

PE1493/I

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The Scottish Parliament

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Dear Mr Howlett,

## **Scottish Parliament Public Petition PE1493 on a Sunshine Act for Scotland**

Thank you for giving us the opportunity to submit our views on the proposed introduction of 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.

I have set out below how our guidance to doctors applies in this area, as well as some work that we will be taking forward which is relevant to the issues raised in the petition.

The status of GMC guidance

The standards we expect doctors to abide by are set out in our ethical guidance. <u>Good medical practice</u> and all its explanatory guidance, including that on <u>Financial and commercial arrangements and conflicts of interest</u>, describes what doctors must do when faced with a conflict of interest, including offers of payment or hospitality made by pharmaceutical or other healthcare companies.

Doctors must demonstrate, through the revalidation process, that they practise in line with the principles and values set out in our guidance. Serious or persistent failure to follow the guidance will put their registration at risk, because these are the standards they'll be judged by if their fitness to practise is called into question.

#### The differences between our guidance and a compulsory register

Our guidance for doctors<sup>1</sup> makes clear that they must be open and honest about any financial and commercial interests, and they must not allow these to affect the way they treat or care for patients. The guidance also sets out that doctors must be open about any conflict, declaring interests formally, and should be prepared to exclude themselves from decision-making.

This guidance on conflicts of interest is not limited to payments (including payments in kind) from Industry and Commerce as proposed in the Petition. Nor is it restricted to doctors working in the NHS. Rather our guidance:

- applies to all doctors, regardless of their grade, specialty and whether they work in the NHS or the independent sector;
- relates to any conflict of interest, not just payments or payments in kind;
- says doctors must not accept any inducement, gift or hospitality that may affect or be seen to affect the way they care for patients, ie it covers perceived, potential conflicts as well as those that are recognised and current.

#### Publishing research results

In the Official Report of 12 November 2013 Dr Gordon made reference to the failure to publish trial data. Our <u>quidance on research</u><sup>1</sup> makes clear that:

- we expect doctors to be open and honest about their research;
- financial interests must not affect completion of research;
- doctors should publish research results, including adverse findings, through peer review journals.

We also state that, as well as reporting adverse findings to the affected participants, and those responsible for their medical care, doctors must report adverse findings to the research ethics committee, and bodies – such as the Medicines and Healthcare products Regulatory Agency – responsible for protecting the public.

Fitness to practise cases relating to conflicts of interest

We can confirm that over the past seven years (since April 2006) over 200 (240) doctors were referred to us with allegations about conflicts of interest (from a total of over 25,000 cases). In 33 cases the doctors were referred to panel hearings. Of those doctors who were referred to panel hearings, 5 were erased, 6 suspended and 4 had conditions put on their licence. As at 21 November 2013, there were also a number of doctors (14) with open cases relating to conflict of interest allegations.

2

<sup>&</sup>lt;sup>1</sup> See Annex A for relevant extracts from GMC guidance.

A compulsory register would require legislative change

We do not currently have any powers in the Medical Act 1983 to require doctors to disclose financial interests to us, and any scheme to publish details of doctor's financial interests would need to be voluntary.

A change in legislation would be needed to establish a compulsory register of doctors' interests. If this were not implemented across the UK simultaneously, it is not clear whether and how a change in legislation in Scotland – as proposed in this Petition – might impact on our regulation of doctors across all four UK countries. As it happens, in the light of a recent review of professional regulatory legislation undertaken by the Law Commission, we understand that a Bill is likely to be brought before the UK Parliament during the course of 2014 which would replace the 1983 Act with a new Act applicable to all the professional regulators.

#### Next steps

We recognise that there is scope for us to promote our guidance on good practice, to continue to raise awareness of it and do what we can to ensure compliance with it. Throughout 2014 we will continue to look for ways to embed the principles in **doctors'** day to day practice.

We will also assess conflicts of interest and the practicality of keeping a list of doctors' interests attached to the Register. Through our Corporate Strategy for 2014-2017 we are committing to considering if there are any changes that we could make to the medical register to make it as relevant, accessible and useful as possible. This review will provide a timely opportunity to address this important matter.

We would welcome information about the progress of this Petition and would be glad to offer a meeting if that would be helpful.

Yours sincerely

Paul Buckley
Director of Strategy & Communication

## Good medical practice

- 77. You must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals.
- 78. You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.
- 79. If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.
- 80. You 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 you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements.

# Financial and commercial arrangements and conflicts of interest

- 10. Trust between you and your patients is essential to maintaining effective professional relationships, and your conduct must justify your patients' trust in you and the public's trust in the profession. Trust may be damaged if your interests affect, or are seen to affect, your professional judgement. Conflicts of interest may arise in a range of situations. They are not confined to financial interests, and may also include other personal interests.
- 11. Conflicts of interest are not always avoidable, and whether a particular conflict creates a serious concern will depend on the circumstances and what steps have been taken to mitigate the risks, for example, by following established procedures for declaring and managing a conflict.
- 12. You should:
  - a. use your professional judgement to identify when conflicts of interest arise
  - b. avoid conflicts of interest wherever possible
  - c. declare any conflict to anyone affected, formally and as early as possible, in line with the policies of your employer or the organisation contracting your services
  - d. get advice about the implications of any potential conflict of interest
  - e. make sure that the conflict does not affect your decisions about patient care
- 13. If you are in doubt about whether there is a conflict of interest, act as though there is.

### Good practice in research

- 11. You should make sure that details of a research project are registered on an eligible, publicly available database that is kept updated, where such a database exists.
- 14. You should make sure that commercial and other interests do not stop or adversely affect the completion of research. If you are concerned about this you should follow the guidance on raising your concerns in paragraph 19.
- 16. You must report adverse findings as soon as possible to the affected participants, to those responsible for their medical care, to the research ethics

committee, and to the research sponsor<sup>2</sup> or primary funder where relevant. You must make sure that bodies responsible for protecting the public, for example, the Medicines and Healthcare products Regulatory Agency, are informed.<sup>3</sup>

24. You must report research results accurately, objectively, promptly and in a way that can be clearly understood. You must make sure that research reports are properly attributed and do not contain false or misleading data. Whenever possible, you should publish research results, including adverse findings, through peer-reviewed journals.

<sup>2</sup> A sponsor is the person, individual or group that takes responsibility for the initiation, management and financing (or arranging the financing) of the research. All research undertaken in the NHS must have a sponsor. You should refer to the *Medicines for Human Use (Clinical Trials) Regulations 2004* for a full definition of a sponsor and its responsibilities in clinical trials of investigational medicinal products.

<sup>&</sup>lt;sup>3</sup> Medicines and Healthcare products Regulatory Agency

<sup>&</sup>lt;sup>4</sup> The EQUATOR Network website provides advice on good practice in reporting health research.

<sup>&</sup>lt;sup>5</sup> Further information on publication and authorship is provided in section 3.15 of the Code of Practice for Research: Promoting good practice and preventing misconduct (UK Research Integrity Office, 2009).