

Methodological Note to 2020 Disclosure Report for Besins Healthcare (UK) Limited

CONTENTS

LIST OF ABBREVIATIONS

BHUK	Besins Healthcare (UK) Limited
BIK	Benefits in kind CCGs Clinical Commissioning Groups
EFPIA	European Federation of Pharmaceutical Industries and Associations
GDPR	General Data Protection Regulation
GP	General practitioner
HCO	Healthcare organisation
HCP	Healthcare professional
IPHA	Irish Pharmaceutical Healthcare Association
TOV	Transfer of value

INTRODUCTIONS

Besins Healthcare UK Limited (BHUK) is committed to transparent interactions with Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs).

HCPs and HCOs offer expert knowledge on patients' behavior and management of diseases and are the primary point of contact with patients. This plays a valuable role in informing BHUK's efforts to improve patient care – which is essential to improving patient outcomes. BHUK compensates HCPs and HCOs for the valuable insights and time they offer and also provide funding for medical education either directly to HCPs, via HCOs or third-party specialist providers.

BHUK is committed to making the transfers of value made to HCPs and HCOs transparent and in doing so all reasonable efforts will go into making sure they are accurate, valid and complete. BHUK complies with all laws, rules and regulations. Laws in the EU protect the rights of citizens in relation to the way their personal data is processed. HCPs are covered by Data Privacy laws and this affects the way in which BHUK can publish the HCP's transfers of value. BHUK will seek permission (consent) from the HCP to individually publish their transfers of value and as such HCPs have the right to opt out of individual disclosure.

BHUK is committed to disclosing all TOV to HCPs and HCOs in accordance with its commitment to the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value.

All required TOVs made in Ireland from January 1st 2020 to December 31st 2020 are disclosed on www.besinshealthcare.ie.

This document summarises the approach taken by BHUK in calculating the figures provided and considers;

[1] IPHA code of Practice 2021. Available from <https://www.ipha.ie/about-us/our-role/codes-of-practice>

[2] EFPIA Code of practice 2019. Available from: <https://www.efpia.eu/relationships-code/disclosure-of-payments-to-hcps/>

[3] PMCPA Disclosure-Methodological Notes points for consideration. Available from; <https://www.pmcpa.org.uk/guidance-and-qas/guidance/disclosure-methodological-notes-points-for-consideration/>

DEFINITIONS from IPHA Code 1st March 2021)

Transfer of Value (ToV)

The term 'transfer of value' (TOV) means a direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicine exclusively for human use. Direct transfers of value are those made directly by a company for the benefit of a HCP. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a HCP, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

The term “healthcare professional” means a person of any of the following classes:

- (i) Registered medical practitioners
- (ii) Registered dentists
- (iii) Registered pharmacists
- (iv) Registered nurses

Healthcare Organisation (HCO)

A “healthcare organisation (HCO)” means any healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for a Patient Organisation within the scope of Annex III of the IPHA Code) whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more HCPs or other relevant decision makers provide services.

HOW WAS THE DISCLOSURE ORGANISED?

Data were collected, reconciled, and reported on the IPHA disclosure template.

All financial TOVs were reconciled against the contractual agreements, the tracker recordings and the actual payments made.

DISCLOSURE CATEGORIES

Sponsorship of HCPs to attend medical meetings.

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

Fee for Service and Consultancy, and associated related expenses agreed in the fee for service agreement

This includes the following services: Speaker and Chairperson fees, Consultancy fees and Training. Where the TOV was provided as a fee for service, the TOV has been calculated based on the fair market value rate for the service provided.

Contributions towards the costs of meetings organised by HCOs

BHUK discloses all payments made to medical associations, healthcare organisations, etc in relation to meetings. This includes direct funding such as sponsorship fees and fees paid to erect an exhibition stand, and indirect support such as providing a logistics agency or subsidising the cost of registration fees.

Donations, Grants and Benefits in Kind (BIK) to HCOs

Donations and Grants to HCOs that support healthcare, including donations and grants to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare. For financial grants the date of TOV has been recorded as the date the payment was processed by BHUK.

Note: The cost of any sponsorship related directly to food is outside the scope of disclosure. All costs associated with meetings run solely by BHUK are outside the scope of disclosure except for fees paid to individual HCPs providing services as speakers, etc.

Joint working

BHUK is not involved with any joint working projects with HCOs.

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.

Patient organisations

There are no disclosures in scope of this category in 2020.

OTHER CONSIDERATIONS

Cross border payments

All disclosures are made in the country in which the HCP or HCO practice is located. Payments made to an IRL based HCP or organisation by Besins entities located in other countries are disclosed within IRL regardless of the source of funding.

Multi-year contracts

There are no multi-year contracts.

Over the counter medicines and medical devices

There are no disclosures in scope of this category for 2020.

VAT

Where payments were made and VAT was applicable, the VAT has been excluded for the purposes of disclosure. Therefore, all values provided are exclusive of VAT. There are no other tax considerations.

Exchange rate and currencies

The amounts disclosed are those actually paid by BHUK. They may differ slightly from the amounts received by the HCP/HCO as they do not take into consideration any exchange fees or other fees applied by the recipient's bank.

On occasions payments are made in a currency other than Euros. In these situations, the exchange rate will mean the exact equivalent in Euros according to the date on which the conversion calculation was made. All disclosures will be displayed in Euros. The Euros totals will be calculated using the exchange rate on the day of payment using Currency Exchange Rates-International at <https://www.xe.com/currencyconverter/> Readers should understand that the total amounts disclosed in Euros 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.

Time of payment

The date recorded for the TOV is the date the payment was processed by BHUK.

Consent for disclosure and GDPR

In accordance with Data Privacy law, BHUK has obtained and retained records of consent from HCPs on an individual activity basis prior to disclosing personal data such as individual transfers of value. Where permission has not been obtained or where HCPs have refused consent, BHUK has declared the total spend as an aggregate figure given on a separate line entry within the relevant disclosure category and the % of non-consenting HCPs given as a percentage of the total HCPs receiving a ToV.

CONTACTS

For other enquiries related to the information in either this Methodological Note or the 2020 Disclosure Report please contact: information@besins-healthcare.com.