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ORIGINAL ARTICLE

"There are ways … drug companies will get into DTC decisions": How Australian drug and therapeutics committees address pharmaceutical industry influence

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Aims: One tool for protecting quality use of medicines in hospitals is a drug and therapeutics committee (DTC) that oversees medicines availability. Pharmaceutical industry marketing to prescribers is associated with less appropriate prescribing and increased costs. There is little data on decision-making practices of DTCs so it is unknown whether or how they might be vulnerable to pharmaceutical industry influence. This project explores DTC decision-making with a focus on how pharmaceutical industry influence on access and use of medicines is identified and managed.

Methods: We used a qualitative methodology with individual interviews of 29 participants who were current or recent members of public hospital DTCs across New South Wales, Australia. Participants included medical, pharmacy and nursing staff and 1 citizen. Committees were linked to specific hospitals or regions, and some were affiliated with paediatric, neonatal, rural or mental health services.

Results: Drug committee processes for oversight of medicines in public hospitals are vulnerable to pharmaceutical industry influence at several points. Applications for formulary additions are sometimes initiated and completed by company representatives. Conflict of interest disclosures among applicants and committee members may be incomplete. In some institutions, medicines are available from pharmaceutical companies without committee review, including through free samples and industry-supported medicines access programmes. Participants noticed the presence and impact of pharmaceutical company marketing activities to local clinicians, resulting in increased prescriber demand for products.

Conclusion: Improved DTC practices and review of hospital policies concerning pharmaceutical marketing activities might preserve the independence of evidence-based decision-making for safe, cost-effective prescribing.

KEYWORDS

drug industry, pharmaceutical policy, pharmacy and therapeutics committee, qualitative research, quality of health care

The authors confirm that the Principal Investigator for this paper is Lisa Parker.

1 | INTRODUCTION

Pharmaceutical industry marketing is seen by many healthcare professionals as an important source of medicines information. However, it is associated with less appropriate and judicious prescribing and it increases costs, thereby reducing rather than improving prescribing quality.[1,2] Many doctors remain in denial about the negative impact of pharmaceutical industry marketing and continue to engage with the industry,[3,4] despite the abundant evidence that the effects are real and corrosive. Industry-funded gifts to doctors, including low-value gifts such as lunch at meetings, alter prescribing habits in favour of brand name products over cheaper generic alternatives with established safety records.[5,6] Doctors who rely on free medicine samples in public hospitals are more likely to prescribe medicines that differ from their preferred choice[7] and practice guidelines.[8] One important tool for optimising quality use of medicines is a drug and therapeutics committee (DTC), also called a medicines committee, a quality use of medicines committee, a prescribing and medicines committee or similar.[9,10] These committees oversee access and use of medicines in their local institutions. They evaluate the efficacy and safety of medicines and create hospital formularies, which are lists of permitted medicines that suit the local patient cohort and institutional budget.[11,12] They protect patients and hospitals from the health and financial harms associated with use of medicines, particularly heavily promoted medicines.[10]

All public hospitals in Australia have a local, regional or state/territory based DTC that has governance over the formulary medicines that clinicians can prescribe for specified purposes.[10] DTCs review applications for new formulary medicines and applications to prescribe medicines for individual patients in exceptional circumstances—so-called *Individual Patient Use* (IPU) applications. Individual use applications request access to a formulary medicine outside the approved formulary use, or use of a medicine that is not on formulary, which are often high cost medicines. This might apply for new drugs or in rare diseases, where there is limited or no evidence from randomised control trials. DTCs also have responsibility for the oversight of medicines that may enter their institutions in other ways, including free samples and pharmaceutical company access programmes where individual companies provide discretionary access to medicines at reduced or no cost, usually within a formal, company-administered framework.[12] Access programmes are often run alongside company applications for national regulatory approval and/or subsidy of medicines, and inclusion criteria for access programmes are generally aligned with the indication for which approval and subsidy are being sought. Companies may also provide access to free or reduced cost medicines on an informal basis, upon request from individual prescribers or patients.[12,13]

DTC membership is typically multidisciplinary; membership is sometimes tied to specific professional roles; alternatively, members are selected from volunteers or recruited by the Chair. DTCs are supported at a state and national level by independent organisations that provide guidance and practical advice, including guidance on how to identify and mitigate the harm from pharmaceutical industry influence.[14] For example, the New South Wales (NSW) Therapeutics Advisory Group (TAG) advises all DTCs to include a section on the formulary application form where applicants must report past or future receipt of pharmaceutical company funds. However, there are few empirical data on the decision-making practices of Australian DTCs around which medicines are put on formulary or approved for IPU,[15] so it is not known whether or how those processes might be vulnerable to pharmaceutical industry influence. There is also a lack of data on what strategies DTCs use to address industry influence within committees and their local institutions.

This project was prompted by ongoing concerns within NSW TAG about the potential for industry influence in public hospitals and an interest in identifying strategies to mitigate such influence. Our aim was to identify and analyse current DTC practices in order to recognise potential points of vulnerability to pharmaceutical industry influence. Our research questions were:

- How do DTCs oversee access and use of medicines in public hospitals?
- What are the potential points of pharmaceutical industry influence on medicine availability and use in public hospitals?
- What strategies do DTCs use to detect and/or reduce the likelihood of pharmaceutical industry influence over DTC decision-making?

What is already known about this subject

- Pharmaceutical industry marketing can negatively affect appropriateness of medicines prescribing and increases costs
- Drug and therapeutics committees (DTCs) have a role in protecting patients and hospitals from harms and costs of company marketing

What this study adds

- DTCs oversight of formulary, off-label use and medicines access programmes is vulnerable to industry influence
- DTC members are aware of pharmaceutical industry influence over local prescribers but may consider it outside their responsibility or feel powerless to intervene
- DTCs and hospitals should collaborate on implementing tighter restrictions on disclosure processes and on industry marketing in hospitals

2 | METHODS

We used the Consolidated Criteria for Reporting Qualitative Research checklist to guide our reporting of the methods and findings.[16] Ethics

approval was obtained through The University of Sydney Human Research Ethics Committee [2018/765] and St Vincent's Hospital Ethics Committee [2018/ETH00701].

2.1 | Design

We used a qualitative methodology for our empirical research, well suited to researching processes and issues where there are few existing empirical data.[17] We conducted individual interviews using sampling, recruitment and data collection methods informed by grounded theory as practiced by Charmaz.[18] We drew on the emerging discipline of empirical ethics, whereby empirical research and theoretical reflection on ethics concepts are combined to inform ethical guidance on a specific topic.[19,20]

The research team included academic experts in commercial influences in health and pharmaceutical policy, health professionals in pharmacy, nursing, and medicine, and experienced qualitative researchers. One of the researchers (A.B.) is the Executive Officer of NSW TAG and has extensive experience with DTC practice and policy. Another researcher (L.P.) attended 2 NSW TAG meetings and 3 different DTC meetings as an observer in order to gain background knowledge of their responsibilities and practices. No data were collected during these attendances.

2.2 | Sampling and context

We used NSW, Australia as our geographic case study. The state is divided into 15 geographic districts and 2 other networks for health administrative and budgetary purposes.[21] NSW government policies set out the governance processes for medicines in the districts/networks, with DTCs having the primary role and responsibility, including oversight over approval of medicines on formulary. Districts may contain >1 major hospital and >1 hospital-based DTC, or have a centralised district DTC with subsidiary committees in local hospitals having defined responsibilities about medicines access and use within that institution. For example, hospital DTCs or subsidiary committees commonly review the IPU applications for nonformulary use of medicines in specific patient situations. NSW TAG estimates there are 50 DTCs across NSW, and the group's support for committees includes collating and sharing decisions from major DTCs in order to reduce duplication of effort and identify emerging formulary issues.[22]

Our study sample consisted of current or recent past members of NSW DTCs. As per widely used qualitative research methods,[17] we aimed to capture a wide range of experiences and perspectives. We used a purposive strategy,[23] recruiting people working across diverse DTCs (centralised district, hospital-based, paediatric, neonatal, mental health), different geographic locations (metropolitan, rural) and with a range of backgrounds (medical, pharmacy, nursing, citizen). Participants were recruited through NSW TAG newsletters, NSW TAG and DTC meetings and recruitment emails to selected individuals using contact details known to the researchers or in the public domain. We carried out sampling, data collection and analysis iteratively, and our sampling strategy evolved as the study progressed in order to obtain diversity of participants and variation in data. We continued sampling until we were no longer hearing new information (thematic saturation).[24]

2.3 | Data collection

L.P. conducted semi-structured interviews[25] between May and October 2019, either face to face (n = 19) in the workplace or over the telephone (n = 10). Using telephone interviews meant that we could include participants from rural districts. There was no appreciable difference in the length or quality of interview between the different modalities. Potential participants were sent an Information Sheet and Consent Form prior to the interview. Consent was obtained in writing before and/or orally at the time of interview and before recording. L.P. introduced herself as a researcher and medical practitioner, partnering with NSW TAG to interview DTC members about decision-making practices and pharmaceutical industry influence. L.P. asked about participants' local DTC policies and practices around pharmaceutical industry interactions and about their individual experiences and perspectives on industry interactions including risks and possible mechanisms of industry influence (see supplementary file). Interviews were audio recorded, professionally transcribed and de-identified. All participants were given pseudonyms for the quotes used in this paper. L.P. wrote field notes after interviews to record contextual information, initial thoughts and reflexive ideas.

2.4 | Analysis

Analysis and data collection occurred iteratively so that each could inform the other.[18] L.P. read interview transcripts repeatedly to identify salient topics and concepts. Three early interviews were shared and discussed with the rest of the research team. L.P. used the emergent data, these discussions and the team's a priori research questions to create a set of thematic and descriptive codes, which she edited according to feedback from the team. L.P. imported transcripts and field notes into NVivo software and organised portions of text according to these initial codes. Data from later interviews were compared against earlier analytic interpretations, and codes were adjusted to accommodate new concepts and understandings. Earlier interviews were re-coded where necessary. Coded interviews were discussed in regular team meetings to check interpretations and any discrepancies were resolved by consensus. Once data collection was complete, L.P. drafted overarching categories that organised and explained the data, which were refined after further discussion with the team.

3 | RESULTS

We interviewed 29 people: 12 women, 17 men. Participants were currently or recently affiliated with 19 different DTCs and all but 1 were active members of a DTC. Twelve were current or previous DTC Chairs (see Table 1 for characteristics of participants and current or recent DTC affiliations). The mean duration of interviews was 60 minutes (range 28–107 min).

As described by participants, the processes for DTC oversight of formulary and IPU medicines (see Table 2) were clear and routinely adhered to by local staff: (i) clinicians made a formal application with supporting clinical trial studies; (ii) the application, including supporting evidence, was reviewed by the DTC executive and/or full committee; and was (iii) approved or rejected or returned to the applicant for additional information. The processes for DTC oversight of industry-provided free samples and medicines access programmes (see Table 3) were less clear, and many participants were aware of situations where free samples or access programme medicines had been used in their local institutions without going through DTC review. DTC strategies to detect and reduce the likelihood of pharmaceutical industry influence over their decision-making processes included: policies requiring committee members to make regular declarations about conflicts of interest; and a requirement that applications for formulary or IPU medications be initiated and signed by senior medical staff. Most DTCs did not take responsibility for regulating pharmaceutical company presence in hospitals or their relationships with hospital staff. Participants generally did not see this as the role of the DTC or felt the DTC had no capacity to influence policy around, for example, pharmaceutical sales representative presence in the hospital. Participants were aware of the risk of pharmaceutical industry influence over the use of medicines in their institutions, including vulnerabilities in DTC processes and external to the DTC. These are discussed in more detail below and in Table 4.

TABLE 1 Characteristics of participants and drug and therapeutics committee (DTC) affiliations

Participants (n = 28)	
Participant's professional role	
Medical	14 (50.0%)
Pharmacy	10 (35.7%)
Nursing	4 (14.3%)
Consumer representative	1 (3.6%)
Participant's DTC location*	
Metropolitan	20 (71.4%)
Regional	10 (35.7%)
Participant's DTC jurisdiction*	
District	21 (75.0%)
Institution	9 (32.1%)
Mental health	1 (3.6%)
Rural	2 (7.1%)
Paediatric/neonatal	4 (14.3%)

*some participants were members of >1 DTC.

3.1 | Industry could influence hospital formulary and IPU processes

Participants described direct company involvement in applications and a lack of clarity around financial conflicts of interests amongst clinician applicants and DTC members.

3.1.1 | There was direct industry involvement in formulary and IPU applications

Although DTC policy required formulary applications to come from senior medical staff (see Table 2) this did not always happen. Some participants spoke of applications being routinely initiated and/or completed by company staff, with a clinical champion providing the necessary signature and company assistance remaining undisclosed even when prompted by the application form (see Table 4). Some applications were preceded by a request from the company representatives to the DTC pharmacist:

> "[They] contact you and say, 'Dr so-and-so wants to add this. Can you send me the form?'" (Pem, pharmacist)

Participants voiced concern that this kind of company involvement in the application process might result in greater use of medicines from companies with a bigger marketing budget, rather than using the most appropriate medicines:

> "Does that mean that it's the drug companies that jump up and down the most and get the clinicians to submit those formulary applications that get [their products] on our formulary?" (Rosa, pharmacist)

Others were concerned that company input might mean that the application form was more complete and more likely to succeed, despite relying on biased and potentially misleading evidence compiled by sales representatives. Participants from well-resourced DTCs had the time and expertise to notice when applicants were being selective about the evidence, they provided to back up the application. For example, they conducted literature searches or had enough content expertise to recognise when "major, major bits of evidence have been omitted" (Arthur, doctor). However, for other participants, the time-consuming nature of an independent evaluation of the evidence meant they relied on the applicant's literature submission despite recognising that might be incomplete:

> "To go through the literature is very difficult so you have to rely on … those papers [that] are submitted by the person who's making the request, [and] there's that

TABLE 2 Participant descriptions of drug and therapeutics committee (DTC) processes for considering medicines access under hospital formulary and Individual Patient Use schemes*

Formulary application process	
Initiating the application	All participants said that it was DTC policy that requests for addition or emendation to the hospital formulary must come from senior hospital clinicians to the institutional or district/network DTC.
Submitting the application	Applicants were required to complete a form and attach supporting research evidence about efficacy and safety (preferably published clinical trials, systematic reviews, observational studies but also unpublished studies and local data if there is nothing else available) and identification of need for the local population. The DTC pharmacist provided advice and guidance to applicants about this process upon request.
Preliminary review	Applications typically received a preliminary review by a DTC executive committee. The make-up of the executive committee varied (e.g. chair and pharmacist, chair and vice-chair and pharmacist). Some executive committees made direct requests to the applicant for more information if they felt the submission was insufficient. For example, Arthur (doctor) said, "I'll normally ring the applicant. Can you please clarify this and that? Why cannot we use this [existing drug]? It's lacking evidence, can you please provide that? Or, as occasionally happens … what you have given me is just what the drug company gave you. That's not going to work. I want an independent assessment of the evidence base." Other executive committees accepted applications even if they appeared inadequate and supplemented with their own research and literature review. For example, Niall (doctor) said, "look we get applications that are clearly written by a rep. That are just boilerplate … as soon as you see that, then the first thing you think is, well, we need to do some of our own research here."
Committee review	Applications were then reviewed by the full committee at the regular meeting. Committee members were provided with the application and evidence in advance and experts outside the committee might be asked for their views. Sometimes DTCs requested that applications be resubmitted with more evidence or more information about the patient group that applicants were aiming to use the product in. The applying clinician might be asked to come to the next committee meeting to explain why their application should be approved. Participants reported that formulary applications were rarely rejected, some suggesting that this was because the executive committee worked closely with potential applicants prior to the formal application to discuss whether there were other therapeutic options that were already on formulary. Most participants could recall at least 1 case of rejection from recent years. Reasons included: lack of sufficient evidence of benefit, uncertainty of benefit and clear evidence of adverse effects; not cost-effective compared with existing formulary medicines; application forms inadequately completed; product no longer available; requested indications too broad. None of the participants could recall an application being rejected because of pharmaceutical industry influence, although the application might be scrutinised more carefully if industry influence was noted. For example, Greg (doctor) said, "I know we as a drug committee have commented on the fact that the application looks like it's been filled out by a drug representative rather than the applying physician … and I think we … read through those a little bit more thoroughly." Most new medicines that were subsidised for use in the community were accepted onto hospital formularies even if similar, cheaper medicines were also available. Reasoning for this was that patients were likely to come into hospital on those medicines and treating doctors would generally wish to continue the same products. It was uncommon for medicines to be removed from formulary lists.
Individual Patient Use application process	
Initiating the application	Was policy in all DTCs that individual patient use applications for 1-off use of a medicine for an unapproved indication must come from senior clinical staff.
Submitting the application	Applications were via a completed form, although some institutions accepted telephone applications and allowed forms to be completed retrospectively if the case was very urgent.
Executive review	Urgent individual patient use applications could be reviewed and immediately approved by the chair, executive committees or nominated *on-call* person.
Committee review	The application, included request for the remaining course, was reviewed later by the full committee. In most (but not all) institutions, courses of medicine that were likely to exceed a certain monetary threshold (typically $AUS10 000/£5500/$US7000) were sent to the medical administration for final approval. Administrators sometimes, although rarely, rejected requests that had been provisionally approved by the DTC. The NSW TAG recommendation for DTCs to request that clinicians submit a formulary application (after receiving 3 individual patient use applications for a similar indication) was not always followed. Participants such as Erica (doctor) were aware that medicines on formulary for specific indications were sometimes used for other indications without individual patient use approval: "We might put, say, [drug A] on the formulary only for people who are already on it and then we'll find that it's being used more widely … without necessarily applying for IPUs [individual patient use applications], which is the process."

*unless otherwise stated the processes were the same across all DTCs.

TABLE 3 Participant descriptions of possible sources of medicines in public hospitals that are outside the formulary/Individual Patient Use system

Free samples	These might be offered directly from a company sales representative to hospital staff. Although it was usually hospital policy that any free samples be kept in pharmacy, this did not always happen. In some hospitals, for example, insulin samples were kept in outpatient diabetes clinics and given directly to patients. In others, starter packs of apixaban, a new oral anticoagulant, were kept in the Emergency Department for patients presenting with a confirmed deep vein thrombosis. One participant refused to accept free samples in her institution: "Not in my hospital under any circumstances whatsoever … Don't bring samples into my hospital." (Leanne, pharmacist).
Compassionate access programmes	Under time-limited compassionate access programmes, drug companies may provide, on request and for specific patients, a medicine that was either not freely available on the hospital formulary or outpatient government subsidy scheme, or not approved for treatment of the condition (*off-label* use). The medicine might be given free or at reduced price with many cost-sharing variations. For example, companies might offer to waive the cost of every second dose, or a third of the total cost, or pay after the first 3 treatments, or "pay a portion of it for a period of time, might be 3 months and then after that you have to pay the full cost." (David, citizen) Some companies had web-based portals that prescribers can log into to request compassionate stock. Compassionate access programmes might have strings attached, for example they might be "conditional to the department not using other company's brands of an equivalent product." (Pem, pharmacist).
Patient familiarisation programmes	Pharmaceutical companies may offer a time-limited programme of reduced or no cost medicines to clinicians as a way of building prescriber confidence in using new products. As Justin (pharmacist) explained, "that was about helping clinicians learn how to use that medicine, and that certainly had a commercial interest." Some DTCs had negotiated with companies offering familiarisation programmes such that companies agreed to continue providing medicines at reduced or no cost for all patients experiencing a clinical response once programmes had ended.
Clinical trials	Pharmaceutical company-funded clinical trials were widespread throughout hospitals, particularly in the metropolitan area. Trial protocols were approved by hospital ethics committees. Clinicians received money for participating in company funded clinical trials. For example, they might be paid an initial upfront payment to cover set up costs such as salaries for research nurses, with additional funding if they recruited the required numbers (say 10 patients) or a set amount, such as $10 000 (£5500/$US7000) for every person that was recruited.

> issue that they are the ones submitting what they want you to see." (Vince, doctor)

3.1.2 | Formulary and IPU applications could be initiated by doctors with financial ties to industry

The current NSW TAG-endorsed templates for formulary and IPU application forms include a section for applicants to declare conflicts of interest with pharmaceutical companies. However, this might be left blank, and even if was completed, participants noted that the declaration might not accurately capture all relevant information about financial relationships between applicants and pharmaceutical companies (see Table 4).

A few participants said that they sometimes actively sought additional information about financial links between applicants and pharmaceutical companies using institutional or publicly accessible databases of industry payments to doctors. Applicant links with industry might be particularly important in circumstances where local hospital politics could affect DTC decision-making processes. Greg (doctor) talked about "animosity between DTC and the clinicians", which could potentially affect formulary or IPU applications, and Tom (doctor) said that the DTCs might feel pressured to accept applications from some local clinicians:

> "Certain sub-specialty groups within hospitals … get a disproportionate amount of influence and leverage on the DTC … some specialists may or may not be leaning on particular individuals within their … DTC."

DTC decision-makers could have conflicts of interest with industry

None of the participants had a policy precluding members with conflicts of interest from attending. Most participants said that members were expected to declare any financial conflicts of interest through annual written forms and verbally prior to each meeting, but implementation was incomplete (see Table 4). For example, there was not always enough time for the usual verbal or written conflicts of interest to be completed. Other participants said that verbal and/or written declarations about conflict of interest were not part of their committee's normal practice. There was little or no discussion about what constitutes a conflict of interest, for example it was left up to individuals to decide whether or not any financial relationships they might have with pharmaceutical companies were relevant to the current agenda. Similarly, no reporting thresholds (in monetary amounts) were mentioned.

DTCs dealt with declared conflicts of interest in different ways. Some participants said that any members with self-identified conflicts "abstained from any comment" (Matthew, doctor) or "would leave the room" (Cherylene, nurse) but others said that a declared conflict "just gets noted." (Brinda, pharmacist) One participant said that asking a conflicted person to leave the room would be received as an insult and others suggested that it would be undesirable to recuse members with financial conflicts of interest because it would mean missing out on the expert views of 1 or more highly regarded clinicians. This could be particularly problematic in smaller institutions:

> It becomes very tricky where all the doctors in an area benefit from money flowing … into their clinical trial fund, directly or indirectly. So … you need the expertise to make a balanced decision about what is the value and worth of this. (Justin, pharmacist)

TABLE 4 Potential mechanisms of industry influence over availability and use of medicines in public hospitals (with explanatory comments from study participants)

Companies directly initiate or assist with formulary applications.

Companies initiate formulary applications.

"[The formulary application] always comes from—well, nearly always comes from the drug company … So they will approach people that they know within the units that are relevant, to facilitate that. And they already know what the application process is like in [our hospital], and who they need to get to sponsor it." (Wanda, nurse).

Companies assist staff with filling out formulary application forms.

"So I suppose that that is some way that industry can influence a decision, just by giving a better filling in of a form… say it's a new product and a VMO [Visiting Medical Officer] wants to have it added to the formulary. And they're not quite certain how to do it and the representative says, "Here's what we did for [Hospital H]" and they just sign that." (Leanne, pharmacist).

Companies put together the evidence to support formulary applications.

"They might give you supporting evidence—like a formulary pack from the actual drug companies because they know the process so they will put a formulary pack—which is a generic pack given to all hospitals that they want to help put the product on the formulary … [It contains] a lot of marketing, their company-sponsored trials, a lot of their marketing promotional material about why their product is better." (Pem, pharmacist).

"The drug company's assessment [of the evidence base] … is almost certainly going to be biased." (Arthur, doctor).

Company assistance with applications is not always disclosed.

"I could see how there are ways that inadvertently the drug companies will get into DTC decisions. So a lot of times … it will be the drug reps who fill out that [application form] … That's kind of a less transparent way that [drug companies] have influence … there is nowhere where it is stated that they have [filled in the application]." (Rosa, pharmacist).

"There is an acknowledgement on the form [about who filled in the form]; sometimes [the companies that complete application forms] don't fill that in." (Leanne, pharmacist).

Companies fund trials of new medicines.

The only available evidence for new medicines might be from pharmaceutical company trials.

"A lot of [the evidence] can be driven by papers that have been provided or come from obviously the pharmaceutical companies. If they are newer drugs on the market there's not lots of randomised, you know, trials to see what the real improvements are." (Tom, doctor).

Clinicians applying for new formulary/IPU [individual patient use application] listings have undisclosed financial links with pharmaceutical companies.

Applicants have undisclosed financial links with pharmaceutical companies.

"Clearly there's more that goes on, but it's not visible through our existing declaration system… Often the person who's filling out the form is, say, the advanced trainee and they don't necessarily have much—but the person who's told them to fill out the form has been a key note speaker at a number of sponsored conferences, and that doesn't come out." (Erica, doctor).

DTC decision-makers have financial links with pharmaceutical companies.

Identification of conflicts of interest relies on self-disclosure.

"So, at the beginning of each meeting of course we have to declare any biases we might have like if we have received any form of sponsorship, and of course everyone's done something and it's up to us to identify that if a medication is coming up that could possibly be related to a company for which we have done work for in the past, then we should withdraw from the discussion." (Owen, doctor).

DTCs may not know what to do about members with financial links to pharmaceutical companies.

"We definitely scrutinise those conflicts, and take them into consideration, but … the other part of that too sometimes is that clinicians would argue around the table, you know, '[Connor is] a world expert in this. He works with a number of companies. He's the guy who's writing the guidelines.' … So it's very difficult for a committee to say, we're excluding [Connor's opinion]." (Justin, pharmacist).

DTC member disclosures about conflicts of interest is not always complete.

"We would try and have an annual disclosure. Not always did we reliably get that completed though through the business of committee work." (Justin, pharmacist).

"We don't have like a declaration every time we meet to say who's got a conflict of interest in this matter." (Kirsty, doctor).

Companies make medicines available to prescribers through pathways that bypass DTCs.

Companies provide free samples directly to clinician prescribers.

"[The issue of free samples] certainly has come up from time-to-time at our [DTC] meetings where that has been found in outpatients or something. For some reason it comes to the attention of Pharmacy and then they find that Dr X has this stash of all these drugs that have been given to them to give to patients, … and then they expect it to be provided for them and it's usually an expensive drug." (Wanda, nurse).

Companies negotiate directly with clinicians on medicines access programmes.

"The biggest challenge for us is compassionate access programmes and familiarisation programmes, in that it's not uncommon for clinicians to, sort of, sneak people through and get it under the radar—getting patients on the programmes without notifying the drug committee." (Cassie, pharmacist)

Companies market their new products within hospitals to DTCs, pharmacists, prescribers.

Companies market directly to DTC members.

"It's becoming more common that drug companies request to make presentations to—it's not usually to the whole committee, it's usually just to the chair and pharmacy … Usually if the original company knows that a biosimilar is coming out and that the [biosimilar] company would be starting to make their rounds they would also make rounds … They would talk about their original research; probably the negative aspects of biosimilars, so research about—they even talk about the process of biosimilars becoming registered, what research they do compared to the biosimilar brand, how much money they spent with their research, if there is lack of evidence for safety in switching … They don't come right out and say it but imply that companies that do R&D [Research and Development] should be supported." (Pem, pharmacist).

Companies market to hospital pharmacies.

"The industry … do approach Directors of Pharmacy. And then it ends up potentially coming to drug committee. So an example that's in play at the moment is [Company A] is about to produce biosimilar [x] and, so they're coming to all the heads of pharmacy, saying it's coming out, we'll offer you a good price." (Edward, doctor).

(Continues)

TABLE 4 (Continued)

Companies provide lunches to clinical staff at hospital meetings.

"[Pharmaceutical reps] provide lunch for our staff at our education meetings … this is the only way they get to see our doctors and tell them whatever is new, what's coming on. And so they might come to that and speak to 1 of our specialists after the meeting and say, drug X has been approved and would you support it going onto formulary, and I could send you all the documentation?" (Wanda, nurse).

"It is just a bad look and I am not sure how you explain it away and it never seems to work to me, someone tried to justify why, why they are putting on lunches and so on, because they are not just putting a lunch on, they have got probably their posters all around the walls and so they are holding up whatever and it is gets to the stage where it is the drug company who is spending the most money on this sort of stuff that gets the business … It is perhaps human nature that that is the case, 'Oh, I need a drug, oh yes I remember that nice guy and we had that nice lunch, we will order off him.'" (David, citizen).

Companies market their products in hospital tearooms.

"The reps will be doing their round every quarter, and they'll be coming up and saying "Hey, do you want us to drop in and have a chat about things?" And usually, when they're coming past, it's, 'We'll come and sit in the tearoom of, or the staff room of, and we'll be there to have a chat about this or that if you want.'" (Greg, doctor).

Companies assist hospital medical staff with internal presentations.

"We had a great—or terrible, whichever way you want to put it—example where a [specialty training] fellow came to give a talk on an update in [disease x] to the [speciality] Department and he was using drug company slides." (Erica, doctor).

Companies market their new products to local clinicians externally.

Companies fund hospital medical staff to attend meetings.

"Because it's an area with lots of expensive new drugs, there's [always] lots of overseas visitors having a meeting in [another city]. They're … good meetings but everyone's flown there [by the companies]." (Barry, doctor).

Companies fund hospital allied health staff to attend conferences.

"Staff are getting the support to go to a conference by a drug company … For nursing and for allied health there's pretty much no [other] options for them to get access to conference registrations or travel." (Yasmin, nurse).

Companies market their products at external conferences.

"I mean, a consultant will email and say 'I was at a conference on Thursday and at the—you know there's the stalls outside major conferences. … And the such-and-such rep was talking to me about whatever it was … can we get it?'" (Leanne, pharmacist).

Companies market their products at local restaurant-based education sessions for doctors.

"I can tell that when there is a dinner in town from a particular drug company who's doing education for the medical staff, I can tell you when the dinners are on. Because there'll be a renewed interest in certain items. I think is perhaps the best way of saying it." (Leanne, pharmacist).

Companies cultivate dependency amongst hospital staff.

Companies provide extra services with clinical trials.

"Clinical trials, it's definitely good for the patients … [but] drug companies support research and provide more than a drug. So I suppose if a drug company supports research with research nursing assistants or—then that can probably influence—potentially influence prescribing practice … How willing would you be as a service deliverer to move away from that company if a new product comes on the market, if company X, Y and Z won't offer the same support?" (Matthew, doctor).

Companies provide extra services with new products.

"Some companies may be providing … a nurse to their clinics or things of that nature to departments who use their product but that might be conditional on them not adopting the biosimilar when it comes out and influencing their prescribing in that way." (Pem, pharmacist).

Company staff interaction with health professionals is normalised.

It is routine to see company staff in hospitals.

"Drug reps are ubiquitous; they're everywhere. If we have a journal club here or a we have weekly something in [specialty area], either a Grand Rounds or a journal club, it alternates, there's always a drug rep associated for that, and [sub-specialty b] drugs are pretty pricy; it's worth their while. Sometimes they do a 1 minute [presentation] but usually there's no presentation, they just rock up, just want to stay on the good side of the prescribing physicians I suppose." (Owen, doctor).

It is routine to accept industry money for health professional education.

"I participate in the [subspecialty] advanced trainee education a bit and there it's just - I think it's the same for most specialties - just accepted that the monthly meeting, for example, is, it's a very good meeting but it's supported by a company … It's normalised that there's big involvement of companies." (Barry, doctor).

A few participants said that disclosures around conflicts of interest were not routinely requested at their DTC meetings.

3.2 | Industry could bypass DTC oversight via free samples and medicines access programmes

DTCs did not necessarily have oversight over the availability and use of medicines that were prescribed by hospital doctors and provided in outpatient clinics through free samples and access programmes such as compassionate access and patient familiarisation programmes (see Table 3). Most participants said that DTC policy was that free samples must be stored in pharmacy and only dispensed via prescription. However, most were also aware that free samples were sometimes given directly by pharmaceutical sales representatives to doctors or nurses, kept in clinic areas and given out without DTC knowledge or oversight (see Table 4).

Many participants said that their DTC also required all medicines supplied under medicines access programmes to go through formal committee review. For example, clinicians were required to submit formal IPU applications even for medicines provided freely or at reduced cost on compassionate access and must apply to the DTC for

approval to participate in product familiarisation programmes. However again, such policies were not always followed (see Table 4). Participants said that access programmes might influence hospital use of medicines in ways that extended beyond the life of the programme. For example, they might lead to clinicians acting favourably towards pharmaceutical representatives in order to maintain open channels of access. They also acknowledged that access programmes might influence DTC decision-making, since committees that regularly reviewed IPU applications for compassionate access could become more familiar with the use of a new product and more likely to approve it for new indications.

A minority of participants said their DTC allowed clinicians to engage directly with companies about access programmes without any oversight. For example, Justin (pharmacist), said that "As a drug committee it wasn't our role to ask" about compassionate access and explained that in his experience, "Companies usually required, and we supported, the clinician to go to [Company A], for example, and say, 'We have someone here who would like to use this medicine.'" Another participant agreed that responsibility for use of medicines from free samples or medicines access programmes should rest with the doctors and was, in their view, outside the remit of the DTC:

> I have heard of some specialists, like in haematology and oncology, potentially getting some starter packs for certain patients but not through pharmacy … I guess it's one of those things where it's just the clinicians use their own professional and ethical judgement to handle whatever interactions that they have with the pharmaceutical's rep, and it's not really the purpose of the DTC telling them how to be a professional. (Tristan, pharmacist)

3.3 | Industry could influence medicine prescribing through marketing and relationship-building with hospital clinicians

Participants talked at length about the potential for pharmaceutical industry influence on the use of medicines in public hospitals through company marketing (see Table 4). They described direct marketing activities occurring in hospital grounds, including personal meetings between sales representatives and DTC members and clinicians, and industry sponsorship of lunches for staff educational meetings, sometimes preceded by brief marketing presentations. They also talked about marketing activities outside of the hospital including company funding for staff conference travel and registration, payment for dinner meetings at local restaurants, and promotional stalls at conferences. Participants recognised the immediate impact of these kinds of activities, noticing increase in prescriptions of relevant medicines or applications for putting new medicines on hospital formularies:

> I can tell when there is a dinner in town from a particular drug company who's doing education for the medical staff. I can tell you when the dinners are on because there'll be a renewed interest in certain items. (Leanne, pharmacist)

Many participants spoke about clinical trials as possible sources of influence of hospital medicine use. Trials were beyond the scope of responsibility for most DTCs, although some did review trial protocols when their institution was taking a leading role in the trial. Participants were generally positive about the opportunities that opened up for patients when their clinicians signed up to trials, but also discussed concerns about ways in which industry-funded research might lead to company influence over medicine use. They knew, for example, that hospitals with strong research agendas might build up well-established research teams, where salaries were funded by pharmaceutical industry money, and that this might create a level of institutional dependence on the industry. Some also spoke about the possibility that "longer-term relationships" between clinicians and drug companies might create "a risk that that can establish a bias in prescribing and a bias in preference." (Matthew, doctor).

3.4 | Strategies and solutions

We employed semi-structured interviews, a strength of which is to allow participants to define their interest in a topic and to share information they find most relevant. Many participants initiated discussion about how to mitigate against risks of pharmaceutical industry influence over medicine use within their local institutions, thus we developed this line of conversation into the analyses presented here (see Table 5). Their suggestions were aimed at all stakeholders, including local and regional DTCs, hospitals, departments, individual doctors and governments. Dominant ideas were: improved conflict of interest declarations in formulary and IPU application processes; more sharing of evidence evaluation and decisions between local DTCs particularly around new and uncertain products; and strengthened hospital policies to limit presence and activities of pharmaceutical sales representatives in local institutions. No participants suggested having a policy that DTC members must be free of industry relationships.

4 | DISCUSSION

The DTC members who we spoke with described standardised and well-defined DTC processes for oversight of availability and use of medicines through formulary and IPU mechanisms within the NSW public hospital setting. However, their descriptions also highlighted that points along the decision-making pathway are vulnerable to pharmaceutical industry influence, particularly the application process, which is commonly instigated and completed by company representatives rather than clinicians. Some DTCs are under-resourced and others may feel pressure to accept requests from local clinicians; industry generated submissions may be particularly problematic in those situations. Current conflicts of interest disclosure practices

TABLE 5 Recommendations for change to reduce the risk of industry influence in drug and therapeutics committee (DTC) processes (including explanatory comments from study participants where relevant)

Recommendations for DTC policies and practices.
Strict conflict of interest rules for committee members and clearer disclosure processes for applicants, including rejection of industry-completed applications.
"I don't want the drug company's assessment which is almost certainly going to be biased." (Arthur, doctor).
Routine review of applicant links with the pharmaceutical industry using transparency databases.
"Whenever I look, particularly at a high cost application or new drug, [I consider] 'Do I need to probe around possible conflicts with the pharmaceutical industry?' … I actually look at that list [of Medicines Australia information on industry payments to doctors] from time to time. … [W]who's receiving money from drug companies? [Who's] on their consulting boards? Opinion leaders? Who's getting travel?" (Arthur, doctor).
Independent search and evaluation of the evidence by local DTCs or centralised bodies.
"[DTCs should be] properly resourced … [to do a] full search … that takes time and you need people. "(Vince, doctor).
"I like the idea of a central committee for tricky decisions … I think for difficult IPUs [individual patient use applications] or difficult formulary applications, having a state-wide approach or second opinion type system would be actually really useful. But it would need to be resourced." (Erica, doctor).
"A group of drug committee people together who would work together to pre-empt all of that … to properly evaluate their request … to work out the guidelines [for accepting or rejecting formulary applications]." (Barry, doctor).
Improved resources to DTCs e.g. via access to all applications, evidence evaluations and DTC decisions nationally.
"So when someone approach[es] their drug committee and says, 'Okay we want to bang this on for this indication,' we [c]ould say 'Well, hang on, here's where we are.'" (Barry, doctor).
A centralised formulary may reduce the issue of clinician pressure on DTCs.
"The single formulary for the rurals … support[s] the DTCs to not be caught into that vicious circle, where some specialists may or may not be leaning on particular individuals within their own DTC. So, it gives a 1-step back objectivity to those decision-making processes." (Tom, doctor).
Regular DTC discussions with staff about pharmaceutical marketing.
"We do attempt to predict marketing, so with respect to [drug a] I had a conversation with the head of oncology more than a year ago that said 'You will begin to receive marketing regarding [drug a]. There'll be representations to you from [drug a] competitors. The TGA [Therapeutic Goods Administration, government drug regulator] has approved the product, but it's held up by patent litigation, so they can't promote quite yet, but we know it's going to come and we're going to want to have conversations with you … We'd like to have a talk about what your perceptions are about the product.' … Do people say 'Oh yes, you were right, I will never, ever talk to a rep again?' Of course not, absolutely not. They say 'Yeah, you know, we should talk about that.'" (Niall, doctor).
Recommendations for institutional policies and practices.
Any pharmaceutical industry donations go into a central pool rather than to a named department or clinician.
"We have a sponsorship policy in this organisation … if a drug company wanted to pay for a nurse to go to a conference we would say no. You make the donation to the organisation, the organisation will then apportion that the way that they think is appropriate. So if you make a donation you can stipulate the way the donation should be spent for education or something like that." (Owen, doctor).
Hospitals to fund lunchtime meetings, ban pharmaceutical industry funding for meals.
"I would provide lunch for every departmental meeting so people would come, and they would not be influenced." (Erica, doctor).
Provide regular, independent education to staff about new medicines.
"I would like to be able to use academic detailing to influence quality use of medicines in the hospitals." (Edward, doctor).
Ban or at least monitor pharmaceutical representative presence in hospitals.
"We should have some way of cataloguing who's come through the door, who of course would ideally be no one, but if they did, who they've seen and what they've been promoting … The dream is to get all drug company representatives out of our hospitals, not let them be there infiltrating our meetings, not let them provide samples direct to physicians … We shouldn't have them in hospitals at all, and certainly not speaking to people who make clinical decisions around drugs." (Erica, doctor).
Ban free samples or (at a minimum) regularly inform staff to ensure samples are housed and controlled by pharmacy.
"And so as soon as [it's found out that there are free samples in the clinic] they hit that on the head immediately, and they'll put a thing about it in the … doctor's newsletter … So, no, there's never free samples in our unit at all … it's got to be controlled by Pharmacy." (Wanda, nurse).
Monitor and mitigate risks associated with clinicians' financial relationships with pharmaceutical companies.
"Any kind of remuneration is actually in a register, so you have a record … of a relationship with a drug company, both from an individual point of view but also from a unit perspective. So if a drug company is buying lots of equipment for a department, not for an individual, then to me that's as important, the risk of influence, for the department as it is for the individual … [And you should have] surveillance that would pick up the person who is actually being deliberately deceptive … if you declared that you have no conflict of interest and you did then that is potentially fraud or we'd go down a more formal process." [Matthew, doctor]
Report companies that breach protocols to the government regulator or the pharmaceutical industry body.
"If we find the issues or problems, we are very quick to report those to the TGA [Therapeutic Goods Administration, government drug regulator], for example, for inappropriate advertising of a therapeutic benefit of something that's not a registered product or to Medicines Australia [pharmaceutical industry body] for anything that we see in any ads or any material that's being given to our staff in the hospital … or we've even reported a rep, when our complaint to the company was not satisfactorily resolved … we reported their behaviour to Medicines Australia and they got the company to withdraw the rep." (Ken, doctor).

TABLE 5 (Continued)

Recommendations for hospital departments and individual doctors.
Refuse pharmaceutical company funding for lunches at departmental meeting.
"Now some of the specialties have still, they have their weekly meeting and the drug companies come in to provide the sandwiches. [The subspecialty] which I'm a part of, decided 15 years ago we said, 'We're not going to have any drug companies, we'll bring our own lunch.'" (Barry, doctor).
Ban pharmaceutical representatives at meetings, tearooms.
"We decided a few years ago that we weren't going to have drug reps and things come up and discuss things at our department meetings or even come to the tea room to discuss things … we made a conscious decision to try and limit the influence as far as is possible … I think the evidence is pretty solid that if you have someone from a drug company come in and talk to you about a drug, it makes you more likely to at least think about prescribing the drug. So, wherever you get an opportunity to limit that influence is worthwhile." (Greg, doctor).
Educate staff about independent sources of drug information.
"Just modelling to them that there are better sources of information and we don't rely on drug companies. I think it's really important … AMH [Australian Medicines Handbook], fabulous book, the NPS [National Prescribing Service] resources, Radar if you're looking at your drugs." (Erica, doctor).
Recommendations for health departments.
Clearer regulation for pharmaceutical industry about limits of ethical marketing activities
"It would be good if the Health Department had some more clear policies specifically around patient-support benefits that might be seen to be supports to the doctor, that might influence the doctor's prescribing. It's a difficult area, because it's not immoral that a company would want to provide benefit to the patients that are using their product … It's not immoral that a company selling [drug y] would employ staff to answer telephone queries from patients. But it has the potential to create roundabout ways that impact on the cost to the hospital." (Niall, doctor).

amongst applicants and DTC members are incomplete, lagging behind policies for national and international bodies that assess drugs and medical devices[26] and behind standards for guideline development [27,28] and there is scope for improvement and tightening up of current policies. Despite clear guidance from the national Council of Australian TAGs (CATAG) that DTCs should oversee all free samples and medicines access programmes,[12] there is variation in practice, with some committees delegating responsibilities to individual clinicians, and some clinicians assuming responsibility against the expressed policy of the DTC. This means that there may be an underregulated pathway for pharmaceutical companies to provide prescription medicines in some institutions. Pharmaceutical companies engage in multiple types of marketing activities to public hospital staff within and beyond the confines of the workplace. In DTC members' experiences, prescriber demand for products closely followed marketing events. Improved DTC practices and review of hospital policies around pharmaceutical marketing activities might reduce the risk of negative industry influence over prescribing quality.

The dominant concern raised by participants around pharmaceutical company marketing to DTCs and hospital staff leading increased use of new and branded company medicines echoes the recent medical literature. New medications are often no more beneficial than older products,[29–31] are more likely to result in unforeseen serious adverse effects[32] and generally incur higher costs. In particular, the emergent field of so-called high-cost medicines places significant financial demands on healthcare institutions.[33] Pharmaceutical companies cultivate demand for new products amongst clinicians, encouraging them to use new products and/or apply to DTCs for formulary inclusion. They familiarise local clinicians with new medicines by offering them at no cost as samples or on access schemes. They indirectly promote new indications for old medicines by encouraging off-label use in public hospitals prior to, or instead of, submission for approval by national drug regulators, although this is in breach of Australian legislation.[22,34,35] Access programmes appear generous but several problems have been identified: they may raise false expectations amongst patients given that there is often a lack of robust evidence for efficacy; they do not contribute to research on real-world use since data on benefits and harms are not routinely collected; and they contribute to higher health expenditure since the costs are recouped by companies from future sales of medicines when access programmes end.[10] Sales representatives encourage doctors to prescribe branded products instead of generics or biosimilars, as a way of showing support for their company's research and development activity, claiming that they need high revenue to support this important work. However, there is already a generous system of patents to protect company profit margins, and income from sale of products is just as, if not more likely to go to marketing than to new research.[36]

This is the first interview study in Australia on interactions between DTCs and the pharmaceutical industry. Our identification of extensive drug company staff involvement in medicines application processes, which echoes findings about widespread industry influence over medical device purchasing in US hospitals,[37] raises concern that medicines availability and use is shaped by industry interests. These may not match the interests of the public or of institutional budgets. DTC decision-making in Australia has been criticised in the past for inconsistent outcomes and deficient processes,[22,34] including inadequate evaluation of the quality and bias of supporting evidence, and insufficient transparency about conflicts of interest. Our results show that some of these concerns are ongoing. In addition, DTCs have limited oversight regarding marketing to hospital staff, and many did not see this as part of their remit, despite it being a clearly identified responsibility of DTCs by the World Health Organisation.[38]

We suggest a multipronged approach to change (see Table 5). We urge DTCs to adopt additional decision-making processes similar to that used for the World Health Organisation Essential Medicines list,[39] with key features being: strict conflict of interest rules for

committee members and clear disclosures for all applications; an independent search for evidence; critical evaluation of the evidence by the committee; and open access to all applications and evidence evaluations so that committees can share resources. These practices should also apply to DTC oversight of medicines access programmes. Hospitals and government health departments will need to allocate funds for this, but costs could be recouped through reduced medicines expenditure.[40] We advocate for banning pharmaceutical sales representative presence in hospitals in favour of academic detailing,[41] and for Medicines Australia, the pharmaceutical industry trade association, to revise their Code of Conduct accordingly.

4.1 | Strengths and limitations

The strengths of this study are its empirical nature and the depth and breadth of interview responses received. We drew on the views and experiences of a diverse sample of committee members, and continued sampling until we were no longer hearing new information. We were able to provide a comprehensive picture of DTC oversight of medicines access and use in public hospitals, and how those processes might be vulnerable to industry influence. The study was confined to NSW, where DTCs operate at local and regional levels. In other countries and other Australian jurisdictions, the hierarchy of decision-making bodies is different, meaning that the responsibilities and roles of committees will vary across different locations. The costs and benefits of the proposals in Table 5 are unknown.

5 | CONCLUSION

DTC oversight of formulary, off-label use and medicines access programmes is vulnerable to industry influence and while DTC members are aware of pharmaceutical industry influence over local prescribers at least some consider it outside their responsibility or feel powerless to intervene. Minimising pharmaceutical industry influence and promoting rational, cost-effective prescribing is important for reducing safety risks associated with new medicines and limiting the costs associated with new medicines, including high cost medicines. DTCs have been described in this journal as the "guardians of safe and rational medicines use."[10] To allow them to fulfil this role, DTC practices and hospital policies around pharmaceutical company marketing should be revised and strengthened. We urge DTC members and hospital administrators to work together on matters such as implementing tighter restrictions on disclosure processes and on industry marketing in hospitals, in order to preserve the independence of evidence-based decision-making for safe, cost-effective prescribing.

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COMPETING INTERESTS

Alexandra Bennett works for NSW TAG, an independent body that supports drug and therapeutics committees in public hospitals across NSW. All other authors declare they have no conflicts of interest.

CONTRIBUTORS

L.P. participated in designing the study, collected all the data, participated in the data analysis and wrote the first and subsequent drafts of the manuscript. A.B. participated in designing the study, facilitated participant recruitment, participated in the data analysis and commented on all drafts, including reading and approving the final manuscript. B.M., Q.G., A.F., E.K. and L.B. participated in the design and data analysis and commented on all drafts, including reading and approving the final manuscript.

DATA AVAILABILITY STATEMENT

In the interests of protecting participant confidentiality and as per the details of participant consent, interview transcripts from this study are not available.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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