

The 'Sunshine Rule'

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Background

There is an increased focus on the transparency of relationships between the pharmaceutical industry and health professionals. It is now more important than ever for pharmacists to be familiar with the rules that govern such relationships.

The 'Sunshine Act' in the US requires manufacturers of drugs, medical devices, biological and medical supplies to collect and track all financial relationships with physicians and teaching hospitals and to report this centrally. The goal of the law is to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers and to uncover potential conflicts of interest.¹

Lord Carter stated, in his 'Review of Operational Productivity in NHS providers: Interim Report, June 2015', that an English equivalent to the US 'Sunshine Act' would be explored.

The Health Secretary Jeremy Hunt has now announced that a new transparency or 'Sunshine Rule' will be written into the 2016-17 NHS standard contract. This rule will, in effect, require NHS providers and commissioners to keep a mandatory log of all payments, gifts and hospitality offered to NHS staff from pharmaceutical companies. Whilst the rule is not legislation, it does mimic the US Sunshine Act in aiming to prevent improper relationships. At this stage it appears that any member of NHS staff found not to be complying with the new rules will be subject to sanctions decided by their employer. Many NHS bodies already keep such a register and require declarations of interest, so this may not be as significant a change as it appears.

It is worth noting the following points about current legislation:

- Under the UK Bribery Act, an individual can be prosecuted if they have improperly accepted money from third parties – the resulting sanctions could include fines and imprisonment.
- The Human Medicines Regulations ban the offer of any gifts in connection with the promotion of medicines, to anybody qualified to supply or prescribe them - again the resulting sanctions could include fines and imprisonment.

Speaking at the Conservative Party conference, Mr Hunt said: "These tough new rules will, for the first time, expose improper

relationships between staff and pharmaceutical companies.

"Only those serving their own self-interest should have anything to fear, with patients and taxpayers set to benefit," he added.

"The Sunshine rule will come into force next year, and NHS organisations will have to maintain a hospitality register where staff will have to declare all gifts and hospitality they receive from pharmaceutical firms and medical devices manufacturers," he said.

Telegraph investigation

When reporters from The Daily Telegraph went undercover in July 2015 to investigate the relationship between drug companies and NHS staff, the resulting headlines made some in the pharmaceutical industry and the NHS alike pretty uncomfortable.

The headlines stated 'Revealed: The NHS officials paid, wined and dined on spa trip' and 'Senior NHS staff are being paid thousands of pounds and taken on expensive trips by drug companies lobbying to get their products used by the health service'.

The investigation focussed on two medicines management pharmacists who were alleged to have received fees from pharmaceutical companies for arranging overseas advisory boards. Whilst the subsequent published article claimed the fees were excessive and the venues used were lavish, it also questioned the 'potential conflicts of interest' and 'the impartiality of public sector staff who control budgets worth millions of pounds'. One of the pharmacists filmed and mentioned by the Telegraph has now resigned and the other has been suspended, pending an investigation by NHS Protect.

Although there will be inevitable repercussions for these pharmacists, individual pharmaceutical companies involved will also be followed up.

In terms of consequences for these pharmaceutical companies, self-regulation should be the first means of dealing with complaints such as public criticisms of pharmaceutical industry activities. The Prescription Medicines Code of Practice Authority (PMCPA), the body that administers the industry's Code of Practice (Code), has confirmed they have

contacted the newspaper for the names of the alleged companies so that formal complaints can be taken up.

Mr Hunt said, “The Telegraph’s investigation suggested that some NHS staff and professionals making these decisions may have been influenced by extravagant hospitality” and “It’s hard not to conclude that some sales reps have been ripping the NHS off, and diverting taxpayers’ money away from patient care.” He went on to say that he does not want to stop “sensible” collaboration between private firms and the health service “but we must not tolerate abuse”.

Top-line principles

The top-line principles that apply to the three key areas that were subject to the Telegraph’s investigation (consultancy arrangements, declarations and advisory boards) are discussed below.

Consultancy Arrangements

Pharmaceutical companies can legitimately engage the services of, and pay, individual pharmacists, BUT this consultancy must comply with strict criteria. These include a genuine need for the service, documented in a written agreement, engaging an appropriately qualified consultant and the fee being reasonable and ‘fair market value’ for the service provided.

Declaration requirements

For some time now the Code has required agreements between pharmaceutical companies and consultants to include provisions regarding the obligation on consultants to declare that they have provided a service to the company. New disclosure rules extend beyond this and mean that unless a consultant has withheld their consent for their individual details to be disclosed, details relating to individual consultancies will be made public on a central, searchable database.

If individual health professionals set up their own limited companies to handle consultancy services, such limited companies would not be considered a ‘healthcare organisation’, for the purposes of public disclosure.

Advisory Boards

Under the 2015 Code, UK companies are responsible for the activities of their overseas parent either in the UK, or with UK health professionals abroad. This means that if UK health professionals are invited to attend a pharmaceutical company advisory board meeting overseas, the arrangements (such as venue, accommodation, travel and subsistence) should be fully approved by UK signatories. If they noted any issue – disguised promotion, lavish hospitality, inappropriate advisor selection, unacceptable payments etc, they would not be able to approve the attendance of UK health professionals.

These, and other areas, will be explored and discussed in more depth at a forthcoming Pharmacy Management Forum.

Further information will be made available on the Pharmacy Management website at www.pharman.co.uk and by personal email in due course.

Any additional enquiries to katie.fraser@pharman.co.uk.

REFERENCES

1. Department of Health. Lord Carter. Review of Operational Productivity in NHS providers: Interim Report, June 2015. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/434202/carter-interim-report.pdf.