METHODOLOGICAL NOTE 2021

INTRODUCTION

Our society expects the pharmaceutical industry to be able to make the best possible medicines available to them. To achieve this objective, it is necessary to invest in Research and Development, as well as in training, requiring close collaboration with Healthcare Professionals (HCPs), Healthcare Organizations (HCOs) and Patient Organizations (POs). This valuable exchange of knowledge and experience makes it possible to have the most innovative treatments, which improves the life expectancy and quality of life of patients.

It is necessary for these collaborations to be transparent and for society to be able to trust that they are due to the need to develop new medicines, to constant updating of HCPs according to scientific evidence and its application to clinical practice, all of this with the common goal of providing better patient care.

When collaborating with medical experts, we comply with applicable laws and regulations such as the EFPIA Disclosure Code in Europe and fully respect the independence and integrity of these professionals.

That is why, since 30 June 2016, companies disclose transfers of value made to HCPs, such as consultancy and advisory boards, speaker fees, and sponsorship to attend meetings. This transformational step in the relationship between industry and health professionals is a result of the EFPIA Disclosure Requirements.

The Disclosure provisions in the EFPIA Code require all EFPIA member companies and companies that are members of EFPIA member associations to disclose transfers of value to HCPs, HCOs and POs. They will also have to disclose – by HCP or HCO – the total amounts of value transferred, by type of activity, which could consist of, for instance, a grant to an HCO, a consultancy fee for speaking, payment for travel, or registration fees to attend a medical education congress. Also each Member Company must disclose a list of POs to which it provides financial support and/or significant indirect/non-financial support or with whom it has engaged to provide contracted services for that Member Company.

More information related to this iniciative: *https://efpia.eu/relationships-code/disclosure-of-payments-to-hcps/*

DEFINITIONS

Recipient: any HCP or HCO or PO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

Healthcare Organisation (HCO): any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Patient Organisation (PO): non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

Transfers of Value (ToV): Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly by a Member Company for the benefit of a Recipient. Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or those made through a Third Party and where the Member Company knows or can identify the Recipient that will benefit from the Transfer of Value.

Donations and Grants: collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

COMPILATION OF INFORMATION TO BE PUBLISHED AND IDENTIFICATION OF RECIPIENTS

COMPILATION OF INFORMATION

The transfers of value made to HCPs, HCOs and POs have been recorded at the time they were managed in the tools specifically adapted for this purpose.

All transfers of value made in 2021 have been published.

In the case of multi-year contracts, the payments registered in our financial system in 2021 have been published.

The publication of the data is declared as a gross amount.

IDENTIFICATION OF RECIPIENTS

There is not individual identification of the recipients. All ToVs related to HCPs have been published on aggregate form.

There is not Transfer of Value for HCOs and POs in 2021.

DISCLOSURE OF ToVs TO HCPs AND HCOs

The different concepts of the collaborations carried out by ROVI for HCPs are described below.

There is not Transfer of Value for HCOs and POs in 2021. There is not ToVs related to Research & Development in 2021.

It must be taken into account that each concept includes the annual amount, so it corresponds to all the collaborations carried out during the period subject to transparency for that HCP.

FEE FOR SERVICE AND CONSULTANCY

Fee/Honorarium

ROVI has needed to contract HCPs to give presentations, prepare scientific content, advice on specific issues as consultants and training activities. The economic remuneration has been moderate and in accordance with the type of activity, the level of knowledge, experience and the time spent.

Contractually agreed related expenses for the provision of these services.

This section reflects the related expenses agreed in the fee for service or consultancy contract, including travel and accommodation relevant to the contract that the HCP reasonably incurs for the execution of the provision of the service.

DISCLOSURE OF ToVs TO POs

There is not Transfer of Value for POs in 2021.

DATA PROTECTION

As stated, the EFPIA Code states the need to publish the transfers of value made by Pharmaceutical Laboratories to healthcare professionals. Accordingly, the data relating to transfers of value deriving from the collaboration of Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) with the ROVI Group will be processed in order to proceed with the individualized or aggregated publication on its website of the following information:

Individualized disclosure	Aggregated disclosure
Personal Data: • Full name • City where the professional practice is carried out • Country where the professional practice is carried out • Professional address	-
Transfers of value: • Contribution to Costs Related to meetings: ○ Registration fees ○ Travel and accommodation • Fees for Service: ○ Fees ○ Expenses agreed in the written agreement covering the activity, including travel and accommodation	**Transfers of value:** • Aggregate amount attributable to transfers of value to such Recipients • Number of Recipients in aggregate disclosure • Percentage of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed

The information shall be publicly available for a minimum period of 3 years from its publication, unless a shorter period is legally established. The Company will keep on file the documentation evidencing the transfers of value for at least 5 years from the end of each period, unless a different period is legally established.

The basic information on the processing of personal data in the context of these activities is:

BASIC DATA PROTECTION INFORMATION	
Controller	Rovi Biotech Limited
Purpose	Transparency of transfers of value made to Healthcare Professionals.
Legal base	Consent
Recipients	Other entities that form part of the ROVI Group The transparency is made public through ROVI's webpage
Rights	You have the right to access, rectify and delete the data, as well as other rights, as explained in the additional information.
Additional information	If you wish to know more about our treatment of personal data regarding the transparency obligations, you can find it below.

Who is the Data Controller?

- Identity: Rovi Biotech Limited – VAT: 272726882
- Postal address: Davis House 4th Floor, Suite 425, Robert Street, Croydon, United Kingdom, CR0 1QQ
- E-mail: protecciondedatos@rovi.es.

Who is the Company's Data Protection Officer (DPO) and how can they help you?

The DPO is a legally established figure whose main functions are to inform and advise the entity on the obligations that affect it in matters of personal data protection and to supervise its compliance. In addition, the DPO acts as a point of contact with the entity for any question relating to the processing of personal data. ROVI's DPO can be contacted at: dporovi@rovi.es

For what purposes do we process HCPs personal data?

We process HCPs personal data for the purpose of managing HCPs relationship of collaboration or provision of services with ROVI and to carry out the transfers of value carried out in this area, including their publication under the conditions previously stated.

The processing of these data is essential for these purposes, so that the HCPs collaboration or provision of services could not otherwise take place.

For how long will we process HCPs data?

The data will be retained until the legal liabilities arising from the service provision relationship expire and, in any case, for the periods indicated on the front of this document for the purposes of individual publication of transfers of value.

What is the legal basis for the processing?

The individual publication of transfers of value finds its basis in the consent.

The aggregated publication does not include personal data.

To which recipients will the data be communicated?

For the centralized management of activities, the data may be communicated to the other entities that form part of the ROVI Group, the identity of which may be consulted at http://www.rovi.es/company/company.php.

Transfers of value will be published on the web site www.rovi.es/uk/

What are the rights regarding personal data?
Any person has the right to obtain confirmation as to whether or not are we processing personal data concerning them. Data subjects have the right to access their personal data, as well as to request the rectification of inaccurate data or, where appropriate, to request its deletion when, among other reasons, the data is no longer necessary for the purposes for which it was collected.
Under the conditions provided for in the General Data Protection Regulation, data subjects may request the limitation of the processing of their data or their portability, in which case we will only keep them for the exercise or defense of claims.
All the aforementioned rights may be exercised through the means of contact listed at the beginning of this clause and by sending an email to the following email address: protecciondedatos@rovi.es.
In the event of any breach of your rights, in particular where you have not obtained satisfaction in exercising them, you may lodge a complaint with the Information Commisioner's Office (contact details accessible at https://ico.org.uk/) or, where appropriate, another competent supervisory authority. You can also obtain further information about your rights by contacting these bodies.
Third party data must not be provided and, in any case, if you do so, you assume the responsibility of informing them in advance of all the provisions of this clause and of article 14 of the General Data Protection Regulation, under the conditions established in said precept.

TYPE OF DISCLOSURE

INDIVIDUAL DISCLOSURE
The procedure for informing HCPs of the individualized publication of their data is based on the signing of a document that includes all the information on transparency, as well as the aforementioned rights. (EFPIA Authorization Form).

AGGREGATE DISCLOSURE
In those cases in which the Healthcare Professional has not given their consent for the publication of the data individually, they have been published in aggregate form.

DISCLOSURE UPDATE
The data responds truthfully and rigorously to the data recorded on the ROVI tools set up for this purpose.

However, if any incorrect information is detected, we will follow up and if necessary, regular updates will be published if there are significant changes in the individual publication.

LEGAL NOTICE

We use a combination of automated systems, standardized procedures and manual data entry through internal and external resources to collect relevant information and its subsequent publication. The published information reflects our good faith and best efforts to comply with the provisions of Chapter 5 of the EFPIA Code of Practice. In the event that, despite our best efforts to ensure a publication that faithfully reflects the transfers of value carried out, we have not managed to include correct and complete information, we will investigate it and give an appropriate response in the event that the information is incorrect. The interested party may exercise their right to rectification, as well as the rest of their rights related to data protection, by the means indicated in the section "What are the rights regarding personal data?".

Information posted as required by the Code on this website will be used solely for the purpose of complying with the provisions of the Code. The data will not be used as a reference by tax authorities or similar.
The publication of these data responds to the transparency obligations derived from the EFPIA Code of Practice.

The publication of the information does not give rise to a general authorization for those who access the website to carry out an additional treatment of the professionals' data, such as crossing it with the information published on the websites of other associates.

ROVI has adopted security levels to prevent information from being indexed by search engines.