



EFPIA Disclosure in Luxembourg

Methodology Note for Zambon Belgium

1. INTRODUCTION

As a research focused healthcare company, the Zambon Group is dedicated to benefiting patients, research and public health by providing support to organizations and entities active in healthcare.

This methodology note specifies in detail the rules resulting from the legal framework regarding the disclosure of information on Transfers of Value towards Luxembourgian Healthcare professionals (HCP), Healthcare organisations (HCO) and Patient organisations (PO).

2. GENERAL METHODOLOGY

2.1. Included Recipients

Any HCP, HCO or PO whose practice, professional address or place of incorporation is in Luxembourg, are considered to be recipients.

Zambon N.V/S.A. used the enterprise number or the NIHDI number to clearly identify the HCP/HCO/PO receiving the Transfer of Value (ToV).

2.2. Types of Transfer of Value

2.2.1. ToV to an HCP

A. Contribution to costs related to events

- Registration fees
- Travel and accommodation costs

B. Fees for service and consultancy and related expenses

ToV related to contracts between Zambon N.V/S.A. and a HCP who provides any type of service to Zambon are covered. Honoraria and the expenses stated in the contract covering the activity are disclosed separately.

C. ToV for attendees

The value for any attending HCP is non-existing or similar to the returning value for Zambon. Since there is no net ToV towards the HCPs, no disclosure is required.

2.2.2. ToV to an HCO

A. Grants

Grants to HCO that support or provide healthcare and/or conduct research.

B. Contribution to costs related to events

- Registration fees
- Travel and accommodation costs
- Sponsorship agreements with HCO or third parties appointed by the HCO to manage a project or event

C. Fees for Service and Consultancy and related expenses

ToV related to contracts between Zambon N.V/S.A. and organisations or HCP associations who provided any type of service to Zambon are covered. Honoraria and the expenses stated in the contract covering the activity are disclosed separately.

3. SPECIFIC METHODOLOGY

3.1. ToV period

The reporting period is from 01-JAN-2020 – 31-DEC-2020. ToV are published for all events paid in 2020.

3.2. ToV in case of cancellation

If an HCP cancelled his/her attendance prior to an event, ToV are not reported unless payments already occurred and are not refundable.

3.3. Cross-border activities

Since Zambon operates globally, our entities across the world have interactions with HCP and HCO in EFPIA countries. ToV are disclosed in the country of the Recipient's Practice (i.e. business address, place of incorporation, ...), irrespective of where the ToV was actually paid or where the HCP/HCO/PO was engaged.

3.4. Longer term (more than 1 year) agreements/projects

Zambon will publish the Transfers of Value on an accrued basis. For multi-year assignments, Zambon will publish the amount pertaining to the year in which the portion of service was provided. This standard will be followed for a minimum of three years.

3.5. Research and Development (R&D)

Research and development expenses are published in aggregate.

This involves

- ToV related to non-clinical trials and non-interventional studies
- Research grants to HCO (institutions, organizations or associations that support healthcare and conduct research)
- Mdeon costs for investigator meetings

4. DISCLOSURE'S SCOPE

4.1. Excluded ToV

Items of medical utility or informational or educational material, meals and drinks, samples and support to Patient Organizations were excluded from the disclosure.

5. DATA PRIVACY

The Sunshine Act imposes the legal obligation to process HCPs personal data. It is not required to obtain the HCPs' consent. However, Zambon informs HCPs about the privacy policy.

6. DISCLOSURE FORM

6.1. Date of publication

The date of publication is June 2021 in Luxembourg.

6.2. Disclosure platform

The disclosure in Luxembourg is available via a link from the APL website to the company transparency web page.

6.3. Disclosure language

The disclosure language in Luxembourg is in French.

6.4. Duration of publication

The information will remain in the public domain for a minimum of three years from the time of publication.

7. DISCLOSURE FINANCIAL DATA

7.1. Currency

ToV are disclosed in local currency, therefore in EUR.

7.2. Value added Tax (VAT) included or excluded

The Transfers of Value are published net of VAT and gross of withholding tax.

8. ABBREVIATIONS

EFPIA: European Federation of Pharmaceutical Industries and Associations

HCO: 'Healthcare Organisation'. According to the Sunshine Act (Art. 41, §1, 2°): Any association or organisation active in the field of healthcare or at the medical or scientific level, irrespective of the legal or organisational form, as well as any legal entity through which one or more healthcare professionals provide services and whose business address, place of incorporation or place of operation is in Belgium.. Some examples: a hospital, foundation, university, scientific associations of doctors or professional congress organizers.

HCP: 'Healthcare professional'. According to the RD Sunshine Act (Art. 1, 4°) : Any natural person who is a member of the medical, dental, veterinary, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose practice is in Belgium. Some examples: doctor, dentist, nurse, paramedic, veterinarian, hospital director, etc

PO: 'Patient Organisation'. According to the RD Sunshine Act (Art. 1, 5°) : A healthcare organisation that is responsible for patient representation . This also includes organisations that act in the form of an "umbrella organisation" grouping different patient organisations, as well as patient support groups. A patient organisation that is composed of both patients and healthcare professionals should be considered as a patient organisation if it is composed mainly of patients and/or volunteer caregivers (non-professional) and if it supports and/or defends the interests of patients and/or volunteer caregivers (nonprofessional).

NIHDI number: National Institute for Health and Disability Insurance (INAMI-RIZIV number)

R&D: Research & Development

ToV: Transfers of Value

VAT: Value Added Tax