



# Methodological Notes for Disclosure 2018

CHUGAI PHARMA UK LTD & CHUGAI PHARMA EUROPE LTD

**CONTENTS**

**Introduction** ..... 2

**Definitions:** ..... 3

**How we manager Transfers of Value**..... 9

**How we manage consent** ..... 9

**How we manage Research and Development** .....10

**Tax and VAT considerations** .....10

**Links to Codes**.....11

**Contacts**.....11

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## Introduction

Chugai frequently collaborates with health experts with a view to developing pragmatic solutions that will help patients across the UK and Ireland access highly innovative medicines and address the current challenges facing the healthcare sector.

Chugai has robust processes for engaging with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) which are subject to internal scrutiny by the appropriate functions. All engagements are planned in accordance with The Association of British Pharmaceutical Industry (ABPI) and Irish Pharmaceutical Healthcare Association (IPHA) Codes of Practice.

The ABPI and IPHA Codes of Practice require Chugai to disclose specific transfers of value to healthcare professionals (HCPs) and healthcare organisations (HCOs). In addition, and where required, such transfers of value (including direct payments) should be disclosed at a named individual level.

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

Chugai is committed to ensuring that the relationship between the industry and HCPs, Other Relevant Decision Makers (ORDMs) and HCOs is better understood. Chugai welcomes this increased transparency and believes it is in the best interests of the pharmaceutical industry, the Irish and British healthcare section and ultimately patients.

This document outlines the methodology and definitions used by Chugai in relation to such disclosure.

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**Definitions:**

Term	Definition
<b>Transfer(s) of Value (ToV):</b>	<p>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 benefit 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 third party’s identity 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 HCP to complete work where the HCP has been contracted by the company (e.g. attending an advisory board meeting).</p> <p>Chugai (including Chugai Pharma Europe (CPE) and Chugai Pharma UK (CPU)) will disclose all ToV to HCPs and HCOs in accordance with its commitment to these Codes on Disclosure of all appropriate Transfers of Value.</p> <p>These payments will be disclosed via country-specific central repositories which will allow the reader to access all payments made by members of the pharmaceutical industry. Payments made to patient organisations will be disclosed separately on the Chugai Pharma UK website (<a href="https://www.chugai-pharm.co.uk/about-us/publications/">https://www.chugai-pharm.co.uk/about-us/publications/</a>).</p>
<b>Healthcare Organisation (HCO):</b>	<p>Chugai regards HCOs as 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 HCPs are regarded as HCOs.</p> <p>Private companies such as medical education agencies, or suppliers of “temp” nurses, etc. are not typically regarded as HCOs, especially where the majority of employees are non-HCPs.</p>
<b>Healthcare Professional (HCP)</b>	<p>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 HCPs 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.</p>

## Methodology for Disclosure 2018

	<p>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.</p> <p>Note that HCPs have the right to opt out from individual disclosure (Refer to Data Privacy and Consent section).</p>
<b>Language and Local Requirements</b>	<p>The ABPI and IPHA Codes require 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 ToV. This includes the information being presented in a local language. Some Member States have developed central repositories where the public can access all ToV 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 local Codes of Practice and legal requirements are strictly adhered to with the most stringent being a benchmark for general guidance.</p>
<b>Fair Market Value</b>	<p>Chugai usually compensate HCPs for their time when working with the company. The decision to not be paid is one made by the HCP. 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 HCP's 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. All arrangements and payments require internal approval which includes review by a compliance officer along with trained staff.</p>
<b>Reporting Date</b>	<p>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 payment is processed. 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 ToV is paid only after the engagement has taken place.</p>
<b>Currency</b>	<p>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. From 2017 Chugai uses a finance system that gives an</p>

## Methodology for Disclosure 2018

	<p>automated currency conversion based on the date of payment. For payments made before 2017 Chugai calculated currency conversion based on an average rate over the year.</p>
<b>Cross-border Payments</b>	<p>Cross-border payments relate to payments made to a HCP or HCO where the HCP is registered in the UK or Ireland and where there is an organised event and/or where the organising company is based elsewhere. Such engagements are highly regulated at an internal level to be sure arrangements are keeping with regulations in the countries of the engagement, where the HCP is registered to practice and the country where the organising 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 (<a href="http://www.efpia-e4ethics.eu/Farma_EFPIA/index.htm">http://www.efpia-e4ethics.eu/Farma_EFPIA/index.htm</a>).</p> <p>Cross border payments are disclosed in the country where the HCP is registered to practice. For engagements that relate to R&amp;D 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.</p>
<b>Non-monetary Transfers of Value</b>	<p>Such ToV 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 Office on a case by case basis and stated in any agreement.</p>
<b>Multi-year Projects</b>	<p>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.</p> <p>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 ToV 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.</p>
<b>Payments to a Charity</b>	<p>On occasion, a 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.</p>
<b>Payments to Healthcare Organisations for Services Provided by</b>	<p>On occasion, a HCO 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 HCO.</p> <p>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 HCO will be disclosed as a fee for service to that organisation.</p>

## Methodology for Disclosure 2018

<b>Individual HCPs</b>	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 HCO as a fee for service.
<b>Private Companies and Associated Charities</b>	<p>Where a 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.</p> <p>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.</p>
<b>Payments to Third Party Organisations for Services Provided by Individual HCPs</b>	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.
<b>Medical Education Grants to Independent Companies</b>	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 ToV related to this type of project.
<b>Contributions to Meetings</b>	<p>Chugai will disclose all payments made to medical associations, HCOs, etc. in relation to meetings. This includes direct funding such as sponsorship fees or the right to erect an exhibition stand, costs for staff to attend as delegates 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.</p> <p>The cost of any sponsorship related directly to food is outside the scope of disclosure unless this is a local code requirement.</p> <p>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</p>
<b>Sponsorship for HCPs to Attend Medical Meetings</b>	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 ToV 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.

## Methodology for Disclosure 2018

	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.
<b>Grants to HCOs for Support to Attend Medical Meetings</b>	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 HCO.
<b>Donations</b>	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 laws. Donations can only be provided to HCOs and patient organisations and in these situations there is mandatory requirement for an approved agreement that is signed by both parties on the basis that both parties will publicly disclose the donation. Such donations to HCOs are disclosed on the central portal. Such donations to patient organisations are disclosed on the company website.
<b>Patient Organisations</b>	<p>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.</p> <p>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 or IPHA disclosure platform against the individual HCP; the overall project will be disclosed on Chugai’s website against the patient organisation entry and will include all payments to patient organisations in the EU.</p>
<b>Chugai Partners</b>	<p>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.</p> <p>Chugai does not disclose payments made by its shareholders or other stakeholders whether those be individuals or organisations.</p>
<b>Co-marketing Projects</b>	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. ToV made by its co-marketing partners will be disclosed separately by those organisations. This information will be stated on Chugai’s website and a link provided to the business partner.
<b>Distributor Projects</b>	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. ToV made by the





Methodology for Disclosure 2018

	Marketing Authorisation Holder will be disclosed separately by those organisations
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## How we manage Transfers of Value

Data is collected, recognised and reported using a commercially available database which was customised to Chugai's organisational requirements. This system is used by Chugai to track payments made to all UK HCPs. ToVs are then reconciled against our financial system which identifies and flags relevant vendors.

Payments made to patient organisations will be disclosed separately on the Chugai Pharma UK website (<https://www.chugai-pharm.co.uk/about-us/publications/>).

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## How we manage Consent

Chugai is an ethical pharmaceutical company and we are required to comply with the relevant laws, regulations and applicable industry codes of practice governing our interactions with HCPs and HCOs, including but not limited to the UK Data Protection Act 1998 (DPA). Chugai is registered with the Information Commissioners Office as a data controller and appointed an external data processor for the purposes for complying with its financial transparency obligations under the APBI Code of Practice.

To legally disclose ToV data on an individual basis Chugai has obtained consent from HCPs 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.

At the time of disclosure if consent has not been given by a UK HCP, the related ToVs will be included in the Chugai aggregated total.

Chugai allows partial disclosure. A UK HCP may consent to disclosure of sponsorship payments and decline to consent consultant payments. In this case the sponsorship ToVs would be disclosed on an individual basis and the consultancy ToVs will be disclosed in the aggregate (non-identifiable format).

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 a 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. In 2017 Chugai has adopted a new policy for UK and Ireland in that HCPs requesting sponsorship (educational grant) to attend an appropriately approved educational conference then such requests can only be considered if consent to disclose is explicitly provided.

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## How we manage Research and Development

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.

Items included:

- Pre-clinical research and clinical research (includes Investigator Sponsored Research (ISR))
- Non-interventional Studies
- Advisory Boards and consultancy services in relation to clinical research
- Real world data studies and Health Outcomes research
- Fees for service to HCPs, ORDMS and HCOs in relation to study sites (including where these fees have been made by CRO on behalf of Roche)
- Travel and accommodation in relation to a fee for service contract
- Items not included
- Overhead cost (including CRO fees)
- Materials (such as study medication/injections/kits)

It is common practice for a pharmaceutical company to engage a clinical research organisation (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, and provided to Chugai or processed through a business partner, Roche and subsequently disclosed by Chugai.

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## 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 third 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.

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## Link to ABPI Code

<http://www.pmcpa.org.uk/thecode/InteractiveCode2016/Pages/default.aspx>

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## Link to ABPI Disclosure Portal

<http://www.abpi.org.uk/our-work/disclosure/Pages/DocumentLibrary.aspx>

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## Link to IPHA Code and Supporting Documents

<http://www.ipha.ie/alist/publications.aspx?article=f8f9c1e9-344a-468c-b7d2-dc83530513b1>

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## Link to IPHA Disclosure Portal

<https://www.transferofvalue.ie/>

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## Link to EFPIA Code

<http://transparency.efpia.eu/the-efpia-code-2>

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## Contacts

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.

Healthcare Compliance Team

Chugai Pharma Europe

For further information, please contact:

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