

Communication on progress 2017

Statement of CEO

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Our vision is to be recognised as a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases. With the ambition to become a global leader, sustainability is a vital part of our vision and overall corporate strategy. We are committed to conduct our business in a responsible way and therefore we support the principles conducted by the United Nations Global Compact.

A sustainable business for Sobi entails a commitment to responsibility for patients and employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability. This Communication on Progress report concludes our actions and results to implement the Ten Principles within the four areas covered by the UN Global Compact – human rights, labour, environment and anti-corruption.

For a full version of our Annual and sustainability report 2017, read more on sobi.com.

Guido Oelkers
CEO

The following pages is an extract from the Annual report 2017.

Sustainability

Sobi contributes to a sustainable future as part of our vision of becoming a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases.

The Group's overall objective from a sustainability perspective is tied to this overall vision: to contribute to the societies in which Sobi

operates by improving access to treatment of rare diseases. A sustainable business entails a commitment to responsibility for patients and

employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability.

Our values

Sobi's values are the starting point for our approach to sustainability. The Code of Conduct & Ethics also contains policies guiding sustainability activities. Together these provide a solid foundation for our work with sustainability.

We care about our world, but primarily we care about people – in particular, people with

rare diseases and our colleagues at Sobi.

During 2017, we evolved our previous CARE values (Collaborative, Accountable, Respectful, Engaged) which have been central to who we are and the way we work. Because we care, we need to act. To ensure that more patients benefit from our advanced therapies now and in the future, and to align with the

company's ambitions for growth, we have identified new values that build on the CARE values. These are Care, Ambition, Urgency, Ownership and Partnership. They will help us to develop the spirit of leadership and entrepreneurship that we need to become recognised as a leader in rare diseases.



Care

We are who we are because of our dedication, our knowledge and our passion. Care is the foundation upon which our strategy, our business and our culture are built.



Ambition

We will set ourselves ambitious goals and do our utmost to achieve them.



Urgency

We need to embrace a sense of urgency, while safeguarding our standards, because the patients cannot wait.



Ownership

It is our duty to act. We therefore encourage intrapreneurship and learn from our experiences.



Partnership

We embrace partnerships and collaboration, within Sobi and with external partners and stakeholders.



Material sustainability issues

Sobi's material sustainability issues were developed during 2017. Based on ongoing input from external stakeholders and an internal analysis of the growth strategy, the Executive Committee approved an updated materiality analysis. Sobi's material sustainability issues have been clustered in relation to their potential to create value, ability to support a responsible business, and expectations to adhere to laws, regulations and society's expectations.

The materiality analysis forms the basis for Sobi's sustainability programme. The programme is under development and current initial activities aim to define the overall objective, targets and indicators to further drive performance.

Material issues	
Value creation	<ul style="list-style-type: none"> • Improving global access to treatments for rare diseases • Quality and supply chain management • Strategic research and development
Compliance and ethics	<ul style="list-style-type: none"> • Regulatory and legal environment • Developing our people • Ethical practices and collaborations
Responsibility	<ul style="list-style-type: none"> • Environmental impact • Patient and customer integrity • Responsible tax • Anti-corruption • Anti-competitive practices

Contribution to the UN's Sustainable Development Goals

The United Nations' Sustainable Development Goals are 17 global goals, approved by more than 150 countries in 2015, to be reached before the end of 2030. Sobi recognises the important role of business in the achievement of these goals. Based on the growth strategy and the materiality analysis, Sobi has identified nine goals to which our operations contribute the most. The most strategic global goal for Sobi is number three "Good health and well-being" and specifically target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all. For Sobi, this is sustainability.

UN'S SUSTAINABLE DEVELOPMENT GOALS

Sobi has identified that, through our actions, we are able to influence a number of the Sustainable Development Goals.



Value creation

Improving global access to treatments for rare diseases

Access to treatments for rare diseases is provided through the business areas Haemophilia and Specialty Care. An integrated approach is required to ensure that patients can access treatment and achieve the best possible outcomes. Successfully providing such treatment requires comprehensive and sustainable solutions in several dimensions, including access to early diagnosis and treatment, a long-term commitment to the community and healthcare systems, and responsible pricing. With a strong focus on patient and medical needs, responsible pricing, adaptive regulatory pathways, partners for manufacturing and an extensive and efficient distribution network, we work continuously to shorten the time it takes for products to reach patients.

Responsible pricing

An effective treatment is one that not only provides a medical benefit but is also both available in the country where the patient lives and is affordable in the healthcare system. One of the most crucial factors to ensure patient access to treatment is responsible pricing.

Sobi is committed to playing an active role in the dialogue with stakeholders, governments and healthcare systems, to ensure that patients get timely and sustainable access to

required medicines, irrespective of where they live and irrespective of the level of development of the local healthcare system. We aim to set prices at a local level according to local needs and preconditions. Our ambition is to work with local health communities to improve health policies and to ensure sustainable access to treatment.

Bridging and access programmes

Sobi acknowledges the fact that where the local government and/or healthcare system has not yet included therapies in their local healthcare provisions, patients suffering from rare conditions do not have access to the same quality of treatment as other patients. In these situations, Sobi is committed to working with governments in finding a way to secure that patients get access to treatments through bridging programmes, to bridge access until reimbursed access is secured. In developing and emerging markets, Sobi also works with governments and local and international patient organisations, to fulfil a humanitarian aid need, while working with key stakeholders to build and lay the foundation to move from donation to sustainable reimbursed access by governments and/or healthcare systems.

In the US, Sobi provides financial assistance for people in need of treatment with Orfadin and Kineret, to bridge access until reimbursement is in place. Sobi is also bridging access in other countries based on individual patient

need and engages in dialogue with authorities to adapt local regulations – a successful approach that has provided access to treatment in Chile.

Since 2015, Sobi in collaboration with Bioverativ, a Sanofi company, has contributed to providing access to a predictable supply of innovative and effective haemophilia treatment to people in developing countries. The companies have pledged to donate up to 1 billion international units of clotting factor between 2015 and 2025. Of these, 500 million have been earmarked for the World Federation of Hemophilia, which is working to ensure a sustainable shift and predictable access to treatment in local markets.

In several European countries with developed healthcare systems but limited budgets, the volumes of factor replacement necessary to treat haemophilia effectively are not available, despite minimum treatment recommendations. In order to bridge the gap between the recommendations and current access in those countries, the European Haemophilia Consortium (EHC) has developed the Procurement of Affordable Replacement Therapies – Network of European Relevant Stakeholders (PARTNERS) programme, in which Sobi is a key player. This is a new and innovative approach to the sustainable procurement of treatment products for haemophilia A and B in select countries meeting EHC-specified criteria and located both inside and outside the EU.



“I have treated patients with HT-1 with Orfadin for over 20 years thanks to the support of Sobi. I am grateful for Sobi’s initiative to work towards securing sustainable treatment for these patients.”

Dr Dweikat, Jerusalem

Quality and supply chain management

Patient safety and product quality

Patient safety throughout the product life cycle is one of our most important tasks. With a robust pharmacovigilance system in place, we continuously oversee the benefit/risk profiles of our products. The pharmacovigilance system complies with all global, national and local regulations. The main purpose of the system is to guarantee patient safety in regards to our products.

Annual training is provided for all employees to ensure that all safety information in relation to our products is reported. By collecting and analysing safety data from all sources, we aim to provide accurate and up-to-date information to regulators, healthcare professionals and patients.

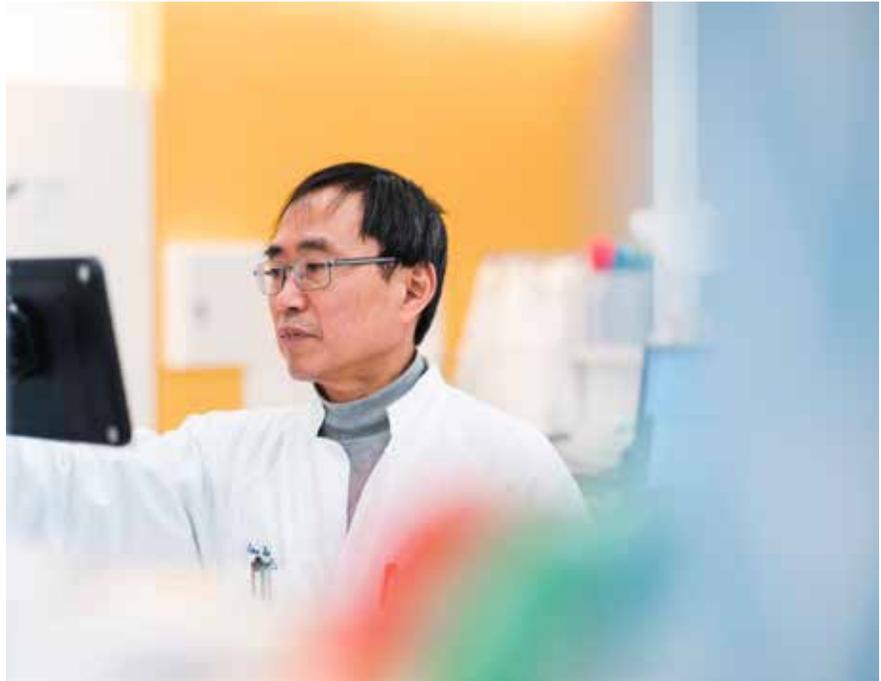
Counterfeit pharmaceuticals are a growing worldwide problem. To combat this hazardous and illegal business, governments all over the world are introducing regulations and systems to detect and prevent the distribution of counterfeit products. Sobi's products have not yet been subject to falsification. All Sobi products will be serialised from February 2019.

Enabling global access to treatments

We market and sell products in more than 70 countries, typically in small volumes aimed for a small number of patients. Because patient safety is our single most important responsibility, ensuring that patients never risk being without their medication is paramount



By 2019, all Sobi products will have a unique identity code.



because it could cause life-threatening situations. We have therefore built up robust supply and distribution processes covering all our markets.

Manufacturing of our products for which Sobi is Market Authorisation Holder is performed by 15 contract manufacturing organisations (CMOs) in Europe and the US, all of which fully comply with good manufacturing practices (GMP) ensuring that all products are produced and controlled according to quality standards for pharmaceuticals.

Full control of supply and distribution

Our Logistics Development and Supply unit is responsible for managing the global CMO network and ensuring uninterrupted, reliable and sustainable transportation of products. Biologics are sensitive and often require cold-chain supply to ensure product integrity and quality. It is vital to have full control of the entire supply and distribution chain – from manufacturing to patient.

The manufacturing process itself contains three steps: manufacturing of drug substance, manufacturing of drug product and finally the packaging of finished goods. Depending on the product, there can be different partners for each step or the same partner for several steps. All manufacturers of products for which Sobi is Market Authorisation Holder are required to meet our Code of Conduct and Ethics. Manufacturers are normally

contracted long-term and are monitored closely. For products sold on a partner basis, we strive to ensure that all providers comply with the code.

Distribution is characterised by collaboration and strong commitment to patient health. We assume responsibility for ensuring the right products of specified quality arrive in the right quantities at distribution units, ensuring their quick and efficient physical delivery to patients when an order arrives. Our Transport and Trade Compliance unit ensures that trade laws and regulations are followed.



"Patient safety is our most important responsibility", Arvid Cronlund, Head of Drug Safety.



Strategic research & development

Research and development activities are of strategic importance for us in our efforts to improve global access to innovative treatments for rare diseases. In these activities, we strive to maintain the highest ethical, technical and scientific standards.

Our ambition is to become a long-term global leader in the rare-disease field. Making a difference to individuals with rare diseases requires us to remain relevant to them throughout their lives. Therefore, we need to reinvest in research and development to be able to continue to provide innovative treatments. We liaise with physicians, payers and patient groups to obtain a good understanding of patients' and society's needs, and design our research and development projects based on the knowledge gained.

An integrated company

Our expertise includes an understanding of the elements needed to successfully scale up and prepare for commercial production. A holistic view of the process, with integrated development and manufacturing approaches, supports our ability to reduce the overall time from early development to products reaching the patients, without compromising safety.

As a mid-sized rare-disease company, our partnerships are key to building a successful pipeline. Our expertise in biologics and protein engineering, in collaboration with partner companies, has allowed us to design and produce therapeutic proteins with the

potential to transform the lives of rare-disease patients – our partnership with Bioverativ regarding the development of Alprolix and Elocta being an example of such a collaboration. We are also developing platforms aimed at extending the time molecules circulate in the body (half-life), which may present both us and other partners with even more opportunities to develop novel and clinically relevant treatments for rare and other diseases (see page 34).

Responding to patient insights

In order to make a significant difference for individuals with rare diseases, we are also developing existing drugs to meet new medical needs. As patients who have not had access to treatments before are given the opportunity to live longer and healthier lives, the medical need changes and new challenges are presented. Orfadin, our treatment for HT-1, has allowed people living with the disease to become adults. To meet the needs of adulthood, new formulations of Orfadin better suited to adults have been developed and introduced.

We secure intellectual property rights to safeguard our investments in research and development, enabling a financial performance that allows us to reinvest in the development of new innovative treatments.

Positioning Sweden as a leader in biologics

We are also participating in the Swedish government's strategic programme in life sciences to support the future development

and production of biologics in Sweden, aimed at positioning Sweden as a leading nation in this field. The programme runs over a period of eight years, until 2024, with government funding of SEK 320 million as well as private funding.

Exploring new technologies

We are working jointly with academia and participated in three centres and projects focused on development and manufacturing of biologics in 2017. Sobi contributes through financial "in-kind" funding and competence. The initiative has allowed us to explore new technologies that are expected to have an impact on development and manufacturing lead times. The academic network provided through this partnership also allows us to connect with students and graduates, both equally benefiting from competence and experience sharing.

"We have been pioneers in haemophilia for the past 35 years – We intend to continue bringing innovation to the community for at least another 35 years to come."

Philip Wood, Head of Haemophilia

Compliance and ethics

Regulatory and legal environment

We operate in a highly regulated environment and are subject to laws and regulations governing research, production and marketing. There is also a general trend towards greater awareness of liability issues and legal risk as well as increased transparency requirements. In parallel, our operating environment is constantly changing, requiring an adaptive and agile approach towards evolving regulatory and legal requirements as well as to stimulate innovation.

Sobi manages regulatory and legal engagement through various internal processes and control measures, such as continuous scientific, regulatory and compliance training. The aim is to secure high-quality research, considering all relevant precautionary principles, and production as well as transparent and comprehensive marketing. During 2017, no incidents of non-compliance concerning marketing communications have been identified or reported.

Developing our people

To continue building a company that remains innovative and high-performing while growing, we aim to foster a strong culture and create and sustain an organisation where continuous learning is key.

Culture-supported performance

We seek to engage our people in high-performing teams to deliver in a competitive market and to reach challenging goals in a way that is aligned with corporate objectives and values. Training in our culture and values (see page 36) plays a vital role in building the business.

We strive to promote a performance-based culture based on individual accountability, mandate and ownership. A critical factor in these efforts is to set, and continuously support, individual goals linked to strategic business objectives. However, performance is not only about what individuals achieve but also how these objectives are achieved.

We are committed to providing a safe and healthy workplace for our

850

people around the world.





Our people are expected to achieve individual and team performance goals in line with the corporate values. We endeavour to offer competitive salaries and benefits, which are individually determined. We perform regular benchmarks to ensure that compensation is on a par with similar companies.

Competence development

Innovation is essential for a growing and research-based company such as Sobi. An adaptive and agile approach to respond to our evolving requirements is important to stimulate innovation. Through feedback and cross-functional teams we aim to develop a change-ready mind-set across our organisation, a learning process that is dependent on individuals across Sobi being engaged in and committed to our shared day-to-day operations.

Professional development for all employees is seen as essential for both development of Sobi's product portfolio as well as the organisation as a whole. In 2017, we implemented a training matrix system across the organisation in line with regulatory requirements, to serve as a comprehensive platform for ensuring individualised and specialised training as well as evidence of learning.

During the year, 99.1 per cent of all employees received a regular performance and career development review. In 2017, Sobi employees spent on average 26 hours completing training through e-learning. This does not include on-the-job or standard oper-

ating procedure (SOP) training or external training opportunities.

Safe and healthy labour practices

We are committed to providing a safe and healthy workplace for our 850 people around the world. Activities to protect labour rights are based on our responsibilities as an employer, and we encourage suppliers and partners to adopt socially responsible labour practices as well. We respect the international labour standards set forth by the International Labour Organization (ILO) and complies with national labour laws.

The Environmental, Health and Safety (EHS) Policy and guidelines aim to promote a working culture where every employee and manager is personally responsible for ensuring a safe and healthy workplace, through preventive measures and regular training.

The health and safety committee represents all employees in Sweden. Country managers have the overall responsibility for health and safety within their own operations.

Investigating and identifying the cause(s) of an accident, dangerous situation or near miss makes it possible to take action to prevent a similar occurrence in the future. All employees are required to report EHS-related incidents to their employer. In 2017, 23 accidents were reported, none of which led to sick leave.

Diversity supports growth

We have expanded internationally in recent years. The successful incorporation of new knowledge and influences is building the future

company. The combination of rare-disease competencies and specific therapeutic knowledge has guided the recruitment process. Our business relies on the knowledge and competence of our people. Competitive terms of employment are a prerequisite for recruiting and retaining high-calibre people. We endeavour to offer competitive salaries and benefits, individually determined and adapted to the local labour market.

We are committed to providing equal employment opportunities regardless of race, age, gender, religion, national origin, sexual orientation or physical ability. During 2017, focus was placed on strengthening the general knowledge about Sobi's Code of Conduct & Ethics and non-discrimination policies. Sobi's guidelines clearly position against sexual harassment. Sobi's Compliance Hotline is a third party whistle-blower service available to all Sobi employees which offers the option of reporting an issues anonymously. In 2017, there was no incident of discrimination.

We believe that diversity among people contributes to progress and mutual enrichment. Of the total number of people in 2017 (2016), 41 (42) per cent were men and 59 (58) per cent women. The corresponding figures for the Executive Committee and Board of Directors (excluding employee representatives) were 78/22 per cent and 67/33 per cent respectively.

Ethical practices and ethical collaborations

Sobi promotes business ethics by enforcing compliance with our corporate principles, and by supporting a culture that promotes an open discussion of ethics in our operations and among key stakeholders.

Ethical standards across the value chain

We work actively to prevent all forms of corruption and to ensure compliance with our ethical standards across the value chain. There is a zero-tolerance policy towards bribery, supported by the Sobi Code of Conduct and Ethics and the Sobi Global Policy on Anti-Corruption, which have both been translated into relevant business processes, such as those governing interactions with healthcare professionals and organisations.

Engagement with organisations

To develop and deliver treatments that help meet the needs of patients and their families, our organisation strives to learn from them

about their challenges, and the success and limitations of current treatment options. For this purpose, we collaborate with stakeholders throughout the value chain: from research and clinical programmes to patient access and pricing. Collaborations span all stakeholders, including national and regional patient organisations, governments and healthcare systems.

There are company-wide guidelines in all business areas that support compliance with the regulations regarding ethics and transparency in engagement with external organisations.

Ethical research standards

The safety of individuals who take part in clinical trials is of the utmost importance, building on rigorous, scientifically based evaluations by clinical experts in cooperation with regulatory authorities, independent ethics committees and stakeholders. To guide the ethical conduct of all research involving humans, we apply the Declaration of Helsinki's principles for medical researchers. All Sobi-sponsored

clinical studies are conducted and reported in accordance with applicable law and the international Good Clinical Practice (GCP) standard. We collaborate to a substantial extent with contract research organisations (CROs) when conducting clinical trials. These collaborations are governed by mutual high standards and procedures.

Sobi follows the European Medicines Agency's (EMA) policy on the publication of clinical trial data.



Responsibility



Environmental impact

Proactive environmental management is part of a sustainable business. We meet our environmental responsibility by performing risk assessments and acting to reduce these risks even further, managing chemicals and waste by phasing out chemicals of high concern, and working with energy and water consumption plans in our production facilities. Environmental considerations are integrated into activities and operational control, and formal responsibility has been delegated across the line organisation. We strive to comply with all environmental laws and regulations.

All employees are required to undergo annual Environmental Training, covering risk assessment, greenhouse gas emissions and the management of chemicals and waste in the environment.

Chemicals management

Chemical regulations, aimed to eliminate adverse effects on the environment and human health, are extensive and continuously expanding. The handling of chemicals in R&D and manufacturing processes within Sobi follows clear instructions, with annual risk assessments and internal audits of processes carried out.

Pharmaceuticals in the environment

The environmental hazard of a specific drug refers to its inherent properties, such as toxic-

ity, the ability to be broken down by nature and the capacity to be stored in the fat of animals. According to EU guidelines on the environmental risk assessment of medicinal products, some drugs are not expected to have any environmental impact, for example products composed of carbohydrates, amino acids, peptides and proteins. A high percentage of our products are biopharmaceuticals composed of amino acids, proteins and peptides, and these are unlikely to pose any significant risk to the environment.

Energy use and greenhouse emissions

Business travel is one of the largest sources of greenhouse gas emissions from our activities. As operations expand, face-to-face meetings with the multidisciplinary teams across the organisation are important to achieving operational goals. The importance of complying with the Travel Policy, which calls for consideration of virtual meetings when possible, is emphasised continuously and the company provides tools for virtual meetings.

We are committed to improving energy efficiency at our sites, and regularly review and monitor the operating costs of our buildings. An energy management plan for the production facility in Stockholm has contributed to reduced energy and water consumption relative to production capacity: although production volumes of ReFacto AF increased by 15 per cent, consumption of energy increased by only 0.8 per cent.

Patient and customer integrity

It is important that customers, clinical trial subjects, staff and others we interact with can rely on Sobi managing and processing personal data in a responsible and safe manner, and in accordance with applicable laws and regulations. Emerging EU legislation imposes additional requirements on businesses processing personal data. To comply with these new requirements, we have assessed our framework and made necessary adjustments: for example the policy on processing of personal data has been updated. Relevant data flows have been analysed in order to close potential gaps under the new legislation. We have adopted a governance model that supports the compliant use of data and have provided relevant training to the organisation. An updated data privacy organisation will secure compliance from 2018.

In 2017, we had one Data Breach incident documented.

Responsible tax

Sobi pays corporate taxes in a responsible way. This means paying taxes where profits are earned in accordance with international transfer pricing rules. It means having a balanced tax risk profile and not engaging in tax-avoidance activities, as well as keeping tax levels stable and predictable, insofar as prevailing business conditions permit.

Anti-corruption and anti-competitive practices

An open dialogue on ethical issues provides the foundation for our efforts to prevent corruption. The dialogue is supported by annual training for all people, where the Code of Conduct and Ethics and other related procedures are translated into a business context; completion of this training is a prerequisite to be eligible for and receive incentive payments. In 2017, 100 per cent of the employees participated in the training. No cases of corruption were reported during the year. Zero cases of non-compliance with laws and regulations within the economic and social area were reported.

Transparency in business operations

In the rare-disease community, collaborations between authorities, healthcare professionals, companies and patient organisations have always been a cornerstone for the development of new and better treatments. Such collaboration needs to be carried out in a correct and transparent manner. By further increasing transparency the community can achieve an even stronger basis for continued collaboration with positive impacts on the quality of research, development and manufacturing.

Sobi has had a programme for Health Care Compliance (HCC) in place for quite some time. HCC within Sobi is defined as the ethical business standard for transparent promotional and non-promotional activities and interactions with healthcare professionals, providers, payers and patient organisations. The programme contains policies and controls aimed at minimising the risk of corruption.

We support transparency initiatives, including the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code in Europe and the Physician Payments Sunshine Act in the US. We have implemented the EFPIA Disclosure Code and made all payments and transfers of value to healthcare professionals and healthcare organisations in Europe publicly available on www.sobi.com, including sponsorships to attend meetings, grants and donations, speaker fees, consultancies and advisory board postings.



Procurement

We procure materials, goods and services from more than 1 000 suppliers. Establishing good relationships with these suppliers promotes sustainability and responsibility in the industry. We strive to apply consistent rules to all suppliers based on our Code of Conduct and Ethics. Our authorisation and sign-off procedures also reflect our anti-corruption commitment and help to ensure that we enter

agreements and perform procurements in a transparent and responsible manner. During 2017, all new suppliers were screened based on requirements in our Code of Conducts and Ethics.

Purchasing can be divided into two main categories: products governed by international and national regulatory requirements and standards, and products of a general nature for all companies regardless of industry.

Purchases in the first category are made after careful evaluation according to our governing documents and procedures, followed by continuous assessments. In the second category, the company procures goods at the best terms, balancing price and quality in consideration of the relevant industry's standards of responsibility. We also work with due diligence to ensure that service providers comply with our anti-corruption standards.





Sustainability and risk management

The aim of our approach to risk management is to identify the risks that could affect the company's ability to achieve our business goals, and to proactively manage those risks in a professional manner to safeguard the company's ability to execute on the strategy.

Sobi has a business-integrated risk management process. Business intelligence, risk management and business continuity management are all integrated into the strategy and business planning process as part of the

regular corporate planning procedure. The risk management process is linked in an integrated and seamless way to all units and other processes – quality evaluation, financial planning and strategy – within the company.

During the year, some areas became more important to address to reduce the potential risk impact. Competition in commercial markets, especially in Haemophilia and for Orfadin, was one such area. Another is the continued need to balance the development

portfolio in terms of the developmental stages. For this reason, a clear strategic direction aimed at acquiring new programmes, projects or treatments through in-licencing or acquisition has been announced.

The assessment of sustainability risks is an integrated part of Sobi's risk management process. The sustainability risk table identifies material risks in relation to our identified sustainability issues. Read more on pages 126–127.



Sustainability Management

Sobi's material sustainability issues, based on an analysis of value creation and critical issues in relation to Sobi and its stakeholders, have been identified as improving global access to treatments of rare diseases, strategic research and development as well as quality and supply chain management. Sobi has also determined to act with compliance and ethics in relation to the regulatory and legal environment, when developing our people and by only engaging in ethical practices and collaborations. In relation to Sobi's responsibility, important sustainability issues are identified as reducing the company's environmental impact, safeguarding patient and customer integrity, ensuring responsible tax payments, ruling out anti-corruption and anti-competitive practices.

Stakeholders and materiality analysis

Sobi's stakeholders are groups and individuals whose interests, directly or indirectly, have influence on or are influenced by the company's actions. Sobi's management and the Board of Directors have the overall responsibility for weighing up these interests, while ensuring the continuity of the company. Following this approach, Sobi aims to create long-term value for and to earn trust of all its stakeholders. To ensure regular dialogue, Sobi engages with a broad range of internal as well as external stakeholders through several different channels. As part of a comprehensive materiality analysis in 2016, web-surveys and targeted interviews were used for internal and external stakeholders to raise relevant issues.

IMPORTANT EXTERNAL STAKEHOLDERS

Important external stakeholders that we are listening to:

- Patient organisations
- Families and carers
- Regulators
- Pharmaceutical companies
- Governments and Government agencies
- Regulatory authorities
- Health care systems
- Budget holders and insurers
- Academic researchers
- Centres of expertise
- Specialist physicians and nurses
- Investors and analysts
- Shareholders

Stakeholder's engaging with Sobi discuss the following sustainability areas:

Internal stakeholders	External stakeholders
Access to healthcare and medicine	Access to healthcare and medicine
Product safety and quality	Sustainable supply chain
Ethics, safety, transparency in clinical trials	Ethics, safety, transparency in clinical trials
Engagement with patient organisations	Regulatory and legal environment
Anti-corruption	Responsible marketing and sales activities
Responsible marketing and sales activities	Product safety and quality
Research and development	Pharmaceuticals in the environment
Sustainable supply chain	Engagement with patient organisations
Diversity and equal opportunity	Anti-corruption
Employee recruitment, development, retention	Research and development

During 2017, the materiality analysis has been further developed and adapted to be in line with the revised corporate strategy aiming to create a more sustainable business growth, both short and long term. Important aspects to consider have been Sobi's value creation model

Sobi's material sustainability issues

Value creation	Material issues
Value	<ul style="list-style-type: none"> Improving global access to treatments for rare diseases Quality and supply chain management Strategic research and development
Compliance and ethics	<ul style="list-style-type: none"> Regulatory and legal environment Developing our people Ethical practices and collaborations
Responsibility	<ul style="list-style-type: none"> Environmental impact Patient and customer integrity Responsible tax Anti-corruption Anti-competitive practices

A detailed description on how Sobi is performing in relation to its material sustainability issues is found in the section Sustainability, page 36–47.

Sustainability governance, management and organisation

Sobi's Board of Directors holds the overall responsibility for Sobi's sustainability performance, while the CEO and the executive management team approve Sobi's sustainability programme and ensure compliance of and decides on overall objectives and implementation of the sustainability programme. All sustainability activities are guided by the Code of Conduct and Ethics and the other sustainability related policies. The Head of Communication is responsible for communication and operationalisation of the programme in close collaboration with the business units. The approved sustainability programme and goals are broken down into specific targets and activities to ensure that sustainability targets are well-integrated with Sobi's overall objectives and business plans. The annual reporting of the sustainability performance is presented in Sobi's Annual- and Sustainability Report.

as well as the new requirements on sustainability reporting found in the Annual Accounts Act. In the end of the year Sobi's Executive Committee approved the updated materiality analysis.

Policies guiding Sobi's sustainability performance
Annual Limits on Compensation for Healthcare professionals
Anti-Corruption Policy
Charitable Contributions and Sponsorships Policy
Code of Conduct and Ethics
Communications Policy
Compensation for Healthcare Professionals Policy
Consultants and Speakers Policy
Educational Grants Policy
Environment Health and Safety Management
Fair Competition Policy
Global Policy Risk Management
Information Security Policy
Insider Policy
Interactions with Patient Organisations Policy
IT Security Policy
Patient Access Bridging Programmes Policy
Procedure for Conducting Market Research Activities
Procurement Policy
Promotional and Scientific Material Review Policy
Publications Policy
Requirements and Approval Process for Non-Promotional Material
Requirements and Approval Process for Promotional Material
Research Agreements, Grants and Fellowships Policy
Sobi Inc Policy on Compliance Enforcement Discipline
Sobi Inc Policy on Reporting Investigating and Responding to Compliance Issues
Travel Policy

Sustainability objectives, targets and programme

Sobi's overall objective from a sustainability perspective is tied to the overall vision: to contribute to the societies in which Sobi operates by improving access to treatment of rare diseases. True availability and access to treatment for patients is what brings long-term value to the patients we serve, our employees, partners and shareholders.

Sustainability is a vital part of Sobi's vision and overall corporate strategy. A sustainable business entails a commitment to responsibility for patients and employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability so that we can continue to reinvest in developing new therapies for rare diseases and serve our communities for many years to come.

During the year Sobi has developed a comprehensive sustainability program. The sustainability programme is based on Sobi's material sustainability issues and will be further developed in terms of activities, targets, key performance indicators and implementation during the current year. The sustainability programme will make it possible for Sobi to follow progress towards the overall sustainability objectives and vision.

Material issues	Overall sustainability objectives
<ul style="list-style-type: none"> Improving global access to treatments for rare diseases Strategic research and development Quality and supply chain management 	<ul style="list-style-type: none"> Ensure that Sobi's products are made available to patients through local health-care budgets Invest in R&D to build a self-sustaining pipeline Our products are to improve the lives of rare disease patients and their families

Material issues	Sustainability targets
<ul style="list-style-type: none"> Regulatory and legal environment Developing our people Ethical practices and collaborations 	<ul style="list-style-type: none"> Always be compliant with laws and regulations Engaged and skilled people who are offered a safe and developing workplace Always be compliant with Code of Conduct and Ethics
<ul style="list-style-type: none"> Environmental impact Patient and customer integrity Responsible tax Anti-corruption Anti-competitive practices 	<ul style="list-style-type: none"> Reduce Sobi's environmental impact Always secure patients integrity Tax to be paid where revenue is generated Always be compliant with laws, regulations Code of Conduct and Ethics

Sustainability risks

Sustainability risks and the assessment of their impact are an integral element of Sobi's risk management process. The sustainability risk table identifies material risks in relation to our identified sustainability strategies. For those areas that coincide with operational risks, see pages 64–65.

Risk	Description of risk	Management and comments
Global access to drugs for rare diseases	<p>The market is increasingly affected by cost-consciousness due to the growing cost of healthcare in many countries. Market approval of drugs in the product portfolio does not guarantee that these products will be granted reimbursement and pricing approval by the national or regional healthcare systems.</p> <p>A decline in revenue from Sobi's key products could have a material adverse effect on Sobi's operations, earnings and financial position – regardless of whether this is due to reduced demand, increased competition or other reasons, such as policy changes for the national drug reimbursement scheme.</p>	<p>Sobi's way of working with most stakeholders throughout the entire development process is designed to anticipate market needs and the demands that will be imposed on the product by paying regulators in the event of approval.</p>
	<p>The use of medications may be affected by the treatment guidelines, recommendations and studies published by regulators and other bodies. The products must achieve market acceptance among physicians, patients and procurement organisations.</p> <p>The degree of market acceptance for each of the Company's products therefore depends on several factors. Many of these are beyond the Company's control and dependent on external decision-making procedures and policy-making bodies.</p>	<p>Sobi's way of working with regulators throughout the entire development process is designed to anticipate market needs and the demands that will be imposed on the product by regulators and prescribers in the event of approval, with the aim of ensuring that patients receive rapid and sustained access to these new and approved therapies, and that they meet the demands that arise over time.</p>
	<p>Sobi donates drugs to patients with rare diseases in cases where humanitarian aid has been considered necessary. These donations require the existence of a long-term plan describing how drugs can be guaranteed aside from the donation.</p>	<p>In developing countries and growth markets, Sobi works in consultation with regulators and international patient organisations in order to meet humanitarian needs. At the same time, Sobi works with key stakeholders to build and lay the foundations for a shift from donations to a sustainable reimbursement system that is owned by governments and/or healthcare systems.</p> <p>In cases where healthcare systems do not yet include Sobi's treatments, Sobi works in consultation with regulators to identify possible ways of making sure that patients are given access to drugs through programmes that provide a bridging arrangement until access through subsidy has been achieved.</p>
Quality and Supply Chain Management	<p>Biologics Manufacturing and Quality in Operational risks, see pages 64–65.</p>	
Strategic Research and Development	<p>Drug Development in Operational risks, see pages 64–65.</p>	
	<p>Sobi develops new drugs for serious diseases for which there is no treatment. Drugs under development must be tested on patients in the first instance and cannot be tested on healthy volunteers.</p>	<p>Looking after the safety of those people taking part in our studies is extremely important and is based on precise, scientifically based evaluations of our clinical expertise in collaboration with supervisory authorities, independent ethical committees and stakeholders. Sobi applies the Declaration of Helsinki's ethical principles for medical research involving human subjects, and all clinical studies that we sponsor are conducted and reported in accordance with current laws, regulations and ordinances as well as the international standard for Good Clinical Practice (GCP).</p>
	<p>Patients who are being treated with Sobi's drugs often have chronic, life-threatening diseases and are expected to be treated with Sobi's drugs for a long time. The safety of the products is extremely important. One of our most important tasks is to secure patient safety throughout the whole life cycle of products.</p>	<p>Sobi has a comprehensive safety system for our drugs and we are constantly monitoring the risk-benefit profile of our products. We provide annual training for all our employees in order to make sure that all safety information for our products is reported. Our goal is to provide correct, updated information to legislators, healthcare personnel and patients by collecting and analysing safety data from all available sources.</p>

Risk	Description of risk	Management and comments
Regulatory and legal environment	Sobi operates in a strictly regulated environment and we must comply with laws and regulations governing not only production, but also research and marketing. Any change in legislation and regulations can have a direct impact on Sobi by limiting access to the market, manufacturing opportunities or development strategies.	Sobi monitors all laws and regulations carefully in order to make sure that the company's work complies with current legislation. In cases where legislation concerns requirements for the approval of drugs, we adopt an agile approach to adapt development processes rapidly in order to meet the new requirements and thereby not risk extending the time it takes for the drug to reach the patient. The handling of chemicals in our R&D and manufacturing processes is covered by annual risk assessments in order to avoid any impact on the future ability to deliver as agreed.
Developing our employees	Sobi operates in a competitive market, where our employees form the basis of the company's ability to develop special drugs to meet our patients' needs. If we are unable to attract employees who can contribute to this work through their various competencies and experiences, we risk becoming less efficient and not being able to produce the right drugs at the right price.	Sobi works with a learning organisation and involves employees in high-performance teams in order to achieve and deliver in a competitive market.
Anti-corruption, anti-competition and ethical approach, as well as collaborations	The risk of corruption is greatest in activities in which Sobi interacts with the healthcare sector.	To mitigate corruption risks, Sobi has for several years had a Health Care Compliance ("HCC") programme in place. Health Care Compliance within Sobi is defined as the ethical business standard for transparent promotional and non-promotional activities and interactions with healthcare professionals, providers, payers and patient organisations. The programme includes processes and controls that aim to mitigate the risks of, for example, corruption.
Environmental impact	Sobi's business activities involve business trips that give rise to greenhouse gas emissions. The consumption of energy, water, products and services as well as the handling of chemicals in the manufacturing facility also have an environmental impact.	Sobi monitors legislation in the environmental field and integrates requirements into controlling procedures for the business activity concerned. A control programme has been agreed with the regulators for the manufacturing facility. Risk assessments of the business are performed annually and in connection with changes, and action plans are drawn up as required.
Patient and customer integrity	Sobi processes personal data in the course of its business. Sobi is committed to protecting the personal rights of any individual whose personal data it processes – including its employees, customers, suppliers and other contractual partners, stakeholders, subjects and patients in clinical trials.	A programme is in place for the purpose of ensuring compliance with emerging legislation regarding the processing of personal data.
Responsible tax management	Sobi carries out decentralised business activities in various different countries. Changing local rules and interpretations may thus lead to incorrect tax treatment in the local companies. All local companies are required to monitor that correct taxes are paid in their respective country.	Sobi's tax policy clearly states that tax must be paid in the countries where revenue is generated in accordance with determined transfer pricing methods.

Sustainability performance 2017

Sobi is committed to report relevant data on economic, social and environmental performance, focusing on material issues and to communicate their progress. The sustainability notes found below complement the performance reporting found in the Sustainability section of this report. Reported data covers all Sobi's business operations unless otherwise stated.

Sustainability notes

Economic Performance

Direct Economic Value Generated (SEK Thousands)	2017
Revenues	6,512,521
Economic Value Distributed	
Operating costs	-3,632,615
Employee wages & benefits	-1,262,850
Payments to providers of capital	-69,161
Payments to government	-209,128
Community investments ¹	-15,471
Direct economic value	1,323,295

Calculation is based on the consolidated statement of comprehensive income 2017.

1. Community investments is based on costs reported in May 2017 related to support to Patients Organisations during 2016. Costs for 2017 will be reported in our Transparency Report to be published in May 2018.

Indirect economic impact

Sobi and Bioverativ, a Sanofi company, have pledged to donate up to 1 billion IUs of coagulation factor to humanitarian aid between 2015–2025.

500 million IUs have been donated in support of the World Federation of Hemophilia's (WFH) humanitarian aid work. Sobi's indirect economic impact is reported in accordance with the WFH's progress report for this programme. The impacts are the result of Sobi's and Bioverativ's contribution to the programme.

	2017	2016	2015
Total MIU's delivered	262	146	19
New patients treated	15,072	12,311	2,347
Acute bleeds treated	40,557	33,876	4,984
Total surgeries	709	719	78
Paediatric patients, %	39	28	14

In developing countries and growth markets, Sobi works in collaboration with regulators and international patient organisations to meet humanitarian needs. Sobi donates drugs to patients with rare diseases in cases where humanitarian aid has been considered necessary.

Environmental Performance

Carbon dioxide emissions

(CO ₂ tonnes)	2017	2016
Indirect emissions from energy (metric tonnes)	221	222
Emissions from travel (metric tonnes)	983	1,112

Reported emissions reflects only operations in Sweden. Travelling emissions include emissions from business travel and company cars.

Waste

Waste (metric tonnes)	2017	2016	2015	2014	2013
Recycled waste	50	46	68	52	42
Hazardous waste	22	16	13	13	16
Landfill	0.1	0.0	1.6	0.1	1.1
Total waste	72	62	82	65	59

Waste reporting is based on Sobi's only production facility found in Solna, Stockholm.

Waste data does not include waste from marketing and sales offices.

Social performance

Employees per region 2017

Region	New employee hires	Female	Male	Employees 2017
Sweden	67	41	26	451
EMENAR (Europe, Middle East, North Africa, Russia) (excluding Sweden)	67	41	26	295
North America (USA & Canada)	10	7	3	54
Total	144	89	55	800¹

1. Per year-end 2017, the number of full-time equivalent employees was 800, while the number of persons employed at the same date was 850.

New hires

Region	Female				Male				Total
	Under 30 years old	30-50 years old	Above 50 years old	Female Total	Under 30 years old	30-50 years old	Above 50 years old	Male Total	
Sweden	8	21	12	41	9	14	3	26	67
EMENAR (Europe, Middle East, North Africa, Russia) (excluding Sweden)	4	29	8	41	2	20	6	28	67
North America (USA & Canada)	1	5	1	7		2	1	3	10
Total	13	55	21	89	9	38	8	55	144

Turnover 2017

Employees	2017	2016
Number of employees ¹	812	757
Departures	90	83
Turnover	11.1%	11%

1. Mean number of employees during the year, including only permanent contracts.

Employees, contract type and type of employment 2017

Employees	Male	Female	Total
Permanent contract	337	497	834
Temporary contract	8	8	16

Employees	Sweden	Other region	Total
Permanent contract	473	361	834
Temporary contract	15	1	16

Employee numbers are expressed as head count. Sobi has no employees working part time. Some employees have been granted a part time equivalent employment type due to issues such as child care.

All employees in the Swedish operations (representing approximately 57 per cent of all employees) are covered by collective bargaining agreements.

Global Reporting Initiative Index

Sobi's Sustainability Report 2017 is defined in the GRI Index below. Its main components are found in the following sections of the Annual and Sustainability Report 2017:

- Business Model is found in the section Sobi's Value Creation, page 12–13
- Description of sustainability approach, activities and performance 2017 are found in the section on Sustainability, pages 36–47.
- Information on objectives and targets on Sustainability issues is reported in the non-financial notes, on pages 128–129.
- Information on the buildup of the Sustainability Report is found in the section Sustainability Management, on pages 123–132.

This sustainability report has been prepared in accordance with the GRI Standards: Core option. It also fulfills the requirements on sustainability reporting in the Annual Accounts Act. The 2016 sustainability report was published in April 2017.

Sobi reports its sustainability performance on an annual basis, as part of the Annual- and Sustainability Report. The indicators below have been selected on the basis of a materiality analysis, which is further described on pages 124–125. All page references below refer to pages in Sobi's 2017 Annual- and Sustainability Report or at www.sobi.com. For questions regarding the Sustainability Report, please contact info@sobi.com.

GRI Standard	Disclosure	Page reference	Comment	UN Global Compact
GRI 101: Foundation 2016			Sobi complies with the reporting principles for defining reporting content and quality stipulated by GRI.	
STANDARD DISCLOSURES				
Organisational Profile				
GRI 102: General Disclosures	102-1 Name of the organisation	76		
	102-2 Activities, brands, products, and services	7, 10–13, 58		
	102-3 Location of headquarters	76		
	102-4 Location of operations	20, 23, 86, 98		
	102-5 Ownership and legal form	76		
	102-6 Markets served	20, 23, 98		
	102-7 Scale of the organisation	6–7, 84		
	102-8 Information on employees and other workers	86, 129		Principle 6
	102-9 Supply chain	12–13, 39		
	102-10 Significant changes to the organisation and its supply chain		No material changes to the organisation and supply chain during the year.	
	102-11 Precautionary Principle or approach	64–65, 126–127		
	102-12 External initiatives	43, 45, 130	Sobi complies with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code in Europe and the Physician Payments Sunshine Act in the US. Sobi's clinical programmes and testing follow the ethical principles of the Declaration of Helsinki and EMA's policy on the publication of clinical trial data.	
	102-13 Membership of associations		See www.sobi.com for current list of memberships.	
Strategy				
GRI 102: General Disclosures	102-14 Statement from senior decision-maker	Statement of CEO, 55		
Ethics and Integrity				
GRI 102: General Disclosures	102-16 Values, principles, standards, and norms of behaviour	36, 124		Principle 10
Governance				
	102-18 Governance structure	108–113, 124		

GRI Standard	Disclosure	Page reference	Comment	UN Global Compact
Stakeholder Engagement				
GRI 102: General Disclosures	102-40 List of stakeholder groups	123		
	102-41 Collective bargaining agreements	129		Principle 3
	102-42 Identifying and selecting stakeholders	37, 123		
	102-43 Approach to stakeholder engagement	37, 123		
	102-44 Key topics and concerns raised	37, 123		
Reporting Practice				
GRI 102: General Disclosures	102-45 Entities included in the consolidated financial statements	98		
	102-46 Defining report content and topic boundaries	124–125, 130, GRI 101		
	102-47 List of material topics	37, 124		
	102-48 Restatements of information	98		
	102-49 Changes in reporting	123–124		
	102-50 Reporting period	130		
	102-51 Date of most recent report	130		
	102-52 Reporting cycle	130		
	102-53 Contact point for questions regarding the report	130		
	102-54 Claims of reporting in accordance with the GRI Standards	130		
	102-55 GRI content index	130–133		
	102-56 External assurance		Sobi's Sustainability Report has not been subject to external assurance.	
MATERIAL TOPICS				
Economic				
Economic Performance				
GRI 103: Management Approach	103-1/2/3 Management approach	124		
GRI 201: Economic Performance	201-1 Direct economic value generated and distributed	128		
Indirect Economic Impacts				
GRI 103: Management Approach	103-1/2/3 Management approach	124		
GRI 203: Indirect Economic Impacts	203-2 Significant indirect economic impacts	128		
Anti-corruption				
GRI 103: Management Approach	103-1/2/3 Management approach	45, 47, 124		Principle 10
GRI 205: Anti-corruption	205-1 Operations assessed for risks related to corruption	47, 127		Principle 10
	205-2 Communication and training about anti-corruption policies and procedures	45		Principle 10
	205-3 Confirmed incidents of corruption and actions taken	45		Principle 10
Anti-competitive Behaviour				
GRI 103: Management Approach	103-1/2/3 Management approach	45, 47, 124		
GRI 206: Anti-competitive Behaviour	206-1 Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices	45		
Environmental				
Emissions				
GRI 103: Management Approach	103-1/2/3 Management approach	124		Principle 7, 8, 9
GRI 305: Emissions	305-2 Energy indirect (Scope 2) GHG emissions	128		Principle 7, 8
Effluents and Waste				
GRI 103: Management Approach	103-1/2/3 Management approach	124		Principle 8
GRI 306: Effluents and Waste	306-2 Waste by type and disposal method	128		Principle 8

GRI Standard	Disclosure	Page reference	Comment	UN Global Compact
Social				
Employment				
GRI 103: Management Approach	103-1/2/3 Management approach	41–42, 124		Principle 6
GRI 401: Employment	401-1 New employee hires and employee turnover	129		Principle 6
Occupational Health and Safety				
GRI 103: Management Approach	103-1/2/3 Management approach	42, 124		Principle 1, 6
GRI 403: Occupational Health and Safety	403-2 Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	42		
Training and Education				
GRI 103: Management Approach	103-1/2/3 Management approach	42		Principle 6
GRI 404: Training and Education	404-1 Average hours of training per year per employee	42		Principle 6
	404-2 Programmes for upgrading employee skills and transition assistance programmes	42		
	404-3 Percentage of employees receiving regular performance and career development reviews	42		Principle 6
Non-discrimination				
GRI 103: Management Approach	103-1/2/3 Management approach	42, 124		Principle 6
GRI 406: Non-discrimination	406-1 Incidents of discrimination and corrective actions taken	42		Principle 6
Local Communities				
GRI 103: Management Approach	103-1/2/3 Management approach	124		Principle 1
GRI 413: Local Communities	413-1 Operations with local community engagement, impact assessments, and development programmes	19, 38		Principle 1
Supplier Social Assessment				
GRI 103: Management Approach	103-1/2/3 Management approach	46, 124		Principle 2
GRI 414: Supplier Social Assessment	414-1 New suppliers that were screened using social criteria	46		Principle 2
Customer Health and Safety				
GRI 103: Management Approach	103-1/2/3 Management approach	124		
GRI 416: Customer Health and Safety	416-1 Assessment of the health and safety impacts of product and service categories	39, 44		
Marketing and Labeling				
GRI 103: Management Approach	103-1/2/3 Management approach	124		Principle 7
GRI 417: Marketing and Labeling	417-2 Incidents of non-compliance concerning product and service information and labeling	39		
	417-3 Incidents of non-compliance concerning marketing communications	41		
Customer Privacy				
GRI 103: Management Approach	103-1/2/3 Management approach	44, 124		
GRI 418: Customer Privacy	418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data	44		
Socioeconomic Compliance				
GRI 103: Management Approach	103-1/2/3 Management approach	124		
GRI 419: Socioeconomic Compliance	419-1 Non-compliance with laws and regulations in the social and economic area	45		



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