

METHODOLOGY NOTE TRANSPARENCY REQUIREMENTS IN ITALY

1. PURPOSE

Methodology for the disclosure of transfers of value of the Italian entity Integra Lifesciences Italy S.r.l. to healthcare professionals (HCPs) practicing in Italy and healthcare organisations and third-party organizers registered in Italy.

The disclosure will be made in the name of Integra Lifesciences Italy S.r.l.

2. DISCLOSURE SCOPE AND TIMELINE

- All the transfers of value in year N will need to be disclosed in year N+1
- The disclosure of the transfers of value in year N will have to be made at the latest on June 30 of year N+1.

The date determining in which reference year a value transfer has been given is the date of the event, except for research and development, speakers contracts and multi-year contract whereby the payment date will be taken into consideration.

3. TYPE OF TRANSFERS OF VALUE TO DISCLOSE

3.1. To HCPs (“Healthcare Professionals”)

Definition: Healthcare Professionals are any individuals performing their professional activities within the health care sector, whether public and/or private, (including but not limited to, physicians, nurses, laboratory scientists, technicians, administrative employees within the health care structures, etc.), that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase, lease or prescription of medical technologies or related services.

- Coverage of the costs of participating in a training, educational and promotional event on Integra’s products (registration fees in case of a satellite symposium/meet-the-expert session, transport or accommodation costs – meals and beverages are excluded) organised by Integra.

- Fees for services to consultants/speakers during Integra organized events (product training, satellite symposium, meet-the-expert session at booth space, advisory board etc ..). Related expenses agreed in the contact including travel and accommodation need to be disclosed (meals and beverages are excluded).

The data relating to healthcare professionals will be published individually if consent is obtained from the HCP or in aggregate if such consent is not obtained from the HCP. Integra must do its utmost to obtain the consent of the HCP. Only after repeated efforts to obtain the consent of the HCP, Integra will then be able to publish the HCP data in aggregate, i.e. anonymously.

Each signed consent form will need to be kept in the file by the business owner in a shared folder for traceability.

3.2. To HCOs (« Healthcare Organizations ») and other third party organizers:

Definition of HCO:

Healthcare Organisations mean any legal entity or body (irrespective of its legal or organisational form) that is healthcare, medical or scientific association or organization through which one or more Healthcare Professionals provide services or which may have a direct or indirect influence on any prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies and related services such a hospital, group purchasing organisation, clinic, laboratory, pharmacy, research institution, association, foundation, university, scientific or other teaching or professional institution (except for patient organisations).

Definition of third-party organizers: Legal entity which purpose is to organize, manage all scientific, logistical and organizational aspects of any events in order to meet a scientific educational/training need

- Sponsoring for the organisation of a third party organized congress (commercial activities: booth, logo, banner, satellite symposium ...). If part of the sponsorship, the transportation of products and the products in the case of a loan of products for the duration of a specific event will need to be valued.
- Sponsoring for the organisation of a third party organized procedure training meeting.
- Donations and educational grants.
- Scholarship
- Research and development activities (consulting, non-clinical studies, clinical studies, non-interventional studies etc...)
- Fees for services or consultancy.

The data relating to HCOs will be published on an individual basis, except the following which will be disclosed on an aggregate basis:

- Costs of research and development activities
- scholarships.

No consent will be required, except in the case of a HCO composed of a single healthcare professional (auto-entrepreneur). In this case, consent will be required.

Concerning donations to third party organizers, they will be disclosed on an aggregate basis.

4. PREPARATION OF THE DATA TO BE PUBLISHED

All the transfers of value to HCPs or HCOs and third-party organisers are added to the workspace, a tool that is accessible to a dedicated team in order to track the data transfers within the company, as described below. This tool enables to extract an Excel spreadsheet that can be published on the Integra website.

A dedicated team has been set up to complete the workspace with the required data.

This team is composed of one representative for the following departments ("business owners"):

- Marketing and sales in Italy for the business unit CSS,
- Marketing and sales in Italy for the business unit TT,
- Speakers Bureau,
- Events Department,
- Clinical affairs.

The following information will have to be populated

- First day of event
- Date of payment
- Name of the event
- HCP's consent
- Comments
- Title of the HCP
- Full name
- HCP :City of principal practice / HCO: city where registered
- Country of principal practice
- Principal practice address
- Donations/Educational Grants
In case of educational grant and, therefore, indirect sponsorship, the beneficiary of the support is the promoter of the training-educational part, i.e. HCO. The HCO in this case will need to be disclosed.
- Scholarship
- Contribution to costs of events (amount of contract, registration fees, travel and accommodation) with HCOs/third party organizers at congress and business meetings
 - ☞ If a third-party organiser is mandated by a HCO, the HCO will need to be disclosed. If no HCO is involved in the scientific organization, the disclosure will be done in the name of the PCO.
 - ☞ If Integra sponsors a third-party event organized by joint scientific societies, all the scientific societies promoting the training event are indicated individually, indicating for each the total amount paid and specifying in the notes field that it is the same contribution.
 - ☞ If Integra paid a HCO or a PCO for an event sponsorship which was supposed to be held in 2021 and the event is postponed until 2022, the payment will need to be disclosed in the 2021 disclosure.

- Contribution to costs of procedure training meeting
- Costs for the participation in product training and scientific events organized by Integra (travel and accommodation)
- Fees for services and consultancy
- Research and development
- Total amount per beneficiary

Business owners ensure that consent has been sought in cases where it is required.

The name of the HCO will be retrieved in the final invoice in the name of said HCO and in the contract between Integra and the HCO/third party organizer.

When the sponsorship contract involves a PCO, in addition to a HCO, for the logistical and organizational part - both in case the contract is stipulated with HCO and PCO and in case in the contract is stipulated with the third party organiser only - for the purposes of Confindustria Dispositivi Medici transparency, the promoter of the training-educational part, i.e. HCO, must be considered as the ultimate beneficiary of the support to be published.

5. GENERAL RULES

- The amounts of meals/beverages will not be published if it is possible to separate them from the total amount from the sponsorship package amount. Otherwise, they will form an integral part of the transfers of value to be published.
- The amounts will be published VAT excluded.
- The currency will be in €. In case of aggregated payments made in different currencies, the latter will be converted into € and a comment will be added in the workspace.
- If the transfer of value results from a contract providing for payments over several years, each payment instalment will be published based on the year of payment. If several payments are to be made for the same contract in the same calendar year, only one line will be published by HCP or HCO. The "comments" column of the workspace should be completed with the details of each payment. If several items are involved, the details of each item (e. g. amount of hotel nights, transfer etc.) will have to be indicated.
- Supporting documents/invoices for transfers of value must be uploaded to the shared file.
- The transfers of value paid to HCO/HCP by a parent company of Integra Lifesciences Italy S.r.l. or its subsidiaries will be published in the name of Integra Lifesciences Italy S.r.l.