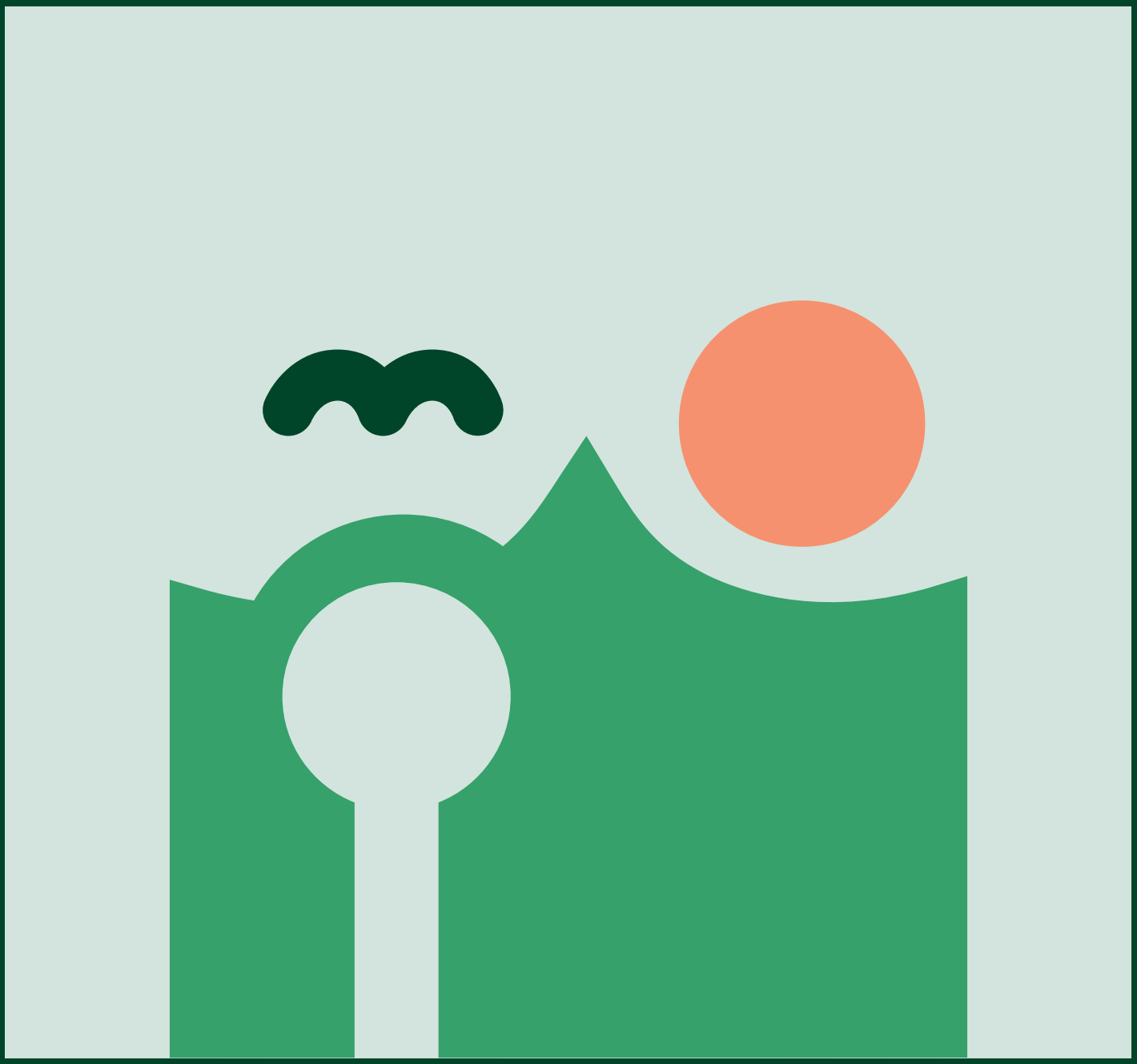

May 2022

Sustainable health – a central feature of the 2030 Agenda

Lif's sustainability strategy

The research-based pharmaceutical industry

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Lif's sustainability manifesto

Our manifesto is intended to help make the Life Science sector a leading player in society's transition to long-term sustainability. The nine commitments, which reflect key elements of the 2030 Agenda and the Sustainable Development Goals for the sector, cover the entire pharmaceutical value chain from research and development through manufacturing to marketing and use, and focus on both the individual patient and society as a whole. The commitments apply to Lif and its member companies, all of which are Swedish legal entities with operations that directly or indirectly also reach beyond Sweden's borders. We will be open and transparent in our efforts to deliver on the manifesto commitments.

Each member company's own sustainability plan should reflect the manifesto, and member companies undertake to collaborate and support Lif and each other in continuously developing and monitoring Lif's sustainability strategy and manifesto and the companies' own plans.

Ethics and transparency	Good health and access to medicines	Reduced environmental impact
We aim to achieve as much collaboration, transparency and openness as possible throughout the pharmaceutical value chain	We aim to achieve good availability of and access to medicines, and push for patients to have the possibility of optimum treatment and equal right to pharmaceutical treatment and care	We are part of the transition to a circular economy
We act to foster trust and with respect in all interactions, and manage and develop an ethical approach in the research-based pharmaceutical industry	We fight the threat of antibiotic resistance	We aim to achieve a fossil-free pharmaceutical industry
Our member companies are good employers	We are a reliable partner in building improved resilience in society, both in normal times and during crises, pandemics and disasters	We aim to achieve reduced discharge of pharmaceutical residues into water.

Ethics and transparency

- **We aim to achieve as much collaboration, transparency and openness as possible throughout the pharmaceutical value chain**

  By increasing their collaboration with suppliers and customers, member companies create opportunities for all actors in the pharmaceutical chain to contribute to achieving the manifesto commitments in their work on sustainable development.

- **We act to foster trust and with respect in all interactions, and manage and develop an ethical approach in the research-based pharmaceutical industry**

  In interactions with other stakeholders and in communications and marketing, we act with high integrity and transparency. The patient's best interests must be our focus, and everything must rest on a solid scientific foundation. Interactions must be characterised by a high level of trust and respect for the independence of the partner.

  The pharmaceutical industry's ethical approach must be managed and developed – both now and in the future, we must be a model for other industries in Sweden and for the international pharmaceutical industry.

- **Our member companies are good employers**

  All member companies must offer good working conditions. Employees must be free to voice their opinions, and there must be whistle-blower protection features. Diversity and inclusion are self-evident elements of the sustainability plans. Through due diligence, this responsibility also extends backwards in the supply chains whenever possible.

Good health and access to medicines

- **We aim to achieve good availability of and access to medicines, and push for patients to have the possibility of optimum treatment and equal right to pharmaceutical treatment and care**

  We work for the best interests of patients and good access to and guaranteed availability of medicines as fundamental prerequisites for long-term sustainable healthcare. We are committed to promoting the equal rights of all patients to pharmaceutical treatment an care, and to ensuring that patients are involved in decisions about their own medical treatment, at both group and individual levels.

  We also work to increase access to precision medicine and the use of health data, which improves patients' opportunities of receiving best possible care and treatment.

  A long-term sustainable innovation climate requires financial sustainability for pharmaceutical companies, which account for the bulk of the pharmaceutical sector's research and development.

  Clinical trials are of great benefit to patient care, the development of healthcare and the entire Swedish Life Science sector. We will work to increase the number of trials in Sweden in accordance with the Government's Life Science Strategy and Lif's action plan for more company-initiated clinical trials.

- **We fight the threat of antibiotic resistance**

  Access to effective antibiotics is a prerequisite for effective healthcare. We work according to the Lif AMR Action Plan to combat the development of antibiotic resistance throughout the product value chain.

- **We are a reliable partner in building improved resilience in society, both in normal times and during crises, pandemics and disasters**

  We are a knowledgeable, reliable partner to all the different stakeholders in healthcare. We are helping increase resilience throughout the care chain. This applies not only to normal situations, but also to crises, pandemics and disasters, where we are generous with our knowledge and experience and commit resources for the benefit of society.

Reduced environmental impact

- **We are part of the transition to a circular economy**

  Resource consumption must be reduced throughout the life cycle of products. We will create opportunities for increased efficiency, reuse and recycling of resources.

  We will contribute to reducing the volume of unused medicines. This will be done by striving for better adherence to prescriptions and more pharmaceutical reviews, and by combating misuse, over-prescription and abuse of medicines.

  We will continue our active work to encourage consumers to return unused medicines to pharmacies for controlled, safe disposal.

- **We aim to achieve a fossil-free pharmaceutical industry**

  Based on Lif's forthcoming roadmap, comprising scopes 1, 2 and 3, for a fossil-free pharmaceutical industry, we will work to achieve Swedish and EU climate targets. In doing so, we will contribute to the Paris Agreement's long-term target of limiting the increase in global average temperature to 1.5°C if possible.

- **We aim to reduce the discharge of pharmaceutical residues into water**

  In all parts of the product life cycle, we will work for the safe discharge of pharmaceutical residues into wastewater.

  We will work hard within the industry to eliminate unacceptable discharges, based on accepted, regulatory measurement and monitoring methods, from the production of medicines and provide our expertise in other parts of the life cycle. In this work, we will also assess the impact of the sector on biodiversity and take appropriate action.

The way forward to achieve the manifesto commitments and report on our progress transparently

To meet the commitments of our Sustainability Manifesto – and thereby meet the challenges of sustainable development while seizing the opportunities of this societal transformation – Lif, the research-based pharmaceutical industry, outlines here the background to the work of the research-based pharmaceutical industry and how it contributes to making the Life Science sector a leading player in the transition to a long-term sustainable society.

Lif is the trade association for the research-based pharmaceutical industry in Sweden and has about 90 members. We work to ensure high quality care and access to new treatments by

strengthening the Swedish Life Science sector in collaboration with healthcare stakeholders, politicians, civil servants and patient representatives. As a trade association, Lif represents a large number of companies in the Swedish pharmaceutical industry on issues of shared interest.

Good access to pharmaceutical treatment and vaccines and effective healthcare saves millions of lives around the world every year and creates the conditions for good health and well-being throughout life. We are proud of this direct industry contribution to building sustainable health and global sustainable development. Lif sees great opportunities for the Swedish part of the pharmaceutical industry to be an international influencer and a driving force in the sector globally. For many reasons, both the Swedish public sector and Swedish business have a strong international position in terms of sustainability.

The pharmaceutical industry strives to be transparent in all aspects of sustainability –environmental, social and financial. We are open to collaboration and dialogue on how the industry can make the greatest possible contribution to achieving society's goals of good health and long-term sustainable economic growth, while minimising the negative impact on the environment.

The sustainability strategy is Lif's guiding document for the industry's work towards sustainable development nationally and internationally. The sector's contribution must be based on scientific evidence and continuous progress. Our hope is that the sustainability strategy will accelerate society's transformation by setting out a way forward based on collaboration and exchange of knowledge. Furthermore, we hope to demonstrate the importance of research-based pharmaceutical companies – and the entire Life Science sector – in helping Sweden and the world achieve sustainable development.

Lif's member companies must have their own sustainability plans that reflect the ambitions of the strategy and the commitments of the manifesto. To ensure that the whole industry moves in a sustainable direction and thereby collectively contributes to the transformation of the Life Science sector and society as a whole, Lif will develop a model in which member companies undertake to collaborate and support Lif and each other in continuously developing and monitoring the sustainability strategy, the manifesto and the companies' own plans. Resources and sustainability expertise differ between companies today but the ambition is that this model, combined with training initiatives from the Lif Sustainable Development Working Group, will ensure that no member company is left on its own. It is only together that we can make a real difference.

Clear milestones and metrics for manifesto commitments need to be developed. We intend to report on them and on how the industry's performance against the metrics is evolving at the Lif Sustain-

ability Conference in November each year. Several of the commitments require the development of specific action plans, such as the Lif roadmap for a fossil free pharmaceutical industry.

We welcome ongoing comments and input on the sustainability strategy and manifesto from our stakeholders, both within and outside our sector. Both documents will be continuously developed. We are convinced that deeper collaboration and a better understanding of other stakeholders' perspectives will increase our ability to work on sustainability issues of real benefit to the transformation of society.

The importance of sustainable development

The UN has designated the years 2020–2030 as The Decade of Action and identifies the main challenges as poverty, inequality, climate change, environmental degradation, biodiversity loss and threats to peace and justice. If they are not addressed, there is a risk that the needs of future generations cannot be met. Therefore, all countries, civil society and businesses need to work actively towards sustainable development that leads to sustainable societies in the long run. Societies in which everyone can realise and demand their human rights while operating in a way that is consistent with what the planet requires within the planetary boundaries.

Sustainable development is complex. Many aspects are involved and influence each other. There is a need to highlight global challenges from a systemic perspective and address conflicting objectives.

Sustainable development

Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs. The concept is based on a holistic approach to the needs, conditions and problems of people and societies. The guiding principle is that economic, social and environmental conditions and processes are integrated. They are essential to each other and support each other.

SOU 2004:104 – p.4

A systemic perspective is important when a specific action to address a problem risk having a negative impact on another. As the challenges are global, individual countries cannot resolve the issues on their own. Collaboration and unity are essential. The premises of transition also differ between societies, and a solution for one country or company is not always the right one for another. To complicate matters further, the time aspects of the challenges may be different, requiring prioritisation between the actions to be taken.

Lif is convinced that transforming today's societies to achieve long-term sustainability is feasible. It will require a great deal of innovation, investment and structural change. However, the transformation is absolutely necessary.

Work on the global challenges needs to be stepped up through increased ambition and continuous progress from all societal actors. And we at Lif are ready to contribute what we can. As part of this, the discussion on societal transformation needs to shift focus from the short-term costs to how the investments and structural changes made can create the greatest value.

The sustainability priorities of the research-based pharmaceutical industry

Specific areas of action are important to address global challenges and contribute to sustainable development. The UN 2030 Agenda and the Sustainable Development Goals (SDGs) play a central role in this, with their 17 overarching goals and 169 targets. They describe how the work on the transformation of society will proceed and how it can be monitored. The timetable and goals are ambitious but necessary for the transformation. Several of the goals require long-term work and a functioning innovation climate.

The SDGs are the guiding principles of sustainable development. However, to ensure the best possible contribution from the pharmaceutical sector, Lif believes that priorities need to be set according to the specific mission, opportunities and challenges of our sector. This shows which SDGs we consider to be most material. With the later parts of the strategy –the account of the factors affecting the opportunities and challenges of the sector and subsequently the definitions of sustainability – this clarifies how the research-based pharmaceutical companies contribute to the transformation of society to long-term sustainability. The prioritisation is illustrated by Lif's sustainability pyramid. We also describe the manifesto commitments to which each SDG can be linked.

SDG 3 – good health and well-being – is the overall aim of research-based pharmaceutical companies. The industry's core business is to develop, manufacture and supply medicines for the benefit of patients, healthcare and society at large. Working for sustainable health, based on Goal 3, is therefore the most material SDG.

Commitments reflected in SDG 3: 3, 4, 5, 6, 7, 8, 9.

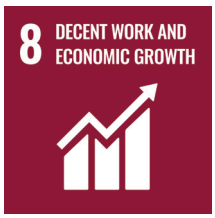
The SDGs in the second row of the pyramid are linked to the industry as a manufacturing industry and its potential to contribute to what is often referred to as the green transition.

SDG 9 – industry, innovation and infrastructure – has several links to the industry's mission to research and develop new medicines and bring them into production so that patients and consumers have access to innovations that contribute to better, long-term sustainable health.

SDG 12 – responsible consumption and production – clarifies the link between the industry's production of medicines and vaccines and their consumption. In addition to making production as sustainable as possible, it is essential that both positive and negative impacts of products are evaluated from a life cycle perspective: production, consumption and waste management.

Commitments reflected in SDG 9: 1, 2, 3, 4, 5, 6, 7, 8, 9.

Commitments reflected in SDG 12: 1, 2, 3, 4, 5, 6, 7, 8, 9.



In the **third row of the sustainability pyramid**, we turn to SDGs of a more fundamental nature that are central to the achievement of goals 3, 9 and 12.

SDG 8 – decent work and economic growth – is important in several respects. Pharmaceutical companies must be responsible employers, offering safe, secure workplaces in which all individuals have the opportunity to be themselves and develop. Without sustainable workplaces and employees, it is not possible to be a sustainable industry.

The companies also contribute to economic growth, which has historically contributed to a sharp rise in living standards and life expectancy and can help reduce poverty and inequality. However, economic growth has also resulted in negative impacts on the environment, such as biodiversity loss. For commercial operators, it is important to find a balance between profit and possible negative consequences.

SDG 16 – peace, justice and strong institutions – is a prerequisite for long-term sustainable development. Peace, justice, stable societies and institutions create greater security and long-term rules of conduct, which are of great importance to individuals and businesses alike.

The climate change we are seeing today not only risks changing the conditions for life on our planet. It may also contribute to the spread of disease and have a negative impact on human well-being and health. SDG 13 – climate action – is therefore another pillar of sustainable production, consumption and ultimately sustainable health.

Access to clean water is fundamental to human survival, and good hygiene and sanitation are central to disease prevention. Therefore, if we do not achieve SDG 6 – clean water and sanitation – it will be impossible to contribute to human well-being and health.

Commitments reflected in SDG 8: 1, 3, 4, 5, 7, 8.

Commitments reflected in SDG 16: 1, 2, 3, 4, 6, 8.

Commitments reflected in SDG 13: 7, 8.

Commitments reflected in SDG 6: 6, 9.

The fourth row of the pyramid, like the third, is fundamental in nature and supports the goals higher up. All of these goals must be at the heart of the activities of research-based pharmaceutical companies.

For SDG 4 – quality education –, 5 – gender equality –, and 10 – reduced inequalities – it is important that companies work both internally and externally on societal transformation. Today, the degree of compliance with the goals varies greatly depending on where in the world an organisation operates, but even in Sweden, which is generally doing well, it is important for the work to continue and not be de-prioritised. Unless these goals are clearly reflected in the way companies operate, they will struggle to be responsible employers and contribute to peaceful, inclusive societies.

SDG 7 – affordable and clean energy –, 14 – life below water – and 15 – life on land –, are important in the fight against climate change and a prerequisite for clean water and good sanitation. The negative impacts of ecosystem degradation and biodiversity loss are currently difficult to assess and evaluate. The pharmaceutical industry's contribution to this is therefore not clearly described.

Commitments reflected in SDG 5: 1, 3, 4.

Commitments reflected in SDG 10: 1, 3, 4, 6.

Commitments reflected in SDG 4: 1, 3, 4, 6.

Commitments reflected in SDG 7: 6, 7, 8.

Commitments reflected in SDG 14: 7, 8, 9.

Commitments reflected in SDG 15: 7 ,8, 9.

At the bottom of the pyramid is SDG 17 – partnerships for the goals –. Global partnership and collaboration will enable the other SDGs in the pyramid to be achieved. There needs to be collaboration between companies, both those competing in the same sector and across sectors, and between companies, academia, civil society and countries. Unless Goal 17 is at the heart of the entire pyramid, there is a risk of the transition being thwarted and inequality increasing.

Commitments reflected in SDG 7: 1, 2, 3, 4, 5, 6, 7, 8, 9.

Guiding principles

Lif has identified five concepts of particular importance for the industry's continued work on sustainable development. They are linked in various ways to the SDGs and can be seen as important principles for the implementation of the strategy: *science-based approaches, transparency and openness, circularity, resilience and carbon-zero*.

Science-based approaches are essential for all activities in the pharmaceutical and the healthcare sector. The priorities that need to be set are based on scientific evidence. The availability of robust data to measure and evaluate interventions is an important part of this.

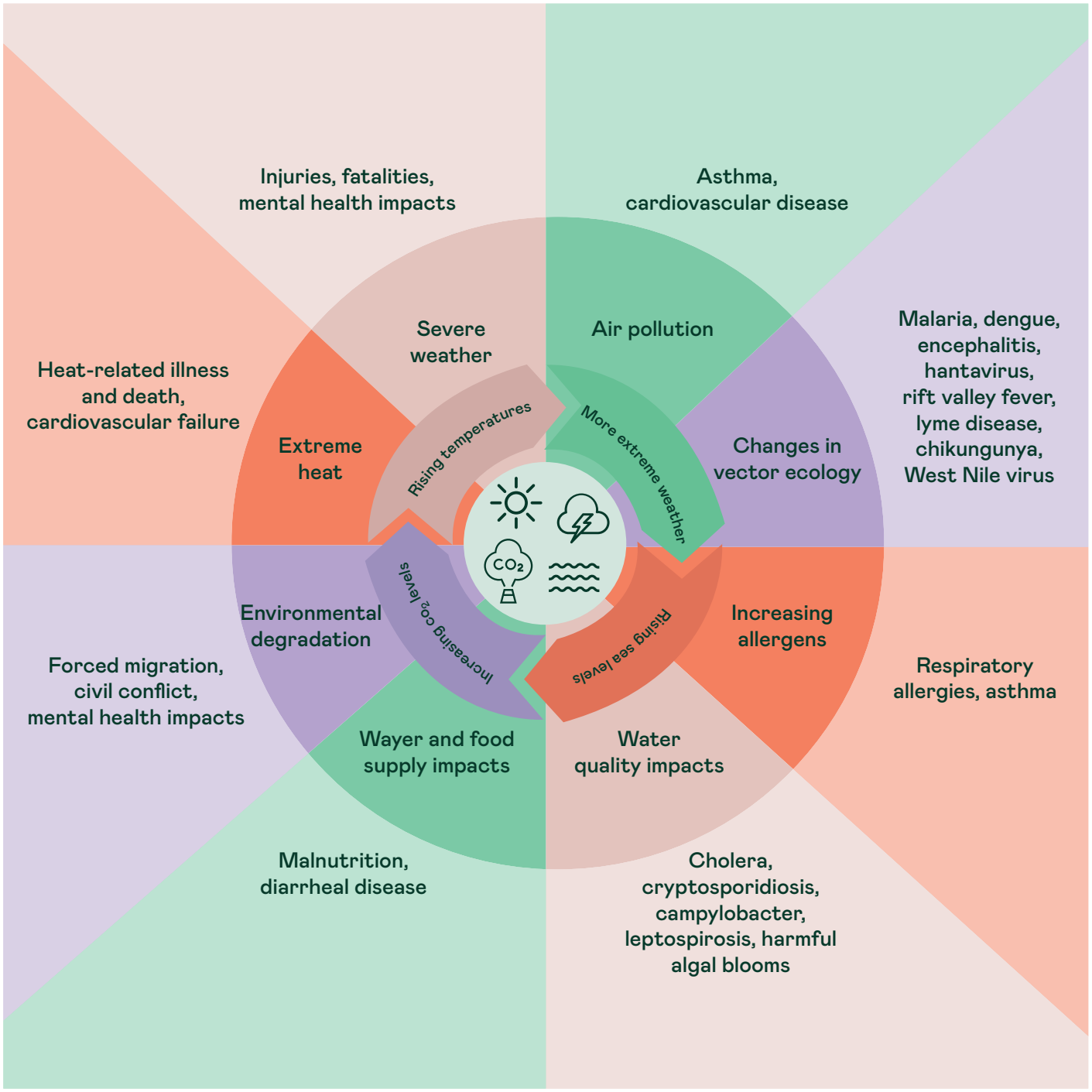
Lif believes that *transparency and openness* should be a guiding principle in all work with sustainable development. Monitoring and review are fundamental to continuous improvement. By actively working towards greater transparency and openness, we hope to contribute to a climate of discussion on sustainability issues in which the industry can share knowledge and insights internally and with other stakeholders to find solutions that contribute to society's transformation.

Circularity is key, as the earth's resources are limited, and ecosystems cannot cope with current consumption patterns. The concept means striving to minimise the volume of raw materials and resources consumed and to recycle or reuse them as much as possible. Lif believes that new methods and processes need to be developed to ensure that the earth's resources are used efficiently. The industry's work on "green chemistry" and "green production" are important contributions to this work.

Resilience refers to a system's ability to resist and cope with change, recover and evolve. We can expect crises and disasters like the COVID-19 pandemic and the consequences of climate change to shape the society of the future. The pharmaceutical industry and other essential actors have gained many lessons during the pandemic that will be valuable in future crises.

In our sustainable development work, we need to design and build resilience into society to cope with large and small changes. Improved resilience is achieved, among other things, through good public health, of which effective healthcare with good access to optimum pharmaceutical treatment is a foundation. And it is important that, even in crises, pandemics and disasters, various actors are generous with their knowledge and experience and commit resources for the benefit of society.

Carbon-zero (or carbon neutrality) means that the world must stop using fossil fuels that contribute to global warming. Climate change is increasing the risk of extreme weather and natural disasters, affecting society's ability to achieve sustainable health. Closely linked to the use of fossil fuels is the choice of materials in products, devices and packaging.



Carbon-zero is central to sustainable development work. Tackling global warming and climate change must be a priority to ensure that future generations can meet their needs. Lif's roadmap for a fossil-free pharmaceutical industry is a contribution from the Life Science sector. One of numerous key initiatives underpinning the roadmap is the Decarbonising the Pharmaceutical Value Chain programme presented by several leading pharmaceutical companies at the COP 26 climate conference in autumn 2021. It will reduce the industry's climate impact by accelerating the use of renewable energy and reducing greenhouse gas emissions in the global value chain. The programme called Energize will help actors in the pharmaceutical supply chain procure renewable energy and thus reduce their carbon emissions.

Sustainable development and the Swedish Life Science sector

Sweden has been actively working on sustainability challenges for a long time, nationally and internationally. Social reforms, freedom of expression and strong environmental legislation are examples of areas in which Sweden has been a pioneering country. Work on sustainable development has therefore been high on the Swedish agenda and has been further intensified as the issue has gained increasing prominence in social debate, including through initiatives such as the UN 2030 Agenda. In addition, the Government has the ambition for Sweden to become the world's first fossil-free welfare state by 2045. This objective addresses how climate change can be mitigated, and this work creates opportunities for growth in new green industries and social value in both the short and long terms.

In addition to a prominent position in sustainable development work, Sweden has long been a prominent knowledge nation. Research and innovation, not least in the Life Science

sector, have been important for our economic prosperity and welfare state. Work on the transformation of society will require innovation, new thinking and technology to make the transition to more sustainable solutions. Knowledge and education are therefore essential to progress towards sustainable development. Within this framework, it is important to provide the conditions for the creation of new knowledge and to draw on valuable experience from previous work.

What is the Life Science sector?

The Life Science sector includes companies, universities and higher education institutions, and public actors at municipal, regional and national level which contribute to the promotion of human health through their activities. The sector includes research, higher education and innovation, development of medicines, medical devices and treatments, prevention, implementation and monitoring.

The Swedish Life Science Strategy

Despite its small population, Sweden is important for the research-based pharmaceutical industry. In addition to a very vibrant pharmaceutical industry, the country's second largest export industry, we also have well-developed healthcare, internationally renowned public authorities in the sector, strong academic institutions and effective collaboration between the different actors. Lif's members, which are usually Swedish subsidiaries of multinational companies, have a relatively strong position within their respective groups, enabling dissemination worldwide of initiatives taken here in Sweden.

The favourable conditions for the Life Science sector and the pharmaceutical industry in Sweden, combined with the rapid development of pharmaceuticals in recent decades, have contributed to the fact that patients who previously could not be offered any treatment can now receive it with good results. Through research and development, this positive trend can continue and more people can have access to new treatments that contribute to sustainable health – for the Life Science sector, today's research is tomorrow's healthcare. A long-term sustainable innovation climate is

therefore essential and requires financial sustainability for pharmaceutical companies, which account for the bulk of the sector's research and development.

A continued strong Life Science sector requires that Sweden is attractive from a business perspective and attracts investment that contributes both to long-term sustainable economic growth and people's opportunities for sustainable health. Focus areas for a viable sector are precision medicine, ATMPs, clinical trials, digitisation and health data, as well as the Life Science Strategy and the National Pharmaceutical Strategy.

Precision medicine and advanced therapies

Precision medicine is usually described as 'the right treatment for the right patient at the right time'. The rapid development of medical research has made precision medicine possible, which in practice means both modernising healthcare and integrating research and innovation more closely into it. Precision medicine increases precision in all aspects of healthcare, from diagnosis to follow-up. In the long term, it is expected to be at the heart of all levels from primary care to university healthcare. Precision medicine is creating the conditions to increasingly tailor treatment, either at individual level or for broader groups, through the implementation of patient segmentation using, for example, biomarkers. In terms of disease prevention, precision medicine increases the chances of early identification and thus prevention or mitigation of disease. This means better opportunities for prevention, both primary and secondary, including through screening programmes and pre-symptomatic diagnosis. These are all essential building blocks for sustainable health.

Advanced Therapy Medicinal Products (ATMPs) are part of the precision medicine system and are based on cells, tissue or genes. At present, there are few approved ATMPs in Sweden and they are given to limited patient groups. In the longer term, it is expected that ATMPs will also be developed for broader patient segments in both oncology and complex diseases, such as autoimmune diseases like type I diabetes. In many cases, the development of an ATMP may also run parallel to the development of specific methods for both diagnosis and treatment follow-up using biomarker monitoring.

For sustainable healthcare, the implementation of precision medicine is important to ensure that diagnosis and treatment are carried out with the greatest possible efficiency and precision. Pharmaceutical developments will continue to make a decisive contribution to increased well-being and health in the population.

Clinical trials

Clinical trials are the research carried out on individuals and patients before a new medicine is approved and can be used. They are a major part of drug development. The results of trials are necessary to demonstrate medical efficacy and safety and are an important part of the documentation required for a medicine to be authorised for use in healthcare. Clinical trials give patients the chance to gain early access to new medicines and treatments, while increasing knowledge in the healthcare sector. They should be seen as an integral part of healthcare, especially in cases in which there is no previous treatment. Integrating research and innovation is a prerequisite for safe, modern healthcare that also provides staff with opportunities for skills development and job variety.

Digitisation and health data

Digitisation has fundamentally changed our societies in a very short time, opening up new opportunities in healthcare and also in research and innovation. As digitisation accelerates exponentially and we become better at harnessing it, we are generating more and more data. In healthcare, the term health data is used to describe the data generated in the treatment of patients and found in health information systems, quality registers and health registries. In Sweden, there is a long tradition of collecting data in national and regional quality registers that contain personal data on diagnosis, treatment and outcomes. Developments in healthcare and the potential for new medicines require the ability to generate high quality health data in a structured way, but most importantly there must be good conditions for making the data available and using it. As the volume of health data increases, ensuring the privacy of the individual and a high level of security in its processing will become increasingly important for all stakeholders. Health data is sensitive personal data about, among other things, medical conditions, which places high demands on the correct, secure processing of the data.

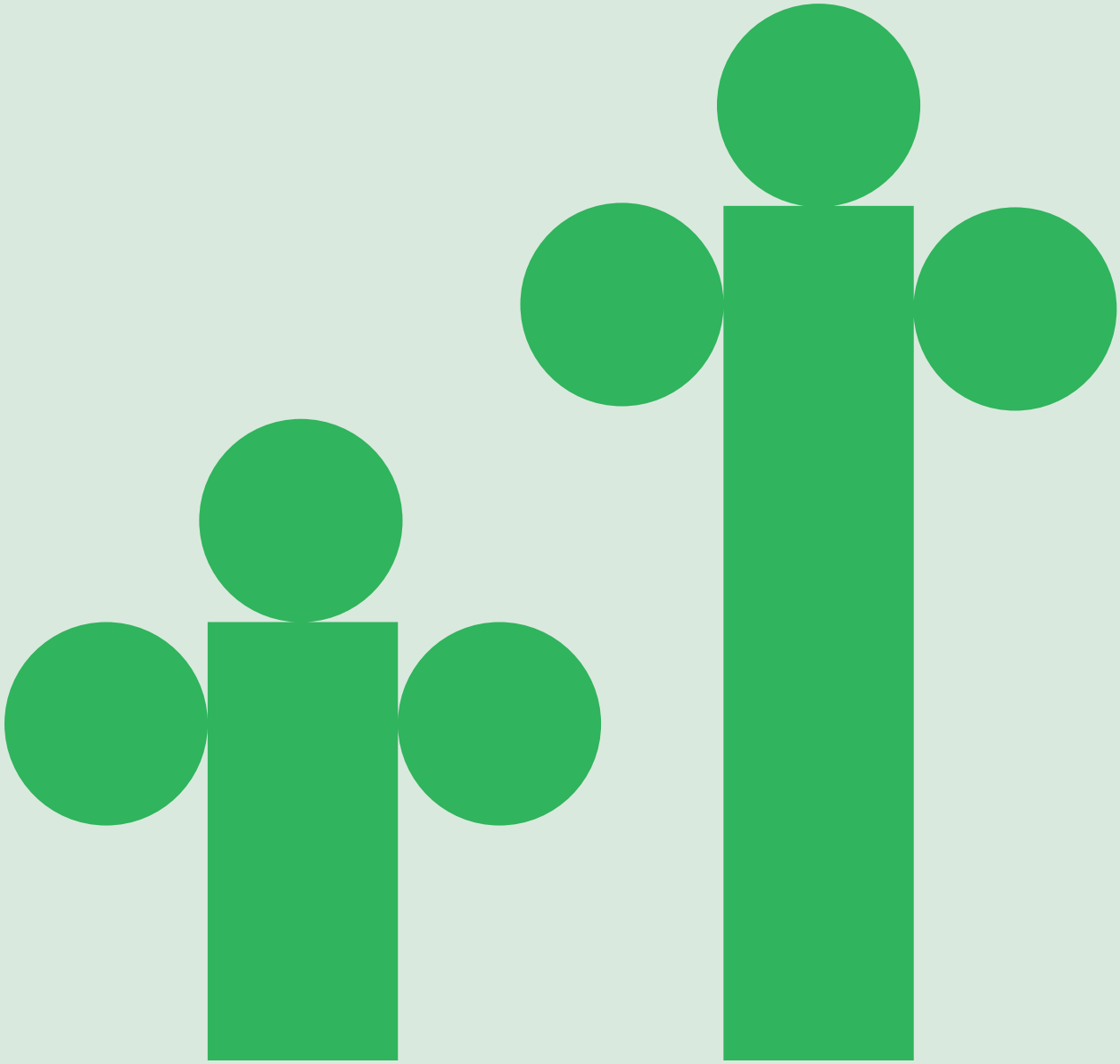
The Life Science Strategy and the National Pharmaceutical Strategy

Given Sweden's history as a leading nation in Llife Sciences and pharmaceuticals, there has been the political will to maintain this position. One initiative is the National Strategy for Life Science, presented in 2019. It identifies thirty objectives in eight priority areas that are deemed particularly important for Sweden to achieve its goal of being a leading Life Science nation. The strategy highlights the sector's potential to contribute to the long-term development efforts for improved health, encompassing social, economic and ecological sustainability. It also emphasises that, from a long-term perspective, health and well-being require a green transition. The UN 2030 Agenda will guide the transformation. The national Life Science Strategy is an important part of the pharmaceutical industry's efforts to make the Life Science sector a leading actor in the transformation of society. Lif believes it is essential that the strategy is continuously updated and clarifies the Government's ambitions in this area.

Another national strategy of importance for the pharmaceutical sector's transition to long-term sustainability is the National Pharmaceutical Strategy. The National Pharmaceutical Strategy is a platform for tackling pharmaceutical challenges that require broad national collaboration. Some 20 public authorities and organisations, including Lif, are involved in the work. Under the umbrella of a vision of the right use of medicines for the benefit of patients and society, the focus is on patient safety, equal right to pharmaceutical treatment and care along with sustainability. Examples of National Pharmaceutical Strategy activities that address sustainable development in different ways are

- improving pharmaceutical information
- preventing prescription forgery and inappropriate prescription of medicines
- developing models that ensure the availability and responsible use of both new and old antibiotics of particular value
- promoting environmental considerations in the production and use of medicines.

In conclusion, the Life Sciences and pharmaceutical sectors are very well placed to become leading actors in the transformation of society. With their activities and expertise, human health and well-being is the area in which the sectors' contributions add most value. The main societal mission of the Life Science sector is therefore to create sustainable health.



The pharmaceutical industry's work on sustainable development

The task of the research-based pharmaceutical industry is to develop, manufacture and supply medicines for the benefit of patients, healthcare and society at large. Through these activities, the pharmaceutical industry, with other sub-sectors of the Life Science sector, contributes to human health and well-being.

To understand how the pharmaceutical industry works, the following chapters describe the industry from Swedish and international perspectives. The descriptions also include the opportunities and challenges for pharmaceutical companies and Lif in working on sustainable development.

Pharmaceutical companies face different sustainability challenges

There are major differences between companies in the pharmaceutical sector. From a sustainability perspective, this means that sustainability challenges vary according to the structure of a company and its product portfolio. Pharmaceuticals and vaccines belong to a category in which there is huge variation. These may be products that were researched decades ago and are used to treat widespread diseases. Many of them consist of chemically synthesised small molecules. However, medicines may also be newly developed products for rare diseases and advanced therapies, and this necessitates special handling and training of healthcare professionals for them to be administered to patients. Many of these are biological products, sometimes called large molecules.

Some companies provide a large number of products in different therapeutic areas, while others have fewer products focusing on one therapeutic area. For a company with many off-patent generic products, it may be difficult to invest in new manufacturing technology, because the products have very low margins and must be attractively priced for healthcare purchases. Reducing resource use, carbon footprint and water consumption in production by investing in new manufacturing technologies may therefore be very challenging. For another company with just a few products, all with patent protection, and focusing on just one therapeutic area, it may be easier to make the necessary environmental investments in production.

As the trade association of the research-based pharmaceutical industry, the role of Lif is to represent the industry on issues of shared interest. Sustainability challenges linked to product portfolios therefore primarily become an area in which individual companies can influence and contribute to society's transformation. However, the opportunity for Lif to work on these issues at industry level can help create better conditions for the individual work of companies

Pharmaceuticals – a product group with great variety and different environmental characteristics

The biological activity, potential toxicity and stability of medicines vary. All these factors in turn affect how products can be manufactured, the resources and raw materials that are needed, where they can be produced, in what quantities and how they need to be handled before, during and after use. The potency and stability of a medicine become particularly important when assessing its potential environmental impact.

For a medicine to have the effect it is designed and manufactured for, it needs to be absorbed in the right place in the body. In many cases, this means that a medicine tablet must be manufactured in such a way that the active pharmaceutical ingredient (API) is not broken down directly when it enters the stomach. This means that it will be difficult for nature to break down the residues if the medicine is not disposed of properly or if pharmaceutical residues are discharged in wastewater after treatment. Incorrect handling may lead to an increase in the concentration of pharmaceutical residues in watercourses, for example. This, combined with the need for the substances to be potent, i.e., effective (biologically active) against the diseases for which the treatment is intended, means that an impact on nature, animals and humans cannot be ruled out.

As a result of the way medicines are designed and manufactured, residues will end up in our local environment and in our water. Pharmaceutical therapies are very important for human health and well-being. Therefore, a balance must be struck. Contraceptives such as the contraceptive pill are an example of medicines that contribute to human health and well-being by enabling women to control their fertility. They contain hormones that may have an endocrine disrupting effect on aquatic organisms and others. The world's population has also grown rapidly in recent decades, and advances in public health and welfare mean that we are living longer, resulting in more and more medicines being produced and consumed.

According to statistics from the National Board of Health and Welfare, the population aged 65 and over accounts for 60% of prescription medicines dispensed in Sweden. With further welfare advances and population growth, we can therefore assume that the production and consumption of medicines will continue to increase. In the transformation of society, it is therefore important to ensure that people have access to medicines, which contribute to health and well-being, while minimising the negative impact on the environment and water. Pharmaceutical companies carry out environmental risk assessments to determine ecologically safe concentrations before a product may be placed on the market. The aim is to protect the most vulnerable species and populations in the areas in which the products are used. Wastewater treatment becomes important when risk assessments indicate that discharges may contain higher concentrations than are deemed safe. The pharmaceutical industry actively contributes to the development of treatment technologies and identification of where they may need to be introduced. It is important to remember that even the most basic wastewater treatment technology is not available in some parts of the world. Advanced wastewater treatment technology is energy-intensive and increases the cost of treatment, so it should only be installed where there is a risk of environmental impact.

Back in 2005, Lif began collaborating with IVL Swedish Environmental Research Institute to provide environmental classification of pharmaceutical substances on medical information website Fass.se and to report "safe discharge concentrations". Since the early 2010s, Lif has been responsible for the National Pharmaceutical Strategy's work to develop an environmental assessment model for

pharmaceutical products. One of the results is a report from IVL Swedish Environmental Research Institute (Reduce environmental impacts of pharmaceuticals along the value chain – Needs, requirements and use of product-specific environmental information by different actors and for different applications, 2020) that describes how the environmental impact of a product during its life cycle can be assessed.

At national level, Lif and other actors have, in recent years, focused on sustainability criteria in public procurement, focusing on API discharge from manufacturing and on the proposal from the report by the Pharmaceutical and Pharmacy Inquiry, "Compensation for pharmaceutical injury and environmental considerations in pharmaceutical benefits" (SOU 2013:23), on the introduction of an environmental premium within the framework of the generic substitution system. In the spending authorisation for 2021, the Government commissioned the Swedish Dental and Pharmaceutical Benefits Agency, in cooperation with the Swedish Medical Products Agency and the Swedish eHealth Agency, to conduct a three-year trial of environmental considerations in the period's VARA system (PV system).

The regulatory framework

Medicines play an important role in human health and well-being, but the properties they need to have to be effective may create sustainability challenges at the level of production and use. For research-based pharmaceutical companies, work to prevent disease and ill-health is preferable to pharmaceutical treatment wherever possible. However, the use of medicinal products or the authorisation of new products should not be refused on the grounds of inherent environmental hazard. Benefits and efficacy should be the primary factor in the choice of treatment, and environmental risks should be managed in an appropriate manner.

The pharmaceutical industry operates in what can be described as a highly regulated market with a limited group of purchasers for prescription products. The industry's heavy regulation is largely based on standardised processes that place high demands on pharmaceutical development and marketing authorisation. Much of the regulatory work and associated legislation and rules have been developed within the framework of EU cooperation. However, the national medicines agencies continue to play an important role, particularly in the national processes.

At a simplified level, the European Medicines Agency (EMA) deals with the overall processes such as common pharmaceutical legislation and when medicines are authorised for use in all Member States at the same time. The authorisation process ensures the efficacy and safety of the product and that the medical benefits outweigh any adverse effects. In connection with the registration, pharmaceutical companies also submit an environmental risk assessment (ERA). The national medicines agencies, in Sweden the Medical Products Agency, are responsible for ensuring that European legislation is transposed into national law and for monitoring and reviewing the domestic pharmaceutical market. The national medicines agencies are also involved in the work of the EMA and act as investigators in the authorisation process at European level.

For the research-based pharmaceutical companies, the medicines regulations and the responsible agencies are central to confidence in medicines, their efficacy and their safety in general. It is therefore essential that the industry and the agencies continue to work together to safeguard the system and confidence in it.

LER – the ethical rules

Marketing rules have been in place since 1969. In 2007, the Swedish pharmaceutical industry put a comprehensive self-regulatory system in place aimed at maintaining a high standard of ethics and credibility. The self-regulatory system is called LER, the Swedish abbreviation for the Pharmaceutical Industry's Ethical Rules. These rules should be seen as a complement to existing legislation, statutes and governmental regulations, and applicable codes such as bribery legislation, the Swedish Anti-Corruption Institute's 'Code to prevent Corruption in Business' and rules on procurement. LER includes provisions on interaction with the actors that often collaborate with pharmaceutical companies, such as the healthcare sector and trade associations, and on the marketing of medicines.

For an industry with a high level of interaction with the healthcare sector, it is important for both parties to have a high level of trust during these interactions. The healthcare sector in Sweden is almost exclusively financed by public funds and is the largest purchaser of the pharmaceutical industry's products. Both aspects reinforce the importance of interaction and collaboration taking place according to common ethical principles so that there is a high level of confidence that they are taking place in a responsible manner. Unfortunately, in the past, the pharmaceutical industry has not always acted on the basis of common ethical principles, which has damaged trust and confidence in the way the industry interacts with the healthcare sector.

For the Swedish pharmaceutical industry, LER is currently a key element affecting Lif and its members. Since its implementation, LER as a regulatory framework and the system around it have been continuously developed, partly by means of collaboration agreements with the Swedish Association of Local Authorities and Regions. LER is therefore an example of the pharmaceutical industry taking responsibility for addressing negative impacts. From an industry perspective, this type of self-regulatory system and its importance for the pharmaceutical industry are unique in many respects. One of the key elements of the sustainability strategy is therefore to manage and develop an ethical approach in the industry as a cornerstone of the work on social sustainability issues, as accountability, trust and transparency are high priority areas.

For research-based pharmaceutical companies, responsible behaviour and ethical conduct are guiding principles in their day-to-day work.

EU – the Green Deal and the Pharmaceutical Strategy

As described earlier, EU cooperation is central to the pharmaceutical industry, including through the EMA. The EU has a major impact on the day-to-day work, development and future prospects of the industry. Two initiatives that are expected to have a strong impact are therefore the EU Green Deal and the European Pharmaceutical Strategy. Both reflect the EU's strong commitment to creating sustainable societies and strengthening the European pharmaceutical industry. This is in line with Sweden's ambition to contribute to the transformation of society. The European Commission's Strategic Approach to Pharmaceuticals in the Environment (March 2019) also has strong links to the Green Deal and the European Pharmaceutical Strategy. The strategy sets out a few areas in which the industry, in close collaboration with all other actors in the pharmaceutical value chain, needs to work to reduce the risks of pharmaceutical residues in the environment from

manufacturing and patient excretion and to manage unused medicines. Lif sees great opportunities to address these concerns, partly through several of the initiatives presented earlier in the sustainability strategy, and partly through increased emphasis on the correct use of medicines. We call for a greater focus on medication reviews and improved monitoring of compliance with prescriptions. Given the environmental impact of production, pharmaceutical companies do not want to produce any pharmaceutical products that are not put to the correct use. The 1,200–1,500 metric tonnes of unused medicines handed in to pharmacies each year indicate that there is a relatively low level of compliance. If this is the case, it means unnecessary environmental impact in the manufacturing and waste management stages of the product chain and costs for society. In addition, patient benefit and societal value are not being maximised.

The EU Green Deal is a package of initiatives covering several areas across different sectors. It is designed to enable a green transition in the EU, and the goals are for net zero emissions of greenhouse gases by 2050, economic growth to be decoupled from resource consumption and no people or places to be left out. One third of the €1.8 billion investment from the Next Generation EU Recovery Plan and the seven-year budget has been allocated for its implementation.

The Pharmaceutical Strategy for Europe is designed to contribute to a future-proof regulatory framework and promote research and development of new medicines. It will involve legislative changes and action in four areas:

- meeting the need for new medicines and patient access to them
- supporting the competitiveness, innovation and sustainability of the European pharmaceutical industry
- improving crisis preparedness and management mechanisms
- giving the EU a strong voice in the world.

The EU Green Deal and Pharmaceutical Strategy for Europe will have a major impact on the industry and its development, but also open up new opportunities and challenges. As with any major initiative, many actors need to work together to produce the best possible results. The research-based pharmaceutical companies welcome European initiatives and ambitions with the aim of accelerating societal transformation and strengthening the pharmaceutical industry as part of the Life Science sector. Collaboration at European level is critical to achieving sustainable development.

Appendix

Appendix 1: Sustainable development – some different concepts and what they mean for the pharmaceutical industry

Sustainability is multifaceted and its meaning may vary depending on the context. In this section we present a few concepts that appear in different contexts when sustainable development is discussed.

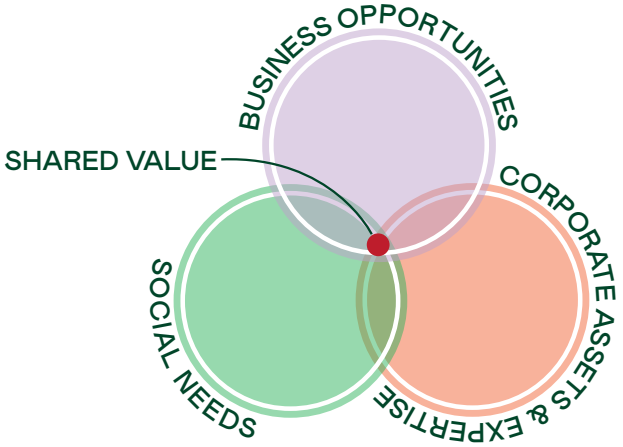
Triple Bottom Line (TBL) and Environmental, Social and Governance (ESG)

When the World Commission on Environment and Development, also known as the Brundtland Commission, defined sustainable development in the report Our Common Future, it included economic, social and environmental conditions and processes. For Lif, these three aspects are fundamental building blocks and a key starting point, regardless of the sustainability challenge being discussed. Breaking down the concept of sustainability in this way is often referred to as the Triple Bottom Line (TBL).

In addition to the Brundtland Commission's definition and the TBL, Environmental, Social and Governance (ESG) is a common definition of sustainable development and is often used by companies. The economic aspect is replaced here by governance, and the focus is thus primarily on how the company is managed. Factors include business ethics, legislative compliance, risk management and transparency. TBL and ESG are closely related and are often used synonymously. .

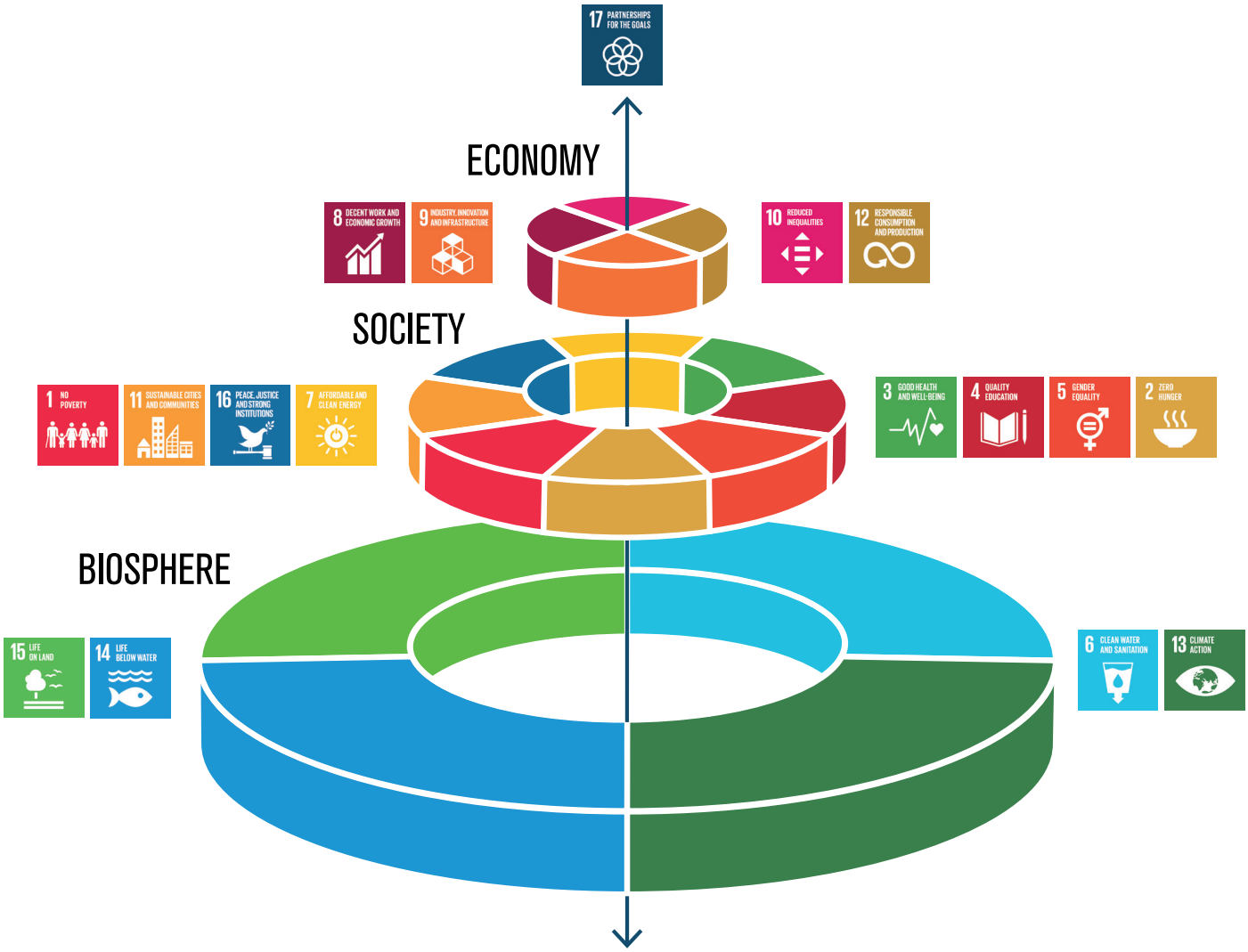
Creating Shared Value (CSV)

Creating Shared Value (CSV) is another cornerstone of Lif's understanding of the concept of sustainable development. CSV means that sustainability must create value for all parties or actors. For example, a company's actions to protect biodiversity should also create opportunities for local people to improve their economic situation, perhaps through the creation of new jobs.



The 2030 Agenda and the Sustainable Development Goals

As mentioned above, TBL and CSV are fundamental to Lif's approach to sustainability but do not identify specific areas for action for sustainable development. This is where the UN 2030 Agenda and the Sustainable Development Goals come in. There are 17 goals with 169 targets and they address the global challenges facing the world. They describe how society should be transformed and how they can be monitored. The timetable and goals of the 2030 Agenda are ambitious but necessary for the transformation. Several of the goals require long-term work and major commitments to be achieved, such as climate action, which needs to be stepped up if global warming is to be kept below the preferred level of 1.5 degrees Celsius compared to pre-industrial levels. As the 2030 Agenda is also widely used by nations, companies and organisations, Lif believes it is important to base its sustainability strategy on this common language.



Appendix 2: Lif's obligations based on its membership of international organisations

As a Swedish trade association with many international members, Lif is also active in relevant international trade associations. Lif is a direct or indirect member of EFPIA (the European Federation of Pharmaceutical Industries and Associations) and AESGP (the Association of the European Self-Care Industry) and their respective global organisations, IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) and GSCF (Global Self Care Federation). Lif is thus obliged to follow the organisations' guidelines on how t heir members should contribute to sustainable development.

Below are some key examples of guidelines that Lif has incorporated in its strategy and manifesto.

IFPMA: Ethos

R&D-based biopharmaceutical member companies of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) are responsible for the discovery of most new medicines and vaccines, which they go on to develop, promote, sell and distribute in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare. In doing so, they provide the healthcare community with the latest scientific and educational information to improve understanding of treatment options available to patients and support high-quality patient care.

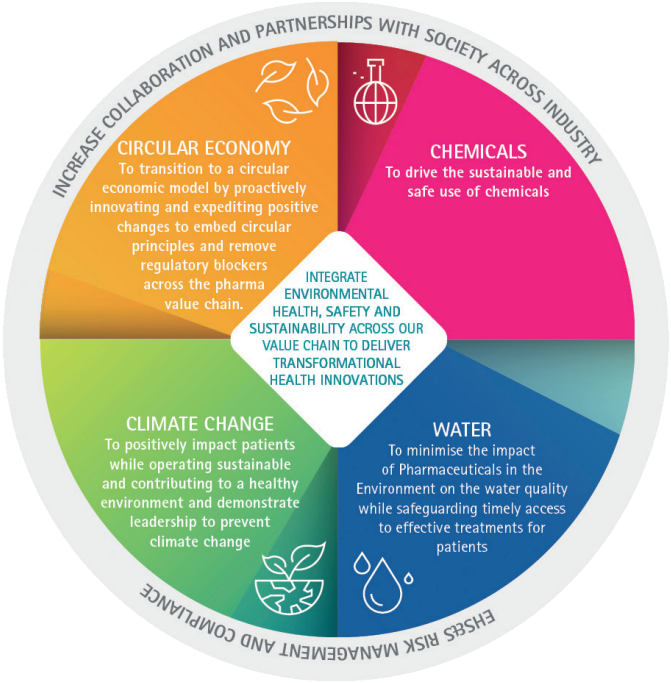
IFPMA has taken a new approach and moved from a Code based on rules to a culture grounded in integrity, values and principles – and, most importantly, patient trust. The Ethos is the foundation that shapes how the R&D based biopharmaceutical industry sustains trust based on the core values of care, fairness, respect and honesty in line with ever-changing society's expectations. The Ethos serves to instil a culture of ethics and integrity needed to guide our business behaviours and interactions between IFPMA members and the healthcare community.

EFPIA: Environment, Health, Safety, and Sustainability (EHS & S)

EFPIA's Environment, Health, Safety and Sustainability (EHS&S) refers to the practices to protect the health and safety of employees and the public as well as the environment. Strong EHS&S management requires the implementation of systems and processes to assess and control the risks of environmental impacts and health and safety hazards. Besides assuring compliance with applicable legislation, EHS&S management systems drive continuous improvement and learning.

Equally important, the rapidly growing rate of resource consumption throughout the world is unsustainable. The pharmaceutical industry recognizes that reversing the use of natural resources, the degradation of ecosystems and the disruption of the environmental systems that support human life, are critical for the benefit of current and future generations. Therefore, EFPIA believe that an increased focus on environmental sustainability is key for the future health of our planet.

EFPIA member companies strive to invent, produce and distribute new medicines and vaccines in a safe and environmentally responsible manner. Furthermore, EFPIA are actively providing a safe and healthy workplace while reducing the environmental impact in our operations and those of our supply partners around the world. A risk management approach is employed to create transformational health innovations, while protecting our employees and employing practical aspects of environmental sustainability.



EFPIA: White Paper on Climate Change

The pharmaceutical industry is committed to making a positive impact on the lives of patients while operating sustainably and therefore strives to contribute to a healthy environment and demonstrate leadership in doing what's necessary to mitigate climate change. This EFPIA commitment is aligned with the ambition the European Commission recently expressed through their European Green Deal and the European Climate policies.

The driving motivation of the pharmaceutical industry is to improve human health and wellbeing. It has been well documented that climate change can adversely impact human health. Further understanding of these impacts and the interface between people, health and the environment is critical to ensuring the pharmaceutical industry can form and execute our response.

EFPIA's White Paper highlights the commitment made by the EFPIA companies to:

- Establish climate change policies and strategies based on materiality and impact for individual companies, whilst addressing their entire value chains
- Pursue science-based CO2 reduction targets
- Contribute to reduced energy consumption and increased energy efficiency and seek opportunities to use more energy from renewable sources throughout the value chain
- Annually and publicly disclose CO2 performance calculated according to recognized methodologies such as the WRI greenhouse gas protocol.

Global Self-Care Federation: Charter for Environmentally Sustainable Self-Care

As a federation of national associations and consumer healthcare manufacturers, GSCF commit to drive environmentally sustainable self-care. GSCF care for the environment by:

- Developing guidance for our members on best practice, how to deliver on our ambitions, and navigating requirements and standards to help raise the bar on environmental sustainability
- Providing a platform for exchange of information, ideas and innovation, finding and creating opportunities to collaborate within and beyond the self-care sector; and
- Enriching dialogue with our stakeholders, proactively informing them of our progress on environmental sustainability and seeking their feedback.

GSCF:s vägledande principer

Individually and together GSCF seek to:

- Maximise our positive environmental impacts and minimise our negative impacts while never compromising health outcomes for consumers
- Promote circular economy principles throughout our value chains, managing the environmental impacts of our products from discovery and development all the way through to post-consumer use and end-of-life
- Contribute to the development and acceleration of innovative technologies and other solutions to address environmental challenges
- We will focus on the priority areas where we can have the most impact:
  - Plastics & Packaging
  - Pharmaceuticals in the Environment
  - CO2 Footprint

Lif 20220

Läkemedelsindustriföreningen is the trade association for the research-based pharmaceutical industry in Sweden with about 90 members and associate companies. Lif Service AB (Lif) represents its members in issues of common concern, assisting and informing them on questions vital to the industry. We are members of the European trade association EFPIA and the international trade association IFPMA as well as of the European associations AESGP.

The research-based pharmaceutical industry

The Swedish Association of the Pharmaceutical Industry AB
Phone +46 8 462 37 00 | info@lif.se | lif.se | fass.se | life-time.se