to react to recognised problems.

Gender does not play a role in determining salaries at Orion. In the Finnish operations, salary equality is assessed using a salary mapping method as specified in the Finnish Act on Equality between Women and Men. The outcome of the mapping is reviewed and assessed by Orion's management and employee representatives and, when necessary, corrective measures are agreed upon.

#### All our Finnish employees are covered by collective bargaining agreements

Orion adheres to current employment legislation and the applicable collective bargaining agreements valid in the country the employee works in. Collective bargaining agreements cover both blue collar and white collar employees at the Group's Finnish locations, about 59% of the workforce in Finland in 2018.

A so-called common pay record concerning exempts in the chemical industry is applied to our exempts. In addition to salary increases, the pay record covers several other terms, such as more extensive sick pay than that specified in the Employment Contracts Act and paid maternity or paternity leave.

# Ensuring human resources. Recruitment: We recruit people with potential, the right experience and attitude

The Orion Group provides roles for a wide range of specialists in the fields of natural sciences, business, mathematics, technology, IT and the humanities. The educational background of persons recruited into production tasks varies widely depending on the requirements of the task, from comprehensive school to bachelor's and master's degrees from universities of applied sciences. Vocational study programmes in pharmaceuticals provide a good basic readiness for a variety of jobs at Orion. Independently of their level of education, all our new employees receive a high-quality and comprehensive induction to their job.

We invest in procedures, which enhance the image of our company as an excellent place to work and as an attractive employer. Our success depends on our ability to employ and recruit the correct kind of professional people, our ability to identify persons and talents suitable for different development paths in order to further enable and support them to develop and train their skills, and to support and act for their well-being at work.

By means of resource planning, we ensure that the organisation has the required capabilities for the goals derived from our strategy and objectives, that the organisations are resourced purposefully, and that the required deputy and back-up arrangements are in place to ensure uninterrupted operations.

In recruitment, we aim to find the best and most motivated people and take both our current and future skills needs into consideration. Successful recruitment supports us in achieving our strategic business goals. Recruitment also offers us opportunities to renew the competences of our organisation. To ensure that our recruitment is successful, we continuously develop the skills of our recruitment organisation and the quality of the recruitment process, applying up-to-date methods such as social media, case-by-case tailored recruitment channels and video interviews, for example.

When looking for people to fill new or open positions, Orionees with a suitable background are considered first. Job rotation is seen as a means for driving change and as an opportunity for professional development.

#### Summer jobs for the young

Every year, we offer summer job opportunities to over one hundred students in different parts of the Group. In summer jobs and on-the-job training placements, they have an opportunity to become acquainted with our industry and our company. In return, they provide us with an opportunity to motivate and attract young people to educate them into vocations in our industry and to provide them with a path into our company. For us, summer jobs and on-the-job training also involve an opportunity to identify attractive talents who could make a career in our company.

In addition to summer jobs, Orion has developed the *Phase 1* summer job programme, which offers opportunities to dozens of students approaching the end of their studies to gain hands-on experience in the fields of natural, pharmaceutical, technical or economical sciences. Phase 1 has gained a great reputation, and in 2018 Orion received hundreds of applications from very talented students. Some students continued to work for Orion after finishing the Phase 1 programme.

# Introduction to work

Supervisors are responsible for organising an adequate induction process for new employees, those starting in new roles and those returning from extended absences. Some organisations have particular employees trained to provide the necessary orientation. A set of documents help to make sure that that all the necessary items are discussed. In the onboarding process, we also use *Orion eOnboarding*, an interactive web-based training programme that offers a comprehensive package of information about the Orion Group's strategy, products, operations and functions, organisation and people, operational codes and practices and the business environment. The service is accessible for all employees, offering them the chance to update their knowledge and understanding of the Company and the working environment.

# Ensuring competences. Talent management: We develop professional and leadership skills

Our aim is for the Group's employees to have the skills and the competencies required for the implementation of our strategy. Supervisors are also responsible for ensuring that everyone in their organisation is familiar with Orion's strategy and objectives, the department-level objectives derived from them as well as their personal objectives. They also play a key role in the competence development of the organisation and the staff, which is why we continually invest in the quality and

skills of our supervisors. We also expect each individual employee to take responsibility for his or her own professional development.

Corporate-level competence requirements derived from the strategy are determined annually at the People Day meeting of senior managers. The corresponding requirements of operational units and functions are determined by their management teams, and the requirements for departments and individual tasks are determined at departments and in the *Succeeding together!* discussions (generally known as Appraisal Discussions). During these discussions, the level of know-how is also assessed and the development needs are defined.

Competence development starts from our strategy and goals and the task-specific requirements derived from them. The planning starts from the Group's strategy and goals: what kind of skills and competence do we need for both short-term and long-term success. The strategic focus is on leadership and management skills, partnership management, business and financial skills and continuous improvement.

**Means of developing supervisory skills** include a Group-level training programme, *As a leader in Orion*, in which supervisors receive comprehensive training in their personal management skills and which also helps to assure that the Group's values and the Orion way of management are adopted. Supervisory training is provided to all supervisors in all countries. This is how the Orion management culture, policies and principles are equally implemented in all locations throughout the Group. Training is organised both in Finnish and in English, and it is mandatory for all managers in the Orion Group in all countries.

In addition to their ordinary professional skills, persons working in specialist positions also need many kinds of general abilities, such as an understanding of business, communication, collaboration, interaction and networking skills. To enhance these assets, among other things, the *As a Specialist in Orion* training programme has been developed and is organised on an annual basis.

Persons in supervisory and specialist positions also receive Orion-tailored training in thematic issues that relate to the key competencies identified as strategic, such as leadership, business understanding, partnership management and continuous management or LEAN.

In addition to the training sessions aimed at all supervisors and specialists, we arrange high-quality supplementary training in business and leadership to middle and top management.

Most of our training is aimed at professional development on a wide scale, for which purpose we provide a wide range of development opportunities, from one-day seminars to long-term training programmes and supplementary training periods. Some of our training courses are compulsory, like for instance the internal supervisor training and many GMP and EHS-related courses.

#### Database helps us manage our employees' competence and training history

The employees' professional skills are a key element in securing the quality and safety of the products, as is the regulatory compliance of the manufacturing process. The regulatory requirement provides that all those employees whose performance directly or indirectly affects the quality or the safety of a medicine shall receive regular GMP (Good Manufacturing Practices) training and that conclusively traceable documentation is available on their competence, training history and familiarisation with the guidance concerning required operational practices. Our training data system helps us manage the competence requirements of individual tasks in our Supply Chain and Quality operations as well as information on the employees' qualifications and training history, with precise documentation.

We also encourage our employees to develop their skills using the various methods of professional development. Our toolbox for the development of skills and competence includes, for example, job rotation, 360 and 180-degree evaluations and the annexed feedback discussions, mentoring, learning at work and coaching. In addition to the many internal training offerings, our employees are encouraged to study alongside work independently.

In 2018, we applied *360 and 180-degree evaluations* in Orion across the board as tools for developing competences. In the 360-degree evaluation, supervisors receive personal feedback from their subordinates, colleagues and their own supervisor. In addition, representatives of our external partners can be asked to give feedback with the purpose of supporting the development of strategic partner collaboration. Employees in expert positions receive 180-degree feedback from their supervisors and colleagues. Team leaders acting with no formal supervisory position are also evaluated using a questionnaire.

The purpose of our *Talent Management* process is to promote every employee's career opportunities and development possibilities and to ensure that we have enough people with the ability to renew and change. Personal career and development wishes shall be discussed with the supervisor in the Succeeding together! discussion, for example. The management teams in the operational units and functions shall discuss the wishes of the respective organisations on an annual basis, and furthermore shall identify persons capable of supporting the Company's success and renewal. At the annual People Day event, senior management shall assess Orion's renewability and generally discuss the job rotation and career opportunities offered by the Company.

#### Performance is reviewed and targets are set in the Succeeding Together! discussions

Performance reviews are conducted as a standard in the Orion Group, and the entire workforce is subject to them. The supervisors shall conduct personal performance reviews with their subordinates at least once a year as part of the "Succeeding Together!" discussions. In certain cases, the Discussion can take place in the form of a group discussion.

In the Succeeding Together! discussions we emphasise equality and good interaction with others. In the discussions, goals are agreed upon and monitored and the employee's achievements in the past period are discussed as are the aspects where improvement is needed, and the skills necessary for successful performance are considered. Concrete action to promote skills and/or well-being at work is also agreed upon. In evaluating the past period, we also discuss how the Group's values and management principles have been met at work and in the working community as a whole. In addition to this, we create a culture of continuous feedback, which we regard as an important tool for operational development and a learning organisation. In 2018, Orion arranged a Feedback Day, including e.g. an external keynote speaker to highlight the importance of so-called constructive feedback.

The performance review sessions of the exempts include an assessment of the employee's performance in relation to the objectives set for the year in the previous review for the purpose of the performance-based bonus, and new personal and department or project-specific targets are agreed upon together with the supervisor.

# We reward good performance

We encourage our employees to achieve good results and commit to the Company for the long term using various means of rewarding them. Rewarding shall be fair and in line with the Group-level principles. Salaries and employee benefits are country-specific and vary depending on national legislation, collective agreements, industry, location and the salary levels and remuneration structures of each country.

Monetary incentives and other employee benefits shall be of a sufficient level and scope to be competitive in comparison with the market salary of each position. Personal salary is determined based on the complexity of the duties and the individual's performance. Productivity, expertise, multiple talents, ambition to develop, initiative and cooperation skills are all considered when assessing an employee's individual performance.

# Occupational health, safety and well-being: We promote health & safety and well-being at work

By taking care of the occupational health, safety and well-being of staff at work, we aim to ensure that each employee is fit for work and is not exposed to occupational diseases by minimising and managing health risks. We want to provide our employees with a healthy and safe working environment and a smoothly functioning working community, which is characterised by an inspiring working atmosphere, good management and motivating colleagues.

We are committed to continuously improving our performance. Our objective is to ensure that Orion employees are fit for work and healthy at work, and are not exposed to occupational diseases. We have set two key performance indicators (KPIs) related to occupational health, safety and well-being to monitor the progress and the fulfilments of our Group-level strategic objectives.

	Our approach	Target	Achievements in 2018
Occupational health & safety and well-being of personnel	By taking care of the occupational health and well- being of the personnel at work, Orion aims to ensure that Orion employees are fit for work and healthy at work, and not exposed to occupational diseases.	Workplace injuries: Our lost time incident frequency, LTIF 1 <sup>1</sup> target 3.5 for 2018	LTIF 1 5.5 (6.3 in 2017) -13% Further work needed to achieve the target set for 2018
	The aim is to work towards a year with no incidents at all, since no one should get hurt in the workplace. We also aim to enhance our employees' working ability.	Sick leave of the personnel: Decrease absences due to illness <sup>2</sup>	3.0% (3.1% in 2017) -3%

<sup>1</sup> Indicates the workplace injury rate as injuries causing an absence of at least one day per million total actual working hours.

<sup>2</sup> Absences due to illness as percentage of total theoretical working hours for own personnel.

Accordingly, our occupational safety and well-being activities focus on the prevention of hazardous situations and occupational diseases and injuries. Well-being actions at work also aim to promote and support the working and functioning capacities of each Orionee. In addition to the two KPIs monitoring the fulfilment of our Group-level strategic objectives, we monitor our progress towards our health and well-being objectives with the help of a variety of other indicators, such as the response received from employee health surveys. Particular attention is paid to absences due to musculo-skeletal problems.

In accordance with our <u>EHS Policy</u>, our occupational health and safety activities are managed with the guiding principle of continuous improvement. The practices applied in the management and development of occupational health and safety are determined in the Group's EHS Management System. The EHS Management System is built upon the principles set out in the ISO standards and that in addition to occupational health and safety comprise the environmental affairs. In the EHS Management System, procedures are determined for predicting, preventing and identifying nonconformities and exceptional situations potentially hazardous to environment, occupational health or safety, and corrective action to be taken. Emergency response procedures are featured in the description of the environmental management approach.

# Improving safety culture

A project to improve Orion's safety culture is currently underway and its goal is to bring Orion's incident frequency to zero. To reach that goal, we must change the way we think, so that intervening in our colleagues' unsafe practices becomes accepted and, indeed, a duty. Intervening shows that you care, and has a clear connection to incident frequency. The least incidents occur in work communities where everyone is responsible for ensuring a safe work environment for themselves and others.

In 2018, a Group-wide Work Safety Network has been working on several programmes especially to enhance the Group's safety culture. Orion is in a good position on the general scale of accident

frequency, which serves as a measure of occupational safety. To raise the bar even higher, more is required than just a commitment from management, regulations and minimised risks.

The Safety Network aims to develop employees' thinking and attitude in order to achieve the level of zero accidents. The implementation of the 'Skills to care' -method is the key for continuous improvement in health and safety issues. When we think before we act and we take care of our workmates, achieving the zero goal is possible. In 2018, "Skills to care" pilot training sessions have been held, which are one tool to boost the implementation of an enhanced safety culture. We are collecting the experiences and feedback from the pilot training sessions to decide the way forward.

In addition to the right attitude, we need also good practices and tools. The safety walks with safety talks have been expanded across the whole company and its departments. Regular safety rounds are used to listen to employees and to talk with them about safety matters related to their jobs and the workplace. In 2017, we improved our sharing of best practices and in 2018 completed a Group-wide safety round model that promotes safety and safety culture even further. The aim is to move from safety walks more in the direction of safety talks, which means that there would also be more emphasis on interaction. We also continuously encourage employees to report their safety observations and the corrective action taken via our online system. This is a valuable tool to help us prevent potential accidents from occurring and to follow the progress of the corrective action taken.

Systematic assessments of the workplace, processes, working conditions and methods and the associated risks are carried out by the occupational health and work safety organisations in order to continuously develop working conditions and safety. In addition, we also develop our own practices and models to improve our risk management processes.

Training sessions are a part of an active safety culture and play an important role in the prevention of accidents. Our online training sessions and short digital occupational safety sessions are well accepted and are considered an effective way of communicating.

Our aim is to help our employees to maintain their working ability, be healthy at work and avoid occupational illnesses. We offer our employees more comprehensive occupational health services than those required by law. Employees are given health check-ups depending on their age group to evaluate their fitness for work and to determine any need for measures to enhance it.

The operational models for *Early support*, *Treatment practices for the occupational healthcare for musculo-skeletal and mental disorders* as well as for the management of ageing employees are examples of the ways via which we promote well-being at work and enable the risks of disability to be better managed. *Managing difficult situations* is our model for facilitating and accelerating the analysis and resolution of conflict situations in the working community, as well as for following up the success of the solution.

Preventive occupational health activities include guidance, consultation and support, both to individual employees and working communities, to maintain their ability to work and function and to manage everyday life, as well as workplace surveys relating to health and safety.

We also encourage our employees to take care of their personal well-being. Employees can, e.g., take part in numerous recreational activities put on by staff clubs supported by the Company, participate in company-sponsored gyms and exercise in the Company's fitness facilities. Sponsored culture vouchers can be used for sports and cultural activities. We also have a recreation area and cottages in Finland where employees and their families can spend their free time. As an important factor of daily well-being, we consider high-quality workplace catering as one of our priorities.

#### Team safety commitments

Team safety commitments are forward-thinking and participatory actions. They promote a transparent safety culture. A commitment is a practical action, which everyone can participate in and fulfil. Orion's Supply Chain Management Team decided that all supply chain teams would make a team safety commitment for 2018. Orion Executive Management Board also made a safety commitment. They promised to take part in and actively participate in safety walks. Other examples of safety commitments included giving positive and corrective feedback on safe and

unsafe actions, not using a mobile phone while walking, holding on to a handrail while walking on the stairs and using a reflector as a pedestrian.

#### Well-being at work is a sum of many factors

The well-being actions at work are versatile measures to develop the working communities and promote the capabilities of individuals to work and function. We are developing measures for wellbeing at work to meet the varied needs of working life. We have defined what we mean by employee well-being at Orion as follows:

- Well-being at Orion means that employees are able to do work matching their competences, with a feeling of doing valuable, rewarding, inspiring and meaningful work in a wellmanaged, safe and coequal working community and environment.
- Well-being at work is carried out and enhanced with co-operation from the management, superiors and every Orionee
- Under the principles of well-being, an employee feels comfortable, is active, has stamina and is energetic both at work and at home, and can deal with both change and misfortune.

	Our ways of building well-being					
Leadership and management	Possibilities of influencing employees' own work and the working community	Common rules at the workplace	Competence and development opportunities	Interactive operational models	Corporate culture	
We develop good and renewing leadership to safeguard our success.	We develop innovative solutions and operational models. This challenges all of us to dare to take on new opportunities in our daily work. We all take responsibility for our duties and the functionality of our working community.	We can trust each other and appreciate everyone's work. Confidence is built upon, promises are kept, and appreciation is built upon our ability to understand the significance of everyone's contribution to the whole.	We support and motivate our employees to continue developing their skills and readiness for change.	Collaboration is fluent in a healthy and functioning working community. Information is shared and interaction is effective in all directions. We dare to speak about problems and we solve them constructively.	Building well-being!	
	Personal health and well-being					

# Management responsibilities in environment, health and safety

In the Orion Group, the conformity of operations with the EHS System is coordinated by the Director for EHS and Facility Management, and the EHS organisation with its EHS Specialists reporting to him. He reports to the Senior Vice President, Supply Chain, who is a member of the Group's Executive Management Board. A safety manager who reports to the President of Fermion coordinates EHS activities in Fermion. Fermion's safety managers are members of the Group-wide safety network. Some of the core tasks of the EHS organisation in promoting occupational health and safety include, among other things, participating in the preparation of continuous improvement programmes, external and internal EHS audits, guidelines and training, following up on safety observations and subsequent corrective action, risk assessments, investigating incidents causing injury, EHS reporting and internal communications about EHS affairs. Occupational Health Services belongs to the HR services organisation headed by the Vice President, Human Resources, who reports to the Senior Vice President, Corporate Functions, the latter being a member of the Group's Executive Management Board.

Occupational Health and Safety Delegates supervise and monitor occupational safety at our operational sites. They report to Production Managers.

The local site managers are responsible for arranging operations at the operational site in accordance with the EHS Management System.

Supervisors shall take care of the safety of their subordinates as well as occupational safety guidelines and the necessary safety training. Supervisors shall also make sure that shortcomings in safety at the workplace are fixed.

As mandated by Finnish legislation, our Finnish units have so-called occupational health and safety committees in which all blue-collar and white-collar workers, i.e. approximately 59% of the total Finnish workforce, are represented.

# Environmental, health and safety guidance and training

The general guidelines and principles concerning corporate safety and safe working are provided in the Group's Corporate Governance Manual, the Orion Management Guide and the Orion Security Guide as well as in more detailed function and location-specific guidelines. Task-specific aspects of safety are observed in the SOPs (standard operating procedures) defined in detail for individual tasks and work phases. All EHS guidelines are maintained in our internal information systems, which are accessible to all employees in the Group.

Training is part of active EHS culture and plays an important role. We emphasise the importance of each employee being aware of the health and safety risks that are involved in their duties, as well as how to avoid them. All employees are required to follow the safety instructions and act without posing a risk to either their own safety and/or that of other employees, and without causing damage to the Company's property. We also encourage employees to report their observations of hazards to help manage potential risks. To ensure that staff act correctly and appropriately, we arrange regular training sessions as part of our good safety and security practices to avoid and prevent hazardous events, not only on the job but also anywhere else in the workplace.

# Employee-employer relations and staff empowerment

Orion takes the opinions of employees into consideration in the decision-making process regarding human resources and implementing decisions related to human resources. Employee representatives mainly take part in preparing new practices or implementing changes to existing ones. In addition to mandatory employer-employee forums, our supervisors and HR department have regular informal meetings with employees and employee representatives. A good example of successful collaboration was the decision to make Orion a completely smoke-free workplace by 2018, which was successfully accomplished and which was initiated by the employee representatives.

Employee representation in the Group management is as a general rule agreed upon with employees. There is one employee representative on Orion's Executive Management Board, who is nominated by the staff groups. The representative however is not a member of the Executive Management Board. There are also employee representatives in the management teams of operational units and functions.

The Group appreciates the work and purpose of trade unions and employee representatives, and collaborates with them with respect and openness. In 2018, a tailored training day focusing on how to handle workplace challenges was organised in connection with a regular co-operation meeting. Both HR and employee representatives participated in the training.

# Staff surveys help us identify the need for further development

With the help of regular staff surveys, we identify our strengths and need for development in terms of the implementation of our strategy. The staff survey is conducted Group-wide in every country in which we employ staff. The survey is an important tool for the development of working communities and for the collaboration between employees and management. Orion's executive management is strongly committed to not only conducting the survey but also to implementing

measures for improvement, which have been agreed upon based on the results. The high response rates show that the employees also consider the survey important. Our staff survey is called Succeeding together! - the survey was conducted in spring 2017 and the response rate across the entire Orion Group was 85%.

In addition to the employee surveys, we occasionally conduct more limited enquiries, surveys and mappings of topics where it is important to learn more or hear the employees' opinions in order to include them in the decision-making.

# Complementary references in the Sustainability section of our corporate website:

Human Resources Policy <u>EHS Policy</u> <u>Code of Conduct</u> <u>Supplier Requirements</u> <u>Our practices in approving suppliers</u> <u>Anti-corruption Policy</u>

# Performance indicators concerning labour

#### Absenteeism

#### Causes of absenteeism and working time lost due to absenteeism

Hours	2016	2017	2018
Paid sick leave	139,418	131,970	132,731
Unpaid absence from work due to illness	28,317	30,207	23,023
Paid absence from work due to child's illness	17,228	15,296	14,102
Unpaid absence from work due to child's illness	91	163	842
Total absence due to illness	185,054	177,635	170,697
Absence of 3 or more days due to injury at workplace	1,674	783	1,376
Absence of less than 3 days due to injury at workplace	56	166	32
Absence due to commuting injuries	1,408	716	1,288
Total absence due to injuries	3,138	1,664	2,696
Total work time lost due to absences	188,192	179,299	173,393
Absentee rate, all absences	3.5%	3.3%	3.5%
Absentee rate due to illness	3.1%	3.0%	3.1%
Absentee rate due to workplace injuries	0.03%	0.01%	0.03%
Actual working hours	4,517,674	4,637,686	4,168,962
Theoretical working hours	5,368,248	5,480,055	4,960,848

Absentee rate of all absences is calculated as the proportion of total working time lost of total theoretical working hours.

Absentee rate due to illness is presented as the proportion of absence hours due to illness of the total regular theoretical working hours.

Total work time lost due to injuries indicates the seriousness of workplace accidents.

Absentee rate due to injuries is presented as the proportion of working hours lost due to injuries having led to an absence of 3 or more days of the total regular theoretical working hours.

#### Injuries and fatalities

Injuries <sup>3</sup>	2016	2017	2018
Workplace injuries causing absence of 3 or more days	15	13	20
Workplace injuries causing absence of less than 3 days	5	16	3
Workplace injuries causing absence,			
total	20	29	23
Workplace injuries causing no absence	44	15	16
Workplace injuries total	64	44	39
Commuting injuries	51	46	48
Fatalities	0	0	0
All injury events total	115	90	87
Injury rate LTIF 3	3.3	2.8	4.8
Injury rate LTIF 1	4.4	6.3	5.5



 Work place injuries causing absence of 3 or more days

**Workplace injuries** include injuries caused by accidents that occur during working time and which require medical treatment from the doctor or sick leave.<sup>4</sup>

**Commuting injuries** include injuries caused by accidents that occur when employees are travelling between home and work.

The number of injuries causing absence from work indicates the level of occupational safety at the Company.

**Injury rate** measures the number of workplace injuries per million working hours. It can be used to compare the injury risks of different industries, professional groups, etc. It is also referred to as the LTIF Rate (Lost Time Injury Rate). In this report, injury rate LTIF 3 includes workplace injuries, which led to an absence of 3 or more days, and LTIF 1 correspondingly those having led to an absence of 1 or more days.

The absences and injuries reported cover the staff working at the Group's Finnish locations. Corresponding statistics cannot be collected for the employees in foreign marketing organisations.

The work done to prevent accidents and injuries at our workplaces and taking care of the occupational health and well-being of staff at work is leading to positive results. We report and monitor indicators annually, however, it is even more important to follow the trends in the longer term.

The number of workplace incidents causing absence decreased from 29 to 23 compared to the previous year. Total absence due to injuries increased mainly due to a couple of severe commuting accidents. The absentee rate due to illness, which indicates our ability to enhance our employees' working capability, was 3.1% (3.0% in 2017). Our strategic objective, the lost time incident frequency rate, LTIF 1, came down from 6.3 to 5.5 compared to the previous year. Despite the

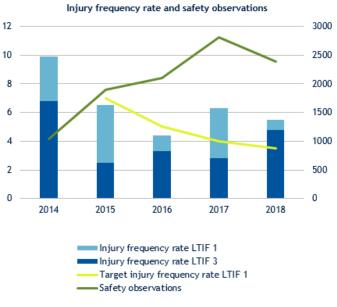
<sup>&</sup>lt;sup>3</sup> Incident events related to muscle or tendon pain if the work-related pain first appeared when the employee was performing a straining work-related motion were excluded in 2016. This is due to the changes in the guidance from the Workers' Compensation Centre in Finland.

<sup>&</sup>lt;sup>4</sup> The reported workplace injuries in 2016 contain also accidents that did not require medical treatment from a doctor.

improvement, we did not achieve our objective of "less than 3.5" for 2018. We took steps in 2018 to focus on improving our company safety culture. We are also continuing this in 2019, and we believe this investment will bear fruit in the long run. To us, a workplace without a single accident is a goal worth aiming at.

Most of the workplace injuries occur in production departments, typically due to tripping and slipping, and when lifting. We have implemented new risk assessment methods to identify spots requiring improvements and rearrangements. We have also widened the scope of safety walks to include all working spaces from production to offices.

Our employees reported a total of 48 commuting injuries, i.e. injuries that occurred on their way between their home and the workplace. Common events were sprains caused by slipping when walking, and falling off bicycles. To reduce the number of commuting injuries, we have widened the scope of the injury investigation process to also include commuting injuries. Corrective action is carried out based on the root causes of the injuries found in the investigation.



Our system for recording safety observations collected as many as 2,388 (2,800) observations of different kinds of dangerous spots at our sites. The decrease in the number of safety observations is mainly due to a change of structure in our new safety system. The new structure allows multiple corrective action to be carried out from one safety observation. We continue to encourage our employees and external partners to report safety observations to improve the safety at our sites. Reporting is made easy: the observations can be easily recorded into the database via the Group's intranet and can be made accessible to those responsible for carrying out corrective action. With the help of the system, employees can also follow the progress of the action.

# **Skills training**

The training offerings comprises hundreds of educational events and courses on a wide range of topics related to job-specific tasks as well as practices in the workplace. Our annual financial input into the training and development of our employees' skills base varies somewhat. In 2018, we invested about EUR 1.7 million (2.2 million in 2017) into training activity.

#### Preventive health and safety training

In 2018, the Group organised about 254 (316 in 2017) training courses focusing on environment, health and safety, with a total of 3,107 (4,569) attendants.

# Personnel structure of the Orion Group

Details of the personnel structures and statistics for 2016-2018 are presented in the <u>Tables</u> section of this Report. In the review of our staff broken down into categories, the breakdowns are presented in amounts representing the full-time equivalent numbers of employees, not true headcounts. The figures are calculated using the same accounting principles as those applied in the Group's IFRS financial reporting. In the "Personnel by reporting unit" graphics, the item named "subsidiaries" includes the foreign Orion Pharma companies for marketing pharmaceuticals and FinOrion Pharma India.

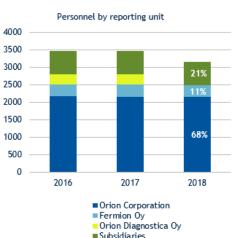
The personnel of the Orion Group's parent company Orion Corporation mostly consists of employees working in pharmaceutical manufacturing, research and development, marketing, business support functions and in financial administration, corporate functions and management.

At the end of 2018, our Group employed about 3,154 people, about 21% of them working outside Finland in the Group's offices, most of which are located in Europe. About 95% of staff were in permanent employment.

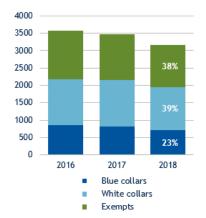
The duration of employment at Orion is typically relatively long. The average duration of employment has exceeded 10 years for several years now, and in 2018 it was 11.3 years.

Employee turnover, calculated in the way recommended by the Finnish Accounting Board, is higher among blue-collar workers than among white-collar workers and exempts.

From 2014-2018, Orion employees retired at an age about 2.5 years higher than the average in Finland. In 2018, the average retirement age in our company was 63.9 years, while the Finnish average was 61.3 years. In the Orion Group, the average age at which an employee claimed their old age pension was 64.2.



Personnel by personnel groups



#### Age breakdown at Orion 2018



The gender structure has also remained almost the same the past three years, women representing approximately 60% and men 40% of the total workforce of the Group. In blue-collar positions, the proportion of women was 39% and that of men 61%. In exempts, i.e. senior salaried employees, 62% of the exempts were women and 38% men. In the white-collar group, the share of women was 70% and men 30%.

In the production of pharmaceuticals at the Orion Corporation, the highest proportion of employees is women at 64%. Fermion's gender structure is almost the opposite: 73% of the total workforce is men. The production processes in particular are predominantly the domain of male workers.

The gender structure of people in supervisory positions shows the differences between the reporting units. In Orion Corporation, 52% of those in supervisory positions are women, while in Fermion supervisors are 80% men. In supervisory positions, the proportional difference compared to the gender structures of the reporting unit are somewhat in favour of men in spite of equal opportunities.

# Business ethics & transparency - doing business in a responsible manner

# Human rights

# Management approach to human rights

Orion is committed to responsible business conduct and strives to promote ethically approved practices. We support and adhere to the principles set out in the United Nations Universal Declaration of Human Rights, and support the principles in ILO conventions and expect the same from our partners. We emphasise social, economic and environmental responsibility as well as fairness and transparency in our relationships with employees, partners, customers, authorities and other interest groups. Our key stakeholders' trust in the Company is of crucial importance for our ability to pursue business and to create added value in a sustainable manner.

Every Orion employee and everyone involved in the manufacturing of our products has the right to be treated well and with respect by supervisors, subordinates and colleagues. We do not accept discrimination in any form. We do not condone or tolerate the use of child labour or forced or compulsory labour in any of our operations, nor in any such operations of our suppliers that are related to our products.

We acknowledge our employees' freedom of association and their legal rights to memberships in labour organisations and collective agreements. Freedom of association is considered a personal matter of privacy. We respect the legal rights of the employees and their representative organisations and treat them openly and honestly. According to the Group's general principle of legal compliance, Orion follows the legislation and binding collective agreements. This is also recorded in our *Human Resources Policy*, which is part of the Group's mandatory Corporate Governance Manual.

Our Code of Conduct defines the Orion Group's ethical practices and commitment to complying with laws, ethically approved practices and respect for human rights. Orion expects all its personnel to comply with the Code of Conduct and practices resulting from it. Correspondingly, our Third Party Code of Conduct applying to Orion's partners defines the minimum requirements which Orion expects partners to be committed to. Both our Code of Conduct and Third Party Code of Conduct reflect our commitment to operating with integrity and high ethical standards in all our business relationships and to implementing systems and controls to ensure that human rights are respected in our supply chain.

We also systematically monitor the compliance of our material and service suppliers and their operations.

In selecting suppliers, we have a critical approach as regards so-called risk countries where there is a risk of human rights or labour rights violations and/or exploitation of child labour, and where national labour legislation is weak or poorly enforced. In countries where a better position for the employees is ensured by international labour norms and the ILO's central labour agreements, we require the supplier to conform to the ILO norms.

We encourage employees and other stakeholders to report in good faith any concerns regarding human rights, as well as any other suspected misconduct of our company's policies. We take any such reports seriously, investigate and take appropriate, case-specific measures to stop behaviour and activity which violate our policies. Non-compliance with our policies may lead to dismissal from employment or the termination of our relationship with third parties.

When reporting any misconduct, primarily the route is to contact our own supervisor, the supervisor's supervisor, the Human Resources department or the Group Internal Audit. Orion also has a public whistleblowing channel that complements the usual communications and reporting channels.

# Organisational responsibility

Every manager at every level of the organisation is responsible for ensuring that the human rights principles are upheld within Orion. Supervisors have an obligation to take the necessary action without delay if the rights are violated. We also emphasise the personal responsibility of every Orion employee to ensure that human rights are respected in the workplace.

The Group's Procurement and Quality Assurance organisations are responsible for following up and monitoring the suppliers' ability to meet our requirements and principles concerning our supply sources.

#### **Training and awareness**

To ensure awareness of our values and policies, we provide training to our staff and our policies are available on our corporate website. All Orion managers receive training on human rights in mandatory supervisor training and in training which focuses on our Human Resources Policy and our procurement and investment principles. Employee rights, including freedom of association, are also discussed during supervisor training. As part of the Human Resources Policy, these rights are also regularly discussed in company-wide human resources information sessions.

The Code of Conduct of the Orion Group obliges all employees to behave and act in ways which respect human rights. Our employees' awareness of the content and spirit of the Code of Conduct, as well as the corporate policies is promoted by ways of internal communication, in the context of our familiarisation processes and training courses, and as part of the web-based e-onboarding programme.

# Monitoring and follow-up

We monitor compliance with human rights principles and react to any violation thereof with the same corporate governance practices as are applied to other corporate internal guidelines. Persons employed by the Orion Group are expected to be familiar with the Code of Conduct.

Orion manages risks in its supply chain through its due diligence practices. Suppliers' compliance with regulations and requirements is monitored through regular or random assessment questionnaires and undertaking risk-based audits of their facilities and operations. If an external party involved in our supply chain is observed to blatantly violate human rights principles, international agreements or legislation, we will undertake corrective action, or in an extreme case terminate the partnerships and replace the party with a compliant supplier. The main principles of our process of approving suppliers are described in the Sustainability section of our corporate website.

# Our performance in human rights

**Non-discrimination.** We have no record of any violations of the discrimination ban during the periods under review.

**Freedom of association and collective bargaining.** There are no such functions or activities in our Group in which the right to exercise freedom of association and collective bargaining is under risk.

**Child labour.** There have been no violations of employee rights or collective agreements during the periods under review. There are no such operations within the Orion Group where the risk of using child labour is significant. We have no record of any situations where child labour has been used in relation to our own or our suppliers' operations during the periods under review.

**Forced and compulsory labour.** We have no record of any situations where forced or compulsory labour has been used in relation to our own or our suppliers' operations during the periods under review.

**Indigenous rights.** No issues related to the rights of indigenous peoples in relation to our business have been brought to our attention during the periods under review.

# Complementary references in the Sustainability and Corporate Governance sections of our corporate website:

Human Resources Policy <u>Code of Conduct</u> <u>Pharmaceutical R&D Ethics Policy</u> <u>Anti-corruption Policy</u> <u>Supplier Requirements</u> <u>Our practices in approving suppliers</u> <u>Slavery and Human Trafficking Statement</u>

# Managing the sustainability of our suppliers

The pharmaceutical industry is a global business and no actor can do everything alone. As other pharmaceutical companies, Orion is also part of the global supply chain. Where Orion buys products and raw materials from others, others also buy them from Orion. Raw material production is highly specialised and there may be only a few companies in the world making one pharmaceutical substance. This also applies the other way around, for example, about half of the world's methotrexate is made at the Fermion plant.

	Our approach	Target	Achievements in 2018
Managing the sustainability of our suppliers	We expect our suppliers to demonstrate their commitment towards Orion's Third Party Code of Conduct and our Supplier Sustainability Requirements. We are committed to improving the management and monitoring of environmental, health, safety and ethical issues in the supply chain.	TBC	12 sustainability audits During the course of the year, we widened the scope of our sustainability audit program from EHS to sustainability i.e. paying more attention to also on topics such as labour and ethics.

Irrespective of where the raw materials are sourced and the products are manufactured, the quality of Orion's products is ensured through rigorous management of the entire supply chain. Following of Good Practices is required in the development and manufacturing of pharmaceutical products. Auditing our suppliers with regards to GxP requirements is an important step in selecting, monitoring and ensuring the continued availability and the consistent quality of the raw materials and making sure that the documentation is traceable.

#### Orion's supplier expectations

We expect our suppliers to demonstrate their commitment towards Orion's Third Party Code of Conduct and our sustainability requirements.

We are committed to responsible business conduct and strive to promote sustainable supply chain management. We are also committed to systematically managing our global supply chain and monitoring our suppliers' environmental, health, safety (EHS) and ethical compliance through assessment questionnaires and by undertaking risk-based sustainability audits, ensuring that necessary corrective action is agreed with the supplier and monitoring that the action is implemented. Suppliers are required to comply with GxP requirements, and in addition to this we expect our suppliers to demonstrate their commitment towards Orion's Third Party Code of Conduct and Supplier Sustainability Requirements. We revised our requirements in 2018 and started their implementation. Our Third Party Code of Conduct defines the minimum requirements to which Orion expect its partners to be committed. In addition to regulatory requirements, it includes key principles for business operations concerning sustainability and ethics. Our Third Party Code of Conduct appliers, but also to our distributors and other partners with which there is a transfer of value.

In addition, Orion expects its suppliers to acknowledge and adhere to the Supplier Sustainability Requirements. These set down a minimum set of requirements that Orion expects from its suppliers and ensure that our suppliers conform to our Third Party Code of Conduct and additional requirements for management systems, safe working practices, environmental, health and safety protection.

We manage our global supply chain and monitor suppliers' environmental, health, safety (EHS) and ethical compliance, taking action if needed. We have a risk-based approach in managing sustainability in the supply chain. Our risk-based management of the supply chain means that we have identified and prioritised risks and that we manage risks and continuously develop our risk management. The factors affecting the supplier's risk level are for example the country of origin and the business criticality of the material being sourced. Based on the risk assessment, we define the needed risk mitigation action for the supplier or manufacturing site. Tools that we use are supplier self-assessment questionnaires and undertaking risk-based sustainability on-site audits to assess suppliers in terms of sustainability.

For audit observations, we ensure that the necessary corrective action is agreed with suppliers and follow the implementation of this action. We conduct risk-based on-site audits at our 1st tier suppliers but also at selected 2nd tier suppliers if appropriate. The on-site audits are therefore commonly carried out on formulated products of pharmaceutical substances, active pharmaceutical ingredients and at intermediate supplier sites. Indicators related to EHS audits are reported on in the *Performance Indicators for Product Responsibility* section of this report.

We continuously reduce our environmental burden and manage social risks in our supply chain. We also see that collaboration at the industry level is key, and in 2018 we joined the Pharmaceutical Supply Chain Initiative (PSCI), which is an industry initiative focusing on promoting and continuously improving the pharmaceutical supply chain in the areas of labour, ethics, environment, health and safety, and responsible procurement practices. We see that in addition to our own efforts, a common vision and shared responsibility is the key and an effective way to be able to improve the sustainability of the supply chain.

In 2018, we made progress internally in raising awareness and updating our processes to even better integrate sustainability into day-to-day activities of our procurement organisation. We ensured that sustainability is well embedded, from sourcing to supplier relationship management. During the course of the year, we also adjusted our sustainability audit program and widened the scope from EHS to sustainability i.e. paying more attention to also on topics such as labour and ethics. Capability building is key, not only internally but also externally. In 2018, we offered our suppliers training on sustainability matters as part of PSCI supplier training sessions in a few regions. Altogether, a total of 26 suppliers were trained.

# Complementary references in the Sustainability section of our corporate website:

EHS Policy Supplier Requirements Our practices in approving suppliers

# Societal relations

# Management of societal relations

The practices and methods pursued by Orion as regards community relations, social and political relations, restrictions of competition and corruption are derived from the general principles of our Corporate Governance Manual, according to which the operations of the Orion Group are based on compliance with the valid laws and regulations issued therein as well as with ethically acceptable operating principles.

This is also the guiding principle of our *Code of Conduct*, which defines the Group's ethical practices and commitment to complying with laws, ethically approved practices and respect for human rights. We expect all our staff in the Orion Group to comply with the Code of Conduct. All community relations are based on open and honest communication and interaction, in which both parties' expectations are considered.

We accept that reasonable gifts are part of normal business culture within the framework of legislation and ethically acceptable practices. The principles that are included in the Code of Conduct and our *Anti-Corruption Policy* require that employees refuse to offer or take a bribe or any comparable benefit. Orion has zero tolerance of all forms of bribery and corruption in its business operations. Identifying and assessing risks relating to corruption is part of the comprehensive overall Group Risk Management. Among other things, assessing bribery risks is also a standard part of the preparation of all collaboration agreements.

According to the donation policy of the Group, when deciding on donations it must be confirmed that each donation adheres to applicable laws and regulations and ethically acceptable operating practices.

Our principal channel for influencing political decision-making is via relevant industry associations.

Political parties or associations do not receive support from Orion. Even though we do not participate in the activities of political parties as a company, we respect the legal right of our employees to take part in political action, which is considered a private matter.

Orion adheres to the current competitive legislation. We are in favour of fair competition and promotion thereof, and we aim to ensure that the objectives of applicable competitive legislation are honoured in our operations. We strive to avoid any breaches of competitive legislation.

Legal and regulatory compliance is the cornerstone of all our operations. We expect every employee to be aware of the legislation and regulations that apply to their work. It is the responsibility of managers and supervisors to ensure that up-to-date regulations are available and that the employees are made familiar with them.

# **Procedures**

The divisions and organisations that make up the Group are responsible for managing authority relations in the areas that fall under the scope of their operations and responsibilities.

When we want to inform political decision-makers and authorities of our opinion, for example when new laws or regulations are being drafted, we aim to do so via channels such as national and international industry organisations. We are a member of the European Federation of Pharmaceutical Industries Associations (EFPIA) and the Chemical Industry Federation of Finland, which is part of the Confederation of Finnish Industries EK. As the voice of business, regional and central chambers of commerce are relevant channels for us, as the International Chamber of Commerce (ICC).

When necessary, our managers can approach decision-makers directly. In terms of being able to voice our opinion we consider good and appropriate relations to be important, especially with local decision-makers in the regions where we have an operational presence, with the relevant regulatory authorities and, most importantly, with the national and municipal decision-makers and officials making decisions which affect the operating conditions of the healthcare industry.

## Our marketing and marketing communications practices are in line with EFPIA codes

In Europe, the practices applicable in the marketing of pharmaceuticals are recorded in the <u>EFPIA</u> <u>Code on the Promotion of prescription-only medicines to, and interactions with, Healthcare</u> <u>Professionals - EFPIA HCP Code</u>, adopted by the European Federation of Pharmaceutical Industries and Associations (EFPIA). The HCP Code determines the practices and obligations which are required to be followed by the EFPIA member companies in the marketing of prescription medicines and in other relationships with healthcare professionals.

Doctors and other healthcare professionals as well the organisations with whom they work are important collaboration partners for the pharmaceutical industry. They provide companies with valuable clinical expert knowledge for the development and improvement of medicinal treatments, which results in significant benefits for both individual patients and society. Healthcare professionals in turn can benefit from the forums for further education and exchange of information offered by the pharmaceutical industry. In order to increase the transparency of the different forms of interaction and the related financial compensation, EFPIA has supplemented its set of principles with the HCP/HCO Disclosure Code, which obliges member companies to publicly disclose the details of transfers of value with healthcare professionals with the right to prescribe and deliver medicines on an individual basis for each identifiable recipient. Pursuant to the Disclosure Code, Orion has reported the data since 2016. We believe that being transparent and publishing the compensation paid to HCPs and HCOs for the time spent working with us every year builds an understanding of this collaboration and helps foster trust with stakeholders. We disclose all the payments made to health care professionals based on the work done for all the countries where we have our own operations. We do not make any payments to HCP's for promotional purposes. Disclosure reports are available in our public webpages and publicly accessible for each country. Individual healthcare professionals however can prevent their names from being disclosed in the report based on their legal right to privacy.

As an EFPIA member company, Orion acknowledges the purpose and spirit of the EFPIA Codes, which is stated in the *EFPIA Leadership Statement on Ethical Practices* as follows:

As industry leaders, we are committed to working in partnership with all stakeholders to improve healthcare across Europe. In doing so, we are conscious of the importance of providing accurate, fair and objective information about our medicines to allow rational decisions to be made about their use. As such, we fully respect the role that EU legislation plays in regulating interactions between pharmaceutical companies and healthcare professionals.

Our sales and marketing organisations for pharmaceuticals primarily follow the locally valid legislation concerning medicinal products, marketing, consumers and competition, the International Code on Advertising and Marketing Communication Practice as well as the Orion Group's Code of Conduct and internal guidelines, which correspond to the EFPIA Codes of Practice. The management responsibilities in our pharmaceutical sales and marketing operations have been arranged in accordance with the requirements provided in the relevant legislation (the Medicines Act in Finland) and the EFPIA codes.

We organise continuous training and regular testing for our sales and marketing organisation to ensure that those involved in marketing can manage and follow both the common codes and practices of our industry and our own practices and principles.

When preparing marketing communications and advertising material, we follow the procedures determined by healthcare authorities for checking and confirming the legal, regulatory and ethical compliance of the content before the material is released for use and publication.

The Global **Medical Affairs** is a headquarter function which coordinates and consults regarding the planning of marketing communication, and monitors the implementation of it in order to confirm its compliance with national and transnational regulations. Medical Affairs is independent from the Sales & Marketing department and reports to the Chief Medical Officer. In order to ensure that the promotional activities are in line with regulatory requirements, the specialists in the Medical Affairs

organisation work closely together with the sales and brand managers and the sales organisation as well as with the non-Orion marketing partners who promote our products in their agreed territories.

#### Transparent collaboration with patient organisations

We support patient organisations with their socially important role in providing information and mental support, arranging rehabilitation and bringing patients and their families together with peers to share experience and advice. In collaboration, we are committed to the commonly agreed code of practice, the *EFPIA PO Code*, on the relationships between pharmaceutical companies and patient organisations operating in Europe.

The purpose of the Code is to ensure ethical and transparent collaboration with patient organisations. The Code emphasises the patient organisations' integrity and the independence of pharmaceutical companies. The promotion of prescription-only medicines via patient organisations is prohibited. Direct and indirect support to patient organisations must be transparently disclosed, and the support must be provided without any terms restricting competition or the supported organisation's freedom of activity. A written agreement on the support must be made.

For transparency, every year we publish a summary of our collaboration with patient organisations by country in the Sustainability section of our corporate website, and the indicator is included in our reporting of our economic performance.

#### Organisational responsibilities

At the Group level, the Executive Management Board is responsible for community relations.

## Training and awareness

The practices and means related to community relations, social and political influencing, competitive legislation and anti-corruption are dealt with in both the company guidelines, the supervisor and expert training, the induction of new employees and other training and information sessions where it is natural to discuss these issues. These issues are also addressed in the Group's Code of Conduct.

The principles concerning anti-corruption are included in the Group's Code of Conduct and in the Anti-Corruption Policy, which unambiguously instruct the employees of the Orion Group to refuse to offer or take a bribe or any comparable benefit. Employees are regularly and systematically educated and trained about the purpose and importance of these principles. The latest training was arranged in 2017, when the total number of employees attending was 2,808. We ensure that the training is completed by all new employees, for whom it is mandatory.

Identifying and assessing risks relating to corruption is part of the comprehensive overall Group Risk Management. Assessing bribery risks is also a standard part of preparing for all collaboration agreements, among other things.

In addition to the principle of legal and ethical compliance and anti-corruption specified in our Corporate Governance Manual and the Code of Conduct, we also have defined specific guidelines concerning competition law, which every Group employee is expected to adhere to. We arrange training related to competitive legislation and agreements for all employees who are involved in making agreements or carrying out other tasks, which may fall under the scope of competition law.

In addition, Group-wide guidelines apply for agreements and documents signed in the names of the Orion Group companies. These guidelines are in place to ensure that all agreements are made with sufficient legal expertise and in writing that agreements are approved at the appropriate decision-making level based on their scope, and that only authorised signatories of the companies can sign agreements.

Our operations are very highly regulated by legislation and special regulations. We arrange a lot of training for our staff in areas related to regulatory compliance by means of courses, information sessions and self-learning. The employees are also expected to be pro-active in acquainting themselves with the relevant provisions.

# Monitoring and follow-up

We monitor legal and regulatory compliance in the same ways as we monitor compliance with internal guidelines. We also react towards non-compliance by applying the same procedures as are applied in the event of breaches of other internal guidelines.

# Complementary references in the Sustainability section of our corporate website:

<u>Code of Conduct</u> <u>Anti-corruption Policy</u> <u>Supplier Requirements</u> <u>Our practices in approving suppliers</u> <u>Patient organisation collaboration</u> Collaboration with healthcare professionals (in Finnish)

# Compliance

Orion is committed to conducting its business in a responsible and sustainable way. Our operations and activities are based on compliance with laws and regulations, as well as with ethically acceptable operating practices.

Orion's Code of Conduct, other company policies, internal work instructions (WI) and Standard Operating Procedures (SOP) guide our everyday work in well-regulated industry. Our Code of Conduct defines the Orion Group's ethical practices and commitment to complying with laws, ethically approved practices and respect for human rights. Persons working for the Orion Group are expected to be familiar with the Code of Conduct and to comply with it. Correspondingly, our Third Party Code of Conduct applying to Orion's partners defines the minimum requirements which Orion expects partners to be committed to.

# Assessing and managing risks

Orion has assessed and identified most material non-financial risks in line with the requirements of the Finnish Accounting Act. You can read more about Orion's non-financial risks and their mitigation in our Financial Statement 2018, p. 21-24.

Training and awareness raising are the most important measures to mitigate compliance and the non-financial risks. To ensure awareness of our values and policies we provide training to our staff and our main policies are available on our corporate website. To be aware of and raise awareness of compliance risks, rules and ethical practices online training on how to prevent corruption and bribery is mandatory for the selected personnel. Orion ensures that the training is completed by all employees for whom it is mandatory.

# **Reporting of ethical concerns**

For reporting any misconduct, Orion has a public whistleblowing channel that complements the usual communications and reporting channels. The channel promotes good governance and ethical operations, and improves processes after any reported incident. We encourage employees and other stakeholders to report in good faith any concerns and any suspected misconduct of our company's policies. We take any such reports seriously, investigate and take appropriate, case-specific measures to stop behaviour and activity which violate our policies. Non-compliance with our policies may lead to a dismissal from employment or the termination of our relationship with third parties.

In 2018, there were no material fines or non-monetary sanctions for non-compliance with laws and regulations related to anti-corruption, human rights violations in own operations, health or safety impacts of our products, provision and use of our products, environment or anti-competitive behaviour. In 2018, Orion has also continued to organise privacy and data protection training for its personnel, built up its privacy framework and revised its documentation to measure up with the new requirements of the EU General Data Protection Regulation. There were no significant breaches of customer privacy or losses of customer or research data.

# Economic responsibility

# Management of economic responsibility

In the Orion Group, economic responsibility means that we produce economic value added for both shareholders and other stakeholders, such as staff, customers and suppliers of goods and services. To this end, we develop our operations systematically and utilise our resources efficiently. We are proactive in dealing with this responsibility, with an aim to identifying and managing the risks related to our operations and their further development in the best possible way. Good corporate governance required from listed companies is also part of our economic responsibility, as well as open and regular communication about the development of our financial performance and the factors affecting it.

Good financial performance is also necessary to enable us to attend to the other areas of corporate responsibility as a corporate citizen and to ensure sustained operational continuity in the future. The better we manage our finances and are able to provide employment, the more society will benefit from our economic added value.

Most of the key figures related to our economic responsibility are presented in our consolidated financial statements and interim reports, which are prepared in accordance with the International Financial Reporting Standards (IFRS). We present some economic indicators in the sustainability reports.

# Management of economic responsibility

The management of our economic responsibility follows the general guidelines established in our Corporate Governance Manual. This involves responsibilities being clearly defined, objectives being set and monitored and internal control systems being organised appropriately. The administration of the Group's financial affairs is a headquarter function headed by the Chief Financial Officer, who is a member of the Group's Executive Management Board. The CFO reports to the President and CEO. The centralised financial administration comprises all financial affairs of the Group companies based in Finland, such as bookkeeping, payment transactions, internal and external financial reporting, Group financing, as well as all Group-level reporting and financial control of the business operations. In the Group's foreign subsidiaries, the financial affairs are mainly administrated locally in each country under the supervision of the Group headquarters.

Monitoring the financial development of the Company and supervising the financial reporting process are among the key duties of the Board of Directors and its Audit Committee.

Detailed descriptions of our corporate governance principles, risk management and internal control are presented in our regular financial statements and Corporate Governance Statements, which are accessible on the Corporate Governance pages in the "Orion Group" section of our corporate website.

# Goals and performance

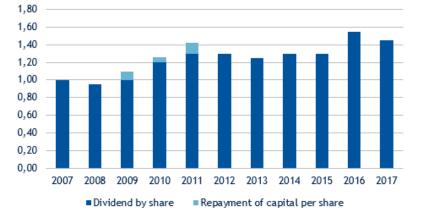
We aim to ensure the economic sustainability of our operations over the coming years. Our objectives for profit development and financial position have been set to ensure economic stability, to create a solid foundation for long-term profitable growth, and to enable operations and profitability even in economically challenging times.

Through the financial objectives, we aim to develop the Group's shareholder value and ensure financial stability and profitable growth. Our financial objectives are:

- Growing net sales more rapidly than growth of the pharmaceuticals market. Achievement of this objective requires continuous investment in development of the product portfolio.
- Maintaining profitability at a good level. The aim is operating profit that exceeds 25% of net sales.
- Keeping the equity ratio at least 50%.
- Distributing an annual dividend that in the next few years will be at least EUR 1.30 per share, and increasing the dividend in the long term.

According to our dividend policy, we take into account the distributable funds, the capital expenditure and other financial requirements in the medium and long term to achieve the financial objectives. In the challenging economic situation and the changes that have taken place in our business environment over the recent years, we have been able to grow in most years, operate profitably and pay good dividends to our shareholders.

Orion share dividend per share, 2007-2017 EUR



Sustained economic success requires us to be able to

continuously ensure competitiveness and cost-effectiveness with the right strategy decisions and by enhancing procedures and the product portfolio. Our growth is based on a competitive pharmaceutical product portfolio, which the Group builds by actively developing new products in both our own R&D organisation and through wide-ranging cooperation with external parties.

#### Creating wealth via taxes and employment, paying dues as agreed

We are committed to paying all taxes that are legally due and meeting all disclosure requirements in the countries where we operate. We have paid the taxes due on the good and stable financial result regularly and on time. In 2018, Orion's taxes and withholding taxes amounted to EUR 114 (133) million. We have also always taken care of our pension commitments in full. In the comparison of financial performance, we have consistently been ranked among the best Finnish listed companies.

Our largest direct economic impacts come from the employment opportunities we provide. Orion is a company whose products are of significant social importance. As a workplace, we offer our employees the chance to develop, manufacture and sell products that promote well-being, health and quality of life, and we offer a fair compensation and good employee benefits in return. Orion is a global company with global policies and processes, but our operations are very local. In our sales subsidiaries, management and personnel are predominantly local. The majority of Orionees work in Finland.

In our procurement activities, we give preference to goods and service suppliers who share our values regarding corporate responsibility. Their invoices for deliveries that meet the agreed terms are paid according to the agreed schedule. Correspondingly, we aim to minimise our own overdue trade receivables.

#### **Reliable communications for Orion shareholders**

Our shareholder base is quite diverse. At the end of 2018, the company had ~73,000 registered shareholders. The largest shareholder group consists of private Finnish households, and at the end of 2018 they held about 42% of the total shares and 62% of the total votes. Detailed information on the shareholder base is presented and updated on a monthly basis in the "Investors" section of our corporate website.

As a public listed company, we fulfil our disclosure obligations diligently. We also actively develop our corporate communications and aim to utilise different communication channels and tools in a versatile, yet purposeful manner. Our focus is on the good quality of the contents of our financial statements and our website to provide capital markets and shareholders with up-to-date information about the Group's operations and performance. We also organise regular meetings with investors in various locations in Finland and abroad. A calendar can be seen under the "Investors" section of our corporate website, containing both past and upcoming investor events and roadshows.

#### **Principles concerning donations**

Most of the annual donations made by the Orion Group for purposes of public interest are based on the decision by the Annual General Meeting to donate part of the distributable assets of Orion Corporation to medical research and other purposes of public interest. The Board of Directors decides on the allocation of the donations.

Donations are granted to non-profit organisations pursuant to the principles determined in the Group's donation policy. The focus of our support is on medical research, patient organisations and other non-profit organisations promoting healthcare, defence and veterans, environmental protection, children and youth, education and culture. As a main rule, the donations shall be made through Orion Corporation, the parent company. The evaluation of applications and the decisions on grants are centralised into the Board of Directors and the Group administration.

At Group level, the prioritised charitable organisation receiving financial support from us is the *John Nurminen Foundation*, which works to save the Baltic Sea and its heritage for future generations. As a corporate partner and sponsor of John Nurminen Foundation, we are a partner in the Clean Baltic Sea projects. Contributing to Clean Baltic Sea is well aligned with our own efforts and the action we have carried out, since we have systematically developed our own water resources and wastewater management. Together and via the John Nurminen Foundation's network of specialists expertise can also be shared and enhanced with others for the good cause.

Information about our collaboration with patient organisations is reported on an annual basis in the Sustainability section of our corporate website. The reports provide details of each collaboration, and they comprise all the countries in which we have our own marketing organisation for pharmaceuticals.

#### Co-operation partner in 2018

In 2017, we at Orion created the Välittämö100 Web service, välittämö100.fi, together with the Central Association of Carers in Finland. Via Välittämö100, individuals in Finland as well as organisations could donate services to carers and their families. The donations included for example, fixed-term newspaper or magazine subscriptions, gift cards for cruise ships, gym memberships or other types of service gift cards. Furthermore, Välittämö enabled anyone to donate their own time to help carers with domestic chores such as tidying, cleaning or gardening, for example. Välittämö100 was in action throughout 2017 to 2018. As of the end of 2018, 318 donations had been made, of which 226 had been reclaimed.

# Indicators of economic performance

Information about the financial performance of the Orion Group is provided in the annual financial statements and interim reports, which are accessible via the Investors section of our corporate website. Selected financial key figures for 2016-2018 are provided in the <u>Tables</u> section of this Report.

#### Coverage of the Group's pension obligations

Our Group has pension plans in accordance with each country's local regulations and practices. In the defined contribution plans, we pay fixed contributions to separate entities such as pension insurance companies in Finland who manage the pensions. We have no legal or constructive obligations to pay further contributions if the recipient of the contribution is unable to pay the employee benefits. Our most important defined benefit pension plans are in Finland, where statutory insurance under the Employees' Pensions Act (TyEL) has been arranged through the Orion Pension Fund for the Group's clerical employees and supplementary pension security for some of the clerical employees.

Our pension obligations are listed under Note 12 "Pension assets and pension liabilities" of the Financial Statements 2018. At the end of 2018, our pension obligations totalled EUR 299.7 (298.1) million. We had a pension asset of EUR 31.5 (asset of 55.2) million from the Pension Fund and a liability of EUR 3.6 (liability of 3.2) million to other units.

#### Significant financial assistance received from government

EUR million	2016	2017	2018
Business Finland grants	1.2	1.1	1.5

Orion has received funding for its development projects from Business Finland, which grants funding to Finnish companies and institutions to promote research, development and innovation as well as to share any related risks. Some Business Finland-funded projects are not public. The figures reported above are based on the Business Finland annual reviews, and they contain both direct cash funding and project-specific loans.

The annual reviews and summaries of public projects receiving Business Finland funding are available at www.businessfinland.fi/en. The total Business Finland funding paid to units of the Orion Group in 2018 totalled EUR 1,521,548, of which pharmaceutical R&D projects of Orion Corporation accounted for EUR 1,393,939.

Orion Corporation received Business Finland funding for research into treatment approaches to certain cancers and central nervous system disorders. In addition, we received funding for the development of biomarker research and analysis platforms to support precision medicine development.

In 2018, Business Finland also granted Orion EUR 127,609 in energy aid for investment projects to develop and replace part of the energy system with a low-carbon alternative.

#### Donations for purposes of public interest

EUR	2016	2017	2018
Donations	350,000	300,000	250,000

Most of the annual donations made by the Orion Group for the purposes of public interest are based on the decision by the Annual General Meeting (AGM) to donate part of the distributable assets of Orion Corporation to medical research and to other causes of public interest. Therefore, note that in this exceptional case, the reporting period used is from AGM to AGM and not a calendar year.

Patient organisations also belong to the scope of instances of public interest. In 2018, the total monetary value of our collaboration with patient organisations came to EUR 78,739 (EUR 109,799 in 2017). This sum is not included in the figures presented in the table above.

# Tables

# Key figures 2016-2018

Indicators of product responsibility	2016	2017	2018
Product recalls due to product defects, total	13	10	8
Product recalls due to product defects, medicinal product	9	7	6
Class 1 (Critical)	1	0	2
Class 2 (Major)	4	1	1
Class 3 (Minor)	4	6	3
Product recalls due to product defects, non-medicinal	4	3	2
Number of audits of Orion's operations	55	81	61
Audits by authorities	12	19	13
Audits by collaboration partners	43	62	48
Critical observations	0	0	0
Number of audits undertaken by Orion	269	314	238
Critical observations	29	26	10
Rejection	5	5	1
Number of customer complaints about the Pharmaceutical business (ppm) <sup>1</sup>		64	56

<sup>1</sup> The number of customer complaints about the operations of the Pharmaceuticals business is reported as the number per million packages (ppm).

Environmental indicators	2016	2017	2018
Use of materials total, tonnes:	13,296	13,656	12,395
Direct manufacturing materials	9,271	9,462	8,155
Packaging materials	4,024	4,194	4,241
Proportion of recycled materials (recycled solvents) of total	14%	15%	15%
Waste total, tonnes:	11,406	12,598	13,725
Energy recovery	1,143	1,101	751
Materials recovery	1,612	1,614	1,768
Incineration, mass burn	8,646	9,882	11,202
Landfill waste	4	0	4
Energy consumption total, MWh:	161,440	160,818	155,198
Direct energy consumption total, MWh	14,797	14,801	13,593
Heavy fuel oil	0	0	0
Light fuel oil	451	402	1,189
Natural gas	14,347	14,399	12,404
Indirect energy consumption total, MWh	146,643	146,017	141,605
District heat	50,298	48,512	42,917
Steam	26,825	27,787	29,714
Electricity	69,520	69,719	68,974
Energy consumption by reporting unit, MWh:			
Orion Corporation	107,507	106,889	106,171
Fermion Oy	45,081	46,097	49,028
Orion Diagnostica Oy	8,852	7,833	NA
Energy saved due to efficiency improvements, MWh:	2,068	3,725	1,074
Electricity	33	-1,841	-346
Heat	2,035	4,992	1,420
Fuels	0	574	0
CO <sub>2</sub> emissions from energy consumption total, tonnes:	44,459	44,589	39,581
Scope 1, direct emissions	3,065	3,089	2,788
Scope 2, indirect emissions	41,394	41,500	36,793

Environmental indicators, continued	2016	2017	2018
Emissions into air from sources other than energy, tonnes:			
CO <sub>2</sub> from production	110	49	15
Methylene chloride (DMC)	1	0	0
Volatile organic compounds (VOC)	19	60	79
Nitrogen oxides, NOx	20	23	23
Sulphur dioxide, SO <sub>2</sub>	4	5	6
Particles	0.1	0.1	0.1
Water withdrawal and consumption total, 1,000 m <sup>3</sup> :	275	266	256
Orion Corporation	183	188	205
Fermion Oy	71	59	51
Orion Diagnostica Oy	21	19	NA
Environmental expenditures and investments total, EUR 1,000:	6,667	8,788	5,896
Environmental investments	1,710	3,550	396
Environmental protection expenses	4,957	5,238	5,500

Personnel indicators	2016	2017	2018
Absenteeism due to illness, hours	185,054	177,635	170,697
Absentee rate due to illness	3.1%	3.0%	3.1%
Absenteeism due to injuries, hours	3,138	1,664	2,696
Work time lost due to absenteeism, hours	188,192	179,299	173,393
Absentee rate	3.5%	3.3%	3.5%
Injury events total	115	90	87
Workplace injuries causing absence of 3 or more days	15	13	20
Workplace injuries causing absence of less than 3 days	5	16	3
Workplace injuries causing absence, total	20	29	23
Workplace injuries causing no absence	44	15	16
Workplace injuries total	64	44	39
Commuting injuries	51	46	48
Fatalities	0	0	0
Injury rate LTIF 1	4.4	6.3	5.5
Injury rate LTIF 3	3.3	2.8	4.8
Actual working hours	4,517,647	4,637,686	4,168,962
Theoretical working hours	5,368,248	5,480,055	4,960,848

Personnel structure	2016	2017	2018
Personnel at the end of the period	3,469	3,464	3,154
Average personnel during the period	3,446	3,513	3,179
Number of employees by region as at 31 Dec:	3,469	3,464	3,154
Finland	2,796	2,802	2,485
Other Nordic countries	113	97	92
Germany	74	73	81
UK and Ireland	52	55	52
Russia	85	84	84
India	127	140	152
Other countries	222	213	208
Employees outside Finland total	673	662	669
Number of employees by reporting unit as at 31 Dec:	3,469	3,464	3,154
Orion Corporation	2,166	2,156	2,141
Orion Diagnostica Oy	284	282	NA
Fermion Oy	346	348	344
Foreign subsidiaries	673	662	669
Number of employees by employee category as at 31 Dec:	3,469	3,464	3,154
Blue collar	831	816	715
White collar	1,357	1,341	1,237
Exempts	1,281	1,307	1,202
Gender structure, all employees:			
Women	61 %	<b>61</b> %	60%
Men	39 %	<b>39</b> %	40%
Gender structure, blue collar:			
Women	42 %	42 %	<b>39</b> %
Men	58 %	<b>58</b> %	61%
Gender structure, white collar:			
Women	63 %	71 %	70%
Men	37 %	<b>29</b> %	30%
Gender structure, exempts:			
Women	70 %	63 %	62%
Men	30 %	37 %	38%
Age structure, all employees:			
Under 20 years	1 %	0 %	0%
20-29 years	11 %	12 %	<b>9</b> %
30-39 years	27 %	26 %	24%
40-49 years	32 %	31 %	30%
50-59 years	24 %	25 %	30%
Over 59 years	6 %	6 %	<b>6</b> %
Employee turnover, average:	14.3 %	14.1 %	12.4%
White collar and exempts	12.7 %	13.6 %	13 <b>.9</b> %
Blue collar	17.9 %	15.8 %	12.5%
Employees with permanent employment contract as at 31 Dec	3,205	3,113	3,010
Average duration of employment, years	11.0	11.1	11.3

# **Gender structures**

#### Breakdown of staff by gender by reporting unit in 2018<sup>1</sup>

Employees (%)	Orion Group	Orion Corporation	Fermion Oy	Foreign subsidiaries
Female	1,861	1,370	93	400
	<b>59</b> %	64%	27%	60%
Male	1,293	771	251	267
	41%	36%	73%	40%
Total	3,154	2,141	344	669

<sup>1</sup> Breakdown corresponds to the true headcount's gender breakdown. The number of employees are reported as full-time equivalent numbers of employees applying the same accounting principles as those applied in the Group's IFRS financial reporting.

#### Breakdown of staff by gender of managers and supervisors in 2018<sup>1</sup>

	Orion Group	Orion Corporation	Fermion Oy	Foreign subsi- diaries
Female	43%	53%	<b>19</b> %	37%
Male	57%	47%	<b>8</b> 1%	63%
Total	100%	100%	100%	100%

<sup>1</sup> Breakdown corresponds to the true headcount's gender breakdown.

# Gender breakdown,

**Board of Directors of Orion Corporation** 

Gender	2016	2017	2018
Female	2	3	3
Male	5	4	4
Total members	7	7	7

#### Gender breakdown, Orion Executive Management Board

Gender	2016	2017	2018
Female	3	3	3
Male	5	5	5
Total members	8	8	8

#### Age breakdown,

Board of Directors of Orion Corporation

Age	2016	2017	2018
Under 50 years	0	0	0
50-59 years	2	4	4
60-65 years	5	3	3
Over 65 years	0	0	0
Total members	7	7	7

## Age breakdown,

**Orion Executive Management Board** 

Age	2016	2017	2018
Under 50 years	2	1	1
50-59 years	4	6	6
Over 59 years	2	1	1
Total members	8	8	8

Financial performance	2016	2017	2018
Net sales, EUR million	1,073.5	1,084.6	977.5
International sales to external customers, EUR million	735.0	753.8	665.3
% of net sales	68.5 %	<b>69.5</b> %	68.1%
Operating profit, EUR million	314.6	293.0	252.8
% of net sales	29.3 %	27.0 %	25.9%
Profit before taxes, EUR million	310.9	286.5	248.4
% of net sales	29.0 %	26.4 %	25.4%
Income tax expense, EUR million	61.9	60.5	51.0
R&D expenses, EUR million	118.2	105.1	104.0
% of net sales	11.0 %	9.7 %	10.6%
Capital expenditure, EUR million	51.1	76.5	64.8
% of net sales	4.8 %	7.1 %	6.6%
Assets total, EUR million	1,062.9	1,055.5	1,146.7
Equity ratio, %	60.8 %	64.6 %	68.8%
ROCE (before taxes), %	40.9 %	36.2 %	44.3%
ROE (after taxes), %	40.3 %	34.2 %	45.5%
Personnel expenses, EUR million	224.4	218.1	202.8
Financial assistance received from government, EUR million	1.2	1.1	1.5