

What is this all about?

- In 2015 the Association of the British Pharmaceutical Industry (ABPI) issued guidance requiring its member companies to disclose payments made to individual healthcare practitioners (HCPs) and healthcare organisations (HCOs) in the UK. This is in response to a Europe-wide initiative to encourage increased transparency of the relationships between HCPs, HCOs and pharmaceutical companies.
- The BHBIA has incorporated this into the **Legal & Ethical Guidelines for Healthcare Market Research**.

What does this mean for Market Research?

Any payment (incentive and/or expenses) made to an HCP/HCO in the context of market research (MR) must be disclosed IF their identity is known to the commissioning company.

When is disclosure required?

Examples where participant identity is likely to be known:

- Internal/Company led MR
- Advisory Board meetings
- KOL mapping studies

When is disclosure not required?

Where HCPs are recruited by an agency and the identity of respondents is not revealed i.e. for the majority of MR studies.

What if...

...the identity of HCP is shared as result of an adverse event (AE) report? The PMCPA has informally advised the BHBIA that disclosure is not required if the HCP provides personal details in respect of an AE report.

...the HCP's identity is revealed when research is viewed? The PMCPA has informally advised the BHBIA that disclosure is not likely to be required if the company representatives happen to recognise respondents whilst watching research.

...the pharmaceutical company supplies a list of HCPs to the agency? The BHBIA view is that if only a subset of the list supplied is interviewed, the HCPs' identity is not known then disclosure is not necessarily required. Only if all HCPs on the list are interviewed, will their identity be known and disclosure will be required.

What do I need to do now?

- If the identity of the HCP is known to the pharmaceutical company, payments made must be disclosed on an individual named basis.
- The use of the respondents' personal data for this purpose requires their prior consent and should be collected at recruitment.
- If consent is not given, the reporting of payment must be done in an aggregated anonymised format.

Clients

1. **Must keep records** of payments made for uploading to a central platform for industry disclosure. A template for recording the data is available on the PMCPA website.
2. **Should update contracts** with suppliers to include the ABPI Disclosure of Payments requirement.

Agencies

1. **Must adapt consent wording** in interview materials to be used with HCPs in research settings where their identity is known to the company so they can give or decline consent to pass on their personal data with payment information. Consent must be compliant with data protection requirements.
2. **Should keep a record** of the required information to pass to the commissioning client. The format of this should be agreed with the client.

What will happen to the information?

This information will be stored on a **central online platform** open to the public.

The ABPI has developed a standardised data entry template to be used by Pharma companies.

For **HCPs** who have given consent, the information to be collected and displayed includes:

- **name and address, speciality and role**
- **honorary/incentive and any expenses**

For those known **HCPs** who have **not given consent**, the aggregated data must include:

- **fees and expenses**
- **numbers of recipients**
- **% of the total fees and expenses these represent**

Further Information

For further detail on all guidelines please see the BHBIA Legal & Ethical Guidelines for Healthcare Market Research at www.bhbia.org.uk/guidelines-and-legislation/legal-and-ethical-guidelines upon which the Quick Guide is based. Alternatively visit www.abpi.org.uk or www.pmcpcpa.org.uk

If you have any queries about this Quick Guide or the BHBIA Legal & Ethical Guidelines for Healthcare Market Research, please visit www.bhbia.org.uk and submit your query via 'My BHBIA'. Please note: this ad hoc advisory service is available to full BHBIA members only.

Disclaimer

This guidance is provided by the BHBIA for information purposes only and is not intended and should not be construed as regulatory or legal advice. It does not cover all legislative and regulatory requirements pertaining to Members and it is the responsibility of all Members to familiarise themselves with these.

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