

Channel Partners Compliance Guidelines

Global programs
Channel compliance

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Introduction

As a global healthcare products company, MiniMed is committed to maintaining the highest standards of integrity in all business practices. Integrity is, and always will be, a fundamental part of MiniMed's culture.

The present guide sets MiniMed's expectations and standards for doing business and applies to all authorized agents, distributors and dealers (distributors) promoting and selling MiniMed products. MiniMed expects its distributors to maintain the highest standards of business ethics and act in full compliance with its Distributor Code of Conduct and all applicable laws and regulations.

As our partner in serving the healthcare needs of our customers, we are confident you share our compliance and integrity goals. Your support of this program and continued collaboration is appreciated. For additional information regarding this expectations and requirements, please contact your MiniMed Compliance representative.

To help our channel partners meet our compliance requirements, we are providing several reference documents, tools and templates for their use that can be found [here](#).

Business principles

- To comply with the laws of the countries where it does business, MiniMed strictly prohibits payment of cash to healthcare professionals (HCPs) and government officials. No payment in cash or in kind may be made on MiniMed's behalf without approval by the MiniMed Legal Department and only if in compliance with the law and MiniMed's policies.
- Also, It is required that all transactions and expenses incurred on behalf of MiniMed be accurately recorded and maintained in the Distributor's books, records and accounts in a timely manner and in reasonable detail in accordance with generally accepted accounting principles. False, misleading, incomplete, duplicated, inaccurate or artificial entries in the Distributor's books and records are strictly prohibited.
- MiniMed distributors are required to comply with all applicable global trade laws, including laws governing the import and export of products, sanctions and prohibitions on dealing with restricted parties and sanctioned countries, and U.S. anti-boycott laws. For further information or if you have questions, please contact your MiniMed Legal & Compliance representative.



Acceptable

- Clearly identify expense items, including description, amount and purpose.
- Retain copies of invoices and original detailed receipts.
- Keep records of samples, free products and discounts.
- Retain copies of written approvals from MiniMed (where applicable) - and agreements with sub- distributors and agents.
- Retain copies of justifications and reasons for the expense.
- Include full names of all participating individuals and the venue for all meals and hospitality.
- Require event planners to keep and preserve their records relating to customer interactions.
- Retain copies acknowledging receipt of grants, product loans, and donations to institutions.
- Retain copies of agreements, proof of activities performed, and payments made.
- Make records available to MiniMed upon reasonable request. and fully cooperate in allowing MiniMed (or its designated representative) to inspect such records and/or facilities.



Not acceptable

- Payments for unknown purposes. False payment records.
- Vague and inaccurate records.
- Destruction of documents and records prior to the legally required retention period.
- Failure to report any irregularity in record keeping.
- Misrepresentation of customers or employee names to justify amounts.
- Underestimate the importance of complete and updated supporting documentation and the relevant auditing and controls.

Anything of value

- We do not give anything of value to any customer, government official or any other third party for the purpose of obtaining any improper business advantage.
- This action, or even contemplation of such an action, may constitute a bribe , but also violation of other laws, like procurement law, etc.

Acceptable

(Within locally defined limits and in accordance with national and local laws, regulations and industry and professional codes of conduct).

- Free pens, hats, t-shirts with company logo during an educational event.
- Reasonable airfare, hotel and transportation for MiniMed training events.
- Occasional meals and beverages at business meetings when the cost is modest, the primary purpose is business, and the setting is conducive to the business purpose.
- Occasional items that have a genuine educational function or benefit patients.

Not acceptable

- Offer free items if costs are more than modest, or if the items are not customary or reasonable.
- Pay for entertainment.
- Pay for the meal, travel and/or lodging expenses of a customer's or government official's guest or spouse or for any person who doesn't have a bona fide professional interest in the information being shared at the meeting.
- Offer or give anything of value as a condition to use MiniMed products.
- Pay an honorarium fee unless it is an appropriate fair market value for valuable services provided.

Acceptable



A government official is any officer, employee or person acting on behalf of a non-U.S. government department, entity or agency or public international organization.

Of specific importance to MiniMed may also be considered hospital employees government officials because they are employed by public hospitals or public entities.

The term government official includes:

- Doctors, nurses, pharmacists, or contracting officers employed by government owned or controlled hospitals;
- Any employees of any government agency or department;
- Any candidate, elected, appointed, or career official;
- Activities not allowed by anti-corruption laws might also extend to the children, spouse or other close relatives of a government official.

Not acceptable



MiniMed expects its Distributors to identify and prevent situations where there is an actual conflict of interest, or even the appearance of a conflict of interest. It is important that business decisions are not improperly influenced by personal interests or relationships. This applies also to the Distributor's interactions with MiniMed employees.

It is important to consider the following concepts when talking of conflict of interest:

- **Personal interest:** The employee or employee's close relative has ownership (i.e., holds a financial interest) in a distributor.
- **Close Relative** means spouse, child, parent, sibling etc.... or any individual with whom an employee has a close personal relationship that may create an actual or implied conflict of interest.
- **Close Personal Relationships** may include, but are not limited to, domestic partners, common-law relationships, legal guardianships, dating relationships, or employees who are in a co-habitation relationship.

Meals and refreshments

- It is permissible to provide occasional and modest meals and refreshments in connection with MiniMed related business meetings held with one or more distributor representatives and a customer.
- MiniMed has internal guidelines on the costs for such meals and refreshments for respective countries.
- Please contact your local MiniMed Business, Legal or Channel Management Compliance representative who will assist you with these details.
- It is never appropriate to give meals to customers as a condition for past, current or future sales.

Acceptable

You may occasionally pay for moderately valued meals if you meet the following rules:

- The primary purpose must be a legitimate business reason.
- The meal is incidental to the business interaction.
- Only pay for attendees who have an appropriate business need to attend the meeting.
- Attend in-person as a representative of the distributor.
- The setting is conducive to the nature of the discussion.
- You maintain accurate records, identified as “Meals and Refreshments,” with copies of receipts, names of individuals attending, reasons and topics of discussion; and Stay within your policy’s, MiniMed’s or industry associations or legal local requirements defined spending limits.

Not acceptable

Incur in a payment for the following cases:

- Expensive meals.
- Meals more than occasionally.
- Meals that are purely social interactions.
- Meal costs incurred by family members, friends or other guests accompanying a customer.
- Meals where no one representing the company attended.
- Host business meetings in venues not appropriate for the nature of the discussion.
- Add names to expense reports in order to stay within spending limits.

Scenario

While dining with Doctor A and a group of HCPs during the recent Scientific Society meeting you observe that several spouses have joined the doctors at the dinner table. What do you do?



You privately approach each of the HCPs who have spouses present and remind them that you're not permitted to pay for the spouses' meal. You continue with the dinner and pay for only the HCP meals.



You pay for the meals of spouses as well, but you alter your records to show that you paid for doctors that were not present at this dinner.

Medical conferences and professional meetings sponsored by others

MiniMed Distributors may provide lump sum sponsorships to accredited conference organizers for bona fide, independent, educational, scientific or policy-making conferences that promote scientific knowledge, medical advancement and/or the delivery of effective healthcare. Such sponsorships may not be directed to the attendance of a specific individual at the request or direction of the Distributor. MiniMed Distributors may also not directly support healthcare professionals to attend third-party conferences or other similar events on MiniMed's behalf unless the healthcare professional is speaking on behalf of MiniMed.

Acceptable

- Training program sponsored by MiniMed in our training centers or other venues previously approved.
- Follow any country specific legislation or industry Code of Conduct guidelines.
- Maintain independency in the selection of the participants and the organization of the agenda of such event.
- Maintain accurate records with copies of receipts, name of event, justification (that should be a legitimate business reason), and topics of discussion.
- Follow applicable disclosure requirements.

Not acceptable

- Pay the expenses of a health care professional to a third-party event.
- Select or influence in the decision for the final attendants to the event with the purpose of compensating past, present or future business.
- Divert expenses, donations u other kind of support to directly support a healthcare professional to attend a third-party event.
- Compensate the doctors and nurses for the days that they will not work and offer them entertainment.

Scenario

You will offer an educational grant to a medical association that organizes a congress in the US. You have some influence in selecting the HCP that may participate so if you invite the HCP you have working with, they will consider this invitation as an acknowledgement for the big purchases they did last year.

Since the HCPs will not be working during the congress, it will be good to give them also an economic compensation.



According to the MiniMed policy, it is not allowed to sponsor attendance of HCPs to third party events (events not organized by MiniMed). However, MiniMed might sponsor the events if the organizer select the participants. MiniMed cannot select or influence in the decision for the final attendants to the event. Paying a compensation to an HCP to for the time of attendance to an event is neither allowed.



You talk with the medical association to appoint the doctors and nurses you would like to attend and select certain transactions to offer the compensation as business expenses so it could seem appropriate.

Hiring physicians as consultants, trainer or proctors

Where there is a legitimate need for a physician to provide services, the following is required:

Acceptable

- Document the specific, legitimate business need and describe the specific services involved.
- Use clear HCP Selection Criteria based on qualification, expertise, and ability to address the identified purpose.
- Remunerate at fair market value.
- Get written agreement signed prior to providing the services.
- Follow local law and industry associations transparency requirements regarding notification/sign-off requirements by the HCP's employer.
- Get fully documented deliverables before paying.

Not acceptable

- Agree on a general services or services on an as-needed basis with payment prior to receipt of services (retainer agreements).
- Use consulting agreement to promote off label uses.
- Pay a Healthcare Professional as an unlawful inducement to purchase, lease, recommend, use, arrange for the purchase/ lease of, or prescription of MiniMed products.
- Pay to speak at a co-marketing event at which the consultant promotes his or her own practice.
- Pay for the appearance at or preparation for a third-party conference presentation or to act as a conference faculty.
- Make any commitment to pay based on the volume of consultant's past, present, or anticipated future business.

Scenario

Doctor A is a Key Opinion Leader (KOL) in cutting edge diabetes technology (e.g., CGM systems, insulin pumps, infusion sets, automated insulin delivery algorithms). You are exploring a new design update for a core MiniMed diabetes product, and you need advice and feedback from KOLs to help assess the safety, usability, and clinical considerations of the design. You set up an Advisory Board and invite Doctor A to participate. Doctor A asks for a flat fee agreement with a specific fixed amount that covers all future participation on the board, paid as “guaranteed” compensation for any future services.



The compensation may consist of an hourly/daily fee per each Advisory Board attendance and may be paid after each service is performed based on relevant documentation and written report documenting the activities were really performed. See MiniMed’s Fair Market Value guidance for additional information.



Retainer agreements that include flat fees independent from the services performed.

Physicians compensation, Fair Market Value

- Fair Market Value (FMV) means the value of any payment or benefit paid in kind as fair and proper remuneration to a HCP in exchange of his/her services, rights provided, or work performed, taking into consideration commercially legitimate factors that can be evidenced. Where there is a legitimate need a customer's services, and these services have value to MiniMed, then the compensation to be paid to the customer must be no more than FMV.
- If you see a need for physician services that have a value to MiniMed market development in your territory, such as training and education, please consult in advance with your local MiniMed Business, Legal or Channel Management Compliance representative for information about specific country laws and regulations that might apply; and calculation of FMV.

Acceptable

- Compensation fee must be clearly outlined in the agreement.
- Payment must be in-line with duly dated and signed agreement to be in-place before the start of activities.
- Preferably, make payment only by bank transfer to a bank account in the country of practice of the physician or if locally required to the medical institution's bank account as notified by the HCP's employer.
- Keep detailed records with copies of executed consulting agreement, methods of FMV calculations, detailed invoices from the customer, evidence of bank transfer, evidence of services provided and how they were of use to Distributor.

Not acceptable

- Make payments with cash or cash equivalents such as gift certificates.
- Make payments via credit card or checks and submit a claim as business expenses.
- Compensate a physician for time spent rendering professional services if the physician is billing the patient or a third party (for example a national healthcare program or a private health insurer) for the same services.

Scenario

Your business participates in the organization of an Advisory Board with Doctor A and other experienced physicians from 10 different countries (including US, India, Germany, Turkey, Portugal, Kazakhstan, etc.) and as all physicians will be meeting several times a year to consult on a given topic, you would like to ensure that all physicians performing the similar duties are paid an equitable fee.



Each HCP's fee must be based on HCP's experience and the FMV of their country of practice.



Agree/commit to equally compensate HCPs for duties performed under an Advisory Board without applying the FMV process.

Gifts

Gifts should be given only occasionally and must have a genuine educational function, be of use in the practice of medicine, or benefit patients (for example medical textbooks, anatomical models). They must be modest in value and given in accordance with the national and local laws, regulations, and industry and professional codes of conduct of the country where the customer is located. Gifts may never be given for the purpose of improperly influencing future purchases or rewarding past ones. MiniMed has internal guidelines on the costs for such gifts and you may refer to these to establish your own. Please feel free to contact your local MiniMed Business, Legal or Channel Management Compliance representative who will assist you on those matters.

Acceptable

- May be given only occasionally.
- Items must have a genuine educational function or benefit patients, such as textbooks or anatomical models.
- Must be modest in value.
- Must be in accordance with national and local laws, regulations and industry and professional codes of conduct.
- Document the description, amount and purpose of any such items given to customers and record them in your financial books as "Gifts to Customer," including the names of the recipients.

Not acceptable

- Gifts in cash.
- Valuable personal items, for example, clothing, perfume, iPads, iPhones, tickets, etc.
- Give items of more than a modest value.
- Gifts given as a reward for a customer's business or to get more business, even if they might be modest in value.
- Give gifts to a customer's spouse, children or friends.

Scenario

One of your company representatives buys an iPad which is meant as a gift for Doctor A. The item is labeled as "Office Supplies" in the financial books.



You can refer to regulations or codes of conduct of the country where the HCP is licensed to practice to identify an appropriate gift (Note: an iPad is not permitted) and train your staff on categorizing it correctly in the financial books. If you have a doubt on how to proceed contact your MiniMed Business, Legal or Channel Management Compliance representative.



Not to inform your representative that an iPad is not an appropriate gift item. Consider that gift giving for personal use and its improper classification in the financial books is a serious violation of many anti-corruption laws.

Grants and donations

Monetary and product donations may be given for appropriate scientific, educational, health care, or other charitable purposes. Donations are limited to certain institutions or organizations and are never allowed for individuals who are Customers. The donation or grant may not be connected to the purchase of MiniMed products and cannot be made for the purpose of influencing the judgment of an individual Customer related to the institution. Please feel free to contact your local MiniMed Business, Legal or Channel Management Compliance representative person who will be available to assist you for specific guidance.

Acceptable

- Must only be intended for a charitable or other philanthropic purpose.
- Must only support bona fide educational or research programs.
- Maintain appropriate documentation regarding the written solicitation of the donation, the signed written agreement, and acknowledgement of receipt.
- Must generally be directed at a health care institution or recognized charity/non-profit association and NOT an individual.
- Document the description, amount and purpose of any such grants or donations and record them in the books as "Grants/Donations" including the names and addresses of the receiving institutions.

Not acceptable

- Grants or donations with any relationship to any value of purchases made by the recipient.
- Grants or donations for the purpose of getting business from the recipients or rewarding past purchases.
- Grants or donations to an individual.
- Grants or donations outside the award tender criteria and not linked to the given procurement.
- Grants or donations in exchange for undue influences.

Scenario

Doctor A's Institution sends your Company a written request for a scholarship grant. You send a note to the business manager handling the transaction: "Have you consulted our attorneys on the legality of this scholarship request? I support it, but it is important that none of this be tied to purchase volumes. Isn't this the account that we recently lost to our competitor?"



Financial support cannot be tied to an institution's purchases, whether current, past or potential future purchases.



Offer financial support in order to win back a customer account.

Use of travel agents or event planners

The use of travel agents or event planners is generally allowed, subject to some conditions and measures to mitigate any compliance risks relating to the selection of the vendor and the correct booking of the expenses. It is never appropriate for travel agents or event planners to provide items of value to reward past business or improperly encourage future business. Please contact your local MiniMed Business, Legal or Channel Management Compliance representative who will be available to assist you.

Acceptable

- Use of travel agents must be reviewed and approved by MiniMed.
- May be done if permitted by local rules and industry codes.
- Travel agents or event planners must follow the substance of MiniMed's Distributors/Agents Anti-Corruption Compliance Policy.
- Distributor or agent must require the event planner to maintain detailed accounting and expense records for each individual event or set of travel arrangements undertaken on behalf of the distributor.
- Make all records available for inspection promptly upon request from distributor/agent or MiniMed.
- Only provide travel for customers to approved events.

Not acceptable

- Allow event planners to hide items.
- Allow event planners to misuse accounts.
- Use event planners in which public officials have a vested interest.
- Use event planners recommended or solicited by customers.
- Allow event planners to create or provide false records.
- Use event planners to do anything that you cannot do under the MiniMed Code of Conduct. For example, pay for spouses or friends of customers or give inappropriate items or gifts.

Scenario

You request the services of an event planner to organize Doctor A's attendance at the Scientific Society meeting on behalf of MiniMed. The event planner boasts that doctors who utilize their services are treated so well that they always return from the events eager to increase use of the products from the companies who sponsor their travel.



After the travel agent has been reviewed and approved by MiniMed, you remind the travel agent that they also must follow the substance of MiniMed's compliance guidelines, they must keep complete and thorough records of all expenses, and that they must not use any portion of the travel to retain or add new business on behalf of MiniMed.



You tell the travel agent you're glad to hear they are so good because you anticipate you will not achieve the sales quotas stipulated in your contract with MiniMed and you could benefit from anything the travel agent can do on your behalf.

Samples and free products

With proper documentation and in compliance with applicable legal and regulatory requirements and in accordance to your internal policies and guidelines for pricing and rebates, it is possible to provide products to Customers at a reduced cost or no charge, including in these situations: demonstration products/samples, products or other allowances provided under a MiniMed warranty, products provided at discounted pricing, products sold under rebate programs, pricing programs that include multiple products, and no-charge evaluation products.

Acceptable

- When you provide samples and free products for evaluation purposes, do so in limited numbers and in accordance with local laws and industry codes.
- Give notice that such products have been provided to the customer on an official invoice, written agreement or other appropriate method.
- Keep detailed records of samples and free products provided to customers properly recorded as "Samples and Free Products," with copies of official invoices, or written agreements or other written record, quantities provided to customer, delivery records including names and addresses of the receiving customers.
- Make all records available for inspection promptly upon request by MiniMed.
- All warranties, discounts, rebates and other pricing programs must be done in accordance with applicable rules and laws. Check with your MiniMed Business/Compliance contact for more information.

Not acceptable

- Provide samples or free products without proper documentation.
- Give samples and free products as a condition for past, current or future sales.
- Provide samples for personal benefit to any Healthcare professional or government official.

Scenario

Doctor A requests support from you through product samples. You received information that Doctor A threatened to stop ordering MiniMed products if you do not provide the samples.



The Company is committed to continuing collaboration with HCPs and their institutions and will review and assess each request in line with its guidelines and before making any commitments. The product should not be condition to sell or be understood as consideration for services.



Offer or give samples or free products to an HCP with an explicit or implicit requirement to use or purchase future and undefined products, or as a reward for prior use or purchase of products.

Clinical studies

Our distributors and agents might conduct, fund, sponsor or support any type of clinical trial and/or study involving MiniMed products with prior written approval by MiniMed.

Acceptable

Obtain prior written approval from MiniMed.

Not acceptable

Conduct, fund, sponsor or support and provide free devices of any type for clinical trial and/or study involving MiniMed products, without prior written approval by MiniMed.

Scenario

Doctor A would like to perform a research project involving MiniMed devices and asks you to provide financial support and free devices for carrying out the study.



You submit the request and any relevant documentation to MiniMed asking to evaluate it and to start the process to properly assess the project.



Agree to provide the support without obtaining written approval from MiniMed.

Tenders

Tenders represent in many countries the typical procurement procedure, which is governed by local laws and regulations that need to be carefully observed. To bid in a tender, a distributor may need a letter of representation from MiniMed. It is a prerequisite for issuing such a letter that the distributor has a current, written and valid contract with MiniMed.

Acceptable

- Follow all requirements of public tender laws.
- Provide only the generally available and official information about MiniMed's products and services.
- Respect confidentiality and maintain transparency.

Not acceptable

- Agree or collude with Tender Authority, healthcare providers or sub-distributors on the set up/structure of public procurement contracts.
- Assist the Tender Authority or healthcare providers with drafting or reviewing of tender specifications.
- Offer to provide additional "free" goods or services that are not reflected in a public tender offer or other commercial contracts meant to influence the tender result.
- Misuse congress attendance, training & education, etc. to inappropriately influence a decision-maker in a tender.
- Provide unofficial marketing and promotional documents.
- Violate contractual terms such as confidentiality regarding prices or other commercial terms.
- Procure or facilitate information which may lead to an unfair competitive advantage.

Scenario

Before launching a tender, Doctor A (representative of the Tender Authority) sends a draft specification list and asks you to review and supplement the specification for the MiniMed products. What do you do?



Return the draft specification and decline to comment, stating that it is the Tender Authority's sole responsibility to draft tender specifications. Also, state that you now may have gained a competitive advantage, which should be counterbalanced by the Tender Authority (e.g., by providing similar information to other bidders or completely revising the specifications).



Assist in reviewing and editing the tender specifications since this will give you an advantage over your competitors.

Sub-distributors

According to the agreement with MiniMed, we expect our Distributors to notify us of any use, or intention to use, of sub-distributors or other similar third-party contractors, to disclose their names, as well as to describe how the Distributor intends to use such sub-distributors or other similar third-party contractors to distribute and market MiniMed products.

Acceptable

- Notify MiniMed about the use of sub-distributors or other similar third-party contractors.
- Screen your partners.
- Have written agreements that include compliance and audit clauses.
- Ensure they accept and observe all compliance obligations in the same manner and standard as your agreement with MiniMed.
- You may share the MiniMed Code of Conduct and Anti- Corruption Policy.

Not acceptable

- Hire sub-distributors or other similar third-party contractors in which public officials have a vested interest to gain favors of that government official.
- Hire sub-distributors or other similar third-party contractors only because they are recommended by customers.
- Ignore a situation of risk with such parties (red flag)
- Allow such parties to act unethically or to violate the MiniMed Code of Conduct, Anti-Corruption Policy or local laws and regulations.

Scenario

Several weeks ago, a new company called you to propose being your partner in the distribution of MiniMed products. You think this is an opportunity worth exploring and you conduct a due diligence of that company which does not reveal any red flags. What else should you do?



Notify MiniMed about your intention to use this sub-distributor and the screening you have conducted. You want also to make sure that a written agreement is in place that includes compliance and audit clauses like your agreement with MiniMed, as well as provide compliance training and documenting such training.



Ignore informing MiniMed and the conclusion of a written agreement with this party now that the due diligence results came back clean

Anti-competitive practices

Anti-competitive practices are business practices that prevent or reduce competition in a market. These can include price fixing, bid-rigging, allocation of markets or customers, exchange of commercially sensitive information with competitors, resale price maintenance, resale restrictions, exclusive purchasing or supply obligations.

Acceptable

- Collaborate with your customers (for example sub-distributors) at arm's length. N.B. Your sub-distributor is an independent buyer and must conduct and decide upon all its commercial activities (such as participation in tenders, sales to customers, prices to offer) independently.
- You can provide a non-binding price recommendation to your sub-distributors provided: no pressure is exercised, and no incentive is offered to enforce the price recommendation.
- Make unassisted and independent decisions regarding whether to participate or not in tenders without communicating them to your sub-distributors or other competitors.

Not acceptable

- Enter into potentially anti-competitive agreements with competitors, customers or suppliers.
- Exchange commercially sensitive information with competitors such as prices, margin, commercial terms, trading volumes, production costs, sales plans and business strategy.
- Exercise any control or influence over customers', sub-distributors' business activities in the market or impose restrictions such as resale price maintenance, exclusive purchasing/supply obligations, restrictions of the territory or customers, export bans, online sales restrictions.
- Abusing a potentially dominant position on the market (exclusivity provisions, fidelity rebates, discrimination).

Scenario

A public tender is about to be issued and you decide to set up a meeting with your sub-distributor in order to discuss who will participate in the tender and the preparation of the bid related to MiniMed products. Which approach is the correct one?



You know that from a competition law perspective, your sub distributor is your competitor. Hence, any discussion, communication or arrangements between you and your sub- distributor about the public tender is prohibited. Each party should decide completely independently from one another whether to participate or not in that tender, incl. the preparation of the bid, the price and commercial conditions to offer etc.



Decide to coordinate with your sub-distributor who will participate and under what conditions since you both don't have a dominant position in the market and the offer you can provide will be beneficial to end users.