



Methodological Note

Disclosure of Data Regarding Transfers of Value to Health Care Professionals
and Health Care Organizations, Third Parties

1. Introduction

The Methodological Note describes methodologies used in preparing Bio-Rad Laboratories S.r.l.'s disclosure according to the Code of Ethics of Confindustria Dispositivi Medici.

As a member, Bio-Rad Laboratories S.r.l is therefore subject to transparency self-regulation in Italy imposed by the Confindustria Dispositivi Medici Code of Ethics.

The Note describes methodologies to prepare the first disclosure which will take place in 1st July 2021 regarding 2020 transfers of value, and for all future disclosures.

The data shall be published on Bio-Rad company's website in compliance with the requirement on personal data protection.

2. Definitions

(i) Recipients:

Any Health Care Professional (HCP) or Health Care Organization (HCO) or Third-Party, whose primary practice, principal professional place incorporation is in Italy.

HCP: Any natural person who is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend, rent, use or administer a medicinal product or medical devices and whose primary practice, principal professional address or place of incorporation is in Italy.

This definition of HCP includes (i) any official or employee of a government agency or other organization (whether in the public or private sector) who may prescribe, purchase, supply, recommend, rent, use or administer medicinal products or medical devices and (ii) any employee of a pharmaceutical, in vitro diagnostics or medical devices company whose primary occupation is that of a practicing HCP.

HCO: any legal entity or body (irrespective of its legal or organizational form), 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, utilization, sale or lease of medical technologies and related services. Some examples: hospitals, group purchasing organizations, clinics, laboratories, pharmacies, research institutions, associations, foundations, universities, scientific or other teaching or professional institutions. This definition also includes Patient Associations, i.e. the Organizations that represent and support the patient and caregiver needs in the context of a specific pathology or health aspect.

Third Party: propose, organize, manage all scientific, logistical and organizational aspects of any events in order to meet a scientific or other educational/training need.

(ii) Transfers of Value:

A transfer of value is defined as any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes otherwise, in connection with the development and sale of medicinal products or medical devices for human use.

Direct transfers of value are defined as transfers of value made directly by a pharmaceutical, in vitro diagnostics or medical devices company for the benefit of an HCP or HCO or Third Party;

Indirect transfers of value are defined as transfers of value made on behalf of a pharmaceutical, in vitro diagnostics or medical devices company for the benefit of a HCP or HCO or Third Party or transfers of value made through an intermediary and where the pharmaceutical, in vitro diagnostics or medical devices company knows or can identify the HCP or HCO that will benefit from the transfer of value.

Transfers of value related to promotional material, meals, beverages and product samples are excluded from the publication obligation.

3. Disclosure Scope

(i) Nature of Transfers of value to HCPs:

Contributions to costs related to scientific events or trainings such as registration fees and travel and accommodation. i.e. costs for the participation in training, educational and promotional events on company's products organized by the company (excluding meals and beverages)

Fees for services and consultancy. This category includes transfers of value resulting from or related contracts between in vitro diagnostics and medical devices companies and HCPs under which such HCPs provide a service to an in vitro diagnostics and medical devices company, as well as any other type of funding not covered by the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to the reimbursement of expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

e.g. including speaking services, set forth in a specific contract between the company and the HCP indicating the type of service rendered, including the related travel and accommodation costs (excluding meals and beverages).

(ii) Nature of Transfers of value to HCOs/Third Parties:

Donations and grants that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.

Contribution to costs of scientific events, including sponsoring of healthcare professionals to enable them to attend these events, such as:

- Registration fees;
- Sponsorship agreements with healthcare organizations or with third parties appointed by these organizations to manage a scientific meeting; and
- Travel and accommodation.

e.g. sponsorship of conventions, congresses and scientific meetings, etc. aimed at meeting a scientific or other educational/ training need (excluded meals and beverages)

Fees for services and consultancy. This category includes transfers of value resulting from or related to contracts between in vitro diagnostics and medical devices companies and institutions, organizations or associations of healthcare professionals under which such institutions, organizations or associations provide any type of services to an in vitro diagnostics and medical devices company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to the reimbursement of expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts e.g. including speaking services, as of a specific contract between the company and the HCO, indicating the type of service rendered, including the related travel and accommodation costs (excluding meals and beverages)

(iii) Date of the Transfers of value:

All transfers of value which will occur between January 1st and December 31st, Y and belonging to one of the categories described in Sections 3 (i) or 3 (ii).

This report includes all direct and indirect transfers of value made by Bio-Rad Laboratories S.r.l to Italian HCPs and HCOs/Third Parties.

4. Data collection and data disclosure

(i) Data were captured from various sources:

- Bio-Rad's financial system (SAP): all direct payments were automatically uploaded in the system.
- Bio-Rad's manual processing of events, activities, transactions registration by local (Italian) Bio-Rad Sales Support employees.
- Bio-Rad's online system to request approval for "business courtesies" named Business Courtesies Portal.
- Bio-Rad's expense reimbursement system (Concur): all payments made via P-card by Bio-Rad Sales administrative employees.

(ii) Currency of the transfer of value:

Transfers of value are paid and disclosed in Euro.

(iii) Date of transfer of value:

The date of transfer of value used is the "clearing date" from our financial system which corresponds to the date of the wire transfer to the recipient bank account.

(iv) Value Added Tax and other Taxes:

All the amounts disclosed as transfers of value are exclusive of all taxes additions and deductions.

(v) Publication on an aggregate basis:

(i) Bio-Rad discloses data on an aggregated basis (i) all donations in cash and cash equivalents to Third Parties, (ii) costs for research and development activities and (ii) scholarships or (iv) transfers of value which cannot be disclosed on an individual basis for legal reasons.

(ii) In all cases where it is necessary to publish data on an aggregate basis (see below), the following information must be identifiable:

- the number of recipients as a whole and as a percentage of the total number of recipients;
- the aggregated data attributable to HCPs who have not given their consent to the processing of data;
- the percentage of the transfers of value in aggregate form over the total number of transfers

(vi) Publication on an individual basis:

Regarding transfers of value to HCPs:

Contributions to costs related to scientific events and fees for services and consultancy.

Regarding transfers of value to HCOs, Third Party:

Contribution to costs of scientific events, and fees for services and consultancy.

5 Consent Management

Bio-Rad has requested consent for disclosure to recipients (HCP).

(i) HCP consent:

Bio-Rad discloses HCP details only when consent has been positively obtained.

If an HCP has not given consent its data will be aggregated prior to disclosure.

If an HCP has not responded to the request of consent for disclosure, the HCP will be considered to have not given consent and its data will be aggregated prior to disclosure.

(ii) HCO / Third Party non consent:

There is no legal frame, Bio-Rad does not collect the HCO/Third Party consent prior to disclosing the transfer of value.

6 Document retention

The information shall remain in the Bio-Rad company website for a period of at least 3 years from the time of publication.

As Member, Bio-Rad shall retain the documentation supporting the data published for a period of at least 5 years and make it available, also in a detailed form upon request of Healthcare Professionals / Healthcare Organizations / Third Party.