A **sustainable model** for **high-quality** patient care

Sobi's strong commitment to improving the quality of life of patients with rare diseases is at the heart of the company's operations.

Ideally all stakeholders should be engaged in ongoing dialogue around a medicinal product – legislators, paying agencies, clients and patients – in order to understand their different needs, from the first phases of development for a new drug candidate and onward through the product's entire life cycle. Creating an effective model for such dialogue is crucial to Sobi's ability to create sustainable solutions for shareholders, employees, the healthcare systems that pay for the products and, not least, the patients.

Sobi's materiality analysis

Sobi's materiality analysis is an important tool for prioritisations in the business strategy, communication and stakeholder dialogue. The three most important aspects are patient health and safety, access to healthcare and medicines, and engagement with patient organisations.

The materiality analysis is based on the aspects listed under the GRI (Global Reporting Initiative Index) Reporting Framework's requirements for

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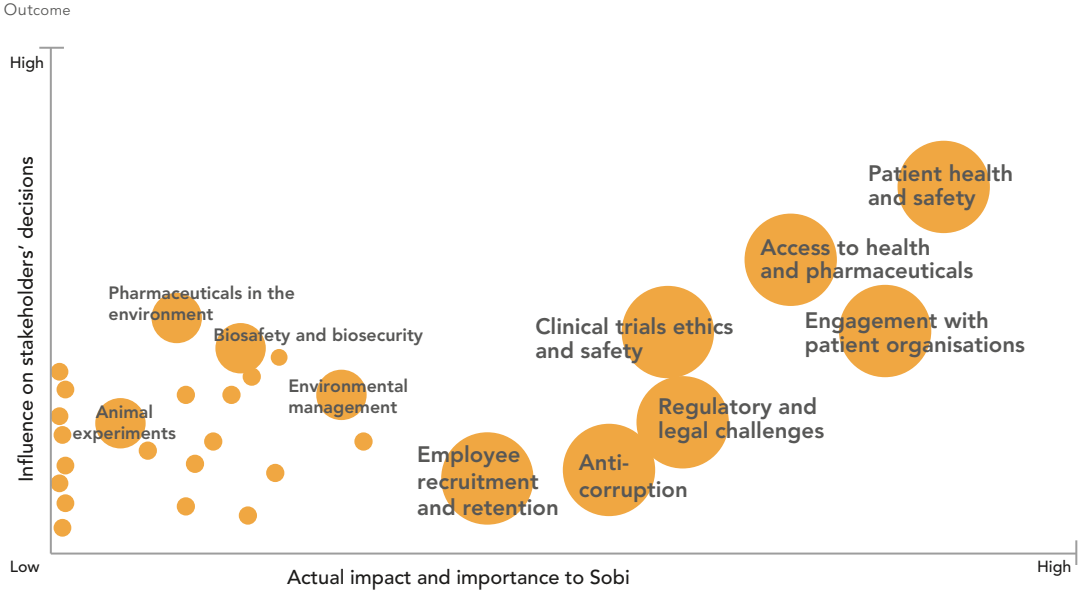
In addition to the material areas described on pages 42-45, Sobi works proactively with several other relevant aspects, including environmental activities.

There are also areas that are crucial for the pharmaceutical industry in general, but are currently of limited relevance to Sobi's operations:
- biosafety; and
- pharmaceuticals in the environment.

Information about these areas is available at **www.sobi.com/About-Sobi/Corporateresponsibility**

MATERIALITY ANALYSIS



The vertical axis shows the importance that stakeholders attach to various aspects relating to Sobi and the pharmaceutical industry.
The horisontal axis shows Sobi's own assessment in relation to the actual business strategy and operations.

engaging industry stakeholders, combined with Sobi's own analysis of issues raised by the media and other companies in the industry. Representatives of a number of strategic functions within Sobi evaluated the listed areas in which Sobi has real impact through its products, services and relationships, and where such impact arises within the operations. The process resulted in a number of relevant aspects that reflect Sobi's financial, environmental and social impact and/or that affect judgements and decisions made by key stakeholder groups.

In 2013, via a survey and targeted interviews, a broader group of internal and external stakeholders was invited to prioritise the relevant aspects and themes identified. The result was a map of the areas that are of material importance to Sobi's external stakeholders, and that are strategically important to Sobi as a company. By weighing the views of stakeholders, the company's strategy and risk profile, and the actual impact Sobi identified the most prioritised issues. The priorities remain unchanged for 2014.

Patient health and safety

Maintaining patient safety is Sobi's most important task. Products are evaluated by international and national regulators according to rigorous, established and harmonised standards before they are granted marketing authorisation. Sobi continuously examines, analyses and balances patient benefits and risks. This includes both marketed products and medicinal products under development.

In clinical applications, Sobi always adheres to the Declaration of Helsinki's ethical principles for medical research involving human subjects. Sobi's employees ensure compliance with both internal and external rules in all clinical studies in which Sobi is a sponsor, and the potential side effects of pharmaceuticals are identified in collaboration with physicians and patients. For the products marketed by Sobi, there is an effective system for collecting, processing and reporting adverse effects and other safety information to drug regulatory authorities in accordance with international laws and regulations. All employees are responsible for reporting product complaints and any side effects of Sobi's products of which they may be aware. Employees receive annual training in this area.

The reporting obligation is regulated in a Standard Operating Procedure (SOP), with which Sobi's employees agree to comply. Sobi regularly updates this SOP to reflect changes in legislation and best practice.

Access to healthcare and medicines

Sobi sees the need for an integrated approach to ensure that patients can access the innovative medicinal products developed by the company, and can achieve the best possible results from the treatment. As a result, the patient journey, from diagnosis and treatment to ongoing care and long-term results, is an important aspect in Sobi's prioritisations. The objective is to identify where the greatest value can be created for patients and their care providers, by reducing time to diagnosis, improving diagnostic precision, developing monitoring tools and understanding the barriers that must be overcome in order to achieve sustainable health outcomes.

By creating and maintaining a dialogue with various stakeholders, including government agencies, Sobi operates on the basis of a sustainable model for how medicinal products are delivered. This is called the Patient and Customer-Centric approach to Commercialisation (PC3).

Engagement with patient groups

Learning that a child has a serious or even life-threatening rare disease can be overwhelming for both the child and the child's family. Since these diseases are rare, knowledge about them may also be inadequate, even among health professionals. Sobi cooperates with a number of patient organisations and engages in active dialogue in order to understand their needs and develop a mutual understanding of how the specific rare disease manifests itself and is best treated. In 2014, Sobi received the European rare disease patient organisation, EURORDIS, Company Award for its contributions to patients with rare diseases, and the European Mediscience Award as a result of the company's ethical stance and social initiatives.

Although medical knowledge of rare diseases is generally increasing, it often differs between geographical areas, even when treatments are already available. Sobi works to facilitate the transfer of knowledge in healthcare and, in collaboration with expert medical groups, has developed several extensive training programmes for healthcare providers who treat patients with rare diseases. Several of these training programmes are now certified by public healthcare providers.

Regulatory and legal challenges

Sobi operates in a highly regulated environment and must adhere to laws and regulations in both research and marketing. There is a general trend today towards greater awareness of liability issues and legal risks and thus, also, increased transparency requirements. Companies are expected to record more information about legal processes and, in the pharmaceutical industry, the requirements for transparency in relation to clinical results have become much stricter. Sobi welcomes this transition and works continuously to maintain its own, and its business partners', standards of transparency.

A new regulatory environment has also developed around marketing authorisation and the pricing of medicines. Applications for marketing authorisation are now often conducted in a step-by-step process, which can result in conditional approvals that must be followed up and continually evaluated. Medicines are priced according to new and more complex models. This is creating challenges for the entire pharmaceutical industry, but Sobi's approach is well-suited to navigating and meeting the requirements in this new environment.

TRADE COMPLIANCE

Compliance with trade laws and regulations is an important matter to Sobi. Both new and current markets are constantly evaluated and the organisation is trained to be aware of related risks and "red flags". The order management team have routines and processes to ship the correct product to the correct market. The process also includes restricted party screening and orders to sanctioned countries cannot be shipped without a proper approval.

Ethical issues and safety in clinical studies

All clinical studies sponsored by Sobi are conducted and reported in accordance with applicable laws and the international standard, Good Clinical Practice (GCP). Before a clinical study commences, it is subject to an internal approval process, as well as review and approval by regulatory authorities and independent ethics committees. Sobi strives to maintain the highest ethical, technical and scientific standards in all clinical research conducted.

Most of Sobi's clinical studies are conducted by contract research companies, in collaboration with physicians and patients. Sobi's outsourcing process is governed by internal Standard Operating Procedures (SOPs). Ultimate responsibility for the strategy, quality and integrity, including implementation and maintenance of quality control systems, and the reporting of a study, always lies with Sobi as a sponsor. Sobi publishes information on www.clinicaltrials.gov regarding the clinical studies that it sponsors. In 2014, there were no breaches of the legislation or standards aimed at protecting the health and safety of people taking part in clinical studies.

Anti-corruption

Sobi's Code of Conduct addresses corruption and bribery. Risk analyses are conducted in every country in which Sobi operates, and issues including bribery legislation and business ethics are reviewed. To raise employee awareness of the rules that apply in the countries where they work, various countries are ranked in regard to transparency. In the compliance area, guidelines have been issued for healthcare and training has been carried out to establish an ethical business standard for transparent sales and non-sales activities, and regarding relationships with the medical profession, care providers, payers and patient organisations. In 2014, work was focussed on preparations for the anticipated launch of haemophilia products.

Recruitment and retention

Sobi is a knowledge-intensive company. Employees are expected to meet high expectations, which is essential for building an innovative and high-performing corporate culture and thereby create value for various stakeholders. Work with recruitment, integration, leadership and process management has been particularly important in 2014 in conjunction with efforts to strengthen the organisation in preparation for the anticipated launch of haemophilia products planned for the end of 2015.

Sobi strives to create a performance-based culture, based on individual accountability, thereby helping the company to address our competitive market and to achieve ambitious objectives. A critical factor in this work is to set and continuously monitor individual goals that are linked to the strategic business objectives. At Sobi, employees and managers work together to define new goals every year, and they are monitored at specific times during the year. Individual employees are appraised not only on their degree of goal achievement, but how their goals are achieved. It is vital that Sobi's values are observed.

Competitive terms of employment are a prerequisite for recruiting and retaining high-calibre employees. Sobi endeavours to offer competitive salaries and benefits. These are determined individually and adapted to the local labour market. For every employee to understand how their own work contributes to the company's mission, Sobi has a strong corporate culture with common goals and transparent communication. Efforts to strengthen the corporate culture are particularly important in the transition that Sobi is currently undergoing in building the enforced haemophilia business.

Providing continuous professional development for all employees is crucial for the development of the product portfolio, and being able to launch and sell our products successfully. A large proportion of Sobi's training courses are web-based and individual.

Of the total number of employees in 2014, 43 per cent were men and 57 per cent were women. The corresponding figures for the Executive Leadership and Board of Directors were 67/33 per cent and 62/38 per cent, respectively (excluding employee representatives). All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Supply chain

Sobi sells and markets a wide range of products, 50 products to 67 countries, many of which are small volumes to a limited number of patients. Since biologics are sensitive and often require cold chain to ensure product integrity and quality, having full control of the entire supply chain is vital – from manufacturing to when the product reaches the patient. Sobi interprets sales patterns and prepares long-term forecasts for each product in order to place timely orders with the manufacturers. The single most important responsibility is to ensure that patients never risk being without their medication, which could be life-threatening. Sobi has therefore built up a robust supply chain. In Europe, when pharmacies and clinics order products, these orders are normally managed by Sobi's logistics partners who perform customer service and ship the products within 24 hours from a local warehouse. In the US, home delivery is an important part of the patient support programmes and is increasingly provided by Sobi through dedicated partners. All local warehouses are, in turn, continuously refilled according to sales forecasts, with products from Sobi's central warehouse in Nijmegen in the Netherlands. Supplies of medications to hospitals or pharmacies in ex-EU/ex-US markets often require substantial trade compliance controls, document preparations and transport monitoring, and are managed through Sobi's central supply chain team and shipped out of Sobi's central warehouse. Sobi's 24/7/365 Emergency Service will then use all the resources it has at its disposal to supply the product as soon as possible to the hospital.

Procurement

Sobi purchases materials, goods and services from more than 1,000 suppliers. Establishing good relationships with these suppliers promotes sustainability and responsibility within the business. Sobi strives to apply consistent rules to all suppliers based on the Sobi Code of Conduct. Sobi's purchasing is mainly conducted in two categories: products governed by international and national regulatory requirements and standards, and products of a general nature for all companies regardless of industry. Purchases in the first category are made after careful evaluation according to Sobi's own governing documents and procedures, followed by continuous assessments. In the second category, Sobi procures goods at the best terms and balances price and quality, with consideration for the relevant industry's standards of responsibility. Sobi's suppliers are primarily based in Europe and the US.

"The so called transparency initiative has been in place in the pharmacertificat industry in France for about a year. For those of us in the field, it has had a major impact on our day-to-day work. Sobi France has established a system that manages and collects data and automatically transfers this to the authorities on a daily basis. It ensures that we maintain complete traceability of payments and expenses to external stakeholders. One of the positive effects of this transparency is the high level of trust we experience in customer meetings, enabling us to engage in an open and equal dialogue."

Alexandra Pruvot
Medical Science Manager, France