

Methodological Note

Calendar Year: 2020



Table of Contents

INTRODUCTION	3
1. DEFINITIONS.....	3
1.1 <i>Healthcare Professionals (HCPs)</i>	3
1.2 <i>Other Relevant Decision Makers (ORDMs)</i>	3
1.3 <i>Healthcare Organisations (HCOs)</i>	3
1.4 <i>Professional Conference Organisers (PCO)</i>	4
1.5 <i>Donations</i>	4
1.6 <i>Grants</i>	4
1.7 <i>Sponsorship</i>	4
2. TYPES OF TOVS BEING DISCLOSED.....	4
2.1 <i>ToVs to HCPs and ORDMs</i>	4
2.2 <i>ToVs to HCOs, including PCOs</i>	4
2.3 <i>ToVs related to Research and Development (R&D) Activities</i>	5
3. ORIGIN OF TOVS	5
3.1 <i>Excluded ToVs</i>	6
3.2 <i>Dates of ToVs</i>	6
3.3 <i>Direct and Indirect ToVs</i>	6
3.4 <i>ToVs to 'individual HCP companies'</i>	6
3.5 <i>Disclosure format of ToVs through PCOs</i>	6
3.6 <i>ToVs in Case of Partial Attendance or Cancellation</i>	7
3.7 <i>Cross Border Activities</i>	7
4. DISCLOSURE CONSENT.....	7
4.1 <i>Management of Consent Withdrawal</i>	7
4.2 <i>Management of Recipient's Queries/Requests</i>	7
5. DISCLOSURE FINANCIAL DATA.....	8
5.1 <i>Publication Currency</i>	8
5.2 <i>VAT</i>	8
5.3 <i>Other Tax Considerations</i>	8
6. DISCLOSURE FORMAT.....	8

6.1	<i>Date of Publication</i>	8
6.2	<i>Reporting Year and Data Retention</i>	8
6.3	<i>Disclosure Platform</i>	8
6.4	<i>Disclosure Language</i>	8
7.	CONTACT	8

INTRODUCTION

The following document outlines the processes and decisions taken in the preparation of the disclosure of certain transfers of value (ToV) from Servier Laboratories Limited (“Servier”) to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) in the United Kingdom. All transfers listed relate to prescription only medicines (POMs) as Servier does not have any activities in “over the counter” (OTC) medicines or medical devices.

Servier fully supports the objectives of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice. Servier believes the Code will contribute to provide a better insight on the long-established relationship between HCPs/HCOs and pharmaceutical companies for the improvement of patient care.

The present document is intended to provide all methodological information relevant for interpretation of the information disclosed by Servier in the United Kingdom, as required by Clause 24 of the 2019 ABPI Code of Practice and applicable supplementary information.

1. DEFINITIONS

1.1 *Healthcare Professionals (HCPs)*

The term ‘healthcare professional’ includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

This definition includes the following professionals Servier is interacting with:

- Physicians,
- Medical doctors,
- Pharmacists,
- Midwives,
- Nurses.

NB: the term “physician” refers in this context to a professional qualified to practice medicine.

1.2 *Other Relevant Decision Makers (ORDMs)*

The term ‘other relevant decision makers’ particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not HCPs.

1.3 *Healthcare Organisations (HCOs)*

The term ‘healthcare organisation’ means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more HCPs or ORDMs provide services.

This definition includes the following organisations Servier interacts with:

- Hospitals,
- Healthcare institutions or clinics,
- Group medical practices,
- Clinical research organisations (CROs) or equivalent service providers,
- Service providers in preclinical research,

- Universities (Medical departments),
- Foundations and charities involved in the medical domain,
- Medical or learned societies,
- Medical education companies,
- Associations of healthcare professionals.

1.4 Professional Conference Organisers (PCO)

A company specialised in the organisation and management of congresses, conferences, seminars and similar events (all considered as events). Commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered as PCOs.

1.5 Donations

Funding provided to an eligible non-profit organisation to support its general mission or on-going charitable efforts without any benefit for Servier in return.

1.6 Grants

Financial contribution provided to an eligible organisation to support a specific, time-limited project or programme with identified objectives without a tangible benefit for Servier in return.

1.7 Sponsorship

Support of congress or third-party event in exchange for a tangible benefit, such as a congress stand, promotional satellite speaker programmes, non-promotional symposia, educational meetings and other third-party meetings.

Financial support provided unconditionally to a HCP or ORDM by Servier to attend third-party meetings. In this context it could include registration fees, costs of accommodation and travel.

Donations, grants and sponsorship can be provided to support HCPs and/or patients only with the aim of benefiting patients and the NHS by improving health outcomes.

2. TYPES OF TOVS BEING DISCLOSED

2.1 ToVs to HCPs and ORDMs

Servier discloses the following ToVs when provided, paid or reimbursed to HCPs and ORDMs, or for their benefit, either directly or indirectly:

- Registration fees,
- Travel and accommodation expenses,
- Fees for services,
- Expenses agreed in the services or consultancy contracts.

ToVs to HCPs and ORDMs are disclosed on an aggregate basis by category type, as described above.

2.2 ToVs to HCOs, including PCOs

Servier discloses the following ToVs when provided, paid or reimbursed to HCOs, including PCOs, or for their benefit, either directly or indirectly:

HCOs:

- Donations and grants,
- Fees for services, including training for Servier employees,
- Expenses agreed in the services or consultancy contracts.

HCOs & PCOs:

- Sponsorship agreements towards an event, which may include contribution towards registration fees and travel and accommodation expenses.

ToVs to HCOs and PCOs are disclosed by category type, as described above.

2.3 ToVs related to Research and Development (R&D) Activities

R&D ToVs disclosed by Servier consist of ToVs to HCPs and HCOs (including CROs) related to the planning or conduct of:

- Non-Clinical Studies (laboratory),
- Clinical Trials
- Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual HCPs, or groups of, HCPs specifically for the study

R&D ToVs also include ToVs to PCOs. ToVs to commercial companies involved in organisation of patient travel and accommodation (travel agencies) are not disclosed. All R&D ToVs are disclosed in aggregate.

3. ORIGIN OF TOVS

Servier has gone through an extensive process of identification and recording of all potential ToVs to ensure compliance with the ABPI Code of Practice.

For UK direct ToVs, all HCPs / HCOs are individually identified in our financial system, with the classification of each payment recorded at the time of entry.

UK indirect ToVs are identified and segregated at the time of recording in the financial system. Data from other sources (internal databases) were then used to assign these ToVs to the relevant HCPs / HCOs.

The information disclosed by Servier in the UK is provided on behalf of the Servier Group. Servier is a Group of companies including affiliates in many other countries that can initiate interactions with UK HCPs, HCOs or PCOs.

A Group process is implemented to ensure the local affiliate disclosure includes all ToVs provided by companies of the Servier Group, either locally or in other countries, during the previous calendar year (1st January to 31st December).

Any non-monetary transfers have been identified and valued at an appropriate market rate.

Multi-year agreements refer to contracts with HCPs or HCOs that generate ToVs beyond a period of twelve months. This kind of agreement has no impact on the disclosure and the date of each ToV during the calendar year, in isolation, is taken into consideration for the purpose of the disclosure.

3.1 *Excluded ToVs*

The ToVs corresponding to the following categories or provided in relation with the following activities, are not included in the disclosed information:

- Subsistence (meals and drinks), unless the ToV forms an integral part of a sponsorship agreement towards a third-party event
- Commercial activities that are part of the ordinary course of business including sales of medicinal products,
- Grants, donations and sponsorship ToVs to patient organisations (POs), which are disclosed separately on the Servier company website.

3.2 *Dates of ToVs*

The date used to define the year of disclosure corresponds to the date of the financial payment made to or for the benefit of the recipient.

3.3 *Direct and Indirect ToVs*

The disclosure includes both direct and indirect ToVs provided to recipients, or for their benefit, as follows:

- Direct ToVs that are made to the recipient directly are disclosed as a ToV to that recipient,
- Indirect ToVs are provided to the recipient through a third party and are either disclosed as a ToV to that recipient or to the third party. In this situation, our third parties are required by contract to share with Servier all information related to ToVs in order to allow an appropriate preparation of the disclosure.
 - o Market Research ToV: where Servier knows the names of the HCPs/ORDMs who received a ToV indirectly via a third-party organisation the ToV is disclosed once as a ToV to the HCP/ORDM. Where Servier does not know the names of the HCPs/ORDMs no ToV is disclosed.
 - o Where Servier contracts with a HCO to provide a contracted service to the company, the ToV is disclosed as a ToV to the HCO, even if Servier knows the name of the HCP/ORDM who provides the service on behalf of the HCO, unless the HCO consists of only one HCP/ORDM (see section 3.4 below).

3.4 *ToVs to 'individual HCP companies'*

If a HCO consists of only one HCP/ORDM, then that HCO is subject to the requirements in the Code regarding individual HCPs/ORDMs. In these situations, ToVs to HCPs/ORDMs via such HCOs (individual HCP companies) are disclosed once as a ToV to the HCP/ORDM.

3.5 *Disclosure format of ToVs through PCOs*

Contributions provided for Events through PCOs (organised either through their own initiatives or at the request of a HCO) will be considered as indirect ToVs and be reported on an individually named basis.

ToVs through PCOs are reported in the name of the HCO.

The full value of the ToVs provided through the PCO may not be deemed as a benefit (in cash or in kind) to the HCO as the PCO may retain a part of this amount as “service fee”.

3.6 ToVs in Case of Partial Attendance or Cancellation

Where a HCP/HCO does not receive any benefit, due to cancellation of an event, costs such as cancelling hotel bookings or accommodation are not reported. In case of partial attendance or cancellation of the participation, the actual ToVs provided to a recipient will be disclosed, unless the ToV can be refunded.

3.7 Cross Border Activities

A Servier Group reporting platform is implemented to ensure the local disclosure by any country affiliate can include all ToVs relevant to that country, irrespective of where in the Servier Group the payment originated.

All ToVs initiated by any country affiliate of the Group are thus captured for disclosure in the country where the physical address or principal place of practice of the recipient is located.

4. DISCLOSURE CONSENT

For the avoidance of doubt, individual disclosure is only made when there is an absolute positive consent from the HCP or ORDM.

An individual HCP or ORDM cannot choose which ToV to disclose within the year so there will be either full disclosure against the individual’s name for all ToVs made in the year or disclosure will be made within the aggregated figure.

If Servier was unable to obtain a completed consent form, the publication is made under the aggregate category.

Servier remains committed to the concept of transparency and will continue to encourage HCPs and ORDMs to opt-in to individual ToV disclosure.

With regards to the aggregated disclosure, the template requires the number of HCPs to be noted against each ToV category type. In cases where a non-disclosing HCP has multiple ToV types (for example registration and travel associated with a meeting), they will be counted in both columns (the registration fees column and the travel & accommodation column). This means that a simple addition of HCPs not disclosing across all categories will overstate the actual number of non-disclosing HCPs worked with. Servier has used the Total Optional column to give a percentage for the total number of HCP’s with aggregate disclosure compared with the total number of HCPs with ToV.

4.1 Management of Consent Withdrawal

A recipient may decide to modify or withdraw consent to individual publication. In that case, the publication will be adapted in accordance with the decision taken by the recipient. Disclosed information will be updated to move the amounts from the individual information category to the aggregated information category as defined by the reporting publication template.

4.2 Management of Recipient’s Queries/Requests

Recipients may initiate queries/requests about the information being published by Servier. All queries will be processed according to Servier internal procedures.

5. DISCLOSURE FINANCIAL DATA

5.1 *Publication Currency*

The currency used for the current publication is GBP (Pound Sterling). For ToVs involving the use of foreign currencies, amounts are converted from the initial currency to the publication currency according to the Servier Group Monthly Average Exchange Rate applicable at the date of the ToV.

5.2 *VAT*

Financial amounts indicated in the publication are expressed inclusive of VAT.

5.3 *Other Tax Considerations*

All ToVs are stated at the gross amount paid to the relevant HCP, ORDM, HCO or PCO.

6. DISCLOSURE FORMAT

6.1 *Date of Publication*

The date of publication is 30/06/2021.

This date has been defined in accordance with the ABPI Code of Practice.

6.2 *Reporting Year and Data Retention*

The publication relates to the previous calendar year (from 1st January to 31st December 2020).

This information will remain publicly available on the local association's website for a period of 3 years after the date of the publication. This information will be retained by Servier for at least 5 years after the end of the calendar year to which they relate.

6.3 *Disclosure Platform*

The publication is provided through the local association's website:

<https://search.disclosureuk.org.uk/>

6.4 *Disclosure Language*

The publication is provided in English.

7. CONTACT

Any questions can be emailed to datamanagement-uk@servier.com