Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013: Submission by Dr Ken Harvey, School of Public Health, La Trobe University

Summary

Senator Di Natale's bill provides an important opportunity to debate various models of ensuring ethical relationships between health professionals and therapeutic goods companies. There is world-wide concern that inducements to health professionals by the therapeutic goods industry can lead to uncritical uptake of newer, expensive and less-well evaluated products and underutilisation of more cost-effective drugs and medical devices. The cost and safety implications of these distortions to our health system are significant.

Several counties have already addressed these concerns. The Dutch have established a central register (managed by an independent Foundation) to record the financial relationships between healthcare professionals, healthcare institutions and the pharmaceutical industry. This is now operational. All financial relationship exceeding €500 in total for 2012 were entered in the register at the start of 2013; this will be open to the public on April 25, 2013.

The U.S. Physicians Sunshine Payment Act became operational earlier this year. It requires pharmaceutical and device companies to report to the Centers for Medicare and Medicaid Services all payments made to individual doctors and teaching hospitals that total more than US$100 per year. Companies must begin to collect the information by 1 August, 2013 and report it to the Centers for Medicare and Medicaid Services by 31 March 2014. The information will be posted by the Centers to a public website on 30 September 2014.

The Australian Government prefers self-regulation. Accordingly, Medicines Australia has set up a Transparency Working Group charged with incorporating similar disclose provisions to the U.S. Sunshine Act into their self-regulatory Code. The group is on-track to report back by June 2013. It has developed principles applicable to all therapeutic goods companies and all health professions, not just doctors. These include providing access to information in a single, public repository, enabling the information to be audited and validated by healthcare professionals and companies, and supported by an educational process to assist all parties to interpret the information in context. It is envisaged that member companies could commence recording payments made to individual health care professionals from Jan 1, 2015 with public reporting starting in 2016.

However, although Medicines Australia might take up the Group's recommendations there is no compulsion on the other eight therapeutic goods industry associations to do so. Most importantly, non-members of industry associations escape self-regulatory Codes yet the latter are often the worst offenders.

The Australian Senate bill (like the U.S. Sunshine Act) has the advantage of compulsion on those to whom it applies. However, unlike the Sunshine Act, the Senate bill only applies to pharmaceutical companies and doctors. It also requires details of payments to be reported on a multitude of individual company web sites. This would make it very difficult to find out how much money a doctor was receiving and from whom. Regardless, the bill has the virtue of stimulating debate.

It's my view that transparency should apply to the relationship of all therapeutic goods companies with all health professionals. Medical device companies and other health professional such as pharmacists have also been implicated in behaviour that needs to be disclosed. Clearly self-regulation cannot be effective unless the government introduces legislation to make compliance with self-regulatory Codes of conduct a condition of obtaining marketing approval for therapeutic goods. There is also a need to ensure that self-regulatory Codes have similar provisions to ensure a

level playing field. In addition, providing access to information about transfers of value from industry to health professionals in a single, public repository will require government &/or Australian Health Practitioner Regulation Agency support. In short, a co-regulatory approach is required. I suggest the Dutch model should be considered; an independent Foundation involving all stakeholders, underpinned by legislation. This Foundation would be tasked with harmonising nine disparate industry Codes into one, providing an educative and administrative structure for Code revision, dealing with complaints and overseeing the transparency register.

The background to the Senate Bill

This draft bill (1) aims to ensure that pharmaceutical companies do not have undue influence on the prescribing habits of doctors by providing them with non-transparent inducements. These include funding the travel and registration of practitioners to attend conferences and payment for providing consultancies, company sponsored lectures and sitting on advisory boards. All these activities can encourage conscious or unconscious reciprocity by the recipients which can manifest itself in uncritical uptake of newer, expensive and less-well evaluated products and underutilisation of more cost-effective drugs and medical devices. In addition, these largely concealed relationships have been shown to distort published medical evidence by influencing how clinical studies are designed and conducted, which studies are published and which are not, which results and side-effects in the published studies are emphasised and which are not. This can have the overall result of "stacking the deck" in favour of new and expensive treatments and has been shown to lead "key opinion leader" doctors to advocate such treatments despite the lack of robust evidence about their safety. These influences can cause rapid take-up of new treatments with disastrous consequences when adverse effects (followed by product withdrawal) become apparent on much larger scale than would have occurred by more prudent use. The cost and safety implications of these distortions for our health system, which are under ever-increasing pressure to continue to meet the aspirations and expectations of an ageing population, are significant. (2-32)

What other countries have done.

In 2009, the then acting Dutch Minister of Health Ab Klink initiated the establishment of a transparent system to disclose the financial relationships between healthcare professionals, healthcare institutions and the pharmaceutical industry. He was inspired by American initiatives that led to the U.S. Sunshine Act. At that time there was a preference for self-regulation by the parties involved. The Dutch Transparency Register was finally set up by the Foundation for the Code for Pharmaceutical Advertising (CGR), in collaboration with the Ministry of Health, Welfare and Sport, the Royal Dutch Medical Association (KNMG), the Association for Innovative Medicines in the Netherlands (Nefarma) and the Association for the Generic Drugs Industry in the Netherlands (BOGIN). Management was entrusted to a new independent foundation. While the establishment of the register was delayed by legal complications it is now operational. All financial relationship exceeding €500 in total for 2012 were entered in the register at the start of 2013; this will be open to the public on April 25, 2013. (33-34).

On February 1, 2013 the U.S. Centers for Medicare and Medicaid issued the final rules related to the Physician Payment Sunshine Act (Section 6002 of the Affordable Care Act) nearly three years after the law that required its creation was signed in March 2010. (35) The bill was co-authored by Senator Chuck Grassley with the then Senator Herb Kohl after Grassley's investigative and oversight work exposed numerous questionable financial relationships between physicians and the

therapeutic goods industry. Ultimately, Congress passed the Sunshine Act in response to growing concerns over industry payments to physicians and their potential negative effects on patient care and efforts to restrain healthcare costs, as evidenced by a growing body of research.

The Physicians Sunshine Payment Act calls for disclosing "transfers of value" by drug and device makers to spotlight possible conflicts of interest that may compromise education, research, and clinical decision making to the detriment of patient care. Specifically, the regulations require pharmaceutical and device companies to report to the Centers for Medicare and Medicaid Services all payments made to doctors and teaching hospitals, who will be named. The payments include speaker and consulting fees, research grants, gifts, food and entertainment, royalties and licensing payments, investments, and other things of value. Single payments less than US $10 will not have to be reported, unless such payments total $100 or more cumulatively for the year. Companies must begin to collect the information by 1 August, 2013 and report it to the Centers for Medicare and Medicaid Services by 31 March 2014. In April 2014, physicians will have 45 days to review and an additional 15 days to dispute the report. The data will be will be posted by the Centers to a public website on 30 September 2014.

What is happening in Australia?

The Australian Government has expressed a preference for self-regulation. (36) While this has the virtue that government does not pay the cost, the cost to industry is passed on to consumers regardless. The following problems with self-regulation are well documented:

- There are currently nine therapeutic goods industry self-regulatory Codes: Medicines Australia, GMIA, ASMI, CHC, MTAA, AusBioTech, IVD Australia, ADA, ACCORD. The content, monitoring provisions, complaint procedures and transparency of their Codes vary substantially across industry sectors (“not a level playing field”);
- Suggestions to improve Codes put forward by consumers and health practitioners are often not taken up because industry is the sole arbitrator of what goes into a revised Code;
- Codes also lag behind the views of more progressive companies because of the need for revisions to be approved by a majority of member companies;
- Numerous sector based industry Codes make it difficult to know where to send complaints;
- Most importantly, Codes don't apply to non-members; a major problem in some sectors of the therapeutic goods industry.

Recognising these problems, in 2010 the government released a Position Paper on the Promotion of Therapeutic Goods. It called for public submissions and set a broad-based Working Group on Promotion of Therapeutic Products which reported in March 2011. (37) A number of submissions from consumer and health professional groups recommended that nine industry Codes be replaced by one Code, one efficient complaint (and appeal) system and one set of effective sanctions applicable to all therapeutic claims and promotional activities regardless of the industry sector, media or target. This was to be administered by an independent Therapeutic Goods Promotion Agency (TGPA) set up under the Therapeutic Goods Act, comprised of all the stakeholders, with product registration, listing or inclusion on the Australian Register of Therapeutic Goods (ARTG) dependent upon compliance. These suggestions were rejected by industry members of the Working Party who preferred to keep their individual Codes.

In the interests of achieving a level playing field, the Working Group recommended that each Code should contain a high level statement of principle, address specific operational areas such as industry-sponsored educational events, conduct of representatives, hospitality and entertainment and specify governance areas to ensure effective implementation. The latter included education on the Code's operation, monitoring of compliance with the Code, enforcement of the Code in response to a complaint or a breach, and sanctions to support enforcement at a level that deters non-compliance.

The Working Group addressed the need for adherence to industry codes by non-members by recommending that all applicants nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing/inclusion of a product on the ARTG. The working group noted the Government's intention was for the 'sign on' process to be voluntary in the first instance but was concerned that voluntary nomination may not be effective to achieve the Government's objectives and that code nomination should be made a mandatory part of product registration. This recommendation was rejected by the government.

In the 2012-13 budget the government allocated $1.4 million over four years to support implementation of the Working Group's recommendations 4, 9-13 and 15-17, which include: making information on industry codes publicly available, providing access to shared systems for reporting complaints, annually evaluating the effectiveness of voluntary registration to a code of conduct, encouraging health professionals to better align their codes with those of industry, and inclusion of education on relationships with therapeutic industry in the training of healthcare professional students. In early 2013, a Codes of Conduct Advisory Group (chaired by Prof Lloyd Samson) was set up by the government to oversee the implementation of the above recommendations. (38) Currently, I can find no information about its activities.

There is some information in the public domain concerning the effectiveness of voluntary registration to industry Codes of conduct. Ms Kate Lynch, the CEO of the Generics Medicines Industry Association of Australia (GMiA) has noted (personal communication) that GMiA already provides an option for non-members to voluntarily sign up to the GMiA Code without joining the association. Despite pro-actively advocating this facility no company has taken up the option. Non-members have stated that they already adhere to the Code and see no need to make any formal declaration. In 2012, Ranbaxy Australia offered pharmacists A$14,648 of free Trovas® (generic atorvastatin) stock and a 90% discount for subsequent orders. This offer appeared to breach the Code of Conduct of both GMiA and Medicines Australia. A complaint was submitted to GMiA but Ranbaxy declined to participate in an investigation of this complaint as it was not a member of any self-regulatory industry association. (39)

Meanwhile, the revision of the 17th edition of Medicines Australia Code of Conduct has also illustrated problems with self-regulation. (40) Medicines Australia now require member companies to submit aggregate amounts of all payments made to healthcare professionals for advisory boards and consultancy arrangements, attendance and speaking at medical conferences and educational events, and sponsorships for consumer organisations including the value of non-monetary support. This falls far short of the full disclosure of payments made to individual healthcare professionals which many consumer and health professional groups argued for, both in the 16th Edition (2009) Code revision, and again in the 17th Edition (2012) Code revision. (41,42)

These concerns were put to the Australian Competition and Consumer Commission (ACCC) in submissions and public hearings about their authorisation of the 17th Edition of Medicines Australia Code. The ACCC determination said: (43)

> "The ACCC notes that Medicines Australia convened a transparency working group following submissions concerning edition 17 of the Code, inviting participation from consumer, healthcare professional and pharmaceutical industry groups, which will look into ways that payments at an individual level can be disclosed appropriately. Medicines Australia advises that this working group will report by December 2013. While the ACCC is encouraged by this, it is concerned that, if the Code is not amended in a timely manner to reflect current community expectations, the public benefits resulting from the Code could be undermined.
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> In order to ensure that the Code continues to meet community expectations the ACCC grants authorisation for two years rather than the five years sought by Medicines Australia. The ACCC expects Medicines Australia to complete the work it has already commenced on increasing the level of transparency provided by the Code and to incorporate new provisions into the next edition of the Code that will facilitate greater disclosure around sponsorship and fees paid to individual doctors. The issue of transparency and the steps taken to implement it will be relevant to the ACCC's assessment of any future application for authorisation of a new edition of the Code. The ACCC is of the view that remaining issues associated with a framework for individual disclosure can be substantially addressed in the next 12 to 18 months, with implementation of an amended Code by early 2015.

Medicines Australia Transparency Working Group (44) is on-track to report back to Medicines Australia by June 2013. Following consultation with members and the public this could allow the adoption by members and authorisation by the ACCC of transparency provisions in a revised Code by late 2014. It is envisaged that member companies would commence recording details of payments made to individual health care professionals from Jan 1, 2015 with public reporting on Medicines Australia web site to start in 2016 (compared to 2014 in the U.S.).

The Transparency Working Group has drafted principles that it believes are generally applicable to reporting transfers of value between all therapeutic industry groups and all health professionals. These include:

- Reporting the monetary transactions and transfers of value by individual, identified healthcare professional and company in a form that is readily accessible and meaningful to the public;
- Providing access to the information in a single, public repository, that is readily searchable;
- Enabling the information to be audited and validated by healthcare professionals and companies; and
- Supported by an educational process to assist all parties to interpret the information in context.

However, while Medicines Australia members may choose to implement these provisions in the next revision of their Code there is no guarantee that they will be taken up by other therapeutic goods industry associations let alone by non-members. Indeed, therapeutic goods industry associations Codes do not need to be authorised by the ACCC; many are not and thus escape the ACCC persuasive powers that have been applied to Medicines Australia. In addition, providing access to the information in a single, public repository, that is readily searchable becomes more problematic if

other industry associations are involved. One suggestion to resolve this problem is that this database should be administered and housed by the Australian Health Practitioner Regulation Agency (AHPRA). (45)

Pros and cons of different models

The above discussion highlights some important differences between the Senate bill and the alternative self-regulatory process.

The Senate bill (like the U.S. Sunshine Act) has the advantage of compulsion on those to whom it applies. It is also broader than the Sunshine Act in that it prohibits a pharmaceutical company to arrange or sponsor a conference or educational seminar for Australian doctors that takes place overseas. However, unlike the Sunshine Act, the Senate bill only applies to pharmaceutical companies and doctors. It also suggests that details of payments should go on a multitude of individual company web sites. This would make it very difficult to find out how much money a doctor was receiving and from whom; in my view this information must be collated on one web site to be useful. I support the suggestion that AHPRA should house this database. I also believe the provisions should apply to all therapeutic goods companies and all health professionals. Medical device companies (22, 46) and other health professional such as pharmacists (47) have also been implicated in behaviour that needs to be disclosed.

Medicines Australia Transparency Working Group proposals have the virtue that they are designed to apply to all therapeutic goods companies and all health professions, not just doctors. They also advocate that information about health professionals earnings from industry should be consolidated on one web site, not a multitude of company web sites. However, they have the fundamental disadvantage that there is no compulsion on other industry associations to take up these proposals and, most importantly, non-members of industry associations escape (the latter are often the worst offenders). In addition, the long lead time proposed for reporting; 2016 (Medicines Australia) compared to 2014 (U.S.) is another concern.

Conclusion

Senator Di Natale's bill provides an opportunity for the Senate and others to debate the merits of various models of ensuring ethical relationships between health professionals and therapeutic goods companies. Clearly self-regulation cannot be effective unless the government introduces legislation to make compliance with self-regulatory Codes of conduct a condition of obtaining TGA marketing approval for therapeutic goods. There is also a need to ensure that self-regulatory Codes have similar provisions to ensure a level playing field. In addition, providing access to information about transfers of value from industry to health professionals in a single, readily searchable, public repository will require government &/or AHPRA support. It can be argued that the Australian public health is being let down by the government's over-emphasis on the virtues of self-regulation and increased public interest regulation would be of benefit. (46) My own view is that a co-regulatory approach is to be preferred and I suggest the Dutch model should be considered; an independent Foundation involving all stakeholders, underpinned by legislation. (33,34) This Foundation would be tasked with harmonising nine disparate industry Codes into one, providing an educative and administrative structure for Code revision, dealing with complaints and overseeing the transparency register.

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Disclosure

Dr Harvey represents CHOICE (the Australian Consumers' Association) on Medicines Australia Transparency Working Group and was also a member of the government's Working Group on Promotion of Therapeutic Products.

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