INTEGRA LIFESCIENCES ITALY S.R.L.

Model of Organization, Management and Control

(pursuant Italian Legislative Decree 231/2001)

[TRANSLATED FROM THE ORIGINAL ITALIAN VERSION]

Special Part B

Marketing and Scientific Dissemination Management

1. Special Part Aim

This Special Part aims to define do's-and-don'ts as well as control activities that all companies are required to adhere to and execute whenever engaging with Healthcare Professionals (HCPs). The controls are in places , for the purpose of *i)* reducing the risk of specific "231" relevant crimes commission as well as of *ii)* assuring correctness and transparency in conducting business activities.

In addition, this Special Part aims to provide Supervisory Body and all other control bodies with relevant information to perform their control activities.

Addressees should adhere to, each of the extent applicable:

- Model of Organization, Management and Control, General Part;
- Standard of Business Conduct and Ethics;
- Delegation of Authorities in place;
- each and all other Company and Group documents addressing activities relevant for the Italian Legislative Decree 231/2001 compliance.

In general, all actions and behaviors in violation of existing and valid laws are forbidden.

2. Special Part Scope

This Special Part and, specifically, do's-and-don'ts as well as control activities detailed in subsequent chapters, apply to all Integra managers, employees and other professionals involved with the below listed processes:

- promotional activities management;
- Health Care Professionals (HCP) relationships management;
- informative material preparation;
- clinical evaluation products management.

3. Applicable 231 crime

231 crimes theoretically applicable to Integra Lifesciences Italy S.r.l. are the following:

- offences against the Public Administration (artt. 24 and 25 Leg. D. 231/2001);
- crimes against industry and trade (art. 25-bis.1 Leg. D. 231/2001);
- corporate offences (including corruption between private parties) (art. 25-ter Leg. D. 231/2001);
- violation of copyright and other related rights (art. 25-novies Leg. D. 231/2001);
- tax crimes (art. 25-quinquiesdecies Leg. D. 231/2001).

4. Do's-and-don'ts

All companies must:

- ensure that the conference events adhere to criteria of a strict technical nature and are oriented to knowledge development in the fields of chemistry, pharmaceutical technology, biochemistry, physiology, pathology and clinical;
- ensure that congress events organized directly by the third-party organizer by the Company (i.e. symposium) are held in not exclusively tourist locations and, whose choice is motivated by logistical, organizational and scientific reasons and which are characterized by a qualifying scientific program;
- comply with fairness and transparency principles in communication and advertising activities addressed to health professionals, including but not limited to doctors, pharmacists, physiotherapists, providers, and bursaries of healthcare companies;
- ensure that the selection of Health Care Professional takes place on the basis of technical and scientific criteria only and that relations between the parties are based on criteria of maximum transparency and scientific seriousness;
- ensure that only services actually provided are remunerated and that related remuneration is proportional to the relative performance, also in relation to the actual market standards;
- ensure that information material is prepared in strict compliance with the relevant regulations and that it is not in any way misleading or inaccurate;
- ensure the distribution of free samples in accordance with contexts, quantities and lawful and non-distortive methods of commercial or market activity.

It is explicitly forbidden to:

- during ECM events, distribute or display devices or informative material, with the exception of the product summary, congress documents and scientific works, only if complete and regularly filed;
- bribe healthcare professional with an invitation to a conference or congress organized by the Company, or any unlawful payment of hospitality expenses for the healthcare professional, their relatives, or others who may unduly influence or manipulate t documentation to facilitate the Company in obtaining medical devices supply for healthcare companies or hospitals;
- bribe a Public Administration Official for scientific informative material creation that is different from the provisions of the law;
- insert protected intellectual works, or parts of them, into the scientific informative material, of which the Company has not acquired a regular license;
- advertise to the public devices that, according to the provisions adopted by decree by the Ministry of Health, can only be sold with a prescription or be used with the assistance of a doctor or other health professional;
- advertise medical devices, other than those of paragraph 1 of the art. 21 of Legislative Decree 46/97, not authorized by the Ministry of Health;

- abnormally manage the finalization of contractual data related to sponsorship initiatives carried out, with the aim of creating conditions for achieving undue savings in tax expenditure;
- record and issue fiscally relevant documents in relation to fictitious services (both objectively and subjectively), or to services rendered, but indicated with a compensation or for a value / quantity not true.

With reference to behavioral principles to be adopted in the management of relations with Public Administration Officers, in relation to the registration and reimbursement of local formulary or during institutional events, please refer to the Special Part "Public Administration Relations Management".

In addition to the above, the behavioral principles and the related regulation listed in the Confindustria Medical Devices Code of Ethics and MedTech Europen Code of Ethics, as well as specific regulations (e.g.: ECM Regulation) must be observed.

5. Promotional activities management

The third-party organized events at which the Company participates have been previously verified and validated by the Conference Evaluation System (SVC) or by the Conference Vetting System (CVS) depending on the scope of the event, a centralized decision-making system that aims at facilitating the Confindustria Medical Devices and Medtech Europe associates in the internal decision-making process of sponsoring events in the healthcare sector. Indeed, associates cannot support a third-party organized event that has not been positively evaluated by the SVC or by the CVS.

Here follow the control activities to be put in place within promotional activities management process.

- Following positive screening by SVC or CVS, the Marketing/Prof Ed/Events Function contacts the organizational secretariat, or the event provider;
- where applicable, all sponsorship agreements will be reviewed and approved by Legal;
- Marketing/Prof Ed/ makes sure that the event is compliant based on the Sponsor Prospectus, the programme and any other valuable information and documentation, and doesn't engage with the organizer unless they receive the SVC/CVS approval and the sponsorship is fair market value
- Marketing/Prof Ed/Events documents the approval of the sponsorship and maintains the documentation for future inquiry and reference. This documentation includes the sponsorship prospectus (or organizer's email stating the sponsorship items Integra chose and the related amount), the SVC or CVS approval, and Integra confirmation of our sponsorship to the organizer.

Marketing/Prof Ed/ records sponsorship payments in Sunshine tool.

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- at least one Company employee or representative (agent) takes part in the event to represent the Company;
- the Marketing Function is responsible for the preparation of appropriate conference reports.

As for the sponsorships budget, the following control activities must be in place:

- the quarterly budget is defined and approved by the EMEA Marketing/ProfEd Function;

- quarterly the budget is reviewed by FP&A;
- the Italy Marketing can sponsor events within their approved budgets;
- quarterly, FP&A reconciles the Italian national budget and the total EMEA budget;
- the local FP&A team is responsible for tracking the expenses of each event:
- with reference to purchases related to conventions and congresses organization, please refer to the Special Part "Procurement management";
- with reference to costs recognition, relevant invoices verification and payments authorization, please refer to the Special Part "Administration, Finance and Control Management";
- with reference to Health Care Professional relations, please refer to the following paragraph;
- all the relevant documentation, highlighting process and critical decision, must be duly archived by the competent function.

6. Health Care Professionals relationships management

Below are the controls in place for engaging with HCPs:

- HCPs selection is under Prof Ed/Marketing Department responsibility, also following requests coming from other Functions (e.g.: Market Access);
- motivations underlying HCPs selection, based on objective technical competence criteria, as well as the subject's details (e.g.: CV and publications, interest that the Company has towards the selected subject, etc.) must be formalized in the Porzio Software, prepared by the Prof Ed/Marketing Function and then validated and approved by Compliance EMEA;
- HCPs selection is subject to approval by Compliance;
- fees are defined in accordance with the Company's FMV compensation methodology;
- HCPs involvement against professional fees must be preceded by the authorization of the entity in which these subjects operate (e.g.: hospital and/or university); the request is sent by the Prof Ed or Marketing Function;
- in case there are no fees to be paid for the collaboration with HCPs, the involvement notification to the institution is sent by the Market Access, the Prof Ed or Marketing;
- at the end of the collaboration, HCPs are required to sign appropriate documentation attesting their participation in the activity, as well as the compensation they will receive. This documentation is reconciled to the service request confirming the hours billed match what was approved in the system. If the hours billed exceed the hours requested, Compliance approval is obtained;
- with reference to budget preparation and approval, please refer to the previous paragraph on the promotional initiatives management;
- collaboration relations must be contracted in written form, drawn up on the basis of standard templates that comply with Confindustria Medical Devices provisions, and signed in line with authorities delegated and powers of attorney;

- contracts include clauses regarding the knowledge and compliance with the provisions of Legislative Decree 231/2001 (or other similar regulations applicable to the counterparty) or compliance with the Code of Ethics and the Model adopted by the Company;
- with reference to administrative management and payments, please refer to the Special Part "Administration, Finance and Controlling Management";
- all the relevant documentation, highlighting process and critical decision, must be duly archived by the competent function.

As for the management of gifts for HCPs, the following control activities must be in place:

- gifts cannot be given at HCP's request;
- only educational gifts complying with local regulations are allowed;
- gifts must be consistent with the activity carried out by the HCP, be for the benefit of patients or have a specific educational function;
- gifts must be of a reasonable amount and cannot exceed the maximum set by local regulations;
- gifts can be provided only in circumstances which the Compliance Function deems appropriate.

7. Informative material preparation

Below are the control activities for the Informative Material Preparation process (e.g.: dossier, brochure, and product information sheet):

- Informative material is prepared at Group level and submitted to the checks of the competent central structures;
- at local level, any translations are carried out by certified translation agencies, selected as indicated in the Special Part "procurement management", according to the operating procedures defined at Group level;
- local Marketing Function is responsible for verifying the translations and for coordinating local printing activities;
- locally, no changes and/or additions to informative materials can be made, which - if necessary - must be requested and motivated by Corporate central function;
- as needed, the suppliers used by the Company are, if recurring, subject to due diligence at EMEA level and registered in Oracle system;
- with reference to costs recognition, relevant invoices verification and payments authorization, please refer to the Special Part "Administration, Finance and Control Management";
- all relevant documentation, highlighting process and critical decision, must be duly archived by the competent function.

8. Clinical evaluation products management

Below are the control activities t in place with reference to products distributed free (generally consumables) for *product evaluation* purposes:

- Samples must be traced into the system (SalesForce) and be previously authorized by the (Regional / National) Divisional Sales Manager and the Financial Controller;
- Free of Charge Product (FOC) and/or Product Evaluation (PE) not authorized according to the envisaged authorization system are automatically blocked by the Company's management system;
- Products for evaluation cannot be submitted for reimbursement;Please refer to the Company's internal policies and procedures.