

Chugai Pharma Europe - Methodology for Disclosure of Transfers of Value for Payments made in 2015

The European Federation of Pharmaceutical Industries and Associations (EFPIA) require all direct and associate member companies to disclose specific transfers of value to healthcare professionals (HCPs) and healthcare organisations (HCOs) for each calendar year starting for payments made in 2015 (Consolidated Version, 2014 <http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code-2014.pdf>) and where required such transfers of values to be disclosed at a named individual level. These disclosures will be undertaken on a European-wide basis and be available to the public no later than July 2016 and presented in a manner where the reader can best understand the nature of the transfer of value.

This requires companies to document and publically disclose certain transfers of value made directly or indirectly to HCPs and healthcare organisations (HCOs). Each company providing transfers of value must publish a note summarising the methodology used by in preparing the disclosure and identifying each category of transfer of value.

Definitions:

Transfer of value:

The term 'transfer of value' means a direct or indirect transfer of value, 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 transfer of value is one made directly by a company for the value of the recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the identify is known to, or can be identified by, the recipient. An indirect transfer of value could also be the cost of travel or accommodation incurred by the company in order for the Healthcare Professional (HCP) to complete work where the HCP has contracted by the company (e.g. attending an advisory board meeting)

Chugai Pharma Europe (CPE) will disclose all transfers of value to HCPs and HCOs in accordance with its commitment to the EFPIA Code on Disclosure on Transfers of Value.

Where Chugai has a business office all required transfers of value will be disclosed in a fashion required by the local Code of Practice or law which may be via a central repository. Payments made to patient organisations will be disclosed separately.

Healthcare organisation (HCO):

Chugai regards all hospitals, universities, private medical groups and other places of work for HCPs treating patients or providing associated advice or management services related to the treatment of patients. In addition, all medical societies (national or local) and all "networks" of associations for healthcare professional (HCPs) are regarded as healthcare organisations.

Private companies such as medical education agencies, or suppliers of "temp" nurses, etc. are not typically regarded as healthcare organisations, especially where the majority of employees are non-HCPs.

Healthcare professional (HCP):

For the purposes of disclosure, Chugai regards all employees of a Health Care Provider as HCPs regardless of their professional status. In addition, Chugai regards all registered or qualified healthcare professionals as within the scope of disclosure regardless of their status. Thus, retired HCPs fall within scope and academic staff who provide clinical services and support.

Where HCPs are employed directly and exclusively by Chugai their salary and benefits are outside the scope of disclosure. Part-time employees will fall within the scope of disclosure for all payments made by the company, including salary.

Note that HCPs have the right to opt out from individual disclosure (see below).

Data Privacy and Consent

Data Privacy law requires that Chugai obtain express permission from individual HCPs prior to disclosing personal data such as individual transfers of value except where a local law overrides the interests of secrecy the principles of data protection. Chugai has made every effort to secure and retain a record of the necessary permissions.

Where permission has not been obtained or where the individual HCP has refused permission, Chugai has declared the total spend as an aggregate figure as a separate line entry within the relevant disclosure category.

Consent was requested per agreement in 2015 and formed part of the agreement. The HCP was requested to check one of two boxes (yes or no consent). If the HCP checked one box then it was determined this was express yes or no consent. Where the HCP did not check one box or checked both then this was determined as a no consent. A decision by the HCP to express preference not to consent in one agreement meant all other consent provided in that calendar year was negated to no consent given in keeping with the EFPIA Code requirement to avoid 'disclosure cherry-picking'.

Chugai fully supports the concepts of transparency and privacy. Information disclosed must remain in the public domain for at least three years from the time of disclosure and Chugai will document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate. If an HCP chooses to withdraw consent for a particular engagement at any time Chugai has decided that the company will not change its relationship with the HCP in those circumstances where consent is not given or subsequently withdrawn in the spirit that consent should be freely given. This will not be the case in those countries where local laws supersede data protection rights.

Research and Development

The growth of the pharmaceutical industry is heavily dependent on its constant research into new products and the enhancement of those products already on the market. The money spent on research and development (R&D) in the pharmaceutical sector compared to other sectors reflects this to ensure the fullest understanding of a product risk assessment (safety) and efficacy.

All payments to a HCP, HCO and patient organisations relating to research and development are disclosed as aggregate figures in accordance with local Codes of Practice. Such payments would include costs to the hospital to run a clinical study and fees for services for the HCP and

supporting staff to participate/attend investigator meetings or for the trial outcomes to be presented to peers.

It is common practice for a pharmaceutical company to engage a clinical research organization (CRO) to manage specific research projects and clinical trials. In these circumstances the CRO may make payments to HCPs and HCOs on behalf of Chugai. Such indirect payments are captured on a quarterly basis, processed through Roche and subsequently disclosed by Chugai in the country where the HCP is registered to practice.

Language and Local Requirements

The EFPIA Code requires disclosure to be available in the country where the HCP is registered to practice and presented in a manner which best allows the reader the opportunity to understand the nature of the relationship between the company, HCP/HCO and transfer of value. This includes the information being presented in a local language. Some Member States have developed central repositories where the public can access all transfers of value in one place. Chugai supports this practice and where data is being disclosed will provide financial support to manage this development. Where a Member State has adopted a legal framework relating to disclosure then the EFPIA and local Codes of Practice and legal requirements are strictly adhered to with the most stringent being a benchmark for general guidance. Methodological notes will be presented in the local language and in English.

Fair Market Value

Chugai compensates HCPs for their time when working with the company. The payment rate is determined by a process known as Fair Market Value (FMV). This is an industry-wide standardised calculation which tells the company what a HCP would actually earn for their time in practice, based on their specific credentials and qualifications. Chugai uses this information to ensure each HCPs compensation is fair and reasonable for the amount of time necessary to provide the requested service. The fee provided by Chugai is a calculation based on preparation, disturbance (travel) and actual time costs.

Reporting date

There is an inevitable delay between the date on which a payment is approved within Chugai and the date on which the payment may be made. Chugai will disclose the details of the payment on the date the transfer is actually made. This may mean that some projects taking place at the end of one year will be disclosed as part of the next annual reporting period because the payment may not occur until the following year when the invoice has been received and settled. A transfer of value is paid only after the engagement has taken place.

Currency

Where payments were made in a currency other than local, the exchange rate will mean the exact equivalent in sterling will vary according to the date on which the conversion calculation was made. For general purposes, the conversion date should be regarded as the date on which the entry was made in the database. Readers should understand that the amounts disclosed in the local currency could therefore vary slightly from the exact amount paid in the local currency; variations will be greater if there have been significant movements in exchange rate during the reporting period. Chugai uses a finance system that gives an automated currency conversion at the time of data entry.

Cross-border payments

Cross-border payments relate to payments made to a HCP or HCO where the HCP is registered in a country different to where there is an organized event and/or where the organizing company is based elsewhere. Such engagements are highly regulated at an internal level to be sure arrangements are in keeping with regulations in the countries of the engagement, where the HCP is registered to practice and the country where the organizing business is based. This includes travel, fees for services, venue, agenda and what materials are available to delegates and speakers, nature and content of the presentation, accommodation and subsistence. The event is also checked against the Educational Events and Ethical Evaluation Assessment service (http://www.efpia-e4ethics.eu/Farma_EFPIA/index.htm).

Cross border payments are disclosed in the country where the HCP is registered to practice. For engagements that relate to research and development then these disclosures are presented in aggregated format. For all other forms of engagement the intention is to always disclose on a named individual basis once the HCP has provided written consent. Where this has not been granted then the payment is disclosed in an aggregated form.

Non-monetary Transfers of Value

Such transfers of value would be quantified on the cost of the apparatus provided (e.g. as part of a clinical trial) or calculated on an hourly basis determined by the Healthcare Compliance Department on a case by case basis and stated in any agreement.

Multi-year projects

Where projects run for several years Chugai will declare the amount paid relevant to the year in which each part of the payment was made. Thus a project which spans 2 calendar years and includes several individual transfers of value during that time will have two associated disclosures; one for each calendar year showing the value of the transfer made in that specific calendar year.

Payments to a charity

On occasion, an HCP who has provided a service to Chugai may ask for their fee to be paid to charity. Chugai does not allow this and all payments are preferred to be made directly to the HCP. Instead the HCP is expected to settle tax costs and make any charitable payment directly of their own volition.

Payments to healthcare organisations for services provided by individual HCPs

On occasion, a healthcare organisation will insist that any services provided by its HCP employees cannot be contracted with the individual HCP but must be a service contracted through the healthcare organisation.

Since Chugai is contracting for the services of a named HCP, the fee received by the HCP will be disclosed under that HCP's entry. Any "administration fee" charged by the healthcare organisation will be disclosed as a fee for service to that organisation.

If the HCP does not receive any additional payment for the service (e.g. because they are speaking at a meeting during normal working hours) then the full amount paid by Chugai will be disclosed against the healthcare organisation as a fee for service.

Private companies and associated charities

Where an HCP runs a private company or partnership, charity, etc., for the purposes of their private income any payments to that organisation will be 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 will be regarded as if it was a direct payment to the HCP.

Payments to third party organisations for services provided by individual HCPs

Chugai regularly contracts with advertising agencies and PR agencies, etc., for services related to its business. On occasion, the work commissioned by Chugai might be contracted out to an individual HCP. Chugai policy is that all such services must be disclosed to Chugai by the contracted service agency. Chugai will disclose any payments made to the individual HCP by the service agency as if the payment had been made directly by Chugai to that HCP.

Medical Education Grants to independent companies

On occasion, Chugai is approached by independent companies to provide funding in relation to medical education projects. The rules related to Chugai's funding in these circumstances require that Chugai has no influence over the details of the project. Chugai would not know whether or which HCPs had been involved in such projects. As such, Chugai does not disclose transfers of value related to this type of project.

Contributions to meetings

Chugai will disclose all payments made to medical associations, healthcare organisations, etc. in relation to meetings. This includes direct funding such as sponsorship fees or the right to erect an exhibition stand, and indirect support such as providing a logistics agency or subsidising the cost of registration fees. The details are provided in the relevant line entry.

The cost of any sponsorship related directly to food is outside the scope of disclosure unless this is a local Code requirement.

All costs associated with meetings run solely by Chugai are outside the scope of disclosure except for fees paid to individual HCPs providing services as speakers or travel reimbursement for speakers or delegates. Such payments are disclosed.

Sponsorship for HCPs to attend medical meetings

Chugai proudly supports the attendance of HCPs at those medical meetings where there is evidence that the HCP will gain knowledge that will improve or maintain patient care. Chugai will disclose the associated transfers of value against the individual attendee. Where costs are not individually itemised (e.g. the cost of a bus transferring a group of HCPs from an airport to a conference venue), the total cost will be split equally between all those receiving the benefit.

Costs declared include transport, registration fees and accommodation. Costs related to subsistence are not declared but the meal costs are regulated by strict industry guidelines.

Grants to HCOs for support to attend medical meetings

On occasion, Chugai is asked by an HCO to provide a financial grant to assist its employees to attend medical meetings. Where the payment is associated with named individuals, the disclosure is made as if the money was transferred directly to the named HCP. Where Chugai is not aware of the names of the HCPs receiving the support, the grant is declared against the named healthcare organisation.

Donations

A donation is defined as a payment where there is no obligation on the part of the receiver and as such is a free contribution. Such donations cannot be given to a HCP as this would be considered a potential breach of any local anti-bribery. Donations can only be provided to healthcare organisations and patient organisations and in these situations there is a mandatory requirement for an approved agreement that is signed by both parties on the basis that both parties will publically disclose the donation. Such donations to HCOs are disclosed on the central portal. Such donations to patient organisations are disclosed on the company website.

Patient Organisations

Patient organisations are providers of essential support and information to those living with medical conditions, as well as their families and carers. Working with these valued organisations allows Chugai to support their efforts with vital resources and is highly regulated.

If the money is associated with an individual HCP working with the patient organisation, then the funding will be disclosed twice – the money for the HCP will be disclosed on the ABPI disclosure platform against the individual HCP; the overall project will be disclosed on the Chugai website against the patient organisation entry.

Chugai partners

As an independently listed company Chugai discloses all payments made directly from Chugai bank accounts and listed in the company records as part of its normal business operations.

Chugai does not disclose payments made by its shareholders or other stakeholders whether those be individuals or organisations.

Co-marketing projects

Where Chugai jointly markets a product with another pharmaceutical company, Chugai will only declare those payments made directly from Chugai bank accounts and listed in the company records as part of its normal business operations. Transfers of value made by its co-marketing partners will be disclosed separately by those organisations. This information will be stated on the Chugai website and a link provided to the business partner.



Distributor projects

Chugai is a marketing distributor for products where the Market Authorisation Holder is a business partner based in another country. Chugai will only declare those payments made directly from Chugai bank accounts and listed in the company records as part of its normal business operations. Transfers of value made by the Marketing Authorisation Holder will be disclosed separately by those organisations

Tax and VAT considerations

It is the responsibility of the receiving HCP to settle local tax requirements. The contract for each engagement should be agreed and signed by both parties prior to any work being undertaken and there is a clear statement regarding tax payment responsibilities. Where a payment has been made to a HCO or 3rd party vendor then where VAT has been included this has been settled by Chugai and where this has occurred this has been highlighted in the disclosure per line.

Multi-year contracts

Chugai will usually engage with a HCP where there is an agreement per engagement. However there may be occasion where the engagement is ongoing. Payments will be disclosed in accordance with the year the payment was made.

Chugai is an ethical pharmaceutical company and as such there is no requirement for any over-the-counter or medical device transfers of value to be disclosed

Chugai welcomes the opportunity to discuss the principles of disclosure and can be contacted in the email below. However Chugai is unable to discuss detail relating to specific payments.

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