Healthcare Interactions Policy

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SCOPE

This policy sets out the founding principles and global minimum requirements that applies to Camurus interactions with healthcare stakeholders, such as healthcare professionals (HCPs), healthcare organizations (HCOs), payors, patient organizations (POs), patients and caregivers, and other public officials, to ensure those interactions are permeated by ethics, integrity, trust, and responsible behavior, and in compliance with applicable laws, regulations, and industry codes.

In conjunction with this policy, other steering documents, such as Standard Operation Procedures (SOPs) and/ or Company Guidance (GUI), that cover healthcare interactions are implemented in Camurus, to provide more specific operating procedures, guidelines, and/ or to ensure compliance with local requirements.

If there is a conflict between the provisions set forth in applicable laws, regulations, local industry code, or other Camurus steering documents, versus the founding principles and global minimum requirements articulated in this policy, the strictest provisions shall apply.

This policy sets the responsibility of applicable Camurus employees, directors, officers, permanent and temporary, contractors, consultants and agents working on behalf of Camurus (below collectively referred to as "employees"), to observe and comply with the founding principles and global minimum requirements set forth herein. The policy applies to all Camurus employees who interacts with healthcare stakeholders.

OVERVIEW

Camurus works in collaboration with various healthcare stakeholders to drive innovation, exchange knowledge and information in medicine, and improve health and quality of life. While such collaborations essentially contribute to an enhanced patient care, at the same time, we recognize that interactions between pharmaceutical companies and healthcare stakeholders are particularly sensitive to conflicts of interest that may be detrimental.

Camurus´ ethics & compliance framework, including this policy, associated procedures and guidance, our Code of Conduct (1) and Anti-Corruption and Third Party Intermediary Risk Management programs (2, 3), are designed to ensure that no illegal, unfair or unethical activities may take place, such as false or misleading information about our products, pre-approval or off-label promotion, bribery, or other inappropriate manners such as provision of excessive hospitality, gifts or entertainment.

Camurus is committed to applying the highest standards of integrity and honesty, and to follow applicable laws, regulations and codes, in all interactions involving healthcare stakeholders. Camurus embrace the importance of self-regulation, and we therefore use the European Federation of Pharmaceutical Industries and Associations Code of Practice (EFPIA Code) (4) as the primary reference for ethical and compliant interactions with healthcare stakeholders, and the basis for the provisions implemented through this policy. We also recognize the role of WHO´s Ethical Criteria for Medicinal Drug Promotion (5), and the International Federation of Pharmaceutical Manufacturers and Associations Code of Practice (IFPMA Code) (6), as additional reference sources of good promotional practices, at an international level.

Whether or not Camurus is a member of the national industry association, Camurus AB and all their affiliates shall follow the applicable pharmaceutical industry code enforced in the country concerned.

With the exception of Chapter 5 ("Disclosure of Transfers of Values from Member Companies") in the EFPIA Code, for which Camurus, being a non-member to EFPIA, have implemented their own disclosure measures, all provisions in the EFPIA Code shall be adhered to, in addition to the standards

set herein. Similar exceptions from the country industry code disclosure requirements may apply, as long as Camurus remain as a non-member to the national industry association at the local level, and no other binding disclosure obligations either exist.

ROLES AND RESPONSIBILITIES

Role	Responsibility and Obligations
Compliance Officer (CO)	• Establish, monitor and maintain this policy • Ensure training and awareness of the policy in Camurus • Provide advice and answers questions relating to this policy, including how to implement it and ensure compliance with the standards set forth herein
Applicable employees	• Follow and respect this policy in interactions with healthcare stakeholders
Line Manager	• Ensure awareness of this policy to their employees, to lead by example and provide guidance to the employees reporting to him or her as needed
Medical Signature (MS	• Person within the Medical functions (e.g., Medical Director, Head of Medical Affairs, Medical Advisor, Medical Program Manager etc.) with responsibility for approval and signatory rights for compliance in a defined geographic region/country or functional area
General manager (GM) /Country Lead/Business Unit Head *(for simplicity collectively referred to as "GM" throughout this Policy")*	• Overall accountable for the compliant performance of all healthcare interactions organized, sponsored or undertaken by the organization under his/her leadership (on a country and/or regional level, as applicable) • Ensure implementation of local and/or regional policies or procedures, as relevant, to ensure compliance with the provisions set out in this policy, and applicable local laws, regulations and industry code

POLICY

Founding Principles

The overarching principles below apply to all interactions with healthcare stakeholders. In addition, the global minimum requirements as articulated below, contain additional provisions on an activity level. Depending on the scope of the activity, provisions from multiple sections in this policy may apply in conjunction.

Independence of healthcare and non-inducement

The ultimate purpose of all healthcare interactions shall be to improve health and quality of life. We work in collaboration with various stakeholders to achieve this. These interactions shall not entail an undue influence and may not jeopardize, or be perceived as jeopardizing, the independence of healthcare. Nothing of value (e.g., gifts, money, benefits, other support or services) shall be offered or provided to a healthcare stakeholder with the intention to influence decisions to prescribe, dispense, recommend, purchase, supply or administer a product, or otherwise gain business.

Trust, reputation and transparency

The prerequisite for trust and reputation is compliance with extensive legal requirements, such as regarding anti-corruption, fair-competition, public procurement and tax. All interactions with healthcare stakeholders must withstand transparent examination and scrutiny of compliance and business ethics practices.

Camurus should always be transparent about the communications, activities and materials we produce, publish, sponsor, fund, or otherwise support or contribute to.

Divide Promotion and Non-Promotion

To ensure the integrity and legitimacy of communications and interactions that are of scientific and medical matters (non-promotional), it is important to separate those activities from activities that are motivated by the objective to promote the prescription, supply, sale, administration, recommendation or use of Camurus products (promotion). Promotional activities must be openly considered as promotion, not disguised, and be managed accordingly.

Non-promotional activities — where Camurus gain knowledge or advice, such as advisory boards or market research, or studies that are performed to obtain medical and scientific data, including Non-Interventional studies (NIS), must not have a promotional purpose. Such activities must have the genuine objective to obtain legitimate, scientifically relevant and unbiased information, and should never be conducted in a way that are intended or perceived to be promotional. Other examples of Non-Promotional Activities are medical education events and programs.

Camurus may receive unsolicited requests for information on unapproved Medicinal Products (“products”) or off-label information from HCPs, patient organizations, and other healthcare stakeholders. Only the Medical function (“Medical”) may provide information in response to pre-approval and/or off-label requests. Camurus employees who receive unsolicited requests for such information must forward these requests to Medical.

Refer to GUI-0004 “Medical Information Enquire Handling” (7) for further details and provisions.

On an activity level, refer to SOP-0158 “Healthcare Compliance” (8) for a detailed charter outlining the separation of promotional and non-promotional activities, and the associated responsibilities and ownership of the Camurus functions involved.

Responsible promotion

All promotional content produced or disseminated by Camurus (in all forms, including oral) must be accurate, scientifically sound, objective, fair and balanced, and must reflect the current state of knowledge. Materials or activities intended to promote Camurus products must only be directed to

HCPs, unless specific country legislation permits direct-to-consumer advertisement or permits promotion to other non-HCPs.

Promotion must maintain high ethical standards at all times. Promotion must:

a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry;
b) be of a nature which recognizes the special nature of Medicinal Products and the professional standing of the intended audience; and
c) not be likely to cause offence
d) be consistent with the approved labelling (Market Data Sheet, MDS)

No Pre-approval or Off-label promotion

No pre-approval or off-label promotion must occur.

However, and on the contrary, Camurus supports the right of the scientific community and the public society to be informed concerning scientific and medical progress. Therefore, where allowed by applicable local laws, regulations and industry codes, Camurus may exchange scientific information. This may include communications at scientific events, such as medical education programs and satellite symposia, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents.

No gifts or Promotional aids

Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of healthcare stakeholders (either directly or indirectly), or the offering of cash, cash equivalents, personal services and favors, are prohibited. This includes any services or favors unrelated to the profession and that confer a personal benefit to the recipient.

The provision of Promotional Aids, i.e., non-monetary items given for a promotional purpose and not primarily for the personal benefit of the recipient, such as pens and other office supplies, coffee mugs, calendars etc., are also prohibited.

Promotional materials, such as product detail aids, leave behind pieces, booklets, etc. are not promotional aids.

Global minimum requirements

Promotional materials & Associated activities

Promotion must be capable of substantiation, with clear references when referring to published studies, and must never be disguised. It must encourage the rational use of Camurus products, by presenting them objectively and without exaggerating their properties. Claims must not imply special merit, quality, or property unless this can be substantiated.

Promotional materials must reflect an up-to-date evaluation of all relevant evidence. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

Any comparison made between products must be based on relevant and comparable aspects. Comparative advertising must not be misleading or disparaging.

On web pages, appropriate measures must be taken to assure access to information is restricted to targeted audiences (HCPs vs. non-HCPs etc.)

The following minimum requirements might be amended by specific local requirements.

- Any promotional material (in printed/electronic form) must include in legible print size:
  - trade name and generic name of the product
  - name, logo and address of the Camurus company marketing the product.
  - Abbreviated Prescribing Information (API)
    - essential parts from the approved labelling (Market Data Sheet)
  - date of production (month/year) together with a unique identifier
- For "brand reminder" advertisements, i.e., advertisements containing no product claims, indication, or indicated disease area, no more than the following information can be included:
  - trade name, trademark and generic name of the product
  - product logo
  - name, logo and address of the Camurus company marketing the product
  - a note that: "Full prescribing information available from …"

Non-Promotional materials & associated activities

"Disease Awareness" concerns information that relates to human health or diseases, and is not considered as promotional, provided there is no reference, even indirect, to medicinal products. Any Disease awareness information, whether pre or post launch, must be accurate, balanced, and Camurus involvement must always be clear from the outset. Any Disease awareness programs or campaigns targeted at potential patients must also be written in appropriate language for the public. The purpose of such programs is to enhance public awareness of disease, to encourage members of the public to seek treatment for their symptoms and thereby save and/or improve the lives of potential patients while not in any way promoting the use of any specific product.

Lifelong learning in healthcare (LLH) is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome. Camurus can be engaged in or support different types of medical educational programs, but such activities must not constitute Promotion. These activities can be one of three types:

1) Camurus medical education programs
2) Programs that are developed in collaboration with another stakeholder; or
3) Independent Medical Education i.e., conducted by an independent organization and funded through grants or sponsorships

Camurus must ensure that the participation and role of Camurus is clearly acknowledged and apparent from the outset. The activities must have content that is fair, balanced and objective (with a proper balance of efficacy and safety matters being appropriately reproduced, and with a fair and balanced overview of available treatment options), and designed to allow the expression of diverse evidence-based science and fulfill unmet educational needs in healthcare.

Other information and communication undertaken by Camurus, and which fall outside the scope of promotion, concerns:

a) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings, trade catalogues and price lists, provided they include no product claims;
b) non-promotional, general information about Camurus, such as information directed to investors or to current/prospective employees, including financial data, descriptions of research and development programs, and regulatory developments affecting Camurus and Camurus products;

c) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Camurus product

Field interactions

Commercial interactions

During each field visit, and subject to applicable laws, regulations and codes, the Camurus representative must give the persons visited, or have available for them, the latest approved regulatory labelling (SmPC, Prescribing information etc.) for each product they present.

Camurus representatives must ensure that the frequency, timing, and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.

Light, moderate snacks and meals (typically coffee, soft drinks, fruits, or lunch) may be offered if the meeting is scheduled during normal break or lunch hours, subject to local rules and meal thresholds (refer to "EFPIA Scorecard Meals and Drinks", (9)).

Medical interactions

Camurus Medical staff may interact with HCPs throughout the lifecycle of a product for the purpose of exchanging scientific information. These interactions must not be promotional in any way and must have clear intent and transparent objectives. If the interaction concerns non-approved use of Camurus product or pipeline, these interactions shall be reactive in nature, unless directed to recipients with whom Camurus otherwise have a legitimate interest to (inform or) exchange information, e.g., in situations such as research collaborations or similar services, and to investigators in Camurus sponsored studies, including in study feasibility activities.

Product experiences

Camurus staff must transmit forthwith any information they receive in relation to the use of Camurus products, particularly reports of adverse events or product quality complaints, in accordance with the established company procedures for Pharmacovigilance and product complaints.

Market access communications

Governmental institutions or authorities at the national- and/or regional healthcare level, and others, (including private based payor organizations, such as healthcare insurance companies) that are involved in the purchase of medicines need to estimate their likely budgets in advance, or that are involved in recommendations concerning product reimbursement.

Thus, subject to applicable local laws, regulations and industry code, Camurus may interact with healthcare stakeholders referred to as "payors", in order for them to receive advance information about the introduction of new medicines or changes to existing medicines which may significantly affect their level of expenditure.

If such discussions relate to products that are not yet regulatory approved, Camurus must ensure that all communications are non-promotional with regards to the content, the intent, as well as the context in which the subject is being addressed. The information must only be directed to those responsible for making policy decisions on budgets and not those only expected to prescribe.

The communications must be transparent and state whether or not the product and/or indication is the subject of an ongoing regulatory assessment, state the likely cost or savings and budgetary implications which must be such that they will significantly change the organization's likely

expenditure, be factual and limited to that sufficient to provide an adequate but brief account of the product's properties. Other products should only be mentioned to put the new product or indication into context in the therapeutic area concerned. The information provided must not:

a) be promotional in style, or include product branding attributes
b) include drafts of either summaries of product characteristics or package leaflets, of non-approved products or uses

If requested, further information may be supplied or a follow up presentation can be made.

Events and venues

Providing HCPs and other healthcare stakeholders with education and opportunities for scientific exchange is critical in ensuring that the latest and most accurate information and insights on therapeutic areas and related interventions to improve patient care is obtained and enhance the healthcare system overall.

Subject to applicable laws, regulations and industry code, Camurus may furthering the access to quality education for qualified healthcare stakeholders by:

a) Camurus-organized programs and Events ("Camurus Programs"), these can be of promotional or non-promotional kind

b) support for the organization of third-party symposia, congresses and other scientific or professional meetings ("Third Party Events"), through grants and sponsorships

c) sponsoring the attendance in Camurus Programs and Third-Party Events, by provision of registration fees, travel, meals and/or accommodation

All Events must be held in "appropriate" locations and venues that are conducive to the main purpose of the Event, avoiding those that are "renowned" for their entertainment facilities or are "extravagant".

Camurus may not organize or sponsor an Event that takes place abroad unless:

a) most of the invitees are from outside of its home country and,
b) given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country; or
c) given the location of the relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country.

Support to organize or attend Events or programs cannot be conditioned on or offered as a reward for prescription, recommendation, purchase, supply, administration or promotion of any products or therapies. The decisions to support the attendance at Third-Party Events must be independent of sales considerations, and for such international Events the proposed arrangements must also be approved in advance by the Camurus Medical Signature.

Where feasible and appropriate in line with educational objectives, consideration should be given to the use of technology and sustainability matters, to facilitate the virtual attendance in Camurus programs (e.g., webinars) or Third-Party Events.

Hospitality and Travel

Hospitality extended in connection with Events must be limited to travel, meals, accommodation and genuine registration fees, and these must comply with any local applicable thresholds (e.g., refer to "EFPIA Scorecard Meals and Drinks", for hospitality in EFPIA countries, (9)).

Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g., disability or injury), the travel, meals, accommodation, and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

All forms of hospitality offered must be "reasonable" in level and strictly limited to the main purpose of the Event. As a general rule, the hospitality provided must not exceed what the participants would normally be prepared to pay for themselves. At all times it must adhere to the applicable industry code requirements and thresholds.

Hospitality must not include sponsoring or organizing entertainment (e.g., sporting or leisure).

Where possible, costs for hospitality shall be paid directly to the service provider (e.g., travel company, restaurant, third-party meeting organizer), with no direct travel and expense reimbursement to participants or consultants (speakers, advisors etc.). Where HCPs or other healthcare stakeholders are reimbursed for hospitality costs paid directly, these must be supported by appropriate documentation (receipts etc.), be justified, and reflected in the relevant contractual arrangement.

Fee for Service (consultancy) Engagements

Contracts between Camurus and consultants under which those provide any type of services are only allowed if such services:

(i) are provided for the purpose of supporting healthcare, research or education; and
(ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

It is permitted to contract consultants, whether in groups or individually, for services *such as* speaking at and/or chairing meetings, scientific review of company materials, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings or research steering committees, and participation in market research where such participation involves remuneration and/or hospitality.

If a fee for service payment is offered, it should be made clear that it is a payment for such work and advice. Compensation must be commensurate with the time and effort involved, the knowledge, expertise and the professional status of the recipients. Remuneration must reflect the fair market value (FMV) of the services provided, where the country of practice of each consultant is taken into account and must adhere to Camurus FMV compliance framework.

Subject to applicable laws, regulations, industry code or employer practices, in particular for HCPs and other healthcare stakeholders that are employed by public institutions or governmental funded healthcare, in some countries, employers need to be notified and/ or approve of the intended consultancy engagement, which must be respected.

In addition, the arrangements must fulfil all the following criteria:

a) a written contract is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for any payment of those services;
b) a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements;
c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultant meets those criteria;

d) the number of consultants engaged and the extent of the service are not greater than reasonably necessary to achieve the identified need;
e) Camurus maintains records concerning, and makes appropriate use of, the services provided
f) When intending to engage foreign HCPs as consultants, a "cross-border" approval by the Camurus Medical Signature from the HCP's practicing country, must be sought before making any commitments.

Advisory Boards

Advisory boards can be arranged when necessary to answer legitimate business questions to which Camurus does not already know the answer. Advisory boards must be held in an appropriate business venue, and any hospitality provided must be moderate and reasonable.

Each consultant should be chosen for their expertise, such that they will all be able to contribute meaningfully to the purpose and expected outcomes of the meeting. The number of consultants should be limited, to allow active participation by all and should not be driven by the invitees' own willingness to attend.

Invitations to advisory boards should state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken.

The agenda should allow adequate time for discussion and must focus on gaining advice. Multiple advisory boards on the same topic should be avoided unless a clear need for Camurus can be demonstrated.

The content of advisory board meetings should relate solely to the matter in hand. Presentation of clinical data about a particular medicine should only take place if discussion of the data is essential to meet the stated objective for the advisory board. Under no circumstances shall advisory boards be arranged with a promotional intent, be disguised, or pre-approval, or off-label promotion.

The output of the meeting shall be documented (in minutes, reports etc.), with records that demonstrate the intended use of the feedback, as gained by Camurus.

Funding arrangements

The general provisions for the various forms of support and funding arrangements are outlined below. Further procedural and documentation requirements are stipulated in SOP-0158 "Healthcare Compliance" (8).

Grants

Grants (monetary, or in kind or otherwise) to HCOs and/or POs are only allowed if:

(i) they are made for the purpose of supporting healthcare, research or education;
(ii) they are properly documented and kept on record by Camurus; and
(iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Camurus products.

Grants can only be given to reputable organizations, and not to individuals, and must not interfere with the independence of the grant recipients and their associates. Grants must be provided without agreement or intent to receive a tangible return and they must not have the promotion of products as their purpose, thus no return-on-investment analysis may be conducted. The contribution to costs for healthcare stakeholders to attend Events is covered through individual sponsorships.

Grants shall be based on an unsolicited request and are only given for a specific purpose. No obligations are undertaken by the recipient entity, with the exception for the grant conditions imposed by Camurus in writing in order to satisfy compliance requirements, e.g., a declaration by the recipient that the granted amount has been utilized in accordance with their grant request.

Grant requests shall be submitted by the external requestor, ideally through the dedicated portal on Camurus corporate website to ensure adequate documentation to support the application, and without any involvement by Camurus sales functions.

Corporate Donations

Corporate donations are contributions to reputable organizations for an altruistic, non-business related purpose, and where Camurus does not receive or will not be perceived to receive a direct or indirect consideration or service in return. The overall purpose of a donation is to support activities/projects with an affinity to our mission in the fields of healthcare and medicine or to support various initiatives, projects or non-profit organizations and charities, in line with our commitment to Sustainability and Corporate Social Responsibility (CSR) matters. Donations may be provided upon review of an unsolicited request, or proactively for matters such as humanitarian aid, disaster relief and through voluntary work assignments and similar Camurus aid programs.

Sponsorships

Camurus may enter into sponsorship agreements with healthcare stakeholder entities (HCOs, POs etc.), and with associated entities such as Professional Conference Organizers (PCOs) that arrange Events and professional activities, targeting healthcare stakeholders as participants.

Sponsorships include support for activities and Events (such as a congress, conference, symposium or similar) performed, organized or created by a HCO (a scientific society, institution etc.), a PO or other third party, to establish a beneficial association between Camurus' image, brands or services, and the sponsored activity or Event. In contrast to for Grants and Donations, Camurus shall be entitled to a benefit in return for the Sponsorship contribution, e.g., to display an exhibition booth, roll ups or other exposure (e.g., agenda slot for a satellite symposia) at a Third-Party Event, or in close connection to it (e.g., banner advertisement at congress website).

The provision of the Sponsorship must not interfere with the independence of the sponsorship recipients. Therefore, when providing Sponsorships for Events, and Camurus shall not control, nor request any involvement in the practical arrangements, agenda items, selection of faculty, speakers and attendees etc.

Apart from sponsoring the organization of an Event as such, subject to applicable laws, regulations and industry code, Camurus may facilitate the individual participation in Events by healthcare stakeholders, by covering costs for registration fees, travel, accommodation and meals, through the means of an individual sponsorship agreement with the participant or (his/her) employer.

Market research

Market research must not have the promotion of products as its purpose, however the results from market research may subsequently be translated into marketing activities/promotional content. Any payment to individuals participating in market research must be fair market value for the services performed.

If market research involves the collection of patient data, steps should be taken not to cross over into non-interventional studies.

In any case, the following principles must be adhered to:

- All safety data reporting obligations must be fulfilled;
- HCP, patient or caregiver data must only be collected, used and disclosed in accordance with applicable privacy laws and policies, and all notice, consent and/or other privacy requirements must be met;
- Only the minimum amount of data should be collected and retained for only as long as needed

Research in humans

Clinical trials, Non-Interventional Studies and Investigator Sponsored Studies must not be disguised promotion, and must comply with all applicable laws, regulations and codes. These must be conducted with a scientific, non-promotional purpose, however data outcomes derived from such activities may subsequently be translated into marketing activities/promotional content.

Any types of research involving humans must be conducted in compliance with the principles of Good Clinical Practice (GCP) as laid down in the Declaration of Helsinki (10). Meaningful medical or scientific topics must be addressed, e.g., the clinical profile of a product such as safety, efficacy, modes of action or performance related to other treatments. The well-being and personal integrity of participants must always be of the highest priority.

Care should be taken to ensure that related communications, including advertisements to improve patient recruitment are not, in effect, promotional, and must not be misused for the promotion of a product for an unlicensed medicine or use.

The details of conducting and financing studies must be set out in a written contract. Camurus will only pay remuneration to HCPs which reflects fair market value for study-related activities.

The conduct or support of studies must not be conditional on the purchasing or prescribing of products.

Interaction with patient organizations, patients and caregivers

Camurus share many common interests with patient organizations (POs), however clear ethical boundaries when interacting with patients (including users, herein collectively referred to as “patients”) and caregivers, individually or as part of patient organizations (including user groups, herein collectively referred to as “POs”) must be observed.

These interactions must always respect the physician-patient relationship, and support provided by Camurus can never be an inducement to prescribe, recommend, purchase, supply, sell, administer, or use a Camurus product. Furthermore, in all such interactions the absolute prohibition concerning direct-to-consumer promotion must be adhered to, unless specifically allowed under local legislation.

When interacting with POs, Camurus must ensure that the following principles are adhered to:

a) The independence of POs, in terms of their political judgement, policies and activities, must be assured and respected;
b) All interactions between POs and Camurus must be based on mutual respect, with the views and decisions of each partner having equal value;
c) Camurus must not request, nor shall POs undertake, the promotion of a Camurus product;
d) The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Camurus must always be clearly acknowledged;
e) Camurus welcome broad funding of POs from multiple sources, and situations where only one company provides all financial support for a Patient Organization shall be avoided;

f) When Camurus provide financial support, significant indirect support and/or significant non-financial support to POs, a written agreement must be in place. This must state the amount of funding and also the purpose. It must also include a description of significant indirect support (e.g., providing free-of-charge support by a public relations agency, and the nature of its involvement) and significant non-financial support (e.g., providing free equipment);
g) Camurus must not influence the text of PO's material in a manner favorable to Camurus commercial interests. This does not preclude Camurus from correcting factual inaccuracies. In addition, at the request of POs, Camurus may contribute to the drafting of the text from a fair and balanced scientific perspective.

When interacting with Patient Organizations, individual patients and caregivers, in addition, the general provisions for healthcare stakeholder interactions e.g., concerning FMV for services provided, appropriate level of hospitality and venues, written contractual arrangements, applies. If a representative from a PO is being engaged as consultant, the contract and any associated payments shall be made with the PO as the counterpart, rather than the individual, unless the engagement is genuinely concerning sharing the individual´s personal lived experience, and as such the individual is not representing the PO.

Transparency reporting

Camurus is committed to the disclosure of payments and other Transfers of Values (ToVs) to healthcare stakeholders, in accordance with the applicable laws, regulations and/or industry code. In addition, Camurus voluntarily discloses grants and donations, and, for certain jurisdictions also other ToVs, in a manner that goes beyond the binding disclosure requirements imposed on Camurus.

Disclosures are made public via the relevant disclosure platforms and/ or websites, as applicable, and via Camurus corporate website (11).

Risk management of Third-Party Intermediaries (TP Intermediaries)

Camurus will only work with TP Intermediaries (such as distributors, contract sales organizations, and agents), that interact on our behalf with healthcare stakeholders and who share our commitment to high ethical standards and that operate in a responsible way. Camurus' zero-tolerance approach to bribery and corruption must be communicated to all TP Intermediaries.

Camurus expects all TP Intermediaries to comply with all applicable laws and regulations and act in a manner consistent with Camurus' Vendor Code of Conduct, and the provisions reflected herein.

Camurus will conduct adequate procedures to identify, evaluate and mitigate risks associated with entering into relationships with TP Intermediaries. This includes assessing risks that may arise from such relationships, such as corruption, or reputational harm.

Refer to SOP-0150 "Anti-Corruption and Compliance Risk Management of Third-Party Intermediaries" (3) for further provisions.

Governance and implementation

The provisions stated herein set out the global compliance and business ethics standards, to be applied across Camurus headquarters and regional/country organizations. In addition, country and/or regional policies or procedures that impose further details and restrictions, may apply.

Any exemptions from these global standards, must be escalated to the global Camurus Compliance Committee, and is thereafter subject to approval by the Camurus Executive Management Team (EMT).

Pre-approval is generally required for the materials and activities in-scope for this policy, including as a minimum the sign-off by an authorized Medical Signature, before being executed.

For a more detailed description of the review and approval processes and documentation requirements, refer to SOP-0158 “Healthcare Compliance” (8).

POLICY COMPLIANCE

Violations

Violation of this policy is not accepted and may result in formal sanctions being administered, depending on the nature and severity of the violation and in accordance with all applicable laws and regulations. Depending on the circumstances, there might be a need for corrective and preventive steps including training and counseling or disciplinary actions including termination of employment.

It is the responsibility of all Camurus employees to immediately report any suspicion of violation of this policy. Such concerns can be reported through ordinary Line manager reporting, HR, Camurus management, or to a representative of Camurus Legal or Compliance functions. Reports can also be made through Camurus’ whistleblowing system, which facilitate anonymous reporting and follow up. The whistleblowing system is available via Camurus intranet and the corporate website. Camurus will not tolerate retaliation against anyone for reporting concerns in good faith.

ABBREVIATIONS AND DEFINITIONS

(Corporate) Donation	Funds, assets or services freely provided by Camurus to legitimate non-profit organizations (generally to non-healthcare-related recipients) for an altruistic, charitable and non-business purpose, without agreement or intent to receive any benefit, consideration or service in return.
Employee	Directors, officers, employees, permanent and temporary, contractors, consultants and agents working on behalf of Camurus
Gift	Gifts are benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return. They include ‘courtesy gifts’, which are small gifts given at culturally recognized occasions (e.g., weddings, funerals) or special times of the year (e.g., Christmas, New Year).
Grant	Funds, assets or services freely given by Camurus to a Healthcare Organization or Patient Organization in response to their independent request, to support a specific purpose (healthcare, scientific research or education) without any tangible benefit (a measurable or quantifiable and objective benefit) in return.
HCO	Healthcare Organization: any legal person/entity (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for Patient Organizations) or (ii) through which one or more HCPs provide services.

HCP	Healthcare Professional: any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product. For the purpose of this policy, the definition of HCPs includes: (i) any official or employee of a government, agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of Camurus whose primary occupation is that of a practising HCP, but excludes (x) all other employees of Camurus and (y) a wholesaler or distributor of Medicinal Products
Healthcare stakeholder	Healthcare Professionals, Healthcare Organizations, Payers, and Non-Profit Organizations such as Patient Organizations, as well as patients or their caregivers, and other Public Officials, etc.
Hospitality	Hospitality generally includes refreshments, meals, and accommodation.
MDS	Market Data Sheet is a common term for national labels, such as US Prescribing Information, AU Product Information (PI) and EU Summary of Product Characteristics (SmPC).
Medicinal Product	Has the meaning set forth in Article 1 of the Directive 2001/83/EC, namely: (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Non-interventional study (NIS)	A study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the Medicinal Product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures must be applied to the patients and epidemiological methods must be used for the analysis of collected data.
Promotion	Includes any activity undertaken, organized or sponsored by Camurus, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of Camurus Medicinal Product(s).
Patient Organization (PO)	A non-for-profit legal person/entity (including the umbrella organization to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers
Public Official (or Governmental Official)	The term “Public official” has been extensively interpreted by regulators and includes: • Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government • Any elected or appointed officers or employees of public international organizations, such as the United Nations • Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization • Politicians and candidates for a political office • Any other person who is considered to be a public official according to applicable laws, regulations and industry codes. Medical and scientific personnel qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government. In some countries, doctors, pharmacists, clinical trials investigators, and nurses are public officials irrespective of whether they are working at a government institution.
Sponsorship	Support provided by Camurus for an activity (including an event such as a congress, conference, symposium or similar) performed, organized or created by a Healthcare Organization (a society, institution etc.), a Patient Organization, or other third party, to establish a beneficial association between Camurus’ image, brands or services, and the sponsored activity or event.

Third Party Intermediary (“TP Intermediary”)	Any external party, whether an individual or an entity which is appointed by Camurus to represent Camurus in a particular matter and to whom Camurus provides money, goods or other assets. A TP Intermediary includes any external party, who interacts with healthcare stakeholders or Public Officials on Camurus behalf, including re-selling Camurus products to the relevant end-customer (e.g. to a pharmacy, hospital, clinic, healthcare region or healthcare organization).
Transfer of Value (ToV)	Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of a Medicinal Product.

REFERENCES

1. GUI-0016 Code of Conduct
2. GUI-0022 Anti-Corruption Policy
3. SOP-0153 Anti-Corruption and Compliance Risk Management of Third Party Intermediaries
4. EFPIA Code of Practice (2022)
5. WHO Ethical Criteria for Medicinal Drug Promotion (1988)
6. IFPMA Code of Practice (2019)
7. GUI-0004 Medical Information Enquire Handling
8. SOP-0158 Healthcare Compliance
9. EFPIA Score Card Meals & Drinks
10. Principles of Good Clinical Practice (GCP), Declaration of Helsinki
11. Transparency reporting - Camurus