



Interactions with Health Care Professionals, Health Care Organizations, and Government Officials Policy

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DEMETRA HOLDING S.P.A.

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1. PURPOSE

This Policy provides ethical parameters for interactions between Demetra Holding, S.p.A. and all its affiliated companies ("Demetra" or "Company") with Health Care Professionals (HCPs), Health Care Organizations (HCOs) and Government Officials.

2. SCOPE

This Policy applies globally to all Demetra Representatives that interact with HCPs, HCOs and Government Officials. The scope of this Policy extends to all interactions with HCPs, HCOs and Government Officials in any country in which Demetra Representatives conduct business. All HCP and HCO interactions must be consistent with the relevant industry Codes of Ethics, including but not limited to AdvaMed Code of Ethics, AdvaMed China Code, MedTech Europe (collectively Industry Code of Ethics), the Company's Compliance Program, any applicable country, federal, state and or local laws, Demetra policies and procedures and relevant local country procedures.

Each of the Demetra companies will have country level procedures that support this Policy.

3. DEFINITIONS

Company Representatives (representatives) include employees (both full-time, part-time and temporary), members of the Board of Directors when acting on behalf of the Company, and relevant independent contractors including distributors, independent sales representatives and consultants performing services on behalf of the Company and/or on behalf of any company affiliated to Demetra.

Demetra includes Demetra Holding and all of its affiliated companies.

Government Official means (i) any individual that works for a government hospital or national health service or other federal, state, national or local government entity and may or may not be an HCP; and (ii) any officer or employee of a governmental entity or any department, agency or instrumentality, including state-owned entities, or of a national/public organization or any person acting in an official capacity for or on behalf of any such government, department, agency, or instrumentality or on behalf of any such public organization and may or may not be an HCP.

HCP means any Health Care Professional working in any country. For the purposes of this Policy, it can be an individual or an entity which is authorized or licensed to be involved in (i) the provision of healthcare services and/or items to patients and (ii) purchasing, leasing, recommending, using, arranging for the purchase or lease of, or prescribing Demetra

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Products. Persons providing services include but are not limited to medical doctors, physicians, physician assistants, registered nurses, nurse practitioners and physician staff members. "HCP" includes both persons providing services and persons who do not provide services directly but who are involved in the decision to purchase, order, lease or recommend Demetra Products. In the latter case, such persons include, but are not limited to, purchasing agents, hospital executives, procurement committees, physicians, clinical providers, practice managers and management within group purchasing organizations.

HCO means those entities that (1) are involved in the provision of healthcare services and/or items to patients, and (2) could recommend or order Demetra Products. "HCO" includes hospitals, ambulatory surgery centers, academic teaching institutions, physician offices, clinics, or other organizations that provide treatment and care services. For ease of reference HCO is included in the definition of HCP for adherence to requirements for this Policy.

Demetra Product(s) means any product manufactured and or sold or distributed by Demetra.

Training and Education: Training means training on the safe and effective use of Demetra Products. Education means communicating information directly concerning or associated with the use of the Demetra Products (e.g., information about disease states and the benefits of the Products to certain patient populations).

4. REQUIREMENTS

This Policy prohibits any interactions with HCPs for the purpose of inducing the use of Demetra Products or any other inducement prohibited by local country laws, anti-bribery anti-corruption laws, foreign corrupt practices act, the U.S. federal Anti-kickback Statute or other similar European or U.S. state laws. All HCP interactions must be consistent with the relevant Industry Code of Ethics, the Company's Compliance Program, applicable federal, statute and/or local laws, as well any other Demetra policies or procedures.

4.1. SPONSORED TRAINING AND EDUCATION

Generally, global regulatory bodies, such as European Union Medical Device Regulations, the U.S. Food and Drug Administration ("FDA") and country specific health authorities recognize training and education to facilitate the safe and effective use of certain medical products. Demetra has a responsibility to make Training and Education on its Products available to HCPs.



Training and/or Education programs and events must be conducted in clinical, educational, conference, remote/virtual, webinar or other appropriate settings, including hotel or other commercially available meeting facilities, that are conducive to the effective transmission of information. In many cases, it may be necessary for a Demetra representative to provide Training and Education at the HCP's location.

Programs requiring "hands on" Training on Demetra Products and/or medical procedures must be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff must have the proper qualifications and expertise to conduct such Training. Training staff may include qualified HCPs, sales or service employees who have the technical expertise necessary to perform the Training.

Participants cannot be compensated for their time related to attending Demetra sponsored Training and Education programs, this includes travel time and attendance at didactic, gel model, cadaveric training and related travel time.

Training and Education programs concerning Demetra Products must be consistent with the indications for use cleared or approved by the relevant regulatory authority and with the regulatory approved labeling of the Product.

4.2. THIRD PARTY EDUCATIONAL CONFERENCES, SPONSORSHIPS, EXHIBITS, ADVERTISEMENTS

Bona fide independent, educational, scientific and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by international, national, regional or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Demetra will not compensate any HCP for time spent participating in any Continuing Medical Education (CME), third party scientific or educational conference or professional meeting.

Demetra may support these conferences in various ways, including grants, exhibits space, advertising/sponsorships. Please refer to your local country procedures for requirements.

4.3. RESEARCH GRANTS/INVESTIGATOR INITIATED STUDIES



Demetra may provide research grants (including investigator-initiated studies) to support independent medical research with scientific merit. Research grants may include funding, product donations and/or equipment loans. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Demetra Products. Demetra initiated or directed research involving Demetra Products (such as clinical study agreements) is addressed separately in the section of this Policy regarding Consulting Arrangements with Health Care Professionals.

All requests must be considered based on the substantive research value of the request.

Sales and marketing representatives are prohibited from implying in any manner that a research grant to an HCP will be approved. Further, sales and marketing representatives may not communicate the approval of a research grant.

Please refer to your local country procedures for requirements.

4.4. CHARITABLE DONATIONS

Demetra may consider product donations to HCPs when the donation benefits society, promotes better healthcare, demonstrates good corporate citizenship and/or serves a genuine educational benefit. Examples include but are not limited to: indigent patient care (requires certification from the HCP that no payor will be billed for the procedure), charitable missions, patient or public education. Donations must be motivated by a bona fide charitable purpose and must be made only to a bona fide charitable organization.

All requests must be reviewed based on the substantive charitable purpose of the request. Any request that is believed to create an unreasonable appearance of an illegal or unethical motive must be denied. Any request that is believed to be implicitly or explicitly linked to the use, purchase, order, referral or recommendation of Demetra Products must be denied.

Sales and marketing representatives are prohibited from implying in any manner that a charitable donation to an HCP will be approved. Sales and marketing representatives may not communicate the approval of a charitable donation.



Please refer to your local country procedures for additional requirements.

4.5. CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

Demetra may engage HCPs to provide a wide-range of valuable, bona fide consulting services through various types of arrangements, such as contracts for research, clinical trials, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Demetra sponsored Training and Education and other approved services. Compensation may be paid to an HCP consultant provided that it is fair market value for the performance of the services, the arrangement fulfills a legitimate business need and the arrangement does not constitute an unlawful inducement. In no event shall a consulting agreement, or any term of an agreement, be based on the volume or value of business (past, present or anticipated) that a consultant generates or influences.

Selection of HCP consultants must be on the basis of the consultant's qualifications and expertise to meet the defined need and must not be based on, or influenced by, the basis of volume or value of business generated by the consultant. Demetra sales representatives are permitted to provide input about the suitability of a proposed HCP consultant; however, they should not control or unduly influence the decision to engage a particular HCP as a consultant. Likewise, sales representatives are prohibited from implying in any manner that a consulting arrangement with an HCP will be approved.

Demetra consulting arrangements with a consultant must be evidenced by a written agreement that has been approved by local country legal counsel that is signed by all parties and that specifies all services to be provided and the compensation to be paid. The fully executed contract must pre-date the activities performed. If Demetra contracts with an HCP consultant to conduct clinical research services, a written research protocol is also required.

Compensation paid to HCP consultants must be consistent with fair market value in an arm's length transaction for services provided and must not be based on the volume or value of the HCP consultant's past, present or anticipated business.

Demetra may pay for documented, reasonable and actual expenses incurred by an HCP consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging costs incurred by the HCP consultant to attend meetings with, or on behalf of, Demetra in accordance with this Policy.



The venue and circumstances for Demetra meetings with HCP consultants must be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information. With the exception of society meetings and national conferences¹, resort locations are generally not acceptable locations for meetings with HCP consultants and require event specific exception approval by the local country compliance officer or legal counsel.

Demetra-sponsored meals and refreshments provided in conjunction with an HCP consultant meeting must be modest in value and subordinate in time and focus to the primary purpose of the meeting. Demetra strictly prohibits recreation or entertainment in conjunction with these meetings or any other HCP interaction.

Please refer to your local country procedures for additional requirements, such as meal limits, allowable hotels, allowable airfare and ground transportation and consulting agreement templates and leadership approval requirements.

4.6. CLINICAL PUBLICATIONS

The local country procedures govern the requirements and approvals for all engagements regarding clinical publications. Demetra adheres to the International Committee of Medical Journal Editors (ICMJE).

4.7. ENTERTAINMENT AND GIFTS PROHIBITED

Demetra representatives are prohibited from providing HCPs (or their spouses/guests) with, or otherwise pay for HCPs (or their spouses/guests) to attend or participate in, entertainment or recreational activities, regardless of the nature or value of the entertainment or recreational activity and regardless of whether the entertainment or recreational activity is secondary to an educational purpose. Prohibited entertainment and recreational activities include, without limitation, theater, sporting events, golf, winery visits, skiing, hunting, boating and leisure or vacation trips.

Demetra representatives must adhere to their local country laws and procedures for educational and promotional items, for example, promotional

¹ Demetra may hold meetings during society meeting or national conference as this is a cost effective manner to interact with consultants without the expense of additional travel.



items are prohibited in the U.S., but may be allowed in Europe, if certain criteria are met. Please refer to your local country procedures for requirements.

Demetra recognizes that representatives may have a personal relationship (e.g., spouse, sibling, child, friend) who is involved in healthcare services (e.g., nurse, doctor, medical technician, etc.) but who may or may not be in a position to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Demetra Products. Demetra representatives must consult their local compliance officer or legal counsel for guidance regarding these interactions.

4.8. MEALS

The Company's requirements for modest meals and beverages is as follows:

- A. Demetra may provide modest occasional meals (in accordance with local country limits that are incidental to the presentation of business, scientific or educational information. A business, scientific or educational discussion (for example, a business discussion regarding features, sales terms or contracts for Demetra Products) should account for most of the time spent during the meal. Likewise, the meal should not be used for entertainment or recreational purposes.
- B. Meals should occur in a setting that is conducive to the business, scientific or educational discussion.
- C. Demetra may pay for meals only for HCPs who are relevant to the business, scientific or educational discussion and who attend the meeting. The Company may not provide a meal for an entire office staff where everyone does not attend, or is not relevant to, the meeting.
- D. Demetra may pay for meals for HCP Consultants while traveling on Company business, as requested by the Company.
- E. Demetra may pay for meals for HCPs while traveling to attend an out-of-town Demetra-sponsored Training and Education program and/or a Company business meeting (e.g. product demonstration). Such meals are limited to meals required for travel and/or meals that are not provided during the Demetra-sponsored program.



- F. Demetra may not pay for meals for spouses or other guests of HCPs, unless they independently qualify as an appropriate attendee.
- G. Demetra may not directly pay for the cost of conference meals at CME conferences, third party scientific or educational conference or professional meetings. However, Demetra may provide an educational grant to a CME provider, and the provider may use a portion of the grant for participant meals at the CME conference, in accordance with the above section of this Policy on Third Party Educational Conferences, Sponsorships, Exhibits, Advertisements and local country procedures for these activities.
- H. All HCP meals and other expenses must be reported according to local country transparency reporting requirements.

4.9. PROVISION OF COVERAGE, REIMBURSEMENT AND HEALTH CARE ECONOMICS INFORMATION

As medical devices have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Products may be dependent on HCPs and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, Demetra may provide such information regarding its Products if it is accurate and objective. Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- A. Identifying the clinical value of Demetra Products and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to HCPs, professional organizations, patient organizations, and payors.
- B. Collaborating with HCPs, their professional organizations and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues.
- C. Supporting HCPs and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- D. Providing accurate and objective information and materials to HCPs regarding Demetra Products, including identifying coverage, codes

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and billing options that may apply to those Products or the services and procedures in which they are used.

- E. Providing accurate and objective information about the economically efficient use of the Demetra Products, including where and how they can be used within the continuum of care.
- F. Providing information related to the Demetra Products regarding available reimbursement revenues and associated costs.
- G. Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes to facilitate an HCP's decision to buy or use Demetra Products.
- H. Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use of Demetra Products.
- I. Sales and marketing representatives must refer any questions regarding coverage, reimbursement and healthcare economic information to their local compliance officer, legal counsel or healthcare economics support representatives as set forth in their local country procedures.
- J. Demetra may not interfere with an HCP's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, Demetra may not provide free services that eliminate an overhead or other expense that an HCP would otherwise incur as part of its business operations as doing so would amount to an unlawful inducement.

4.10. EDUCATIONAL ITEMS

In regard to educational items, there are the following expectations:

- A. Demetra's provision of educational items to HCPs must be in compliance with the requirements set forth in this Policy. Under no circumstances may an educational item be offered or provided with the intent of, directly or indirectly, influencing or encouraging the recipient to purchase, lease and/or refer purchases for any Demetra Product. Additionally, educational items may not be provided in



connection with discussions, negotiations or decisions involving product pricing or purchasing.

- B. Demetra may occasionally provide educational items to HCPs that benefit patients or serve a genuine educational function. All educational items must adhere to your local country procedures.
- C. Educational Items for Patients: Anatomical models for examination rooms, educational videos, and other educational related items (e.g., written informational materials and patient demonstration items) that are (i) designed primarily for the education of the patient; and (ii) have no independent value to the HCP and are not capable of use by the HCP (or his or her family members, office staff or friends) for non-educational purposes.
- D. Educational Items for HCPs: Medical textbooks, medical education on video, and other educational related items (e.g., single-year subscription to a scientific journal) that are (i) designed primarily for the education of the HCP; and (ii) have no independent value to the HCP and are not capable of use by the HCP (or his or her family members, office staff or friends) for non-educational purposes, such as an iPad..
- E. Value: All educational items must adhere to local country procedures and monetary limits.
- F. All HCP educational items must be reported as required by local country procedures and transparency reporting requirements.

4.11. EVALUATION AND DEMONSTRATION PRODUCTS

Providing products to HCPs at no charge for evaluation or demonstration purposes can benefit patients by improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating HCPs regarding the use of products. Under certain circumstances, Demetra may provide reasonable quantities of its Products to HCPs at no charge for evaluation and demonstration purposes.

Demetra may provide HCPs with a limited number of evaluation Products to allow HCPs to assess the appropriate use and functionality of the Product and determine whether and when to use, order, purchase, or recommend the Product in the future. The transfer of an evaluation Product must be clearly documented (e.g., invoices must reflect "No-charge Evaluation.") and include the language that no payors, federal, national, commercial or self-pay may be billed for the evaluation Products.

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Demetra demonstration Products are typically unsterilized single use products or mock-ups of such Products that are used for HCP and patient awareness, education, and training. Demonstration Products must be identified as not intended for patient use by use of such designations as "Sample-Not for Human Use," or other suitable designation on the Product, the Product packaging, and/or documentation that accompanies the Product.

4.12. FAMILIAL RELATIONSHIP POLICY

All Demetra representatives who have sales and marketing responsibilities or receive compensation based on sales to HCPs must immediately disclose all familial relationships with any HCPs within their prospective sales territory or that of their distributor as required by their local country procedures. "Familial relationship" includes: spouse, domestic partner; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

4.13. TRAVEL AND LODGING

In regard to travel and lodging, there are the following expectations:

- A. Demetra may pay for modest travel and lodging expenses incurred by HCPs for travel to on-site Product demonstrations, Training and Education programs and services provided under a consulting arrangement. Demetra will not pay for the travel, lodging or other related expenses of any non-HCP accompanying an HCP to a Demetra-approved meeting, program or service. In order for the Company to pay for air travel to a Training and Education program the program must be at least five hours in length.
- B. For Demetra approved meetings, programs or services that require air travel and/or ground transportation, the Company may reimburse or pay directly for air travel and ground transportation in accordance with local country monetary spending limits.
- C. For Demetra approved meetings, programs or services that require lodging, the Company may reimburse or pay directly for hotel expenses in accordance with local country monetary spending limits.
- D. Demetra meetings with HCPs that require Demetra to provide lodging cannot be held at five-star hotels or destination resort locations. The number of nights of hotel expenses paid by Demetra may not exceed that necessary for the approved meeting, program or service with the

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Company. If a Demetra meeting, program or service lasts into an afternoon, Demetra may pay for hotel expenses for that night. Demetra will not pay for the lodging or other related expenses of any non-HCP accompanying an HCP to a meeting.

- E. All HCP travel and lodging must be reported as required by local country procedures and transparency reporting requirements.

4.14. GOVERNMENT OFFICIALS

Government Officials (who may or may not be HCPs) and government institutions are subject to rigorous restrictions with respect to how they may interact with and what they may accept from our Company and others in our industry. Therefore, Demetra representatives are responsible for knowing and adhering to the stricter standards of Government Officials, public or national hospitals or government institutions including obtaining any required permission or authorization from the facility or institution to avoid any violation of law, regulation or institution policy, and following all relevant Company policies/procedures, including this Policy, expense policies, and local country procedures, as applicable.

Since government institutions may impose their own restrictions on interactions, Company representatives are expected to know the restrictions that apply to these facilities and abide by them.

4.15. CUSTOMER-SPECIFIC REQUIREMENTS

Demetra representatives are responsible for checking with HCPs to determine if the HCP has limits or requirements that are stricter than those set forth in this Policy. For example, an HCP's employer (an HCO such as a national health system or teaching institution) may prohibit meals unless provided in connection with programs accredited by the Accreditation Council on Continuing Medical Education (ACCME) or approved congresses. Therefore, it is important to be aware of and/or inquire regarding the HCP's requirements.

4.16. USE OF PERSONAL FUNDS

Demetra representatives may not provide or pay for meals, travel, lodging, gifts or entertainment in a manner inconsistent with this Policy, with his or her own funds, even if the individual does not intend to seek reimbursement from the Company.



4.17. TRAINING

Training on this Policy is provided through specific HCP Interactions Training deployed through local country in person training or the Company's learning management system. Your local country training may require a post-training comprehension test.

4.18. MONITORING AND AUDITING

The Company will perform or may delegate periodic auditing and monitoring to ensure adherence to this Policy.

4.19. DISCIPLINARY ACTION

Interactions with HCPs that are inconsistent with the requirements of this Policy represent a violation of this Policy and may subject the Demetra representative to disciplinary action as set forth in the local country procedures.

4.20. REPORTING OBLIGATIONS

Demetra is committed to ensuring that its interactions with HCPs comply with all applicable laws and regulations. This Policy does not address every situation, but its principles should provide a good "starting point". However, one should seek guidance on the appropriate course of conduct or application of this Policy from the local compliance officer or legal counsel when you have questions.

Demetra representatives should immediately disassociate themselves from taking part in any discussions, activities or other situations that they recognize to be potentially illegal or unethical. No supervisor may direct a subordinate to violate this Policy. If a Demetra representative becomes aware of any illegal or unethical behavior in violation of this Policy, it must be promptly reported to the local compliance officer, legal counsel, Demetra legal counsel or when relevant local anonymous reporting system.

It is Demetra's policy to comply with all applicable laws that protect Company representatives against unlawful discrimination or retaliation as a result of their lawfully reporting information regarding, or their participation in investigations involving, alleged misconduct by Demetra. If any person believes that they have been subjected to any discrimination or retaliation or other action by Demetra or its representative for reporting suspected misconduct in violation of the Demetra' policy against unlawful discrimination or retaliation, they may file a complaint with their local compliance officer, legal counsel or the Demetra legal counsel. If it is determined that an employee has experienced any improper employment action in violation of this Policy, Demetra will endeavor to promptly take appropriate corrective action.

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