Cabinet Secretary for Health, Wellbeing and Sport
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Mr Michael McMahon MSP
Convener
Public Petitions Committee

By Email.

22 March 2016

Dear Michael,

I am writing to provide you with a copy of the report prepared by the Scottish Health Council on their engagement exercise relating to petition PE01493 on a Sunshine Act for Scotland. The report provides us for the first time with views from patients and the public on the issues raised by the petition.

Although the numbers involved are small, a majority of participants felt that publication of financial payments to healthcare professionals should be mandatory.

In terms of next steps, the Scottish Government will discuss the contents of this report with the appropriate regulators and scope out options of how mandatory publication of payments to healthcare professionals from industry could be delivered. As part of this work we will ensure that options are proportionate and respectful of NHS resources.

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Healthcare Improvement Scotland

scottish health council

making sure your voice counts

Register of interests for Scotland

Gathering public views

March 2016

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1 Background

1.1 Some healthcare professionals (people employed in the NHS and who provide health services such as doctors, consultants, nurses, etc) can receive payments from the pharmaceutical industry. Figures from the Association of British Pharmaceutical Industry (ABPI) show that payments to healthcare professionals throughout the United Kingdom were estimated to be around £38.5 million in 2013. This was made up of £27.7 million for activities including speaking at meetings, involvement in training, clinical and medical trials, media activity, or taking part in market research. £10.8 million was also paid for things like sponsorship to attend medical education meetings (covering registration fees, international travel, accommodation and reasonable refreshments and subsistence).

1.2 Currently, there is no publicly searchable way for people to see how much is paid to healthcare professionals in Scotland by the pharmaceutical industry. From later this year, however, the pharmaceutical industry will publish details of staff who receive payments in the United Kingdom. Healthcare professionals will be able to 'opt out' of having their information published if they wish. The publication, which is currently being called a 'Register of Interests', will be available to the general public via the internet.

1.3 As well as the new Register, there is legislation which prohibits healthcare professionals from taking bribes. There are also regulations restricting the promotion of drugs, accepting incentives and receiving hospitality. All healthcare professionals must act within their own professional regulation and codes of best practice.

1.4 A public petition has been lodged before the Scottish Parliament which calls for legislation for a Register of Interests specifically for Scotland. This would create a searchable record of all payments (including payments in kind) to NHSScotland healthcare workers from industry and commerce. The petition and correspondence with the petitioner can all be found on the Scottish Parliament website under public petitions at: http://www.scottish.parliament.uk/GettingInvolved/Petitions/sunshineact

2 Gathering public views approach and process

2.1 The Scottish Health Council was asked by the Scottish Government to obtain views from the public on the potential introduction of a Register of Interests for Scotland. Our approach to this request was consistent with our normal practice which aims to provide a means of gathering public views on a specific subject; it is not undertaken either as formal research nor as a full public consultation exercise.

2.2 We regard gathering views through small groups of people as a particularly effective way of obtaining feedback and generating discussion. Our main consideration is always about the quality of that engagement rather than the quantity of people involved and experience demonstrates that feedback from participants tends to be consistent regardless of the numbers involved.

2.3 To generate views on a Register of Interests, we organised and facilitated discussion groups in all 14 NHS Board areas across Scotland. A standard set of questions, which was developed in conjunction with the Scottish Government, formed the basis of the discussions. The appendix to this report contains the background information which was shared with participants together with a list of the questions.

2.4 A total of 81 people were involved. This included 20 participants who were keen to share their views but were unable to take part in a discussion session and so responded to the questions either by questionnaire (18) or over the telephone (2). People who took part included:

- members of the public recruited through our local office community contacts (46)
- representatives from Public Partnership Forums, Patient Participation Groups or Patients' Councils(18)
- members of voluntary organisations or community groups (6)
- NHS Board committee public representatives (7)
- Healthcare Improvement Scotland public partners (4)

2.4 Whilst we experienced an unusually high drop-out rate by people who had originally agreed to take part in the discussion sessions and the numbers involved were lower than we expected, the quality of feedback received was nonetheless of a high quality. It was also clear from the views expressed that participants understood and grasped the various issues associated with healthcare professionals being offered payment from the pharmaceutical industry as well as the complexities of potentially recording the information through a Register of Interests. The feedback received from participants is summarised below.

3 Feedback and views

3.1 Were you aware that healthcare professionals can be offered payments from the pharmaceutical industry?

Most people who took part told us that they were aware that healthcare professionals were offered payments from the pharmaceutical industry.

3.2 What do you think about this or how does it make you feel?

There was mixed reaction both across and within the discussion groups to the practice of offering payments to healthcare professionals with views varying widely.

Some people said they were uncomfortable about healthcare professionals accepting payments because they felt it could influence clinicians' decisions about prescribing medicines to patients. Others described it as a "conflict of interest" and some felt it was "not a moral thing to do" and suggested that any payments received within, for example, general practice should be used to benefit the whole community. Several concerns were raised about whether general practitioners would be influenced or inclined to prescribe certain drugs as a result of being offered incentives.

In a couple of discussion groups, participants disagreed with the practice and felt it was wrong to have an incentive for prescribing drugs which should instead be based entirely on the clinician's judgement on what was right for their patients (rather than an incentive payment having an influence). Some participants were concerned that offering payments could have an impact on public funds in relation to increasing prescribing costs and so were not in favour of it.

Some participants who felt that it was not acceptable for healthcare professionals to accept payments felt more comfortable with them being offered "low value" incentives such as hospitality and meals. In one discussion group, participants described offering payments as "similar to bribery", whereas another described it as "unethical". In a similar context, some participants were concerned that healthcare professionals could be prescribing medicines as a result of "backhanders" from pharmaceutical companies and one person described it as "a perk and there should be tax implications".

Participants also expressed concern about healthcare professionals being "unaccountable" when receiving payments for personal gain particularly as there was no way currently of sharing that information with the general public. In a number of discussion groups, it was acknowledged that some healthcare professionals received payments for positive reasons and if the process was transparent and regulated then it would help to alleviate public concern.

Some participants were fairly comfortable with healthcare professionals receiving payment to attend, for example, seminars or courses whilst others felt it could also lead to bias in the use (prescribing) of medicines.

Some said that they felt it was more acceptable than at other times for healthcare professionals to accept payments, for example payment to conduct a clinical trial was seen as more acceptable than a general payment to a consultant which could then influence their prescribing. One participant said that it made them feel “uneasy and suspicious” because they felt that payments could currently be a hidden way of influencing a healthcare professional - another person said it made them feel “very cautious”.

Participants were also concerned about the impact on general practitioner prescribing in rural areas where there were limited or no alternative places for patients to obtain prescriptions.

A number of participants agreed that making payments to healthcare professionals by the pharmaceutical industry more visible was a good approach and offering payment for “work done” was not necessarily wrong providing it was declared. The importance of clinical trials was mentioned frequently within a number of discussion groups and there was an acknowledgement that this relied heavily on co-operation between healthcare professionals and the pharmaceutical industry. Generally, participants were far more accepting of payments to healthcare professionals if it contributed in some way to medical research or increased education and training about treatments for certain conditions. In a similar context, participants in one discussion group felt that payments to clinicians should not be automatically seen as negative as they had an important part to play in research and grants for clinical trials.

The amount of the payment was considered by participants as an important factor, as was the importance of clinicians providing feedback to pharmaceutical companies to further develop clinical products. Receiving payment for feedback on the effectiveness of clinical products was regarded by some as useful, providing the rewards for doing so were moderate and proportionate; participants in one discussion group said that “being entertained in lavish style” for example was not considered acceptable.

There were also concerns about the amount of time healthcare professionals were devoting to supporting the activities of pharmaceutical companies and any impact on patient care (some participants referred to “absence from the day job”).

Participants in one discussion group felt that more clarity was required around the “rules” for offering payments and more information needed to be available on what constituted a payment. Participants in the same discussion group suggested that a percentage of the payment made to healthcare professionals should be re-invested back into the NHS.

3.3 How likely would you be to access information which the pharmaceutical industry will publish next year which shows any payments made to healthcare professionals?

The majority of people said they would be inclined to access information which showed what payments were made to healthcare professionals. Participants in one discussion group (who generally felt they would not access the information) said that they would be inclined to do so if there was any “big news stories” about payments to doctors. Most participants agreed that they would be more likely to access information about payments relating to their own medication and prescriptions; participants in one discussion group said they would be interested to see any “local information”. Others mentioned that the general public would need to know that a Register existed in the first instance and how to access it.

Participants in one discussion group felt that the information might be used routinely by journalists and possibly “disgruntled” members of the public; beyond that they felt that the average member of the public was unlikely to be interested in the information although they welcomed the transparency it would bring. Participants in three discussion groups said that they would be more likely to access the information and a Register due to their involvement in the discussion group and their awareness of it.

In one discussion group where there was a mixed response from participants, a few said that they would potentially look up information if they had personal queries regarding a drug they had been prescribed or if they had concerns about certain drugs being “pushed” by healthcare professionals.

3.4 Do you think current arrangements are sufficient and that healthcare professionals can ‘opt out’ of having details of payments from the pharmaceutical industry being included in the Register (given that professional regulations already exist)?

The majority of participants felt that the current arrangements, whereby healthcare professionals could ‘opt out’ of having to declare payments from the pharmaceutical industry, were not sufficient. Some participants felt there was no point in having a Register if healthcare professionals could ‘opt out’ and the view was that the process was far too lenient at present and payments needed to be recorded and regulated.

One person said they were unsure about whether there should be an ‘opt out’ arrangement and expressed concern that mandatory reporting may deter some healthcare professionals from taking part in research on behalf of the pharmaceutical industry. Within another discussion group, there was a view that a compulsory declaration of payments could deter good and competent healthcare professionals from taking part in clinical trials if they feared their details would be publicly available. There were other concerns about whether publicising a healthcare professional’s involvement in research might be seen as “controversial”, for example if it involved genetic research or testing medication on animals.

Most participants agreed that healthcare professionals would automatically ‘opt out’ if the option existed and this would make the Register pointless. A question raised in one discussion group was if a healthcare professional was not on the Register, how would a member of the public know if that person had not received a payment or had ‘opted out’? A couple of participants questioned whether the information would currently be available in the form of receipts that may be accessible via a Freedom of Information request.

3.5 Do you think the publication of financial payments should be mandatory?

The majority of participants felt that the publication of financial payments to healthcare professionals should be made mandatory (one person did not agree and another was unsure). One participant said “it would give the public a greater understanding of the pharmaceutical industry’s involvement and give members of the public a point of reference if they had an issue”.

3.6 Who do you think the Register of Interests should apply to (all healthcare professionals or just some)?

The majority of participants agreed that a Register of Interests should apply to all healthcare professionals including those who were self employed and in receipt of payment (salary) from the NHS. Participants in one discussion group highlighted that most local pharmacists were independent of the NHS and they felt that this was a “grey area” which needed to be clarified in terms of whether a Register would apply to them or not. Equally, a participant questioned whether the Register would cover part-time staff and those consultants who had university contracts and so would not necessarily be on the payroll of the NHS (albeit that they would be working for the NHS). Another participant suggested that there needed to be clarity about whether hospital pharmacies which received money from the pharmaceutical industry for dispensing and handling trial medication would be involved.

3.7 What information do you think the Register should contain?

Participants suggested a range of information that should be included in a Register of Interests, namely:

- name and details of who the payment was to
- the amount and date of the payment
- what the payment was for (including whether it was for travel or hospitality)
- details of any gifts or incentives which had been offered (not just monetary payment)
- details of any medical equipment which had been provided
- the length of time engaged in the activity which attracted the payment
- name and details of the pharmaceutical company making the payment
- the name of any clinical drug trial or research associated with the payment and details of the expected outcome (as a result of receiving the payment)
- whether any prescribing practice(s) had changed as a result of the payment, and

- whether the payment was made to an individual, a GP practice, department or hospital.

In terms of practicalities, participants in one discussion group advocated for a Register to have the ability to search for condition specific drugs and for it to be in a "patient friendly" format similar to Scottish Intercollegiate Guidelines Network (SIGN) guidelines.

One person suggested that there should be something in the Register to enable people to see if it had been influenced by "specific visits" from pharmaceutical company representatives before the payment had been made. Another participant suggested that, as well as including the name of the drug itself, the Register should contain details of whether it complied or contradicted national prescribing policy. It was also suggested that the Register should include information about what the healthcare professional intended to spend the money on and in instances where they had attended training and declared that on the Register, details of what the benefits were to the NHS or the individual's personal/professional development.

One discussion group which had recommended an approach whereby payments received by healthcare professionals were partly paid back into the NHS (in response to an earlier question), suggested including details of how much had been re-invested.

Some participants mentioned that the inclusion of any information should always be sensitive to data protection for the individuals themselves. One participant felt that it was sufficient to include the name of the healthcare professional's host NHS Board area or general practice and individual names were not seen as necessary information.

3.8 Who should be responsible for organising and running a Register?

The views gathered in relation to who should be responsible for organising and running a Register of Interests were wide ranging. Throughout the discussions participants clearly recognised potential cost implications and, moreover, how onerous maintaining a Register could become in practice. Some participants suggested that, regardless of who was responsible for organising and maintaining a Register, the pharmaceutical industry should be making a financial contribution in some way.

Suggestions about who could potentially be responsible for running a Register (in no specific order) included:

- NHS Boards for their local areas
- independent (possibly national) body
- General Medical Council or similar healthcare regulator
- Scottish Government
- local authorities

- patient representative organisation (and independent from the NHS)
- Scottish Health Council
- Audit Scotland
- establishment of a separate public body
- healthcare professional body (or combination of more than one)
- Healthcare Improvement Scotland
- NHS National Services Scotland (Information Statistics Division), and
- combination of NHS Board (for local data collection) and independent body (for national data collection and publication).

3.9 Do you think there should be any payments or items of value which should not be included in the Register?

Most participants felt that all payments regardless of their monetary value should be included in a Register although a significant number suggested an exemption of anything below a certain amount. The suggested amounts varied from between £25 to £200 (£100 was the most common) although it was acknowledged in one group that individual perceptions of value could be different, i.e. what was considered low to one person could be viewed as high to another. A number of participants expressed concern that healthcare professionals could potentially choose to declare multiple lower payments if a threshold was introduced thereby allowing them to “conceal larger amounts”.

Whilst some participants felt strongly that nothing should be exempt from a Register, others suggested that low value gifts should not be included (examples included chocolates, flowers, bottles of whisky). Participants in one discussion group suggested that payments should be declared through income tax and standard sanctions imposed if the individual did not comply and for whatever reason.

3.10 Do you think that healthcare professionals who have not received payments should be required to register that too?

Most respondents felt that healthcare professionals who had not received payments should be included in the Register. Reasons given were that it demonstrated openness and honesty and demonstrated a publicly transparent process. One discussion group mentioned the practice of MSPs having to declare a “nil return” and the view was that this should apply equally to healthcare professionals.

Notwithstanding, some participants felt that if a person was not on the Register then it already implied that they had not received any payments. The thinking was that the Register needed to avoid becoming too large or unwieldy thereby making it difficult for the public to search for information.

Others were keen that any “administrative burden” associated with maintaining a Register should be kept low. In one discussion group, participants felt it was a “waste of time and effort to collect (what was seen as) worthless data” if a healthcare professional had not received payments.

3.11 Should there be consequences for healthcare professionals who fail to declare receiving financial payments or the details they recorded are not accurate and where there has been no breach of professional regulations or the law? If so, what should those be?

The majority of participants felt that there should be consequences for healthcare professionals who failed to declare receiving financial payments in the interest of openness and honesty. They also felt that there should be consequences for failing to declare although the suggested “sanctions” varied greatly. Participants also felt there should be clear guidelines and timescales for healthcare professionals to declare payments with consequences if these were not adhered to. Suggested consequences included:

- monetary fines
- “black marks” against the person with five occurrences leading to being “struck off” their professional register
- requirement to repay the money to a charity or NHS funds
- being held to account for an explanation
- tax liability and fine
- criminal proceedings and/or sentence depending on the severity of the non disclosure
- direct referral to the relevant professional body, and
- working time back to the NHS equivalent to the value of the money not declared.

Notwithstanding, participants in some discussion groups did not feel that there should be consequences if not declaring the financial payment did not breach professional regulations or the law. They acknowledged, however, that failure to declare a payment would breach current General Medical Council professional regulations (around honesty in financial dealings) and so there should be a consequence attached to that which should be determined by the professional body and be proportionate to the level of the breach.

3.12 How do you feel about public funds being used to run and maintain the Register?

Most participants were comfortable with public funds being used to run and maintain a Register although they were keen that the costs associated with it should be kept to a minimum. Participants acknowledged that there could be a lot of administration associated with a Register and for that reason some felt that it should not be funded using public money (or at least kept to a minimum). A couple of participants held the view that if the cost of developing a Register was high then consideration should be given to its affordability versus need.

A number of suggestions were received as alternative funding sources. These were:

- contributions from the pharmaceutical industry
- joint funding between the Scottish Government and the pharmaceutical industry
- publicly funded but supplemented with contributions from other bodies
- contributions from healthcare professionals who chose not to declare payments
- income generated through fines levied by the General Medical Council for non compliance
- professional healthcare bodies
- income generated through a "taxation system", and
- through charging to access more detailed information (with basic information being free).

3.13 Would you personally find a Register of Interests useful? If so, how?

Whilst a number of participants said that they would not find a Register useful and so would be unlikely to access it, the majority felt that it would be helpful for the likes of:

- NHS Boards sharing and comparing data and practices
- personal learning and being able to search on specific drugs and medications
- checking to see if a clinician had received a payment for a drug they had prescribed
- looking at local details and practices
- to assist individuals with NHS complaints or claims
- accessing information about clinical trials and research, and
- information for patients about their medications.

3.14 How would you prefer to access (look at) a Register (internet, publication, other)?

Being able to access a Register of Interests via the internet was the preferred approach although participants acknowledged that this would not suit everyone so it needed to be supplemented with the information being available in written format (and other languages). It was also recommended that it be available through local libraries and publicising the existence of it was important.

One participant recommended that a freephone telephone number be available for people to obtain more details. Other suggestions included making a Register available through:

- the Scottish Government's website
- an annual publication
- local authorities and their associated websites, and
- general medical practices.

3.15 Do you think that the introduction of a mandatory introduction of the Register will make a difference to healthcare being provided? If so, how?

In a couple of instances, participants felt that the introduction of a mandatory Register would make no difference to healthcare being provided. However, most felt that it would make some difference such as empowering patients and improving public understanding of what was going on around Scotland. There was some concern that it may be misinterpreted by some with a potential detriment to health (for example if someone refused a correct drug because they thought it was prescribed for the wrong reason). Others felt that for a Register to make a real difference it needed to be promoted and widely advertised, otherwise the general public would not know it existed.

Other participants felt that there were advantages in “professionals being aware that patients could see the medications being prescribed which attracted payment” whereas others were concerned about the negative impact and consequences on research and fitness to practice initiatives. Some participants felt that a Register would help to highlight any bias within the pharmaceutical industry (especially between one company and another).

There were some views that a Register may affect the number of healthcare professionals who accepted payments and this was seen as a positive step that would lead to a more “balanced view” of what they could prescribe. One participant advised that more clarity was needed so as to avoid confusion for healthcare professionals who were registered with a UK or EU regulator.

Generally, most participants felt the introduction of a Register would improve transparency around prescribing and openness about the practice of healthcare professionals receiving payments from the pharmaceutical industry.

3.16 Should a Register of Interests also include payments made by the pharmaceutical industry to voluntary organisations and charities (such as Alzheimer’s Scotland etc)?

The majority of participants felt that they did not have an issue with voluntary organisations and charities receiving payments although they were of the view that the information should be captured in a Register in the interests of openness and transparency.

One participant questioned whether payments received by charities would be declared as a matter of course in their published annual accounts.

Participants in one group felt they did not have enough of an understanding about what the pharmaceutical industry would be giving charities to offer a view about whether it should be included in a Register. There was a suggestion that there might be merit in developing a separate Register of Interests dedicated to voluntary organisations and charities.

APPENDIX

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Register of Interests for NHS Scotland

This information has been provided by the Scottish Government to give some background to help gather feedback from members of the public on a possible register of interests for NHS Scotland.

Some healthcare professionals (for example doctors, consultants, etc) receive payments from the pharmaceutical industry. Figures from the Association of British Pharmaceutical Industry (ABPI) show that payments to healthcare professionals throughout the United Kingdom are estimated to be around £38.5m in 2013. This is made up of £27.7m for things like speaking at meetings, involvement in training, clinical trials, media activity, taking part in market research, etc. £10.8m was also paid for things like sponsorship to attend medical education meetings (covering registration fees, international travel, accommodation and reasonable refreshments and subsistence).

Currently, there is no publicly searchable way for people to see how much is paid to healthcare professionals in Scotland by the pharmaceutical industry. From next year, however, the pharmaceutical industry will publish details of staff who receive payments in the United Kingdom. Healthcare professionals will be able to opt out of having their information published if they wish. The publication, which is being called at the moment a *Register of Interests*, will be available to the general public via the internet.

As well as the new Register, there is legislation which prohibits healthcare professionals from taking bribes. There are also regulations which restricting the promotion of drugs, accepting incentives and receiving hospitality. All healthcare professionals must act within their own professional regulation and codes of best practice. For example, the General Medical Council (which is the professional regulator for doctors) has guidance which states that doctors:

- must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals

- must not allow any interests to affect the way they prescribe, treat, refer or commission services for patients

- if faced with a conflict of interest, must be open about the conflict, declaring the interest formally and 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 you prescribe for, treat or refer patients or commission services for patients.

Discussion questions

a) Were you aware that healthcare professionals can be offered payments from the pharmaceutical industry?

b) What do you think about this or how does it make you feel?

c) How likely would you be to access information which the pharmaceutical industry will publish next year which shows any payments made to healthcare professionals?

d) Do you think current arrangements are sufficient that healthcare professionals can opt out of having details of payments from the pharmaceutical industry being included in the Register (given that professional regulations already exist)?

e) **If no to (d):** do you think that the publication of financial payments should be mandatory (required by law)?

- Who do you think the Register of Interests should apply to (all healthcare professionals or just some)?

- What information do you think the Register should contain?

- Who should be responsible for organising and running a Register of Interests (healthcare professional regulators such as the General Medical Council, NHS organisations, industry, individual healthcare professionals)?

- Do you think there should be any payments or items of value which should not be included in the Register (for example, where these are of low value)?

- Do you think that healthcare professionals who have not received any payments should be required to register that too?

- Should there be any consequences for healthcare professionals who fail to declare receiving financial payments or the details they record are not accurate and where there has been no breach of professional regulations or the law? If so, what should those be?

- How do you feel about public funds being used to run and maintain the Register?

- Would you personally find a Register of Interests useful? If so, how?

- How would you prefer to access (look at) a Register (on the internet, publication, other)?

- Do you think that the introduction of a mandatory Register of Interests would make any difference to health care being provided? If so, how?

- Should a Register of interests for Scotland also include payments made by the pharmaceutical industry to voluntary organisations and charities (such as Alzheimer's Scotland etc)?

16 October 2015

Acknowledgement

The Scottish Health Council would like to thank all participants who shared their views about a Register of Interests for NHSScotland. We also thank them for giving us their time and willingly sharing their feedback. The Scottish Health Council conducted an evaluation of the discussion groups and received feedback. The results of the evaluation are available from the Scottish Health Council on request.

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- بذریعہ ای میل
- چھاپے کے بڑے حروف میں
- آڈیو ٹیپ یا سی ڈی کی شکل میں
- بریل میں ؛ اور
- دیگر زبانوں میں

The Scottish Health Council has a national office in Glasgow and a local office in each NHS Board area. To find details of your nearest local office, visit our website at: www.scottishhealthcouncil.org/contact/local_offices.aspx

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