

Policy Document

Pharmaceutical Financing and Relationship with Industry (2022)



Position Statement

The Australian Medical Students' Association (AMSA) believes that:

1. As future prescribers, medical students have a responsibility to ensure prescribing for the best patient outcomes is in line with available evidence;
2. In light of the evidence of influence upon prescribing, AMSA should not receive sponsorship or undergo partnerships with pharmaceutical companies; and
3. AMSA believes that medical students should consider the ethical implications of sponsorships with pharmaceutical and medical device industries.

Policy Points

AMSA calls upon:

1. The AMSA Executive and its subcommittees, including but not limited to events and sponsorship teams, to:
 - a. Be open and transparent with members and medical students about all sponsorship received;
 - b. Not accept sponsorship, or enter into partnership arrangements with, pharmaceutical companies;
 - c. Avoid sponsorship and partnership arrangements with medical device companies, where there is a reasonable basis to believe that there could be an association between the sponsorship or agreement and the medical devices produced by that company;
 - i. In the first instance, the Executive should interpret the background to this policy in determining if a company falls into this classification, with regard to the products produced, their listing with relevant bodies and use in Australian prescribing.
 - ii. Where it is unclear if a company falls under the definition of pharmaceutical or medical device company, the Executive should refer the matter to the members for consideration.
 - d. Maintain awareness about measures taken by other medical schools, student organisations or other professional bodies, both domestically and internationally, which may be relevant for Australian medical students, including but not limited to:
 - i. Measures in raising awareness about conflicts of interests arising from interactions with pharmaceutical industries and medical device companies.
 - ii. Policy and measures addressing and preventing potential conflicts of interest.

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- iii. Evidence of this awareness through AMSA publications and/or the introduction of initiatives to enhance awareness of industry influence for its members.
 - e. Respect, honour and uphold the right of AMSA members to:
 - i. Request further information about the nature and extent of any sponsorship or partnership agreements;
 - ii. Set additional standards for sponsorships or partnerships where necessary to support the language and principles outlined in this policy.
 - f. Consider implementing a national initiative to reduce conflicts of interest across Australian medical schools similar to the American Medical Student Association's "PharmFree" scorecard campaign.
- 2. Medical student societies to:
 - a. Take all reasonable steps to cease any pre-existing sponsorship or partnership arrangements with pharmaceutical companies in a timely manner;
 - b. Not accept sponsorship, or enter into partnership arrangements with, pharmaceutical companies;
 - c. Avoid sponsorship or partnership arrangements with medical device companies, where there is a reasonable basis to believe that there could be an association between the sponsorship or agreement and the products produced by that company;
 - d. Prioritise measures that raise awareness of, and address, potential conflicts of interest arising between medical students or professionals and pharmaceutical or medical device companies, and consider whether they may be applicable to medical students in Australia
 - e. Advocate to their respective medical schools regarding the importance of educating medical students about the evidence of the potential negative effects of interactions and the risks of conflict of interest associated with pharmaceutical and medical device companies.
- 3. Australian medical schools to:
 - a. Ensure that medical students receive comprehensive education regarding conflicts of interest including:
 - i. Quality, up-to-date, unbiased and evidence-based teaching on medical devices, pharmaceuticals and prescribing;
 - ii. Evidence-based teaching surrounding pharmaceutical and medical device marketing and its impact on prescribing;
 - iii. Skill teaching regarding critical appraisal and sourcing of independent evidence;
 - iv. An overview of drug development and approval;
 - v. Education regarding the ethical implications of interactions between health professionals and pharmaceutical and device industries.
 - b. Take all reasonable steps to raise awareness among medical students regarding the evidence of the potential conflicts of interest which can arise from interactions with pharmaceutical and medical device companies and advice for managing such conflicts and raising awareness about options for locating independent medical information;
 - c. Mandate full disclosure of conflicts of interest by all academic staff members, including at conference presentations, in

- medical journal articles, in lectures, and other educational activities with students;
- d. Ban formal education given by pharmaceutical and medical device companies at medical schools;
 - e. Ensure students are not penalised for non-attendance at any educational or other university organised sessions provided by industry;
 - f. Refuse to accept sponsorship or donations from industry that is not for the purpose of research;
 - g. Declare all funding from industry annually.
4. Australian medical students and medical professionals to:
- a. Carefully consider decisions about event attendance, scholarship acceptance, social media sponsorship, and involvement in industry-sponsored research;
 - b. Exercise their right to non-attendance of industry-sponsored events, if desired;
 - c. Be informed of and comply with necessary legislative requirements around sponsorships including in research and social media.
5. The Australian Government to:
- a. Further restrict the distribution of medication samples to doctors;
 - b. Fine companies or researchers who fail to submit for publication results of a clinical trial that enrolls patients in Australia in a timely manner, in the absence of exceptional circumstances;
 - c. Restrict pharmaceutical and device company education in hospitals and private practices to instructional rather than promotional content;
 - d. Mandate full disclosure of expenditure at educational events by pharmaceutical and medical device companies, including gifts, cost of transporting speakers, speaker fees, food, beverages, residential costs and other associated expenditure;
 - e. Develop legislation to address the issues of potential conflict of interest associated with the relationships between the pharmaceutical industry and health professionals, and with the wider community;
 - f. Mandate that pharmaceutical and medical device companies fully disclose, in a timely manner, any meals, gifts or other incentives they offer to hospitals, medical practices or individual clinicians;
 - i. Disclosure should include comprehensive reporting of any specific drug or product being promoted to allow the payments to be linked to them,
 - ii. Reports of payments should be available to the public permanently.
 - g. Mandate that hospitals, medical practices fully disclose any payments, transfers of value and other incentives offered by manufacturers of drugs and medical devices as well as the companies involved;
 - i. Ensure ongoing, permanent public access to this data.
 - h. Continue to ban direct-to-consumer advertising of prescription medication and investigate legislative or regulatory actions to prevent hidden forms of such advertising through social media;
 - i. Restrict pharmaceutical industry presence on regulatory bodies, to encourage regulatory bodies to become independent of industry.

6. Specialist medical colleges and representative groups for medical professionals, including the Australian Medical Association (AMA), to:
 - a. Ensure all relationships with industry are ethical, compatible with best practice and not biased by conflict of interest;
 - b. Not accept, and encourage their members not to accept gifts, sponsorship, compensation for services and research funding from industry;
 - c. Make publicly available records of all donations, sponsorships, remunerations and gifts from industry to the representative groups;
 - d. Minimise prescription bias to the best of their ability in line with recent evidence;
 - e. Encourage their members to seek education on pharmaceuticals and medical technologies from unbiased, peer-reviewed publications rather than company representatives;
 - f. Advocate for a structured education program for relationship with industry to be implemented in medical schools;
 - g. Ensure that all clinical treatment guidelines sponsored by professional associations are not unduly influenced by conflict of interest.

Background

What is pharmaceutical industry financing and why is it important?

Pharmaceutical industry financing refers to efforts made by the medical industry to influence doctors' and medical students' prescription decisions in favour of the company in question. In Australia, the medical industry includes the pharmaceutical industry, medical device and technology industry, other healthcare product suppliers, healthcare facilities, and medical services providers [1]. Medical devices and technology include any devices used for the diagnosis or management of patients. Pharmaceuticals include all products listed as 'medicines' under the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods [2]. Sponsorship is commonly pursued through cash payments, in-kind gifts, and free samples, in addition to lesser-observed means involving product sale royalties, employment opportunities, and funding doctors' continued medical education [3]. In Australia and abroad, pharmaceutical industry financing has been widely demonstrated to succeed in realising its goals: receipt of sponsorship is closely associated with increased rates of prescription [1, 2].

The pharmaceutical industry plays an integral role in the development, production, and distribution of medicines. They improve the market uptake of their products and subsequent revenue by investing in pharmaceutical sponsorship assisting in offsetting the considerable costs associated with product research and development. Between May 2016 and April 2017, payments made from the pharmaceutical industry to individual healthcare practitioners exceeded \$23 million, with the average size of an individual payment eclipsing \$1600 [4,6]. According to the World Health Organisation, herein lies "an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of

providers and the public to select and use drugs in the most rational way" [5]. As defined by the Medical Board of Australia, "conflict of interest in medical practice arises when a doctor, entrusted with acting in the interests of a patient, also has financial, professional or personal interests, or relationships with third parties, which may affect their care of the patient" [8].

Altered prescribing practices among health practitioners on account of pharmaceutical sponsorship commonly compromises patient care by giving rise to suboptimal clinical outcomes and incurring unnecessarily high costs upon patients [9-15]. In 2010, a systematic review found that where a significant association between a health practitioner and a pharmaceutical company was discernible, it resulted in increased rates of prescribing, prescribing that was less aligned to prescribing guidelines, or increased prescribing of more expensive, branded drugs even when such prescribing was not supported by scientific evidence [9]. Despite this trend, literature suggests that many doctors consider themselves immune from the influence of pharmaceutical sponsorship, even though many believe large proportions of their colleagues would not be immune [9, 10, 12].

There is evidence that similar attitudes are held by medical students. A systematic review indicates that medical students exposed to direct-to-clinician advertising during their studies may develop a more positive attitude towards the product or service advertised, although many students believe themselves to be immune to bias [11]. This phenomenon has been echoed in more recent studies based abroad [12, 16, 17]. Students who received small promotional items have also been shown to develop implicitly positive attitudes towards the relevant pharmaceutical company [18]. Importantly, the same study found more sceptical attitudes towards pharmaceutical companies among senior students who had attended a medical school with more restrictive policies regarding interactions with pharmaceutical companies. Among medical students, higher levels of exposure to pharmaceutical branding were also correlated with inferior knowledge of evidence-based prescribing principles and an increased likelihood of selecting brand-name pharmaceuticals [19]. However, restrictions on student and resident interactions with the pharmaceutical industry, and education about ethical issues, have been associated with critical attitudes towards industry and higher quality prescribing [20, 21].

Despite the relationship between promotional items and prescribing rates, medical students are influenced by pharmaceutical companies and open to pharmaceutical sponsorship [22-25]. A 2014 cross-sectional study found 81% of surveyed medical students had a high level of acceptability for pharmaceutical sponsorship, and over one-third of medical students were open to receiving gifts from pharmaceutical companies [22]. Based on a national survey with participants from 40 of the 80 medical schools in Japan, more than 98% of medical students had previously accepted some form of gift from a pharmaceutical company [23]. This is supported in another review article which

suggests the majority of medical students surveyed had a prior established exposure to pharmaceutical promotion [24]. Some medical schools have introduced policies to limit students receiving these gifts in a bid to reduce their future prescribing rate of the newly marketed drug. Following the introduction of the “PharmFree” scorecard initiative by the American Medical Student Association, which grades medical schools on the basis of their policy regulating interactions between students and faculty with the pharmaceutical and medical device industry, the number of medical schools in the US with effective conflict of interest policies has grown exponentially [25]. However, no such policies yet exist in Australian medical schools. Although there is international evidence for the influence of pharmaceutical companies on future medical professionals, more research within Australia is necessary for the development of an evidence-based approach to the issue in a domestic context.

Restrictions around pharmaceutical sponsorship in Australia

In Australia, marketing by the pharmaceutical industry is heavily restricted. Direct advertising of pharmaceuticals to consumers is prohibited by the *Therapeutic Goods Act 1989*, although the Act does not prohibit the advertising of medical devices [26]. Advertising to healthcare professionals is permitted; however, per the *Competition and Consumer Act 2010*, it must only involve the promotion of indications for which the medicine is registered [27]. All TGA registered medications must ensure their marketing methods adhere to the *Medicines Australia code of conduct*. [8]. This *code of conduct* restricts how pharmaceutical companies can advertise medicines. For example, the *code* expressly prohibits the provision of gifts, such as stationary, to healthcare professionals. However, funding to speak at conferences, commensurate with the work done, and meals may be provided to healthcare professionals under the *code* [8].

Pharmaceutical companies may also sponsor educational events, including those for medical students. The code states that the purpose of this funding must be to enhance medical knowledge and improve the quality use of medicines. Sample medications may be provided by pharmaceutical companies, for reasons including “gaining familiarisation with the product” and “the use of alternative treatments prior to writing a prescription”. Providing gifts or money to healthcare professionals with the stated expectation that they will prescribe a drug is not permitted under states’ bribery laws [28].

Under the *Medicines Australia Code of Conduct*, pharmaceutical companies must disclose any transfers of value made to healthcare professionals, except for meals. This includes, but is not limited to, hospitality to attend conferences and speakers’ fees.

The industry is also capable of self-regulation. Since 2015, all member companies were required to collect information about Australian healthcare workers who receive any sponsorship; workers could opt-out of having this data publicly reported. In 2016, the reporting of payments was made compulsory.

Since 2019, this information was made available as a consolidated database called Disclosure Australia, developed in consultation with the Australian Competition and Consumer Commission (ACCC) to ensure the information is displayed in a consistent and easily searchable format for three years after the payment is reported [8]. However, there are limitations to relying on industry self-regulation, as some major pharmaceutical companies operating in Australia are not trade association members, and so do not have to adhere to these regulations.

The medical field itself has produced awareness campaigns into the negative effects of relationships between doctors and the pharmaceutical industry. In Australia, the 'No Advertising Please' campaign of 2014 asked Australian GPs to sign a pledge not to see representatives from the industry for a year [30]. Medical students have also been involved with these efforts, with initiatives from the American Medical Students' Association such as the PharmFree Scorecard which rates medical schools on their conflict of interest policies [12], and in Australia the student organisation Pharma Phacts [30]. However, it is unclear what sort of impact 'No Advertising Please' and 'Pharma Phacts' had among the broader community of health care professionals in Australia. Education is associated with a decrease in the number of gifts received from the industry, and no change, or modest changes, in attitude towards pharmaceutical representatives and their gifts. [31, 32].

The *Australian Medical Council*, which is responsible for the accreditation of medical schools, makes specific mention of conflicts of interest in its standards for accreditation [33]. The *Standards* require that medical schools equip students with the ability to critically appraise literature and contribute to evidence-based medicine, as well as understand the impact of financial conflicts of interest. The *Australian Medical Association*, in its policy on the relationship between doctors and industry, calls on medical schools to provide "formal training" on identifying and managing conflicts of interest; recognising the effects industry sponsorship has on prescribing behaviour; independently sourcing and critically appraising evidence; and understanding the role of industry in patient care and healthcare system [34]. The impact of this policy remains to be investigated.

Although some countries have found different ways to regulate the pharmaceutical industry, Australia's regulatory framework is not an outlier. The United States and New Zealand are the only countries that allow direct advertising of pharmaceuticals to consumers [36, 37]. Transfers-of-value worth over \$10 to doctors or hospitals must be reported in the USA under the *Physician Payments Sunshine Act 2010* and in the EU under the EFPIA Code [36, 38]. In the US, companies face strong penalties under law for failure to disclose and reporting is comprehensive, including all gifts of food and drink. The EFPIA Code is self-regulatory, similarly to the Medicines Australia Code, and similarly omits food and drink. The penalties for failure to disclose are particularly strong in the US.

Australia's regulatory framework regarding educational events is in line with those of the US, EU and UK [39]. The provision of medication samples is much more strongly regulated in the UK and certain EU countries. In the UK, samples of a certain product may only be provided four times in one year and only if the doctor has submitted a written request to the company [40]. Dutch legislation is more stringent, requiring that samples of a product only be provided once every two years [41]. France prohibits the provision of samples by pharmaceutical sales representatives, under its sales representatives charter (co-signed by the national drug reimbursement agency and the industry association). It only allows samples in the first 2 years of marketing and prohibits samples for psychotropics or narcotics [42].

Extent of the problem in Australia

Pharmaceutical sponsorship interacts closely with health professionals, medical research and health consumer groups through various means. Several cross-sectional studies have been undertaken to quantify these interactions and their consequences. In one such study regarding pharmaceutical industry-funded events for health professionals, between 2011 and 2015, 42 companies together hosted an average of 608 events per week with around 30 attendees per event. There was a significant interaction of sponsors with doctors in training, as 38% of attendees were trainees. 82% of attendees were medical doctors [43]. Of these events, over 90% involved food and beverages [43], which are evidenced to increase prescribing of promoted medications [4, 5].

A search showing that over two-thirds of medical societies in Australia and New Zealand had sponsorship from healthcare companies further displays the relationship of health professionals with related commercial industries. Of these societies with sponsorship, only 16% had policies guiding the interactions between the two parties [44]. This partly hidden influence of pharmaceutical sponsors is also evident in research. In a survey of 2120 Australian researchers carrying out pharmaceutical industry-sponsored research, there were reports of delayed publication (6.7%), non-publication of key negative findings (5.1%) and concealments of events (2.2%). The study estimated an equivalent of 21% of researchers with an active relationship with the industry to have had at least one event that could breach research integrity [45].

While pharmaceutical companies are prohibited from using direct-to-consumer advertising, industry sponsorship of health consumer groups can give companies access to patients, via sponsored events or support groups. The pharmaceutical industry spent \$34,507,810 on 230 such organisations from 2013 to 2016 [46]. Many consumer groups rely on pharmaceutical industry sponsorship to widen their reach and the services that they provide. However, this funding can also influence the scope of available services. In Australia, the industry was shown to prioritise payments to health consumer groups which focused on diseases for which new drugs were available. Furthermore,

sponsors were more likely to fund activities which led to increased sales, such as disease education and campaigning, while neglecting important services such as patient support [47].

It is difficult to understand the complete extent of the consequences of pharmaceutical sponsorship in Australia as there is no nationalised review. Further, many aforementioned studies extract their data from groups such as Medicines Australia, which do not include an exhaustive list of pharmaceutical companies. Therefore, it is likely that many results are underestimated. This calls for a robust, preferably nationalised survey of pharmaceutical sponsorship to inform regulations.

Australian pharmaceutical companies are not required to disclose sponsorship of medical practitioners in relation to particular products and subsequent prescribing [48, 49]. Disclosed payments of \$89,658,566 were made from October 2014 to September 2015 to healthcare professionals including direct cash payments disguised as fees [48]. Although the ACCC mandated Medicines Australia to disclose transfers of value, expenditure on food and beverages are not included [48].

In 2019, one in five doctors responsible for authoring influential clinical guidelines had financial relationships with drug companies not disclosed in said guidelines [48]. This is a concern as these guidelines impact the care received by patients and which drugs they prescribe.

Pharmaceutical industry presence in drug trials

Studies that are funded by the pharmaceutical industry, or where the researchers have financial ties to the industry, are more likely to find results that favour the sponsor's products [50, 51, 52]. Conflicts of interest (COI) can influence a researcher's final study design and interpretation. Furthermore, industry-sponsored studies are typically more highly cited than non-industry sponsored studies [53]. The pharmaceutical industry can increase exposure and citing of their article by hiring thousands of 'key opinion leaders' to give talks to physicians [53]. Concerns have been raised that even the regulatory agencies whose job it is to evaluate the research evidence supporting applications for marketing, such as the European Medicines Agency and the US Food and Drug Administration, may not be fully impartial as they rely partially on industry financing through application fees [54].

If research trials and regulatory bodies move to a funding model where they are not reliant on industry money, these commercial influences can be removed. It may be possible for governments to fund some types or phases of drug testing. A model that could be followed is Italy's requirement that all international and national pharmaceutical companies operating in its country contribute 5% of their yearly expenditure from promotional initiatives targeting Italian health

professionals to a national fund for independent research [55]. This money is mainly used to support independent research in areas of importance to health but of little commercial interest.

Pharmaceutical industry presence in medical education

Places of medical education may have a financial reliance upon sponsorship by the pharmaceutical industry. Monash Health (covering five major hospitals), and the Monash Doctors Workforce and Education units at Monash Health have already successfully transitioned financial reliance away from pharmaceutical company sponsorship for training events and expos [30].

Dedicated education on relationships with the pharmaceutical industry may allow medical students to better recognise everyday interactions with the industry, and give students a framework to make clinical decisions with. Studies on the effectiveness of such courses have shown mixed results, with some educational interventions producing more scepticism about industry marketing, some showing no change, and others resulting in a more favourable view toward industry [33].

Lastly, staff members should maintain transparency; for example, any presenter with a conflict of interest should declare this on the first slide of any oral presenter [56]. This would extend to university lecturers, who may also have relationships with the industry.

Social media and relationship with industry

As stated by the *Australian Medical Association*, *doctors' relationship with industry* should

- reflect core professional values such as transparency, accountability, trust and fairness;
- not compromise, or be perceived to compromise, doctors' professional judgement and professional integrity;
- be open and transparent, able to withstand public and professional scrutiny, meet public and professional standards and expectations and adhere to relevant legislative and regulatory requirements;
- promote effective stewardship and responsible use of healthcare resources [35].

A core role of pharmaceutical corporations is to increase sales of their products, this can include through mediums such as advertising. As such, industries and corporations have an incentive to market their products in the best light. The *Australian Medical Association* highlights why doctors may be targeted or influenced by corporations:

- many products require a doctor's prescription before being purchased by the patient;
- direct-to-consumer advertising of prescription medicines is prohibited in Australia;

- doctors play an important role in influencing institutional purchasing of products (those products purchased by healthcare facilities and related institutions)
- doctors may influence their colleagues' opinions of particular products [35].

Social media includes any technology that facilitates the sharing of ideas and information including pictures, videos and messages [57]. 96.4% of Australian internet users between 16 and 64 accessed a social media network or messaging service in December 2020 [58].

Social media use is also an increasing avenue for direct-to-consumer information with influencers producing a 60% greater shift in brand perception measurements [59].

Social media posts, including from “influencers” with large followings, can influence and impact the beliefs and attitudes of followers regarding pharmaceutical products [60]. The underlying belief that therapeutic goods should be given to patients based on medical needs underpins the guidelines for sponsorship and promotions of pharmaceutical products by businesses and influencers. In particular, medical students and doctors may gain trust and confidence from their followers due to their roles within society, perceived education and understanding of therapeutic and clinical products. As such, sponsorship of products by medical students and doctors may distort views regarding therapeutic goods and more importantly is subject to legislative requirements.

The TGA maintains a guide, based on legislation, regarding the use of social media for the promotion of pharmaceutical products. This includes

- Any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the products is an advertisement.
- A social media post that promotes the use or supply of therapeutic goods is an advertisement. Whether an advertisement for therapeutic goods appears on social media or in any other media, the advertisement must comply with therapeutic goods legislation.
- Claims such as 'removes toxins', 'fades age spots', 'relieves pain', 'aids sugar metabolism', 'reduces inflammation in the body' are all therapeutic use claims.
- Business owners are responsible for the content of any social media page created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums Any comments you make about your personal experience with the goods amounts to a testimonial.
- Testimonials are not permitted by those involved in the production, sale, supply or marketing of the goods.



- This includes influencers who are engaged by a therapeutic goods company to promote the goods, or anyone who receives valuable consideration (payment or goods, for example) for making a testimonial [61].

The TGA also maintains enforceable legislation around advertising of pharmaceutical products. In particular this includes

- That some therapeutic goods, including prescription and certain pharmacist-only medicines, as well as biologicals, are prohibited from being advertised directly to the public.
- Only goods administered within the Australian Register for Therapeutic Goods are eligible to be advertised, unless excluded under the Therapeutic Goods Advertising Code [62].

The TGA administers the Commonwealth therapeutic goods legislation to regulate the advertising of therapeutic goods in Australia, primarily through the Therapeutic Goods Advertising Code [63]. This is underpinned by the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990* [64, 65].

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