

Briefing for the Public Petitions Committee

Petition Number: PE01493

Main Petitioner: Peter John Gordon

Subject: A Sunshine Act for Scotland

Calls on the Parliament to urge the Scottish Government to introduce a Sunshine Act for Scotland, creating a searchable record of all payments (including payments in kind) to NHS Scotland healthcare workers from Industry and Commerce.

Background

In the background material accompanying the petition, the petitioner appears to be particularly concerned about the relationship between the health service and the pharmaceutical industry.

Whilst there is no central register of any payments between health service staff and industry, there is UK legislation prohibiting the taking of bribes (see below) and professional regulatory guidance that would need to be adhered to (see below). In addition there is guidance made under the auspices of the Scottish Government (see 'Scottish Government Action'), below.

The Bribery Act 2010

The Bribery Act 2010 is a piece of UK legislation covering all the countries of the UK. Bribery is defined as the giving or taking of a reward in return for acting dishonestly and/or in breach of the law. Under the Act there are four possible offences:1) Bribing another person; 2) being bribed; 3) bribing a foreign public official; and 4) failure to prevent bribery. Under the Act it would be a criminal offence for an employee of an NHS Board to give or to receive a bribe. It is a corporate offence if the NHS Board is found to have failed to prevent bribery. The NHS Board could also be liable where someone who performs services for it (like an employee or agent) pays a bribe specifically to get business, keep business, or gain a business advantage from the Board. However, if the Board can show it had adequate procedures in place to prevent bribery, then it will have a full defence for this particular offence, and can avoid prosecution.¹

¹ NHS Confederation (2011) 'The Bribery Act 2010'

Professional regulation

Healthcare professionals subject to statutory regulation are required to adhere to standards of ethical and professional conduct set by their regulatory bodies. Thus, the same professional standards are expected regardless of whether a health professional works directly for NHSScotland, under contract with NHSScotland, or in the private sector. For example, as part of its role in regulating doctors, the General Medical Council publishes advice which outlines the standards that are expected of doctors. The key guidance in this regard is 'Good Medical Practice' (2013). In its section on Maintaining Trust (para 77-80) it states doctors:

- must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals
- must not allow any interests they have to affect the way they prescribe for, treat, refer or commission services for patients
- if faced with a conflict of interest, must be open about the conflict, declaring their interest formally, and should be prepared to exclude themselves from decision making
- must not ask for or accept from patients, colleagues or others any inducement, gift or hospitality that may affect or be seen to affect the way they prescribe for, treat or refer patients or commission services for patients.

Further specific guidance on these matters is contained in <u>'Financial and commercial arrangements and conflicts of interest'</u> (2013). Failure to meet these standards can result in disciplinary action being taken by the regulator.

International examples of the use of a Sunshine Act

The petitioner makes reference to developments in several countries on this issue:

- United States: The Physician Payments Sunshine Act requires
 manufacturers of drugs, medical devices and biologicals that participate in
 US federal health care programs to report certain payments and items of
 value (of \$10 or more) given to physicians and teaching hospitals. It came
 into effect on 1 August 2013. (American Medical Association)
- France: The Sunshine Act was adopted on 29 December 2011. The
 decree implementing the legislation was issued on 21 May 2013. Its aim is
 to specify the scope of disclosure obligations, which affect all agreements
 concluded between health care professionals and companies, as well as
 every benefit in kind or in cash. (McDermott Will & Emery)
- Australia: There are two initiatives taking place in Australia, which largely seek to arrive at a similar goal, but which differ on whether legislation is necessary. The first is the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013. This Bill was introduced in the Australian Senate and is currently at the second reading stage of Parliamentary scrutiny. It seeks to place restrictions on the way that

pharmaceutical companies interact commercially with doctors and creates the requirement for more transparent reporting of such interactions. The second initiative relates to a consultation that is currently underway seeking views on a Transparency Model that was developed by the Transparency Working Group of Medicines Australia (the representative body of the pharmaceutical industry in Australia). This model is based on the Physician Payments Sunshine Act in the US, though would be taken forward through a system of self-regulation.

Scottish Government Action

There are two pieces of guidance that are of relevance to the petition.

NHS Circular MEL (1994) 48

This circular, entitled 'Standards of Business Conduct for NHS Staff', specifies the general standards which should be maintained by all staff working in the NHS. It covers all health professionals including independent contractors (e.g. General Practitioners) and locum practitioners working under NHS terms and conditions. It was written at a time when the legislation governing the acceptance of gifts by way of inducements or rewards were the Prevention of Corruption Acts of 1906 and 1916, both of which were repealed and replaced by the provisions in the Bribery Act 2010. However, the core of the guidance is still current.

The Circular contains a number of principles of conduct in the NHS including that the interest of patients are paramount; the importance of impartiality and honesty; and the appropriate use of public funds. However, it is also states that it is the responsibility of staff to ensure that they do not: abuse an official position for personal gain or to benefit their family or friends; and, seek to advantage or further their private business or other interests, in the course of their official duties. Specific guidance is given on casual gifts and hospitality, namely:

- Casual gifts offered by contractors or others, e.g. at Christmas time, may
 not be in any way connected with the performance of duties so as to
 constitute an offence under [the Bribery Act 2010]. Such gifts should
 nevertheless be politely but firmly declined. Articles of low intrinsic value
 such as diaries or, or small tokens of gratitude from patients or their
 relatives need not necessarily be refused [...]
- Modest hospitality provided it is normal and reasonable in the circumstances e.g. lunches in the course of working visits, may be acceptable, though it should be similar to the scale of hospitality which the NHS as an employer would be likely to offer. Staff should decline all other offers of gifts hospitality or entertainment. [...]

There is also a section providing guidance on declaring conflicts of interest. In this NHS Boards are encouraged to: ensure staff are aware of their responsibilities; consider keeping registers of all such interests and making them available for inspection by the public; and to develop a local policy for implementing the guidance. Thus, local implementation is a matter for NHS

Boards themselves. For example, the <u>Code of Conduct</u> (2013) at NHS Greater Glasgow and Clyde makes reference to the Bribery Act 2010 and relevant guidance, and has established separate registers for gifts and rewards and declaration of interests.

Guidance on Joint Working between NHSScotland and the Pharmaceutical Industry

The Scottish Government recently published 'A Common Understanding 2012 — Working with Together for Patients'. This is a revision of previous guidance published by the then Scottish Executive in 2003. It sets out a set of principles and processes under which joint working between the NHS in Scotland and the pharmaceutical industry should take place. In the document, a distinction is made between "joint working" and "sponsorship", emphasising how, under the former, the NHS and the industry both contribute knowledge, skills and resources to support an activity that will benefit patients. The principles set out in the document cover a range of areas, including:

- The interests of individual patients must be protected, and joint-working should not undermine or conflict with the ethical requirements of any healthcare professional, including the duty of clinicians to provide the treatment considered to be clinically appropriate. Collaboration between NHSScotland and the pharmaceutical industry should not be represented as endorsement by NHSScotland of any specific medicine or technology.
- The pharmaceutical industry must comply with the relevant code of practice at all times. All NHSScotland staff/independent contractors must comply with NHS (and relevant professional bodies') codes of conduct.
- Healthcare professionals should not achieve any personal financial benefit from joint-working.
- NHS Boards should establish monitoring arrangements to ensure accountability. An official register of interests should be established as part of the monitoring arrangements and all relevant individuals must subscribe to this. This register should be published on the websites of all the Boards involved.

Other relevant information

The Association of the British Pharmaceutical Industry (ABPI), which is a member organisation representing the pharmaceutical industry has its own code of practice, which covers a range of matters, including joint working with the NHS. It is administered by the Prescription Medicines Code of Practice Authority, which is a self-regulatory body, at arm's length from the ABPI.

In addition, there is joint <u>guidance</u> on collaboration between health care professionals and the pharmaceutical industry, which was produced by representatives of the pharmaceutical industry and the healthcare community. This contains a series of "do's and don'ts" for the industry and individual

healthcare professionals. It is reviewed regularly by the <u>Ethical Standards in Health and Life Sciences Group</u>² (ESHLSG).

The ESHLG itself recently undertook a consultation into the public disclosure of payments to health professionals. The <u>results</u> show that 77% of all respondents supported the public disclosure of payments through a single, searchable database. Support was particularly strong in the healthcare community and across life science companies.

Scottish Parliament Action

The issues raised in the petition have not been addressed by a Committee of the Parliament or in a plenary session of Parliament.

Jude Payne Senior Research Specialist 31 October 2013

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² On its website, ESHLSG states that it is a multi-stakeholder group consisting of 20 healthcare organisations, with representation from the medical community and the pharmaceutical, medical device and diagnostic industries in the UK.