

Sustainability & values

Sobi's mission is to develop and deliver innovative therapies that improve the lives of patients. Rare diseases are chronic, debilitating and often life-threatening; and have a severe impact on patients and their families. Providing treatment options for patients with rare diseases very often results in improved quality of life and enhanced independence: factors that are important, not only to the individual patient and their families, but to society at large.

In our overarching ambition to provide valuable medicines and improve lives, Sobi strives to always ensure the highest levels of patient and product safety, research ethics, environmental protection and working conditions. We believe that, in order to ensure our long-term sustainability and to effectively serve the patients who depend on us, we must always act in an open and responsible way in relation to our stakeholders.

At Sobi, we believe that an integrated and holistic approach to developing and delivering innovative therapies to patients is essential to ensuring that they benefit from the medicines we develop. We recognise that, in order to optimally serve the patients who rely on our products, we must create and maintain an on-going dialogue with all stakeholders at all stages of the patients' journey in the healthcare system. Through these discussions with patients, employees, decision-makers, government bodies, healthcare system developers and managers, industry organisations and other stakeholders, Sobi continues to develop an understanding of how we can best meet the needs of all our stakeholders.

Dialogue with patients, families and carers

Learning that a child has a serious or even potentially fatal rare disease is a life-changing moment for both the child and the child's family. The diagnosis must be followed up with the greatest of care. Treatment and related supportive healthcare is often complicated. Due to the rarity of these diseases, knowledge about the condition in question, even amongst healthcare professionals, may be limited. Patients and relatives often have a great desire for knowledge. Sobi prioritises investment in education and information materials for medical staff, patients and relatives. Sobi supports numerous patients' organisations and maintains an active dialogue with them to understand their needs and to build mutual understanding of the nature of specific rare diseases and

their treatment. A complete list of patient organisations supported by Sobi is available on www.sobi.com.

Workplace and employees

Sobi's business model combines advanced research with commercial activity. Sobi is a knowledge-intensive company with high expectations of the individual employees. This is essential for creating a shared culture of innovation and high performance; and this is central to our ability to create value for our stakeholders. Our objective is to attract, retain and nurture the best talent in our field and to create an environment where our people can thrive and feel engaged in their contribution to Sobi's mission of improving the lives of patients.

Competence development, shared values, innovation & engagement

At Sobi, we aim to create a culture of individual responsibility and accountability. In order to help each person understand how their individual efforts contribute to our mission, Sobi has a strong internal culture of shared goal-setting and transparent communication.

Continuous development for each employee at Sobi is a vital element of ensuring that we can develop our portfolio, strengthen production processes and successfully launch and sell products in the market. The company has a well-defined Performance Management Process to ensure that managers and employees jointly set personal objectives, based on the corporate objectives, on an annual basis. These are formally followed up on at defined points during the year.

The objectives are set and evaluated on what individual employees achieve, but also how they achieve it. The Sobi "CARE" values – Collaborative, Accountable, Respectful and Engaged – measure both elements, and form the foundation for the annual evaluation of employee performance.

Attracting, retaining and nurturing a world-class workforce

Good terms of employment are required in order to recruit and retain qualified employees of the highest standard. Sobi strives to offer competitive salaries and benefits packages, determined on an individual basis and reflecting the local labour market. Sobi aims to offer a working environment that promotes health and wellness, which comprises various elements aimed at fostering this. We strive to offer a healthy work-life balance within the framework of the company's operations.

Diversity and equal opportunity

In 2012, 40% of the total employees were men and 60% were women. In the Executive Leadership Team and the Board of Directors the corresponding figure was 50/50% and 71/29%¹, respectively. All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Employee turnover

The employee turnover within the Sweden-based headquarters operations (385 people) was 6.5% during 2012.

Respect for labour market regulations

Sobi complies with and respects labour market regulations. The company works constructively with trades unions and employee-employer organisations and makes it a priority to continue to foster an ongoing and collaborative understanding.

¹ This figure does not include employee representatives.

Maria Berggren

Sobi, Vice President,
Human Resources



“ At Sobi we firmly believe that each one of us has to take responsibility for our own development and lead through example. We recognise that, in order for our company to develop and for us to reach our collective goals as an organisation, we continuously have to develop as individuals. We view all of our people as leaders in the organisation, regardless of their title. Our collective desire to develop and to drive our business forward through strong leadership at every level of the organisation is inspired by our mission to help people with rare diseases. That is the beating heart of this company: the desire to make a difference in the lives of people with rare diseases. This is what motivates everything we do.”





Bruce Faulkner-Dunkley
Sobi, Managing Director
for UK Ireland and BeNeLux

“ Our mantra of People with Passion and Pride in their Performance is, without doubt, ingrained throughout Sobi. We are not confined by titles; and that is very empowering and enhances the entrepreneurial spirit. Senior management speak to people – and they listen and act on what they hear. There is a strong sense that people have a voice here and that they are heard. Ultimately, I firmly believe we at Sobi have some of the best people in the world, working in the development and delivery of innovative therapies to patients with real unmet needs. At Sobi we all feel the same – we’re here because what we do makes a difference.”

Ongoing medical education

Knowledge about rare diseases is often scarce, inadequate and geographically diverse, even after treatments become available. Knowledge about the condition in question, the natural history and other aspects is increasing on an on-going basis. Sobi is committed to facilitating enhanced knowledge-sharing amongst healthcare providers. To this end Sobi has produced, in collaboration with medical expert groups, several extensive training programmes for healthcare providers who treat rare disease patients. Several of these training programmes are now certified by public health services.

Working with industry colleagues

In order to stay up-to-date with the changing external environment; and to contribute to evolving the robust systems that govern pharmaceuticals and healthcare systems, Sobi is a member of several representative industry bodies, both at national and international levels. It is also important for our business model to be part of creating and sustaining a public environment that favours research, development and investment in the knowledge-based economy and the scientific sector. Sobi is also a member of a number of industry groups committed to building understanding and fostering a collaborative external environment. A list of organisations that Sobi is a member of is available on www.sobi.com.

Product liability and research ethics

Patient safety

Sobi’s products are subject to strict, well-established and harmonised standards by existing national and regional regulatory frameworks before they are granted a marketing authorisation. For products on the market, as well as molecules in all stages of development, Sobi continually

monitors, analyses and balances the risks and benefits for patients. Protecting patient safety is our most important obligation and, in our clinical programmes, we always adhere to the Helsinki declaration for human rights. Employees are tasked with ensuring compliance with both internal and external rules with respect to any clinical trials that Sobi sponsors.

In Sweden, Sobi is part of the Pharmaceutical Insurance scheme, a funded system for those in Sweden suffering from any adverse effects that may have arisen from pharmaceutical treatment or participation in clinical trials.

Clinical trials

All Sobi-sponsored clinical trials are conducted and reported in accordance with applicable laws and global standards of good practice. All Sobi-sponsored clinical trials undergo an internal Sobi approval process, as well as regulatory authority and independent ethics committee review and approval, prior to trial initiation.

Sobi strives to maintain the highest ethical, technical and scientific standards in all clinical research conducted. The company ensures that the clinical investigators and sites participating in Sobi-sponsored trials are qualified by training and experience; and that they have adequate resources to conduct the trial.

The majority of our clinical trials are operationally executed by Contract Research Organisations and the Sobi outsourcing process is regulated in internal Standard Operating Procedures (SOPs). The ultimate responsibility for the strategy, quality and integrity, including the implementation and maintenance of quality control systems; and the reporting of a trial always remains with Sobi as the sponsor.

Sobi publishes information about all company sponsored clinical trials on www.clinicaltrials.gov.



Our Core Values – Collaborative, Accountable, Respectful and Engaged – are an essential part of our culture and guide us in our day-to-day interactions with all stakeholders, including our colleagues.

Handling of adverse event reports

Sobi has marketing authorisation for a number of drugs in different markets. This brings an obligation to collect, process and report adverse events and other safety information to regulatory authorities in accordance with international laws and regulations.

Sobi maintains an efficient system and network for the collection, analysis and communication of adverse effects and other safety information associated with the products we market and develop. Sobi's Drug Safety Unit is tasked with capturing, analysing and communicating signals to secure the benefit of our products and the well-being and safety of patients on an ongoing basis. All employees are responsible for reporting any suspected adverse effects of Sobi's products that come to their attention, a process that is governed by internal SOPs, which all Sobi employees are required to review and commit to on a regular basis. Sobi regularly updates these SOPs to reflect changes in legislation and best practice.

Animal experiments

Safety legislation at national and international level requires pharmaceuticals to be tested on laboratory animals at certain stages in their development. An important part of Sobi's commitment to safety and compliance with the law therefore requires us to conduct safety testing on laboratory animals. Sobi adhere to legislation for animal protection, and is striving to reduce the number of tests conducted on animals. We therefore follow the "three Rs" – Replace, Reduce and Refine – in animal research to ensure that, wherever possible, we can reduce the number of animals to a minimum. This means, in practice, that animal research programmes are designed to ensure that the most appropriate laboratory model is being used, in order to reduce the number of animals needed to obtain the necessary information.

Drug development can also use a large number of methods that are not based on laboratory animals – e.g. *in vitro* tests. Sobi's aspiration is to continue to develop *in vitro* methods, amongst others, to replace or reduce the number of laboratory animals needed to demonstrate the safety data required by governments.

Safe production of pharmaceutical proteins

Sobi complies with Good Manufacturing Practice (GMP) requirements. Sobi manufactures the active ingredient for ReFacto AF in its Stockholm facility and Multiferon® in its facility in Umeå, Sweden. Other production is outsourced to external manufacturers. External manufacturing is covered by specific agreements to ensure supply and quality. The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) regulatory authorities, as well as authorities from other countries, regularly inspect the production facilities of both internal and external manufacturers and suppliers.

Safe purchasing procedures

Raw materials, other material, equipment and other services for manufacturing are purchased according to Sobi's SOPs. The SOPs require that all procurement and purchasing takes place professionally and competitively, in accordance with Sobi's rules and GMP requirements. Our Environmental Health and Safety (EHS) policy requires that suppliers conduct their activities in such a way that employee health and the environment are protected and that energy and natural resources are saved.

Environmental protection

Environmental management

Managing our environmental impact is a core commitment. Proactive environmental management is part of creating a sustainable business. Sobi works according to an environmental management system based on the

international standard ISO 14001, but is not certified. The responsibility for EHS management is delegated to the line managers and coordinated by the environmental coordinator.

Sobi strives to fully comply with all environment-related laws and regulations. The management system links current legislation and rules to internal control documents and procedures. Sobi's production facilities in Stockholm and Umeå are licensed for hazardous operations in compliance with the Swedish Environmental Code, including conditions for waste-water management. The company has a licence to work with radioactive substances from the Swedish Radiation Safety Authority, but no such work was performed during 2012. Sobi also has an import licence from the Swedish Board of Agriculture for animal by-products and a licence to handle flammable goods. Sobi takes producer's responsibilities for packaging by being associated with recycling systems, such as the REPA register in Sweden.

In order to protect people and the environment, as well as Sobi's business interests, a variety of Environmental Health & Safety issues are considered while developing and continuing supplier relationships. Sobi has issued a standard Contract Manufacturer Environment, Health and Safety Due Diligence Questionnaire to assist in the evaluation of EHS management systems of current and candidate contract manufacturers.

Environmental training

Environmental awareness among all personnel is crucial for successful environmental management. As of 31 December 2012, 76% of all employees in Sweden had completed a general environmental training programme covering sustainable development, recycling and the greenhouse effect, amongst others. The company offers continuing education and relevant environmental training is included in the annual action plans.

Work environment

Sobi complies with occupational health and safety related laws and regulations and the formal responsibility is delegated to line managers. All operations are required to perform annual safety inspections, surveys and risk assessments for fire safety, security, ergonomics and electrical safety.

For Manufacturing and Research & Development, there are additional requirements for annual safety inspections concerning chemicals and Genetically Modified Microorganisms (GMMs). In 2012 Sobi did not handle any chemicals that require permission from the Swedish Work Environment Authority and there was no work performed with radioactive substances. The company reports to the Swedish Work Environment Authority regarding its use of biological agents and the contained use of GMMs. The GMM systems are all established models in the biopharmaceutical industry.

There were no workplace accidents to report to the Swedish Work Environment Authority in 2012.

Pharmaceuticals in the environment

The environmental hazard of a specific drug refers to its inherent properties, including toxicity, ability to break down in nature and potential to be stored in the fat of animals, amongst others. Pharmaceutical substances are classified with respect to their decomposition, based on standardised laboratory tests. EU guidelines on environment risk assessment of drug substances have established that certain drugs are not expected to have any environmental impact – including products composed of carbohydrates, amino acids, peptides and proteins, amongst others. The majority of Sobi's products are biopharmaceutical products composed of amino acids, proteins and peptides, therefore, their environmental impact is considered insignificant.



Stephen James

Sobi, Vice President, Head of
Drug Design and Development

“ At Sobi, we have a clear understanding of what it means to be a leader. I think we understand the importance of collaboration. And we also understand that success can only come through strong partnerships. This collaborative approach is at the heart of our approach towards leadership and people. We recognise that we must create an environment in which people feel empowered to contribute to the advancement of the business. This collegiality is very important at Sobi and, in my view, is what makes it such a challenging and fun environment to work in. The whole team works well together and there is a clarity of purpose right throughout the organisation.

When I look at our later-stage pipeline, I can see how close we are to making a difference to patients who are still in need of new or better treatments; and that is genuinely exciting. I believe that everyone at Sobi recognises that they are part of something potentially very special.”

Energy and resource consumption

Sobi continually works to improve the energy efficiency at our sites and we regularly review the operating costs in buildings in which we operate. A programme to review and reduce the water consumption in the Stockholm production facility was initiated in 2011 and resulted in a decrease of 35% to 105,809 m³ in 2012, compared with 162,956 m³ in 2011. The total consumption of electricity, district heating and cooling in 2012 for the two Stockholm and the Umeå facilities was 17,845 MWh, see table below. We intensified the efforts to reduce the energy and resource consumption in the production facility in Stockholm by starting an energy-efficiency project in late 2012. Knowledge and experience from the project will be used in other buildings where Sobi operates.

The active management of waste is another key aspect of our commitment to reducing our impact on the environment. The total amount of waste decreased in 2012 compared with 2011; see the diagram below. Air emissions in the Sweden-based companies primarily come from travel. Air emissions from flights during 2012 was 570 tonnes of carbon dioxide, compared with 582 tonnes of carbon dioxide during 2011. Sobi is working to reduce this. Sobi is also working on improving the reporting systems to be able to gather data from subsidiaries and generally reduce costs and environmental impacts.

GRI reporting

Sobi is applying level C in accordance with the Global Reporting Initiative (GRI) guidelines for reporting on sustainability. The company's GRI report is available at www.sobi.com.

Resource consumption (Stockholm and Umeå facilities)

	2012	2011
Electricity (MWh)	6,742	9,442
District heating (MWh)	4,288	4,887
District cooling (MWh)	3,562	4,622
Steam (MWh)*	3,253	–
Total energy (MWh)	17,845	18,951
Water consumption (m ³)	105,809	162,956

* From 2012 Steam will be reported separately.

Waste disposal 2006–2012

