Ethical Standards in Health & Life Sciences Group

Guidance on collaboration between healthcare professionals and the pharmaceutical industry

Ethics, transparency, partnership

This document has been jointly produced by senior representatives of the pharmaceutical industry and the healthcare community with the aim of promoting positive collaboration between industry and healthcare professionals to support high quality patient care.

The document is based on the following core principles:

- Collaboration between industry and healthcare professionals has the potential to deliver significant patient benefit above and beyond what may be delivered by any party in isolation.
- Healthcare and industry professionals are able to manage their relationships with each other without compromising clinical decision making.
- A comprehensive and robust set of regulations, including UK law, health professionals' codes and standards and the ABPI Code of Practice for the Pharmaceutical Industry ensure professional and ethical standards are upheld.

The facts

Examples of great collaborative working between healthcare professionals and the pharmaceutical industry can be found everywhere and include early scientific research, clinical trials, advisory boards, support for medical education and joint working projects to support patient care. Opportunities may be missed or even rejected because of misconceptions stemming from historical practices that are no longer acceptable, or the actions of a few individuals that are not typical of the working relationship between healthcare professionals and the industry.

The most recent update to the ABPI Code of Practice incorporates a number of important changes that were made in consultation with leading healthcare organisations. They reflect the industry's determination to ensure that relationships with healthcare professionals are based on integrity, honesty, knowledge, appropriate behaviours, transparency and trust.

So here are 10 things you should know:

1. ### The pharmaceutical industry is critical to delivering innovation in medicine

   Industry is responsible for the vast majority of medicines research and development (R&D) in the UK (92% according to Office for National Statistics UK Business Enterprise Research and Development, 2009. This figure is industrial R&D only and does not include charities or NHS). Pharmaceutical industry investment is the source of most of the scientific breakthroughs and innovations in medicines that are saving and improving patients' lives. It takes 10 to 15 years to develop a new medicine and typically costs £550 million to do all the work necessary before a medicine can be licensed for use.

2. ### Bringing medicines to patients is a collaborative process

   Most of the clinical trials conducted in the UK are collaborations between industry and academic centres. Principal investigators will usually be independent healthcare professionals rather than industry employees and they share the responsibility for ensuring trials are conducted ethically and with the appropriate level of scientific rigour.

3. ### Information about industry-sponsored trials is publicly available

   All trials are subject to rigorous scrutiny: trial design and protocols need to be approved by research ethics committees and the results of controlled clinical trials are made available in the public domain through clinical trial registries and portals, peer reviewed publications, medical meetings and company websites. The ABPI Code of Practice requires disclosure of details of clinical trials and non-interventional studies.

4. ### Industry plays a valid and important role in the provision of medical education

   Companies clearly know a lot about the medicines they make and the disease areas they set out to tackle. It is right and proper that healthcare professionals have access to this wealth of knowledge so they can exercise their clinical judgement based on the latest and most comprehensive information.

5. ### Industry relies upon the information it receives from healthcare professionals

   It is critical for industry to understand clinical practice in context and the considerations for the prescribing of medicines. For example, through advisory boards, healthcare professionals give valuable advice to companies and help shape future plans.

6. ### Medical representatives can be a useful resource for healthcare professionals

   Whilst medical representatives are employed to promote medicines, they can be a useful source of information for healthcare professionals and are another vital feedback mechanism to the companies they represent. However, recognising and respecting the needs of those they call upon, representatives are required by the ABPI Code of Practice to ensure they do not cause inconvenience and there are strict rules governing their activity. Many companies also employ people in other roles to work with healthcare professionals in a variety of ways not directly linked to promotion of medicines.

7. **Hospitality must be secondary to the main purpose of any meeting**

   Whilst industry may provide hospitality in association with scientific/educational meetings etc, this is strictly regulated by the ABPI Code of Practice and must never be excessive or out of proportion to the main purpose of the meeting. Meetings that are wholly or mainly of a social or sporting nature are not permitted.

8. **Information provided to patients is tightly controlled**

   Industry is able to provide factual information to patients about the medicines they have been prescribed including patient information leaflets and websites. It is also acceptable to make certain other information available to the public but this is highly regulated. The ABPI Code of Practice prohibits statements for the purpose of encouraging members of the public to ask their healthcare professional to prescribe a specific prescription only medicine.

9. **Industry takes its responsibility to monitor adverse events very seriously**

   Strict rules govern adverse event reporting. Companies have pharmacovigilance teams dedicated to post-marketing surveillance and the Medicines and Healthcare products Regulatory Agency's (MHRA) yellow card system enables collation of data on potential adverse events. Healthcare professionals should utilise these channels to ensure all adverse events are tracked and action is taken when needed.

10. **Joint working programmes must deliver patient benefit**

    The guiding principle for joint working as defined by the Department of Health is that patients benefit. Joint working is covered by the ABPI Code of Practice and other guidance. All those participating should understand and agree to their role and responsibilities.

DOs and DON'Ts for healthcare professionals

Do treat pharmaceutical industry staff as partners in healthcare. There are genuine areas of common ground for industry and healthcare professionals, with shared aims and objectives. In working together, both sides can access a broader range of knowledge and expertise and ultimately ensure high quality patient care.

Don't establish blanket policies denying interaction with industry or regard it merely as a source of funding.

Do look for opportunities to get involved: in clinical trials, in joint working and/or with opportunities provided by industry for medical education.

Don't be tempted to accept the negative myths about cooperating with industry. Undertaken appropriately, working with industry will not harm objectivity of clinical decision-making and should not be perceived negatively by peers.

Do take time to understand the rules and restrictions governing industry practice and what can and cannot be done.

Don't request or expect industry to undertake or provide things that are not permitted within the ABPI Code of Practice. Healthcare professionals have a shared responsibility to maintain high standards in any collaboration and to abide by the appropriate regulations and ethical codes governing their own activities.

Do declare all relevant conflicts of interest and always be transparent about any involvement with industry. (Industry will be required to collect and declare anonymised information about the total payment to healthcare professionals for certain services such as speaker fees and participation in advisory boards with the first annual declaration of payments to be made in 2013 for payments in 2012.)

Don't tolerate unacceptable practice. Challenge any behaviours that seem inappropriate and report any suspected contraventions of the ABPI Code of Practice to the Prescription Medicines Code of Practice Authority (PMCPA).

DOs and DON'Ts for the pharmaceutical industry

Do be clear on the objectives of collaborating with healthcare professionals.

Don't embark on collaborative working without being able to demonstrate the value of the collaboration to third parties who may know less about it.

Do ensure that any collaboration is in line with both the letter and spirit of the ABPI Code of Practice and remember that the rules concerning relationships with patients (and the strict prohibition of the promotion of prescription only medicines to the public), also apply to collaborative activity.

Don't forget to carry the joint statement with you so that you can explain the recent changes to the ABPI Code of Practice.

Do keep up-to-date with the requirements of current relevant legislation including the Bribery Act.

Don't expect healthcare professionals to do things that are outside their professional code of ethics and understand the obligations and limitations placed upon them.

Do be transparent about your involvement in any activity and meet the requirements of the ABPI Code of Practice regarding declaration of payments to healthcare professionals.

Don't engage in collaboration with healthcare professionals without ensuring that there is a written agreement or contract in place setting out the details of the partnership.

Do alert your NHS employer or NHS Contracting body when entering in to a joint working programme with the pharmaceutical industry as the NHS will be held accountable for work involving NHS staff time and resources

Further information

The ABPI Code of Practice, including an e-learning module designed specifically for healthcare professionals, can be found at: www.pmcpa.org.uk

Clinical trial registries and databases: http://clinicaltrials.ifpma.org/clinicaltrials/no_cache/en/myportal/index.htm

Resources for joint working are included in the ABPI guidance and available on the DH website at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840