

METHODOLOGY NOTE FOR 2023 DISCLOSURE OF ToVs TO HCPs AND HCOs

AOP Orphan Pharmaceuticals Greece LTD (hereafter AOP) interacts with Healthcare Professionals (hereinafter HCPs) and Healthcare Organizations (hereinafter HCOs) to collect as much information and knowledge as possible on a wide range of issues that contribute to the development of high-quality pharmaceutical products, which develops, manufactures and promotes. Our primary concern is to comply with applicable legislation, and we are committed to transparency in our business practices and when interacting with HCPs and HCOs.

Pursuant to the requirements of Article 66 (7a) of Law 4316/2014, pharmaceutical companies in Greece are required, for transparency purposes, to disclose both on their website and on the National Organization for Medicines' (EOF) special platform, all ToVs granted towards HCPs and HCOs in accordance with the above provisions. This note describes the basic terms and the methodology for disclosing AOP's ToVs to HCPs and HCOs, whose main professional occupation is in Greece, for the calendar year of 2023 starting from 1/1/2023 until 31/12/2023.

It should be noted that this note refers to the disclosure of ToVs granted by AOP to HCPs and HCOs for the full year 2023.

It is expressly noted that this disclosure was made taking into account the content of the Hellenic Data Protection Authority's Opinions no. 5/2016 and 2/2017 and the as of 02/01/2024 Announcement of EOF. This report, therefore, complies with the most updated regulatory rules and legal framework. Our company however reserves the right to update the present disclosure in case new guidelines and instructions are given by the competent authorities (EOF) as well as by the Hellenic Data Protection Authority.

In particular, for the period from 1/1/2023 to 31/12/2023, AOP, being in compliance with the local legislation on ToVs disclosure as well as the General Data Protection Regulation 2016/679 (GDPR) and the respective opinions of the Hellenic Data Protection Authority (No. 5/2016 and 2/2017) proceeds to the aggregated disclosure on her website of all ToVs granted to HCPs related to scientific events, to the disclosure by name of respective ToVs granted to HCPs regarding promotional events as well as to the disclosure by name of respective ToVs granted to HCOs.

Definitions

HealthCare Professionals (HCPs)

Any natural person that is a member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Greece.

HealthCare Organizations (HCOs)

Any legal person that is a healthcare, medical or scientific association (scientific society or an association of HCPs) or healthcare organization, such as a hospital, clinic, foundation, university or other educational institution or learned society of any type sponsored by pharmaceutical companies, which has registered office or is active in Greece.

Disclosure of ToVs towards HCPs:

- Registration fees and travel and accommodation expenses
- Fees for consulting and other services
- Honorarium remuneration

Pursuant to Law 4316/2014, excluded from the scope of the disclosure obligation are transfers of value that:

- market research
- meals and drinks
- medical samples and medical utility items of insignificant value that are directly related to the conduct of the daily medical practice of HCPs and HCOs, i.e. any item whose value does not exceed the total amount of fifteen (15) euro including of VAT.

Disclosure of ToVs towards HCOs

- Donations (donations and grants to HCOs that support science, technology, medicine, health care, research or education).
- Sponsorship related to scientific events organized by HCOs
- Fees for service and consultancy.

When a third company (ie PCO) organizes a conference and acts on behalf of an HCO, AOP shall disclose the sponsorship in the name of the beneficiary HCO, even if the payment is paid to the third party.

Costs related to research and development activities

Transfers of value related to the planning or conduct of (i) non-clinical studies (ii) clinical trials and (iii) non-interventional studies that are prospective in nature shall be disclosed on an aggregated basis.

All direct payments will be recorded excluding VAT including the withholding tax (if applicable) attributable to the authorities. For all ToVs, the gross amount will be recorded, including VAT on a case-by-case basis. The amounts of ToVs disclosed should not be used for tax or VAT inspection purposes. Cancellation costs before the event will not be recorded as they are considered a ToV.

Time of disclosure

The disclosure of information relating to ToVs towards HCPs and HCOs is made on an annual basis. All data are recorded throughout the year and are published by the end of the next year's first semester at the latest. The information disclosed shall remain available for 3 years.

Personal Data Protection

Pursuant to Article 6 of General Data Protection Regulation (EU) 2016/679 the processing of personal data is considered lawful as long as such processing is necessary in order for the Data Controller to comply with a legal obligation.

AOP is the data controller of the personal data of HCPs with whom she interacts. In view of the above, there is no obligation for AOP to obtain prior consent from HCPs for the disclosure of ToVs which she has granted, insofar as such disclosure is a legal obligation of the company such being the data controller. It is noted that all data subjects

have the right to access and correct their data, the right to object to the processing of their data, the right to be forgotten, and the right to portability, to the extent that such rights are not limited in order for AOP to comply with her legal obligation as set by Law 4316/2014.

AOP has made every effort to ensure that the attached disclosure report is in full compliance with the current legislative and regulatory framework. Our goal is to keep the highest possible accuracy and completeness in the published data.

In the event any HCP or HCO disagrees with the present disclosure, AOP shall investigate any matter raised so that it can be appropriately addressed, within the limits of the law and other regulations, in accordance with the above. Relevant requests may be sent by e-mail to privacy@aoporphan.com
You can download AOP's disclosure 2023 file [here](#).