



# Delivering on our commitment to patients.

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**Zealand Pharma  
Corporate Responsibility  
Report 2019**

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## Corporate Responsibility Report 2019

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## About this Report

This statutory report on corporate social and environmental responsibility is for the financial year 2019, cf. section 99a and 99b of the Danish Financial Statements Act. This report is a supplement to the management's review in the Annual Report 2019 covering the period January 1 to December 31, 2019.

## Changing lives.

We work every day with patient communities and thought leaders to change the lives of people with severe medical conditions.



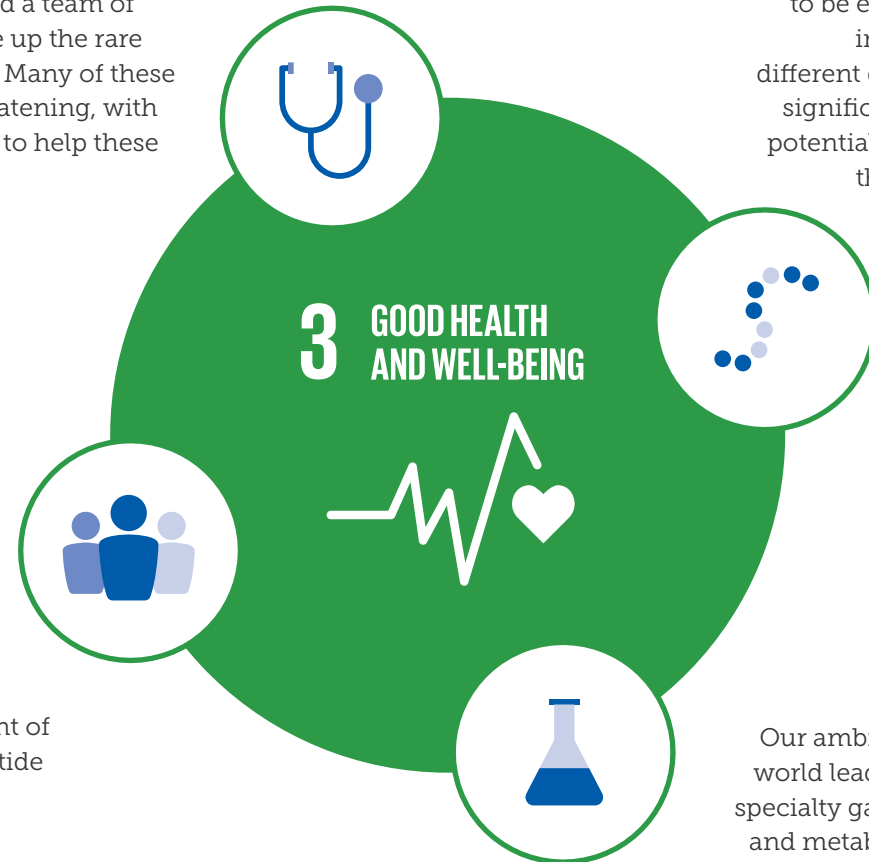
**SDG 3:** Ensure healthy lives and promote well-being for all at all ages



Find out more about Zealand at [zealandpharma.com/csr](https://zealandpharma.com/csr)

There are over 300 million people living with one or more of over 6,000 identified rare diseases around the world<sup>1</sup>, each supported by family, friends and a team of caregivers that make up the rare disease community. Many of these diseases are life threatening, with no available therapy to help these patient groups.

We are passionate about changing the lives of people with severe medical conditions through targeted development of next generation peptide therapeutics.



Peptides have proven to be effective drugs in a number of different diseases, with significant untapped potential across many therapy areas.<sup>2</sup>

Our ambition is to be a world leader in treating specialty gastrointestinal and metabolic diseases. We intend to deliver best-in-class treatment options that meet patient medical needs and ease the burden on the health care system.

<sup>1</sup> INSERM (Institut national de la santé et de la recherche médicale). (2019, October 24). Rare diseases: Over 300 million patients affected worldwide. ScienceDaily.

<sup>2</sup> J. Lau and M. Dunn, Therapeutic peptides: Historical perspectives, current development trends, and future directions. Bioorganic & Medicinal Chemistry, version 26, issue 10, 1 June 2018, p. 2700-2707.

# Transforming peptides.

We leverage our 20 years of experience discovering and developing peptide drugs to transform peptide projects into next generation therapeutics.



Find out more about Zealand at [zealandpharma.com/about-us](https://zealandpharma.com/about-us)

## Discovering and optimizing peptides to create new medicines

For more than twenty years, Zealand has been successfully optimizing peptide hormones to confer the necessary properties to be a safe and effective drug.

Peptides represent a growing therapeutic modality with over 60 approved and marketed peptide drugs and many more in clinical development.<sup>2</sup> Zealand uses its unique in depth understanding of peptide chemistry and biology to focus the substitution process on key amino acids to remove the weak points that result in poor solubility, stability or activity, and thus create new drug candidates.

We have four late stage programs with the potential to launch into major markets over four years beginning in 2021. Three of these programs are based on dasiglucagon, a stable glucagon analog: a new drug application will be submitted in 2020 for treatment of severe hypoglycemia in diabetes; ongoing Phase 3 for treatment of the rare pediatric condition, congenital hyperinsulinism; and Phase 3 planned for use in dual-hormone fully automated pump therapy for management of type 1 diabetes. Our fourth late stage program is ongoing Phase 3 with glepaglutide, a long-acting GLP-2 analog for treatment of short bowel syndrome.

Our early development pipeline includes a GLP-1/GLP-2 agonist for treatment of short bowel syndrome in Phase 1, two clinical programs partnered with Boehringer Ingelheim, and one pre-clinical program partnered with Alexion Pharmaceuticals. We continue to leverage our established peptide platform, which has already led to two approved medicines and provides multiple opportunities for near-term pipeline expansion.

## Zealand Pharma in brief



### 20+ years in biotech

Founded 1998 in Copenhagen, locations in Boston and New York



### Leading peptide platform

A world leading peptide platform, with two medicines on the market



### Four potential launches in four years

Accelerating late stage programs to launch new products into major markets beginning in 2021



### Experienced team

179 employees of which 85% are in R&D

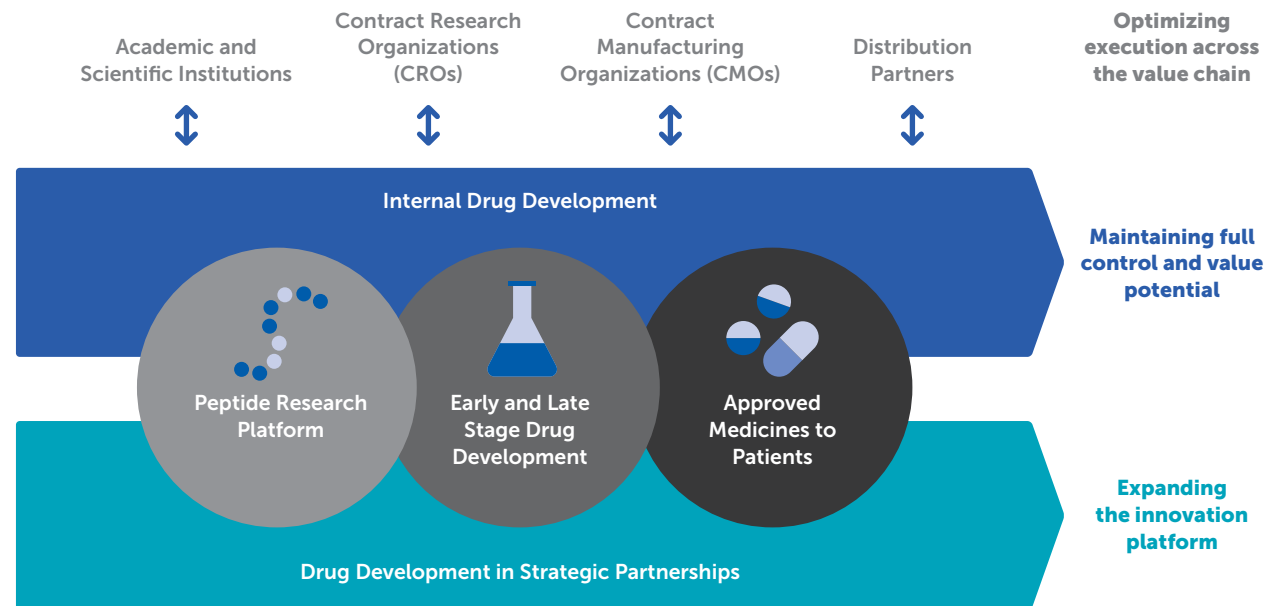
## Our business model.

To deliver best-in-class treatment options that meet patient needs and ease burden on the health care system, we utilize a business model with two approaches.

First, we aim to retain full ownership and control of product candidates all the way to market in selected geographies. Alternatively, we may progress clinical development ourselves to the point at which it makes business sense to engage in partnerships that expand the opportunity and probability of success by providing additional resources and investment.

Our agile organization engages with partners across the value chain, such as academic and scientific institutions, leading contract research organizations (CROs) and contract manufacturing organizations (CMOs), and distribution partners.

### Optimizing value through internal drug development *and* partnerships



Find out more about Zealand at [zealandpharma.com/strategy](https://zealandpharma.com/strategy)

# Focus on Corporate Responsibility.

As we work toward realizing our ambition of becoming a fully integrated biotech that improves care for patients and maximizes value for our shareholders, we recognize the importance of protecting the world around us. We believe in operating as a responsible company that serves broader economic, societal, and environmental interests.



## We aim to do this by:



Enabling health, well-being, and competency development of our employees, while ensuring a safe workplace



Focusing collaboration with advocacy groups to consolidate relations and obtain better treatment options for patients



Conducting business according to the highest ethical standards



Working actively and systematically to minimize our impact on the environment and climate



Communicating our CSR policy openly and honestly to external collaboration partners, including our suppliers

These are our guiding principles for corporate responsibility, upon which we have formulated our policies specified throughout this report.

### Reporting framework

We adhere to requirements of the Danish Financial Statements Act, and comply with relevant laws, standards and guidelines for reporting on corporate social responsibility activities. We respectfully adhere to the UN Guiding Principles on Business and Human Rights. In last year's report, we incorporated selected UN Sustainable Development Goals that are aligned to our business impact and connect Zealand's efforts with those of other companies to address global challenges.

### Engaging our organization

To ensure the importance of environmental, social and governance responsibility is understood and acted upon throughout our organization, we established a CSR steering committee comprised of senior representatives in the company. This committee will work to facilitate initiatives that increase our contributions in corporate responsibility, and to improve transparency on the activities.

### Scope of our reporting

In 2019, Zealand Pharma began a relocation from our facility in Glostrup, Denmark, which was our home for the past twenty years, to a new facility in Søborg, Denmark. The relocation will provide sufficient space and modern facilities for our growing workforce, and will be completed in 2020. This report presents some of the actions implemented to minimize the new facility's impact on the environment and climate. Also, we established our presence in the United States by opening locations in Massachusetts and New York, and will continue building our U.S. operations in the coming years. While not yet a significant part of our current reporting, our expanding global footprint is expected to change the scope of our future reporting.

# Our People.

At Zealand, employees are our most important resource. We aspire to attract, develop and retain the best people and to be a company where every employee thrives.



**SDG 3:** Ensure healthy lives and promote well-being for all at all ages



**SDG 5:** Achieve gender equality and empower all women and girls



**SDG 10:** Reduce inequality within and among countries

Highly qualified and motivated employees are a prerequisite for achieving the ambitious Zealand business goals. A diverse workforce enhances innovation, and increases our ability to work cross-culturally. Ensuring every employee has opportunity to improve upon their existing strengths while developing skills is critical to attracting and retaining qualified and engaged employees.

We strive to ensure our employees' well-being and have a number of policies in place to promote physical and psychosocial health. We work systematically to maintain a safe and healthy work environment.

We have a number of committees, including a Works Council and an Occupational Safety and Health Committee (OSHA Committee), on which both management and employees are represented and regularly discuss matters related to our work environment. Employees are also represented with two seats on the company's Board of Directors.

Labor unions currently representing our employees include HK it, medie & Industri Hovedstaden. Zealand negotiates a collective agreement in good faith every three years. The next negotiation is scheduled for 2020.

## Risk and mitigation

Zealand is not a high-risk company regarding safety, yet we do work systematically to maintain a safe and healthy work environment. Numerous procedures are in place, including a manual describing our policies on occupational safety and health (OSHA). All Zealand employees are trained in the standard safety protocol, whereby they are given the tools to manage their own occupational safety.

## Zealand Pharma employees in brief

### 46.1

The average age of Zealand employees at the end of 2019 (2018: 46.3)

### 17%

Portion of employees with a nationality other than Danish at the end of 2019 (2018: 16%)

### 60%

In corporate management the number of non-Danish nationalities was 60% (2018: 50%).

### 85%

Employees working in R&D (2018: 87%).

Workplace audits (Arbejdspladsvurderinger, APV) are conducted regularly. Risk assessments are reviewed quarterly, and Zealand’s OSHA Committee conducts surveys on a regular basis. A near-accident reporting initiative is maintained to build on Zealand’s strong safety track record and safeguard against potential future accidents.

**2019 Highlights**

In 2019, we initiated a relocation within Denmark into larger and more modern facilities. This was driven by the need for additional space to support our growing employee base. Also, we initiated the build-up of operations in the United States, where we have started to recruit key personnel. A location in New York was opened in 2019, and an additional location in the Boston area opened in early 2020.

**Diversity**

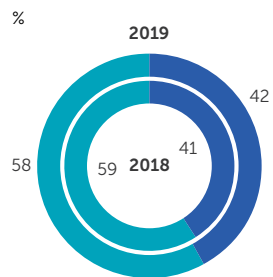
We strive to achieve equal representation of both genders at all management levels, from the Board of Directors to the heads of departments. Zealand has an even distribution of female and male managers and slightly more women than men across the organization in general. The overall management level is made up of 59% females (2018: 41%).

In 2013, the Board of Directors set a target to have a minimum of 25% female board members elected by the shareholders within the following three years. The target was first met in 2015. As of December 31, 2019, the Board of Directors consisted of three women and six men, of whom one woman and two men were elected at the Annual General Meeting in 2019, giving a female representation of 33% (2018: 50%).

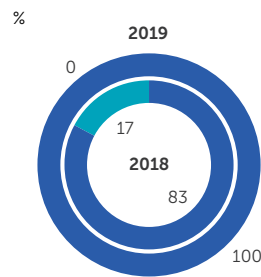
**Privacy and data protection**

We have developed a Data Protection Impact Assessment covering all Clinical Trials conducted from 2018 forward. All employees have received training in general procedures and data retention guidelines as well as the information security procedures.

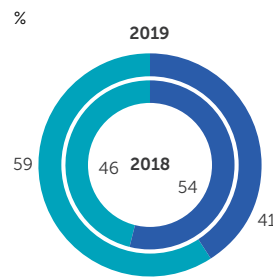
**Zealand Pharma**



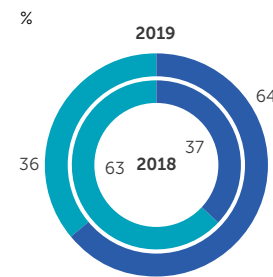
**Corporate Management**



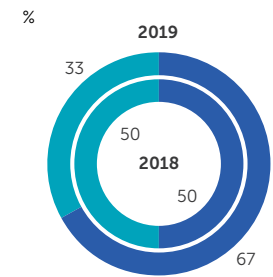
**People Managers**



**Other Employees**



**Board of Directors**



■ Men ■ Women



	Achievements in 2019	Focus areas in 2020
<b>Diversity</b>	<ul style="list-style-type: none"> <li>Zealand remains committed to providing equal opportunities for women and men at all management levels.</li> </ul>	<ul style="list-style-type: none"> <li>Zealand will continue to focus on gender diversity of employees at all levels of the organization and provide equal opportunities for women and men, at all management levels.</li> <li>We will continue to encourage female candidates to take on managerial tasks.</li> </ul>
<b>Engagement</b>	<ul style="list-style-type: none"> <li>Annual engagement survey to help leaders and employees continuously improve the working environment. The response rate was 89% (or 160 respondents; 2018: 85% or 127 respondents). 90% of responses were favorable (2018: 97% favorable).</li> </ul>	<ul style="list-style-type: none"> <li>Maintain employee engagement as reflected in the annual engagement survey scores.</li> </ul>
<b>Personal and Organizational Competency Development</b>	<ul style="list-style-type: none"> <li>Activities conducted to continue focus on the Zealand DNA, which is a set of common values uniting all employees in their daily work. In 2019, a Zealand DNA Awards program was launched recognize recent accomplishments within our organization that demonstrate our values in action. The awards are intended to encourage employees to reflect and articulate how the Zealand DNA comes alive in every day work, and ideally how our values contribute to our success.</li> <li>All management levels have received leadership training.</li> </ul>	<ul style="list-style-type: none"> <li>Leadership training will continue.</li> <li>We will focus on competency development and improve employability with the following objectives: <ul style="list-style-type: none"> <li>Zealand's ability to execute the business strategy</li> <li>Employees' opportunity to get motivating tasks</li> <li>Enhance employees' employability</li> </ul> </li> <li>Workshops based on the trends from the competency development plans will be conducted with the objectives to strengthen skills and improve the ability to work effectively across organizational borders.</li> </ul>
<b>Employee health and well-being</b>	<ul style="list-style-type: none"> <li>Workshops to avoid stress among employees were conducted.</li> <li>Employee turnover was 12% (2018: 6%).</li> <li>Due to a change in internal systems, data to calculate the absence rate in 2019 was not available (2018: 2.8%).</li> </ul>	<ul style="list-style-type: none"> <li>We aim for an absence rate at the same level, or lower, as in previous years.</li> <li>Zealand will continue to work on maintaining a healthy and motivating working environment.</li> </ul>
<b>Safety</b>	<ul style="list-style-type: none"> <li>3 near accidents were reported under our near accident reporting initiative (2018: 7).</li> <li>No "obligated to notify" accidents were reported.</li> <li>Zealand had no significant injuries in 2019 (2018: 0), as measured by days off due to work-related injury.</li> </ul>	<ul style="list-style-type: none"> <li>We strive to ensure that all accidents are reported, and that employee safety is maintained or improved.</li> </ul>

## Quality.

Zealand's quality policy describes compliance with rigorous internationally recognized standards and guidelines at all stages of research and development, to ensure that we do not endanger patients safety, quality or efficacy.

Zealand's Development area outsources good practice (GxP) activities to qualified and approved vendors, where the sponsor responsibilities remain at Zealand. Oversight of the activities is carried out to ensure compliance with the requirements of, for example, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), and others.

We work in close partnerships with vendors, and when evaluating these partners we focus both on business ethics, as well as capability and capacity of the service. Elements in the assessment include quality audits, supplier management assessment, and financial stability.

Zealand's Pharmaceutical Quality System for development activities is described in our Quality Manual, which also defines our Quality Policy. Ongoing evaluation of our quality system is performed continuously.

### Risk and mitigation

Our reliance on external partners to perform GxP activities poses risk that partners do not follow requirements of pharmaceutical quality standards. Such noncompliance would in turn jeopardize patient safety, quality and efficacy of our medicines. Our vendor oversight program is intended to mitigate this risk through thorough and ongoing assessment of all GxP vendors.

Achievements in 2019	Focus areas in 2020
<p><b>Quality assurance and vendor management</b></p>	<ul style="list-style-type: none"> <li>• Zealand launched an NDA-readiness program to ensure that required processes for commercial operations are in place before a §39 inspection.</li> <li>• Zealand implemented a new electronic Document Management System to facilitate regulatory submissions.</li> <li>• Zealand has an outsourced business model for GxP work and matured the vendor oversight program to cover all GxP vendors.</li> <li>• As an integrated part of the Vendor Oversight Program, Zealand successfully conducted 21 external audits.</li> </ul>

§39 inspection is conducted by the Danish Medicines Agency (DMA) in order to obtain a manufacturing authorization.

# Patients.

We work every day with patient communities and thought leaders to change the lives of people with severe medical needs.



**SDG 17:** Strengthen the means of implementation and revitalize the global partnership for sustainable development

## Passionate about changing lives

We work to create better lives for patients through collaborations with advocacy groups and patient organizations. We demonstrate our long-term commitment to patients and caregivers by consolidating relations and obtaining better treatment options.

	Advocacy groups and patient organizations	Type of collaboration
<b>Short bowel syndrome</b>	The Oley Foundation, U.S.	Patient insights, partnering in clinical development, and educational initiatives in short bowel syndrome. Part of the Oley Corporate Partnership Program
	Association for Crohn's and Colitis, Denmark	Membership
	Association for Users of Home Parenteral Nutrition, Denmark	Educational grant to support initiatives for home parenteral nutrition consumers
<b>Diabetes</b>	Juvenile Diabetes Research Foundation	Patient insights and general diabetes collaboration
	DiaTribe, U.S.	Collaboration and patient journey insight
	T1D Exchange, U.S.	Patient insights on diabetes management, educational and scientific publications
	American Diabetes Association, U.S.	Collaboration and support of furthering the cause to drive awareness of diabetes and its complications
<b>Rare Diseases</b>	NORD – National Organization of Rare Diseases, U.S.	Corporate Council Membership, rare disease advocacy
	CHI – Congenital Hyperinsulism International	Patient insights, collaboration on global patient registry and global development program, generally supporting the CHI community

## Risk and mitigation

The safety and efficacy of our therapeutics is the foremost concern regarding patients. Such risk is addressed throughout the development process and within the rules and guidance provided by regulatory entities.

**2019 Highlights**

Zealand indirectly supports the improvement of management and care for short bowel syndrome patients by supporting the Learn Intestinal Failure Tele-ECHO clinic (LIFT-ECHO) initiative. It is an online community of medical professionals dedicated to supporting the treatment and management of patients with intestinal failure. LIFT-ECHO utilizes the ECHO®

model, which links specialist teams at academic ‘hubs’ with primary care clinicians or other non-specialists in local communities. During teleECHO clinics, non-specialist clinicians from multiple sites can present patient cases to the specialist teams and to each other, discuss developments relating to their patients, and together determine the best course of treatment.

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<b>Achievements in 2019</b>	<b>Focus areas in 2020</b>
<p><b>Patients focus</b></p> <ul style="list-style-type: none"> <li>• Development and launch of the patient-centric educational initiative LivingWithSBS.com in partnership with the Oley Foundation.</li> </ul>	<ul style="list-style-type: none"> <li>• Build organization and operations in the United States to foster a medical and patient-community network, and to prepare for introducing new treatments in the coming years.</li> <li>• Continue to drive patient-centric development, including patient advocacy as a partner in the clinical development, in dialogue with regulatory bodies as well as in disease educational initiatives.</li> <li>• Continue to expand patient-centric education initiatives.</li> </ul>

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# Environment.

Zealand's environmental policy outlines our commitment to minimizing our impact on the environment and climate through responsible consumption and production.



**SDG 12:** Ensure sustainable consumption and production patterns

By conducting business in a safe and environmentally friendly manner, we aim to reduce our impact on the environment and climate as far as possible. We have policies and procedures to encourage recycling, efficient use of electricity and heating, and responsible travel.

## 2019 Highlights

In the second half of 2019, we initiated a relocation to new facilities within Denmark. The move will accommodate Zealand's continued workforce growth, which has been steadily increasing to support the number of clinical development programs as well as the longer-term strategic initiative for introducing commercial support. Operations will be able to expand within 7,100 square meters of newly renovated offices and laboratories, which is approximately 34% more area than the old facility.

The relocation has enabled us to take actions, both within our own facility as well as in coordination with our neighboring community, to support a more sustainable approach to environmental and climate.

- Solar panels have been installed.
- Electric/hybrid car charging stations will be installed, and we are discussing with our neighbors the possibility of adding more.
- Ample covered bicycle parking is provided.
- Teleconferencing is enabled in more than half of the dedicated meeting rooms, and videoconferencing in three rooms in the Meeting Center.
- Rideshare has been facilitated for employees traveling between Zealand's old and new sites, throughout the transition period until the relocation is complete.
- We are partnering with other companies in our area to encourage co-commuting enabled via a common mobile app.

## Risk and mitigation

Handling of materials and waste from our laboratories poses risk of spills. Thorough employee training as well as proper outsourced removal mitigates this risk.

### Achievements in 2019

#### Environmental sustainability and climate

- Zealand continued to encourage employees to take environmental and climate friendly initiatives.
- Various methods implemented in our new Denmark facility to enable energy efficiency, sustainable energy sourcing, and responsible travel.

### Focus areas in 2020

- Zealand will examine in which areas we can provide relevant metrics, and potentially drive measurable improvement in our environmental impact.
- Zealand will continue to minimize the environmental impact and encourage employees to continue with environmental and climate friendly initiatives.

# Ethics.

We strive to operate according to the highest ethical standards, and safeguard our business against corruption and noncompliance.



**SDG 16:** Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels

## Business Ethics

Zealand's reputation as a trusted business and scientific partner are of the utmost importance. Therefore, our employees are trained and kept updated with policies on good business practice and compliance, insider trading, and appropriate legal management of third party intellectual property.

We strive to operate according to the highest ethical standards, and safeguard our business against corruption and noncompliance where employees are most at risk. Zealand will proactively engage in a positive dialogue with all regulatory and advisory authorities and with stakeholders from relevant industries in order to be inspired to make further improvements.

As part of its program of maintaining a robust ethical working environment, Zealand maintains a whistleblower program that is monitored by an external law firm to ensure that issues that need to be examined by senior management and members of the Board of Directors are brought to their attention when appropriate.

We actively promote and maintain a policy of transparency and honesty with our employees. Zealand's Employee Handbook stipulates a set of policies that specify the company's standards regarding its employees' general and legal conduct.

Zealand has taken every precaution to keep all employees, board members and certain stakeholders up to date and compliant with our internal rules. We distinguish carefully between those who are listed on its permanent insiders' list and those who are exposed to what is deemed insider information. In the latter case, Zealand takes every precaution to keep an up-to-date list of employees' knowledge of insider

information. All new employees are introduced to our internal rules and have to sign a document stipulating that they have read and understood these rules.

We have strict policies regarding the proper use and transfer of intellectual property. Since it was founded, Zealand has refined its confidentiality and material transfer agreements to reflect critical changes in the industry, building on the extensive industry experience of many of its senior members.

Zealand is at an early stage of its development and does not have a fully established supply chain of vendors. During its ongoing vendor selection process it reviews its potential partners as part of the process to engage with them in supply agreements. At present all our vendors are located in the United States, Canada or the European Union that we believe these territories operate to a high standard of human rights protections.

The process of launching its first commercial products will require it to assess the human rights impact of its supply chain and consider ways in which future vendors and suppliers show appropriate respect for key elements of human rights protections. As Zealand prepares for entry into the market this will be an area of focus and development of appropriate metrics, checks and contractual guarantees.

## Risk and mitigation

The main risks related to our activities include employees' and business partners' violation of our anti-corruption commitment and potential legal and financial consequences thereof. Zealand's whistleblower program and insider information list are two methods for mitigating such risk. We are developing programs to support ongoing maintenance of code

**Achievements in 2019**

**Business ethics**

- All new employees have been introduced to Zealand’s internal rules as part of the introduction program.
- No issues were reported under our whistle blower program.
- Zealand developed a Data Protection Impact Assessment covering all Clinical Trials.
- New policies and standard operating procedures have been developed. Assessment that vendors and suppliers are located in territories that have high regard for human rights protections.
- Assessment that Vendors and Suppliers are located in territories that have high regard for human rights protections.

**Focus areas in 2020**

- Zealand will continue to have focus on Privacy regulation and the GDPR.
- Zealand will continue to operate according to the highest ethical standards.
- Our code of business conduct is part of the introduction program for all new employees. All employees will be periodically reminded of its scope, and document that they are aware of it.
- A Data Protection Policy will be adopted.
- New affiliates in the U.S. will in some respects adopt Data Protection Policies.
- Development of appropriate and clear vendor selection criteria for new vendors and ways to ensure that vendors that are selected have appropriate respect for Human Rights.

of business conduct understanding among employees, as well as a more robust program to ensure data privacy and protection.

**Animal Welfare**

To allow for the discovery of new therapies and to ensure the efficacy and safety of new pharmaceuticals as required by regulatory authorities, it is necessary to conduct *in vivo* experiments using laboratory animal species.

Zealand’s policy on animal ethics and welfare is to use animal studies only where no available and acceptable *in vitro* alternative exists. All laboratory animals used under our responsibility must be treated humanely and with respect, and only purpose-bred animals are

used. Zealand adheres to the principles of the 3Rs (reduce, refine, replace) and works to integrate these principles in all studies carried out, wherever possible.

All in-house animal studies are carried out in accordance with specific licenses issued by the Ministry of Environment and Food of Denmark and international guidelines, as appropriate. Danish law stipulates regular inspections of the animal facilities as well as comprehensive reporting protocols overseeing experiments conducted during the year, processed through The Animal Experiments Inspectorate. The continuous dialogue between lab technicians, veterinarians, academic staff and heads of department, ultimately ensures the highest animal welfare standards in all studies conducted.

All employees working with laboratory animals have appropriate and documented education and training. Veterinary checks of our animals are performed regularly and always when needed.

In addition, Zealand’s internal ethical committee scrutinizes all proposed in-house *in vivo* pharmacology, toxicology and PK experiments for compliance with regulatory permissions and highest ethical standards.

The necessity of animal experiments to Zealand’s research and development activities cannot be overstated, and thus we constantly strive for the greatest vigilance and care in our treatment of animals.

**Achievements in 2019**

**Animal welfare**

- No incidents of negligence were reported.

**Focus areas in 2020**

- Zealand will continue to focus on animal welfare and comply with the principles of the 3Rs.



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