

# Code of Ethics

**on Interactions with  
Healthcare Professionals**



# Code of Ethics

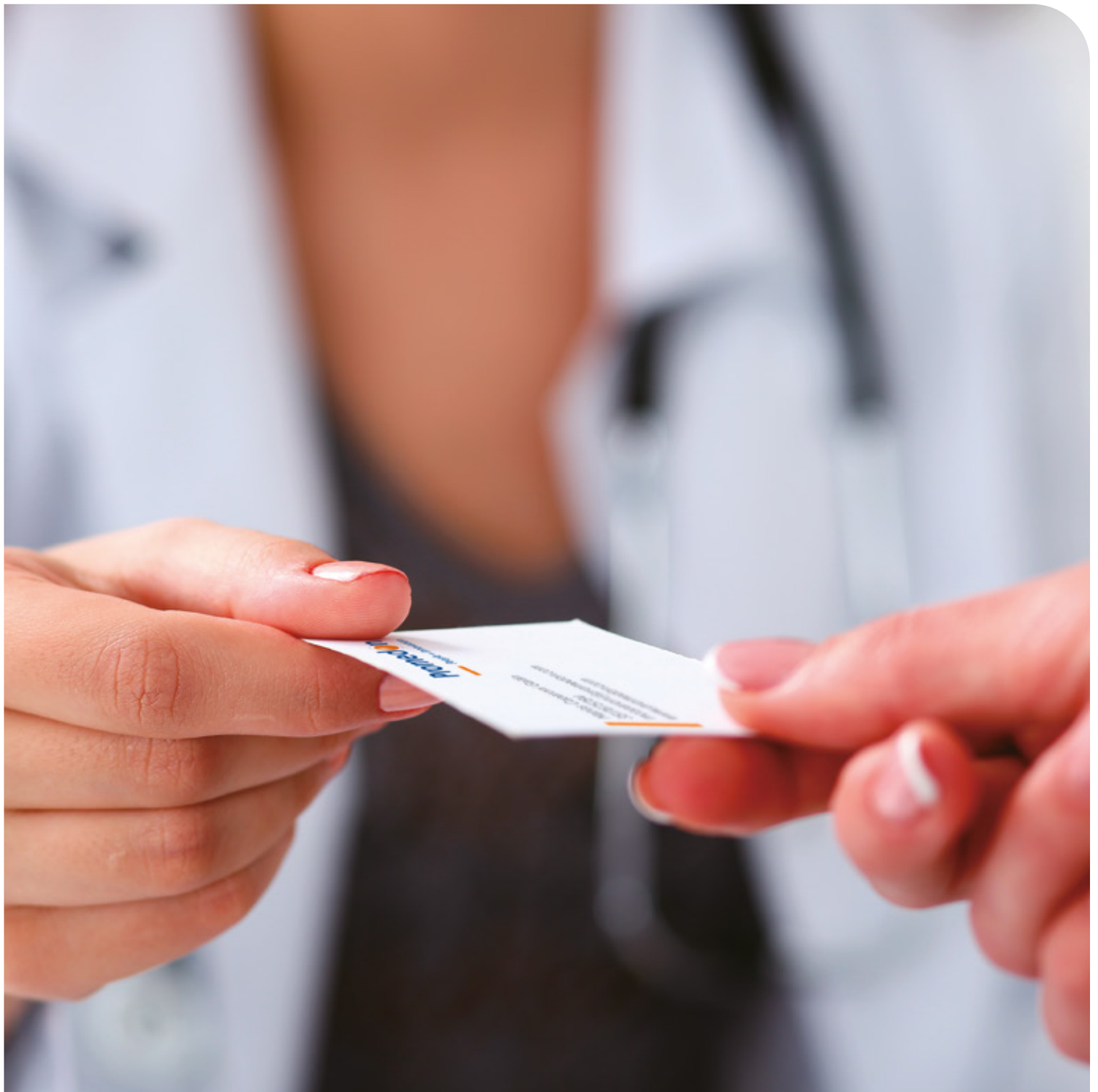
## **on Interactions with Healthcare Professionals**



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## Preamble:

# Objective and Scope of PROMEDON's Code of Ethics on Interactions with Healthcare Professionals.



PROMEDON, a leading international company in the research, development, production and distribution of innovative medical technology (hereinafter also referred to as the "Company"), encourages, supports and promotes training events for professionals related to Services or Products manufactured, marketed or provided by PROMEDON (the "Medical Technologies").

The Company understands these activities as essential elements to achieve compliance, within the framework of its Values<sup>1</sup>, with its mission: **"To contribute to restoring people's quality of life by developing and making available to Healthcare Professionals safe and effective medical technology" (the "Mission")**.

PROMEDON, in order to fulfil the Mission, assumes the obligation to maintain an ethical and transparent relationship with those individuals or entities involved in

the provision of medical assistance Services or Products for Patients (the "Healthcare Professionals").

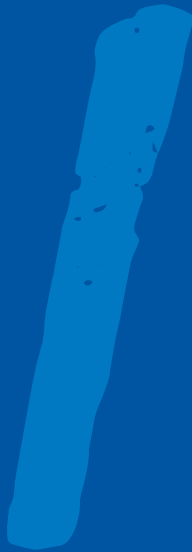
This **Code of Ethics on Interactions with Healthcare Professionals** (the "Code") applies to all PROMEDON Collaborators, Leaders and Directors.

PROMEDON's Ethical Commitment, as well as any Policy, Procedure or legal or contractual obligation assumed by the Company regarding the subject matter dealt with herein, complement the Code, and are considered integral parts of it.

Every year, all PROMEDON employees will renew the certification of their knowledge of the terms contained herein and will once again grant their express commitment to comply with the provisions herein.

<sup>1</sup> For more information on the company's Values, please visit: <https://goo.gl/MNS7jQy>

Chapter



Relationship  
**with Healthcare  
Professionals**





The scope of interactions between Healthcare Professionals and PROMEDON is broad and is always oriented towards fulfilling the Mission within the framework of the company's Values. This includes relationships intended to:

- **Promote the progress of Medical Technologies.** The development and improvement of cutting-edge Medical Technologies arises from the collaboration between PROMEDON and Healthcare Professionals. Innovation and creativity are essential for the development and evolution of Medical Technologies.
- **Promote the safe and effective use of Medical Technologies.** The safe and effective use of electronic medical, surgical or other technologies requires PROMEDON to

provide Healthcare Professionals with the appropriate instruction, training, education, service and technical support.

- **Promote research and training.** PROMEDON's support for bona fide medical research, education and professional skills enhancement promotes the safe and effective use of Medical Technologies.
- **Make charitable donations.** PROMEDON can make monetary and Medical Technology donations for charitable purposes, such as supporting free medical care and patient and public education. This increases access to and quality of healthcare and medical treatment.



Chapter



**The purpose**  
of the Code



PROMEDON recognizes that the main function of Health-care Professionals is **to act for the benefit of patients**. The Company can contribute to the benefit of patients through a continuous and appropriate relationship with Healthcare Professionals.

To ensure that these collaborative relationships meet the highest ethical standards, they must be conducted **with appropriate transparency and in compliance with applicable laws, regulations, and governmental and contractual guidelines**. The rules and ethical principles that govern them and their proper implementation are the subject of this Code.



Chapter



Code  
**compliance**



PROMEDON adopts this Code for the purposes already expressed and proposes a continuous improvement of it and of the policies adopted previously and consequently.

Collaborators, Leaders, Directors and any Third Party acting on behalf or in the interest of Promedon and any other person who has information to report to Promedon about a behaviour that in any way affects the principles and provisions set forth in this Code should contact the **Legal & Compliance Area** ([compliance@promedon.com](mailto:compliance@promedon.com)).

It is reiterated that PROMEDON will interact with Healthcare Professionals in an ethical and transparent framework. This relationship shall be in accordance with all applicable Laws, Regulations and standards, which may establish

greater specificity than this Code. Any interpretation of the provisions of this Code, as well as any relationship of PROMEDON with Healthcare Professionals not specifically addressed here, should be made under the following principle:

**PROMEDON promotes ethical commercial practices and does not participate, promote or take part in any way in the granting or facilitation, by itself or by Third Parties, of incentives or illicit payments<sup>2</sup> of any kind; PROMEDON acts and will always act within the framework of Law and ethics to fulfil the Mission.**



<sup>2</sup> Including the so-called "Facilitation Payments".

Chapter



**Education**

on Medical  
Technologies  
carried out by  
PROMEDON



PROMEDON, in accordance with its Mission, has **the responsibility to provide and promote medical education for the safe and effective use of available Medical Technologies** for the benefit of patients.

That is why in this context **“Education”** refers to the training of Healthcare Professionals on the safe and effective use of Medical Technologies and the communication of information related to or associated with the use of Medical Technologies; for example, information on disease states and the benefits of Medical Technologies for certain patient populations.

Education programmes include, but are not limited to, **practical training courses, internships with corpses, lectures and other presentations.**





## PROMEDON adopts the following rules and principles when, by itself, it carries out Education programmes related to Medical Technologies:

- **Programmes and events should take place in places that are conducive to the effective transmission of information<sup>3</sup>.** In no case will the location where the programme or event is carried out be the fundamental reason for the decision to carry it out. It is appropriate for PROMEDON to offer Education on the Health Professional's premises, or on the Company's premises. PROMEDON has rooms specially designed for this purpose.
- **Programmes providing Practical Medical Technology Education should be conducted in training centres, medical institutions, laboratories or other appropriate facilities.** The instructional personnel chosen by the Company must have adequate preparation and experience to carry out such training.
- **All programmes will be governed by a scientifically rigorous and bona fide agenda.** Programmes, in turn, must relate directly to the specialty or medical practice of

the Healthcare Professionals who will attend the programme, or at least be relevant enough to justify their participation in it.

- **PROMEDON can offer Healthcare Professionals appropriate meals and snacks** in connection with these programmes. These meals and snacks should be inexpensive and subject in a timely manner to the designed programme or activity.
- **When there are objective reasons to support the need to travel outside of a Healthcare Professional's usual place of work** to effectively provide Education, PROMEDON may cover reasonable travel costs. Under no circumstances will PROMEDON pay for meals, snacks, travel or other expenses of Healthcare Professional companions or any other person who does not have a good faith professional interest in the information being shared at the meeting.

<sup>3</sup> These may include medical, training, conference or other facilities, such as hotels or other commercially available meeting facilities.



Chapter

## **Support for Third Party**

educational  
programmes,  
activities,  
or events.

Good faith Third Party scientific and/or educational programmes, activities or events **promote scientific knowledge, the advancement of medicine and the provision of effective medical care**. They usually include: (a) activities sponsored by national, regional or specialty medical associations; and/or (b) activities sponsored by recognized providers of continuing medical education.

PROMEDON, after considering the content of the agenda or programme of each activity or event, and in strict compliance with its Mission and this Code, may support these activities in different ways.





- **Support for programmes, activities or events:**

PROMEDON may collaborate, through the delivery of sums of money or other economic aid, to the organising entity of a programme, activity or event of this type, in order to promote the development and realisation of the same. It may also support a training institution or the organiser of the activity, to enable the attendance of medical students, resident physicians, fellows and other Healthcare Professionals. PROMEDON can only provide support when the meeting is primarily designed to promote objective scientific and educational activities and dissertations. Such support may be given directly to organisations with a genuine educational function and may only be used to cover reasonable and documented costs relating to training activities. In addition, these supports must be in accordance with the applicable criteria established by the conference organiser and also, where appropriate, the body approving the training activity.

- **Agenda of programmes, activities or events:** The agenda of the programme, activity or event must be under the control of the organiser and/or its co-organisers.

- **Location:** PROMEDON will only support programmes, activities or events held in places that are conducive to the effective transmission of information; in no case will it provide support to events where the location where the event is held is the fundamental reason for the decision to hold a particular programme or event.

- **Meals and refreshments of the event:** PROMEDON can provide funds to the organiser of a programme, activity or event to provide meals and refreshments for the attendees. In addition, PROMEDON may directly offer meals and refreshments to them, if they are provided in compliance with the provisions set forth in Chapter IX<sup>4</sup>. All meals and refreshments should be appropriately priced, subject in time and form to the purpose of the conference, and clearly separated from the medical training part.

- **Entertainment:** PROMEDON will not support any Third-Party educational programme, activity or event when it exists, in overlap or conflict with the educational agenda of the same, leisure or entertainment activities, or when the main motive of the same is constituted by an activity of this type.

- **Faculty expenses:** PROMEDON may collaborate with the organiser of an event in the financing of reasonable and documented expenses for fees, travel, lodging and appropriate meals for Healthcare Professionals who are bona fide members of the faculty of the activity. It is reiterated that PROMEDON will have no interference in the selection of such Health Professionals.

- **Publicity and demonstrations:** PROMEDON may advertise, rent stands and carry out all ethical and legally permissible marketing activities to promote its Medical Technologies in activities organised by Third Parties. The Company will ensure that the image and message projected by the advertising and promotional activity is professional and ethical.

<sup>4</sup> "Appropriate meals associated with business relationships with Healthcare Professionals".

Chapter

11

Sales,  
promotional  
and other  
**business  
meetings**



**PROMEDON may hold sales, promotional and other commercial meetings with Healthcare Professionals** to discuss, for example, the characteristics of Medical Technology, or the conditions of sale of the same.<sup>5</sup>

**The information provided to Healthcare Professionals must be true, balanced, and consistent with available scientific studies.** Under no circumstances may promotional information on products be in contradiction with the indication regulatorily established for them.

As a rule, these meetings will be attempted to take place near the Healthcare Professional's business address. It is appropriate to pay reasonable travel expenses for those

attending when necessary, as well as to provide appropriate and occasional meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, snacks, travel or accommodation for companions or anyone else who does not have a bona fide professional interest in the information being shared at the meeting.<sup>6</sup>

PROMEDON will also comply, in these cases, with the other rules and principles relating to the provision of meals associated with the commercial relationship with Health Professionals, in accordance with the provisions of Chapter IX.

<sup>5</sup> They can only be organized if they are permitted by the internal policies of the Healthcare Organizations for which the Healthcare Professionals who will attend work.

<sup>6</sup> Activities strictly related to compliance with local customs are permitted when they cannot induce or influence commercial or medical decisions of Healthcare Professionals, or contradict the essence of this Code, contracts or applicable Laws. In case of any doubt, the Legal & Compliance Area should be consulted beforehand.



Chapter



**Consultancy  
contracts**  
with Healthcare  
Professionals



**PROMEDON may contract Healthcare Professionals to provide, in good faith, consulting services through various types of agreements,** such as research contracts, product development contracts, intellectual property development or transfer, marketing, participation in advisory boards, presentations at training sessions sponsored by the Company and other services.

**PROMEDON may pay consultants remuneration at fair market value for the provision of such services,** provided that it is intended to satisfy a legitimate need and does not constitute an incentive or unlawful payment. In this regard, all hiring shall be permitted under the laws and regulations of the country where the Healthcare Professional is licensed or authorized to work.





## PROMEDON undertakes to comply with the following rules and principles in relation to consulting agreements with Healthcare Professionals:

- **Consultancy contracts should be entered into** only when a legitimate need for services is identified in advance and documented.
  - **Consultancy contracts should be in writing** and adequately describe all services to be provided. Likewise, when PROMEDON hires a consultant to provide clinical research services, there must be a **written research protocol**, unless such consulting services are directly or indirectly linked to the consultant's design.
  - **The number of consultants hired** should not exceed the number reasonably expected to meet the identified legitimate need for services.
  - **The choice of a consultant should be based on** his or her qualifications, preparation, specialist knowledge and accredited experience to meet the identified need. The same principle applies in respect of the remuneration paid to the consultant for services rendered, which must be consistent with fair market value through good faith negotiations between independent parties and must in no case be determined or conditioned by the volume or value of the consultant's past, present or expected business activity.
  - **PROMEDON may pay for documented, reasonable and actual expenses** that a consultant needs to incur in order to carry out consultancy agreements, such as travel expenses, meals and appropriate accommodation. These provisions will be included in the contracts to be concluded with Healthcare Professionals.
  - **The place and circumstances of PROMEDON's meetings** with consultants should be appropriate for the purpose of the meeting. These meetings should take place in medical, training, conference or other centres conducive to the effective exchange of information subject to consultancy.
  - **Meals and refreshments provided by PROMEDON** at a consultant meeting shall be appropriate and subject in time and form to the main purpose of the meeting. PROMEDON shall not offer any kind of recreation or entertainment in conjunction with or on the occasion of these meetings.
  - **PROMEDON sales personnel should not** unduly determine or influence the decision to hire a specific Healthcare Professional as a consultant.
- Provisions for royalty payments.** Contracts involving the payment of royalties to a Healthcare Professional must comply with the contractual rules set forth above.



Chapter



Entertainment  
and leisure  
**activities**



PROMEDON's interaction with Healthcare Professionals must be ethical and of a professional nature, facilitating the exchange of medical or scientific information that benefits Patient care.

In order to ensure proper interaction with Healthcare Professionals, and to avoid any situation that may be associated with a lack of ethics or decorum, **PROMEDON will not provide or finance any event or entertainment or leisure activity for Healthcare Professionals other than its employees.**<sup>7</sup>

In relation to Education or Medical Training activities organised by PROMEDON, entertainment and leisure activities shall be governed by the provisions of Chapter V, referring to support for educational activities organised by Third Parties.

<sup>7</sup> These activities include, by way of example, tickets for plays or sporting events, invitations to golf matches, skiing activities, hunting, fishing, and pleasure or holiday trips.



Chapter



## **Appropriate meals**

associated  
with business  
relationships  
with Healthcare  
Professionals



PROMEDON's commercial relationship with Healthcare Professionals may involve the exchange of scientific, educational or commercial information, and includes the different types of relationship described in Chapters III to VI in a non-exhaustive manner. Such exchanges can be productive and effective, when they take place during a meal. Accordingly, **appropriate meals may be provided as an occasional business courtesy**, in accordance with the limitations of this Code.





- **Purpose.** Food must play a secondary role to the bona fide commercial purpose for which it is intended.
- **Place and location.** Meals should be organised in places that are conducive to the fulfilment of the business purpose of the meeting. The place where the food is made will not be the main reason for the decision to make it there.
- **Participants.** PROMEDON can only offer meals to those Healthcare Professionals who actually attend the meeting. The Company cannot arrange a meal for the whole office staff, if all staff does not attend the meeting. The Company also cannot arrange a meal, if its representative is not present. The Company may not pay for food for companions of Healthcare Professionals or any other person who does not have a good faith professional interest in the information being shared at the meeting.

- **Other rules and principles.** Depending on the type of business relationship or meeting, other rules and principles may apply, as described in other chapters of this Code. Specifically:

**Chapter IV: Education on Medical Technologies carried out by PROMEDON.**

**Chapter V: Support for Third Party educational programmes, activities or events.**

**Chapter VI: Sales, promotional and other business meetings.**

**Chapter VII: Consultancy contracts with Healthcare Professionals.**



Chapter



**Educational**  
and other  
elements<sup>8</sup>



PROMEDON may occasionally provide Healthcare Professionals with articles that benefit patients or have a genuine educational function for Healthcare Professionals. All items should in principle have a fair market value of less than 100 USD.<sup>9</sup>

Goods or items will never be given in the form of money or money equivalents.

<sup>8</sup> This section is not intended to address the legitimate practice of delivering products for evaluation and demonstration purposes referred to in Chapter XIII.

<sup>9</sup> Notwithstanding the foregoing, PROMEDON may exceptionally provide low-value items to Health Professionals as a business courtesy, but will only do so when they cannot induce or influence their professional decision or contradict the essence of this Code, contracts or applicable laws. In such cases, the Legal & Compliance Department should always be consulted beforehand.



Chapter

XI

Provision of  
health economic,  
coverage and  
reimbursement  
**information**



As Medical Technologies become more complex, so do the coverage and reimbursement and/or payment policies of health system insurers and funding agencies.

The access of patients to Medical Technologies depends on the indications of the Healthcare Professionals, of the insurances and financing organisms, and/or also on the possession of health economic information, of coverage and of timely and complete reimbursement. Consequently, PROMEDON, in compliance with its Mission, can provide such information regarding its Medical Technologies, if it is accurate and objective.

**Lawful activities involving the provision of health economic information, coverage and reimbursement may include, but are not limited to:**

- **Identify the clinical value** of the Company's Medical Technologies and the services and procedures in which they are used, providing materials and health economic information, coverage to Healthcare Professionals, professional organisations, patient organisations and insurers and/or funders.
- **Provide accurate and objective information, in the context of education programmes** for Healthcare Professionals, designed to provide technical or other support that assists in the safe and effective use of the Company's Medical Technologies.

PROMEDON may not interfere with the independent clinical decision making of a Healthcare Professional or offer coverage assistance, reimbursement or health economics as an unlawful incentive. In addition, PROMEDON will not suggest billing mechanisms for services that are not medically necessary or for engaging in fraudulent practices to obtain improper payment.

Chapter

XIII

Support  
for medical  
research and  
training, and  
**charitable  
donations**



PROMEDON can, in fulfilment of its Mission, support medical research and training, and make charitable donations. All these supports will only be granted **in response to a written request** made by a Healthcare Organisation or Institution.

Exceptionally, PROMEDON may, on its own initiative, **support medical research and training, and make charitable donations**, but always and beforehand, it must objectively evaluate and record in writing that such support or donation complies with this Code. In no case will they be granted without a written agreement between the Company and the recipient of the same.

However, PROMEDON will not grant such support or donations as an illicit incentive, nor will it determine or condition them according to the commercial profile of the

potential recipient. Therefore, PROMEDON will be based for the **evaluation and granting of supports and donations** in:

- (a) **objective criteria that do not consider the volume or value of the purchases made or expected by the recipient;**
- (b) **appropriate procedures to ensure that supports and donations are not used as an illegal incentive; and**
- (c) **adequate and transparent documentation policies.**





### **a. Support for medical research<sup>10</sup>**

Medical research helps in an essential way to the fulfilment of PROMEDON's mission and because PROMEDON can support independent medical research with scientific merit. The same may consist of:

(a) in-kind support (including PROMEDON products intended specifically and directly for research) or,

(b) financial support, to develop the corresponding research (for example, solving documented expenses directly related to it).

These research activities must have well-defined objectives and endpoints and cannot be connected directly or indirectly with the purchase of Medical Technologies, or other PROMEDON products or services.

PROMEDON's sales staff will not unduly determine or influence the decision to grant a support or charitable donation.

### **b. Support for medical training**

PROMEDON may grant training scholarships for legitimate purposes related to the fulfilment of the Mission. In this regard, the Company can support the genuine medical training of medical students, resident physicians, fellows and other Healthcare Professionals.

Any support related to programmes, events or educational activities of Third Parties shall be in accordance with the provisions of Chapter IV, which deals with the subject.

### **c. Charitable donations and other charitable activities**

PROMEDON may make monetary and in-kind donations (including Medical Technology) for charitable purposes. Donations must be motivated by good faith charitable purposes and will only be made to an organisation whose purpose is such.

Exceptionally, certain donations to hospitals, clinics, or non-profit health care facilities may be permissible: (a) demonstrated financial hardship of the recipient of the donation; (b) the donation is in the direct benefit of the patient; (c) the donation, in principle, is limited in value; and (d) is not prohibited by applicable law or regulation.

PROMEDON will try to improve the accessibility to Medical Technologies of high complexity to those of socially vulnerable populations.

<sup>10</sup>Chapter VII deals separately with research initiated or directed by PROMEDON involving the Company's Medical Technologies (such as clinical study contracts).



Chapter

XIII

Medical  
**evaluation and  
demonstration  
Technologies<sup>11</sup>**



Providing Medical Technologies marketed by PROMEDON to Healthcare Professionals at no cost for evaluation or demonstration purposes **can benefit patients in a variety of ways.**<sup>12</sup>

- **Evaluation.** The Medical Technologies that the Company may provide to Healthcare Professionals for evaluation include single-use products (e.g., consumable or disposable products) and multi-purpose products (sometimes referred to as "capital goods"). Both types of products can be provided free of charge to allow Healthcare Professionals to evaluate the functionality and proper use of the product.

- **Single use / consumable / disposable products.**

The quantity of single-use products provided free of charge should never exceed the quantity reasonably necessary for their proper evaluation.

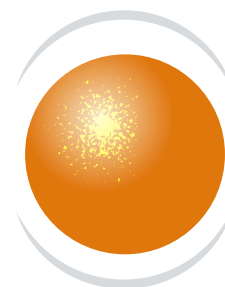
- **Products of various uses / capital.** Products of various uses provided without transfer of title for

evaluation should be delivered only for a reasonable period of time to allow for their proper evaluation. The conditions for the evaluation of products for various uses must be established in writing prior to their delivery. PROMEDON shall retain title to such multi-purpose products during the evaluation period and shall have a procedure to promptly remove such products from the Healthcare Professional's premises at the end of the evaluation period.

- **Demonstration.** Generally, PROMEDON Medical Demonstration Technologies are non-sterile products or models of such products that will be used for the awareness, training and education of the Healthcare Professional and the patient. For example, a Healthcare Professional may use a demonstration product to show a patient the type of device to be implanted.

<sup>11</sup> This chapter is limited to the supply of evaluation and demonstration products only and is not intended to refer to any other agreement.

<sup>12</sup> These benefits include improved patient care, promotion of safe and effective use of the products, patient awareness and training of the Healthcare Professional in the use of the products.



**PROMEDON may provide Medical Technologies from other companies together with the evaluation/demonstration products that it commercializes, in an exceptional manner and as long as these other products are necessary for the effective demonstration/evaluation of PROMEDON's products.**

The provision of Medical Demonstration and/or Evaluation Technologies shall in no case constitute an undue incentive for Healthcare Professionals to purchase, rent, recommend, prescribe, use or supply products marketed by PROMEDON.

**PROMEDON will appropriately document the provision of Medical Demonstration and/or Evaluation Technologies.**





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