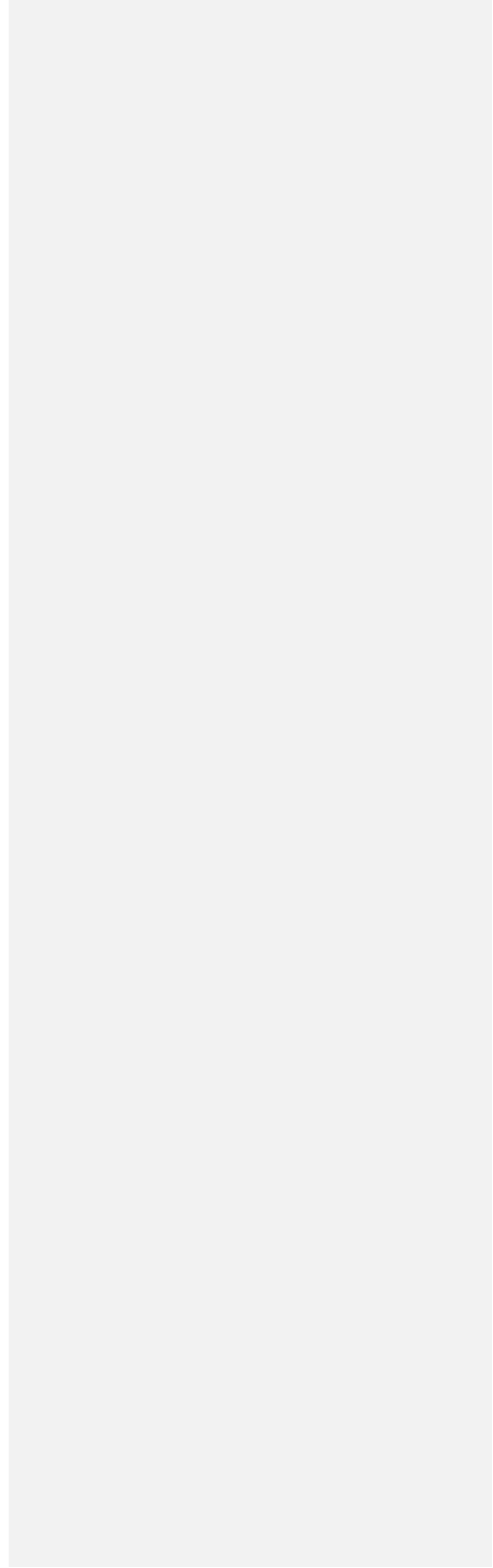


Guerbet Methodology for ABPI Disclosure 2018



Guerbet Methodology for ABPI Disclosure 2018

Prepared by: Susy Matthews, Sales & Marketing Manager, Guerbet UK

Validated by: Evelyne Giacosa, Pharmaceutical Affairs Compliance Manager, Guerbet Headquarters

Approved by: Lee Scott, General Manager, Guerbet UK

Guerbet strives to conduct itself and our dealings with UK Healthcare Professionals in a manner that is compliant with UK Law, EU Law, MHRA directive and the PMCPA Code of Practice.

For the 2018 disclosure, Guerbet UK is working with the Code of Practice 2016. At point of disclosure, the Code of Practice 2019 has been published. The disclosure relates to transfers of value to healthcare professionals prior to the publication and implementation date of the 2019 Code of Practice.

The Disclosure relates to:

- UK HCPs/HCOs and ORDMs where their primary practice is in the United Kingdom. This includes agreements and contracts drawn up between Guerbet affiliates or with Guerbet Headquarters with UK HCPs/HCOs and ORDMs where the service may be conducted within or outside of the UK
- UK HCPs where a fee is paid by the UK affiliate for a service conducted outside of the UK for example as a speaker at a European event.

Exceptions for Disclosure:

- EU HCPs/HCOs and ORDMs contracted to provide services for the UK affiliate either outside or within the UK. In this case the disclosure will be done in the public site of the country where the expert is having their main activity. Guerbet UK will provide disclosure information to the compliance manager in charge of the disclosure in the affiliate.
- EU Contracts that do not directly make Transfers of Value to UK HCPs/HCOs/ORDMs and that are drawn up by Guerbet affiliates or by Guerbet HQ for services in other EU countries are disclosed by the affiliate or by Guerbet HQ according to local regulations.

Definition: 'Transfer of Value' as defined by several clauses and supported by supplementary information within the 2016 Code of Practice as follows:

Clause 1.10 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 a recipient. An indirect transfer of value 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 transfer of value.

Clause 22.5 Pharmaceutical companies must publicly disclose financial details of sponsorship of UK health professionals and other relevant decision makers in relation to attendance at meetings. Sponsorship in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK.

Clause 24 including supplementary information directly relating to **Clause 24.1** Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe.

Individual disclosure: the transfers of value to individual named Healthcare Professionals (HCPs) Healthcare Organisations (HCO's) and Other Relevant Decision Makers (ORDM)

Aggregate disclosure: the transfers of value to HCPs who cannot be named with the exception of transfers of value to HCP's and HCO's in connection with certain Research and development (R&D) activities including clinical trials.

Scope

Activities where a transfer of value took place which includes but is not limited to Joint Working arrangements, Consultancy fees, Sponsorship of HCO/HCP/ORDM, Support of an HCP/HCO/ORDM to manage an Event, Honoraria, Registration Fees, Travel & Accommodation and Related Agreed Expenses.

For the purpose of transparency, where an HCP/HCO/ORDM is involved in an Advisory Board, Round Table or as part of a 'Voice of the Customer', as well as basic research for product handling or validation, this is declared within the main disclosure rather than under research and development. This is due to the results of such activities being of benefit for Marketing and Promotion activities thereafter. For the purpose of the 2018 disclosure, Research and Development is defined as research into efficacy of product and development of medicinal or diagnostic agents in clinical or non-clinical studies.

Guerbet supports the continued education of HCPs through educational events. These events are organised by a 'Course Director' who is responsible for transactions between themselves and speakers. This is to ensure balanced educational content. Where Transfers of Value are made between Guerbet and the Course Director, these are disclosed in the 2018 Disclosure. Contracts stipulate a declaration of sponsorship on course material and any conflicts of interest must be declared.

Method

Consent: Agreements/contracts made with HCPs, HCOs and ORDMs which outlines Guerbet's intention to disclose transfers of value including the definition outlined in the Code of Practice 2016.

- a. Article 6 of the agreement refers to Regulatory Provisions:
Item 6.8 states the following:

Disclosure of transfer of value

According to the ABPI code of practice and its implementation of clause "24: Transfers of Value to Health Professionals and Healthcare Organisations" in the UK, Guerbet Laboratories Ltd will proceed to the disclosure of all transfers of value mentioned in the contract in the public site of the country where the expert is having their main activity.

Clause 24.1 of the ABPI code states; Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe.

Please indicate on the consent form if you would prefer individual or aggregate disclosure.

"Individual disclosure" means transfers of value to individual named Healthcare Professionals (HCPs) and Healthcare Organisations (HCO's)

“Aggregate disclosure” means transfers of value to HCPs who cannot be named with the exception of transfers of value to HCP’s and HCO’s in connection with certain R&D activities including clinical trials.

Commented [MK1]: I have added this section and also the final page for consent

b. A disclosure consent form is included in the Appendices of the agreement/contract

Agreement/Contract: A written document between Guerbet Laboratories and the HCP/HCO/ORDM which contains scope, obligations, exclusions, caveats, acknowledgements, rights, details of activity, intellectual property rights and disclaimers.

Reconciliation: Consent forms are reconciled with Transfers of Value and compiled into the Disclosure Template.

Considerations

Intention: Guerbet declares intention to disclose within Regulatory Provisions within the Contract: This included the Regulatory provision set out in the Method above and Guerbet’s obligations to disclose transfers of value.

Consent: A form indicating ‘Individual’ or ‘Aggregate’ disclosure is returned to Guerbet. A consent form is included within the appendices of the agreement/contract. Returned forms are retained and reconciled according to the 2018 Disclosure.

Exchange rate considerations: Where the payment details were received in euros the exchange was converted using the prevailing market rate at the time of payment.

Reporting Period: Activities contracted by Guerbet UK are short. For Contracts made across two reporting periods, the Disclosure is made in the period that the payment is made. If the agreement outlines more than one Transfer of Value across more than one reporting period, the Transfer of Value will be reported separately for the periods for which the activity has been invoiced.

Contract Research Organisations (CROs): Transfers of Value disclosures will be made where CROs engage with HCPs/HCOs/ORDMs on behalf of Guerbet. Consent forms are provided to the CRO.

Medical Devices Transfers of Value: Transfers of Value were generally made to support education or for consultancy. Due to the nature of the equipment marketed by Guerbet (be it for use with or independently of Guerbet Pharmaceutical agents) and the roles of those HCPs/HROs/ORDMs contracted, no distinction is made between Medical Devices and Pharmaceutical agents for the 2018 Disclosure and all Transfers of Value are disclosed. Transfers of Value for Medical Devices, usually ‘Voice of the Customer’ projects are not connected with Guerbet Pharmaceutical agents however the HCP/HCO/ORDM that is engaged is often also a user or decision maker for products which could be marketed by Guerbet.

Over the counter transfers of value: No over the counter transfers of value are made by Guerbet.

Joint working with other Pharmaceutical Companies: Guerbet does not currently collaborate with other pharmaceutical companies and no Transfers of Value have been made based on Joint Working arrangements.

Individual/Aggregate percentage: The percentage was calculated by the number of aggregate HCPs and total number of HCPs who consented to disclosure individual Transfers of Value.

Queries: Queries raised after pre-disclosure will be investigated and rectified accordingly. Process to follow is mapped out in section 15.6 of the Disclosure Manual.

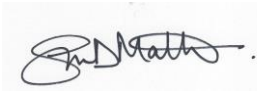
Disclosure Declaration

All data contained within the 2018 Disclosure is true and correct to the best of our knowledge and I undertake to inform the ABPI Disclosure Team of any changes herein. If any information is found to be inaccurate or deficient, Guerbet UK will undertake to rectify immediately.

Inaccuracies, additions, omissions: Contact susy.matthews@guerbet.com

Data Protection: Enquiries should be sent to susy.matthews@guerbet.com

Disclosure withdrawal: Under General Data Protection Regulation (GDPR) HCPs/HCOs/ORDMs disclosed under Individual Disclosure are entitled to withdraw consent at any time by contacting Susy Matthews (susy.matthews@guerbet.com) Where consent is withdrawn, data will be disclosed in 'Aggregate'.



Dated and Signed: 20/03/2019 for and on behalf of Guerbet UK, Avon House, 435 Stratford Road, Shirley, Solihull, B90 4AA Registered in England No. 02940474