



COMPLIANCE MANUAL FOR 3DIEMME SCREENED BUSINESS PARTNERS OUTSIDE THE U.S.

2022

3DIEMME

Compliance Manual for Screened Business Partners of 3Diemme outside of the US (OUS Manual)



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Our mission at 3Diemme is to improve the quality of life for people around the world. We commit to conduct business ethically as a central part of our culture. In order to achieve our mission and uphold our legacy, we only do business with third parties who demonstrate our same level of commitment to ethical business practices. We depend on third parties, like you, to conduct business on our behalf all over the world, and we have a due diligence screening process in place to ensure our third parties have a history of operating in accordance with all applicable laws, regulations, and industry codes. Auditing and monitoring activities, along with periodic due diligence renewals and annual check-ins, are a key part of our compliance program to ensure continued commitment to ethical business practices by our third parties.

All the guidelines and requirements in this OUS Manual shall be understood at all times as referring to the Business Partner's activities in relation to 3Diemme business and products or services, and can never require disclosure of your company's confidential information or business affairs outside of the business relationship with 3Diemme.

Compliance Training

All employees of your organization who are involved in 3Diemme business should plan to complete and/or attend compliance trainings offered by 3Diemme or by 3Diemme's group ultimate holder, or its affiliates, whether electronically or in person. Attendees may include your Finance, Sales and Marketing managers and other administrative staff involved in 3Diemme business, such as logistics.

Please remember that it is your responsibility to train your employees and agents who cannot attend the 3Diemme compliance training, and you should keep attendance records of these trainings. Also remember the compliance training requirements also applies for your sub-distributors, including trainings records. Please maintain training records as auditable records.

The training will help you to understand the compliance requirements of 3Diemme by going through scenarios and case studies and simple explanations. It will also review lessons learned regarding audit findings and explain how rules are applied correctly to satisfy 3Diemme's compliance requirements. Wherever possible, trainings are conducted in local language.

The scope of the trainings will include ZimVie's Code of Business Conduct and Ethics, anti-corruption and anti-bribery requirements, and the contents of the OUS Manual.

Appointment of Sub-Distributors

In some countries it is common practice for distributors to appoint sub-distributors. This may help the business operate, but at the same time can also increase the risk for 3Diemme. 3Diemme and you are both responsible and liable for any misconduct of a sub-distributor. Sub-distributors are expected to follow the same ethical standards that are required of you for all 3Diemme business. Therefore, it is important that you follow the steps below when you want to engage a sub-distributor:

1. **Information:** Inform your Business Sponsor that you want to engage a sub-distributor. This needs to be done prior to any engagement of a sub-distributor.
2. **Due Diligence:** In certain instances, 3Diemme may require Due Diligence on your sub-distributors and/or audit their books and records for 3Diemme products / business.



3. **Approval/Contract Amendment:** Upon approval of 3Diemme, your distribution contract with 3Diemme may be amended to reflect the engagement of the sub-distributor.
4. **Contract with sub-distributor:** You must enter into a contract with the sub-distributor to bind it to all 3Diemme compliance conditions that you have, including:
 - a. ZimVie’s Code of Business Conduct and Ethics
 - b. This Manual
 - c. Applicable local and global laws and regulations (such as FCPA) and industry codes
 - d. Right to audit
5. **Compliance Training:** It is your obligation to provide regular compliance training to the sub-distributor and to ensure that you maintain records of this training (e.g., email communication or attendance records). Similar to the compliance training 3Diemme provides to you, we suggest that you provide compliance training to sub-distributors at least every two years.
6. **Auditing:** You are responsible for your sub-distributors and must ensure they uphold the terms of their contract, and they must avoid misconduct. Your contract with the sub-distributor must include 3Diemme’s right to audit and monitor activities related to 3Diemme products/business, if requested, and sub-distributors must agree to provide access to relevant records.

Sub-distributors are entities appointed by a 3Diemme distributor pursuant to a valid agreement, to sell and distribute 3Diemme Products in a specified region, which take ownership of 3Diemme Products, deliver 3Diemme Products, and invoice customers. Sub-distributors do **not** include: (1) group purchasing organizations (as determined by the Healthcare Compliance Department); (2) entities purchasing fewer than three non-stocking orders per year from a 3Diemme distributor; (3) distributors of other brands that purchase instrumentation from 3Diemme for use when servicing a surgery and not to resell individually; and (4) entities that work on behalf of Healthcare Professional (“HCP”) entities to optimize their logistics operation processes

Conflicts of Interest

Conflicts of Interest (“COIs”) pose a compliance risk to 3Diemme and your company. Therefore, it is critical to understand, identify and mitigate potential COIs.

Understand: A conflict of interest can occur when an individual's personal interests (e.g., family, friendships, financial, or social factors) – could impact his or her judgment, decisions, or actions in the workplace.

Identify: The following are examples of potential conflicts of interest which require disclosure and a compliance review to assess if there is a necessary mitigation:

- One of your owners, shareholders or employees is an HCP or Public Official
 - An HCP is an individual, entity, or employee of such entity, within the continuum of care of a patient, which may purchase, lease, recommend, use, prescribe, or arrange for the purchase or lease of 3Diemme products and services.
 - A Public Official is any officer, agent, employee, or any person acting for or on behalf of:
 - A government, including any legislative, administrative, or judiciary branch of such government
 - Any department, agency, or arm of a government, including wholly or majority state-owned or controlled enterprises



- Any public international organization, such as the United Nations or World Health Organization
- A political party
- Any candidate for political office
- You are selling products to an HCP who is one of, or a close family member of one of your owners, shareholders, or employees.
 - A 'close family member' Includes parents, siblings, spouses or partners, children, grandparents, grandchildren (whether adopted or by birth), step or half-relatives, in-laws, or any other individuals who reside in the same household or have a close relationship (i.e., girlfriend, boyfriend, etc.).
- You are hiring an employee who has been recommended by an HCP

You must avoid using family or other close relationships to improperly influence purchasing decisions by HCPs and Public Officials.

Mitigate: If you have a COI situation, reach out to your Business Sponsor or to the Healthcare Compliance Department to assess the situation and develop a mitigation plan wherever possible. Always remember, transparency allows 3Diemme and its business partners to uphold the company's high ethical standards!

Books & Records Accuracy

Companies must maintain Books and Records that provide a true and fair view of all transactions relating to 3Diemme business. This includes, but is not limited to following, as they relate to 3Diemme business:

- documents of the sale of 3Diemme products
- documentation with regards to discounts, rebates, and pricing concessions
- payments to and for an HCP or to any third party
- anything of value provided to any HCP, customer, or third party

From time-to-time 3Diemme may conduct an audit of your business activities and books and records related to 3Diemme business. It is therefore crucial that you maintain accurate books and records in relation to your business activities and in such a way that all 3Diemme-related transactions are distinguishable.

Discounts, Rebates and Pricing Concessions

When providing a discount, rebate, or pricing concession relating to 3Diemme Products make sure you respect the following regulations:

- Verify that there is a legal, legitimate, commercially reasonable, and transparent reason for the discount, pricing concession, or rebate
- Retain written documentation memorializing the specific terms and conditions of how the discount, rebate, or pricing concession will be earned and the justification for the discount
- Ensure that discounts, rebates, and pricing concessions comply with all applicable laws
- Record all discounts, rebates, and pricing concessions accurately in books and records
- All discounts should be reflected on the invoice and there should be no after-sales discounts (i.e., credit notes or adjustments to selling price documented as a discount)
- Selling price after discount should not be below cost of goods.



- Terms and conditions should indicate whether exchanges are allowed and the number of days of the credit term.

Tender Submissions

You may participate in tenders on behalf of 3Diemme. Please remember to request the Healthcare Compliance Department approval if the tender submission includes:

- Any expenses other than reasonable application fees and associated costs and travel expenses, or
- Value Add items

A Value-Add item is a product or service that is not mandatory in the tender but adding value points to your submission in the tender. Value adds are permissible provided they are linked to the tender scope.

To request the Healthcare Compliance Department approval for a tender Value-Add:

1. Step: Contact your 3Diemme Business Sponsor and ask for the “Tender Pre-Approval Form”
2. Step: Submit the form to your Business Sponsor at least 10 days prior to tender submission.
3. Step: The Business Sponsor will provide you with the feedback/approval.

Promotional Activities

When you are doing marketing and promotional activities with regards to the 3Diemme business, there are a couple of points that you must consider. Marketing activities are not supposed to cover for inappropriate purposes such as entertainment for HCPs, leisure travel and meals without business justification. Also make sure you follow these guidelines:

1. The location should:
 - a. Be modest, convenient, and not overly luxurious.
 - b. Be near HCPs location (e.g., no extensive travel required to reach the location)
 - c. Not offer entertainment, leisure or recreational features offered at the location (or nearby)
2. A Commercial Sponsorship constitutes a payment or in-kind support provided by the Distributor to a third party in exchange for advertising or promotional opportunities.
 - a. Distributors are permitted to purchase booth/tabletop space or commercial sponsorships at third-party educational events if all the following conditions apply:
 - i. Payment is not made to an individual HCP or HCP Practice;
 - ii. Fees are reasonable and consistent with fair market value for what you receive in tangible benefits (i.e., booth space, attendee list, logo representation); and
 - iii. Fees are documented in a written agreement between both parties.

Always remember: You cannot provide cash or other forms of compensation for HCPs to attend these promotional activities.

Social Media

We recognize that the responsible use of social media can benefit the public and our customers; however, to ensure that patient privacy is protected and to avoid misinformation about our products, health conditions, and treatment options, all social media activity related to 3Diemme



business for commercial use must be consistent with our policy on the use of social media (please contact your Business Sponsor for more details).

Interactions with HCPs

Providing business courtesies to HCPs and Public Officials for a legitimate business purpose is an accepted practice under appropriate conditions. Examples of acceptable Business Courtesies are meals, travel, or accommodations that are related to a legitimate business purpose. Please see below our requirements that must be followed:

Meals

You may provide meals to HCPs and Public Officials, but not in order to gain or retain business or business advantages. When providing a meal to an HCP or Public Official, the following conditions must be met:

- Business meals must be permissible under local laws
- There needs to be a clear business purpose in connection to providing scientific, educational, or business information
- Occasionally only, modest in perception, and reasonable in price (include reference to meal limit appendix)
- Appropriate location for a business meeting
- No guests, only attendees directly involved in 3Diemme business

Be aware that your representative should be present throughout the entire meal.

Important: Business meals need to be documented and accounted in the books and records for audit purposes! This documentation should include at least:

- All attendees: full name, position and hospital
- Business purpose
- Itemized receipt

Travel and Accommodation

You can arrange and pay for HCPs travel and accommodation only in limited cases and in close collaboration with 3Diemme or your Business Sponsor. Travel and accommodation must never be given to inappropriately influence the purchase, lease, recommendation, use or prescription of 3Diemme products.

Travel and accommodation can be provided to HCPs for example in case of:

- Participation in 3Diemme Medical Education events
- Participation in 3Diemme organized facility tours

When you book travel and accommodation, always make sure the following conditions are met:

- Travel must be limited to a direct itinerary to and from the HCP's primary place of residence and the location of the event
- The travel dates must be tailored to the event(s) dates
- Air travel for HCPs must generally be booked in economy or economy plus class
- If the itinerary includes at least one leg scheduled for six or more hours, business class may be booked for all segments



- Always request prior approval of the proposed travel arrangements by 3Diemme or your Business Sponsor.

Important: You may not provide travel and accommodation for participation in Third Party Educational Conferences (TPEC) directly to HCPs.

Booking Method: You must book travel and accommodation through:

- 3Diemme directly (contact 3Diemme or your Business Sponsor)
- 3Diemme approved travel agency
- Directly through an airline's website, hotel's website, or an online booking provider

Record Keeping: Travel and accommodation expenses need to be documented and accounted in the books and records for audit purposes! This documentation should include at least:

- Itinerary documenting the HCPs travel details (incl. dates, schedule, class, fare)
- Invoice for flights, train and accommodation
- Receipts for all ground transportation and incidental charges (e.g., baggage fee)

Restrictions: You may not:

- Provide, arrange, reimburse travel and accommodation for anyone other than the HCP who has no business purpose.
- Incur any extra expenses or make arrangements related to extend or modified travel arrangements for personal reasons
- Provide, arrange or reimburse any entertainment for an HCP
- Provide an HCP with any per diems, pocket money, or other cash and cash equivalents
- Provide First Class flight tickets

No Entertainment & Gifts

Business courtesies in the form of entertainment and gifts are not permissible. This applies to HCPs, Public Officials and/or their close family members.

Cultural Courtesies

Cultural Courtesies, which are small, low-value, and / or perishable items, may be provided but only if permissible under applicable local laws and industry codes.

- EMEA: no cultural courtesies are permissible.
- APAC: permissible for limited occasions (TBD)
- LATAM: TBD

Giving cash or cash equivalents, such as gift certificates, vouchers, or coupons, is strictly prohibited.

Conference Support Materials and Educational Items

Conference support materials and educational items may be permissible, but please contact your 3Diemme Business Sponsor before providing any items as restrictions may be country specific.

Conference support materials are typically used during a conference, are of low value and 3Diemme branded. Unless local law prohibits, you can provide conference support materials to HCPs. Examples of are:

- Pens



- Paper notebooks
- Tote bags

Educational items benefit patients or serve an educational purpose for the HCP. They do not have an independent value to the HCP outside of their professional responsibilities. Unless local law prohibits, you can provide educational items to HCPs. Examples of are:

- Textbooks
- Anatomical models/Bone Models

Important: When you plan to provide conference support materials or educational items contact your 3Diemme Business Sponsor for pre-approval.

Evaluation and Demonstration Products

Evaluation and Demonstration products are free of charge to the customer and can only be provided on a need basis, in limited quantities and infrequently. They must never be given to inappropriately influence the purchase, lease, recommendation, use or prescription of 3Diemme products.

Evaluation and Demonstration products are at your costs and 3Diemme will not reimburse.

Evaluation products are consumable or durable products used during a real surgery. They can be provided to HCPs to allow the HCP to assess the appropriate use and functionality of the product. The criteria for your company to provide an evaluation product are:

- HCP must be new to the specific technique or 3Diemme product
- Patient cannot be charged for the evaluation product
- Written disclosure of evaluation and no charge products
- Cannot be provided as a form of compensation for an HCP

The use of capital equipment for evaluation purposes is permissible but must be documented with an agreement between parties (including any industry association templates, where applicable) and is subject to a maximum evaluation period of not more than 90 days, excluding days for delivery and return of equipment (placement and removal dates must be documented). Capital equipment evaluations require consultation with the 3Diemme Commercial Business and under no circumstances may a capital equipment evaluation exceed 90 days total, excluding delivery and removal.

Demonstration products can be provided for HCP and patient education and information. Demonstration products must be permanently marked or engraved with language clearly indicating that the demo product is for demonstration purposes only and not for implantation and human use. If the product is too small to be engraved or marked, the packaging can include such wording as well.

All requests to provide HCPs with 3Diemme products as an Evaluation or Demonstration Product must be documented and retained. Documentations should include:

- Recipients name/hospital
- Date of providing eval product
- Date of providing/return date for demo products



HCPs may not resell, charge, or seek reimbursement from government or commercial payors for any free-of-charge 3Diemme products or services, and you should disclose this in writing to recipients of Evaluation and Demonstration products.

Educational Grants and Charitable Donations

Occasionally you may wish to provide funds or products for educational or charitable purposes to HCPs. When providing educational grants and charitable donations in connection to 3Diemme business, please be aware of the following restrictions:

Educational Grants: You cannot independently provide such grants. Only through the 3Diemme grants review process, the following educational grants may be provided:

- third-party medical education (including grants for Third Party Educational Conferences or “TPEC”)
- research activities/initiatives
- educational conferences, and
- patient and public educational initiatives

Contact your business sponsor for information on how a third party can request a grant or in-kind donation.

Important: You cannot select a specific HCP to attend a TPEC, whether as a delegate or a speaker. Therefore, you cannot directly pay or reimburse the expenses of any individual HCP. Only through providing a TPEC Grant to an organization or hospital the attendance of HCPs can be supported.

Please contact your 3Diemme Business Sponsor for additional guidance and submit your requests according to your Business Sponsor’s indications.

Charitable Donations: You can independently provide such donations if there is no connection to potential 3Diemme product use or referral. Always remember the image and perception when providing these.

Charitable contributions are permitted by Distributors if all the following conditions are applied:

- Request is unrestricted;
- Payment is not made to individual HCPs or HCP Practices;
- Proceeds are used for patient education and/or indigent care (for HCP related charities) and not for educational or research grants, fellowships, or third-party educational meetings; and
- Requests are made in writing from the organization and charitable donations are documented in a written agreement between both parties.

Educational grants and charitable donations need to be documented and accounted in the books and records for audit purposes!



Engagement of HCPs

In limited circumstances where 3Diemme is not already providing training and does not have the resources to do so, you may enter into an HCP consultancy agreement for training and education services following the 3Diemme HCP Arrangement Guidelines for Distributors. Contact your Business Sponsor if you see the need for an HCP engagement.

Trade Compliance

As the ultimate holder of 3Diemme is ZimVie Inc., headquartered in the US, you are required to comply with US Export Administration Regulations, embargo, sanction, and anti-boycott programs for any 3Diemme related activities. Distributors and agents are required to make sure that 3Diemme products are not diverted, re-exported or otherwise provided to any destination or party that is not allowed by the distribution agreement or would violate any export control or sanction programs such as:

- [OFAC sanctions program](#)
- Listed on the "[List of Parties of Concern](#)"
- [U.S. Anti-boycott Laws](#)
- [EU Sanctions Regulations](#)
- [Swiss Export Control Policy and Sanctions/Embargos](#)

Import and export laws as well as customs regulation set requirements that you must comply with when importing and exporting products. You are required to verify that all necessary documentation is obtained prior to the importation or delivery of 3Diemme products.

Important: 3Diemme does not permit the hand carry of any 3Diemme product across borders due to restrictions and declaration requirements of Customs authorities worldwide. Hand carrying refers to carrying on one's person or within one's luggage while traveling.

Transparency Reporting

In certain countries medical device manufacturers and distributors are required by law or industry codes to report payments made to HCPs and Public Officials. It is your responsibility to fulfill this requirement if applicable in your country. Therefore, you must ensure that you keep records of all payments and transfers of value that result from your interactions with HCPs and Public Officials. Examples of such payments and transfers of value are:

- meals
- travel and accommodation expenses
- educational items and grants
- consulting payments

Please contact your 3Diemme Business Sponsor for additional guidance.

3Diemme Audit of Business Partners

We expect the highest standard of integrity and ethical business practices from our business partners. This also means that we will from time-to-time check if our business partners comply with our requirements. 3Diemme may also conduct non-programmed audits that arise out of compliance investigations, employee initiatives, or other sources such as, but not limited to, other distributors or gatekeepers (Finance, Trade Compliance, et cetera).



The audits are aimed to provide assurance, for you and 3Diemme and only cover the 3Diemme aspect of your business activities, in no case will information unrelated to 3Diemme business be requested to your company. In scope of the audit are all requirements per the ZimVie Code of Conduct and Ethics and the OUS Manual. 3Diemme will not use these audits to identify or collect non-3Diemme business information.

An audit can be divided into three stages:

1. **Planning:** You will be contacted by your Business Sponsor to inform you of an audit and to find a time for the audit fieldwork that works for you and 3Diemme. Several weeks before the fieldwork, you will receive a document request list and a questionnaire to help the audit team scope their work. As a next step, the audit team will select samples which you will be requested to provide supporting documentation. At this stage the audit team will also check if translation support for documents and interviews is needed.
2. **Fieldwork:** The fieldwork may take one to two weeks. During this time, you will be requested to be available for interviews and follow-up questions to samples and processes. You will receive regular updates from the audit team and at the end, the audit team will present you the preliminary observations.
3. **Reporting:** The audit team will finalize the audit report after 3Diemme's internal review of the audit results and remediation action plans.

You can find below some lessons learned and common observations identified that you can easily prevent when being audited:

- Ensure that all employees who work on 3Diemme-related business receive compliance training and that training records are kept on file
- Make sure you only engage sub-distributors in accordance with 3Diemme requirements, in particular: pre- approval, contracting and training (link to chapter)
- Maintain proper documentations when providing discounts and rebates
- Maintain documentations when providing meals to HCPs
- Disclosure of changes in ownership

Compliance Hotline

At 3Diemme, we are committed to creating a culture in which business partners and Team Members at every level feel comfortable raising their hand when they see something wrong. Whenever you have a concern about a potential or actual violation of ZimVie and/or 3Diemme policies, procedures, or internal controls you have many options for speaking up without the risk to face retaliation.

Our Code of Conduct and Ethics strictly prohibits retaliation against anyone who raises concerns. If you see something, you should say something – to your Business Sponsor or to the Healthcare Compliance Department.

Please note that you must also immediately notify us if you are contacted by a government investigator in relation to 3Diemme business. You must also notify us of any known or suspected violations of any law, regulation, industry code, government health care program requirement, ZimVie's Code of Business Conduct and Ethics, or the requirements in this Manual, even if not directly related to 3Diemme products

Reports may be made directly to the Healthcare Compliance Department or the ZimVie Hotline.



- Visit: zimvie.com/speakup
- Call: Country-specific phone numbers are located on the website
- Email: compliance.hotline@zimvie.com

Below are five important things to know about the ZimVie Hotline:

- It's a confidential reporting tool to raise a potential or actual violation of ZimVie and/or 3Diemme policies, procedures and internal controls
- It's designed for anonymous reporting where possible per local legislation
- It's operated by an independent company, neither ZimVie nor 3diemme
- It's part of our compliance program
- It's supported by our 3Diemme leadership team

Reports to the ZimVie Hotline are followed up by the Legal / Healthcare Compliance Departments. In cases where allegations are substantiated, ZimVie will define remediation actions, guided by ZimVie's Disciplinary Matrix for third parties. Depending on the severity of the misconduct, the results can include termination of the business relationship.