

DORC Policy for interactions with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) (excluding USA)

October 1st 2017

1. Introduction

Responsible behavior of all DORC employees is vital to support our mission to supply high quality and innovative techniques, instruments and equipment for ophthalmic surgery to enhance global eye surgery, to ease suffering and to enhance the quality of patients' lives. This document serves as a guide to ethical business practices in all our interactions with HCPs and HCOs in support of our aim to conduct business with integrity.

2. Purpose

This policy establishes global guidelines for professional interactions with HCPs and HCOs and outlines the conduct expected of DORC employees with respect to their professional activities.

3. Compliance with Local Laws, Regulations and Industry Codes

This policy defines global standards. In addition, any business practice must comply with all applicable national and local laws, regulations and industry codes.

4. Common principles

4.1 Independence of HCPs and HCOs

Nothing may be offered or provided to HCPs and HCOs with the intention of having an inappropriate influence on their decision to purchase, supply, recommend, prescribe, dispense or administer DORC products.

4.2 Interactions with HCPs and HCOs

The ultimate purpose of all interactions with HCPs and HCOs is to enhance patient care and/or the practice of medicine.

4.3 Separation between Promotion and Non-Promotion

Activities and interactions that are intended to promote products must be openly considered as promotion, not disguised, and be managed accordingly.

Activities and interactions that are conducted to foster scientific exchange or non-promotional medical education must be structured and managed accordingly.

Non-promotional activities such as advisory boards, market research, clinical studies, etc., must have as their genuine objective to obtain needed, scientifically relevant and unbiased information and must not be designed in a way to achieve promotional objectives.

4.4 Promotional Material

All promotional content produced or disseminated by DORC (in printed or electronic form, or communicated orally) must be accurate, scientifically sound, objective, reflect the current state of knowledge and must be consistent with the information approved by local regulatory authorities.

DORC employees must not promote a product until all necessary approvals have been received. Products must only be promoted for use in indications as approved by local regulatory authorities.

4.5 Adverse Events Reporting

All DORC employees are required to inform the DORC Chief Technical Officer immediately of any adverse event. Regulatory requirements relating to the content, format and timing of reporting adverse events to health authorities may vary. It is important to comply with all such requirements.

4.6 Privacy of patient data

DORC must safeguard all confidential patient data in its possession against misuse or inappropriate disclosure and void any unauthorized access in accordance with applicable laws.

5. Policies for Professional Activities

5.1 Events

The purpose and focus of all congresses, symposia and other scientific and professional meetings for HCPs and HCOs organized or sponsored by DORC must be to provide scientific or educational information.

5.1.1 Funding

DORC may fund HCPs and HCOs to attend events and congresses in the HCP/HCO's country of practice/home country under the following conditions:

- Funding must not interfere with the independence of HCPs.
- Funding is limited to moderate costs for travel, meals and accommodation, and to registration fees. HCP/HCOs must not be compensated for time spent.
- DORC must not pay for any costs associated with persons accompanying HCPs.
- All engagements must be reflected in appropriate contractual documentation signed by the HCP/HCO prior to the event.

5.1.2 Appropriate Venues

All events must be held at an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the event or meeting, and should reflect the principle of moderation, e.g. no resort-like venues. DORC employees must avoid using renowned or extravagant venues.

5.1.3 Hospitality and Entertainment

When DORC organizes a meeting, refreshments and/or meals incidental to the main purpose of the event may be provided. Refreshments and/or meals may only be provided (1) exclusively to participants of the event; and (2) if they are moderate and reasonable as judged by local standards. As a general rule, the value of hospitality should not exceed what HCP/HCOs would be prepared to pay for personal purposes.

No entertainment or other leisure or social activities should be provided or paid for by DORC. It is not allowed to fund attendance at concerts, to purchase entertainment tickets or pay for entertainment in any form.

5.1.4 Speakers

The purpose of engaging HCP/HCOs to speak at events is to share relevant scientific/educational information. Accordingly, engaged HCP/HCOs must be experts in a given field. The engagement must be based on a written contract containing a clear description of tasks and responsibilities signed prior to the event. Fees and expenses must be reasonable and fair market value in relation to the services rendered.

5.1.5 Accompaniment of Invited HCP/HCOs

Invitations to events should only be extended to HCP/HCOs. If permissible under local law/industry code, DORC may accept spouses to accompany invited HCP/HCOs but at no additional cost. However, all cases of a spouse accompanying HCP/HCOs must receive prior approval from the Compliance Department.

5.2 Promotional Interactions with HCP/HCOs

Promotional interactions must not interfere with the independence of HCP/HCOs.

5.2.1 Promotional Aids

Promotional aids are non-monetary items intended to be given to HCP/HCOs related to their work. Such items (e.g. pens and notepads, mugs, etc.), regardless of value and quantity, whether branded or unbranded, may not be provided or offered to HCP/HCOs.

5.2.2 Items of Medical Utility

Unless restricted by local law, regulation or industry code, unbranded (no product or company logo) items of Medical Utility may be provided to HCP/HCOs. (Items of Medical Utility are items that are (1) intended for the direct education of HCP/HCOs or patients and (2) do not have value to HCP/HCOs outside of the scope of their practice and educational needs.)

Medical Utility items may be supplied to HCPs, provided the items:

- Do not offset the operating or routine business expenditure that an HCP might otherwise incur;
- Are offered only on an occasional basis
- Are modest in value, as judged by local standards

5.2.3 Cash, Cash Equivalents and Personal Gifts

Payments or gifts in cash or cash equivalents, such as gift vouchers, must not be provided or offered to HCPs or HCOs. Gifts for the personal benefit of HCPs (such as sporting or entertainment tickets, electronic items, etc.) must not be provided or offered.

5.2.4 Courtesy Gifts and Cultural Acknowledgment Items

A cultural acknowledgment item is a small, inexpensive gift, not related to the practice of medicine, which is given to acknowledge significant national, cultural or religious events. These are sometimes known as courtesy gifts. Such items may not be given to HCPs.

5.3 Grants, Donations, Sponsoring and Other Funding

5.3.1 Grants

Grants can only be given to reputable healthcare or healthcare-related organisations, and not to individuals.

Grants must be provided without agreement or intent to receive a tangible return in exchange and they must not have the promotion of products as their purpose. Grants must not interfere with the independence of grants recipients. All grants must be properly documented.

5.3.2 Donations

DORC may make donations to reputable healthcare or healthcare-related institutions for charitable, non-business related purposes, and where DORC does not receive or will not be perceived to receive direct or indirect consideration or service in return. The overall purpose of a donation is to support activities/projects in alignment with DORC's stated mission. All donations must be properly documented.

NB: difference between Grants and Donations

Grants must serve a specific purpose, for example to support the education of HCPs or to support HCOs in improving infrastructure. Donations must have a charitable, non-business purpose.

5.3.3 Sponsoring

Sponsoring is an agreement with a non-healthcare institution or company with the purpose of enhancing the general image or reputation of DORC. The purpose of sponsoring is not product promotion, and it should not be a frequent activity.

5.4 Public Officials/Institutions

HCPs working at public hospitals or government institutions may be defined as “public officials” by anti-corruption laws. In order to ensure strict compliance with US Foreign Corrupt Practices Act (FCPA), UK Bribery Act and other relevant legislation, interactions with public officials must comply with the following additional requirements (please note that an increasing number of countries have changed/are changing their laws to extend the applicability of these anti-corruption requirements to interactions with private persons):

- All benefits conveyed to public officials must be fully transparent, properly documented and accounted for;
- If required by local law, DORC shall demand written assurance from the relevant public hospitals/government institutions, that benefits conveyed (for example funding attendance at events or engaging public officials as experts/speakers) do not violate applicable local law and regulations. If obtaining that written assurance is unduly challenging, the invited public official shall confirm in writing that the collaboration is in line with his/her professional duties.

6. Implementation

6.1 Training and Awareness

Employees must familiarize themselves with this Policy and participate in periodically held training sessions, including e-learning. Managers should additionally be trained on their specific responsibility to evaluate and effectively address potential bribery and corruption issues. Attendee lists should be signed, retained and archived for every mandatory training event.

6.2 Reporting Potential Misconduct/Non-Retaliation

Any employee who learns of a potential violation of applicable laws or this Policy is required to report his or her suspicion promptly in accordance with the DORC Speak-Up Policy.

Employees who report potential misconduct or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliation. However, an employee who makes a report of potential policy violations is not automatically immune from disciplinary procedures, if he/she is involved in misconduct.

6.3 Breach of this Policy

Breaches of this Policy will not be tolerated and can lead to disciplinary and other actions up to and including termination of employment.

6.4 Responsibilities and Implementation

It is the responsibility of every DORC Manager to adhere to this Policy within his or her area of functional responsibility, to lead by example, and to provide guidance to those employees reporting to him or her.

All employees are responsible for adhering to the principles and rules set out in this Policy.