

Version 1.0 (November 2019)

1. PURPOSE

The purpose of this Policy is to set out ConvaTec's position in relation to the key ethical issues that we believe are relevant to the development of new products. This involves addressing issues relevant to:

- how we select the disease areas, and patient groups, on which to focus the development of new products
- how we determine which technologies are acceptable to use
- how we determine which materials are acceptable to be used in our products, packaging and used in our operational processes
- how we approach testing our products and packaging.

2. SCOPE

This Policy applies to those employees engaged in new product development across ConvaTec and its wholly-owned subsidiaries and, in particular, employees in research and development ("R&D") and quality and regulatory functions.

3. POLICY

3.1. Policy Statement

ConvaTec exists to improve the lives of the people it touches and its core business involves providing products and services that help people with certain chronic and other conditions to live improved lives through enhanced mobility, confidence and freedom. It strives to develop innovative, safe, effective and reliable products which meet urgent health needs and to do so in ways which minimise negative impacts on people and the environment.

3.2. General Principles

- 3.2.1. We ensure our R&D approach complies with all relevant regulatory requirements and standards
- 3.2.2. We focus our R&D effort on chronic disease areas which are becoming more prevalent and where our products and services provide a measurable improvement in quality of life
- 3.2.3. We aim to design and develop products that are safe, effective and of high quality, and that are accessible to as large a proportion of the population as possible
- 3.2.4. We adopt a precautionary approach and will only make use of emerging technologies that support our aim of designing and developing products that are safe, effective and high quality

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- 3.2.5. We adopt a precautionary approach and will only use chemical substances in our products and packaging that support our aim of designing and developing products that are safe, effective and high quality
- 3.2.6. We will test our products and services with human subjects in compliance with best practice and internationally recognised standards and regulations
- 3.2.7. We will only test our products and services with animals where this is mandated by regulatory authorities or when there is no other alternative to advancing development of a product through use of other laboratory processes or clinical data.

3.3. Specific Provisions

3.3.1. Focus of our R&D

ConvaTec is a business which aims to deliver reasonable financial returns to its shareholders. Our focus is on providing products and services that meet the needs of people who have chronic conditions, or which support surgical processes. At present, the burden of disease relevant to the areas where we provide products and services is high, and is predicted to continue to grow. We have no current plans to re-focus our R&D activities on so-called 'lifestyle' health issues.

3.3.2. Accessibility of our Products and Services

We aim to make our products and services available in as many countries as is commercially viable and, where relevant, to design product variants such that they are appropriate for a range of patient types (e.g. in relation to body shape and type). We aim to develop products that are safe, effective and high quality whilst designing them to be cost-effective to manufacture and distribute, such that pricing recognizes the value of innovation while addressing barriers relating to affordability.

3.3.3. Emerging Technologies

We adopt a precautionary approach when considering new and emerging technologies which may bring relevant benefits to product development. New technologies are only considered if they contribute positively to new products being safer, more effective or of higher quality. A number of new technologies have raised particular public concerns and our approach to these is as follows:

- **Human biological samples.** These are occasionally used for R&D purposes. Such samples could include devitalised human tissue, wound exudate, wound swabs, fecal effluent, gastrointestinal effluent or urine. Our use of these human biological samples is always minimised and performed in a safe manner, but is sometimes necessary in order to better understand the

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performance of our products and to develop better medical technology products. None of our current products contain human biological materials.

- **Human embryonic stem cells.** We have not and do not perform any research utilising human embryonic stem cells. Such research is currently not relevant nor applicable to the medical technology areas that we work within. In the future, some research may utilise stem cell technologies for the purposes of better understanding skin physiology and/or epithelial physiology, but such stem cell technologies would not be from embryonic sources, but would be mesenchymal epithelial or skin stem cells obtained from adult humans.
- **Nanotechnology.** We do not currently provide products that contain nanotechnology of any kind. We would not rule out exploring nanotechnology options from a research perspective in the future if we consider potential applications of the technology might make our products safer, more effective and of higher quality.

3.3.4. Chemical Substances

We adopt a precautionary approach when considering selection of chemical substances for inclusion in our products and packaging, and these must contribute to making our products safer, more effective and of high quality. We consider two main issues when assessing inclusion of chemical substances:

- **Regulatory or other restrictions.** Any proposed substance is assessed against possible regulatory restrictions, such as California Proposition 65 and EU regulations (e.g. REACH) to determine if it represents a Substance of Very High Concern (“SVHC”), before inclusion in the new product development process. SVHCs would only be included at concentrations well below statutory limits and only when their presence is essential for the safe and effective functioning of the product. Specific substances of concern currently used within ConvaTec devices include PVC, PVdC and phthalates. In relation to these substances we aim to:
 - avoid their use in new products
 - prioritise their substitution when products are modified
 - reduce the amount contained within existing products
 - reduce the number of products that contain them.

In general, we aim to reduce the level of chlorine-containing polymers in our products.

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- **Environmental footprint.** We use life cycle assessment and other processes, to identify and quantify the broader environmental impacts of a range of raw materials, for example, their carbon and water footprint, the level of recycled content, and product recyclability (particularly of product packaging). Where feasible, we aim to use the R&D process to systematically design in a reduction in the environmental impact of our products

3.3.5. Product Testing – Human Subjects

We are committed to conducting clinical trials an ethical way, in accordance with recognised international best practice standards¹. We only perform clinical studies in countries that are in compliance with international guidelines, and in countries where we intend to make the product available.

We are dedicated to maintaining the transparency of our clinical trial results, while respecting a company's proprietary information and a patient's personally identifiable information, as well as ensuring the safety, dignity, well-being, and legal rights of those taking part in trials. Controlled clinical investigations are submitted to an external independent ethics committee. For example, in the US, Institutional Review Boards ("IRBs") are used, and in the UK, Health Research Authority-approved ethics committees. These types of ethics committees are able to approve, modify and stop studies.

Our procedures ensure that informed consent is obtained in accordance with applicable regulations and after obtaining IRB (or similar) approval. As part of the informed consent process, participants will be provided with local grievance details as required by local guidelines.

All controlled clinical studies are registered on a recognised clinical trials data base (such as www.clinicaltrials.gov) including those studies that have been terminated early, and results are disclosed in accordance with international standards. We do not share raw data but this can be requested by the relevant independent ethics committee and the regulatory body (if appropriate).

Post-Registration studies and Post-Market Clinical Follow up ("PMCF") studies may be conducted using in-house resources or via a Clinical Research Organisation ("CRO"), dependent on size and location. If managed by an external CRO, they are audited in accordance with our procedures, including initial vetting, and ongoing monitoring. All CROs must meet ConvaTec and external regulatory requirements.

¹ The Declaration of Helsinki: World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and ISO:14155:2011: Clinical investigation of medical devices for human subjects – Good clinical practice.

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3.3.6. Product Testing – Animal Subjects

Our policy is never to use testing on animals unless this is mandated by regulatory authorities or when we cannot support a product or product development through the available laboratory and/or human clinical data. We report the number of animals involved in testing in our Corporate Responsibility Report and the numbers are relatively low when compared to many medical businesses.

When we are mandated to perform testing on animals, or when this is our only option to further product development which will advance clinical practice, we ensure that such testing is performed in accordance with Good Laboratory Practices and in accordance with Animal Care & Use requirements and guidelines, including the internationally recognised principles of Replacement, Reduction and Refinement (“the 3Rs”) to minimise the use of *in-vivo* tests.

We use only reputable contract research organisations and ensure these are audited on a regular basis.

Originated by:	Group Director, Corporate Responsibility
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