

Expanding opportunities

Annual and Sustainability Report 2020



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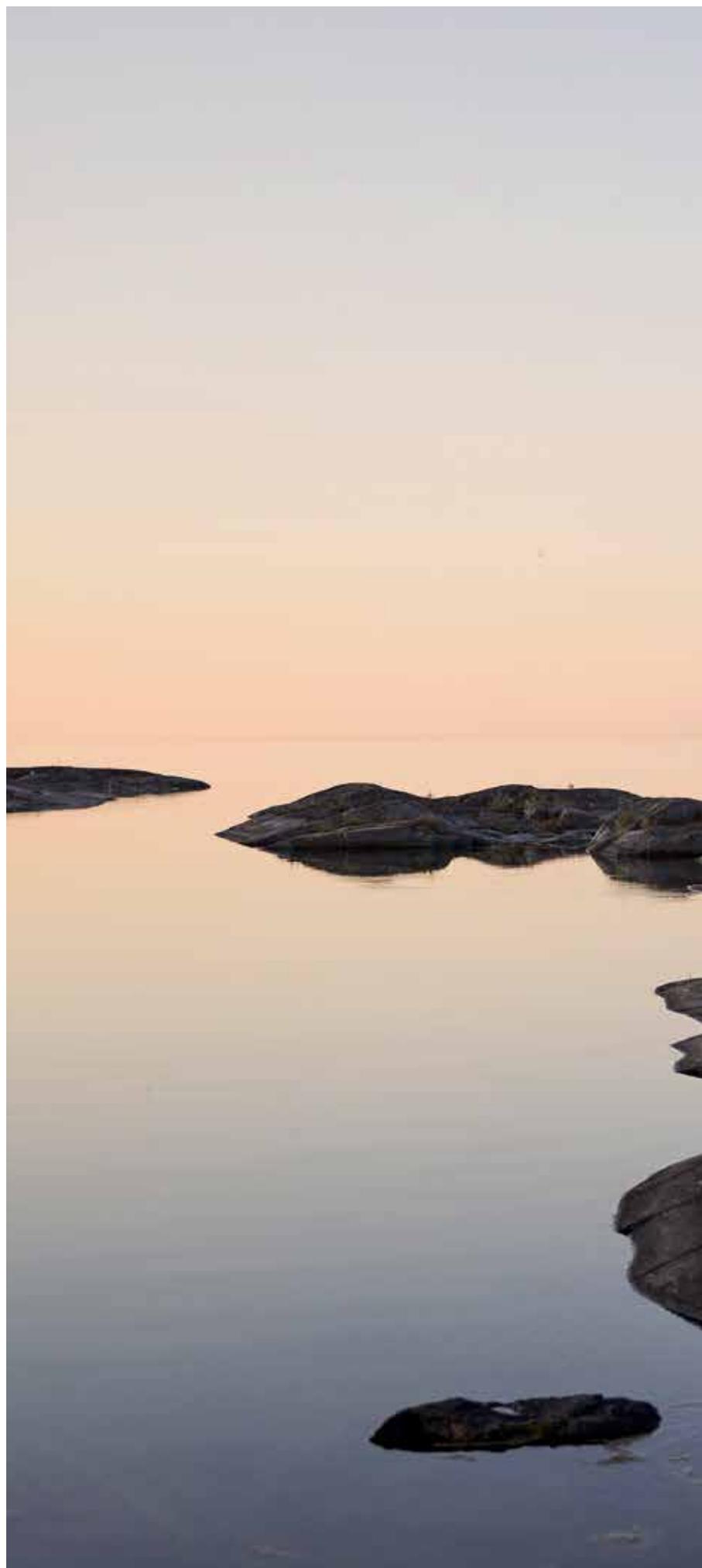
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This is Sobi's Annual and Sustainability Report 2020. The audited Annual Report includes pages 34–91. The Sustainability Report is on pages 23–27 and 108–131 and consists of the Company and the Group's legally required sustainability report according to the Annual Accounts Act. The report is also Sobi's Communication on Progress (COP) to the UN Global Compact.



Sustainability

Our commitment to providing access to treatment for people with rare diseases is not only our company vision but also our main contribution to sustainable development.



Commitment to Agenda 2030 and the Paris Agreement

Sobi's sustainability strategy is focused on two main areas, aimed at transforming lives for people living with rare diseases:

- Supporting the rare disease community through our **commitment to patients**, working actively by enabling connect- edness, ensuring sustainable and secure access to care, and giving a voice to patients. A strong pipeline and expanded access through geographical growth are

key elements of our commitment, which puts patient safety first by adhering to the highest pharmaceutical standards

- Acting responsibly** in everything we do, through high research standards, business ethics and policies aimed at creating a sustainable organisation with the purpose of serving the community. We show our commitment to sustain- ability by measuring and mapping our emissions, setting ambitions and targets,

and working together with our partners to reduce our environmental footprint.

Sobi is a signatory of the UN Global Compact, and we have integrated the ten principles of the Global Compact into our core business operations. Our sustainability strategy is based on our willingness to contribute to the real- isation of Agenda 2030 and the Paris Agreement.

Commitment to patients

Our business strategy reflects our ambition and commitment to reach more patients in more markets with novel and transformative treatments in areas of high unmet medical need.

R&D focused on medical need

In 2020, our R&D portfolio was expanded to include more drug candidates and investigations in multiple indications, increasing the potential to make more treatments available to more patients.

To realise the potential of the portfolio, the R&D budget was increased to 13–15 per cent of revenue for 2021–2022.

Six products are currently involved in 12 development programmes; five medicines in the pipeline either have novel mechanisms of action or are first-in-class.

Where orphan drug regulations can shorten time to patient, they will be used, as was the case when the FDA granted a priority review designation for pegcetacoplan for the treatment of paroxysmal nocturnal haemoglobinuria (PNH).

The development strategy also includes exploring innovative approaches that help optimise treatment outcomes. In the digital health area, Sobi's subsidiary Florio launched the digital medical device florio HAEMO and the florio HAEMO kids app. Within precision medicine, Sobi's partnership with bioMérieux aims to develop a companion diagnostic

to detect HSCT graft failure. We are also exploring the potential of genetic screening to gain deeper insights into patient care in HLH.

Patient access

In 2020, we expanded the potential for access to treatments in three new markets, by establishing and enlarging operations in China, Japan and Australia.

We also took part in many events advocating for support for people living with rare diseases. At one such event, we joined EUCOPE (European Confederation of Pharmaceutical Entrepreneurs) at the World Pharma Pricing, Market Access & Evidence Congress 2020 to discuss how to evaluate innovation.

Humanitarian aid

In 2020, we announced an extension of our support for the World Federation of Hemophilia (WFH) Humanitarian Aid Program with an additional donation of up to 500 million international units (IU) of factor therapy for humanitarian use,

fulfilling the 2014 pledge to donate up to an unprecedented 1 billion IU over a 10-year period.

Since the initial pledge, more than 538 million IU have been donated and over 17,330 people with haemophilia have been treated with factor donated by Sobi and Sanofi. Both companies are recognised by the WFH as Founding Visionary Partners of this programme.

By providing a more predictable and sustainable flow of treatment, the WFH programme allows patients to receive consistent and reliable access to therapy and care. In addition, educational programmes for treaters and patients are critical for developing domestic capacities to improve diagnosis and treatment monitoring, and enabling long-term sustainable change.

Realising that donations do not provide sustainable or long-term access to treatment, we strive to transform donations to access within the regulated healthcare system where possible.

12

programmes in rare diseases

5

novel mechanisms of action

Sobi's and Sanofi's contribution to the WFH Humanitarian Aid Program



17,330 people reported treated in 43 countries



Over 198,000 acute bleeds treated



Over 2,960 surgeries, including limb-saving



538 million IU of factor donated





Community engagement

At the 10th European Conference on Rare Disease & Orphan Products (ECRD) in May 2020, the rare disease community voiced the need to be included in efforts to achieve Universal Health Coverage (UN SDG3, Good health and Well-being), as well as efforts to ensure non-discrimination on the basis of health or disability status (SDG 10, Reducing Inequalities). Sobi aims to support the achievement of these goals in collaboration with the patient community.

In 2020, Sobi supported several social media and online communities as well as networking events and patient summits specifically addressing the COVID-19 situation. Informational tools and materials for patient caregivers and healthcare personnel to facilitate knowledge sharing were part of this support.

Knowledge sharing

Each rare disease is so uncommon that knowledge about the disease is also

rare, often leading to delayed diagnosis. Understanding the experience of living with a rare disease can provide important information and increased knowledge about disease burden and treatment options.

Sobi regularly attends scientific meetings to share medical advancements and to take part in discussions to enhance the practice of medicine. We also arrange advisory boards to seek advisor input into key clinical and scientific questions, continuing to develop our medicines to meet unmet needs. The challenges of COVID-19 were met by the widespread adoption of virtual meetings and webinars, and online events.

Sobi is a long-term supporter of patient organisations such as the European and North American rare disease organisations EURORDIS and NORD, respectively, the World Federation of Hemophilia (WFH) and the European Haemophilia Consortium. Sobi's annual support to the WFH Corporate

Partner Program has enabled country development programmes, educational resources, training for healthcare professionals, capacity building and training for patients and patient organisations as well as support for the World Bleeding Disorder Registry.

Focus on patient safety

The patients we serve are among the most vulnerable. Many are children with a rare disease they will have to live with for the rest of their lives. Working with rare diseases adds another dimension to patient safety, because less information is available than for more widespread illnesses, and skilled analytical thinking is required.

Patient safety is part of a medicine's journey from development and into real-world use. Our global safety organisation focuses on detection, assessment, understanding and the prevention of adverse effects.

Responsible behaviour

We aim always to act ethically and expect the highest standards of ethical behaviour from our employees. In return, we offer a healthy workplace with continuous professional development opportunities.

Our five core values – Care, Ownership, Urgency, Partnership and Ambition – aim to ensure that more patients benefit from our therapies, now and in the future.

Caring for our employees

Our workforce is essential for our ability to deliver on our strategy. Over the course of 2020, we welcomed over 400 individuals to Sobi, and finished the year with more than 1,500 highly skilled employees in more than 30 countries around the world.

During the year, the COVID-19 pandemic greatly impacted employees across the world. Sobi protected the health and safety of employees by promoting working from home and allowing only business-critical international travel. For employees who were needed physically in the workplace, necessary distancing and safety precautions, such as additional personal protection equipment (PPE), flexible working hours and office attendance planning were implemented.

To retain a high level of employee engagement during the pandemic, Sobi

worked extensively to enhance the digital workplace and communication tools, and used surveys to understand perceived challenges and involve employees in Sobi's future.

Engagement survey

In 2020, a Global Engagement Survey was conducted with over 85 per cent of employees responding. Employee engagement was on par with the industry, strongly correlated to high employee competence-fit and patient focus.

Positive relationships with our employees support their development, wellbeing and job satisfaction, and we are proud to offer a safe, healthy and inclusive workplace with equal development opportunities for all.

No tolerance for corruption

Responsible behaviour is promoted through the company values and Code of Conduct. In 2020, a new, updated Code of Conduct was launched and made available for internal as well as external stakeholders. The whistleblower hotline was also extended to include external parties.

In 2020, a geographic shift increased Sobi's risk exposure to new markets in Asia and Russia. Organic growth also continued, with new employees joining the company. In line with these changes, policies, systems and training are con-

50%
reduction of Sobi's
CO₂ emissions since 2016

>30
countries

tinuously reviewed to ensure our high standards are maintained.

97 per cent of Sobi's employees completed the Code of Conduct training in 2020.

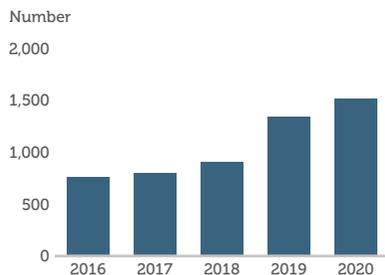
Responsible sourcing

With a largely outsourced supply chain, we rely on sustainable and robust suppliers to produce, package and distribute our products. Sobi's application to join the Pharmaceutical Supply Chain Initiative (PSCI) was approved in January 2020.

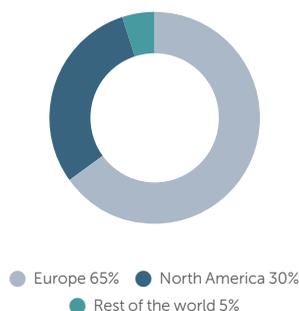
The Responsible Sourcing Programme, introduced in 2019, was implemented across Sobi during 2020. This includes the Partner Code of Conduct, which is available in several languages on Sobi's

Employees

Number of employees



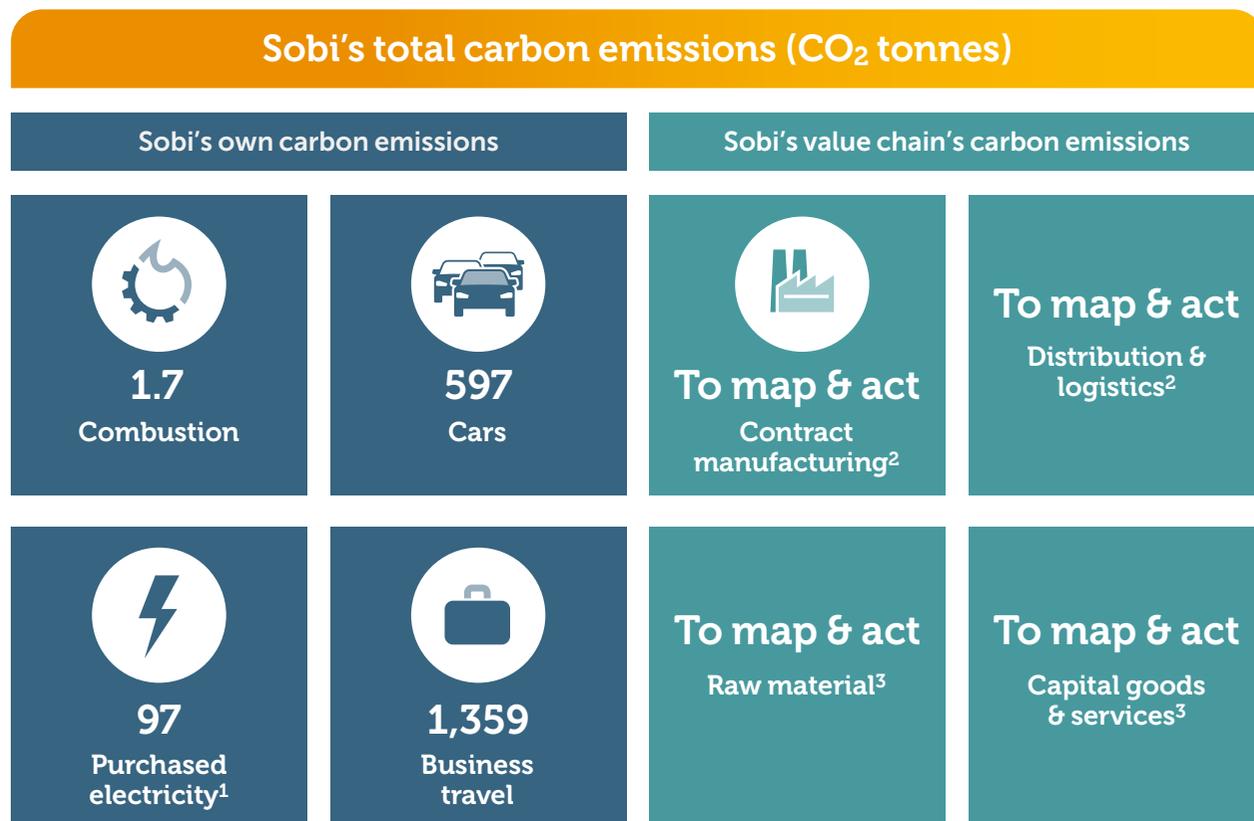
Geographical distribution



Gender distribution



Sobi's greenhouse gas emissions



Direct and indirect emissions (Scope 1, 2 and parts of Scope 3)
 1. Calculation methods have been adjusted. See Sustainability notes p 122.

Other indirect emissions (rest of Scope 3), in the value chain to be mapped by 2022.
 2. Hybrid method based on supplier direct reporting will be used
 3. GHG-protocol calculations based on spend will be used

website, and risk-based screening of suppliers for compliance with management, labour, human rights, and environmental standards.

Reducing our environmental footprint

Sobi's direct Scope 1 and indirect Scope 2 emissions from our own operations are limited. In 2020, we expanded our reporting practice to include all global operations (leased premises and vehicles).

We have most control over our own operations, and by avoiding, reducing and substituting we are aiming to achieve net zero emissions from our sites and ground fleet by 2030.

The direct emissions derived from the Parent Company's operations have been

reduced by 50 per cent since 2016. All electricity consumed at the Stockholm facility was produced from a mix of certified renewable energy sources. The impact of our offices, laboratory and manufacturing facility is described in detail on pages 123–124.

Due to our business model, we can assume that most of our impact on the environment is a result of the activities we source from our contract manufacturers, and the logistics in our supply chain and for the distribution of our products. The greenhouse gas (GHG) emissions derived from sourced activities are classified as indirect Scope 3 emissions.

While the reduction of indirect Scope 3 emissions could have a significant impact, this is also where we have the least control. By 2022, Sobi intends to fully map and calculate the indirect emissions from our supply chain and prioritise the most significant reduction opportunities with Scope 3 emission targets.

We will focus on areas of producer responsibility. In 2021, as a part of our Responsible Sourcing Programme, we will start communicating our ambitions to suppliers, integrating emissions reporting in business follow-ups and working together with our partners to reduce emissions wherever we can.

Sustainability Report 2020

At Sobi our key contribution to sustainable development and our overall sustainability objective – to transform the lives of people living with rare diseases – is closely aligned with our vision and our operations.

Business model and sustainable growth

At Sobi, we are transforming the lives of people living with rare diseases. We provide access to innovative treatments in the areas of haematology and immunology. Sobi’s business model (read more on page 10) spans from clinical research to patient access and international commercialisation.

Our sustainability strategy is closely linked to the business and based on two priorities – our commitment to patients and our responsible behaviour. By expanding our geographical reach, investing in the development of novel products and deepening our engagement in the areas of haematology and immunology, we can

improve access to rare disease treatments for patients worldwide. If we are successful in our operations, we will positively impact the communities we serve.

Sobi is a signatory of the UN Global Compact, and we have integrated the ten principles of the Global Compact into our core business operations. We commit to operating in a way that contributes to achieving the UN Sustainable Development Goals (SDGs) and the Paris Agreement to address society’s greatest challenges by 2030. We are in a unique position to improve health globally within our areas of focus and believe that aligning our business with the SDGs will help us to be stronger and more sustainable.



Material sustainability topics

Our material sustainability topics reflect those sustainability areas where our business has significant impact on our environment from the economic, environmental and social perspectives.

It is essential that we understand the outcome of our materiality assessment as it highlights sustainability topics that are important to our stakeholders and our strategy. In 2019, we performed a comprehensive materiality assessment including web surveys and targeted interviews with internal and external stakeholders such as employees, internal and external experts, owners, suppliers, partners and patient organisations. In 2020, we deepened the assessment by attending conferences, participating in ESG ratings and research, and following and reviewing new legislation.

Measures to address the patient perspective included attending the 10th European Conference on Rare Disease and Orphan Products, ECRD 2020, the largest, patient-led rare disease event for dialogue and learning shaping future rare disease policies. In November 2020, the European Commission communicated its Pharmaceutical Strategy for Europe which has an impact on our business and is aligned with our ambitions.

In 2020, governmental procurement bodies and tender processes have to a greater extent included sustainability requirements in order to be eligible to participate. Shareholders, institutional owners and banks have also increased expectations regarding Sobi's sustainability performance, reflected by an increased number of meetings with a sustainability focus.

The materiality assessment performed in 2019 remains in place, identifying the possibility to transform lives as Sobi's key long-term sustainability objective. The evolution of Sobi's corporate strategy, relying on sourced/acquired research and geographical expansion, has accentuated the need to focus on responsible partnerships and sourcing strategies. The material sustainability topics as defined through the materiality assessment and stakeholder dialogues are summarised in our sustainability strategy and its two priority areas:

- Commitment to patients
- Responsible behaviour

Sustainability governance

Management

Sobi's Board of Directors has overall responsibility for Sobi's sustainability performance, which is publicly reported each year in the Annual and Sustainability Report. The CEO and the Executive Committee approve Sobi's sustainability strategy, ensure compliance, and decide on overall objectives and implementation of the sustainability strategy. The leadership teams in each respective area are responsible for implementing and following up on the strategy. The Director of Sustainability is, on behalf of the Executive Committee, responsible for operationalisation and communication of the strategy in close collaboration with the business units.

Policies and responsibilities

All sustainability activities are driven by the sustainability strategy and based on the Code of Conduct and other sustainability-related policies. The Sobi Code of Conduct provides a framework for what Sobi considers to be responsible and appropriate conduct, and applies to all Sobi employees worldwide as well as temporary personnel. The most important practices and policies guiding Sobi's sustainability work and processes are listed below. Visit the website www.sobi.com for a list of policies governing sustainability-related areas.

Important responsibilities in terms of managing Sobi's material sustainability topics and delivering on the sustainability strategy are:

- The Sustainability function, which evaluates materiality, creates guidelines, supports implementation of the strategy programme and reports on outcomes.
- Corporate Compliance, responsible for the implementation of anti-corruption and healthcare interaction policies, data privacy and the compliance hotline (whistleblower hotline).
- Technical Operations, which includes Procurement, is responsible for environmental compliance and performance regarding in-house operations, and for monitoring suppliers' and partners' adherence and development in accordance with the Responsible Sourcing Programme.
- Internal Control, which evaluates and improves processes for management, internal control and risk management.
- Business units, which are required to run the business in compliance with the Code of Conduct, realise the elements of the sustainability strategy and drive progress.

Sustainability-related policies

Commitment to patients

- Policy on Healthcare Interactions
- Good Pharmaceutical Practice including Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP)

Responsible behaviour

- Anti-corruption policy
- Sobi Group Authority Policy
- Policy on Anti-Corruption Due Diligence on Third Parties
- Entertainment policy
- Policy on Healthcare Interactions
- Communication Policy
- Insider Policy
- Finance Policy

- Procurement Policy
- Environmental Policy
- Health and Safety Policy
- Policy on Processing of Personal Data
- Policy on Investigations

External recognition

Sobi's sustainability performance and progress is validated by external CSR specialist firm EcoVadis on an annual basis. Sobi also actively partakes in environmental, social and governance (ESG) evaluations with the aim of ensuring continuous improvement. The following sustainability rating agencies are rating our performance from an ESG perspective.

Sustainability Rating Agencies

Rating	2020	2019	2018
MSCI	A	A	A
Sustainalytics	26.4 medium risk	26.2 medium risk	
ISS	C High relative performance	C High relative performance	C High relative performance

Sustainability risk management

The Sobi risk management process is documented in the Sobi Group Risk Management Policy and the Sobi Group Risk Management Instructions.

Sobi applies a business risk-management approach where sustainability risks that may impede our ability to achieve set objectives are included. The organisation works actively to identify and address any uncertainties related to our ability to achieve our objectives. Identified risks are analysed using relevant values for the operations, enabling subsequent prioritisation on a commercial basis, whereby uncertainties and untapped opportunities around the company's strategy can be identified and managed. Sobi's Risk Manager reports the current risk status to the Executive Committee, and a review of this process is presented to the Board of Directors on a regular basis.

As part of the risk management process, the company's critical flows are identified and business continuity plans for these are implemented.

Sobi is following the development of the current Task Force on Climate-related Financial Disclosures (TCFD) recommendations and EU Taxonomy regulations. Our sustainability risks are presented on pages 41–43.

Sustainability reporting and communication

Sobi's sustainability reporting and communication aims to provide correct and relevant information regarding sustainability performance, goals and strategy to investors and stakeholders. We have committed ourselves to be transparent on our sustainability performance and progress.

Based on the outcome of the materiality assessment and the defined sustainability strategy, Sobi has identified material topics and their boundaries, taking into consideration reporting principles such as stakeholder inclusiveness, sustainability context, materiality and completeness.

Sobi's Sustainability Report has not been subject to external assurance. The Sustainability Report has been approved by Sobi's auditors in line with requirements in the Swedish Annual Accounts Act.

Sustainability strategy

The aim of the Sobi sustainability strategy is to deliver on the vision of transforming the lives of people living with rare diseases. It also aims to support Sobi's business strategy and deliver progress in terms of sustainability. The strategy is based on two priorities – our commitment to patients and our responsible behaviour – and includes nine sustainability commitments. Each priority is, in addition, linked to UN's Sustainable Development Goals (SDG) and targets that are perceived as critical for our business. The sustainability strategy is based on our commitment to always be transparent and our willingness to contribute to the realisation of Agenda 2030 and the Paris Agreement.



Commitment to patients

For Sobi, meaningful engagement and cooperation with the rare disease community is essential. Engaging with the rare disease community requires a specialised skill set and a high level of engagement. The community's collaborative commitment to reach common goals

is important, as rare diseases are still undefined in many areas and cannot be charted in isolation.

We are in a unique position to improve health on a global scale for a number of small and often overlooked patient populations and we take action to contribute to the SDGs via specific targets.

Commitment to patients and the SDGs

Sustainable Development Goals	Sustainable Development targets	Action and ambitions	Progress	Read more	
SDG 3 Good health and wellbeing	3.2 End preventable deaths of newborns and children under 5 years of age	Promote life expectancy by expanding access to paediatric treatments	Synagis (palivizumab) is the only approved medicine for the prevention of serious lower respiratory tract infections caused by RSV in high-risk infants, and significantly reduces the risk of RSV hospitalisation. Continued investments in expanding indications for Kineret (anakinra), approved in certain indications for children from 8 months of age. Continued efforts to ensure widespread sustainable access to Orfadin for children with HT-1. Regulatory filing in China.	p 16 p 15 p 17	
	3.4 Reduce premature mortality from non-communicable diseases (NCDs)	Increase number of R&D programmes in rare diseases and areas of high medical need	12 late-stage programmes in our pipeline as of 31 December 2020 Orfadin, the first pharmacological treatment approved for the ultra-rare disease AKU	p 20–22 p 17	
	3.8 Achieve universal health coverage		Continue 10-year commitment to the WFH Humanitarian Aid Program	Signed additional 5-year contract for a total 1 billion IU donation. To date, WFH donations have reached 17,329 patients in 43 countries.	p 24, 113 p 113
			Contribute to cost-support programmes	Continued support of Kineret OnTrack and Orfadin4U support programmes in the US	p 112
			Support charities in under-developed and underserved areas	Medical grant to FYMCA Medical Ltd for continued rare disease education in developing countries.	p 114
	3b Support R&D and access to medicines for diseases		Increase number of first-in-class products in R&D pipeline	5 first-in-class products	p 24
10–15% of turnover in R&D spend			R&D spend increased to 13–15% of revenue 2021–2022	p 24	
Expand products' global market reach			3 new indications approved 1 approval in a new market Expansion into China, Japan, Australia in 2020.	p 127–128 p 24	
SDG 10 Reduced inequalities	10.3 Equal opportunity	Expand rare disease and orphan drug innovation pipeline	3 new partnerships for products with orphan drug status. 2 orphan drug designations for new indications of on-market products.	p 24	
SDG 16 Peace, justice and strong institutions	16.7 Inclusive, participatory and representative decision-making	Include patient and healthcare representatives in decision-making	Co-developed patient support programmes, advocacy and evidence generation activities with patient advocacy groups.	p 113–114	
SDG 17 Partnerships for the goals	17.16 Global and multi-stakeholder partnership for sustainable development	Support rare disease organisations and participate in multi-stakeholder organisations	Provided support to patient organisations as well as local patient organisations. Approved members of PSCL in January 2020.	p 113–114	
	Science and technology innovation for recovery from COVID-19	Provide treatment to investigator-sponsored studies (ISS) and conduct own studies to support use in COVID-19	18 ongoing or planned, external, randomised controlled studies of anakinra in moderate-severe COVID-19. Sobi is supporting 10 ISS across the US and EU.	p 20, 112	

Our R&D is ethical and focused on medical need

High-quality and ethical science is of the greatest importance to us and contributes to the expansion of treatments for rare diseases in areas of unmet medical need.

Sobi's pipeline has a tight focus on innovative and differentiated medicines, enabling a step change in therapy in cases of unmet medical need where there is no available treatment. Sobi intends to take leadership in medicine development within rare diseases. Sobi's products are already being developed and evaluated for multiple indications and an integrated life-cycle management approach is applied. Sobi is also exploring the possibilities of precision medicine in the use of digital health, companion diagnostics and genetic screening to optimise treatment outcomes.

Our research is founded on scientific and medical need, and the design of our studies and the studies we support enables a scientifically sound evaluation of the treatments we develop and provide.

Ethics in clinical development

To avoid exposing participants to unnecessary risks, all studies are ethically and scientifically reviewed and approved, and conducted and reported in compliance with the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) and the latest revision of the Ethical Principles for Medical Research Involving Human Subjects (the Declaration of Helsinki).

When conducting clinical studies, we make sure that we give participants comprehensive, easy-to-understand information so that they enrol only of their own free will and with informed consent. Patients also have the right to withdraw from a study without compromising the care they receive.

Working in the area of rare diseases may pose extraordinary requirements regarding paediatric and vulnerable patients and people with genetic diseases. This can include special precautions in areas such as gaining consent, considerations for data privacy in small patient populations and research of genetic diseases. Through close collaboration with patient representatives, we act in the belief that this group should stand to benefit from the knowledge, practices or interventions that result from the research.

We conduct our research openly and publish clinical studies on clinicaltrials.gov. We register and report all our clinical studies and share the complete and accurate results of our clinical studies even if they show an outcome that is not beneficial for our business. Most clinical research is outsourced. Training on the medical aspects of the disease as well as processes and monitoring is done regularly for both our own and sourced personnel.

Sobi recognises the important role that investigator-sponsored studies (ISS) can play in expanding the knowledge related to Sobi's products and their associated disease areas. In an ISS, an investigator independently generates a research proposal, and Sobi provides

support for the proposal if it is approved. Support can include drug material, expert advice, funding and more. The investigator serves as the study sponsor and assumes full responsibility for ensuring compliance with regulatory requirements.

Bioethics

The use of human biological samples in research and therapy development is a potentially sensitive area and internal standard operating procedures (SOPs) ensure that all use complies with all relevant external legislation, regulations and guidelines. Sobi does not currently conduct stem-cell research.

Where animal testing is necessary, it is carefully considered and justified, with the 3R (replacement, reduction and refinement) principles applied. Sobi does not perform in-house animal studies and contracts only from highly qualified suppliers.

We expand access to treatment

Sobi's growth strategy and market expansion enable us to reach more patients with our treatments and regulatory approvals are necessary for commercialisation in new markets. Sobi has set an ambitious target to expand operations and access to treatments into Asia, the Pacific and South America over the coming five years which will broaden access to treatments outside our core markets. Sobi also has a partnership strategy to serve currently underserved markets.

For a review of current approval and reimbursement status in markets, see the table on pages 127–128.

A treatment is of value only if it reaches patients and physicians. One of the most powerful ways in which we work with the community is through patient access – ensuring rapid and sustainable access to treatment for people with rare diseases through the established healthcare system. Responsible pricing and reimbursement are essential components in enabling access.

Ensuring sustainable and secure access to care means that patients, caregivers and patient organisations can access the care they need when they need it without significant physical, social, financial or emotional burden. Some solutions created to support access include home nursing and product delivery programmes, telemedicine, patient navigation tools, culturally and linguistically adapted tools as well as adherence programs.

Product delivery programmes to support people living with haemophilia are currently in place in Saudi Arabia, Italy and Spain. In the United States, Sobi has been running the patient support programmes Kineret OnTrack and Orfadin4U for several years; these programmes include services such as financial assistance and reimbursement, treatment guidance, mentor programmes, injection training and support, home delivery and waste management. Similar services are also available for patients and caregivers on other treatments in the US.

Pricing and reimbursement

Pricing and reimbursement are two essential areas of patient access following regulatory approval. Each market has its own regulations and demands regarding approval of the proposed price and the degree to which reimbursement is provided.

Sobi strives to set a price that reflects the benefit that the innovation delivers to patients, healthcare systems, societies and payers, creating sustainable access to medicines for patients and continued long-term affordability to health systems to meet their patient and healthcare priorities.

Sustainable reimbursement is achieved through evidence generation that enables the clinical and patient value of a treatment to be quantified. Sobi works continuously to develop data that reflects resolution of unmet medical need on both initial and ongoing bases.

Ethical R&D focused on medical need – Ambitions

- Committed R&D budget in rare diseases
- Increase number of R&D programmes in rare diseases and areas of high medical need
- Use orphan drug regulations to shorten time to patient
- Optimise treatment outcomes through innovative approaches
- Increase number of clinical studies on Sobi products
- Perform consultations of patients and payers to ensure endpoints and outcomes that are meaningful for payers and patients.
- Support investigator-sponsored studies

The EU Pharmaceutical Strategy aims to facilitate collaboration on unmet needs and evidence generation in joint meetings of existing committees/networks of regulators, health technology assessment (HTA) bodies and payers, involving key stakeholders in the development, authorisation and access to medicines for a life-cycle approach and improved availability and affordability. Sobi has pioneered and participated in these collaborations over many years and intends to continue doing so.

In some markets, patient access to treatments may be limited by the lack or complexity of reimbursement processes. We have several initiatives in place e.g. in the US to support patients and treaters to gain access, bridging the gap.

Acting with urgency

Regulatory pathways for orphan drugs are implemented in several markets. Sobi's pipeline is positioned to use these pathways to shorten time to access for patients. A priority review will direct overall attention and resources to the evaluation of applications for therapies that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared with standard applications.

Sobi recognises that there may be instances when patients with serious or life-threatening diseases have exhausted all treatment options currently available to them and are unable or ineligible to participate in a clinical trial. Additionally, new medicines are normally not available between completion of a clinical trial and regulatory approval or commercial availability. For such patients, upon an

independent request from their treating physician and where legally permissible, Sobi considers making access of our medicines available via Managed Access Programmes¹. Requests from treating physicians for Managed Access are assessed based purely on medical need and managed by the R&D and medical organisation.

Sobi has an established process for emergency orders within the EU and the US for life-saving products (Orfadin, Kineret and Gamifant) which is also available during non-office hours 365 days a year for immediate service if needed to save a patient's life.

WFH Humanitarian Aid Program donation

More than 75 per cent of people with haemophilia around the world have limited or no access to diagnosis and treatment, particularly in the developing world. The World Federation of Hemophilia Humanitarian Aid Program helps address the lack of access to care and treatment by providing much-needed support for people with inherited bleeding disorders in developing countries.

By providing a more predictable and sustainable flow of humanitarian aid donations, the programme makes it possible for people living with haemophilia to receive consistent and reliable access to treatment and care. In addition, educational programmes for treaters and patients are critical initiatives helping to develop in-country capacities to improve diagnosis and treatment monitoring. In 2020, due to the COVID-19 pandemic, the training workshops were mainly conducted in a virtual setting, resulting in almost a three-fold increase in the number of attendees. While personal interactions are important, the WFH will evaluate how a multi-channel approach may further expand the reach and accessibility of training.

Since 2015, and renewed in 2020, Sobi and Sanofi have pledged to support of the WFH Humanitarian Aid Program with a total of 1 billion IU of factor therapy for humanitarian use over a ten-year period. See Sustainability Notes on page 122 for details on impact to date.

Actions to ensure continued access to treatment during the COVID-19 pandemic

Supply-chain continuity

In 2020, our product supply chain withstood the challenges of the COVID-19 pandemic and there was no interruption to the safe and secure production, supply and logistics of Sobi products. Sobi – with its collaboration partners, contractual manufacturers and distribution network – has been able to manage the effects of the pandemic. This is a result of strong partner relationships, intensified communications and clear supply planning to secure product availability and manage fluctuating product demand.

Home delivery in Saudi Arabia during COVID-19 lockdown

Just as COVID-19 emerged, several major hospitals in Saudi Arabia switched haemophilia patients to Sobi products. The lockdown of the capital Riyadh meant patients outside the city were at risk of not receiving treatment. Sobi introduced a home delivery service in collaboration with local hospitals, pharmacies and Sobi supply chain/logistics, sending refrigerated trucks with products from Riyadh to 12 cities around Saudi Arabia.

COVID-19 educational material for haemophilia

Educational videos on COVID-19 were co-created with stakeholders from the haemophilia community, sharing insights, expertise and their experience on how best to manage haemophilia and maintain good health during the pandemic. There is a significant need to maintain exercise and adherence to prescribed treatment and support a healthy immune system.

Expand access to treatment – Ambitions

- Increase geographical reach of operations
- Ensure sustainable access to care
- Continuous product launches in areas of rare diseases in key geographies
- Support managed access¹
- WHF Humanitarian Aid Program
 - 2015–2019 – 500 million IU donated
 - 2020–2025 – 500 million IU to be donated

Actions to ensure continued access to treatment after Brexit

Since 2018, Sobi has prepared for different possible outcomes of the Brexit Free Trade Agreement negotiations. The project has involved representatives from a multitude of functions. To ensure supply for patients in the UK, extra stock was organised in the UK and Sobi signed the UK Government's secured freight capacity for supply of medicines. When the UK left the EU on 1 January 2021, no patients experienced interruptions of product supply. Sobi is also well prepared for future regulatory changes.

¹ Managed Access describes areas regularly known as compassionate use, expanded access and other similar programmes.

Patient-centricity & community engagement

Our patient community engagement is based on three elements: enabling connectedness, ensuring sustainable access to care, and giving a voice to patients to express their needs related to care.

Sobi supports connectedness so that patients, caregivers and patient organisations can connect to each other and the community, and to relevant information and resources to support timely diagnosis, optimal treatment and living well with their condition. Sobi applies a proactive outreach to patient organisations and supports the establishment or strengthening of patient organisations and networks in accordance with the Healthcare Interactions Policy.

Sobi is a long-term sponsor of patient organisations such as the European and North American rare disease organisations EURORDIS and NORD respectively, the World Federation of Hemophilia (WFH) and the European Haemophilia Consortium. Sobi also supports the European Haematology Association (EHA), The Irish Platform for Patient Organisations, Science and Industry (IPPOPI), The AKU Society, the Histiocytosis Association, AlArthritis Association, and other local patient organisations. A yearly summary of support provided to patient organisations is made public on www.sobi.com.

Sobi has been giving a voice to patients to express their needs related to care, offering a platform to build awareness and to advocate for their needs to be considered in current and future decisions related to care. This is done through patient advisory boards and involvement of patients in R&D and clinical study design to ensure we continue to develop our medicines to meet unmet needs, and by sharing patient stories. Sobi co-develops patient support programmes, advocacy and evidence generation activities with patient advocacy groups in disease areas such as haemophilia, ITP, PNH, HLH, FMF, AKU and refractory gout.

Sobi also contributes to the wider community through collaborations with third parties. In 2020, Sobi entered into an agreement with QBE Europe to invest 25 per cent of our corporate insurance premium into investments with an additional social objective via Premiums4Good.

Community engagement – Ambitions

- Support patient connectedness
- Give a voice to patients

Knowledge contribution to enhance the practice of medicine

Within rare diseases, knowledge about each disease is rare too, and Sobi is committed to contributing to increased understanding, diagnosis and treatment of these underserved diseases. Sobi engages in advancement of knowledge by sponsoring and attending scientific meetings and arranging medical training designed to share medical advancements, and taking part in discussions to enhance the practice of medicine. Participation in medical events is governed by the Healthcare Interactions Policy. Sobi sponsored and participated in six international scientific meetings as well as several local events in 2020.

Sobi's annual support to the WFH Corporate Partner Program has enabled country development programmes, educational resources, training for healthcare professionals, capacity building and training for patients and patient organisations as well as support for the World Bleeding Disorder Registry.

For almost ten years, Sobi has been a sponsor of SSIEM, the Society for the Study of Inborn Errors of Metabolism. Sobi has taken part in the organisation's meetings, which offer a unique opportunity for the community to meet, train and learn from each other.

Sobi also provides a medical grant to FYMCA Medical Ltd for continued rare disease education and services in developing countries. The FYMCA programme aims to develop the skills of the healthcare personnel in diagnosing and managing metabolic diseases, as well as providing genetic counselling in countries where equipment and resources are not available.

Knowledge contribution – Ambitions

- Active participation and sponsorship of medical conferences
- Continued support of community-led initiatives to increase knowledge sharing

We focus on patient safety

By adhering to pharmaceutical standards, we strive to provide products that meet the high quality and regulatory expectations of the pharmaceutical field. The safety profile and monitoring of our products is of utmost importance.

Safety surveillance, pharmacovigilance, continues across the life cycle, allowing us to identify safety risks sooner so that we can mitigate them and minimise or avoid harm. For all our medicines, under development or on the market, we have systems in place for identifying and evaluating possible adverse drug effects. With a robust pharmacovigilance system, we continuously monitor the benefit/risk profiles of our products and ensure our alignment with the precautionary principle. Our Chief Medical Officer is accountable for the benefit and risk profiles of our products, providing medical oversight and enforcing risk assessment processes that help us make efficient and informed decisions about patient safety. Each product also has a dedicated safety team, which includes a responsible global safety physician.

As part of our commitment to patient safety we continue to improve the competence of our staff, and develop our processes, systems and tools. Annual training is provided for all employees to ensure that all safety information – such as adverse events, product complaints and incorrect use – in relation to our products is reported.

Product quality regulations

As part of the pharmaceutical industry, Sobi works in a heavily regulated environment. Therefore, it is essential that Sobi meets all regulations, and acts in compliance with Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP) including the requirement in the regulatory dossier in all countries where our products are licensed, manufactured or sold.

Good Practice guidelines are maintained to monitor and ensure product safety and quality compliance during the products' life cycles. The Quality Assurance department is responsible for product release to the market; this process includes the evaluation of product testing and the manufacturing steps. In the EU, product release to the market is performed by a Qualified Person (QP). For drug safety (pharmacovigilance) the responsibility is held by the Qualified Person Pharmacovigilance (QPPV).

To ensure and evaluate compliance with current requirements, inspections of our facilities by regulatory authorities are performed regularly. In addition to external inspections, Sobi continuously monitors the performance of our suppliers and internal processes and operations.

Ensuring product integrity

Sobi works to improve patient safety through updated product information, safe packaging and extensive safety monitoring of known or new side effects.

Product recall is governed by standard operating procedures (SOP) and managed for all products for which Sobi is Marketing Authorisation Holder (MAH), and for Investigational Medicinal Products (IMP) in Sobi-sponsored clinical trials in cases when a product may cause damage, injury or inconvenience to the consumer and may affect one or several batches or the whole product. An Expert Committee is responsible for assessing product quality and compliance risks for products released to market and clinical studies, and a Recall Decision Body will take the decision on a recall together with the relevant regulatory authority or authorities.

Correct labelling is important to ensure proper use, and current and new safety information needs to be communicated consistently and promptly to authorities, prescribers, patients and within the organisation. SOPs are in place to ensure timely updates to Product Information and Patient Information Leaflets in the product packaging. The labelling process consists of a series of processes and is a cross-functional responsibility involving the Benefit-Risk Council,

Drug Safety, Regulatory Affairs, Medical Affairs, External Manufacturing/Packaging and Quality Assurance, and Supply Chain.

Counterfeit pharmaceuticals are a growing worldwide problem. Governments all over the world are introducing regulations and systems to detect and prevent the distribution of counterfeit products. All Sobi products are serialised and given unique identification codes. Sobi's products have not yet been subject to falsification.

Patient safety – Ambitions

- All Sobi employees trained in patient safety
- No critical or major incidents of product recall
- No incidents of incorrect labelling



Responsible behaviour

At Sobi, we promote business ethics in everything we do by setting high ethical standards and providing policies to support employees by defining responsible behaviour. The aim is to build a sustainable organisation by enforcing compliance with our corporate principles,

and by supporting a culture that promotes an open discussion of ethics in our operations. Through our actions, we take action to contribute to the SDGs via specific targets.

Responsible behaviour and the SDGs

Sustainable Development Goals	Sustainable Development targets	Action and ambitions	Progress	Read more
SDG 7 Affordable and clean energy	7.2 Increase share of renewable energy	Shift to 100% renewable energy and LED lighting	100% renewable energy at head office and manufacturing site in Sweden.	p 121
		Transition to 100% hybrid/electrical car fleet by 2030	Environmental limits and increased nominal value introduced in car policy for Sweden and Italy	p 121
SDG 8 Decent work and economic growth	8.8 Safe and secure work environments	Ambition for zero work-place incidents	Updated Health & Safety Policy. Reduced number of incidents in 2020.	p 117, 125
			Supplier requirements stipulated in Partner Code of Conduct.	p 119
SDG 12 Responsible consumption and production	12.1 Implement programmes on sustainable production	Implement the Sobi Responsible Sourcing Programme in supplier relationship management	Partner Code of Conduct in place.	p 119
	12.4 Achieve the environmentally sound management of chemicals and all wastes throughout their life cycles	Comply with REACH legislation	Sobi granted REACH authorisation for the use of Triton X-100.	p 120
		Environmental assessments of products	Environmental assessments updated for Sobi's two small molecule treatments	
		Increase data collection on waste to enable reduction of waste volumes	Waste project initiated. Established process for reuse and recycling of IT equipment.	p 121
SDG 13 Climate action	13.2 Integrate climate change measures	Apply TCFD risk analysis and adopt climate strategy in response.	Strategy on environmental sustainability in place. Environmental policy updated with training.	p 120
		Complete Scope 1, 2 and 3 reporting with targets	Scope 1 and 2 reporting for whole organisation. Enhanced Scope 3 data collection and reporting with target set for 2022.	p 121–123
SDG 16 Peace, justice and strong institutions	16.4 Combat organised crime	Zero incidents of product counterfeiting	100 % serialisation of products to prevent counterfeiting.	p 115
	16.5 Anti-corruption and bribery	Zero incidents of bribery or corruption	New Code of Conduct approved. Training distributed with a 97% completion rate. Healthcare Compliance structure strengthened and continued transparent reporting on monetary transactions and transfers of value. Whistle-blower functionality made available to external parties.	p 118

We help our people to develop and keep them safe & healthy

Sobi is a responsible employer. We rely on our people to deliver on our business strategy. Our social impact is derived from our commitment to patients as described in this report, but also through our interactions with our employees and the work opportunities and conditions we provide.

Employee survey

Sobi has committed to perform an annual all-employee survey, including pulse surveys to monitor employee satisfaction, inclusion and engagement.

In 2020, the Global Engagement Survey was conducted with a response rate of 87 per cent including all employees and full-time consultants in wholly owned subsidiaries. Employee engagement ranked on 73 (benchmark 74), on par with the industry.

Workshops throughout the organisation have identified areas for development in three main areas: culture, career opportunities and work-life balance. Culture is seen as an aspect important to maintain and nurture during the organisation's growth and strategic shift. Career opportunities are also valued, and while employees believe that their competence is a good match with their roles, there is a continued desire to develop to contribute even more and that opportunities for career development are recognised in the expanding business strategy. Finally, work-life balance was impacted negatively during the COVID-19 pandemic, as seen in many organisations last year. It was noted however that workload ranked better in the Engagement Survey in September 2020 than in the COVID Pulse Survey in June 2020, after which actions were taken to improve the workload situation.

Development, training and compensation

Sobi is a values-driven company with a scientific and patient-centric organisation. Highly skilled and high-performing teams have been identified as a key success factor for meeting our ambitious strategic objectives. This involves developing our methods to help managers, leaders and colleagues facilitate continuous growth. An example of a Sobi leadership training programme is the Sobi Management Toolbox training which is designed to develop Sobi's leadership population in the fundamentals of people management. The training, which is now available digitally, offers managers the opportunity to practise leadership skills, identify their own strengths and development areas, and learn from peers.

Sobi also offers regular business introduction sessions that are open to the whole company where corporate leaders present their respective areas.

Creating a safe working environment during COVID-19

COVID-19 impacted our employees across the world in a professional and private perspective.

Actions implemented to ensure a safe working environment included more flexible working hours, initiatives to ensure necessary distancing and safety precautions such as additional personal protection equipment (PPE), desk dividers, information signs and office attendance planning. International travel restrictions were applied March to December, allowing only business-critical international travel.

Sobi conducted a global COVID-19 employee pulse survey (response rate 85 per cent) in June that showed strong engagement from employees and an eagerness to influence working conditions.

All Sobi's employees receive regular performance and career development reviews. A talent management process was presented in 2020 to support employee evaluation and development. Sobi applies a 70:20:10 learning and development model: training opportunities are offered as part of the role (70), through interactions with others (20), and formal educational events (10).

All Sobi employees have access to the Sobi Learning Management system and are assigned training based on role, supported and documented by a training matrix system. The system also lists available business, management and product training, meets regulatory requirements in the pharmaceutical field and serves as a comprehensive digital platform for ensuring individualised and specialised training as well as evidence of learning. Internal processes and control measures involve scientific, regulatory and compliance training which covers all employees (including part-time) and contractors. In 2020, an online Learning Resource Guide was also made available to all employees.

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. All employees (with exception of North American and Asian based employees due to tax reasons) are offered long-term as described in Note 10.

Health and safety

Sobi enforces a global Health and Safety Policy. Occupational health and safety (OHS) management is integrated into overall activities and operational control as an ordinary part of daily work. OHS should be regularly addressed at meetings and any OHS aspects regarding activities considered. Managers are responsible for addressing any concerns raised. The joint management-worker health and safety committee operates from head office and includes representatives from all operations. The committee meets quarterly and reports to the Executive Committee.

Investigating and identifying the cause(s) of an accident, dangerous situations or near-misses makes it possible to take action to prevent a similar occurrence in the future. All employees are required to report OHS-related incidents to their employer; this is done through an electronic system. Managers are required to report serious incidents and significant OHS risks, and ensure that regulatory requirements and internal procedures for reporting of incidents are followed.

Diversity and equality

Every employee is offered equal opportunities regardless of ethnicity, age, gender, religion, sexual orientation or physical ability. Our guidelines clearly prohibit any sexual harassment. In the US, a Diversity, Equity & Inclusion programme was initiated, including an Employee Resource Group, manager training on inclusion and belonging as well as unconscious bias training.

In Sweden, our gender equality analysis carried out annually is designed to prevent discrimination and promote equal rights and opportunities. We carefully evaluate the results in collaboration with trade unions and act when needed. We also map roles and responsibilities proactively to ensure that salaries and development opportunities are provided in an equitable manner.

Caring for our employees – Ambitions

- Perform annual employee engagement survey
- All employees offered annual performance and career development discussions
- Zero-tolerance approach to discrimination and sexual harassment
- Target of no workplace accidents leading to lost workdays

We have no tolerance for corruption

Transparency and open dialogue about ethical issues form the foundation of strong collaborations. The Sobi Code of Conduct provides a framework for what Sobi considers to be responsible and appropriate conduct. It is approved by the Board of Directors and applies to everyone working at Sobi and its subsidiaries – including employees, temporary personnel and on-site consultants. The Code of Conduct connects to essential corporate policies, Sobi values and sustainability areas.

During the year, a fully digital version of the Code of Conduct (www.coc.sobi.com) was launched, accessible for both employees and external audiences, replacing the previous version. Topics include human rights, health in the workplace, freedom of association, zero tolerance of child and forced labour, patient and community interactions, product safety and quality, ethical research, anti-corruption, fair competition, handling of conflicts of interest, data privacy, intellectual property and environmental responsibility. The Code of Conduct has been translated into major languages and is supported with e-learning focusing on practical dilemmas.

We also promote high ethical standards by supporting a corporate culture that promotes open discussions of ethics both in our operations and among key stakeholders.

Sobi's employees are encouraged to report potential misconduct or unethical behaviour openly, to line management, Human Resources, Corporate Compliance or the Legal Department, or by using the Sobi Compliance Hotline, a whistleblowing hotline run by a third party to allow for the possibility of anonymous reporting and legal protection. During 2020, the Sobi Compliance Hotline also became available for external audiences via a link on the company website. All reports made through the whistleblowing hotline are reviewed by the Corporate Compliance Department, are subject to investigation according to Sobi's Investigational Policy and are followed up with appropriate remediation measures as needed.

Compliance

Sobi's compliance programme aims to enable our business by handling risk before it arises; it follows the elements and principles for effective compliance programs established by regulators. Compliance is introduced to all new employees and included as a topic in induction programmes. As Sobi is expanding and entering into markets with higher risk, specific focus has been applied to introduce new markets to Sobi's compliance programme including on-site visits, training and increased monitoring of new service agreements.

The Global Compliance Governance Charter ensures management oversight of the compliance programme, including a governance structure with compliance committees, clear compliance accountability at different levels of the organisation and a network of compliance subject-matter experts in the countries. The Chief Compliance Officer reports directly to the General Counsel, and regular updates on the compliance programme are provided to the Corporate Compliance Committee and the Board of Directors.

Anti-corruption

The pharmaceutical industry presents several corruption risks. It is a highly regulated sector with global operations, multiple interactions with government officials and widespread use of third parties throughout the pharmaceutical value chain. We work actively to prevent any form of corruption.

Sobi's Anti-Corruption Policy, approved by the executive management, has a global scope and complements the Code of Conduct with Sobi's global minimum standards to prevent corruption in activities under Sobi's control. It is aligned with industry codes and legislation, such as the Foreign Corrupt Practices Act and the UK Bribery Act.

Key principles outlined include not accepting any nature of bribe, no offer or provision of facilitation payments, accurate bookkeeping and records, and ensuring that no gifts are made to public officials or to healthcare professionals. Risk assessments shall be carried out on a regular basis and risk-based due diligence procedures shall be carried out in respect of third parties.

Sobi's Internal Control function governs standards across the organisation, including the Risk Management Policy, the Authority Policy, conducting yearly walk-throughs and testing of previously mapped processes to identify changes in activities, risks and controls. Collaboration and audits with the Compliance department occur on a regular basis or when reason arises.

All employees are required to undergo regular e-learning compliance training on the Code of Conduct, anti-corruption and data privacy, with records kept of training. Additional training for specific audiences is defined in yearly compliance training plans, and may include areas such as "train the trainer" materials on relevant topics from appointed compliance subject-matter experts or face-to-face training on key compliance topics.

Considering the risk exposure related to corruption and Sobi's zero-tolerance policy, significant efforts are made to promote the reporting of suspected corruption incidents. Sobi's Compliance Hotline has a dedicated reporting section for potential bribery and corruption concerns to facilitate reporting.

Managing corruption risks in the pharmaceutical industry

As a pharmaceutical company, the most apparent corruption risk lies within Sobi's interactions with healthcare stakeholders. All engagements are governed by Sobi's Code of Conduct, while a majority are also covered by the Anti-Corruption Policy and the more specific Policy on Healthcare Interactions. Other policies with relevance to corruption prevention are: Policy on Anti-Corruption Due Diligence on Third Parties, Group Authority Policy, Entertainment Policy, Procurement Policy and Risk Management Policy.

We have an established Healthcare Compliance (HCC) programme including system support to minimise the risk of corruption; this includes policies, mandatory training for customer-facing employees, as well as reporting and controls. The HCC programme is an important tool for ensuring that all interactions and value transfers remain legal and can withstand external scrutiny. All healthcare interactions are intended for the benefit of patients or to enhance the practice of medicine, and all interactions require prior approval and appropriate documentation. A compliance monitoring plan is adopted and executed on an annual basis, involving sample testing and verification of key controls for different activity types and processes. Findings are categorised, logged and reported.

Monetary transactions and transfers of value with healthcare providers and patient organisations follow local transparency initiatives such as under the EFPIA Code, US Sunshine Act and national transparency laws, and are made public on an annual basis on our website, www.sobi.com. Sobi currently publishes Transfers of Value to healthcare providers in 33 markets across Europe (including Russia and Ukraine) and the US. In 2020, we launched an updated programme and system support for transparency reporting for increased effectiveness and rapid adaptation to new geographic areas.

Responsible marketing and sales

We are committed to employing high ethical standards of sales and marketing practice worldwide, in line with our Code of Conduct and supporting policy framework. Employees involved in promotional activities are trained regularly.

The Policy on Healthcare Interactions guides promotional activity and provides relevant tools. The policy applies to Sobi employees,

contractors, agents and third parties. General managers are accountable for ensuring compliance at local level and for instructing qualified representatives to design processes for local implementation and training, including approval processes incorporating the appropriate internal stakeholders. Promotional materials are always approved prior to external use and after each modification, by a cross-functional team of qualified representatives, and review and approvals are documented in a digital vault. Approvals relating to promotional and non-promotional material are retained for ten years after final use.

Data privacy

Data privacy is part of Sobi's Code of Conduct and a prioritised area across Sobi. It is important that our customers, clinical study subjects, employees and others we interact with can trust that Sobi processes personal data in a responsible and secure manner.

Sobi has implemented a data privacy programme in order to promote data privacy compliance, including appointing a Data Protection Officer (DPO), a global Policy on Processing of Personal Data and procedures on how to respond to data breaches and data subject access requests, and monitoring procedures. In addition, data privacy champions have been appointed throughout the Sobi organisation to promote compliance and support the business.

EU data privacy legislation requires Sobi to assess all suspected and confirmed personal data breaches. If a personal data breach is confirmed, Sobi must also assess if reporting to supervisory authorities and/or data subjects is required. In order to be able to comply with these requirements, Sobi has implemented a personal data breach process globally, requiring all staff to report suspected and confirmed personal data breaches immediately to Sobi's DPO. The DPO assesses all cases and ensures that appropriate actions are taken.

We source responsibly

To ensure sustainable and responsible sourcing, we launched the Sobi Responsible Sourcing Programme in January 2020, including the introduction of a Partner Code of Conduct and sustainability screening. Contracts include a requirement to comply with the Sobi Partner Code of Conduct. Sustainability screening of partners involves ensuring compliance with standards in the areas of governance, labour rights, human rights and environmental responsibility through EcoVadis third-party evaluation. Yearly assessment by EcoVadis is conducted for strategic suppliers in direct categories and for those in high-risk countries, in 2020 covering top 100 suppliers in spend.

In January 2020, Sobi's membership application to the Pharmaceutical Supply Chain Initiative (PSCI) was accepted, and requirements for supplier behaviour and performance have been aligned with the PSCI principles.

During the year, the Procurement department has been trained in responsible sourcing, and an assessment of supplier sustainability performance has been included as a qualifier in supplier selection. Suppliers that do not reach a total EcoVadis score of >40 or which have a score <40 in any theme will be further evaluated and encouraged to improve their score.

Sobi intends to expand the Responsible Sourcing Programme in 2021 to include a materiality and risk-based approach to sustainability audits, and introduction of continuous improvement plans and non-compliance procedures.

Sobi's human rights statement and statement against child and forced labour are included in the Partner Code of Conduct to address potential risks and manage compliance in the supply chain.

Third-party due diligence

Sobi's commitment to prevent bribery and corruption in connection with our business activities around the world extends to third parties engaged to perform services on Sobi's behalf. In accordance with Sobi's Anti-Corruption Policy, Sobi conducts appropriate risk-based anti-corruption due diligence of third parties ("TPDD") to identify and mitigate bribery and corruption risks and address any "red flags" prior to engagement of third parties. Third parties in scope for TPDD are re-evaluated periodically. Sobi contracts include standard compliance with laws clauses and related anti-corruption protections.

Compliance – Ambitions

- All employees to undergo regular e-learning training with the following being mandatory for all employees: Code of Conduct, Anti-corruption and anti-bribery, Data privacy, and Product safety training
- Zero-tolerance approach to bribery
- No major violations of data privacy
- Transparent reporting of monetary transactions to healthcare professionals and organisations
- Deliver on Responsible Sourcing Programme
- Participate in supplier sustainability networks
- Conduct ESG due diligence and promote the responsible business conduct of suppliers

Reducing our environmental footprint

Our materiality assessment shows that our environmental and climate-related impact is limited. It can be broken down into direct and indirect impacts, through sourced activities both upstream and downstream and through activities caused by our operations.

Our carbon footprint arises from energy consumption during the production of products, business travel, logistics within the supply chain and the distribution of our products. Environmental impacts from production and the laboratories are mainly due to the use of energy, water, chemicals, generated waste and discharge of sewage.

Management of water and energy consumption, chemicals, waste and emissions have high priority in our production and laboratory facilities. More specific and detailed environmental guidance for the facilities is given in specific standard operating procedures and in the environmental compliance programme, which aims to improve control of the environmental impact from the production.

We continuously evaluate and monitor the energy and water consumption of our production facility. Sobi reports energy and water consumption annually and measures internal KPIs with the aim of improving environmental performance.

Sobi's current reporting practice covers Scope 1 and 2 for all our wholly own operations as well as Scope 3 for business travel.

Responsible handling of chemicals

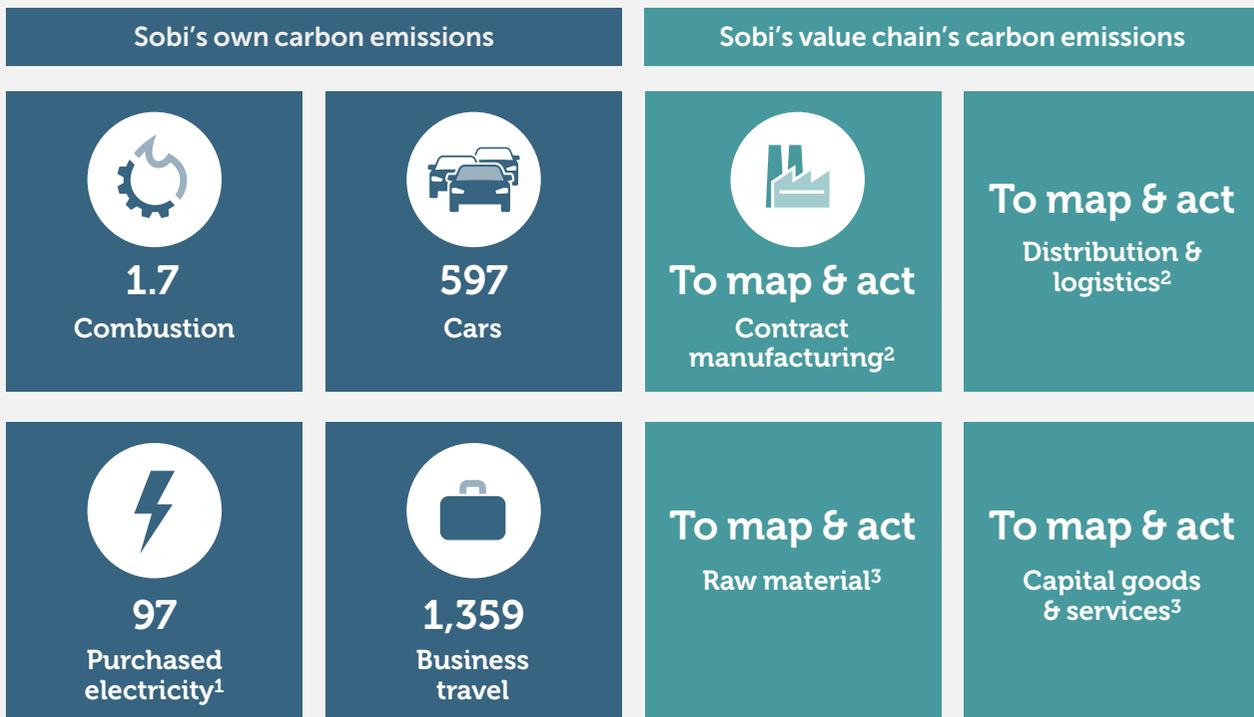
All applicable chemical regulations are monitored closely and naturally constitute an important aspect of Sobi's business. A recent example is the use of Triton in the ReFacto production process. Triton X-100 is subject to REACH authorisation. It is not possible to replace Triton in the process, so Sobi applied for and was granted authorisation for its use. Strict requirements are applied on filter cleaning and waste handling to ensure that environmental discharge is avoided as far as possible.

Chemicals regulations are extensive and continuously expanding; all handling of chemicals in our laboratory and manufacturing processes therefore follows strict instructions. We perform continuous risk assessments and internal audits. The Responsible Sourcing Programme is an important tool to influence, manage and follow up sourcing and handling of chemicals in our supply chain.

Pharmaceuticals in the environment

The environmental hazards of a specific drug refer to its inherent properties, such as toxicity and its ability to be broken down by nature. According to existing EU and US guidelines on environmental risk assessments of medicinal products, biopharmaceuticals composed of for example proteins and peptides are not considered to have a significant negative environmental impact. A high percentage of Sobi's products are protein-based and are therefore considered

Sobi's total carbon emissions (CO₂ tonnes)



Direct and indirect emissions (Scope 1, 2 and parts of Scope 3 in CO₂ tonnes)
1. Calculation methods have been adjusted to previous years.

Other indirect emissions (rest of Scope 3), in the value chain to be mapped by 2022.
2. Hybrid method based on supplier direct reporting will be used
3. GHG-protocol calculations based on spend will be used

not to have a significant impact on the environment. Environmental assessments of active pharmaceutical ingredients (API) have been conducted on Sobi's two small molecule treatments, nitisinone and avatrombopag, and they are considered to be of low risk to the environment.

Direct carbon emissions (Scope 1 and 2)

Sobi's direct emissions arise from our commercial operations in 30 countries with 20 offices as well as our biological production facility (reported as Manufacturing/Haematology) in Stockholm, Sweden, and our laboratory in Geneva, Switzerland.

Our direct operations are where we have the most control. We commit to substantially reducing emissions from our sites and ground fleet by 2025 by avoiding, reducing and substituting, and have the ambition to reach zero emissions by 2030. Electricity from renewable sources is currently sourced for offices and facilities in Sweden, Switzerland and Denmark. Mapping and review of energy sources as well as extent of use of LED lighting for local offices was initiated in 2020.

Indirect carbon emissions (Scope 3)

All production of our commercial products is outsourced to contract manufacturers. Sobi's supply chain sources production from CMOs in Europe and the US, with distribution to over 70 markets worldwide. Across our value chain (Scope 3), this is where reductions potentially could have the biggest impact but also where we have least control.

During 2020, Sobi participated for the first time in the PSCI Supplier Survey led by Ecodesk to collect Scope 1 and 2 emissions data from contract manufacturers.

Sobi intends to increase our awareness of our climate impact by mapping the supply chain by 2022, using surveys and other methods of direct reporting for CMOs as well as distribution and logistics services. Remaining emissions from raw materials, packaging, capital goods and services will be calculated using industry-specific guidance on spend from the GHG Protocol where possible. Sobi will aim to apply the boundaries "from cradle to customer", limiting reporting to areas within our producer responsibility - production, formulation, packaging and delivery of sold goods to wholesaler or partner. Emissions calculations will not cover a full consumer life-cycle analysis as the prescription and use of our products is beyond our control.

We will continue to use the Responsible Sourcing Programme and supplier relationship management to increase reporting coverage as well as influencing suppliers to participate in emission reductions with a focus on areas of our producer responsibility. The safe and timely delivery of our products will always be the primary consideration.

Development of climate-based targets

Target year	Topic	Ambitions
2022	Emissions – Scope 3	Map emissions in supply chain (CMO, distribution, waste and spend) – set baseline and reduction targets
2025	Emissions – Scope 1 and 2	Reduce operational GHG footprint by 50% from 2015 baseline
2030	Emissions – Scope 1 and 2	Reduce operational GHG footprint to net zero emissions Shift to 100% renewable energy
2030	Emissions – Scope 3	Set reduction target in 2022
2030	Vehicle fleet	Achieve a 100% hybrid or electric vehicle fleet

Business travel

In 2020, Sobi expanded the reporting scope of business travel emissions to cover all global operations (in 2019, 80 per cent of operations were included) with the intention of setting a baseline year for business travel. However, in 2020 the COVID-19 pandemic had a substantial impact on business travel as Sobi limited all non-essential business travel from 15 March until the end of the year.

Business travel also includes a Sobi leased car fleet (Scope 1) as well as employee-owned cars (Scope 3). The practice of car management and policy is dependent on local regulations and culture. In Sweden and Italy, further sharpened environmental limits were introduced in 2020 for local car policies as well as the provision of an increased nominal value to include electric and hybrid cars. Charging facilities are available at offices in Italy, Belgium and Finland with economic compensation for the installation of charging facilities at employees' homes provided in Italy, UK, Ireland, Spain and Portugal. According to policies for the newly opened operations in Japan, only employees' public transport is compensated.

A significant shift has been made to transition to digital internal and external meetings as well as scientific congresses reducing the need for travel. Sobi has accelerated the implementation of modern workplace technology across the entire organisation.

Waste

Sobi strives to continually increase data collection on waste and thereby enable continual reductions in waste volumes wherever possible. Measures are also taken to prevent generation of waste.

In 2019, Sobi discontinued and moved the majority of the laboratory operations from the Solna head office. In 2020, all equipment was evaluated for further use within Sobi's operations. To further limit the volume of waste caused by this action and promote reuse, functioning laboratory equipment was sold to external parties.

Sobi has an established process for reuse and recycling of IT equipment in Sweden via a certified technology lifecycle management service partner. This process will extend to all Sobi's operations worldwide as of 2021.

Sustainability Notes

Sobi updated its materiality assessment process in 2020. For a detailed description of stakeholder groups and outcomes of the assessment, see page 109. The materiality assessment identified the most important topics for Sobi's sustainability reporting.

Economic performance

In 2020, revenue growth was 7 per cent with revenue of SEK 15,261 M. Adjusted EBITA was SEK 6,301 M, resulting in an adjusted EBITA margin of 41 per cent for the full year. Cash flow from operations totalled SEK 5,214 M.

Direct economic value generated

SEK M	2020	2019
Revenue	15,261	14,248
Operating costs	7,575	6,430
Employee wages and benefits	2,250	1,748
Payments to providers of capital	249	86
Payments to government ¹	918	520
Community investments ²	20	23

Calculation is based on the consolidated statement of comprehensive income.

- Includes corporate income tax (CIT) payments (i.e. no special payroll tax on pensions, VAT or social security contributions). Does not include other taxes such as pharmaceutical, environmental and individual employee's income tax.
- Community investments are based on costs for financial support to patient organisations. The largest recipients are the World Federation of Hemophilia and the European Haemophilia Consortium. Patient organisations receiving support are made public on www.sobi.com.

Indirect economic impact

Sobi reports on the humanitarian aid donation of haemophilia factor treatments as a significant indirect economic impact in the stakeholder community and developing countries.

In June 2020, Sobi and Sanofi committed to an additional 500 million IUs to the initial donation, in support of the World Federation of Hemophilia (WFH) Humanitarian Aid Program, fulfilling the pledge to donate up to 1 billion IUs of coagulation factor to humanitarian aid between 2015–2025.

Sobi's impact is reported in accordance with the WFH's progress report for this programme and is the result of Sobi's and Sanofi's contribution to the programme.

Number	2020	2019	2018
Total M IUs ¹ delivered	538	449	362
Total patients treated (cumulative)	17,329	17,223	16,885
Acute bleeds treated	21,900	42,881	37,896
Surgeries	470	355	461
Number of workshop attendees	691	250	240

1. International units

In addition to the humanitarian aid donation to the WFH, Sobi contributes to the WFH Corporate Partner Program. Read more about the impacts of the Corporate Partner Program on the website www.sobi.com.

Environmental performance

The scope of Sobi's environmental impact reporting includes Sobi-owned biological manufacturing facility, headquarters in Sweden and international offices and business travel. Reporting for 2020 includes environmental data from subsidiaries, not previously included.

Sobi aims to report comprehensively on supply chain emissions by 2022.

E1. GHG Emissions

GHG emissions (CO₂) (tonnes)

	2020	2019	2018	2017	2016
Own activities (direct and indirect)					
Total	3,096	4,326	1,326	1,207	1,331
Scope 1 (direct emissions)					
Facilities' energy use	1.7	2.2	3	3	2.6
Fleet cars ¹ (Parent)	88	98	129	153	167
Fleet cars ¹ (Subsidiaries)	509	—	—	—	—
Total	599	100	132	156	170
Scope 2 (indirect emissions)					
Heating (Parent) ²	61	82	119	129	130
Cooling (Parent) ²	0	0	0	0	0
Electricity (Parent) ²	0.02	0.02	0.02	—	—
Unspecified energy (Subsidiaries)	36	—	—	—	—
Total	97	82	119	129	130
Scope 3 (indirect emissions)					
Business travel - flight, taxi (Parent)	295	971	981	830	945
Business travel - flight (Subsidiaries)	1064	3099	—	—	—
Business travel - cars (Subsidiaries)	977	—	—	—	—
Heating (Parent) ²	43	74	94	92	86
Cooling (Parent) ²	3 ³	0	0	0	0
Electricity (Parent) ²	0.01	0.01	0	0	0
Energy (Subsidiaries)	17	—	—	—	—
Total	2,400	4,144	1075	922	1,031

1. Includes fleet cars included in IFRS16 reporting of leased properties.

2. Parent company emissions adjusted from previous years' reporting in alignment with GHG-protocol. Energy at the head office is purchased indirectly through landlord.

3. Indirect effects of district cooling included in Scope 3 from 2020.

Scope 1 and 2 emissions include data from Sobi's global operations, defined as Parent for emissions from the biological manufacturing facility and headquarters in Sweden, and Subsidiaries for emissions from the international offices.

Scope 1 and 2 emissions from the Parent have reduced 47 and 53 per cent respective from 2016, 50 per cent in total. Total Scope 1 and 2 emissions for 2020 cannot be compared with prior years due to the expanded requirement to include all global operations. Scope 2 and 3 emissions from the Parent have gradually declined due to better energy mix from the supplier in Sweden and more efficient energy use.

In 2020, the reporting of business travel is complete covering all of Sobi's operations as well as employee-owned cars used for business purposes. Travel emissions decreased substantially during the year due to reduced travel during the COVID-19 pandemic. Sobi intended to set 2020 as a new base line year for calculation of total emission reductions, but due to the pandemic reported emissions are not representative of expected emissions.

Emission factors used

Aspect	Emission factor	Source
Electricity, Sweden	0.003 g CO ₂ /kWh	A mix of certified renewable energy sources
Cooling, Sweden	S2: 0 g CO ₂ /kWh S3: 1 g CO ₂ /kWh	Annual environmental report, District heating supplier
Heating, Sweden ¹	48.6 g CO ₂ /kWh	Annual environmental report, District heating supplier
Heating values fossil fuel consumption in facility, Sweden	35.82 GJ/m ³	Emission factors and heating values 2020, Swedish Environmental Protection Agency (Naturvårdsverket)
Emission factor fossil fuel consumption in facility, Sweden	74.26 kg CO ₂ /GJ	Emission factors and heating values 2020, Swedish Environmental Protection Agency (Naturvårdsverket)
Air travel	—	Emission factors provided by flight operators and US Environmental Protection Agency
Car travel	—	Individual factors depending on type of car
Rail travel	—	Emission factors provided by different train operators

1. Emission factor for heating in Sweden was reduced due to the supplier's decommission of coal as energy source. The compensation made by the supplier is not included in Sobi's calculations.

E2. Energy use and mix

Energy consumption refers to all operations, including Sobi's contract and in-house manufacturing and all offices. Energy consumption by source of origin and the proportion that is renewable is included where data is available.

In 2020, a mapping of energy sources for all offices was initiated. Renewable energy is sourced for offices and facilities in Sweden, Switzerland and Denmark.

In an effort to transition to more renewable energy in the company and employee car fleet, electrical cars are subsidised in Sweden, Italy, Norway, Finland, UK and Ireland. In Sweden, the nominal price was increased in 2020 to include electric and hybrid cars.

Energy consumption (facilities' energy use) (MWh)

	2020	2019	2018	2017	2016
Electricity	8,318	7,518	7,694	7,852	7,687
of which renewable	8,318	7,518	7,694	7,852	7,687
District heating	2,133	2,550	2,596	2,690	2,713
of which renewable	1,770	2,015	2,051	1,991	2,116
Fossil fuel (oil) ¹	5,6	7,2	10,0	8,4	8,8
Cooling	2,902	3,059	3,167	2,793	2,745
Total	13,358	13,127	13,457	13,335	13,145

1. Direct energy

E2.1 Total amount of energy directly consumed

The direct energy produced and consumed on-site (Scope 1 Facilities' energy use) is generated by an emergency generator that is tested every month. In mid 2019, the process to test the generator was made more efficient and the time spent was cut in half, as were the emissions.

E2.2 Total amount of energy indirectly consumed

Energy consumption is regularly followed up in relation to internal performance indicators. In 2020, energy consumption from the manufacturing of steam increased at the production site. The production of more steam was intentional and used to extend life duration of certain machinery.

Energy-saving possibilities are regularly evaluated at the production facilities in Stockholm, Sweden.

E3. Energy intensity

Total direct energy use for in-house manufacturing per output scaling factor.

Total direct energy use (MWh/SEK M)

	2020	2019	2018	2017	2016
Energy (MWh)	6,173	5,867	6,313	6,480	6,425
Revenue manufacturing (SEK M)	481	376	436	559	569
MWh/SEK M	12.8	15.6	14.5	11.6	11.3

E4. Water use

Water consumption refers to Sobi's head office and production facilities in Stockholm, Sweden. Water consumption is regularly followed up in relation to internal performance indicators.

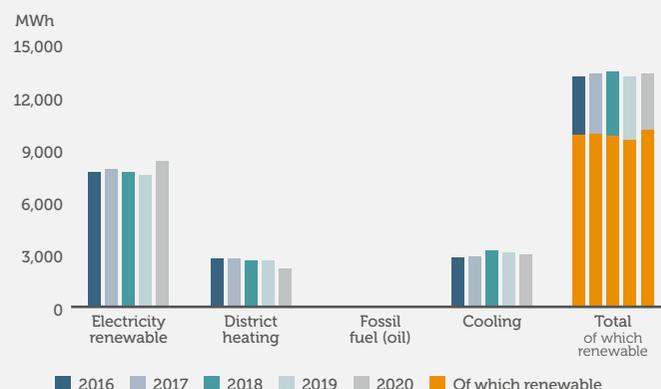
Water consumption

	2020	2019	2018	2017	2016
Purchased water	56,725	31,776	57,374	45,913	40,491
Reclaimed water	—	—	—	—	—
Total	56,725	31,766	57,374	45,913	40,491

In 2020, an incorrect reading of water consumption for the head office was adjusted, resulting in a considerably higher reading compared to previous years. During 2021, a validation of the reading will be conducted to certify proper reporting for actual consumption. The actual water consumption at the head office should most likely have decreased during 2020 compared to previous years, since the laboratory work performed there was discontinued in 2019.

Water in the production facilities is not reclaimed, but warm water is recycled from the production of steam to extract heating and cooling.

Energy consumption



E5. Environmental operations

The Environmental Policy emphasises the importance of management and states the basic overall principles and guidelines for managing environmental issues within Sobi.

To our knowledge, there have been no confirmed incidents resulting in administrative and judicial sanctions for failure to comply with environmental laws and/or regulations in 2020.

In an effort to reduce energy and water consumption by half at the Stockholm production site, several initiatives in 2014 reduced energy use by 45 per cent and water use by 60 per cent over a two-year period. The reductions achieved in 2014 remain in relation to production volumes (see Sobi’s Annual Report 2016 and 2017 for details).

E6. Climate oversight and risk mitigation

Sobi’s direct GHG emissions are limited and the company is not at risk of substantial exposure to climate change in the short-term.

Supply chain partners with a high impact on Sobi’s operations and that are impacted by climate-related risks are continuously monitored as part of Sobi’s responsible sourcing programme and risk-assessment process.

Sobi is following the development of the EU Taxonomy Regulation and recommendations from the Task Force on Climate-related Financial Disclosure (TCFD) with the aim of adapting the company’s climate-related financial disclosures to evolving reporting practice. Sobi’s direct and indirect climate-related risks and opportunities will be assessed in accordance with the TCFD’s recommendations in 2021. At this point in time, it is Sobi’s understanding that none of our economic activities are covered by the technical screening criteria in the EU Taxonomy Regulation so far released. We are continuously following the development of the EU Taxonomy Regulation and Sobi’s operations do not make a substantial contribution, and do no significant harm, to the six environmental objectives established by the regulation.

E7. Waste

Waste reporting is based on Sobi’s head office and production facilities in Stockholm, Sweden. Waste data does not include waste from marketing and sales offices outside Sweden. Non-hazardous waste has decreased as a result of several measures, including digitalisation of deviation management and changes to available archive spaces.

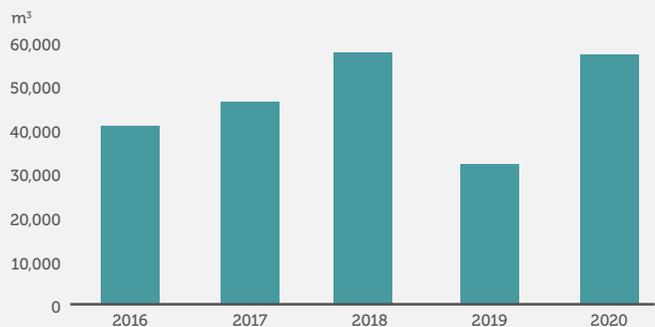
Office and production site waste (tonnes)

	2020	2019	2018	2017	2016
Total amount of waste	35	39	42	72	61
Non-hazardous waste					
Recycling	5	6	–	–	–
Combustion with energy recovery	16	17.5	–	–	–
Other treatment	0	0.6	–	–	–
Landfill ¹	1	0.2	0.1	0.1	0
Total	22	24.3	24	50	46
Hazardous waste					
Recycling	6	5	–	–	–
Reuse ²	1	–	–	–	–
Combustion with energy recovery	0	0	–	–	–
Other treatment	7	8.6	–	–	–
Landfill	0	0	–	–	–
Total	13	14.4	18	22	16

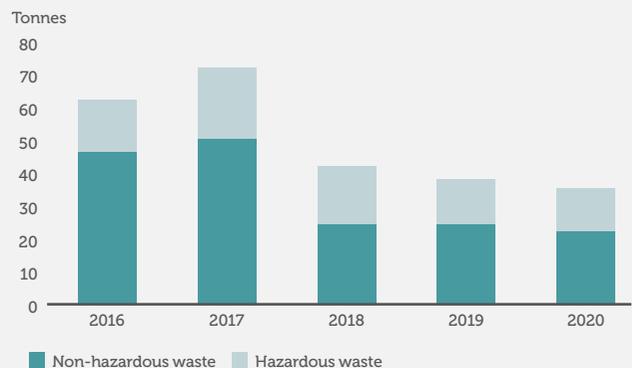
1. A limited amount of Sobi’s waste cannot be recycled and is therefore sent to landfill. The waste is non-hazardous and consists for example of insulation, bricks, ceramics and tiles. All waste is disposed of and treated by authorised companies.

2. IT-equipment sent for repurposing

Water consumption



Office and production sites waste



Social performance

In 2020, Sobi's commercial operations were based in Europe, North America, North Africa and the Middle East, and new offices were established in China, Japan and Australia. Biological manufacturing is based in Sweden with one laboratory facility in Switzerland. In terms of number of employees, Sobi grew organically in 2020.

To our knowledge, there were no confirmed incidents resulting in administrative or judicial sanctions for failure to comply with laws and/or regulations in the social and economic area in 2020.

S1. CEO remuneration

See Note 10 for information about CEO remuneration. See also the Remuneration report available on the www.sobi.com website in connection with the documentation for the 2021 Annual General Meeting.

S2. Gender pay ratio

In Sweden, our gender equality analysis is carried out annually and it is designed to prevent discrimination and promote equal rights and opportunities. We evaluate the results in collaboration with trade unions, and take action if necessary. We also map roles and responsibilities proactively to ensure fair and equitable salaries and development opportunities.

S3. Employee turnover

In 2020, Sobi had a turnover rate of 11 per cent due to voluntary terminations. Sobi did not introduce any furlough schemes or layoffs during the COVID-19 pandemic.

Year	New hires	Hires women	Hires men	Voluntary termination	Total number employees
2020	390	221	169	166	1509

S4. Gender diversity

Sobi has strong representation of women in management roles within STEM-related (Science, Technology, Engineering, and Mathematics) areas. Positions such as CIO, Head of Global Manufacturing and Infrastructure, Head of R&D Operations, and Head of Project and Portfolio Management are all held by women.

%	2020		2019		2018	
	Female	Male	Female	Male	Female	Male
Board	38	62	38	62	38	62
Executive Committee	18	82	27	73	18	82
Senior management ¹	42	58	–	–	–	–
All employees	59	41	60	40	59	41

1. Senior management - management positions reporting to Executive Committee.

S5. Temporary worker ratio

Typically, Sobi does not have part-time positions. Employees may be granted voluntary part-time equivalent employment for personal needs such as child care.

Employees, contract type

Employees ¹	Male	Female	Sweden	Other Regions	Total 2020
Employees	615	894	438	1071	1509
Permanent contract	608	881	403	–	1491
Fixed-term contract	7	11	7	11	18
Substitute	1	1	1	1	2

1. Employee numbers are expressed as full-time equivalents (FTE).

S6. Injury rate

Total number of accidents includes those that did not lead to absence from work but that may have required medical care.

The number of incidents was lower in 2020, partly due to the closure of the laboratory facilities at the head office in 2019. For 2020, statistics include all operations globally. Up to 2019, the data only included reports from Sweden.

Incidents	2020	2019	2018	2017	2016
No. of accidents	10	26	28	23	22
Lost workday injury (LWI)	0	0	1	0	0
Lost time incident rate (LTIR)	0	0	0.39	0	0

LWI – Accidents that led to sickness absence (in addition to the day of the accident)

LTIR – Lost time incident rate per million hours worked

S7. Global Health and Safety

Sobi applies a global Health and Safety Policy and Occupational Health and Safety (OHS) management is integrated into the company's overall management and business. Health and safety is addressed regularly at meetings and any OHS risks associated with activities are considered. Managers are responsible for addressing any concerns raised.

The joint management worker health and safety committee is based at the head office and consist of representatives from all operations. The committee meets quarterly and reports to the Executive Committee.

S8. Training and education

All of Sobi's employees receive regular performance and career development reviews. Training documentation and performance management processes are digitalised.

All employees completed their performance management process (PMP) in 2020.

S9. Patient safety

To ensure and evaluate statutory compliance with quality and patient safety regulations, our facilities are regularly inspected. In 2020, Sobi hosted four inspections (3 GVP, 1 GMP). In addition to external inspections, Sobi continuously monitors the performance of our suppliers and internal processes and operations.

Sobi had no incidents of product recall in 2020.

S10. Marketing and labelling

In 2020, Sobi was sanctioned by the UK self-regulatory body PMCPA for one (1) instance of misleading advertising. The ad has since been removed.

No incidents of non-compliance with regulations and/or voluntary codes concerning product and service information and labelling were reported.

S11. Forced and Child Labour

Sobi's statement on forced and child labour is included in the Code of Conduct and Partner Code of Conduct (which applies specifically to the supply chain), both of which are available on www.sobi.com.

S12. Human rights

Sobi's human rights statement is included in the Code of Conduct and Partner Code of Conduct (which applies specifically to the supply chain), both of which are available on www.sobi.com.

Governance performance

Sobi promotes business ethics by setting high ethical standards in our operations globally. The aim is to create a sustainable organisation by building a culture of compliance with our corporate principles. The objective of maintaining ethical standards extends to our supply chain.

G1. Board diversity

The Nomination Committee applies rule 4.1 of the Swedish Corporate Governance Code in regard to composition of the Board.

Board diversity

	2020	2019	2018
Male	5	5	5
Female	3	3	3
Nationalities	4	4	4
30–50 years	0	1	1
Over 50 years	8	7	7
Committee chairs (three committees)			
Male	2 (3)	2 (3)	2 (3)
Female	1 (3)	1 (3)	1 (3)

G2. Board Independence

See the Corporate Governance Report.

The company meets the Swedish Corporate Governance Code's requirements that a majority of Board members must be independent of the company and its executive management, and that at least two Board members must also be independent of the company's major shareholders.

G3. Incentivised Pay

Executives are formally incentivised for objectives that are determined for the promotion of the Company's business strategy and long-term development, including its sustainability, in accordance with the Remuneration Guideline set out in Note 10.

In the Shareholding Guidelines, the Board recommends that the CEO and other members of the Executive Committee, within three years of their appointment, accumulate personal holdings in Sobi shares representing one annual gross base salary for the CEO, and 50 per cent of annual gross base salary for other members of the Executive Committee, and maintain these shares for the duration of their appointment as CEO or other Executive Committee member.

G4. Collective bargaining agreements

All of Sobi's employees are free to form, join or refrain from joining organisations that represent their interests as employees. All employees are also allowed to negotiate collectively. 40 per cent of Sobi's employees (Sweden, Austria, France, Italy, Spain/Portugal) are covered by collective bargaining agreements.

Employees covered by collective bargaining (%)

Region	2020
Sweden	100
Europe ¹	31
North America ²	0
Rest of the world	0
Total	40

1. Excluding Sweden

2. US and Canada

G5. Supplier Code of Conduct

In 2019, Sobi introduced a Partner Code of Conduct for vendors, suppliers and partners. The Code is available on www.sobi.com.

In January 2020, Sobi became a formal associate member of the Pharmaceutical Supply Chain Initiative (PSCI) and during the year, participated in several PSCI working groups.

The sustainability assessment of 86 partners was monitored by EcoVadis.

- 3 suppliers scored <40 using the EcoVadis CSR Rating Methodology.
- No supplier scored <40 using the EcoVadis theme score of Labour Practices and Human Rights.

G6. Ethics and Anti-Corruption

Sobi's ethical standards statement is included in the Code of Conduct and Partner Code of Conduct (which applies specifically to the supply chain). Sobi's Anti-corruption Policy applies to all employees.

In 2020, five reports of alleged misconduct were reported to the Corporate Compliance Department. All cases were investigated and the appropriate corrective and disciplinary actions were taken where needed.

97 per cent of Sobi's workforce completed the Code of Conduct e-learning. 95 per cent completed the assigned anti-corruption training.

G7. Data Privacy

Please see page 119 for a high-level overview of Sobi's data privacy program.

To allow for continuous improvements as well as complying with data protection legislation, it is of great importance to establish and maintain a robust data breach reporting process.

Sobi's data protection office received 16 internal reports of suspected personal data breaches during 2020, showing that there is an awareness within the company regarding integrity issues, an inclination to report potential issues, and that there are open lines of communications enabling such reporting. The reports range from minor incidents such as e.g. emails sent to the wrong recipient to potentially more severe breaches. All incidents were investigated and corrective actions taken. Two cases were reported to the supervisory authority, as required by applicable data privacy legislation.

Market availability of Sobi products

Regulatory approvals and indications for Sobi's products vary according to geographical region. In addition to regulatory approval, local agreements on pricing and reimbursement are also required for the product to be fully available through regular healthcare pathways.

The table below shows the countries for which Sobi has been granted marketing authorisation (MA), including the indication, and whether market access is achieved through approved pricing and/or reimbursement (marked with x) or managed access pro-

grammes (MAP). In the EU, the marketing authorisation approval and indication is valid for all EU member and EFTA states.

Sobi is commercialising the following proprietary products: Alprolix, Elocta, Doptelet, Gamifant, Kineret and Orfadin. As Sobi only holds the rights to Synagis in the US, Synagis is not included in the table. Sobi also commercialises Kepivance in the US.

See the glossary on page 134 for a definition of the listed indications.

Region	Access to Sobi's products – *new in 2020					
	Alprolix ¹	Elocta ¹	Doptelet ²	Kineret	Gamifant	Orfadin
EU and EFTA states	Haemophilia B	Haemophilia A	CLD	RA, CAPS, Still's, FMF ³		HT-1 & AKU ⁴
Austria	x	x	x*	x		x
Belgium	x	x		x		x
Bulgaria	x	x		x		x
Croatia	x	x		x		x
Cyprus				x		
Czech Republic	x	x		x		x
Denmark	x	x	x*	x		x
Estonia		x		x		x
Finland	x	x		x		x
France	x	x		x		x
Germany	x	x		x		x
Greece	x	x		x		x
Hungary	x	x		x		x
Iceland				x		
Ireland	x	x	x*	x		x
Italy	x	x		x		x
Latvia				x		
Liechtenstein	x	x		x		x
Lithuania				x		
Luxembourg	x	x		x		x
Malta				x*		
Netherlands	x	x		x		x
Norway	x	x	x*	x		x
Poland	x	x		x		x
Portugal	x	x		x		x
Romania	x*	x*				x
Slovakia	x	x		x		x
Slovenia	x	x		x		x
Spain	x*	x		x		x
Sweden	x	x		x		x

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.

2. Doptelet received approval for primary chronic immune thrombocytopenia (ITP) in January 2021.

3. FMF – Familial Mediterranean Fever (FMF) indication approved in Europe 28 April 2020.

4. Adult patients with alkaptonuria (AKU) indication approved in Europe 22 October 2020.

Market availability of Sobi products, cont.

Region	Access to Sobi's products – *new in 2020					
	Alprolix ¹	Elocta ¹	Doptelet ²	Kineret	Gamifant	Orfadin
Europe – other	Haemophilia B	Haemophilia A	CLD	RA, CAPS		HT-1
Russia		x*		x	x (MAP ²)	x
Switzerland	x	x		x		x
Turkey				x*		
United Kingdom	x	x	x*	x		x (HT-1 & AKU*)
Ukraine						x
North America	Not Sobi territory	Not Sobi territory				HT-1
Canada				RA, NOMID x		x
Mexico			x			x
United States ³			CLD, ITP x	RA, NOMID x	pHLH x	x
Asia						HT-1
Bahrain	x			x		x
China	Not Sobi territory	Not Sobi territory	Out-licensed		submitted for approval	submitted for approval
Kuwait	x	x		x*	x*	
Israel	Not Sobi territory	Not Sobi territory		x + FMF*		x
Japan	Not Sobi territory	Not Sobi territory		x*		x
Jordan						x
Oman	x	x		x		
Palestine						x
Qatar	x	x		x		x
Saudi Arabia	x	x			x (MAP)	x
United Arab Emirates	x	x			x (MAP)	x (MAP)
Africa	Not Sobi territory	Not Sobi territory				HT-1
Algeria						x
Tunisia						x
South America	Not Sobi territory	Not Sobi territory				HT-1
Argentina						x
Chile						x
Australia	Not Sobi territory	Not Sobi territory		RA, CAPS, Still's x		x

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.

2. MAP - Managed access programme

3. In the US, Sobi also markets Synagis and Kepivance.

Global Reporting Initiative Index

Sobi's Sustainability Report 2020 is defined in the GRI Index below. Its main components are found in the following sections of the Annual and Sustainability Report 2020:

- Business Model is found on page 10.
- Description of sustainability approach is found on pages 108–121.
- Information on performance is reported in the Sustainability notes section, on pages 122–128.

This sustainability report has been prepared in accordance with the GRI Standards: Core option. It also fulfils the requirements on sustainability reporting in the Annual Accounts Act.

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 page 109. All page references below refer to pages in Sobi's 2020 Annual and Sustainability Report or at www.sobi.com.

Our sustainability report serves as our UN Global Compact Communication on Progress report.

For questions regarding the Annual and Sustainability Report, please contact info@sobi.com.

GRI Standard	Disclosure	Page reference	Comment	UN Global Compact Principle
GENERAL DISCLOSURES – 102				
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102-3	Location of headquarters	54, 97		
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102-7	Scale of the organisation, including total number of employees, operations, net sales, and capitalisation	26, 32, 34–37		
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102-12	External initiatives	7, 108, 116		
102-13	Membership of associations	www.sobi.com		
Strategy and analysis				
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102-41	Collective bargaining agreements	126		
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GRI Standard	Disclosure	Page reference	Comment	UN Global Compact Principle
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	102-52	Reporting cycle	97, 110	
	102-53	Contact point for questions regarding the report	www.sobi.com	
	102-54	Claims of reporting in accordance with the GRI Standards	39, 129	
	102-55	GRI content index	129–131	
	102-56	External assurance	132	
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	103-2	The management approach and its components	108–121	1, 2, 6, 7, 8, 9, 10
	103-3	Evaluation of the management approach	108–126	1, 2, 6, 7, 8, 9, 10
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GRI 203: Indirect economic impacts 2016				
	203-2	Significant indirect economic impacts	122	
GRI 205: Anti-corruption 2016				
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Auditor's report on the statutory sustainability statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321

Engagement and responsibility

It is the Board of Directors who is responsible for the statutory sustainability statement for the year 2020 on pages 23–27 and 108–131 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevR 12 The auditor's opinion regarding the statutory sustainability statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions

A statutory sustainability statement has been prepared.

Stockholm, March 26, 2021
Ernst & Young AB

Jonatan Hansson
Authorized Public Accountant



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