Croma Pharma UK Methodological Note

On the Disclosure of Transfers of Value made to Healthcare Professionals and Healthcare organisations in 2023

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List of abbreviations

ABPI Association of the British Pharmaceutical Industry

CCGs Clinical Commissioning Group

EFPIA European Federation of Pharmaceutical Industries and Associations

HCO Healthcare OrganisationHCP Healthcare Professional

ORDM Other Relevant Decision Makers

TOV Transfer of Value

<u>Introduction</u>

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2021 requires all companies to document and publicly disclose certain transfers of value (TOVs) made directly or indirectly to healthcare professionals (HCPs) and healthcare organisations (HCOs) located in Europe (Clauses 28-31)¹.

Each company providing TOVs must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of TOV (Clause 28.6)¹.

The term 'transfer of value' (TOV) means a direct or indirect TOV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct TOV is one made directly by a company for the value of the recipient. An indirect TOV is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the TOV (Clause 1.25)¹.

The term 'health professional' (HCP) 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 (Clause 1.9)¹.

The term 'other relevant decision makers' (ORDM) 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 (Clause 1.13)¹.

The term 'healthcare organisation' (HCO) 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 (Clause 1.8)¹.

Croma discloses all TOVs to HCPs, ORDMs and HCOs in accordance with its commitment to the ABPI Code of Practice which is aligned with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value².

All required TOVs made in the UK from January 1st 2023 to December 31st 2023 are disclosed on the ABPI central platform.

This document summarises the approach taken by Croma in calculating the figures provided.

Croma Pharma UK joined the ABPI in 2022 when a prescription medicine became part of our portfolio.

Definitions

HCPs and ORDMs

Croma regards all registered or qualified HCPs as within the scope of disclosure regardless of their NHS status. Payments made to HCPs are disclosed by category type (see below) and reflect the total annual amount of TOV made for each category.

HCOs

Croma regards all hospitals, Clinical Commissioning Groups (CCGs), General practitioner (GP) practices and other places of work for HCPs treating patients or providing associated advice or management services related to the treatment of patients as HCOs. In addition, all medical societies (national or local) and all "networks" of HCP associations are regarded as HCOs.

Payments made to HCOs are disclosed by category type (see below) and reported on a per activity basis.

TOVs

Payments have been disclosed under the following TOV category types:

<u>Collaborative working with HCOs:</u> Croma is not currently involved in or a partner of any collaborative working (including joint working) projects with HCOs.

<u>Donations</u>, <u>Grants and Benefits in Kind to HCOs</u>: Croma have not been asked or provided any donations, grants or benefit in kind to HCOs.

<u>Contributions towards the costs of meetings organised by HCOs:</u> Croma discloses all payments made to medical associations, HCOs, etc. in relation to support for third party meetings. This includes direct funding such as sponsorship fees or the right to erect an exhibition stand. Croma UK have not been involved in these for 2023.

Sponsorship of HCPs to attend medical meetings: Croma supports the attendance of HCPs at medical meetings, including conferences and congresses. Croma discloses the associated TOVs against the individual attendee. Where costs are not individually itemised (e.g. the cost of a taxi transferring multiple HCPs from an airport to a conference venue), the total cost is split equally between all those receiving the benefit. Costs declared include registration fees, travel and accommodation.

<u>Fees for service and consultancy, and related expenses:</u> Croma discloses all payments made to HCPs and ORDMs for their services provided to Croma in the form of service and consultancy fees; any related expenses agreed in the fee for service or consultancy contract, including transport and accommodation, are disclosed as related expenses.

Research and Development: All payments to HCPs and HCOs related to research and development are disclosed as an aggregate figure in accordance with the ABPI Code of Practice.

Scope of Disclosure

Recipients

All TOV made to HCPs/ORDMs and HCOs practicing in the United Kingdom (England, Scotland, Wales and Northern Ireland) have been disclosed.

Products concerned

Croma Pharma markets both prescription-only medicines, as well as medical devices. Consequently, all TOVs relating to prescription-only medicines have been disclosed.

Excluded TOVs

The following TOVs have not been disclosed:

<u>Hospitality costs:</u> the cost of subsistence (food & drinks) is generally not disclosed, unless it forms an integral and inseparable part of the cost of an event, e.g. sponsorship of a third party HCO event. We confirm we remain within the ABPI guidelines for food and subsistence.

<u>Informational and educational materials:</u> any information or educational materials provided to HCPs/ORDMs or HCOs have not been disclosed.

<u>Donations to Patient Organisations:</u> We currently do not make donations to patient organisations.

<u>Donations to charitable organisations:</u> all TOV made to charitable organisations are outside the scope of disclosure.

Data Privacy

The Data Privacy law requires that Croma obtains permission from individual HCPs/ORDMs to publicly disclose their personal data such as their name, address and individual TOVs.

Where consent has been obtained, Croma has declared the TOV against the individual HCP's/ORDM's names.

Where permission has not been obtained, Croma has declared the total TOV as an aggregate figure for all anonymous TOVs made to HCPs (so not against their individual names).

Croma fully supports the principles of transparency and privacy. Information disclosed must remain in the public domain for at least three years from the time of disclosure (Clause 31.2) and Croma will document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate (Clause 31.3)¹.

Private companies

Where a HCP runs a private company for the purposes of their private income, any payments to that organisation is regarded, for disclosure purposes, as a payment to the HCP directly. Similarly, organisations where the majority of employees or contracted suppliers are comprised of HCPs, the full value of payments made to such organisations associated with the services of a named or identifiable individual is regarded as if it was a direct payment to the HCP.

Cross border activities

Payments to UK HCPs or HCOs by other Croma affiliates

Payments made to HCPs practising in the UK or to UK-based HCOs by Croma overseas operations are disclosed, regardless of the source of funding.

Currency

Where payments were made in a currency other than UK sterling, the average Euro exchange rate for 2023 was used.

Tracking and collation of disclosures

All activities and payments related to TOV are pre-approved according to Croma standard operating procedures (SOPs). All direct payments are captured via the internal accounting software. All indirect payments are captured via contracted agencies and the TOV information provided to Croma post event.

References:

- 1) ABPI Code of Practice for the Pharmaceutical Industry 2021. Available from: https://www.pmcpa.org.uk/the-code/2021-interactive-abpi-code-of-practice/
- EFPIA Code of Practice 2019. Available from: https://www.efpia.eu/media/676434/220718-efpia-code.pdf