Introducing more openness in commercial relationships

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As the NHS and the ABPI introduce measures to improve transparency in drug development, Prescriber reports from the recent Guardian debate in London examining this thorny issue.

Amid increasing calls for transparency, medical staff, GPs and the pharmaceutical industry are forging a new era of openness in their commercial and clinical relationships. Taking a lead from practice in the USA, the aim is to achieve a world in which all cooperation is seen to be fair.

In a radical step, the ABPI is to launch a database at the end of June, to show payments made from the pharmaceutical industry to healthcare professionals – including dentists, pharmacists and nurses. The information will be up to date, public and easy to search, opening up the terms of relationships between partners in the development and prescription of drugs.

In a separate development, a new transparency clause or ‘sunshine rule’ requiring CCGs and hospital trusts to keep a list of gifts and payments from pharmaceutical companies to NHS staff, will be written into the 2016–2017 NHS standard contract. NHS medical staff in England and Wales will have to declare gifts and hospitality received from pharmaceutical companies and medical device manufacturers. Failure to do so could result in dismissal or prosecution. Although not government legislation, this so-called ‘sunshine rule’ mimics the US Physician Payments Sunshine Act.

Both the database and the transparency clause constitute a response to increasing concerns about prescribers working as consultants to drug companies.

The measures have the broad support of a majority of health professionals, yet some are concerned that there is a downside to transparency. A poll of more than 500 healthcare professionals carried out on behalf of the ABPI found 64 per cent of those surveyed thought payments from pharma companies to individually named people should be publicly declared on a database. However, 24 per cent thought disclosure of payments may “adversely affect” medical innovation in the UK.

Healthcare professionals who have been paid by pharma companies to carry out work have come under criticism recently. An investigation by the Daily Telegraph reported that more than 130 NHS officials involved in medicines procurement are also paid to carry out work for pharma companies. The newspaper said “the practice of officials taking prescribing and ‘medicines management’ roles while acting as consultants to drug firms is systemic within the NHS”. On the face of it, this can lead to a clear conflict of interest.

Debating the relationship

So how does the industry ensure transparency and accountability in the relationship between prescribers and pharmaceutical companies without sti-
flying collaboration and problem solving in the service of patient needs? That was the question at the heart of a recent Guardian debate in London, which was sponsored by the ABPI.

Ash Soni of the Royal Pharmaceutical Society told the debate that transparency is “absolutely key”, and it was important for people to know the narrative behind any payment. “Disclosure is very much about being engaged in that company and how real-time data is produced, and what it means for patients and their outcomes, so we are not wasting resources and we are able to give the best advice to CCGs, organisations and the NHS about the value of the medicines we are using.

“There is the ability to react and respond to disclosure but sometimes people are doing things in the best interest of collaboration and they get tarred with the brush of accepting money from someone for something but they don’t get the opportunity to say why, what the purpose was, what it was designed to do and why their engagement was there,” said Mr Soni.

The chief executive of Myeloma UK, Eric Low took a different view. He believes collaboration is paramount to patient outcomes. Mr Low argued the reason Myeloma UK and other charities collaborate with pharmaceutical companies and compete to get clinical trials is because they care about their patients. “It would be unthinkable for me, as leader of a patient organisation, not to work with industry because they play such a critical role. We have to find ways of optimising medicines and creating flexible pathways to do our best for patients. Industry speaking to pharmacists and clinicians speaking to industry is key. But it has to be done the right way,” Mr Low remarked.

Myeloma UK collaborates with industry to get the right data and research for patients with myeloma in the UK. The organisation receives free drug treatments from industry to use in studies and the procurement cost of these drugs may amount to six or seven million pounds, Mr Low noted. “That could raise some eyebrows. But we should celebrate it: there’s nothing inappropriate about the relationship.”

Nikki Yates of GlaxoSmithKline (GSK) told the debate that the industry is “marching together” on the issue of transparency – with GSK at the forefront. Ms Yates said that, since 2014, the pharmaceutical company has had a disclosure clause in its contracts. “If we can’t agree on disclosure, we won’t work with those people. This is a step towards transparency and a foundation of trust,” she said.

Systemic issue

Some clinicians want disclosure to go even further. Glasgow GP Dr Margaret McCartney has campaigned for complete transparency in clinical data and payments to healthcare professionals, saying “every pen” received at a conference should be declared because even small gifts have been shown to cause problems.

Dr McCartney told the debate how her practice was approached to take part in clinical research. When she asked if the results would be published no matter what they showed, she was told that was not the case, and that a legal process would start should she choose to publish them without agreement. “How can I trust an industry that says they will not guarantee to publish the results no matter what they show?” she asked.

The panel went on to discuss the relationship between CCGs and pharma companies. Dr McCartney said she was “morally distressed” at the number of pharmacists were leaving GP surgeries, audit patient notes and make recommendations for treatments. As a doctor and a patient, she was unhappy with this practice, and said patients have not given their permission for this to happen.

Ms Yates argued there were clear guidelines about appropriate practice. Companies are not allowed access to patient records and data, and GSK does not take part in any such activity. The panel agreed poor practice such as this should be reported to the Prescription Medicines Code of Practice Authority (PMCPA). As should inappropriate “hype” around new drugs coming to market, added Ms Yates.

The issue of managing expectations and hype around new treatments and drugs in an age of social media campaigns was highlighted at the debate.

Dr McCartney said she believes the term ‘innovation’ is used as a way to introduce drugs that have not been adequately tested. Drugs are hyped up through publicity campaigns, patient groups, media coverage and the government, which is largely irresponsible, added Mr Low.

Ms Yates argued that many patient groups drive high expectations regarding drugs. “There is hype that happens through patients themselves and viral marketing, which the industry has nothing to do with.”

She cited the recent campaign for the meningitis B vaccine, Bexsero. The death of a two-year-old child, Faye Burdett, sparked a debate as to whether the vaccination should be made available to more children in the UK. Faye died from septicaemia as a result of meningitis B. Her mother released a photograph of Faye to raise awareness of the effects of meningitis B and campaign for the vaccine to be extended to all children under the age of 11 years on the NHS.

The campaign went viral, forcing the issue to be debated in Parliament. Private practices suffered a shortage of the vaccine after parents rushed to get their children vaccinated. “GSK had nothing to do with the hype [for the meningitis B vaccine]. Sometimes what you might believe is behind things isn’t actually behind them,” stressed Ms Yates.

Trust is required

The minister for life sciences, George Freeman, told the debate that partnership between research and healthcare professionals was crucial. He believed the best way of delivering results was through trust, and he was not in favour of a legislative approach.

“There is a choice between an approach that is based on conspiracy theory and distrust, with legislation as the only solution, which I think can drive a defensiveness, or an approach that is based on mutual respect for each other’s perspectives and on the UK leading a progressive race to the top,” he explained.

“If we put the patient’s voice right at the heart of it, I don’t think we can go far wrong and I think that will accelerate us into this landscape of a more transparent healthcare innovation ecosystem.”