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## **METHODOLOGY NOTES**

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From: GALDERMA ITALIA S.P.A.

To: FARMINDUSTRIA

Cc: EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND

ASSOCIATIONS (EFPIA)

Subject: GALDERMA ITALIA S.P.A. - HCP/HCO Disclosure Methodology Notes 2020

Contact

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# **BACKGROUND**

GALDERMA ITALIA S.P.A. (Galderma) is a member of FARMINDUSTRIA. Galderma is obliged to publish the data in connection to the interactions with HCPs and HCOs according to FARMINDUSTRIA DEONTOLOGICAL CODE (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 its information in order to comply with the Code in 2020.

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

When errors are identified in the report after the disclosure, the contact person will be informed. The report will be uploaded again once the correct information is verified.

# **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 (shall be the same name as in 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 HCP/HCO identification number:**

This is the unique internal identifier code for HCP and HCO

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

The scope is defined as per Article 5 (5.6 and Annex 2) of the 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 parties
- Travel & Accommodation To the extent governed by Article 3.3 of the Code.

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

TOV resulting from or related to contracts between Galderma and HCPs or HCOs under which such HCPs or HCOs provide any type of services to Galderma 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.

#### **Total TOV of HCPs or HCOs interactions**

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

# Aggregate amount attributable to transfers of value to HCPs:

Total amount of transfer of value to those HCPs who have not given their consent to disclose the data (for HCOs, as they are legal entities, it is not necessary to ask for their consent to publish the respective TOVs)

# Number of Recipients (HCPs) in aggregate disclosure:

Total number of HCPs with aggregate disclosure

# % of the number of Recipients (HCPs) 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.

#### R&D

In 2020, there were no R&D transfers of value.

# **DATA STANDARDIZATION GUIDANCE**

Galderma applies the following approaches when considering:

# **Applicable National Code:**

TOV is disclosed in a manner consistent with the Code.

# **Consent Management:**

Galderma ensures that the consent of TOV disclosure is obtained from the HCPs in each engagement according to applicable laws.

For partial consent from the HCPs, Galderma publishes the data in an 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:**

Galderma has worked with all Galderma's affiliates worldwide to capture data relating to TOVs made by them to (i) HCPs with their principal practice in ITALY and (ii) HCOs based in ITALY. Hence, to avoid duplication, only one country always reports such TOVs irrespective of whether the activities occurred outside of ITALY, or the HCPs and HCOs were engaged by other Galderma legal entities. Galderma has used its best endeavours to include all such TOVs within its disclosure report for ITALY.

# **Currency or Exchange rates used:**

The reporting currency is EURO. Foreign currency is converted based on the date of the service.

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

All TOVs are documented pursuant to Section 5 of the Code and Galderma maintains 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 laws or regulations.

#### Language of disclosure:

English

## 'No show' of HCPs

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

#### **Patient Organization TOV**

In 2020, there were no transfers of value with Patient Organization.

# Reporting format or platform of disclosure:

The format of the report will be made on corporate website of Galderma according to the Code In the same section is published the methodology note (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 2020 and 31 December 2020 are disclosed

It covers all the TOVs according to the competence (the date when the HCP or HCO provides the service)

# **Treatment of multi-year contracts:**

If Galderma entered in a multi-year contracts with HCPs and/or HCOs, we report the data whenever a financial transaction (TOV) occurred during the reporting year in relation to such 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

# Change to disclosure process due to Covid-19:

According to FARMINDUSTRIA in case of events canceled for Covid -19:

- if the amount paid to the HCO is returned  $\rightarrow$  the TOV is not tracked
- if the amount paid is withheld by the HCO  $\rightarrow$  the disclosure must be made on this subject.