



Interactions in the Healthcare Sector: Disclosure of Transfers of Value

Healthcare professionals and the pharmaceutical industry collaborate in many critical areas to support scientific advancement and serve the best interest of patients. Examples of this collaboration include:

- Sharing information to help ensure that healthcare professionals have access to up-to-date, scientific and comprehensive information about the medicines they prescribe to support high quality patient care.
- The provision of advice and information by healthcare professionals on a broad range of topics including diseases, treatments and medicines are used to help improve healthcare delivery models, deliver effective new treatments and improve access and outcomes for patients.
- Healthcare professionals participate in clinical trial research which examines the efficacy and safety of potential new drugs and treatments that may improve or save patients' lives. This input is integral to the success of these trials, as healthcare professionals conduct research, track patient progress, and participate in reporting results of research in peer-reviewed journals.

Instilling and maintaining trust in the healthcare sector is essential. The pharmaceutical industry and healthcare professional organizations promote ethical collaboration through self-regulatory codes of practice and guidelines to help ensure that collaborations are ethical and appropriate. It is this shared commitment that contributed to the establishment of the *Consensus Framework for Ethical Collaboration between Patients Organizations, Healthcare Professionals and the Pharmaceutical Industry* in January 2014. The Consensus Framework aims to serve as a global model and is based on four overarching principles:

- 1) Put patients first
- 2) Support ethical research and innovation
- 3) Ensure independence and ethical conduct
- 4) Promote transparency and accountability

In some countries, disclosure of payments and other transfers of value between pharmaceutical companies and healthcare professionals have been implemented as a way to further demonstrate that interactions between companies and healthcare professionals are appropriate and lead to high quality patient care. Where there are requirements to disclose transfers of value, different countries have taken different approaches ranging from national law to self-regulation by means of regional and/or local codes. These initiatives, however, have proven to be complex and resource intensive. Therefore, if disclosure systems are undertaken, it is important to ensure that their value is measured in the context of wider health system needs, that they are appropriate and proportionate to the national context and beneficial to patients and society.

If national disclosure measures are to be undertaken, the following factors should be considered to help support a sustainable, balanced and credible approach:

- The collaboration and support of relevant stakeholders such as healthcare professionals, healthcare industry, patients, consumer groups, and government officials should be sought.
- Disclosure measures should apply to all healthcare industries, including innovative, generic, domestic, devices and diagnostic manufacturers.
- All healthcare professional associations and individual healthcare professionals should participate in the disclosure process.

- As implementation of disclosure measures is complex and resource-intensive discussions with stakeholders need to cover a variety of definitional issues and topics such as:
 - Type of platform (e.g. industry, company, government, foundation),
 - Type of reporting (i.e. aggregate or individual payments);
 - Thresholds for reporting, costs (e.g. regulator, resource and IT);
 - Who reporting should cover (e.g. licensed physicians, medical residents, nurses, etc.);
 - Categories of payment and transfers of value (e.g. commercial, research, educational sponsorship, patient educational material, travel and expenses, etc.);
 - Relevant laws and obligations (e.g. privacy, taxation, fair competition etc.);
 - Timelines (e.g. period of data collected, when it is disclosed and for how long); and
 - Protection of, and respect for, intellectual property rights.

Furthermore, if disclosure measures are to be implemented consideration should be given to the need to:

- Ensure that no harm is brought upon patients and that mutual respect and trust between stakeholders is protected;
- Provide appropriate contextual information with the published data so that interactions between healthcare professionals and companies are well understood by patients and the public;
- Report the transfers of value in a form that is readily accessible, adds value and is meaningful to the public;
- Enable the information to be reviewed by healthcare professionals prior to publication to ensure accuracy;
- Exclude business-to-business trading arrangements relating to the purchase of medicines etc.

In addition, it is also important to address payments or transfers of value that occur indirectly, such as through industry grants to patient organizations or medical societies that are used to fund, for example, independent clinical research or continuing medical education.

The global pharmaceutical industry is committed to supporting information sharing that aims to benefit patients and foster scientific advancement, while ensuring that concerns about the legitimate relationship between healthcare professionals and companies are addressed. If disclosure of transfers of value is to be considered as helpful to these aims, it important that the arrangements are appropriate to the national context and are conducted in collaboration with all relevant stakeholders. Commitment from governments, patients, healthcare professionals and the healthcare industry is essential to ensure a credible, balanced and pragmatic approach that brings practical benefit to all stakeholders including patients.

| <i>Examples of appropriate interactions between healthcare professionals and pharmaceutical companies that contribute to scientific advancement and improve patient care.</i> | |
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| <i>Activity</i> | <i>Value</i> |
| Clinical Trials (i.e. medical and scientific studies) | <i>Healthcare professionals who undertake clinical trials have an important role in evaluating the efficacy and safety of new potential treatments.</i> |
| Consultancy: <ul style="list-style-type: none"> • <i>Advisory Boards</i> • <i>Market Research</i> • <i>Speaking and/or Chairing Meetings</i> | <i>Healthcare professionals provide detailed advice and guidance on the future development of new treatments as well as information on the use of current treatments.</i> |
| Continuing Medical Education <ul style="list-style-type: none"> • <i>Pharmaceutical companies may sponsor healthcare professionals' attendance to scientific and medical events.</i> | <i>Sponsorship enables healthcare professionals to attend events to obtain the latest information and insights on diseases, therapeutic areas and interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system.</i> |