

OFFICE OF ETHICS AND COMPLIANCE

# Global Third-party Compliance Manual

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## I. Introduction

### a. Statement of Purpose

Convatec Group plc and its subsidiaries ("Convatec" or "Company") have always taken pride in pioneering trusted medical solutions to improve the lives we touch. This Global Third-Party Compliance Manual (the "Manual") explains Convatec's basic expectations of third parties engaged to provide services for or acting on behalf of Convatec ("Third Parties").

Third Parties such as suppliers, distributors, brokers, consultants, agents, and vendors are an integral part of Convatec's business and we rely on you to help build and maintain this reputation as you carry out Convatec's business. Please note that, while we ask you to review this Manual in its entirety, the General Compliance Requirements section is applicable to all third parties and the remaining sections are applicable to third parties that may interact with healthcare professionals ("HCPs")<sup>1</sup> or Government Officials<sup>2</sup> or distribute Convatec products.

Third Parties are expected to comply with this Manual and any other compliance policies Convatec may send to you from time to time. This is a condition of maintaining a business relationship with Convatec. If any of the compliance requirements in this Manual conflict with the terms and conditions in a written agreement between the Third Party and Convatec, the terms of this Manual prevail. **In the event applicable laws, medical device industry association codes of conduct, or other regulations in a particular country or region are more restrictive, or require government approval of a transaction, then you must fully comply with the more restrictive requirements.** Any questions or concerns regarding this Manual or related inquiries may be directed to Convatec's Office of Ethics and Compliance at [ethics.compliance@convatec.com](mailto:ethics.compliance@convatec.com)

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<sup>1</sup> Any individual or entity involved in the provision of health care services and/or items to patients, and/or are in a position to purchase, lease, recommend, use, arrange for, or influence the purchase or lease of, or prescribe Convatec products or services. This definition includes, but is not limited to: a licensed physician, medical resident or fellow; non-physician health care practitioner, such as a nurse; medical student; and/or an institutional educational or health care facility, entity, or organization, including an academic medical center, as well as agents and employees for each of the above individuals or entities.

An HCP is considered to be affiliated with an entity if the HCP is employed by, has staff privileges at, or otherwise has a position of influence with the entity.

<sup>2</sup> 1) Any officer or employee of a government, its armed forces, or any department, agency, or instrumentality of a government, such as a state-owned or -controlled company

2) Any person acting in an official capacity for or on behalf of that government or department, agency, or instrumentality

3) Any official, employee, or person acting on behalf of a public international organization, such as the European Union, the Red Cross, or the World Health Organization

4) Any officer or employee who is remunerated either directly or indirectly by a government, or any department, agency, or instrumentality of a government, including without limitation a Healthcare Professional

5) Any Healthcare Professional working in, on behalf of, or otherwise affiliated with a government health care facility, institution, university, or hospital

6) A candidate for a political office

7) Any relative of the persons listed above

## b. General Principles

You are required to maintain your operations in strict compliance with all applicable policies, codes, procedures, laws, regulations, ordinances, and any governmental requirements. You will be responsible for obtaining all permits or licenses required by governmental authorities necessary for your business in relation to Convatec. Policies, codes, and procedures governing our business relationship include, but are not limited to:

- This Manual;
- Your country's applicable medical device industry's code of conduct or ethics, if any, or any other applicable industry code (i.e., AdvaMed or Eucomed);
- All applicable import and export control laws;
- All applicable human rights and labour standards;
- Convatec's compliance training; and
- Other policies, procedures, and programs of Convatec, as are in effect or may be adopted by Convatec from time to time with notification to you.

In all dealings with the public and others, you will adhere to the highest standards of honesty, integrity, fair dealing, and ethical conduct.

Please ensure that all of your owners, employees, sub-distributors or contractors, agents, and representatives comply with this Manual and all applicable laws and regulations. Please distribute - or otherwise make available - this Manual and trainings to your owners, employees, sub-distributors, agents, and representatives working on Convatec matters.

## II. General compliance requirements

### a. Training

Applicable Third Parties are obligated through contract, to complete all required education and training issued by Convatec from time to time. Education and training provide Third Parties with information about rules, procedures, restrictions and best practices. Third Parties must keep records of any Convatec trainings provided to their employees or sub-Third Parties.

As you retain new or additional employees, sub-distributors, agents, and representatives that will be involved in work with or on behalf of Convatec, you must train or otherwise inform the new employee(s) or sub-Third Parties of the requirements set forth in this Manual. In some instances, Convatec may require you to notify us of any new employees or sub-Third Parties hired to work with or on behalf of Convatec.

### b. Anti-Bribery and Anti-Corruption

Convatec is committed to complying with the anti-bribery and anti-corruption laws in all countries in which it operates. In most countries, including in the United Kingdom United States, and other countries, it is illegal to offer, promise, give, receive, or request a kickback or bribe. A kickback or bribe is offering, promising, giving, receiving, or requesting “anything of value,” not only money, to obtain or reward favourable treatment in a business transaction. “Anything of value” includes, but is not limited to, fees, commissions, credits, gifts, gratuities, rebates, employment, or a service contract.

Convatec’s policy on kickbacks, bribes and all improper payments is clear—Convatec or Third Parties that work with or on behalf of Convatec will not offer, promise, give, receive, or request them, nor tolerate those that do. This prohibition is not limited to improper payments paid to - or received from - Government Officials or HCPs—it applies to all persons and entities that Third Parties may encounter while working for or acting on behalf of the Company. For this reason, all arrangements with Government Officials, HCPs or Immediate Relatives of Government Officials or HCPs, including distributors, and retailers of Convatec products, will be submitted in writing and approved by the Company.

### c. Human Rights and Labour Standards

Convatec supports and complies with the United Nations’ Universal Declaration of Human Rights and the UK Modern Slavery Act and seeks to protect the human rights and well-being of all employees within Convatec. Convatec requires its Third Parties to operate in a manner consistent with these principles and Convatec’s expectations regarding human rights, prohibition of child labour, compulsory labour or trafficked labour, non-discrimination and the general health and safety of third-party employees.

#### d. Environmental Protection

Convatec expects its Third Parties to have and maintain a system of continuous improvement to reduce the environmental impact of its operations and must fully comply with applicable environmental laws. Convatec also expects its Third Parties to ensure its products do not contain restricted or prohibited materials.

#### e. Reporting and Product Complaints

You must immediately notify Convatec in writing of any violations or suspected violations of any law, regulation, government health care program requirement, Convatec's Global Anti-Corruption and Bribery Policy, or your or Convatec's policies or procedures relating to legal or regulatory compliance matters. Notification may be made through the Compliance Helpline at <https://Convatec.ethicspoint.com/> or via email at [ethics.compliance@Convatec.com](mailto:ethics.compliance@Convatec.com).

To the extent allowed by applicable law, your reports will be treated as confidential and be used only for the purpose of addressing the specific problem reported.

You must also notify Convatec within 24 hours of any product complaint that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any device or product of Convatec or any subsidiary by contacting the following email address: [wwps.complaints@convatec.com](mailto:wwps.complaints@convatec.com). For product complaints that are generated from inside the United States, please call Convatec's Customer Interaction Center at 1-800-422-8811.

#### f. Conflicts of Interest

Convatec expects Third Parties to make sound business decisions involving Convatec products based on Convatec's best interests, using care to avoid even the appearance of a conflict of interest. Third Parties should avoid situations where they are in a position to derive personal benefit from actions or decisions made in their capacity acting on Convatec's behalf or through a relationship with an Immediate Relative<sup>3</sup>.

In certain situations, avoiding a conflict of interest may not always be possible. Be aware that facilitating or supporting a conflict of interest will likely violate Convatec policies and procedures and may trigger some form of corrective action by Convatec or other legal authorities. Therefore, transparency, in the form of disclosure, is critical to help protect the integrity and reputation of Convatec and Third Parties.

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<sup>3</sup> An employee's husband, wife, birth or adoptive parent, child or sibling, stepparent, stepchild, stepsibling, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent, grandchild, spouses of grandparent or grandchild, aunt, uncle, cousin, domestic partner and fiancée.

Third Parties must be careful to avoid any actual or perceived undue influence, therefore, Convatec prohibits Third Parties to solicit, accept, or permit any Immediate Relative to solicit or accept any gifts, gratuities or other favours from any customer, supplier, payer, competitor or other person who does or seeks to do business with Convatec unless what is offered is of nominal value (e.g., less than 25 USD or country equivalent) and consistent with applicable local laws, regulations and industry codes. Convatec also expects Third Parties to disclose any potential or actual conflicts of interest or if you become aware of any Convatec employee that may have an ownership or other financial interest in your company or its dealings with Convatec.

#### **g. Extension of Relation to Further Parties (i.e., sub-distributors or subcontractors)**

Third Parties are generally allowed to appoint further parties (i.e., sub-distributor or subcontractor) for all or a portion of the services to be provided to or on behalf of Convatec. Convatec expects Third Parties to obtain approval from Convatec before appointing any further parties and provide training on this Manual and Convatec's expectations.

#### **h. Books and Records**

Convatec expects Third Parties to maintain accurate books and records involving transactions related to services provided to or on behalf of Convatec. Third Parties must permit Convatec's internal or external auditors access following reasonable prior written notice, during Third-Party's normal business hours, no more than once in a twelve-month period and at Convatec's expense unless the audit is being performed for cause to any relevant books, documents, papers, and records involving transactions related to Convatec or any other transactions that are deemed relevant in Convatec's discretion, subject to applicable data privacy and confidentiality laws. Third Parties should ensure that their books and records are accurate in all transactions related to their business relationship with Convatec.

### III. Specific compliance requirements for third parties that distribute Convatec products

#### a. Gray Market Reduction

Gray market sales are sales through unofficial or unauthorized channels. Gray market sales can expose Convatec and distributors to liability because: (1) products intended for sale in one country or region may not comply with all applicable regulations, particularly labeling requirements, in another country or region; (2) gray market products are subject to damage and tampering; and (3) gray market sales can result in violations of economic sanctions or export control laws.

**As consistent with local law and your written agreement with us, distributors may not sell any Convatec products in any country or region besides the one for which the products are intended.** Distributors should not provide Convatec products to sub-distributors or customers who cannot adequately describe where the products will be used or who place unusually large orders without explanation. Products with improper labels or other indications of gray market sales should be reported to Convatec's Office of Ethics and Compliance.

#### b. Books and Records

Convatec expects its distributors take special care of discounts, rebates, credits, and similar transactions. Convatec encourages distributors to verify that there is a legitimate, commercially reasonable, and transparent reason for granting a customer a discount, rebate, or credit. Distributors should retain written documentation memorializing the specific terms and conditions of any discount, rebate, or credit and the means by which any such price reduction will be earned or applied (for example, as a purchase-specific volume-based discount reflected in the invoice price, a volume-based rebate to the customer based on purchases made over time, or a volume-based credit earned on purchases made).

## IV. Specific compliance requirements for third parties that may interact with hcps or government officials

### a. Meals, Hospitality, and Travel

From time to time, a Third Party may be in the position of providing hospitality to an HCP or Government Official. This could include a one-on-one business breakfast, lunch or dinner or a larger conference with many attendees. Such occasions should always be professional in nature and principally concern the presentation of product education, promotional material, business information, or other business needs.

As stated earlier in this Manual, if applicable laws, codes of conduct, or other regulations in a particular country or region are more restrictive on this subject, or require government approval or disclosure of the interaction, you must then fully comply with the more restrictive requirements.

Hospitality may only take the form of meals, receptions, or similar events within a business context. No entertainment or similar activities are permitted (e.g., theater, sporting events, museums, golfing, skiing, massages, dinner cruises, hunting, leisure or vacation trips, and city tours).

Where Convatec will be paying (in whole or in part) for an HCP or Government Official's travel or accommodations, you may only make such arrangements **after receiving approval** from Convatec's Office of Ethics and Compliance. If Convatec will not be paying for the travel or accommodations (i.e., you will be paying for it yourself), you need **NOT** obtain Convatec's approval in advance, though the arrangements may be the subject of periodic monitoring and auditing by Convatec for compliance with this Manual.

Any meals, hospitality, business travel, or lodging must meet all of the following criteria (for more detail, consult Convatec's Code of Ethics and Business Conduct):

- It is incidental to a bona fide business purpose and each person attending must have a legitimate business need (i.e., you cannot provide a meal for the entire staff of an office when all the staff do not have a business purpose to participate in the meeting/meal. Similarly, spouses, guests, and immediate family members cannot participate in meetings/meals without a business justification);  
It is modest, reasonable, and infrequent;
- It is not provided as an incentive or reward for the purchase, prescription, use, order, or recommendation of Convatec's products;  
It does not create the appearance of impropriety;
- For meals and hospitality events, a Third-Party employee is present for the entire duration of the event; for travel, the duration of the trip does not include days beyond which the HCPs are engaged in the Third-Party business-related activities; and,

- The amount spent is in line with Convatec-issued guidance on how much can be spent on meals, hospitality, and travel in your particular region.

## b. Gifts

Third-Parties shall not provide directly or indirectly gifts or other transfers of value that would ordinarily be purchased by the HCP or Government Official in order to perform their job responsibilities, job function, or involvement or support with patrons, customers or patients.

For example: Third-Parties should not provide business supplies or other similar items to HCPs or Government Officials. The provision of these items would constitute a prohibited gift under this Manual.

### Restricted gift examples:

- Holiday or thank you gifts, gifts for significant life events (e.g., childbirth, birthday, wedding, anniversary, graduation, new job, funeral, professional recognition).  
Candy, gift baskets, gift cards, cash or cash equivalents, electronics,
- entertainment or sporting event tickets, cakes, alcohol, meals, or meal vouchers.

Educational items (e.g., medical textbooks or anatomical models) do not fall under the gift restrictions outlined in this section.

### Restricted entertainment examples:

- Entertainment or recreational event or activity for HCPs, or Government Officials such as: theater, sporting events, museums, golfing, skiing, massages, dinner cruises, hunting, leisure or vacation trips, and city tours.

## c. Consulting & Speaking Arrangements

At times, you may wish to enter into service agreements with HCPs for product development services, evaluation services, research services related to Convatec products or speaking services. Arrangements for such services must not be used to induce or reward the purchase, use, or recommendation of Convatec products. If you arrange any HCP services in relation to Convatec products, please document the services and ensure that they have a bona fide business purpose. You may contact Convatec to help provide appropriate guidelines for such contractual arrangements.

If Convatec is sponsoring or co-sponsoring the agreement with you, you must obtain approval from Convatec prior to entering into the agreement. If Convatec will not be sponsoring the agreement (i.e., you will be paying for it yourself), you need not obtain Convatec's approval in advance, though the agreement may be the subject of periodic monitoring and auditing by Convatec.

From time to time, Convatec may request that you identify an HCP with specific expertise for a potential speaking or consulting arrangement

directly with Convatec due to your knowledge of HCPs within your territory. Under no circumstances should you consider sales or potential sales in identifying an HCP with qualifications and expertise. You must not contact or make any commitments to an HCP regarding Convatec's request; all contacts regarding such arrangements will come from Convatec.

#### d. Educational Grants, Sponsorships, & Charitable Donations

Educational grants, sponsorships and charitable donations that are made on behalf of Convatec must have a bona fide educational, business, or charitable purpose and may not be promised or given to induce or reward the purchase, use, or recommendation of Convatec products. All such expenditures should be accurately recorded in your books and records. If Convatec will be paying for the grant, sponsorship, or donation (in full or in part), the expense must be preapproved by Convatec. If Convatec will not be paying for the arrangement (i.e., you will be paying for it yourself), you need not obtain Convatec's approval in advance, though the arrangement may be the subject of periodic monitoring and auditing by Convatec. Relatedly, you should not commit to making any grants, sponsorships, or donations on Convatec's behalf without Convatec's permission.

#### e. Samples

Sample, evaluation and demonstration products may be provided at no charge to HCPs and patients to facilitate the safe and effective use of Convatec products and technologies in a manner that is consistent with the indication for use in the product labeling, and to increase awareness of a product's technology and use. As a condition of providing product samples, HCPs and other third-party recipients are prohibited from re-selling or seeking reimbursement for the sample product. Products used for demonstration purposes should be properly disposed of after a demonstration, unless the product maintains its integrity for further use or demonstration. The number of product samples given to an individual HCP or patient must be appropriate for the evaluation or demonstration activity only.

Convatec products must never be given as a way to inappropriately gain or obtain a business advantage or improperly arrange or influence the purchase, lease, recommendation, use, or prescription of Convatec products and services, and may not be provided as a form of payment for services rendered.

Furthermore, Convatec prohibits the distribution of samples for HCP personal use, pricing concessions, expired exchanges, competitive swap-outs, replacement or consignment, tenders, research, charitable donations, indigent care and for externally sponsored education and training events.

Third Parties are required to track sample distribution in accordance with local laws, regulations, and industry codes and report this information back to the appropriate business contact at Convatec.

<b>Company</b>	
<b>Name (Print Name)</b>	
<b>Title</b>	
<b>Date (mm/dd/yyyy)</b>	
<b>Signature</b>	
<i>(Signed by its duly authorised representative)</i>	