

Brainlab

Policy on Interactions with Healthcare Professionals

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This Policy outlines the Brainlab engagement with healthcare professionals. It details the general principles from our [Code of Conduct](#) regarding these interactions.

Interactions with Healthcare Professionals

Our relationships with Healthcare Professionals are intended to:

- benefit patients and enhance the practice of medicine,
- inform Healthcare Professionals about the benefits and risks of our products,
- obtain feedback and advice regarding the clinical use of our products to enhance them,
- provide scientific and educational information, and
- further develop medical research and education.

This Policy is founded on the principle that a Healthcare Professional's care of patients should be guided solely by a patient's medical needs and the Healthcare Professional's medical knowledge and experience.

In addition to ethical standards, this Policy is based on industry guidelines¹ and mandatory legal requirements. Any interaction with Healthcare Professionals that does not follow this Policy is likely to be prohibited by the laws of most countries, may be prohibited by the laws of one or more states and may lead to criminal prosecution of the individual employees involved.

It is possible that certain jurisdictions may have more stringent requirements and it is our policy at Brainlab to comply with such requirements, where applicable.

Definitions

Healthcare Professionals. The term Healthcare Professionals (HCPs) as used in this Policy means any individual or entity that is involved in the provision of healthcare services and/or items to patients or that may purchase, lease, rent, use, recommend or arrange the purchase, lease, rental, or use of Brainlab products. This includes clinical and non-clinical individuals (e.g. surgeons and hospital administrators) who make or have influence on product-related decisions. In addition, associations of HCPs and healthcare students, decision-makers within group purchasing organizations and in certain cases government employees are to be considered Healthcare Professionals.

Benefits The term "benefits" means all tangible or intangible items that could potentially, directly or indirectly, be of advantage for the individual or a person in a close relationship to the individual to

¹ AdvaMed Code of Ethics, Medtech Europe Code of Ethical Business Practice



whom the item is provided. It is to be interpreted in a broad sense and includes, without limitation, monetary benefits as well as, for example, the use of Brainlab products.

Basic Requirements for all Interactions with Healthcare Professionals

The following are the basic transparency and documentation requirements:

- All obligations of the parties must be documented in writing in detail. The **documentation** must be completed and signed prior to the beginning of any service, performance or payment.
- The actual receipt by Brainlab of **services performed** or deliverables provided by Healthcare Professionals must be documented in detail in order to be able to show that the arrangement was not only documented appropriately, but actually performed according to the documentation.
- Any **compensation** paid or benefit provided must be fair market value and may only be paid or provided if services are actually performed. Any costs may only be refunded against the presentation of actual invoices. No cash payments are to be made.
- The **venue** and circumstances of any meeting must be conducive to informational communication and the transmission and exchange of scientific or educational knowledge. Venues should be centrally located, easily accessible and conducive to the exchange of information. The venue should not be the main or primary attraction for an HCP to attend a meeting, and luxury venues or those associated with recreational or entertainment attractions should be avoided.
- Any **event program** should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the event or be sufficiently relevant to justify the attendance of the Healthcare Professionals. A detailed program should be available in sufficient time prior to the event and present a clear schedule with no gaps during the sessions in the case of in-person events.
- Any **meals** that are provided must be modest, as judged by local standards and subordinate to the “bona fide” (appropriate) presentation of scientific, educational or business information.
- Payments or benefits may not be provided in connection with a **sales transaction**. Also, any appearance of such connection is strictly to be avoided.

To avoid doubt, it is never appropriate to fund any activities, meals, or other expenses for **spouses or other companions of a Healthcare Professional**, whether in the framework of a meeting attendance, dinner reception, product presentation or otherwise.

Similarly, it is never appropriate to organize or pay for any **entertainment** or recreational activity or event for any Healthcare Professional. Such activities include, but are not limited to, theater, sporting events such as golf or skiing, leisure or vacation trips, or arrangements where music/dancing is the main attraction. Such entertainment or recreational events and activities may not be provided, regardless of (1) their value; (2) whether Brainlab engages the Healthcare Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.



For more detailed instructions depending on the type of interaction, please refer to the criteria set forth below. Please note that these basic requirements apply to all types of interactions.

Educational Events/Company-conducted Training & Education

There is a legitimate need and responsibility for companies in the health sector to conduct training and education for Health Care Professionals regarding their medical technology. This includes the procedures in which these medical technologies are used and related information. Such trainings and informational presentations held by Brainlab representatives and others speaking on behalf of Brainlab (e.g. Symposiums, User Meetings) provide valuable scientific and educational benefits. In connection with such events, occasional meals (but no entertainment or recreational events) may be offered in accordance with the restrictions set forth herein. Offering "take-out" meals or meals to be eaten without a Brainlab representative being present is not appropriate.

Brainlab may pay for Health Care Professionals' modest and reasonable travel and lodging costs to attend a company-conducted program or meeting if there is an objective, legitimate reason that supports the Healthcare Professional's in-person attendance.

Company Business Meetings/Sales Meetings

Brainlab may identify a legitimate need to conduct other types of business meetings with Health Care Professionals to discuss, for example, medical technology features, sales terms, company service offerings and their impact on healthcare delivery, product line offerings, health economics information, or purchase contract arrangements. Other examples could include plant or facility tours (Inhouse Visit), meetings to demonstrate equipment, meetings to explore product development or clinical testing needs, or meetings to discuss value-based solutions, services, or arrangements.

The rules for offering meals and compensation for travel and lodging costs described under "Educational Events/ Company-conducted Training & Education" apply accordingly.

Product Evaluation Visits and Product Trainings

Product evaluation visits and product training may be conducted at Brainlab premises, at selected customer sites or in other appropriate settings such as convention centers or other commercially available meeting facilities. Product evaluation visits and product training are considered appropriate if, in addition to the general restrictions provided herein:

- The main purpose of the event is the provision of product information to Healthcare Professionals, including but not limited to events that address product features, equipment demonstrations and meetings to explore product development or clinical testing needs.



- HCPs attending such events must have an objective, legitimate need to attend. This, by negative implication, means spouses, family and others without a legitimate need should not be permitted to attend.
- The total costs for an event remain equal to or below the costs of alternative ways of providing a comparable quantity and quality of information to the attending Healthcare Professionals.

If these requirements are met, and where there are objective reasons to support the need for out-of-town travel to efficiently deliver the product evaluation and/or product training, Brainlab may pay **reasonable travel and modest lodging costs** (as well as **meals**) of the attending Healthcare Professionals during the time of their stay at the event. It is not appropriate to pay the Healthcare Professionals for their time attending the event.

Third-party educational Conferences or Meetings

Continuing medical education (“CME”) or bona fide independent third-party scientific, educational or policymaking conferences can contribute to the improvement of patient care. Therefore, financial support from Brainlab (monetary, in-kind, and other) to support such educational, charitable and research programs is permissible under certain circumstances.

Commercial Sponsoring A conference or meeting may only be sponsored by Brainlab if the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse, and the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

The level of commercial sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by Brainlab (such as advertising, display/exhibit space, or other promotional opportunities).

Meals/Receptions Financial support for meals or receptions may be provided to the conference organizers or sponsors who in turn can provide meals or receptions for all attendees. Brainlab may also provide meals or receptions directly to Healthcare Professionals attending the conference or meeting if such meals and/or receptions are provided:

- to all Healthcare Professional attendees, and
- in a manner that is consistent with the applicable standards established by the conference sponsor and the body accrediting the educational activity.

Notwithstanding the foregoing, meals meeting the criteria of “Company Business Meetings/Sales Meetings” may also be provided during Third-Party Educational Conferences also to individual Healthcare Professionals (and not all conference attendees).

Educational Grants The provision of any subsidy directly to a Healthcare Professional by a company is likely to be viewed as an inappropriate cash gift. Therefore, financial support may only be given to the conference’s organizer who, in turn, can use the money to reduce the overall conference costs. In addition, when Brainlab financially supports medical conferences or meetings,



responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings.

Costs of travel, lodging or other personal expenses of Healthcare Professionals (Educational grants) may not be offered, neither directly to the attendees nor indirectly to the conference's organizer. However, Brainlab may provide grants to a training institution or the conference organizer to allow attendance by medical students, residents, fellows and others who are Healthcare Professionals in training but only if the training institution or conference organizer selects the attending Healthcare Professionals in training who may receive such a grant.

Such grants should be paid only to organizations with a genuine **educational** function and may be used to reimburse only legitimate expenses for bona fide educational activities. Such grants should also be consistent with applicable standards established by the conference organizer and anybody accrediting the educational activity. Before authorizing the payment of any such grants, employees should contact the Compliance and Legal department.

Funding may not be offered to compensate Healthcare Professionals for their time spent attending the conference or meeting.

Satellite Symposium

A Satellite Symposium is a company-organized and funded program that is appended to a third-party program agenda that the third-party organizer does not control. These programs often take place during meal breaks at the third-party program and may address education and training topics that coincide with the third-party program's focus.

Brainlab can host a Satellite Symposium and provide Commercial Sponsorships in support of a third-party program. Although Brainlab would be responsible for the content of the Satellite Symposium, these programs may be subject to the third-party organizer's application and approval process. While Satellite Symposia are generally included on the third-party program's agenda and promotional materials, these are company-conducted events. Brainlab should be transparent in promoting these as such.

Brainlab may offer modest meals and refreshments at a Satellite Symposium. If Brainlab engages a Health Care Professional as faculty (**speaker**) at the Satellite Symposium, Brainlab can pay for **modest travel and lodging expenses as well as registration fees** of that specific Healthcare Professional. This is not possible if a Healthcare Professional is only attending the Satellite Symposium, since attendees do not offer any services to be compensated and a company generally draws its audience for Satellite Symposia from the attendees of the related third-party program.



Consulting Agreements

Brainlab may engage Healthcare Professionals to provide consulting services to Brainlab (for example, participate in usability evaluations, give professional and/or scientific feedback on the use of Brainlab products). In addition to the general restrictions provided herein, the following standards must be followed:

- A legitimate **business need** for the services must be clearly identified before requesting the services and entering into an agreement with the consultant.
- A written **agreement** specifying the exact nature of the services to be provided and the basis for payment of those services must be executed by the parties. Such an agreement must be executed prior to the provision of any service and before any payment is made. The consulting agreement may never be undertaken for the purpose of inducing the consultant to purchase Brainlab products.
- The criteria for **selecting consultants** shall be directly related to the identified purpose and the persons responsible for selecting the consultants shall have the expertise necessary to evaluate whether the particular Healthcare Professionals meet those criteria. Brainlab sales personnel may provide input about the suitability of a proposed consultant but sales personnel may not control or influence the decision to engage a particular Healthcare Professional as a consultant. Consultants shall not be selected based on the volume or value of past, present or anticipated **business** generated by them.
- **Sales** personnel cannot control or unduly influence the decision to engage a particular Healthcare Professional as a consultant.
- When the consulting agreement involves the performance of **clinical research** services, there shall be a written research protocol.
- The number of Healthcare Professionals retained shall not be greater than the number reasonably necessary to achieve the identified purpose.
- The **hospital** or any other entity that employs the consultant or whose facilities might be used in the performance of the consulting agreement (e.g. customer site visits) shall be a party to the agreement or **acknowledge** the agreement in writing, if applicable.
- The consulting agreement shall require the consultant to **disclose** his or her financial engagement with Brainlab.
- Any compensation paid to a consultant shall reflect the fair-market value for the services provided according to our [Guideline for Compensation of Speaker and Consultant](#), and shall only be paid out following the provision of services (no “flat-fee agreements”). Hourly rates may not exceed USD 650 unless a fair market value analysis conducted by an independent organization with the necessary expertise is obtained.
- Reasonable **travel expenses** (only travel, modest meals and lodging) incurred in the performance of the services may be reimbursed against the provision of receipts.



Clinical Cooperation Agreements

Brainlab may engage Healthcare Professionals to provide services under a clinical cooperation agreement (for example, to conduct clinical studies or clinic investigations). In addition to the general restrictions provided herein, the following standards must be followed:

- A legitimate **business need** for the clinical cooperation agreement must be clearly identified before requesting the services and entering into an agreement with the hospital.
- Such an **agreement** must be executed prior to the provision of any service and before any payment is made. Clinical cooperation agreements may not be entered into with individual surgeons but only with **hospitals**. They may only be signed by hospital representatives who have the necessary authority (hospital administration). On the Brainlab side, clinical cooperation agreements may only be entered into by **Brainlab SE**, Germany. The clinical cooperation agreement may not be undertaken for the purpose of inducing the hospital to purchase Brainlab products.
- When an agreement involves the performance of **clinical research** services, there shall be a written research protocol.
- The criteria for **selecting hospitals** must be directly related to the identified purpose and the persons responsible for selecting the hospitals have the expertise necessary to evaluate whether the particular hospital meets those criteria. Hospitals shall not be selected based on volume or value of past, present or anticipated **business** generated by them.
- The number of clinical cooperations initiated shall not be greater than the number reasonably necessary to achieve the identified purpose.
- For clinical cooperation agreements, the **online template** is to be completed and signed before the clinical cooperation is initiated. Particularly, the services and deliverables to be provided by the hospital as well as any compensation to be paid by Brainlab must be specified in detail.
- Any **compensation** paid to a hospital shall reflect the fair-market value for the services and/or deliverables provided and shall only be paid out following the provision of services or deliverables (no “flat-fee agreements”). Hourly rates may not exceed USD 650 unless a fair market value analysis conducted by an independent organization with the necessary expertise is obtained.
- Reasonable **travel expenses** (only travel, modest meals and lodging) incurred in the performance of the services may be reimbursed against the provision of receipts.

Loaner Agreements

The provision of Brainlab products to Healthcare Professionals for evaluation or demonstration purposes allows the Healthcare Professionals to make an informed purchase decision. The provision of loaner systems is appropriate if:

- Brainlab retains the **title** to the product.
- The sole purpose of the loan is restricted to the **evaluation** of the system.



- The **duration** of the loan is no longer than is reasonably necessary to perform such evaluation, in general not longer than two months.
- The terms of the loan are documented, in advance, in a **loaner agreement**, including the process for promptly removing such product from the Healthcare Professional's location at the conclusion of the evaluation period unless the Healthcare Professional purchases or leases the product.
- The loaner agreement also provides that the customer must abide by applicable healthcare reimbursement guidelines and regulations, and the customer **cannot charge** patients, healthcare insurances or other payers for the use of the Brainlab product provided free of charge.
- For equipment loans in the **United States**, reference the United States Supplement to this Policy, section I. Equipment Evaluation Loans.

Gifts

Items that

- primarily relate to the Healthcare Professional's practice,
- benefit patients or
- serve a genuine educational function

may be offered to Healthcare Professionals.

Such items (branded or non-branded) may not exceed a value of **EUR/USD 35** (excluding tax, individually or in an annual aggregate). For example, an anatomical model for use in an examination room primarily involves a patient benefit.

Items intended for the personal benefit of Healthcare Professionals (including, but not limited to, floral arrangements, gift baskets, wine, artwork, music CDs or tickets to a sporting event) may not be offered, regardless of their value or the time of year (e.g. holidays).

The only exception is the provision of a cultural courtesy gift (e.g. flowers, fruits, fruit juices) offered under local law and in accordance with local practice as an acknowledgement of a significant national, cultural or religious holiday or special event (e.g. opening ceremony). Such gifts are also subject to the value limit stated above.

It is possible that certain jurisdictions may have more strict requirements, especially for public officials, and it is our policy at Brainlab that you shall comply with such requirements, where applicable.

Payments in cash or cash equivalents (including, but not limited to, gift certificates or vouchers) may not be offered to Healthcare Professionals either directly or indirectly.



Grants and Donations

Research Grants Supporting third-party research programs and partnering with Health Care Professionals to advance independent research can provide valuable scientific and clinical information. Such activities can improve clinical care, lead to promising new treatments, promote improved delivery of healthcare, and otherwise benefit patients. To help meet these objectives, Brainlab may provide in-kind or monetary research grants to support independent medical research. Clearly defined objectives or milestones need to be documented in clinical or research protocols.

The recipient of a research grant should retain independent control over the research.

Brainlab sales personnel may not control or influence the decision of whether a particular organization or institution will receive a grant or the amount thereof.

Brainlab will not issue any unrestricted research grants.

Educational Grants Brainlab may provide educational grants for the advancement of medical education for the following (non-exhaustive) purposes:

- Support for Third Party Organized Educational Events (see above under “Third-Party Educational Conferences or Meetings”)
- Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals
- Support general medical education topics for Healthcare Professionals
- Grants for public awareness campaigns for the legitimate purpose of providing information, promoting awareness and/or educating patients or the general public about relevant healthcare topics, medical conditions or diseases in areas in which Brainlab is interested and/or involved

Charitable Donations Brainlab can also make monetary or in-kind (product or equipment) charitable donations for charitable purposes, such as indigent care, patient or public education or sponsoring events where the proceeds are intended for charitable purposes. Charitable donations may only be made to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

Sales personnel should not control or unduly influence the decision of whether a particular entity will receive a donation or the amount thereof. Brainlab sales personnel may, however, provide input about a proposed charitable program or recipient.

No donation shall be made to any organization that is, to the best of our company’s knowledge, controlled by a consultant, or an immediate family member of a consultant, or at which the consultant or an immediate family member of the consultant is employed. In the case that a consultant/customer raises a donation from Brainlab for an organization that is not the hospital or entity that employs the consultant/customer, the administration of this hospital or entity shall be informed by the consultant/customer about the donation in writing in advance. Brainlab may provide the donation only after having received proof of such information.



Examples of forbidden donations are: donations for the annual party of hospital employees or donations for political or religious purposes.

General All grants and donations must be: (1) based on objective criteria that do not take into account the volume or value of purchases made by, or anticipated from, the receiving organization; (2) not constitute an inducement to purchase Brainlab products or services; (3) be appropriately documented; and (4) not made to a private account or individual.

Prior to the making of any donation, the Brainlab Legal and Compliance department should be consulted to ensure compliance with the foregoing.



United States Supplement

Notwithstanding anything to the contrary contained in this Policy, the following shall apply to all Brainlab personnel who are engaged in sales or marketing activity or otherwise doing business or interacting with any United States-licensed or -based Healthcare Professional. This supplement applies to interactions with U.S. HCPs regardless of whether the interaction takes place within or outside the United States.

To avoid doubt, Brainlab employees or representatives may not offer any payment or remuneration, in cash or in kind, directly or indirectly, whether or not reimbursable through the Brainlab expense policy or reimbursed as a business expense by Brainlab, including any rebate or “kickback” that is prohibited under applicable federal or state “fraud and abuse” laws or regulations including the federal “Anti-Kickback Statute” (42 U.S.C. 1320a-7b). Additionally, be aware that Brainlab is responsible for such interactions, even where the employees or agents pay for the interactions themselves.

I. Gifts

Brainlab may not provide items that are capable of use by the Healthcare Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes. For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a DVD player or MP3 player does not.

Brainlab may not give Healthcare Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Healthcare Professional’s work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, mousepads, and other items that have the Brainlab logo or the name or logo of a Brainlab product.

II. Equipment Evaluation Loans

Brainlab Inc. may provide an equipment loan of Brainlab products to a customer for the purpose of evaluating such products in order to make a purchasing decision. Any provision of equipment for these purposes shall be subject to the Brainlab Inc. equipment loan process, which sets forth requirements based on the products to be evaluated and the corresponding evaluation term. The Brainlab Inc. equipment loan process is documented in the SOP Clinical Demonstration. In no event shall the evaluation term exceed sixty (60) days without the prior approval of the President, North America, or the Director of Finance and Operations, North America. Contact the Brainlab Inc. Legal department for information regarding the evaluation.

III. Massachusetts Healthcare Professionals

In addition, all Brainlab employees and representatives who participate in the sales, promotion, and marketing for and of Brainlab must abide by the following when interacting with Massachusetts licensed Healthcare Professionals or hospitals:



Provision of Meals. Modest meals and refreshments, as defined by Massachusetts law as “food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a healthcare practitioner that, as judged by local standards, are similar to what a healthcare practitioner might purchase when dining at his or her own expense,” may be provided to Healthcare Professionals inside and outside of the Healthcare Professional’s office or hospital setting solely in connection with educating and informing Healthcare Professionals about the benefits, risks and appropriate uses of Brainlab products or other scientific information. Appropriate uses of Brainlab products do not include the promotion of off-label uses.

Notwithstanding the foregoing, neither Brainlab nor any of its employees or representatives may provide payment for meals directly to a Healthcare Professional at any CME event, third-party scientific or educational conference, or professional meeting, regardless of whether such meals occur in a hospital, an academic medical center, or any other facility allowed by state law.

Continuing Medical Education. Brainlab may not sponsor or provide payments related to any continuing medical education program in the state of Massachusetts that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education (“ACCME”) or equivalent commercial support standards of the relevant continuing education accrediting body.

Informational Presentation, Product Evaluation Visit. Brainlab may not pay for or reimburse Massachusetts Healthcare Professionals’ expenses, including travel and lodging-related expenses, related to information presentations or product evaluation visits.

Record of Payments. Brainlab shall keep a record of the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least USD 50, which Brainlab provides to any Massachusetts licensed Healthcare Professional or hospital in connection with Brainlab sales and marketing activities. For purposes of calculating the USD 50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual basis and shall not be aggregated. Fees, payments, subsidies and other economic benefits to Healthcare Professionals shall not be structured to circumvent the reporting requirements of this section.

Activities outside of Massachusetts The Massachusetts Code of Conduct provisions apply to activities that involve a Massachusetts-licensed Healthcare Professional regardless of where such activity takes place. The disclosure requirements apply to any sales and marketing activity directed at and benefiting a Massachusetts-covered recipient. Therefore, activities occurring outside of Massachusetts are subject to regulation if they involve a Massachusetts-licensed Healthcare Professional.

IV. Vermont Healthcare Professionals

In addition, all Brainlab employees and representatives who participate in the sales, promotion and marketing for and of Brainlab must abide by the following when interacting with Vermont-licensed Healthcare Professionals or hospitals.

Allowable Expenditures and Gift. The following shall apply to all sales, promotion, and marketing for and of Brainlab in the state of Vermont:



“Allowable Expenditures” means

- Any payment to the sponsor of a significant educational, medical, scientific or policy-making conference or seminar, provided: (i) the payment is not made directly to a Healthcare Professional, (ii) funding is used solely for bona fide educational purposes and (iii) all program content is objective, free from industry control and does not promote specific products.
- Honoraria and payment of the expenses of a Healthcare Professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities and (ii) the content of the presentation, including slides and written materials, is determined by the Healthcare Professional.
- Payments for a bona fide clinical trial, which include (i) gross compensation for the Vermont location or locations involved, (ii) direct salary support per principal investigator and other Healthcare Professionals per year and (iii) expenses paid on behalf of investigators or other Healthcare Professionals paid to review the clinical trial.
- Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual Healthcare Professionals on the use of a medical device, if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the Healthcare Professional and Brainlab.
- Royalties and licensing fees paid to Healthcare Professionals in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the Healthcare Professional holds an ownership right.
- Payment for other reasonable fees, payments, subsidies or other economic benefits provided by Brainlab at fair market value.

“Gift” means

- Anything of value provided to a Healthcare Professional for free.
- Any payment, food, travel, subscription, advance, service or anything else of value provided to a Healthcare Professional, unless: (i) it is an Allowable Expenditure or (ii) the Healthcare Professional reimburses the cost at fair market value.

Provision of Meals. Neither Brainlab nor its employees or representatives may provide meals to a Vermont Healthcare Professional (regardless of the location of or the nature of the meal), unless the Healthcare Professional reimburses Brainlab for the fair market value of the meal.

Product Training. Brainlab may only provide payment or reimbursement for reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual Healthcare Professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the Healthcare Professional and Brainlab.



Charitable and other donations Brainlab may not make any monetary donations to a doctor or clinic or charitable donations to a hospital. Brainlab may not provide financial support to a fellowship for a residency, regardless of the circumstances.

Record keeping Brainlab shall keep a record of the value, nature, purpose and particular recipient of any Allowable Expenditure or Gift, including product training expenses and equipment loan agreements, which Brainlab provides to any Healthcare Professional or to any academic institution or professional, educational, or patient organization representing or serving Healthcare Professionals or consumers, except (i) royalties and licensing fees as described above and (ii) rebates and discounts for prescribed products provided in the normal course of business.



France Supplement

There are comprehensive and important regulations and reporting obligations regarding interactions with France-licensed or -based Healthcare Professional. These regulations apply and need to be adhered to by all Brainlab personnel who are engaged in sales or marketing activities or otherwise doing business or interacting with any France-licensed or -based Healthcare Professionals. Please refer to the separate document “[France Regulations and Reporting obligations](#)” for the details.

China Supplement

Notwithstanding anything to the contrary contained in this Policy, the following shall apply to all Brainlab personnel who are engaged in sales or marketing activities or otherwise doing business or interacting with any China-licensed or -based Healthcare Professional.

I. Donations

- In China, it is generally allowed and in line with local law to grant donations directly to a hospital/medical association with the intended non-profit charitable use for specific persons and specific purposes.
- A donation offer needs to be prepared outlining the intention and purpose of the non-profit charitable donation; the offer must then be accepted by the receiving organization in their capacity as a legal person in a written agreement stating the kind of donation, quantity, quality, intended use, and rights/obligations. The recipient also needs to issue an officially chopped receipt of the donation. In no case should any internal department or individual thereof be a contracting party of the written donation agreement, or otherwise accept the donation.
- To adhere to the rules outlined above, the Brainlab template "donation letter" should be used for donations in China since it covers the offer, the acceptance, the necessary content as well as the recipient's obligation to issue a receipt. The donation letter must be signed/chopped prior to the donation by an authorized representative of the recipient's administration with the official stamp of the organization.
- Prior to any donation, the Brainlab Legal department should be consulted.

II. Medical Records, Prescription Data and Data of the Use and Consumption of Medicines and Pharmaceutical Products

- Brainlab shall not offer any benefits to any Healthcare Professional in exchange for patients' medical records, doctors' prescription data, and/or data of the use and consumption of medicines and pharmaceutical products.



Italian Supplement

I. Information and Approval Requirements with HCP's Employer (Employer refers here to Public Hospitals and other Public entities)

- The invitation of an HCP to product evaluation visits, product training sessions, meetings or seminars, whether organized by Brainlab or by a third party, must be communicated with appropriate notice (45 days before the event) to the administrative department of the public body to which the HCP belongs, to allow the administration to take a position on the notice to the extent it wants to do so.
- For the appointment of an HCP as a speaker, as well as any other appointment that is performed upon the payment of consideration to an HCP, a separate written authorization from the public body is required at least 45 days in advance. While the authorization could also be sought by the interested HCP, you shall make sure that it is obtained before the appointment.
- Please be aware that the amount paid as consideration for the service shall be communicated by you to the administrative department of the public body to which the HCP belongs within 15 days from the payment.
- Different rules may apply to HCPs who are university employees. In that case, you shall check with the university administration which is the applicable regulation.

Belgium Supplement

According to Belgian law, the sponsoring of so-called “scientific events” is under certain circumstances subject to a “visa”. The law thereby differentiates between Healthcare Professionals that are invited to take part in the event (sponsoring participants) and organizers of these events (sponsoring organizers).

I. Sponsoring Participants of Events

- The visa is required for events (in Belgium or abroad) with Healthcare Professionals working in Belgium that proceed over several (at least 2) consecutive calendar days.
- The term “scientific event” covers inhouse visits, reference site visits, international conferences/congresses, training sessions, meetings of experts, symposia, seminars, practical courses, etc. as well as speaker engagements for such events, and means the scientific event as such, as well as the stay necessary to take part in the event.
- The costs of traveling, registration, accommodation and meals may be sponsored. The sponsoring must be reasonable and subsidiary to the aim of the event.

The following cost-ceiling for meals and overnight stays needs to be considered:

- a maximum of EUR 40 for lunch (drinks included),



- EUR 80 for dinner (drinks included) and
- EUR 250 for an overnight stay (breakfast and local taxes included).

Speaker fees do not have to be submitted.

- The term Healthcare Professionals comprises in this case doctors, pharmacists, nurses, vets, dentists, truss-makers, opticians, hospital directors, hospital equipment purchasers, chiropodists, midwives, laboratory directors, bio-medical operatives, wholesalers, physiotherapists, nutritionists, hospital technicians, etc.
- Brainlab has to make a request for a visa for the participants it is sponsoring in such an event. The visa ID then provided by an agency called Mdeon has to be mentioned in any correspondence with the participants, so they can check the availability of the visa. The participants and Brainlab share the responsibility for compliance with the visa procedure.
- The Brainlab person responsible for organizing the participant's sponsoring is also responsible for submitting the visa request online with the Belgium agency Mdeon. Fees will have to be paid by credit card and a decision about the visa will be received within 5 working days.
- The visa has to be obtained prior to inviting/sponsoring the participants. The visa application has to be made in general no later than the 15th working day preceding the day when the event starts.

II. Sponsoring Organizers of Scientific Events

- A visa is required for events that proceed in their totality over several (at least 2) calendar days and are organized by an association managed by a majority of Healthcare Professionals working in Belgium and/or attract a majority of healthcare professionals practicing in Belgium.
- Companies may sponsor the costs related to the scientific activities of the event (most of the time through the hiring of an exhibition stand). Social or cultural activities have to be financed by sources of revenue other than sponsoring by the industry of medicinal products and medical devices; companies also do not organize such activities.
- It is up to the scientific organizer to present a visa application featuring all the event sponsors. The number of the visa provided then has to be mentioned in any correspondence with the sponsors, who have to be able to verify whether their sponsoring is consistent with the relevant legislation and ethical codes. A company inviting a number of participants at the same time has to submit a visa application (see I.) separate from the visa application made by the organizer.
- If Brainlab is a sponsor, you shall ensure that a visa has been obtained by the scientific organizer before any funding is made available to the organizer.

III. Sanctions

In case of a visa requirement not being adhered to, the sponsoring company and the Healthcare Professional receiving the sponsorship can be liable for legal proceedings (punishable by a prison sentence of between 1 month and 1 year and/or a monetary fine).



Denmark Supplement

I. Promotion/Advertising

- Medical devices that are only intended to be used by doctors for the treatment of patients may only be promoted to doctors and people commercially buying medical devices.
- A promotion must not give the impression that there are no risks associated with the use of the medical device.
- A promotion comparing medical devices must encompass all similar devices within the same application field unless a device has an unsubstantial market share.

II. Information Requirement towards Healthcare Professional

- A HCP who has participated in professional activities outside Denmark (e.g. product evaluation visit, product training) and had expenses (e.g. travel, accommodation, meals) related to this participation covered by Brainlab must report this to the Danish Health and Medicines Authority (DHMA).

Brainlab must inform the HCP of this obligation.

Japan Supplement

I. Provision of Meals

- During lectures, seminars and in medical offices: the value shall not exceed JPY 3,000 per participant.
- The total value shall not exceed JPY 20,000 per participant, incl. Brainlab employees, for holding a lecture or conference, including, for example, venue costs, food and beverage costs, banner charges, flower prices and service charges. For such an event, Brainlab shall keep documentation of event planning and implementation. In any case, refreshments and meals provided during the meeting shall not exceed JPY 3,000 per participant.
- During and after informational presentations, product evaluation visits and product training: the value shall not exceed JPY 10,000 per participant.

Brazil Supplement

In addition to this Policy and to the Brainlab Code of Conduct, the following shall apply to all Brainlab personnel who are engaged in sales or marketing activity or otherwise doing business or interacting with any government employee.



I. Definition of Government Employee

The definition of “government employee” should be broadly interpreted and includes, but is not limited to:

- any person acting in official functions for or on behalf of any federal, state, county or municipal, local or other government or entity (whether of the United States, Brazil or anywhere else), including any department, ministry, agency or entity belonging to or controlled by the government
- any officer, employee, agent or other person (paid or unpaid, temporary, part-time or full-time) acting for or on behalf of a state-owned or state-controlled company, including businesses that are owned, in whole or in part, or controlled (via board membership, voting rights, or otherwise) by the government
- an official or employee of an international organization (such as the World Bank or the United Nations)
- a member of the royalty or the family that governs a country
- a political party or an employee of a political party
- any candidate for a political function
- any person acting on behalf of a regulatory agency.

II. Prohibited Activities

Brazilian anti-corruption laws aim to preclude the direct or indirect payment of bribes towards Brazilian or foreign government employees (or third parties related to any government employee), or the attempt thereof. The law determines that the following actions are illegal and damaging to the public administration:

- promising, offering or giving, directly or indirectly, any undue advantage to a government official or related third party
- financing, sponsoring or subsidizing, in any manner, the practice of illegal actions
- use of an individual or a legal entity to conceal or suppress the actual interests or the identity of beneficiaries of such actions
- engaging in any anti-competitive conduct that involves hindering or defrauding the competitive nature of a public procurement process
- preventing, disturbing or defrauding any act in a public procurement process
- fraudulently or improperly creating a legal entity to participate in a public procurement process or government contract
- fraudulently obtaining an improper advantage involving extensions or modifications of the public procurement process rules or government contracts
- manipulating or defrauding the economic and financial balance of contracts entered into with the public administration



- hindering investigations or inspections by governmental entities, bodies or officials as well as intervening in such activities, including investigations conducted by regulatory agencies and inspection entities of the national financial system.

Russia Supplement

I. Gifts, Agreements, Visits

Under Russian law, there are certain restrictions for the actions and conduct of Healthcare Professionals vis-à-vis medical equipment developers, producers or distributors and/or their agents or representatives. In particular, Healthcare Professionals may not:

- accept any gifts
- enter into an agreement with regard to the prescription or the recommendation of specific medical equipment to patients (except for agreements on clinical trials of medical equipment)
- accept visits, except (i) visits in connection with clinical trials and (ii) meetings/events of Healthcare Professionals that are aimed at improving professional standards or providing information with regard to the monitoring of the safety of medical equipment.