

Date: June, 17<sup>th</sup> 2020

From: Galderma Italia S.p.A.

To: European Federation of Pharmaceutical Cc:

Industries and Associations - Farmindustria

Subject: Galderma Italia S.p.A. EFPIA HCP/HCO Disclosure Code Methodology Notes 2019

Contact Maria Paola Carosio - Regulatory, Medical Affairs, Quality & Compliance Director

Person:



### **BACKGROUND**

Galderma Italia S.p.A. (Galderma) is a member of Farmindustria. It is an obligation for Galderma to publish the data in connection with the interactions of HCPs and HCOs according to the EFPIA HCP/HCO Disclosure Code and Farmindustria Deontological Code. In addition, it is Galderma's responsibility to publish a methodology note as required, to summarize the methodologies used in preparing the disclosures and identifying Transfers of Value (TOVs). This document supports and explains how Galderma publishes this information in order to comply with the EFPIA Disclosure Code and Farmindustria Deontological Code in 2019.

Galderma commits to comply with the national transparency laws/regulations and the EFPIA Disclosure Code fully. It is our responsibility to make all the possible effort to disclose the TOVs and obtain the consents from the HCPs.

### **SELECTION OF DATA**

Galderma reports the data in the standardized template with the following criteria.

### Full name:

- HCP: (1) surname and (2) first name.
- HCO: full official name (must be the same name as the official registry).

# **HCPs:** city of principal practice:

This is the city of principal practice of the HCPs.

### **HCOs:** city where registered:

This is the city where the HCOs are registered.

# **Country of Principal Practice:**

Always mentioned as Italy.

### Principal practice address:

Further details of the address that are not yet included in the preceding columns.

# Unique country identifier/ HCP identification number:

This is the unique internal identifier code for HCP and HCO.

### **Donations and Grants to HCOs:**

See the scope in Article 3.01.1.a of the EFPIA HCP/HCO Disclosure Code.

### ToV or contribution to costs of events for HCOs:

- Sponsorship agreement with HCOs, third parties appointed by HCOs to manage an event
- Registration fees according to sponsor prospectus or agreement between the parts
- Travel & Accommodation To the extent governed by Article 10 of the EFPIA HCP Code

## Fee for service and consultancy for HCPs or HCOs:

ToV resulting from or related to contracts between Galderma Italia S.p.A. and HCPs or HCOs under which such HCPs or HCOs provide a service to Galderma Italia S.p.A. 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 expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts. This is in accordance with Article 3.01.1.c of the EFPIA HCP/HCO Disclosure Code.



### Total ToV of HCPs or HCOs interactions:

The total amount of ToV in relation to HCPs or HCOs interactions.

## Aggregate amount attributable to transfers of value to such Recipients (HCPs and/or HCOs):

Total amount of transfer of value to those HCPs who have not given their consent to disclose the data. Being the HCOs legal entities, the disclosure is always in aggregate.

# Number of Recipients (HCPs and/or HCOs) in aggregate disclosure:

Total number of HCPs and HCOs with aggregate disclosure.

# % of the number of Recipients (HCPs and/or HCOs) included in the aggregate disclosure in the total number of Recipients Disclosed:

Percentage of HCPs who have not given their consent to disclose the data. For HCOs is always 100% (the disclosure is always in aggregate because they are legal entities).

#### R&D

ToV referring to Research & Development as defined - Article 3.04 and Schedule 1 of the EFPIA HCP/HCO Disclosure Code.

## **DATA STANDARDIZATION GUIDANCE**

Galderma applies the following approaches when considering:

# **Applicable National Code:**

ToV is disclosed in a manner consistent with Farmindustria Deontological Code to which it is subject for transparency.

### **Consent Management:**

Galderma ensures that the consent of ToV disclosure is obtained from the HCPs in each engagement and proceed with the relevant disclosure to the applicable local data protection laws before publication.

For partial consent from the HCPs Galderma publishes the data in an aggregated amount. For example if the same HCP has 1 "yes consent" and 1 "no consent" Galderma publishes all the 2 ToVs as "no consent" in the aggregated amount.

The consent from the HCPs can be withdrawn during the reporting period. Galderma should respect the correct and most up-to-date consent status.

### **Cross-border ToVs:**

While the recipients of the ToV are HCPs of Galderma Italia S.p.A., in which it is their country of principal practice, is disclosed by Galderma Entity of the country of principal practice in the report even if the activities have occurred outside Galderma Italia S.p.A.

The disclosure is always reported by the country of principal practice of the HCPs in such Galderma affiliate country. In this case, only one country reports the ToV to avoid duplication. When the ToV is shared by several Galderma entities, the home country of the HCPs having their principal practice in such Galderma affiliate country discloses the ToV.

# **Currency or Exchange rates used:**

The reporting currency is in Euro. Foreign currency is converted based on the rate on the date of the service.



### **Documentation and Retention of Records:**

All Transfer of Values documented are required to be disclosed pursuant to Section 1.01 in EFPIA Disclosure Code and maintain the relevant records of the disclosures made under this Code for a minimum of 3 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national data privacy or other laws or regulations.

## Language of disclosure:

**English** 

### 'No show' of HCPs:

In the situation of 'no-show', the payment is reported if there is no transfer of value to an HCP from Galderma. When the travel and accommodation are arranged via an agency and the booking cannot be cancelled, this cost is not reported while there is no transfer of value to an HCP from Galderma.

### Reporting format or platform of disclosure:

The format of the report will be made on corporate website of Galderma. The report is then published on Galderma site in a section dedicated to Galderma Italy according to the EFPIA HCP/HCO Disclosure Code and Farmindustria Deontological Code. In the same section as the report is published, the methodological note (with reference year in the title) is also published for 3 years.

# Reporting period:

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year.

For this reporting period, the ToVs between 1 January 2019 and 31 December 2019 are disclosed. It covers all ToVs according to the competence (the date when HCP or HCO provides the services).

# Treatment of multi-year contracts:

Galderma executes the payments yearly, or at the end of the multi-year contract, or a lump-sum to the HCPs or HCOs within certain number of years based on the terms of the contracts. Galderma reports the data whenever a financial transaction occurred during the reporting year in relation to the multi-year contracts.

### **VAT** and other tax aspects:

The costs must be considered net of VAT, but inclusive of the withholding tax. In the case of conferences and congresses held abroad, VAT must also be considered.