

Disclosure UK: Frequently Asked Questions

The relationship between the pharmaceutical industry and healthcare professionals (HCPs) and healthcare organisations (HCOs) plays a vital role in the development of life-enhancing and life-saving medicines.

It is a relationship we are proud of. At the core of the relationship is sharing knowledge to improve patient outcomes. We want to ensure that patients have confidence that this relationship is open and transparent, and this is why the pharmaceutical industry is taking the lead on disclosing details of transfers of value (ToVs) - payments and benefits in kind - made by industry to HCPs and HCOs through Disclosure UK - the disclosure database.

Disclosure UK and is part of a Europe-wide initiative to increase transparency between pharmaceutical companies and healthcare professionals and organisations.

Here you will find answers to many of the frequently asked questions about Disclosure UK and the relationships between industry and the UK's healthcare professionals.

Disclosure of payments and benefits in kind to HCPs and HCOs

What is Disclosure UK?

Disclosure UK is a searchable database, published on the Association of the British Pharmaceutical Industry (ABPI) website, detailing transfers of value – payments and benefits in kind – made to UK HCPs and HCOs by pharmaceutical companies. The database contains details of certain payments and other benefits in kind made to individual, named HCPs annually, unless there is a legal reason why a HCP cannot be named.

Disclosure UK is the means by which UK pharmaceutical companies are meeting their obligations under the <u>EFPIA Code</u>.

Who manages Disclosure UK?

Each company disclosing on Disclosure UK is responsible for maintaining records of transfers of value to HCPs and HCOs and for uploading the data to Disclosure UK for publication. The database is managed by the ABPI and supported by IT specialists C&C Group.

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Why is payment data published at an individual level?

The pharmaceutical industry is committed to ensuring the transparency of relationships with HCPs.

The drive to increase transparency of relationships with HCPs and HCOs is a Europe-wide initiative. The European Federation of Pharmaceutical Industries and Associations (EFPIA) agreed the EFPIA Code in June 2013. The EFPIA Code includes requirements for public disclosure of certain payments to individual HCPs and HCOs and began with 2015 payments published in 2016.

Disclosure UK, together with the changes introduced in the 2015 ABPI Code, finalise the implementation of the EFPIA Disclosure Code in the UK and represent a journey of transparency for the UK industry. Since 2012 pharmaceutical companies in the UK have disclosed in total their annual payments to HCPs and HCOs. From 2016 they have published this information on an individual, named basis as part of the industry commitment to greater transparency.

What types of payments are disclosed?

Companies disclose payments made to HCPs such as sponsorship to attend meetings, speaker fees, consultancy and advisory boards.

More specifically, coverage of costs to participate in events (including registration fees, travel and accommodation), fees-for-service and consultancy, where a contract is in place for activities such as speaking at, or chairing meetings, attending advisory boards and media consultancy.

Details of Joint Working and grants and donations to healthcare organisations are disclosed, alongside research and development transfers of value, which are being disclosed in aggregate.

Does Disclosure UK cover all payments to HCPs at an individual level?

No. Payments made for research and development activities are disclosed in aggregate. The EFPIA Disclosure Code and the ABPI Code defines these activities as transfers of value to HCPs or HCOs related to the planning or conduct of:

- non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
- clinical trials (as defined in Directive 2001/20/EC); or

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 Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

Meals and drinks are not disclosed, as there are strict requirements including a threshold for hospitality in the <u>ABPI Code</u>, permitting food and drink up to a maximum of £75 per head.

Why are payments made for research and development not included in the disclosures?

As per the EFPIA Disclosure Code, Disclosure UK focuses on showing individual transfers of value for attending educational meetings and for the provision of services, such as speaking at events or attending advisory boards. Since 2012 the UK has been disclosing this information as a total and this is a significant step in bringing greater transparency to the relationship between industry and the health professional community.

It is worth noting that research and development, and in particular clinical trials, are subject to transparency legislation under the EU Clinical Trial Regulation (2001/20) and the European Medicines Agency Transparency Policy (Policy 0070). The names of investigators working on industry-sponsored trials will be disclosed publicly in the Clinical Study Reports published by the European Medicines Agency.

Individual company spending on research and development is disclosed in aggregate.

Why are meals and drinks not included in the disclosures?

Very often these transfers of value are for small amounts such as a coffee or sandwich. Disclosing these small transactions would place a disproportionate administrative burden on industry and HCPs, for little value. Instead, a threshold has been applied in each country, limiting hospitality under a certain amount. In the UK this is capped at no more than £75 per person. This maximum would be appropriate only in very exceptional circumstances. The cost of a meal should normally should normally be well below this figure.

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The relationship between pharmaceutical companies and HCPs

Why do pharmaceutical companies work with HCPs?

Industry works with HCPs to advance patient care – to develop and deliver medicines that can change and save lives.

Working closely with these experts helps us to develop life-changing, new medicines for diseases such as cancer, dementia and diabetes, and get them to patients – improving the quality of their lives and often saving their lives. These relationships are good for UK patients, good for their families and good for the NHS

Companies can shape their future research programmes based on the scientific and medical expert opinion of HCPs. For example, ensuring studies are developed in the right way to enable a meaningful assessment of clinical benefit.

Understanding how a medicine would be used in clinical practice can help companies provide the right information, education and training, to support the introduction of a new medicine, to ensure the best outcomes for patients.

We're committed to transparency about our working relationships with doctors, nurses and other HCPs. It helps us get feedback on new medicines through education and training or by carrying out market research to ensure the right medicines get to the right patients.

How do patients benefit from HCPs and industry working together?

Patients and their families are the ultimate beneficiary of the interaction between HCPs and the industry, through advancements in clinical practice and patient care and the development of new, innovative treatments:

- Take HIV, seen as a death sentence in 1980s and now viewed as chronic condition that can be managed through the use of innovative medicines.
- In cancer, death rates have fallen by 20% since the 1990s in some countries.
- Recent pharmaceutical innovation means around 90% of patients living with Hepatitis C can be cured through a 12-week course of medicine.

Why do pharmaceutical companies pay HCPs?

Most of the work HCPs undertake for industry is in addition to their existing jobs, often carried out in their own time. As with all industry experts it is appropriate that they are

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remunerated for their time and expertise. How much a HCP is paid depends on the time involved and their level of expertise, experience and must be in line with their normal levels of pay.

When HCPs are employed by companies to provide consultancy services such as attending advisory boards, speaking or chairing meetings, then strict rules apply including the <u>ABPI Code of Practice for the Pharmaceutical Industry</u> and UK law. There must be a legitimate need for the services; the services must be provided under a written contract, agreed in advance and compensation for the services must be reasonable.

In addition, doctors, nurses, pharmacists and other health professionals have their own codes of conduct which cover areas such as making prescribing decisions on clinical grounds, conflicts of interest, transparency, gifts and hospitality.

If a HCP has a strong relationship with a company, is their clinical judgment compromised?

No. Independent, evidence-based clinical decision making is a key principle of European healthcare systems.

Requirements for all aspects of the interaction between industry and health professionals are clearly defined and serve to protect clinical independence and decision making.

HCPs will often collaborate with several pharmaceutical companies working in a particular therapy area.

How is the relationship between industry and HCPs regulated?

The industry/HCP relationship is extensively regulated in the interests of patients. Requirements for all aspects of the interaction between industry and HCPs are clearly defined, in law and the <u>ABPI Code of Practice for the Pharmaceutical Industry</u> which serve to protect clinical independence and decision making.

These requirements continue to evolve over time as the nature of healthcare, medical science and societal expectations change.

If you have any further questions about Disclosure UK, please email info@disclosureuk.org.uk

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