Sustainability Report 2018

octapharma

Our passion drives us to provide new health solutions advancing human life.

About the Sustainability Report

This is the Octapharma Group Sustainability Report and it relates to the financial year 2018. The Report covers Octapharma Nordic AB (Corporate ID No. 556614-9794) and all entities included in the consolidated accounts for the same period. These entities are specified in the Notes of the consolidated accounts. In accordance with the provisions of the Swedish Annual Accounts Act (chapter 6, paragraph 11) the Report has been prepared separately from the Annual Report.

This is Octapharma's second Sustainability Report, and there have been no significant changes in the principles applied to its reporting and scope. In signing the annual financial statements and consolidated accounts of the company, the Board of Directors has also approved the Sustainability Report.



- R&D sites
- Countries where patients are treated with our products

Who we are

Octapharma is one of the largest human protein product manufacturers in the world, developing and producing human proteins from human plasma and human cell lines. As a family-owned company, Octapharma believes in investing to make a difference in people's lives and has been doing so since 1983; because it's in our blood.

Octapharma employs more than 8,300 people worldwide to support the treatment of patients in 115 countries with products across three therapeutic areas:

- Haematology (coagulation disorders): In people with bleeding disorders, the blood clotting process doesn't work properly. In haemophilia A and B and Von Willebrand disease (VWD), the protein factor VIII, IX or Von Willebrand factor (VWF) respectively are missing or don't work as they should.
- Immunotherapy (immune disorders): For inherited or acquired deficiencies of the immune system (missing or faulty antibody production), which can lead to increased susceptibility to infections. Also for various autoimmune diseases where the patient's own immune system mistakenly attacks part of the patient's body.
- Critical care: Patients in intensive care, emergency care or during surgical procedures often require immediate medical attention to prevent shock and to quickly restore the body's natural balance - such as normal blood volume and clotting (coagulation) function.

The Octapharma Vision

"Our passion drives us to provide new health solutions advancing human life"

Octapharma's corporate vision drives all company decisions and underpins everything we do at work each and every day anew. Our vision describes the overarching idea of Octapharma and serves as the company's navigational reference point.

Our Mission

For the safe and optimal use of human proteins.

Our Values

The five values of Octapharma are the principles and beliefs that guide our behaviour, decisions and actions at work. They articulate the philosophy by which each of us lives and acts every day. Our values are also the fundamental basis for our performance management and the respective evaluation process at Octapharma.

- Ownership
- Integrity
- Leadership
- Sustainability
- Entrepreneurship

Social and employee-related information

Octapharma has a zero tolerance approach to discrimination, regardless of reason and works to achieve a culture characterised by equality and diversity. This is clearly expressed in the company's Code of Conduct as well as our Corporate Sustainability Policy. Octapharma recognises that society as a whole still has a way to go in reaching gender equality, diversity and the abolition of discrimination in all its forms and realises that the company is not immune to these issues. Octapharma therefore needs to work actively in promoting equality and diversity as well as working against all forms of discrimination.



Headcount men/women

Board of Directors

Number of men and women on the parent company Board of Directors

Managers

Total number of managers in the Group by gender (excluding Group executive management)

Employees

Total number of employees (excluding Board of Directors, Group executive management and other managers) in the Group by gender

Total Workforce

Employee age groups	2017 2018			18
breakdown (%)	No.employees	% of total	No.employees	% of total
Under 30 years old	2,515	33%	2,605	31,3 %
Between 30 and 50 years old	3,896	51%	4,280	51,5%
Over 50 years old	1,263	16%	1,429	17,2 %
Total Workforce	7,674		8,314	

2017		2018		
Men	Women	Men	Women	
11	0	11	0	
251	293	579	643	
2,939	4,180	2,934	4,147	
3,201	4,473	3,524	4,790	

Plasma collection and manufacturing

Octapharma collects plasma and manufactures it into lifesaving plasma derived therapies. Each therapy we create is controlled, fractionated, purified, virus inactivated and inspected before being used to change and save the lives of patients worldwide.

Plasma-based therapies treat rare, genetic and chronic diseases such as haemophilia and immune deficiency disorders. They are also used to treat trauma and burn victims and for critical care procedures including major surgeries, cancer treatments and organ transplants.

Plasma collection methods

Source plasma is collected from healthy, voluntary donors through a process called plasmapheresis. Donors may be compensated for their time and efforts, depending on country regulations.

Octapharma owns and operates 86 source-plasma donation centres in the USA (*FDA-approved) and 13 in Germany (approved by the Federal State authority). Recovered plasma is collected through whole blood donations. The plasma is then separated from its cellular components. Octapharma collaborates with a variety of blood banks and not-for-profit organisations (e.g. the Red Cross) for the additional supply of recovered plasma.

* Food and Drug Administration

Manufacturing

Using the latest technology and a strict quality control process, Octapharma's production plants carry out plasma fractionation and purification, pharmaceutical production, packaging, storage and distribution.

Distribution channels

The entire production of plasma-derived products takes place at production facilities in Austria, France, Germany, Mexico and Sweden, all of which have the required licences for manufacturing pharmaceuticals. The production output is sold worldwide. Octapharma's customer base is well diversified and does not depend on one single customer group or national tender. Octapharma's main customer groups are hospitals (public and private), pharmacies, national public bodies including self-sufficiency tenders or specific hospital based tenders for certain products.

Quality assurance, plasma and control

Quality assurance

Quality assurance is a way of preventing mistakes or defects in manufactured products and avoiding problems when delivering medicinal products to patients. The quality assurance system has the overall objective of providing confidence to our customers, patients and government agencies by fulfilling set requirements and improving work processes and efficiency internally in the company.

Quality plasma

Delivery, Look-Back, PDI Management, Deviations & Complaints The Corporate Quality Plasma (CQP) department ensures all relevant consistent quality parameters for plasma. From delivery to the checking and preparation of plasma units for production.

All information on units, the accurate traceability of each plasma unit, including Look-Back and Post Donation Information and deviated processes which may have an influence on the quality of a plasma unit are covered by this process function. Furthermore, the department is responsible for handling "Look-Back" donations, including measures and systems to prevent "Look-Back" plasma being used for production. CQP ensures the accurate traceability of each plasma unit.

Supplier qualification

CQP evaluates plasma supplier compliance with applicable regulations and quality standards.

CQP is also responsible for the qualification and regular audit of all plasma suppliers in order to guarantee a constant supply of human plasma that is compliant with the quality defined in the Plasma Master File. Furthermore, CQP is responsible for handling complaints to suppliers.

Quality control

Octapharma Quality Control (OQC) is in charge of product control at various stages of the production process. These controls are applied to starting material in order to verify they are of the required quality, corresponding to our requirements and specifications. OQC also continuously monitors that the products are being processed in a controlled environment.

In addition, through testing plans all along the production process up to and including the final product itself, OQC ensures that the process is conducted to pharmaceutical standards of quality, safety, efficacy, stability and compliance. In this task, OQC applies validated methods, standardised sampling, and test plans and stability studies.

Supply chain

The single most important suppliers for Octapharma are company-owned donor centres. Octapharma does not have any major suppliers in countries where there is likely to be risk of unfair labour conditions or human rights violations.



Materiality analysis

In preparation for our Sustainability Report, Octapharma's management carried out an analysis of the most material sustainability aspects with regard to the company's operations, including those issues where the company is deemed to have a significant impact. The analysis covered both sustainability risks and opportunities in our operations and value chain, mainly concerning the environment, social and employee matters, respect for human rights and anti-corruption. The results of the materiality analysis can be seen from the topics and KPIs presented in this report.



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- Initiatives to improve public health and access
- 16 Educational and research partnerships
- 17 Anti-corruption policy and communication
- 18 Whistleblower cases and actions taken

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- 24 Ethical considerations in marketing and

Governance and management of sustainability

The Board of Directors has overall responsibility for the management and execution of the Group's decisions and strategies, which also includes issues related to sustainable business operations. Environmental matters at our production sites is the responsibility of local environmental and operations managers, as is quality control. Human Resources (HR) is responsible for all people-related issues and Group compliance together with local compliance officers are responsible for ensuring compliance with all laws and permits at all times.

Governing norms, policies and guidelines

Octapharma's Corporate Sustainability Policy outlines our overall commitments and viewpoints with regards to sustainability.

The policy recognises that we are committed to treating resources with care and to minimise negative environmental impacts that could result from our processes and activities. Octapharma is committed to providing a safe and healthy working environment and strives to reduce workplace accidents and sickness, as well as to promoting and further develop the skills of our employees. Product responsibility and quality are indispensable prerequisites of our business and Octapharma is committed to complying with all regulatory requirements and internationally established best practices. Lastly, Octapharma is committed to supporting and respecting human rights within our sphere of influence. The sustainability policy is reinforced by local policies and instructions at our research facilities, manufacturing sites and offices.

In order to communicate our corporate values and norms and to support all people working for Octapharma in making the right decisions, the Board of Directors has also adopted a company-wide Code of Conduct, based on our core values:

- Ownership
- Integrity
- Leadership
- Sustainability
- Entrepreneurship

The Code of Conduct expresses the Octapharma Group's expectations as an employer and sets professional standards to be adhered to throughout the Group. It covers several aspects of the business such as professional integrity, respect for competition law, our zero tolerance approach to corruption, how to handle conflicts of interest, respect for others and the promotion of diversity and equality of opportunity, to name a few. All employees, and everyone who acts on behalf of Octapharma, must comply with the Code of Conduct. Online compliance trainings have been developed to help explain the importance of integrity in our activities and cover the key messages of the Code of Conduct. All relevant employees are expected to complete the trainings.

These online courses are split into three different areas: Code of Conduct, Corruption Prevention and Antitrust Law. Pending on the individual's function and responsibilities the Corporate Compliance Office decides on a selection of the relevant trainings.

To encourage our employees to speak out on suspected non-compliant behaviour, misconduct and violations of the Code of Conduct, Octapharma has implemented several communication channels to report such incidents. Inter alia we have implemented an internal whistleblowing system (the integrity reporting system) permitting everybody to report such incidents in most countries anonymously (unless restricted by law). Reported matters are then forwarded to Corporate Compliance which will – on a case by case basis – involve HR or internal audit for further investigation.



Environmental performance

Octapharma's annual Sustainability Report provides details of the company's environmental strategy and performance. The main environmental impact is caused by our daily operational business. We have expanded the scope of this year's report to include the Heidelberg site in our Biopharmaceuticals organisation, in addition to our packaging and logistics centre and production facilities in Europe. Other facilities and business activities in the Octapharma Group will be assessed in terms of environmental impact as we continue to develop our reporting.

The Group's commitment to operate with a focus on reducing environmental factors that have the greatest global impact is continuing, and in this way we are contributing to a sustainable society. In addition to the main areas of climate change and clean water scarcity, we have concentrated our efforts towards transport and emissions.

With regard to energy efficiency, our manufacturing sites have continued improvement work by focusing on local energy areas. Greenhouse gas (GHG) emissions from different sources such as fossil fuel use and refrigerant leakage have been identified, and actions have been taken to drive the phase-out of fossil fuels, replacing equipment and cooling media systems in order to reduce fugitive emissions.

Concerning water, we have identified manufacturing processes with high use of purified water and the next step will be to assess improvement measures, while retaining patient safety and addressing challenges with validated and registered processes. Considerable work has been done to reduce adverse emissions in process waste water at all production sites by introducing collection of environment-adverse streams for treatment at off-site plants. This work will continue, but adverse site emissions into local water have already been significantly reduced.

The challenge of addressing these important global environmental issues while at the same time ensuring a growing economy is handled well at the different sites.



Environmental KPIs

	GROUP		
	2016	2017	2018
KPI Energy Use (MWh/tonne plasma)	33.61	32.56	31.89
KPI Renewable electrical energy (% of electrical energy renewable)	52	62	62
KPI Emission (tonne CO2e/tonne plasma)	7.24	7.45	5.88
KPI Municipal water use (kCbm/tonne plasma)	0.20	0.18	0.21
KPI Waste water (kCbm/tonne plasma)	0.16	0.16	0.17

Conclusions

During 2018, the Group's energy use included 62% of renewable electrical energy. This is the same percentage compared to the previous year. However, important decisions for the phase-out of fossil fuels have been made for several sites during 2018, thus making the business more sustainable in terms of environmental impact. The effect is likely to be seen in next year's reporting figures.

Together with the KPI for renewable electrical energy, the KPI for global warming equivalent is perhaps the most important measure in terms of actual environmental impact. For the Group, this KPI indicates that a decrease in both absolute and relative figures has been achieved, in spite of the Group's increased capacity and the expanded reporting scope. The main reason for the reduced environmental impact during the year is the work that the different sites have performed on refrigerant leakage control.

During the year, the Group increased the use of municipal water. This is an increase compared with previous years in both absolute and relative water use. The main reason for the increase was the exceptionally warm summer period in Scandinavia. Rising seawater and air temperatures, in combination with our increased production capacity, meant large volumes of municipal water were needed to aid the cooling processes during manufacturing.

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