Opening Statement to the Joint Committee on Health

Scrutiny of the Medical Practitioners (Amendment) Bill 2017

9.15 am on Wednesday 6 December 2017

Good morning Chairman,

My name is Mary Jackson, Principal Officer in Governance and Clinical Indemnity Unit in the Department of Health. I'm joined by my colleague Mr Eugene Lennon, Principal Officer in the Medicines and Controlled Drugs Unit.

I would like to thank the Committee for the opportunity to provide the Department of Health's observations on the Medical Practitioners (Amendment) Bill 2017 as this scrutiny stage of the Bill.

Background

By way of background this Private Members Bill was published by Deputy Billy Kelleher on 28 March 2017. The Bill would require medical practitioners to declare any income or gift received from medical suppliers or pharmaceutical companies, which exceeds €600 in value to the Medical Council in a statutory declaration annually. It was introduced at 2nd stage on 19 October last.

The Minister strongly agrees with the general principles behind this Bill. There should be transparency about transactions between commercial interests and healthcare providers so that the public can be assured that healthcare providers recommend treatment, or administer appropriate care based solely on clinical evidence and experience and in the best interests of their patients and patient safety.

The tabling of this proposed legislation is timely. There have been a number of similar developments across Europe in this important area since 2010, when the Sunshine Act was first introduced in the United States. Under that legislation the pharmaceutical industry must report relationships with doctors and teaching hospitals to the Government-run programmes, Medicaid and Medicare. In France, for example, disclosure under similar type legislation, covers relationships with all health professionals and associations representing them, scientific societies, patients' associations and the press. In the Netherlands a Healthcare

Transparency Register was introduced in 2013 to disclose payments/gifts to health professionals from pharmaceutical companies. This publicly accessible Register was extended in 2016 to cover medical devices also.

Various European reports have compared the laws, regulations and codes across Europe. Common to all is the European Federation of Pharmaceutical Industries and Associations (EFPIA) self-regulatory "Transfers of Value" Code, introduced across Europe in 2015. However, one of the shortcomings of this Code is that healthcare professionals may choose not to allow their individual details be published, which means that there is not full transparency, as only the composite totals of payments to those individuals is then published. Furthermore EFPIA and its member associations represent only part of the pharmaceutical industry.

In Ireland the Irish Pharmaceutical Healthcare Association (IPHA), applies this "Transfers of Value" voluntary Code to its 44 members. In 2016 €30 million was provided to Irish healthcare organisations and healthcare professionals by IPHA. Of this sum, however, just over €7 million was to healthcare professionals while €10 million was to healthcare organisations and the balance of €12.6 million was to clinical trials and R&D. In addition, because of the voluntary nature of the Code, we understand that only around half of healthcare professionals in Ireland permit their information to be published.

So we have problems with transparency – and other countries have experienced the same problems, with some health professionals choosing not to register "Transfers of Value". To address this some countries have introduced anti-corruption laws, such as in the UK, Germany and Italy, while other have adopted so called "Sunshine Laws" or regulations similar to those enacted in the US, for example the Netherlands, Belgium, Denmark and Portugal.

General Comments on the Bill

The current proposal is straightforward, requiring doctors to make a declaration to the Medical Council every year on funding and supports received from commercial interests. The definitions and terminology in the Bill require amendment in order that it is consistent with existing Irish and European pharmaceutical and medical device legislation.

We also believe the scope of the Bill may be too narrow to achieve the overall objective of transparency as it limits transparency to doctors only, while we know that other health professionals and healthcare organisations are also involved.

Also, if we are to consider broadening the scope, we should also look at where the register should be located and maintained.

Another point is whether the register should be populated by the recipients of "Transfers of Value" or by those providing "Transfers of Value".

We question whether it would not be better to set up a register in an alternate location to the Medical Council, so that there would be the potential to cover "Transfers of Value" to other health professionals and healthcare organisations.

Specific comments on the Bill

In **Section 1** many of the definitions need to be more specific and we hope the following observations are helpful.

Defining "Declarable Income" as "money or other form of payment" is too narrow. A transfer of value can be monetary, such as a fee for service or loan for the purchase of a device, but it can also be a non-monetary benefit such as a flight or a registration fee or hotel accommodation. A broader definition is required, and perhaps "transfer of value", with a specific definition of what this entails may be better. Also, the reference to the term "gift" needs to be checked to ensure that it does not conflict with Advertising Regulations, which allow for free samples to be provided in certain circumstances.

The terms "Medical Equipment" and "Supplier" are not recognised terms under EU and Irish legislation. The term Medical Device, which is used in existing legislation, includes medical equipment. In relation to the term "Supplier" EU legislation on medical devices defines a manufacturer as a "natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished and markets that device under its name or trade mark". EU legislation also defines a "distributor" and "authorised representative", but there is no definition of supplier. "Transfers of Value" may be made by distributors and authorised representatives also so it is not enough to refer to manufacturers only.

There is no definition of pharmaceutical company in EU medicines legislation. EU legislation refers to marketing authorisation, which means approval to market a medicine, and there is a lengthy definition of what a marketing authorisation is. Companies are known as "marketing authorisation holders", where the company or other legal entity is granted approval to market a medicine in one, several or all EU Member States.

We suggest that a value of above €600 may be too high. This figure is set at a total of €500 per annum in the Netherlands, comparable legislation in other jurisdictions set a value at a much lower rate e.g. France transaction above €10 are covered. As worded the legislation does not pick up on multiple payments to a medical practitioner of less than €600, which together would breach the threshold. For example, a doctor could receive two or more payments of €400 each.

The Bill references the Statutory Declarations Act 1938 as the means by which doctors would declare the gifts and support received and can see potential problems. A statutory involves a person making a statutory declaration in front of one of the following – a notary, commissioner for oaths or a peace commissioner.

Scrutiny of the Bill should examine whether a more workable system is to oblige the payer rather than the recipient to simply register all "Transfers of Value".

Section 2 of the Bill proposes amending section 8 of the Medical Practitioners Act to mandate that doctors would make an annual declaration to the Medical Council of any declarable income or gifts which would be placed on a publicly accessible register. Failure to do so would result in a complaint being made to the Council.

New function for the Medical Council

Placing the onus on the Medical Council to collect annual declarations from doctors of their supports/gifts from commercial interests and placing this information on a publicly accessible register would create a new function for the Council. Currently the Council does not deal with pharmaceutical or medical device legislation so if it is to maintain and respond appropriately to declarations received, it will have to build competence in this area. It has a challenging role in regulating around 21,800 medical practitioners and in promoting good professional practice in the interest of public safety. It also deals with complaints, which may

be escalated to its Fitness to Practice Committee, which may, in turn, result in a medical practitioner being removed from the register.

The Council must also, since the commencement of the Medical Practitioners (Amendment) Act 2017, on 6 November last, check that all medical practitioners on applying to be placed on the Council's register and on annual renewal of registration, have minimum levels of clinical indemnity cover.

Options for consideration by the Committee

The proposed Bill puts the burden on doctors to report. Approaches in other jurisdictions require pharma and medical device companies to report on their affiliations and financial relationships. Recognising that the objective of this Bill can be met by different approaches we believe more time should be taken to consider these options, fully examining the benefits and drawbacks of each in order to adopt legislation, which is robust, fair and which achieves the objective of transparency for the public. The options depend on whether it should be the payer of "Transfers of Value" or the receivers of "Transfers of Value" who populate the register.

The five potential options we have identifies are:

Option one would be to proceed with the current Bill, which covers payments and supports received by doctors. This requires amendment of the definitions and confirmation that a clause is not required regarding data protection, given that this is the single biggest obstacle to full transparency in the current "Transfers of Value" self-regulatory code.

Option two would still only apply to doctors, but it would establish a register elsewhere and have commercial interests populate the information on the register rather than individual doctors.

Option 3 would be to extend the scope of the Bill to cover all healthcare professionals, including nurses, pharmacists, dentists and allied health professionals.

Option 4 would be to extend the scope of Bill to cover all healthcare professionals and healthcare organisations in the public system. Commercial interests would populate the register with all "Transfers of Value" to the public health service.

Finally, option 5 would extend the scope of the Bill to cover all healthcare professionals and healthcare providers in both the public and private healthcare systems.

Maintenance of the Register

A major consideration is where the register of "Transfers of Value" should be located and maintained. The following questions arise:

- Should the register relate to doctors only and be the responsibility of the Medical Council as per the current legislation?
- Should it be established where all health professionals can be registered, as it would not make sense that each regulator would set up a separate register?
- Should there be a national register which includes "Transfers of Value" to healthcare organisations as well as healthcare professionals?
- Should HIQA, which oversees standards within the healthcare system hold the register or should it be the Health Products Regulatory Authority, which already has responsibility for regulation of pharmaceuticals and medical devices?
- Should it be located in the HSE or the Department of Health, or indeed should it be an independent entity, external to all of those I have listed?

The cost of setting up and maintaining the register could be significant, so a costing model is needed to assess the respective costs of the options proposed and the optimum solution.

The legislation may be too ambitious in including medical devices. It may be prudent to commence with pharmaceuticals only, test the workability of the system and then extend as soon as possible thereafter to medical devices, because of the different regulatory regime applying to both areas. This stepwise approach worked well in the Netherlands.

Conclusion

I hope the Department's comments are helpful and constructive. The Bill gives the opportunity to address a gap in legislation which many other European States are also in the process of addressing. With robust legislative scrutiny and consultation the resultant legislation will be based on the best models currently in place in other jurisdictions and what

would work best for Ireland. The Committee may wish to consider inviting other witnesses to advise on the best fit for this legislation, as the obstacles to effective regulation of this area can be overcome through consultation and collaboration of relevant parties, who wish to see full transparency in the interest of best patient care.

I would like to reaffirm that the Minister and Department strongly agree with the principles underpinning this Bill. We are committed to working with Deputy Kelleher and his legislative advisers on this important proposal.

Thank you Chair and we will be happy to answer any follow-up questions.