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Keywords:	pharmaceutical industry, transparency, industry relationships

Title page

Eroded transparency around Pharma payments to the healthcare sector in Australia: Observational database study

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Abstract

Objectives: To describe and quantify disclosed payments from the pharmaceutical industry to the healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system of transparency.

Design: Observational database study

Setting: Australia

Participants: Publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to April 2017).

Exposure: Changes to transparency reporting requirements with the updates of pharmaceutical industry Codes of Conduct in 2015.

Main outcome measures: Elements of healthcare sector spending that members of industry organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly average, pre and post October 2015).

Results: New transparency requirements from 2015 require disclosure of identification of recipients of Medicines Australia member funding, including individual medical professionals. Reporting of many hospitality and event costs has declined, with an overall 34.1% decrease in reported industry spending amongst Medicines Australia members, from $AUS 89,658,566 to $AUS 59,052,551.

Conclusions: This study shows the limitations of a self-regulatory system around industry disclosure of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory long-lasting public transparency.

Strengths and Limitations of this Study

- We compiled and analysed over 950 transparency reports on pharmaceutical industry payments to the Australian healthcare sector, including payments to medical practitioners and other healthcare professionals, third parties such as medical organisations and hospitals, and health consumer groups.
- We identified key changes in the industry's self-regulatory codes regarding transparency reporting and examined changes in disclosed spending occurring concurrently with these changes; our analysis could not determine causality.
- We relied on information provided by pharmaceutical companies in their transparency reports and did not verify the accuracy or completeness of the data
- Only member companies of Australia's pharmaceutical industry trade organisations are required to submit transparency reports, therefore our data do not reflect total spending and changes in membership status may impact disclosed payments.

Introduction

Financial relationships between healthcare professionals and the pharmaceutical industry influence healthcare.[1] Exposure of health professionals to the pharmaceutical industry is widespread[2] but the financial details and extent of these relationships may be unclear. The United States and some European countries have legislated mandatory reporting of payments from pharmaceutical and medical device manufacturers to healthcare professionals[3] and Ontario, Canada has recently introduced similar legislation.[4] Other jurisdictions rely on self-regulation governed by industry associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).[5]

Australia has previously been at the forefront of transparency reporting.[6] For example, the prominent trade association Medicines Australia (MA) introduced a self-regulatory transparency program over a decade ago, when its 2007 Code of Conduct required member companies to publically report their spending on educational events for health professionals.[7] Importantly, this included spending for "educational" events and spending on health professionals from many disciplines including nurses, pharmacists, physiotherapists and dieticians, as well as medical practitioners. The Generic and Biosimilar Medicines Association (GBMA), formerly the Generic Medicines Industry Association, introduced a similar requirement for its members in 2010, although this became non-compulsory in 2013.[8] GBMA also requested that members report "non-price benefits" to pharmacists, including, for example, provision of training, pharmacy aids, merchandising, software and vouchers.

In 2015, after pressure from the Australian Competition and Consumer Commission, Medicines Australia amended their Code to require public reporting of the amounts paid to individual health professionals. At the same time, however, the requirements to report on spending for educational events were watered down.[9] The GBMA followed suit, noting that 'Medicines Australia has removed this requirement [for educational event reporting] of its members', and citing the 'significant compliance burden placed on members' and the 'consistently demonstrated … appropriate conduct over the past five years' as further reasons to remove these reports on spending.[10p6] Unlike Medicines Australia, the GBMA did not introduce any requirements to report spending to individual practitioners, educational events run by third parties, or consumer groups. These transparency losses

were criticised at the time.[11] The objective of this paper is to describe changes in the types of spending disclosed and cumulative amount of spending following the 2015 changes in industry-regulated reporting requirements. In this paper we highlight exactly what information has been lost from the public record in Australia, and report on the impact of these changes.

Methods

We conducted an observational study of publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to April 2017).

Details on current and previous Medicines Australia and GBMA reporting requirements are available through their respective websites: https://medicinesaustralia.com.au/ and https://www.gbma.com.au/. We used the relevant Codes and/or related documents associated with the current[9] and previous[12] Medicines Australia Codes of Conduct, and the current[10] and previous[13] GBMA Codes of Practice to identify changes to transparency information required from organisation members.

Data sources and analysis. Transparency reports on Medicines Australia and GMBA member company spending are available through the respective industry body websites as separate reports (usually PDF files) for each company, reporting period, and report category. Our research group has previously downloaded and compiled Medicines Australia reports on educational events for healthcare professionals (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically accessible) and payments to individual healthcare professionals (May 2016 to Apr 2017), converting them into databases for research purposes and public use.[5,6] These data are publically available for download: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB and https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a respectively. The current project extends on this work by updating these pre-existing databases and compiling additional databases from more recent reports downloaded from Medicines Australia and GMBA. In total, this project employed 895 Medicines Australia reports (Oct 2011 - Apr 2017) collated into six distinct databases (see Table 1) detailing Medicines Australia member payments related to: (1) Educational Events for Healthcare

Professionals (Oct 2011 – Sep 2015); (2) Healthcare Professional Consultants (Jan 2013 – Sep 2015); (3) Advisory Board Meetings (Jan 2013 – Sep 2015); (4) Health Consumer Organisations (Jan 2013 – Dec 2016); (5) Third Party Educational Events (Oct 2015 - Apr 2017); (6) Individual Healthcare Professionals (Oct 2015 - Apr 2017). We also generated two databases (see Table 2) from the 64 available GBMA reports (Oct 2011 – Jun 2015) detailing GBMA member payments related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Jun 2015); and (2) Non-Price Benefits to Pharmacists (Oct 2011 – Jun 2015).

We identified 39 Medicines Australia members filing transparency reports in the year preceding the changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most recent period for which reports were requested by their industry body (i.e. ending June 2015), compared to none in the following year, and since.

Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each category as a monthly average over the given reported period. Change in total expenditure from Medicines Australia and GBMA member companies over time was used to assess the impact of changes in reporting requirements in October 2015 and July 2015 respectively.

Patient or public involvement. No patients or members of the public were involved in this study.

Ethical approval. None required.

Results

The changes to self-regulatory codes regarding transparency reporting in 2015 have resulted in increased transparency on specific items but a decrease in transparency regarding other items (Table 1). Specifically, there has been enhanced transparency around individual health care provider recipients of Medicines Australia member funding such that it is now possible to identify payments received by named healthcare professionals. However, the changes in 2015 resulted in reduced transparency around Medicines Australia member spending on running costs, including food and

beverages, for industry-run events and meetings; and hospitality to sponsored professionals attending events and meetings (See Table 1). In addition, there has been a complete loss of transparency around GBMA member spending on education and other forms of promotion within the healthcare sector (Table 2).

Figure 1 shows that the 2015 changes to the Medicines Australia and GBMA Codes were associated with a large overall reduction in reported spending. In the year preceding the regulatory changes, industry payments disclosed by Medicines Australia members totalled $AUS 89,658,566 (Oct 2014 – Sep 2015). The corresponding figure in the following year was $AUS 59,052,551, a drop of 34.1%.

An additional $AUS 2,580,402 (88.3% non-price benefits to pharmacists) in payments were disclosed by GMBA members in the year preceding regulatory change (Jul 2014 – Jun 2015), with $AUS 0 payments reported after this, a drop of 100%.

Discussion

Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient identities but an overall reduction in transparency around industry funding in the healthcare sector. Dropping the requirements for transparency around items such as expenditure on food and beverages means that over a third of industry spending on healthcare professionals is now hidden.

This erosion of transparency has taken place in a time of increasing societal interest in disclosure. The public have an expectation that all transfers of value between the pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and judge the appropriateness of such interactions. Transparency is unlikely to be a complete solution to concerns about commercial sway within the healthcare sector.[14] There are many other important elements involved in managing this issue, including, for example, stamping out clinical trials that seek to familiarise prescribers with new medications rather than add to scientific knowledge (so-called “seeding trials”), banning honorary authorships for healthcare professionals, and stopping the release of free drug samples into clinic rooms.[15] However transparency is a necessary first step towards assessing and analysing the level of

industry influence, and may act as a deterrent to individual professionals engaging inappropriately with industry.

Self-regulated transparency programs may avoid the usual checks and balances of a more formal regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical industry to make changes associated with significant reductions in disclosed spending. Self-regulated transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It also fails to regulate companies that are not members of the relevant industry body. We advocate for legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise loss of transparency data in ways such as we report on here. In this particular case, we recommend that the Australian Government introduce transparency legislation. We advocate for new legislation that maintains the current Medicines Australia transparency focus around spending on healthcare professionals and health consumer groups, and extends this requirement to include all companies in the pharmaceutical and medical device sector including GBMA members and companies with no affiliation to trade organisations. We also recommend that legislation should reinstate previously compulsory reporting of food, beverages and venue costs at company-run educational events and advisory board meetings; and food and beverages provided to individual healthcare professionals.

Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015 and post-2015 periods may be an under-estimate. There may be some companies that are not members of Medicines Australia or GBMA and hence do not disclose their spending. In addition, compliance with the GBMA Code was not compulsory for GBMA members from 2013,[16] so the true pre-2015 spending figure is likely to have been higher than our calculated figure. There may be inaccuracies in the spending disclosed by the companies in the original reports: we could not verify the accuracy and completeness of the data, but many companies do provide independent audits of their reports. The reduction in Medicines Australia member companies submitting reports, from 39 in the year prior to the change in reporting requirements to 34 after the change, contributed to the reduction in the cumulative disclosed sum, although was unlikely to have had a big impact. Together, these five companies only disclosed a total of $4,199,674 between October 2014 and September 2015,

which was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot prove a causal relationship between changing industry Codes and cumulative disclosed spending. We think it likely that current spending remains similar to 2015 levels, and that the apparent reduction in cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative spending may have truly decreased, or that spending patterns may have coincidently (or even deliberately) altered at the same time that the new Code came in, perhaps reflecting different ways of industry promotional spend in the healthcare sector that were not captured by the previous or current transparency program.

Once a leader in transparency, Australia is now falling behind other countries. This study provides a clear example of the limitations of a self-regulatory system, which can be quietly changed in such a way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend that countries insist on legislation rather than self-regulation to promote long-lasting public transparency around industry spending.

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Competing interests: The authors have no completing interests.

Contributors: All authors conceived of the study. LP wrote the first and subsequent drafts. EAK extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB participated in creating the original database and critically revised the manuscript. All authors reviewed and approved the final manuscript.

Patient and public involvement: Not required.

Ethics approval: Not required.

Data sharing statement: Limited data from this study are publically available. Data on Pharmaceutical Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are available at: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB. The Pharmaceutical Industry Payments to Healthcare Professionals (May 2016 to Apr 2017) database is available at: https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a. Neither of these available databases currently include all Educational Events Reports or Individual Payments Reports included in this manuscript.

Figure Legends and Tables

Table 1. Characteristics of reports from Medicines Australia members. Shading indicates major differences in data capture in current/ongoing versus discontinued reports.

	DISCONTINUED REPORTS			ONGOING REPORTS		
	Educational Event Reports	***HCP Consultants Reports***	***Advisory Board Meeting Reports***	**Health Consumer Organisation Support Reports**	**Third Party Educational Events Reports**	**Healthcare Professionals Report**
DESCRIPTION	*Payments related to educational events for HCPs that are held or sponsored by the company*	*Payments to HCPs for consultancy services/advice*	*Payments to HCPs contracted to provide advice to the company as part of an advisory board*	Support for not-for-profit organisations representing the interests of health consumers	Sponsorship of educational events for HCPs independently organised by a third party (e.g. hospital, medical organisation)	Payments to individual HCPs for provision of services or to engage in education
REPORTING PERIOD	*Oct 2011 – Sep 2015*[#]	*Jan 2013 – Sep 2015*	*Jan 2013 – Sep 2015*	Jan 2013 –	Oct 2015 –	Oct 2015 –
PAYMENTS REPORTED						
Educational events for HCPs held by the company						
Fees to individual HCPs for provision of services (e.g. speaking/chairing)	✓					✓
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓					✓[+]
Sponsorship of HCP for event attendance	✓			Payments no longer captured		

(food/beverages)				
Food and beverages at event	✓			
Event running costs (e.g. venue hire, event organiser)	✓			
Internal company meetings and consulting				
Fees to individual HCPs for consulting or other services (e.g. speaking/chairing)	✓			✓
Hospitality (accommodation, travel) associated with HCP services	✓			✓+
Hospitality (food/beverages) associated with HCP services	✓		Payments no longer captured	
Advisory boards				
Fees to advisory board members		✓		✓
Hospitality (accommodation, travel) for board members		✓		✓+
Hospitality (food/ beverages) for board members		✓	Payments no longer captured	
Food and beverages at meeting		✓		
Event running costs		✓		
Third party (independent) meetings				

Food and beverages at meeting	✓			✓‡	
Event running costs	✓			✓	
Trade display space	✓			✓	
Fees to HCP for provision of services (e.g. speaking, chairing)	✓				✓
Sponsorship of HCP for meeting attendance (accommodation, travel, registration)	✓				✓+
Sponsorship of HCP for meeting attendance (food/beverages)	✓		Payments no longer captured		
Health consumer organisation meetings					
Event sponsorship	Enhanced transparency from January 2013		✓		
Trade display space			✓		
Other support (e.g. publications)			✓		
REPORT FORMAT					
Itemised (per event/individual)	✓		✓	✓	✓
Aggregated (no. per period)		✓ ✓			§
Disclosure of recipient required	Enhanced transparency from October 2015		✓ (Organisation)	✓ (Third Party)	✓ (Individual HCP)§

HCP: Healthcare professional

Reports go back to 2007, but they are not available prior to Oct 2011

[+]Excludes ground transfers, taxis, parking.

[‡] Reporting is not required if food and beverages are the company's only contribution to the event.

[§] Prior to the introduction of mandatory reporting of payments to HCPs on 1 October 2016, disclosure of a HCP's identifying information was contingent on the consent of the HCP. All payments received by non-consenting HCPs were reported in aggregated format.

227 **Table 2: Characteristics of reports from GBMA members.**

	DISCONTINUED		ONGOING
	Educational Event Reports	**Non-Price Benefits to Pharmacists**	**NIL**
DESCRIPTION	Payments related to educational events for HCPs[1] that are held or sponsored by the company	Payments and benefits provided to pharmacists	
REPORTING PERIOD	Apr 2010 – Jun 2015	Jan 2010 – Jun 2015	Jul 2015 –
PAYMENTS REPORTED			
Educational events for HCPs held by the company			
Fees to individual HCPs for provision of services (e.g. speaking/chairing)	✓		Payments no longer captured
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓		
Sponsorship of HCP for event attendance (food/beverages)	✓		
Food and beverages at event	✓		
Event running costs (e.g. venue hire, event organiser)	✓		
Non-Price Benefits to Pharmacists			
Access to training and education events		✓	Payments no longer captured
Event running costs and hospitality		✓	
Pharmacy aids, software and merchandising		✓	
Small coupons/vouchers		✓	
REPORT FORMAT			
Itemised (per	✓		

event/individual)			
Aggregated (payments per period)		✓	
Disclosure of recipient required			

[1] Reports limited to prescribing HCPs and pharmacists

Figure 1. Cumulative monthly expenditure disclosed in transparency reports from Medicines Australia and GBMA members*

Legend: *arrow indicates date of change to Medicines Australia reporting requirements

NB: The health consumer organisation reports are submitted per calendar year, and therefore only extend to Dec 2016 rather than to April 2017. This doesn't impact the calculations in the text, but for the purpose of this graph, we have extrapolated the monthly average from Jan-Dec 2016 ($674,491.91) to cover the missing data Jan-April 2017.

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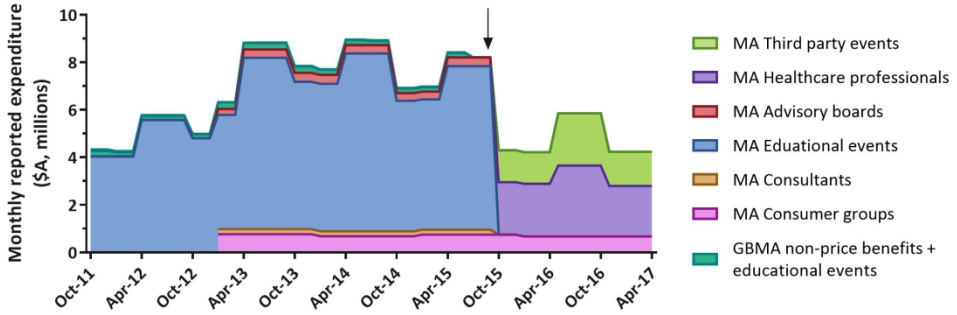

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NB: The health consumer organisation reports are submitted per calendar year, and therefore only extend to Dec 2016 rather than to April 2017. This doesn't impact the calculations in the text, but for the purpose of this graph, we have extrapolated the monthly average from Jan-Dec 2016 ($674,491.91) to cover the missing data Jan-April 2017.

207x80mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-6
Bias	9	Describe any efforts to address potential sources of bias	Not possible, discussed 7-8
Study size	10	Explain how the study size was arrived at	5-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5-6
		(*b*) Describe any methods used to examine subgroups and interactions	5-6
		(*c*) Explain how missing data were addressed	5-6
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
Outcome data	15*	Report numbers of outcome events or summary measures	6-7
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	9

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an observational study

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Primary Subject Heading:	Health policy
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Title page

Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an observational study

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Abstract

Objectives: To describe and quantify disclosed payments from the pharmaceutical industry to the healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system of transparency.

Design: Observational database study

Setting: Australia

Participants: Publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to Oct 2017).

Exposure: Changes to transparency reporting requirements with the updates of pharmaceutical industry Codes of Conduct in 2015.

Main outcome measures: Elements of healthcare sector spending that members of industry organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly average) in the year prior to and following the revision.

Results: There was a 34.1% reduction in disclosed spending from Medicines Australia member companies in the year after the 2015 changes to the Code of Conduct were introduced ($AUS 89,658,566 in the preceding year, Oct 2014 to Sep 2015; $AUS 59,052,551 in the following year). The new Code allowed for reduced reporting of spending on food and beverages at events and for sponsored healthcare professionals. However, there was enhanced transparency around identification of individual health professionals receiving payments. GBMA member reporting totalled $AUS 2,580,402 in the year prior to the revision, then ceased.

Conclusions: This study shows the limitations of a self-regulatory system around industry disclosure of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory long-lasting public transparency.

Article Summary

Strengths and Limitations of this Study

- We compiled and analysed over 900 transparency reports on pharmaceutical industry payments to the Australian healthcare sector, including payments to medical practitioners and other healthcare professionals, third parties such as medical organisations and hospitals, and health consumer groups.
- We identified key changes in the industry's self-regulatory codes regarding transparency reporting and examined changes in disclosed spending occurring concurrently with these changes; our analysis could not determine causality.
- We relied on information provided by pharmaceutical companies in their transparency reports and did not verify the accuracy or completeness of the data.
- Only member companies of Australia's pharmaceutical industry trade organisations are required to submit transparency reports, therefore our data do not reflect total spending and changes in membership status may affect disclosed payments.

Introduction

Financial relationships between healthcare professionals and the pharmaceutical industry influence healthcare.[1 2] Exposure of healthcare professionals to the pharmaceutical industry is widespread[3] but the financial details and extent of these relationships may be unclear. The United States and some European countries have legislated mandatory reporting of payments from pharmaceutical and medical device manufacturers to healthcare professionals[4] and Ontario, Canada has recently introduced similar legislation.[5] Other jurisdictions rely on self-regulation governed by industry associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).[6]

Australia has previously been at the forefront of transparency reporting.[7] For example, the pharmaceutical industry trade association Medicines Australia introduced a self-regulatory transparency program over a decade ago, when its 2007 Code of Conduct required member companies to publically report their spending on educational events for healthcare professionals.[8] Importantly, this included spending for "educational" events attended by healthcare professionals from many disciplines including nurses, pharmacists, physiotherapists and dieticians, as well as medical practitioners. The Generic and Biosimilar Medicines Association (GBMA), formerly the Generic Medicines Industry Association, introduced a similar requirement for its members in 2010, although this became non-compulsory in 2013.[9] GBMA also requested that members report "non-price benefits" to pharmacists, including, for example, provision of training, pharmacy aids, merchandising, software and vouchers.

In 2015, after pressure from the Australian Competition and Consumer Commission, Medicines Australia amended its Code to require public reporting of the amounts paid to individual healthcare professionals. At the same time, however, the requirements to report on spending for educational events were watered down.[10] The GBMA followed suit, noting that 'Medicines Australia has removed this requirement [for educational event reporting] of its members', and citing the 'significant compliance burden placed on members' and the 'consistently demonstrated … appropriate conduct over the past five years' as further reasons to remove these reports on spending.[11p6] Unlike Medicines Australia, the GBMA did not

introduce any requirements to report spending to individual healthcare professionals, educational events run by third parties, or consumer groups. These transparency losses were criticised at the time.[12] The objective of this paper is to describe changes in the types of spending disclosed and cumulative amount of spending following the 2015 changes in industry-regulated reporting requirements. We highlight exactly what information has been lost and gained from the public record in Australia, and report on the financial changes.

Methods

We conducted an observational study of publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to Oct 2017).

Details on current and previous Medicines Australia and GBMA reporting requirements are available through their respective websites: https://medicinesaustralia.com.au/ and https://www.gbma.com.au/. We used the relevant Codes and/or related documents associated with the current[10] and previous[13] Medicines Australia Codes of Conduct, and the current[11] and previous[14] GBMA Codes of Practice to identify changes to transparency information required from organisation members.

Data sources and analysis. Transparency reports on Medicines Australia and GMBA member company spending are available through the respective industry body websites as separate reports (usually PDF files) for each company, reporting period, and report category. Our research group has previously downloaded and compiled Medicines Australia reports on educational events for healthcare professionals (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically accessible) and payments to individual healthcare professionals (May 2016 to Apr 2017), converting them into databases for research purposes and public use.[6 7] These data are publically available for download: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB and https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a respectively. The current project extends on this work

by updating these pre-existing databases and compiling additional databases from more recent reports downloaded from Medicines Australia and GMBA. In total, this project employed 905 Medicines Australia reports (Oct 2011 - Dec 2017) collated into six distinct databases according to the report categories defined by Medicines Australia. Specifically, these databases contain reports on payments related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Sept 2015); (2) Healthcare Professional Consultants (Jan 2013 - Sep 2015); (3) Advisory Board Participation (Jan 2013 - Sep 2015); (4) Health Consumer Organisation Support (Jan 2013- Dec 2017); (5) Third Party Meeting Sponsorship (Oct 2015 – Oct 2017); (6) Payments to Healthcare Professionals (Oct 2015 – Oct 2017). We generated two databases from the 64 available GBMA reports detailing GBMA member payments related to: (1) Educational Events (for healthcare professionals) ; and (2) Non-Price Benefits to Pharmacists. See Table 1 for a description of each category and Figure 1 for a timeline of available reports. Further information about each report category is provided in Supplementary Files 1 and 2.

Table 1 – Description of required reporting categories from Medicines Australia and GBMA members

Report category	Dates reported	Description	Payments reported
MEDICINES AUSTRALIA REPORTS			
Educational Events for Healthcare Professionals	Jul 2007 - Sep 2015[a]	Payments related to educational events for HCPs that are held by the company or a third party (e.g. hospital, medical organisation)	Fees to individual HCPs for services at events (e.g. speaking, chairing) Sponsorship to individual HCPs to cover costs of event attendance (e.g. registration, travel, accommodation, food and beverages)

			Event running costs (e.g. venue hire, food and beverages)
Healthcare Professional Consultants	Jan 2013 - Sep 2015	Payments to HCPs for consultancy services	Consultant fees and associated costs (e.g. travel, accommodation, food and beverages)
Advisory Board Participation	Jan 2013 - Sep 2015	Payments to HCPs contracted to provide advice to the company as part of an advisory board	Advisory Board participation fees Board meeting running costs (e.g. food and beverages; venue hire; costs associated with HCP attendance including travel, accommodation, food and beverages)
Health Consumer Organisation Support	Jan 2013 - ongoing	Support to not-for-profit organisations representing the interests of health consumers	Financial and non-financial support (e.g. for events, activities, publications)
Third Party Meeting Sponsorship	Oct 2015- ongoing	Payments related to educational events for HCPs that are held by a third party (e.g. hospital, medical organisation)	Fees to individual HCPs for services at third party events (e.g. speaking, chairing) Sponsorship to individual HCPs to cover costs of attendance at third party events (e.g. registration, travel, accommodation)

Payments to Healthcare Professionals	Oct 2015-ongoing	Payments to individual HCPs for providing advice or other services or to attend educational events	HCP service fees (e.g. advisory board participation, consultancy, speaking or chairing at events) Sponsorship to individual HCPs to cover costs of attendance at events (registration, travel, accommodation)
GBMA REPORTS			
Educational Events	Apr 2010 Jun 2015 [a]	Payments related to educational events for HCPs that are held by the company or a third party (e.g. hospital, medical organisation)	Fees to individual HCPs for services at events (e.g. speaking, chairing) Sponsorship to individual HCPs to cover costs of event attendance (e.g. registration, travel, accommodation, food and beverages) Event running costs (e.g. venue hire, food and beverages)
Non-Price Benefits to Pharmacists	Dec 2010-Jun 2015[a]	Sales incentives provided to pharmacists	e.g. pharmacy aids, merchandising, vouchers, access to training opportunities

[a]Data presented from Oct 2011

Figure 1. Timeline of required reporting by Medicines Australia and GBMA members according to industry defined categories (see Table 1 for further information)

Figure 1 footnotes:

- Dates are approximate only
- Educational Events disclosures started July 2007
- The Payments to Healthcare Professionals category is a partial merger (with some exclusions) of three former categories: Healthcare Professional Consultants; Advisory Board Participation; Educational Events
- The Third Party Educational Events category is a subset of the former Educational Events category

We identified 39 Medicines Australia members filing transparency reports in the year preceding the changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most recent period for which reports were requested by their industry body (i.e. ending June 2015), compared to none in the following year, and since.

Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each category as a monthly average over the given reporting period. Change in total expenditure from Medicines Australia and GBMA member companies over time was used to assess the impact of changes in reporting requirements in October 2015 and July 2015 respectively.

Patient or public involvement. No patients or members of the public were involved in this study.

Ethical approval. None required.

Results

The 2015 changes to the Medicines Australia code resulted in merging and crossover of pre-existing reporting categories, as well as inclusion of some new elements and discontinuation of others. For example, information formerly captured in the Educational Events Database is now reported in the Third Party and Healthcare Professional databases. The main required reporting elements in the old and new Medicines Australia Codes of Conduct are listed in Table 2 with further details in Supplementary Files 1 and 2. The transparency gains and losses from Medicines Australia and GBMA members are summarised in Table 3.

Table 2. Types of payments publically reported by Medicines Australia members before and after the change to reporting requirements in October 2015.

	Pre Oct-2015	Post Oct 2015
Payments to HCP consultants[a]		
Fees for provision of services	✓	✓
Sponsorship of HCP for educational event attendance (travel, accommodation)	✓	✓#
Sponsorship of HCP for educational event attendance (food and beverages)	✓	
Payments related to company-run educational events and advisory boards[b]		
Fees for provision of services (e.g. speaking, chairing, advisory board participation)	✓	✓
Event registration costs	✓	✓
Sponsorship of HCP for educational event and meeting attendance (travel, accommodation)	✓	✓#
Sponsorship of HCP for educational event and meeting attendance (food and beverages)	✓	
Food and beverages at meeting	✓	
Event running costs (e.g. venue hire, event organiser, trade displays)	✓	
Payments related to third party (independent) educational events[c]		
Fees for provision of services (e.g. speaking, chairing)	✓	✓
Event registration costs	✓	✓

Sponsorship of HCP for meeting attendance (travel, accommodation)	✓	✓[#]
Sponsorship of HCP for meeting attendance (food and beverages)	✓	
Food and beverages at event	✓	✓[+]
Other event costs (e.g. venue hire, event organiser, trade displays)	✓	✓
Payments to health consumer organisations[d]		
Sponsorship, trade displays for consumer events	✓	✓
Other (e.g. publications)	✓	✓

HCP: Healthcare professional

[a]Captured in the HCP Consultants Reports (pre-2015) and HCP Reports (post-2015)

[b]Captured in the Educational Events and Advisory Board Reports (pre-2015) and HCP Reports (post-2015)

[c]Captured in the Educational Events Reports (pre-2015), and Third Party and HCP Reports (post-2015)

[d]Captured in the Health Consumer Organisation Reports (pre- and post-2015)

[#]Airfares only

[+]Reporting is not required if food and beverages are the company's only contribution to the event.

Table 3. Summary of gains and loss in current Medicines Australia and GBMA reports compared with pre-2015 reports.

Gains	Losses
Identification of healthcare professionals receiving payments from Medicines Australia member companies for provision of services or sponsorship for event attendance (registration costs, travel, accommodation)	Spending from Medicines Australia member companies associated with:- - Food and beverages and small travel costs (taxis, ground transfers) to sponsored HCPs attending or providing services at educational events - Event running costs (e.g. venue hire, event organiser, food and beverages for industry-run events and advisory board meetings

	- Food and beverages served at third party events where no other sponsorship was provided All GBMA member company payments related to educational events and non-price benefits for pharmacists

In the year preceding the 2015 changes to the Medicines Australia code, industry payments disclosed by Medicines Australia members totalled $AUS 89,658,566 (Oct 2014 to Sep 2015) across four reporting categories. Reported payments included $74,264,438 (82.8%) on Educational Events run by the company or third party, $8,743,250 (9.8%) on Health Consumer Organisation Support, $4,158,819 (4.6%) on costs associated with Advisory Board Participation, and $2,492,059 (2.8%) on Healthcare Professional Consultants.

In the year following the 2015 change, reported payments from Medicines Australia members totalled $59,205,301 (Oct 2015 to Sep 2016), an overall reduction of 34.1%. Payments reported in the new categories, Healthcare Professional Reports and Third Party Educational Events, totalled $30,380,145 and $20,364,929 respectively. There was little change in the total reported expenditure on Health Consumer Organisation Support ($8,461,228), which was the only reporting category to remain unchanged in the revised code (See Figure 2). Excluding payments associated with this category, there was a 37.3% reduction in disclosed Medicines Australia payments. As shown in Table 2 the reduction in disclosed payments coincides with loss of information about spending on: running costs for industry-run events and meetings (including food and beverages); hospitality to sponsored healthcare professionals attending events and meetings.

Figure 2. Cumulative monthly expenditure disclosed in transparency reports from Medicines Australia and GBMA members*

Legend: *arrow indicates date of change to Medicines Australia reporting requirements

In the year preceding the 2015 changes to the GBMA code, industry payments disclosed by GBMA members totalled $AUS 2,580,402 (Jul 2014 – Jun 2015). 88.3% of these reported payments were for Non-Price Benefits to Pharmacists and the remainder were for Educational Events. After July 2015, $AUS 0 payments have been reported by GBMA members, a drop of 100%.

Discussion

Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient identities but an overall reduction in transparency around industry funding in the healthcare sector. Dropping the requirements for transparency around items such as expenditure on food and beverages means that over a third of previously reported industry spending on healthcare professionals is now hidden. In addition, the new Code failed to include other disclosures about industry interactions with health professionals that countries such as the UK and USA have introduced, such as pharmaceutical company spending on free drug samples and funding for research.[6] The changes have also added an extra layer of complexity to what is already difficult-to-understand data on disclosed payments. This complexity hinders transparency.

This erosion of transparency has taken place in a time of increasing societal interest in disclosure. Transparency around pharmaceutical industry spending in the healthcare sector is important for several reasons. First, the public have a legitimate expectation that all transfers of value between the pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and judge the appropriateness of such interactions. Second, transparency may assist those reading or receiving the disclosure to judge the risk of bias in those making the disclosure. For example, disclosures of competing interests by research authors makes academic readers more critical of an article.[15] Receiving conflicts of

interest information may, however, have limited impact on the audience. Individuals disclosing conflicts of interest are more likely to exaggerate their claims,[16] and even critical readers tend not to sufficiently discount the credibility of biased information sources,[17] Third, transparency requirements may change behaviour of those making the disclosure. In situations where disclosures are required or expected, individuals may avoid accepting the conflicts of interest in order to avoid making the declaration [18] and the same may apply to corporations. For example, if industry is required to declare costs associated with food and beverage provision at third party events such as medical grand rounds and journal clubs, they may be less likely to provide this kind of sponsorship. While doctors may be disappointed at the reduction in 'free' lunches, this change would reduce industry influence on healthcare, because receipt of industry-sponsored meals, even low-cost meals, influences doctors to prescribe more of the brand-name drug being promoted at the time.[1]

The erosion of organisational transparency that we document in the paper is particularly significant. Although disclosure is a burden for the pharmaceutical industry, organisational transparency has the advantage of not relying on disclosures from individual healthcare professionals. These disclosures are potentially counterproductive since patients may feel extra pressure to follow the advice of those who declare conflicts of interests, in order to avoid implying distrust of their practitioner.[16 19] Dropping organisational disclosure of food and beverage spending also seems to send the wrong message to potential recipients, i.e. that this transfer of value is not significant enough to warrant reporting. As a result, doctors may be more likely to participate in industry-sponsored lunches,

Transparency is unlikely to be a complete solution to concerns about commercial influence within the healthcare sector.[20] There are many other important elements involved in managing this issue, including, for example, the prohibition of: clinical trials that seek to familiarise prescribers with new medications rather than add to scientific knowledge (so-called "seeding trials"), honorary authorships for healthcare professionals, and the release of free drug samples into clinic rooms.[21] However transparency is a

necessary first step towards assessing and analysing the level of industry influence, and may act as a deterrent to inappropriate interactions between individual professionals and industry.

Self-regulated transparency programs may avoid the usual checks and balances of a more formal regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical industry to make changes associated with significant reductions in disclosed spending. Self-regulated transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It also fails to regulate companies that are not members of the relevant industry body. We advocate for legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise loss of transparency data in ways such as we report on here. In this particular case, we recommend that the Australian Government introduce transparency legislation. We recommend new legislation that maintains the current Medicines Australia transparency focus around spending on healthcare professionals and health consumer groups, and extends this requirement to include all companies in the pharmaceutical and medical device sector including GBMA members and companies with no affiliation to trade organisations. We propose mandatory disclosure on spending on drug samples and research. We also recommend that legislation should reinstate previously compulsory reporting of aggregated food, beverages and venue costs at company-run educational events and advisory board meetings; and food and beverages provided to individual healthcare professionals where costs per head are over a minimum amount as required by the US legislation.

Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015 and post-2015 periods may be an under-estimate. There are companies that are not members of Medicines Australia or GBMA and hence do not disclose their spending. In addition, compliance with the GBMA Code was not compulsory for GBMA members from 2013,[22] so the true pre-2015 spending figure is likely to have been higher than our calculated figure. There may be inaccuracies in the spending disclosed by the companies in the original reports: we could not verify the accuracy and completeness of the data, but many companies do provide independent audits of their reports. The reduction in Medicines

Australia member companies submitting reports, from 39 in the year prior to the change in reporting requirements to 34 after the change, contributed to the reduction in the cumulative disclosed sum, although was unlikely to have had a big impact. Together, these five companies only disclosed a total of $4,199,674 between October 2014 and September 2015, which was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot prove a causal relationship between changing industry Codes and cumulative disclosed spending. We think it likely that current spending remains similar to 2015 levels, and that the apparent reduction in cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative spending may have truly decreased, or that spending patterns may have coincidently (or even deliberately) altered at the same time that the new Code came in, perhaps reflecting different ways of industry promotional spend in the healthcare sector that were not captured by the previous or current transparency program. Finally, as mentioned above, the program of required reporting is complex, and changes are difficult to follow. There may be some elements that we have misinterpreted.

Once a leader in transparency, Australia is now falling behind other countries. This study provides a clear example of the limitations of a self-regulatory system, which can be quietly changed in such a way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend that countries insist on legislation rather than self-regulation to promote long-lasting public transparency around industry spending.

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Contributors: All authors conceived of the study. LP wrote the first and subsequent drafts. EAK extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB participated in creating the original database and critically revised the manuscript. All authors reviewed and approved the final manuscript.

Patient and public involvement: Not required.

Ethics approval: Not required.

Data sharing statement: Limited data from this study are publically available. Data on Pharmaceutical Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are available at: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB. The Pharmaceutical Industry Payments to Healthcare Professionals (May 2016 to Apr 2017) database is available at: https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a. Neither of these available databases currently include all Educational Events Reports or Individual Payments Reports included in this manuscript.

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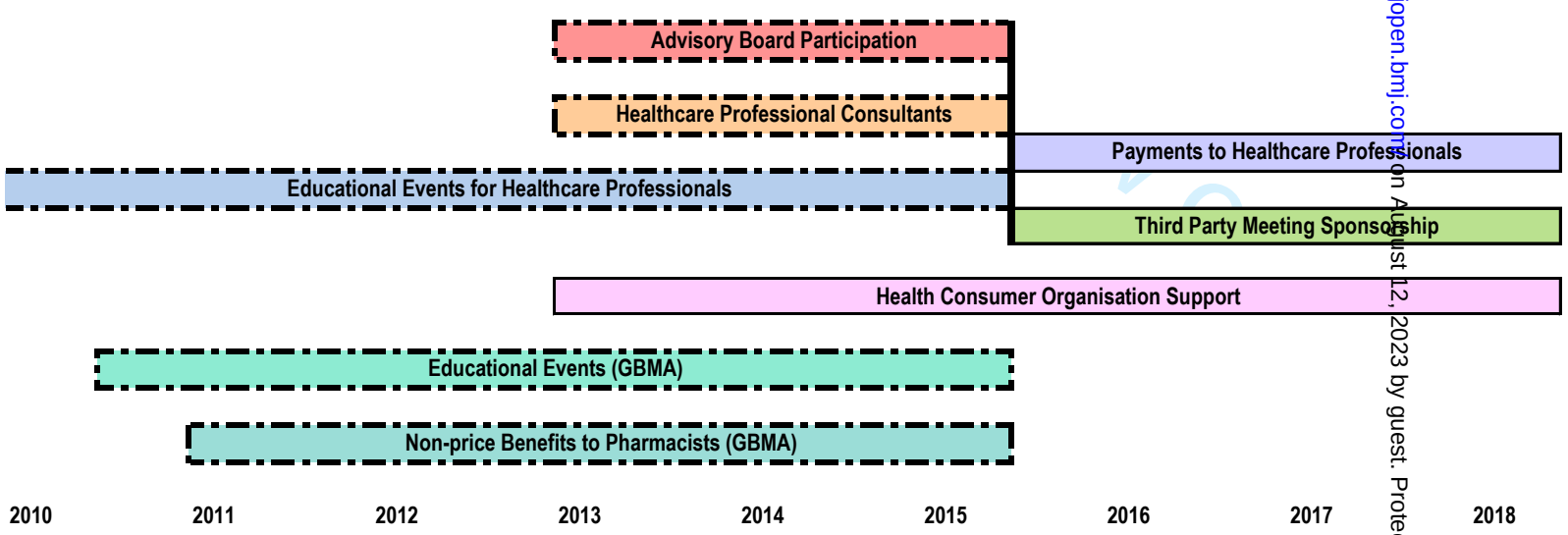

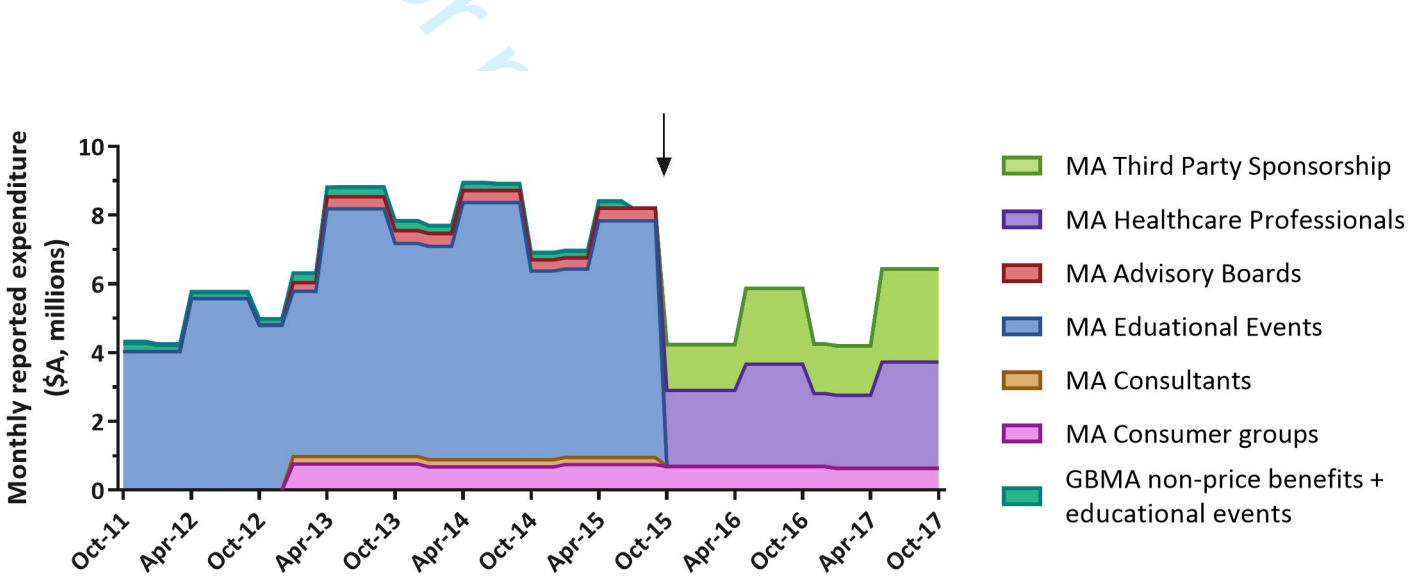

Supplementary File 1. Characteristics of reports from Medicines Australia members. Shading indicates major differences in data capture in current/ongoing versus discontinued reports.

	DISCONTINUED REPORTS			ONGOING REPORTS		
	Educational Events for Healthcare Professionals	***Healthcare Professional Consultants***	***Advisory Board Participation***	**Health Consumer Organisation Support**	**Third Party Meeting Sponsorship**	**Payments to Healthcare Professionals**
DESCRIPTION	*Payments related to educational events for HCPs that are held or sponsored by the company*	*Payments to HCPs for consultancy services/advice*	*Payments to HCPs contracted to provide advice to the company as part of an advisory board*	Support for not-for-profit organisations representing the interests of health consumers	Sponsorship of educational events for HCPs independently organised by a third party (e.g. hospital, medical organisation)	Payments to individual HCPs for provision of services or to engage in education
REPORTING PERIOD	*Oct 2011 – Sep 2015*[#]	*Jan 2013 – Sep 2015*	*Jan 2013 – Sep 2015*	Jan 2013 –	Oct 2015 –	Oct 2015 –
PAYMENTS REPORTED						
Educational events for HCPs held by the company						
Fees to individual HCPs for provision of services (e.g. speaking/chairing)	✓					✓
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓					✓[+]
Sponsorship of HCP for event attendance (food/beverages)	✓			Payments no longer captured		
Food and	✓					

beverages at event				
Event running costs (e.g. venue hire, event organiser)	✓			
Internal company meetings and consulting				
Fees to individual HCPs for consulting or other services (e.g. speaking/chairing)		✓		✓
Hospitality (accommodation, travel) associated with HCP services		✓		✓+
Hospitality (food/beverages) associated with HCP services		✓	Payments no longer captured	
Advisory boards				
Fees to advisory board members		✓		✓
Hospitality (accommodation, travel) for board members		✓		✓+
Hospitality (food/ beverages) for board members		✓	Payments no longer captured	
Food and beverages at meeting		✓		
Event running costs		✓		
Third party (independent) meetings				
Food and beverages at	✓		✓‡	

meeting					
Event running costs	✓			✓	
Trade display space	✓			✓	
Fees to HCP for provision of services (e.g. speaking, chairing)	✓				✓
Sponsorship of HCP for meeting attendance (accommodation, travel, registration)	✓				✓+
Sponsorship of HCP for meeting attendance (food/beverages)	✓		Payments no longer captured		
Health consumer organisation meetings					
Event sponsorship	Enhanced transparency from January 2013		✓		
Trade display space			✓		
Other support (e.g. publications)			✓		
REPORT FORMAT					
Itemised (per event/individual)	✓		✓	✓	✓
Aggregated (no. per period)		✓ ✓			§
Disclosure of recipient required	Enhanced transparency from October 2015		✓ (Organisation)	✓ (Third Party)	✓ (Individual HCP)§

HCP: Healthcare professional

Reports go back to 2007, but they are not available prior to Oct 2011

[+]Excludes ground transfers, taxis, parking.

[‡] Reporting is not required if food and beverages are the company's only contribution to the event.

[§] Prior to the introduction of mandatory reporting of payments to HCPs on 1 October 2016, disclosure of a HCP's identifying information was contingent on the consent of the HCP. All payments received by non-consenting HCPs were reported in aggregated format.

Supplementary File 2: Characteristics of reports from GBMA members.

	DISCONTINUED		ONGOING
	Educational Events	**Non-Price Benefits to Pharmacists**	**NIL**
DESCRIPTION	Payments related to educational events for HCPs[1] that are held or sponsored by the company	Payments and benefits provided to pharmacists	
REPORTING PERIOD	Apr 2010 – Jun 2015	Jan 2010 – Jun 2015	Jul 2015 –
PAYMENTS REPORTED			
Educational events for HCPs held by the company			
Fees to individual HCPs for provision of services (e.g. speaking/chairing)	✓		Payments no longer captured
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓		
Sponsorship of HCP for event attendance (food/beverages)	✓		
Food and beverages at event	✓		
Event running costs (e.g. venue hire, event organiser)	✓		
Non-Price Benefits to Pharmacists			
Access to training and education events		✓	Payments no longer captured
Event running costs and hospitality		✓	
Pharmacy aids, software and merchandising		✓	
Small coupons/vouchers		✓	
REPORT FORMAT			

Itemised (per event/individual)	✓		
Aggregated (payments per period)		✓	
Disclosure of recipient required			

[1] Reports limited to prescribing HCPs and pharmacists

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-6
Bias	9	Describe any efforts to address potential sources of bias	Not possible, discussed 7-8
Study size	10	Explain how the study size was arrived at	5-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5-6
		(*b*) Describe any methods used to examine subgroups and interactions	5-6
		(*c*) Explain how missing data were addressed	5-6
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
Outcome data	15*	Report numbers of outcome events or summary measures	6-7
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	9

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an observational study

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Title page

Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an observational study

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Abstract

Objectives: To describe and quantify disclosed payments from the pharmaceutical industry to the healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system of transparency.

Design: Observational database study

Setting: Australia

Participants: Publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to Oct 2017).

Exposure: Changes to transparency reporting requirements with the updates of pharmaceutical industry Codes of Conduct in 2015.

Main outcome measures: Elements of healthcare sector spending that members of industry organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly average) in the year prior to and following the revision.

Results: There was a 34.1% reduction in disclosed spending from Medicines Australia member companies in the year after the 2015 changes to the Code of Conduct were introduced ($AUS 89,658,566 in the preceding year, Oct 2014 to Sep 2015; $AUS 59,052,551 in the following year). The new Code allowed for reduced reporting of spending on food and beverages at events and for sponsored healthcare professionals. However, there was enhanced transparency around identification of individual health professionals receiving payments. GBMA member reporting totalled $AUS 2,580,402 in the year prior to the revision, then ceased.

Conclusions: This study shows the limitations of a self-regulatory system around industry disclosure of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory long-lasting public transparency.

Article Summary

Strengths and Limitations of this Study

- We compiled and analysed over 900 transparency reports on pharmaceutical industry payments to the Australian healthcare sector, including payments to medical practitioners and other healthcare professionals, third parties such as medical organisations and hospitals, and health consumer groups.
- We identified key changes in the industry's self-regulatory codes regarding transparency reporting and examined changes in disclosed spending occurring concurrently with these changes; our analysis could not determine causality.
- We relied on information provided by pharmaceutical companies in their transparency reports and did not verify the accuracy or completeness of the data.
- Only member companies of Australia's pharmaceutical industry trade organisations are required to submit transparency reports, therefore our data do not reflect total spending and changes in membership status may affect disclosed payments.

Introduction

Financial relationships between healthcare professionals and the pharmaceutical industry influence healthcare.[1 2] Exposure of healthcare professionals to the pharmaceutical industry is widespread[3] but the financial details and extent of these relationships may be unclear. The United States and some European countries have legislated mandatory reporting of payments from pharmaceutical and medical device manufacturers to healthcare professionals[4] and Ontario, Canada has recently introduced similar legislation.[5] Other jurisdictions rely on self-regulation governed by industry associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).[6]

Australia has previously been at the forefront of transparency reporting.[7] For example, the pharmaceutical industry trade association Medicines Australia introduced a self-regulatory transparency program over a decade ago, when its 2007 Code of Conduct required member companies to publically report their spending on educational events for healthcare professionals.[8] Importantly, this included spending for "educational" events attended by healthcare professionals from many disciplines including nurses, pharmacists, physiotherapists and dieticians, as well as medical practitioners. The Generic and Biosimilar Medicines Association (GBMA), formerly the Generic Medicines Industry Association, introduced a similar requirement for its members in 2010, although this became non-compulsory in 2013.[9] GBMA also requested that members report "non-price benefits" to pharmacists, including, for example, provision of training, pharmacy aids, merchandising, software and vouchers.

In 2015, after pressure from the Australian Competition and Consumer Commission, Medicines Australia amended its Code to require public reporting of the amounts paid to individual, identified healthcare professionals. At the same time, however, the requirements to report on spending for educational events were watered down.[10] The GBMA followed suit, noting that 'Medicines Australia has removed this requirement [for educational event reporting] of its members', and citing the 'significant compliance burden placed on members' and the 'consistently demonstrated … appropriate conduct over the past five years' as further reasons to remove these reports on spending.[11p6] Unlike Medicines Australia, the GBMA did not introduce any requirements to report spending to individual

healthcare professionals, educational events run by third parties, or consumer groups. These transparency losses were criticised at the time.[12] The objective of this paper is to describe changes in the types of spending disclosed and cumulative amount of spending following the 2015 changes in industry-regulated reporting requirements. We highlight exactly what information has been lost and gained from the public record in Australia, and report on the financial changes.

Methods

We conducted an observational study of publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to Oct 2017).

Details on current and previous Medicines Australia and GBMA reporting requirements are available through their respective websites: https://medicinesaustralia.com.au/ and https://www.gbma.com.au/. We used the relevant Codes and/or related documents associated with the current[10] and previous[13] Medicines Australia Codes of Conduct, and the current[11] and previous[14] GBMA Codes of Practice to identify changes to transparency information required from organisation members.

Data sources and analysis. Transparency reports on Medicines Australia and GMBA member company spending are available through the respective industry body websites as separate reports (usually PDF files) for each company, reporting period, and report category. Our research group has previously downloaded and compiled Medicines Australia reports on Educational Events for Healthcare Professionals (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically accessible), and Payments to Healthcare Professionals (May 2016 to Apr 2017), converting them into databases for research purposes and public use.[6 7] These data are publically available for download: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB and https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a respectively. The current project extends on this work by updating these pre-existing databases and compiling additional databases from more recent reports downloaded from Medicines Australia and GMBA. In total, this project employed 905 Medicines Australia reports (Oct 2011 - Dec 2017) collated into six distinct databases according to the

report categories defined by Medicines Australia. Specifically, these databases contain reports on payments related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Sept 2015); (2) Healthcare Professional Consultants (Jan 2013 - Sep 2015); (3) Advisory Board Participation (Jan 2013 - Sep 2015); (4) Health Consumer Organisation Support (Jan 2013- Dec 2017); (5) Third Party Meeting Sponsorship (Oct 2015 – Oct 2017); (6) Payments to Healthcare Professionals (Oct 2015 – Oct 2017). We generated two databases from the 64 available GBMA reports detailing GBMA member payments related to: (1) Educational Events (for healthcare professionals) ; and (2) Non-Price Benefits to Pharmacists. See Table 1 for a description of each category and Figure 1 for a timeline of available reports. Further information about each report category is provided in Supplementary Files 1 and 2.

Table 1 – Description of required reporting categories from Medicines Australia and GBMA members

Report category	Dates reported	Description	Payments reported
MEDICINES AUSTRALIA REPORTS			
Educational Events for Healthcare Professionals	Jul 2007 - Sep 2015[a]	Payments related to educational events for HCPs that are held by the company or a third party (e.g. hospital, medical organisation)	Fees to HCPs for services at events (e.g. speaking, chairing) Sponsorship to HCPs to cover costs of event attendance (e.g. registration, travel, accommodation, food and beverages) Event running costs (e.g. venue hire, food and beverages)

Healthcare Professional Consultants	Jan 2013 - Sep 2015	Payments to HCPs for consultancy services	Consultant fees and associated costs (e.g. travel, accommodation, food and beverages)
Advisory Board Participation	Jan 2013 - Sep 2015	Payments to HCPs contracted to provide advice to the company as part of an advisory board	Advisory Board participation fees Board meeting running costs (e.g. food and beverages; venue hire; costs associated with HCP attendance including travel, accommodation, food and beverages)
Health Consumer Organisation Support	Jan 2013 - ongoing	Support to not-for-profit organisations representing the interests of health consumers	Financial and non-financial support (e.g. for events, activities, publications)
Third Party Meeting Sponsorship	Oct 2015-ongoing	Payments related to educational events for HCPs that are held by a third party (e.g. hospital, medical organisation)	Fees to HCPs for services at third party events (e.g. speaking, chairing) Sponsorship to HCPs to cover costs of attendance at third party events (e.g. registration, travel, accommodation)[b] Event running costs (e.g. venue hire, food and beverages)[c]
Payments to Healthcare Professionals	Oct 2015-ongoing	Payments to individual, identified HCPs for	HCP service fees (e.g. advisory board participation, consultancy, speaking or chairing at events)

		providing advice or other services or to attend educational events[d]	Sponsorship to HCPs to cover costs of attendance at events (registration, travel, accommodation)
GBMA REPORTS			
Educational Events	Apr 2010 Jun 2015 [a]	Payments related to educational events for HCPs that are held by the company or a third party (e.g. hospital, medical organisation)	Fees to HCPs for services at events (e.g. speaking, chairing) Sponsorship to HCPs to cover costs of event attendance (e.g. registration, travel, accommodation, food and beverages) Event running costs (e.g. venue hire, food and beverages)
Non-Price Benefits to Pharmacists	Dec 2010-Jun 2015[a]	Sales incentives provided to pharmacists	e.g. pharmacy aids, merchandising, vouchers, access to training opportunities

[a]Data presented from Oct 2011

[b]Airfares only; excludes ground transfers, taxis, parking.

[c]Reporting is not required if food and beverages are the company's only contribution to the event.

[d]Prior to 1 October 2016, disclosure of a HCP's identifying information was continent on the consent of the HCP. All payments received by non-consenting HCPs were reported in aggregated format.

Figure 1. Timeline of required reporting by Medicines Australia and GBMA members according to industry defined categories (see Table 1 for further information)

Figure 1 footnotes:

- Dates are approximate only
- Educational Events disclosures started July 2007

- The Payments to Healthcare Professionals category is a partial merger (with some exclusions) of three former categories: Healthcare Professional Consultants; Advisory Board Participation; Educational Events
- The Third Party Educational Events category is a subset of the former Educational Events category

We identified 39 Medicines Australia members filing transparency reports in the year preceding the changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most recent period for which reports were requested by their industry body (i.e. ending June 2015), compared to none in the following year, and since.

Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each category as a monthly average over the given reporting period. Change in total expenditure from Medicines Australia and GBMA member companies over time was used to assess the impact of changes in reporting requirements in October 2015 and July 2015 respectively.

Patient or public involvement. No patients or members of the public were involved in this study.

Ethical approval. None required.

Results

The 2015 changes to the Medicines Australia code resulted in merging and crossover of pre-existing reporting categories, as well as inclusion of some new elements and discontinuation of others. For example, information formerly captured in the Educational Events Database is now reported in the Third Party and Healthcare Professional databases. The main required reporting elements in the old and new Medicines Australia Codes of Conduct are listed in Table 2 with further details in Supplementary Files 1 and 2. The transparency gains and losses from Medicines Australia and GBMA members are summarised in Table 3.

Table 2. Types of payments publically reported by Medicines Australia members before and after the change to reporting requirements in October 2015.

	Pre Oct-2015	Post Oct 2015
Payments to HCP consultants[a]		
Fees for provision of services	✓	✓
Sponsorship of HCP for educational event attendance (travel, accommodation)	✓	✓[#]
Sponsorship of HCP for educational event attendance (food and beverages)	✓	
Payments related to company-run educational events and advisory boards[b]		
Fees for provision of services (e.g. speaking, chairing, advisory board participation)	✓	✓
Event registration costs	✓	✓
Sponsorship of HCP for educational event and meeting attendance (travel, accommodation)	✓	✓[#]
Sponsorship of HCP for educational event and meeting attendance (food and beverages)	✓	
Food and beverages at meeting	✓	
Event running costs (e.g. venue hire, event organiser, trade displays)	✓	
Payments related to third party (independent) educational events[c]		
Fees for provision of services (e.g. speaking, chairing)	✓	✓
Event registration costs	✓	✓
Sponsorship of HCP for meeting attendance (travel, accommodation)	✓	✓[e]
Sponsorship of HCP for meeting attendance (food and beverages)	✓	
Food and beverages at event	✓	✓[f]
Other event costs (e.g. venue hire, event organiser, trade displays)	✓	✓

Payments to health consumer organisations[d]		
Sponsorship, trade displays for consumer events	✓	✓
Other (e.g. publications)	✓	✓

HCP: Healthcare professional

[a]Captured in the HCP Consultants Reports (pre-2015) and HCP Reports (post-2015)

[b]Captured in the Educational Events and Advisory Board Reports (pre-2015) and HCP Reports (post-2015)

[c]Captured in the Educational Events Reports (pre-2015), and Third Party and HCP Reports (post-2015)

[d]Captured in the Health Consumer Organisation Reports (pre- and post-2015)

[e]Airfares only

[f]Reporting is not required if food and beverages are the company's only contribution to the event.

Table 3. Summary of gains and loss in current Medicines Australia and GBMA reports compared with pre-2015 reports.

Gains	Losses
Identification of healthcare professionals receiving payments from Medicines Australia member companies for provision of services or sponsorship for event attendance (registration costs, travel, accommodation)	Spending from Medicines Australia member companies associated with:- - Food and beverages and small travel costs (taxis, ground transfers) to sponsored HCPs attending or providing services at educational events - Event running costs (e.g. venue hire, event organiser, food and beverages for industry-run events and advisory board meetings - Food and beverages served at third party events where no other sponsorship was provided All GBMA member company payments related to educational events and non-price benefits for pharmacists

In the year preceding the 2015 changes to the Medicines Australia code, industry payments disclosed by Medicines Australia members totalled $AUS 89,658,566 (Oct 2014 to Sep 2015) across four reporting categories. Reported payments included $74,264,438 (82.8%) on Educational Events run by the company or third party, $8,743,250 (9.8%) on Health Consumer Organisation Support, $4,158,819 (4.6%) on costs associated with Advisory Board Participation, and $2,492,059 (2.8%) on Healthcare Professional Consultants.

In the year following the 2015 change, reported payments from Medicines Australia members totalled $59,205,301 (Oct 2015 to Sep 2016), an overall reduction of 34.1%. Payments reported in the new categories, Healthcare Professional Reports and Third Party Educational Events, totalled $30,380,145 and $20,364,929 respectively. There was little change in the total reported expenditure on Health Consumer Organisation Support ($8,461,228), which was the only reporting category to remain unchanged in the revised code (See Figure 2). Excluding payments associated with this category, there was a 37.3% reduction in disclosed Medicines Australia payments. As shown in Table 2 the reduction in disclosed payments coincides with loss of information about spending on: running costs for industry-run events and meetings (including food and beverages); hospitality to sponsored healthcare professionals attending events and meetings.

Figure 2. Cumulative monthly expenditure disclosed in transparency reports from Medicines Australia and GBMA members*

Legend: *arrow indicates date of change to Medicines Australia reporting requirements

In the year preceding the 2015 changes to the GBMA code, industry payments disclosed by GBMA members totalled $AUS 2,580,402 (Jul 2014 – Jun 2015). 88.3% of these reported payments were for Non-Price Benefits to Pharmacists and the remainder were for Educational Events. After July 2015, $AUS 0 payments have been reported by GBMA members, a drop of 100%.

Discussion

Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient identities but an overall reduction in transparency around industry funding in the healthcare sector. Dropping the requirements for transparency around items such as expenditure on food and beverages means that over a third of previously reported industry spending on healthcare professionals is now hidden. In addition, the new Code failed to include other disclosures about industry interactions with health professionals that countries such as the UK and USA have introduced, such as pharmaceutical company spending on free drug samples and funding for research.[6] The changes have also added an extra layer of complexity to what is already difficult-to-understand data on disclosed payments. This complexity hinders transparency.

This erosion of transparency has taken place in a time of increasing societal interest in disclosure. Transparency around pharmaceutical industry spending in the healthcare sector is important for several reasons. First, the public have a legitimate expectation that all transfers of value between the pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and judge the appropriateness of such interactions. Second, transparency may assist those reading or receiving the disclosure to judge the risk of bias in those making the disclosure. For example, disclosures of competing interests by research authors makes academic readers more critical of an article.[15] However, authors who disclose conflicts of interest are more likely to exaggerate their claims,[16] and even critical readers tend not to sufficiently discount the credibility of biased information sources, so the audience may still take home a biased message.[17]

Third, transparency requirements may change behaviour of those making the disclosure. In situations where disclosures are required or expected, individuals may avoid accepting payments in order to avoid making the declaration [18] and the same may apply to corporations. For example, if industry is required to declare costs associated with food and beverage provision at third party events such as medical grand rounds and journal clubs, they may be less likely to provide this kind of sponsorship. While healthcare professionals may be disappointed at the reduction in 'free' lunches, this change would reduce industry influence on healthcare, because receipt of industry-sponsored meals, even low-cost meals, increases prescribing of the brand-name drug being promoted at the time.[1]

The erosion of organisational transparency that we document in the paper is particularly significant. Although disclosure is a burden for the pharmaceutical industry, organisational transparency has the advantage of not relying on disclosures from individual healthcare professionals. These disclosures are potentially counterproductive since patients may feel extra pressure to follow the advice of those who declare conflicts of interests, in order to avoid implying distrust of their practitioner.[16 19] Dropping organisational disclosure of food and beverage spending also seems to send the wrong message to potential recipients, i.e. that this transfer of value is not significant enough to warrant reporting. As a result, healthcare professionals may be more likely to participate in industry-sponsored lunches,

Transparency is unlikely to be a complete solution to concerns about commercial influence within the healthcare sector.[20] There are many other important elements involved in managing this issue, including, for example, the prohibition of: clinical trials that seek to familiarise prescribers with new medications rather than add to scientific knowledge (so-called "seeding trials"), honorary authorships for healthcare professionals, and the release of free drug samples into clinic rooms.[21] However transparency is a necessary first step towards assessing and analysing the level of industry influence, and may act as a deterrent to inappropriate interactions between individual professionals and industry.

Self-regulated transparency programs may avoid the usual checks and balances of a more formal regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical industry to make changes associated with significant reductions in disclosed spending. Self-regulated transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It also fails to regulate companies that are not members of the relevant industry body. We advocate for legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise loss of transparency data in ways such as we report on here. In this particular case, we recommend that the Australian Government introduce transparency legislation. We recommend new legislation that maintains the current Medicines Australia transparency focus around spending on healthcare professionals and health consumer groups, and extends this requirement to include all companies in the pharmaceutical and medical device sector including GBMA members and companies with no

affiliation to trade organisations. We propose mandatory disclosure on spending on drug samples and research. We also recommend that legislation should reinstate previously compulsory reporting of aggregated food, beverages and venue costs at company-run educational events and advisory board meetings; and food and beverages provided to healthcare professionals where costs per head are over a minimum amount as required by the US legislation.

Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015 and post-2015 periods may be an under-estimate. There are companies that are not members of Medicines Australia or GBMA and hence do not disclose their spending. In addition, compliance with the GBMA Code was not compulsory for GBMA members from 2013,[22] so the true pre-2015 spending figure is likely to have been higher than our calculated figure. There may be inaccuracies in the spending disclosed by the companies in the original reports: we could not verify the accuracy and completeness of the data, but many companies do provide independent audits of their reports. The reduction in Medicines Australia member companies submitting reports, from 39 in the year prior to the change in reporting requirements to 34 after the change, contributed to the reduction in the cumulative disclosed sum, although was unlikely to have had a big impact. Together, these five companies only disclosed a total of $4,199,674 between October 2014 and September 2015, which was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot prove a causal relationship between changing industry Codes and cumulative disclosed spending. We think it likely that current spending remains similar to 2015 levels, and that the apparent reduction in cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative spending may have truly decreased as a result of the changes in reporting and/or other requirements introduced in the new Code (e.g. introduction of a $120 limit per head on meals for healthcare professionals), or that reductions in spending may reflect a move toward alternative methods of promotion to healthcare professionals not captured by the previous or current transparency program. Finally, as mentioned above, the program of required reporting is complex, and changes are difficult to follow. There may be some elements that we have misinterpreted.

Once a leader in transparency, Australia is now falling behind other countries. This study provides a clear example of the limitations of a self-regulatory system, which can be quietly changed in such a way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend that countries insist on legislation rather than self-regulation to promote long-lasting public transparency around industry spending.

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Competing interests: The authors have no completing interests.

Contributors: All authors conceived of the study. LP wrote the first and subsequent drafts. EAK extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB participated in creating the original database and critically revised the manuscript. All authors reviewed and approved the final manuscript.

Patient and public involvement: Not required.

Ethics approval: Not required.

Data sharing statement: Limited data from this study are publically available. Data on Pharmaceutical Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are available at: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB. The Pharmaceutical Industry Payments to Healthcare Professionals (May 2016 to Apr 2017) database is available at: https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a. Neither of these available databases currently include all Educational Events for Healthcare Professionals Reports or Payments to Healthcare Professional Reports included in this manuscript. The complete Health

Consumer Organisation database (Jan 2013 to Dec 2016) is available at:

https://researchdata.ands.org.au/pharmaceutical-industry-funding-december-2016/1330638.

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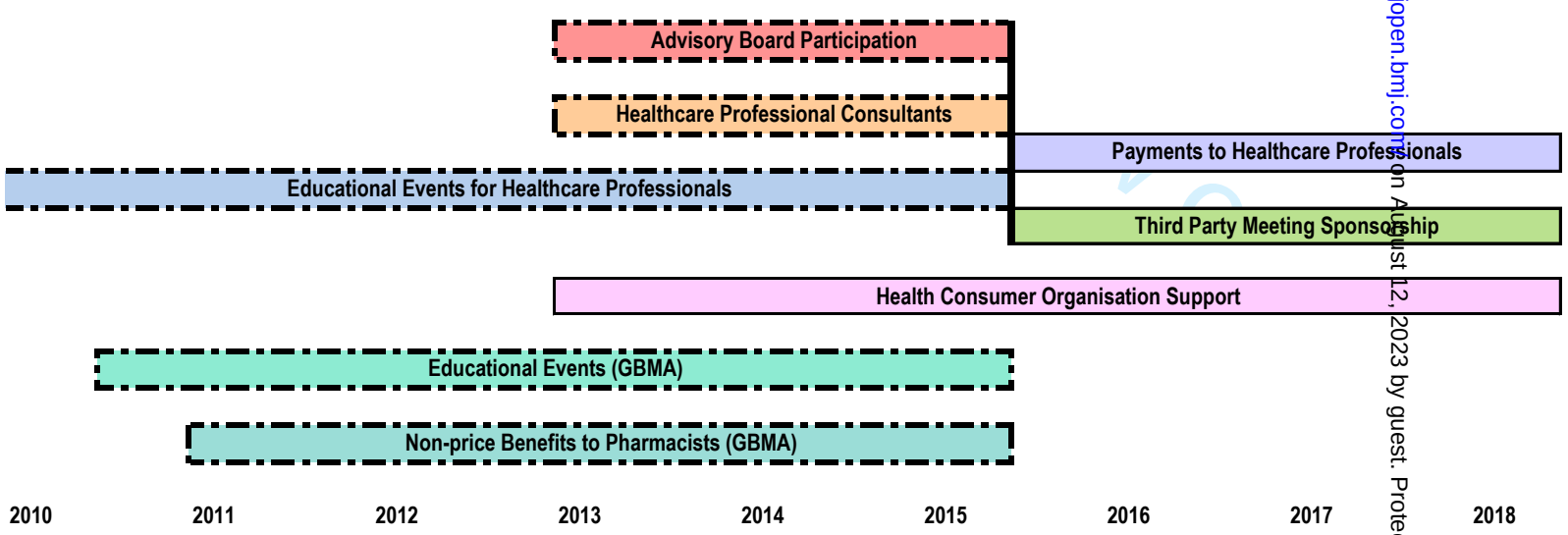

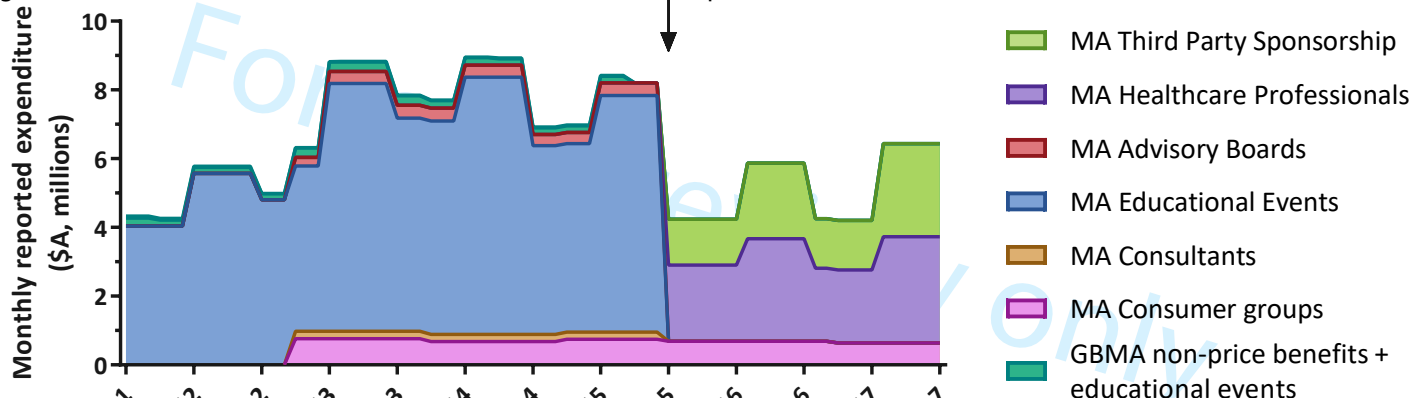

Figure Legends and Tables

Table 1. Characteristics of reports from Medicines Australia members. Shading indicates major differences in data capture in current/ongoing versus discontinued reports.

	DISCONTINUED REPORTS			ONGOING REPORTS		
	Educational Event Reports	***HCP Consultants Reports***	***Advisory Board Meeting Reports***	**Health Consumer Organisation Support Reports**	**Third Party Educational Events Reports**	**Healthcare Professionals Report**
DESCRIPTION	*Payments related to educational events for HCPs that are held or sponsored by the company*	*Payments to HCPs for consultancy services/advice*	*Payments to HCPs contracted to provide advice to the company as part of an advisory board*	Support for not-for-profit organisations representing the interests of health consumers	Sponsorship of educational events for HCPs independently organised by a third party (e.g. hospital, medical organisation)	Payments to individual HCPs for provision of services or to engage in education
REPORTING PERIOD	*Oct 2011 – Sep 2015*[#]	*Jan 2013 – Sep 2015*	*Jan 2013 – Sep 2015*	Jan 2013 –	Oct 2015 –	Oct 2015 –
PAYMENTS REPORTED						
Educational events for HCPs held by the company						
Fees to HCPs for provision of services (e.g. speaking, chairing)	✓					✓
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓					✓[+]
Sponsorship of HCP for event attendance (food, beverages)	✓			Payments no longer captured		
Food and beverages at event	✓					
Event running costs (e.g. venue hire, event organiser)	✓					

Internal company meetings and consulting				
Fees to HCPs for consulting or other services (e.g. speaking, chairing)	✓			✓
Hospitality (accommodation, travel) associated with HCP services	✓			✓+
Hospitality (food, beverages) associated with HCP services	✓		Payments no longer captured	
Advisory boards				
Fees to advisory board members		✓		✓
Hospitality (accommodation, travel) for board members		✓		✓+
Hospitality (food, beverages) for board members		✓	Payments no longer captured	
Food and beverages at meeting		✓		
Event running costs		✓		
Third party (independent) meetings				
Food and beverages at meeting	✓		✓‡	
Event running costs	✓		✓	
Trade display space	✓		✓	
Fees to HCP for provision of services (e.g. speaking, chairing)	✓			✓
Sponsorship of HCP for meeting attendance (accommodation, travel, registration)	✓			✓+
Sponsorship of HCP for meeting	✓		Payments no longer captured	

attendance (food, beverages)						
Health consumer organisation meetings						
Event sponsorship	Enhanced transparency from January 2013			✓		
Trade display space				✓		
Other support (e.g. publications)				✓		
REPORT FORMAT						
Itemised (per event or individual)	✓			✓	✓	✓
Aggregated (no. per period)		✓	✓			§
Disclosure of recipient required	Enhanced transparency from October 2015			✓ (Organisation)	✓ (Third Party)	✓ (Individual HCP)§

HCP: Healthcare professional

Reports go back to 2007, but they are not available prior to Oct 2011

+Excludes ground transfers, taxis, parking.

‡ Reporting is not required if food and beverages are the company's only contribution to the event.

§ Prior to the introduction of mandatory reporting of payments to HCPs on 1 October 2016, disclosure of a HCP's identifying information was contingent on the consent of the HCP. All payments received by non-consenting HCPs were reported in aggregated format.

Table 2: Characteristics of reports from GBMA members.

	DISCONTINUED		ONGOING
	Educational Event Reports	**Non-Price Benefits to Pharmacists**	**NIL**
DESCRIPTION	Payments related to educational events for HCPs[1] that are held or sponsored by the company	Payments and benefits provided to pharmacists	
REPORTING PERIOD	Apr 2010 – Jun 2015	Jan 2010 – Jun 2015	Jul 2015 –
PAYMENTS REPORTED			
Educational events for HCPs held by the company			
Fees to HCPs for provision of services (e.g. speaking/chairing)	✓		Payments no longer captured
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓		
Sponsorship of HCP for event attendance (food/beverages)	✓		
Food and beverages at event	✓		
Event running costs (e.g. venue hire, event organiser)	✓		
Non-Price Benefits to Pharmacists			
Access to training and education events		✓	Payments no longer captured
Event running costs and hospitality		✓	
Pharmacy aids, software and merchandising		✓	
Small coupons/vouchers		✓	
REPORT FORMAT			

Itemised (per event/individual)	✓		
Aggregated (payments per period)		✓	
Disclosure of recipient required			

[1] Reports limited to prescribing HCPs and pharmacists

Supplementary File 2: Characteristics of reports from GBMA members.

	DISCONTINUED		ONGOING
	Educational Events	**Non-Price Benefits to Pharmacists**	**NIL**
DESCRIPTION	Payments related to educational events for HCPs[1] that are held or sponsored by the company	Payments and benefits provided to pharmacists	
REPORTING PERIOD	Apr 2010 – Jun 2015	Jan 2010 – Jun 2015	Jul 2015 –
PAYMENTS REPORTED			
Educational events for HCPs held by the company			
Fees to individual HCPs for provision of services (e.g. speaking/chairing)	✓		Payments no longer captured
Sponsorship of HCP for event attendance (accommodation, travel, registration)	✓		
Sponsorship of HCP for event attendance (food/beverages)	✓		
Food and beverages at event	✓		
Event running costs (e.g. venue hire, event organiser)	✓		
Non-Price Benefits to Pharmacists			
Access to training and education events		✓	Payments no longer captured
Event running costs and hospitality		✓	
Pharmacy aids, software and merchandising		✓	
Small coupons/vouchers		✓	
REPORT FORMAT			

Itemised (per event/individual)	✓		
Aggregated (payments per period)		✓	
Disclosure of recipient required			

[1] Reports limited to prescribing HCPs and pharmacists

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-6
Bias	9	Describe any efforts to address potential sources of bias	Not possible, discussed 7-8
Study size	10	Explain how the study size was arrived at	5-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5-6
		(*b*) Describe any methods used to examine subgroups and interactions	5-6
		(*c*) Explain how missing data were addressed	5-6
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
Outcome data	15*	Report numbers of outcome events or summary measures	6-7
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	9

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Title page

Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an observational study

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Abstract

Objectives: To describe and quantify disclosed payments from the pharmaceutical industry to the healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system of transparency.

Design: Observational database study

Setting: Australia

Participants: Publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to Oct 2017).

Exposure: Changes to transparency reporting requirements with the updates of pharmaceutical industry Codes of Conduct in 2015.

Main outcome measures: Elements of healthcare sector spending that members of industry organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly average) in the year prior to and following the revision.

Results: There was a 34.1% reduction in disclosed spending from Medicines Australia member companies in the year after the 2015 changes to the Code of Conduct were introduced ($AUS 89,658,566 in the preceding year, Oct 2014 to Sep 2015; $AUS 59,052,551 in the following year). The new Code allowed for reduced reporting of spending on food and beverages at events and for sponsored healthcare professionals. However, there was enhanced transparency around identification of individual health professionals receiving payments. GBMA member reporting totalled $AUS 2,580,402 in the year prior to the revision, then ceased.

Conclusions: This study shows the limitations of a self-regulatory system around industry disclosure of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory long-lasting public transparency.

Article Summary

Strengths and Limitations of this Study

- We compiled and analysed over 900 transparency reports on pharmaceutical industry payments to the Australian healthcare sector, including payments to medical practitioners and other healthcare professionals, third parties such as medical organisations and hospitals, and health consumer groups.
- We identified key changes in the industry's self-regulatory codes regarding transparency reporting and examined changes in disclosed spending occurring concurrently with these changes; our analysis could not determine causality.
- We relied on information provided by pharmaceutical companies in their transparency reports and did not verify the accuracy or completeness of the data.
- Only member companies of Australia's pharmaceutical industry trade organisations are required to submit transparency reports, therefore our data do not reflect total spending and changes in membership status may affect disclosed payments.

Introduction

Financial relationships between healthcare professionals and the pharmaceutical industry influence healthcare.[1 2] Exposure of healthcare professionals to the pharmaceutical industry is widespread[3] but the financial details and extent of these relationships may be unclear. The United States and some European countries have legislated mandatory reporting of payments from pharmaceutical and medical device manufacturers to healthcare professionals[4] and Ontario, Canada has recently introduced similar legislation.[5] Other jurisdictions rely on self-regulation governed by industry associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).[6]

Australia has previously been at the forefront of transparency reporting.[7] For example, the pharmaceutical industry trade association Medicines Australia introduced a self-regulatory transparency program over a decade ago, when its 2007 Code of Conduct required member companies to publically report their spending on educational events for healthcare professionals.[8] Importantly, this included spending for "educational" events attended by healthcare professionals from many disciplines including nurses, pharmacists, physiotherapists and dieticians, as well as medical practitioners. The Generic and Biosimilar Medicines Association (GBMA), formerly the Generic Medicines Industry Association, introduced a similar requirement for its members in 2010, although this became non-compulsory in 2013.[9] GBMA also requested that members report "non-price benefits" to pharmacists, including, for example, provision of training, pharmacy aids, merchandising, software and vouchers.

In 2015, after pressure from the Australian Competition and Consumer Commission, Medicines Australia amended its Code to require public reporting of the amounts paid to individual, identified healthcare professionals. At the same time, however, the requirements to report on spending for educational events were watered down.[10] The GBMA followed suit, noting that 'Medicines Australia has removed this requirement [for educational event reporting] of its members', and citing the 'significant compliance burden placed on members' and the 'consistently demonstrated … appropriate conduct over the past five years' as further reasons to remove these reports on spending.[11p6] Unlike Medicines Australia, the GBMA did not introduce any requirements to report spending to individual

healthcare professionals, educational events run by third parties, or consumer groups. These transparency losses were criticised at the time.[12] The objective of this paper is to describe changes in the types of spending disclosed and cumulative amount of spending following the 2015 changes in industry-regulated reporting requirements. We highlight exactly what information has been lost and gained from the public record in Australia, and report on the financial changes.

Methods

We conducted an observational study of publically available reports submitted by members of Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct 2011 to Oct 2017).

Details on current and previous Medicines Australia and GBMA reporting requirements are available through their respective websites: https://medicinesaustralia.com.au/ and https://www.gbma.com.au/. We used the relevant Codes and/or related documents associated with the current[10] and previous[13] Medicines Australia Codes of Conduct, and the current[11] and previous[14] GBMA Codes of Practice to identify changes to transparency information required from organisation members.

Data sources and analysis. Transparency reports on Medicines Australia and GMBA member company spending are available through the respective industry body websites as separate reports (usually PDF files) for each company, reporting period, and report category. Our research group has previously downloaded and compiled Medicines Australia reports on ~~educational~~ Educational ~~events~~ Events for ~~healthcare~~ Healthcare ~~professionals~~ Professionals (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically accessible), and ~~payments~~ Payments to ~~individual healthcare~~ Healthcare ~~professionals~~ Professionals (May 2016 to Apr 2017), converting them into databases for research purposes and public use.[6 7] These data are publically available for download: https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB and https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a respectively. The current project extends on this work by updating these pre-existing databases and compiling additional databases from more recent reports downloaded from Medicines Australia and GMBA. In total, this project employed 905

Medicines Australia reports (Oct 2011 - Dec 2017) collated into six distinct databases according to the report categories defined by Medicines Australia. Specifically, these databases contain reports on payments related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Sept 2015); (2) Healthcare Professional Consultants (Jan 2013 - Sep 2015); (3) Advisory Board Participation (Jan 2013 - Sep 2015); (4) Health Consumer Organisation Support (Jan 2013- Dec 2017); (5) Third Party Meeting Sponsorship (Oct 2015 – Oct 2017); (6) Payments to Healthcare Professionals (Oct 2015 – Oct 2017). We generated two databases from the 64 available GBMA reports detailing GBMA member payments related to: (1) Educational Events (for healthcare professionals) ; and (2) Non-Price Benefits to Pharmacists. See Table 1 for a description of each category and Figure 1 for a timeline of available reports. Further information about each report category is provided in Supplementary Files 1 and 2.

Table 1 – Description of required reporting categories from Medicines Australia and GBMA members

Report category	Dates reported	Description	Payments reported
MEDICINES AUSTRALIA REPORTS			
Educational Events for Healthcare Professionals	Jul 2007 - Sep 2015[a]	Payments related to educational events for HCPs that are held by the company or a third party (e.g. hospital, medical organisation)	Fees to ~~individual~~ HCPs for services at events (e.g. speaking, chairing) Sponsorship to ~~individual~~ HCPs to cover costs of event attendance (e.g. registration, travel, accommodation, food and beverages) Event running costs (e.g. venue hire, food and beverages)

Healthcare Professional Consultants	Jan 2013 - Sep 2015	Payments to HCPs for consultancy services	Consultant fees and associated costs (e.g. travel, accommodation, food and beverages)
Advisory Board Participation	Jan 2013 - Sep 2015	Payments to HCPs contracted to provide advice to the company as part of an advisory board	Advisory Board participation fees Board meeting running costs (e.g. food and beverages; venue hire; costs associated with HCP attendance including travel, accommodation, food and beverages)
Health Consumer Organisation Support	Jan 2013 - ongoing	Support to not-for-profit organisations representing the interests of health consumers	Financial and non-financial support (e.g. for events, activities, publications)
Third Party Meeting Sponsorship	Oct 2015-ongoing	Payments related to educational events for HCPs that are held by a third party (e.g. hospital, medical organisation)	Fees to ~~individual~~ HCPs for services at third party events (e.g. speaking, chairing) Sponsorship to ~~individual~~ HCPs to cover costs of attendance at third party events (e.g. registration, travel, accommodation)[b] Event running costs (e.g. venue hire, food and beverages)[c]

Payments to Healthcare Professionals	Oct 2015-ongoing	Payments to individual, identified HCPs for providing advice or other services or to attend educational events[d]	HCP service fees (e.g. advisory board participation, consultancy, speaking or chairing at events) Sponsorship to ~~individual~~ HCPs to cover costs of attendance at events (registration, travel, accommodation)
GBMA REPORTS			
Educational Events	Apr 2010 Jun 2015 [a]	Payments related to educational events for HCPs that are held by the company or a third party (e.g. hospital, medical organisation)	Fees to ~~individual~~ HCPs for services at events (e.g. speaking, chairing) Sponsorship to ~~individual~~ HCPs to cover costs of event attendance (e.g. registration, travel, accommodation, food and beverages) Event running costs (e.g. venue hire, food and beverages)
Non-Price Benefits to Pharmacists	Dec 2010-Jun 2015[a]	Sales incentives provided to pharmacists	e.g. pharmacy aids, merchandising, vouchers, access to training opportunities

[a]Data presented from Oct 2011

[b]Airfares only; excludes ground transfers, taxis, parking.

[c]Reporting is not required if food and beverages are the company's only contribution to the event.

[d]Prior to 1 October 2016, disclosure of a HCP's identifying information was continent on the consent of the HCP. All payments received by non-consenting HCPs were reported in aggregated format.

Figure 1. Timeline of required reporting by Medicines Australia and GBMA members according to industry defined categories (see Table 1 for further information)

Figure 1 footnotes:

- Dates are approximate only
- Educational Events disclosures started July 2007
- The Payments to Healthcare Professionals category is a partial merger (with some exclusions) of three former categories: Healthcare Professional Consultants; Advisory Board Participation; Educational Events
- The Third Party Educational Events category is a subset of the former Educational Events category

We identified 39 Medicines Australia members filing transparency reports in the year preceding the changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most recent period for which reports were requested by their industry body (i.e. ending June 2015), compared to none in the following year, and since.

Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each category as a monthly average over the given reporting period. Change in total expenditure from Medicines Australia and GBMA member companies over time was used to assess the impact of changes in reporting requirements in October 2015 and July 2015 respectively.

Patient or public involvement. No patients or members of the public were involved in this study.

Ethical approval. None required.

Results

The 2015 changes to the Medicines Australia code resulted in merging and crossover of pre-existing reporting categories, as well as inclusion of some new elements and discontinuation of others. For example, information formerly captured in the Educational Events Database is now reported in the Third Party and Healthcare Professional databases. The main required reporting elements in the old and new Medicines Australia Codes of Conduct are listed in Table 2 with further details in Supplementary Files 1 and 2. The transparency gains and losses from Medicines Australia and GBMA members are summarised in Table 3.

Table 2. Types of payments publically reported by Medicines Australia members before and after the change to reporting requirements in October 2015.

	Pre Oct-2015	Post Oct 2015
Payments to HCP consultants[a]		
Fees for provision of services	✓	✓
Sponsorship of HCP for educational event attendance (travel, accommodation)	✓	✓[#]
Sponsorship of HCP for educational event attendance (food and beverages)	✓	
Payments related to company-run educational events and advisory boards[b]		
Fees for provision of services (e.g. speaking, chairing, advisory board participation)	✓	✓
Event registration costs	✓	✓
Sponsorship of HCP for educational event and meeting attendance (travel, accommodation)	✓	✓[#]
Sponsorship of HCP for educational event and meeting attendance (food and beverages)	✓	
Food and beverages at meeting	✓	
Event running costs (e.g. venue hire, event organiser, trade displays)	✓	
Payments related to third party (independent) educational events[c]		
Fees for provision of services (e.g. speaking, chairing)	✓	✓
Event registration costs	✓	✓
Sponsorship of HCP for meeting attendance (travel, accommodation)	✓	✓[#] ✓[e]

Sponsorship of HCP for meeting attendance (food and beverages)	✓	
Food and beverages at event	✓	✓[#e]✓[f]
Other event costs (e.g. venue hire, event organiser, trade displays)	✓	✓
Payments to health consumer organisations[d]		
Sponsorship, trade displays for consumer events	✓	✓
Other (e.g. publications)	✓	✓

HCP: Healthcare professional

[a]Captured in the HCP Consultants Reports (pre-2015) and HCP Reports (post-2015)

[b]Captured in the Educational Events and Advisory Board Reports (pre-2015) and HCP Reports (post-2015)

[c]Captured in the Educational Events Reports (pre-2015), and Third Party and HCP Reports (post-2015)

[d]Captured in the Health Consumer Organisation Reports (pre- and post-2015)

[#e]Airfares only

[#f]Reporting is not required if food and beverages are the company's only contribution to the event.

Table 3. Summary of gains and loss in current Medicines Australia and GBMA reports compared with pre-2015 reports.

Gains	Losses
Identification of healthcare professionals receiving payments from Medicines Australia member companies for provision of services or sponsorship for event attendance (registration costs, travel, accommodation)	Spending from Medicines Australia member companies associated with:- - Food and beverages and small travel costs (taxis, ground transfers) to sponsored HCPs attending or providing services at educational events - Event running costs (e.g. venue hire, event organiser, food and beverages for industry-run events and advisory board meetings - Food and beverages served at third party events where no other sponsorship was provided

	All GBMA member company payments related to educational events and non-price benefits for pharmacists

In the year preceding the 2015 changes to the Medicines Australia code, industry payments disclosed by Medicines Australia members totalled $AUS 89,658,566 (Oct 2014 to Sep 2015) across four reporting categories. Reported payments included $74,264,438 (82.8%) on Educational Events run by the company or third party, $8,743,250 (9.8%) on Health Consumer Organisation Support, $4,158,819 (4.6%) on costs associated with Advisory Board Participation, and $2,492,059 (2.8%) on Healthcare Professional Consultants.

In the year following the 2015 change, reported payments from Medicines Australia members totalled $59,205,301 (Oct 2015 to Sep 2016), an overall reduction of 34.1%. Payments reported in the new categories, Healthcare Professional Reports and Third Party Educational Events, totalled $30,380,145 and $20,364,929 respectively. There was little change in the total reported expenditure on Health Consumer Organisation Support ($8,461,228), which was the only reporting category to remain unchanged in the revised code (See Figure 2). Excluding payments associated with this category, there was a 37.3% reduction in disclosed Medicines Australia payments. As shown in Table 2 the reduction in disclosed payments coincides with loss of information about spending on: running costs for industry-run events and meetings (including food and beverages); hospitality to sponsored healthcare professionals attending events and meetings.

Figure 2. Cumulative monthly expenditure disclosed in transparency reports from Medicines Australia and GBMA members*

Legend: *arrow indicates date of change to Medicines Australia reporting requirements

In the year preceding the 2015 changes to the GBMA code, industry payments disclosed by GBMA members totalled $AUS 2,580,402 (Jul 2014 – Jun 2015). 88.3% of these reported payments were for

Non-Price Benefits to Pharmacists and the remainder were for Educational Events. After July 2015, $AUS 0 payments have been reported by GBMA members, a drop of 100%.

Discussion

Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient identities but an overall reduction in transparency around industry funding in the healthcare sector. Dropping the requirements for transparency around items such as expenditure on food and beverages means that over a third of previously reported industry spending on healthcare professionals is now hidden. In addition, the new Code failed to include other disclosures about industry interactions with health professionals that countries such as the UK and USA have introduced, such as pharmaceutical company spending on free drug samples and funding for research.[6] The changes have also added an extra layer of complexity to what is already difficult-to-understand data on disclosed payments. This complexity hinders transparency.

This erosion of transparency has taken place in a time of increasing societal interest in disclosure. Transparency around pharmaceutical industry spending in the healthcare sector is important for several reasons. First, the public have a legitimate expectation that all transfers of value between the pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and judge the appropriateness of such interactions. Second, transparency may assist those reading or receiving the disclosure to judge the risk of bias in those making the disclosure. For example, disclosures of competing interests by research authors makes academic readers more critical of an article.[15] ~~Receiving conflicts of interest information may, however, have limited impact on the audience.~~ However, authors who disclose ~~ndividuals disclosing~~ conflicts of interest are more likely to exaggerate their claims,[16] and even critical readers tend not to sufficiently discount the credibility of biased information sources, so the audience may still take home a biased message.[17]

Third, transparency requirements may change behaviour of those making the disclosure. In situations where disclosures are required or expected, individuals may avoid accepting ~~the conflicts of interest~~payments in order to avoid making the declaration [18] and the same may apply to corporations.

For example, if industry is required to declare costs associated with food and beverage provision at third party events such as medical grand rounds and journal clubs, they may be less likely to provide this kind of sponsorship. While ~~doctors~~ healthcare professionals may be disappointed at the reduction in 'free' lunches, this change would reduce industry influence on healthcare, because receipt of industry-sponsored meals, even low-cost meals, ~~influences~~ increases ~~doctors to prescribe more~~prescribing of the brand-name drug being promoted at the time.[1]

The erosion of organisational transparency that we document in the paper is particularly significant. Although disclosure is a burden for the pharmaceutical industry, organisational transparency has the advantage of not relying on disclosures from individual healthcare professionals. These disclosures are potentially counterproductive since patients may feel extra pressure to follow the advice of those who declare conflicts of interests, in order to avoid implying distrust of their practitioner.[16 19] Dropping organisational disclosure of food and beverage spending also seems to send the wrong message to potential recipients, i.e. that this transfer of value is not significant enough to warrant reporting. As a result, ~~doctors~~ healthcare professionals may be more likely to participate in industry-sponsored lunches,

Transparency is unlikely to be a complete solution to concerns about commercial influence within the healthcare sector.[20] There are many other important elements involved in managing this issue, including, for example, the prohibition of: clinical trials that seek to familiarise prescribers with new medications rather than add to scientific knowledge (so-called "seeding trials"), honorary authorships for healthcare professionals, and the release of free drug samples into clinic rooms.[21] However transparency is a necessary first step towards assessing and analysing the level of industry influence, and may act as a deterrent to inappropriate interactions between individual professionals and industry.

Self-regulated transparency programs may avoid the usual checks and balances of a more formal regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical industry to make changes associated with significant reductions in disclosed spending. Self-regulated transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It

also fails to regulate companies that are not members of the relevant industry body. We advocate for legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise loss of transparency data in ways such as we report on here. In this particular case, we recommend that the Australian Government introduce transparency legislation. We recommend new legislation that maintains the current Medicines Australia transparency focus around spending on healthcare professionals and health consumer groups, and extends this requirement to include all companies in the pharmaceutical and medical device sector including GBMA members and companies with no affiliation to trade organisations. We propose mandatory disclosure on spending on drug samples and research. We also recommend that legislation should reinstate previously compulsory reporting of aggregated food, beverages and venue costs at company-run educational events and advisory board meetings; and food and beverages provided to ~~individual~~ healthcare professionals where costs per head are over a minimum amount as required by the US legislation.

Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015 and post-2015 periods may be an under-estimate. There are companies that are not members of Medicines Australia or GBMA and hence do not disclose their spending. In addition, compliance with the GBMA Code was not compulsory for GBMA members from 2013,[22] so the true pre-2015 spending figure is likely to have been higher than our calculated figure. There may be inaccuracies in the spending disclosed by the companies in the original reports: we could not verify the accuracy and completeness of the data, but many companies do provide independent audits of their reports. The reduction in Medicines Australia member companies submitting reports, from 39 in the year prior to the change in reporting requirements to 34 after the change, contributed to the reduction in the cumulative disclosed sum, although was unlikely to have had a big impact. Together, these five companies only disclosed a total of $4,199,674 between October 2014 and September 2015, which was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot prove a causal relationship between changing industry Codes and cumulative disclosed spending. We think it likely that current spending remains similar to 2015 levels, and that the apparent reduction in cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative

spending may have truly decreased as a result of the changes in reporting and/or other requirements introduced in the new Code (e.g. introduction of a $120 limit per head on meals for healthcare professionals), or that reductions in spending may reflect a move toward alternative methods of promotion to healthcare professionals not captured ~~, or that spending patterns may have coincidently (or even deliberately) altered at the same time that the new Code came in, perhaps reflecting different ways of industry promotional spend in the healthcare sector that were not captured~~ by the previous or current transparency program. Finally, as mentioned above, the program of required reporting is complex, and changes are difficult to follow. There may be some elements that we have misinterpreted.

Once a leader in transparency, Australia is now falling behind other countries. This study provides a clear example of the limitations of a self-regulatory system, which can be quietly changed in such a way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend that countries insist on legislation rather than self-regulation to promote long-lasting public transparency around industry spending.

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