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

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3 **1 Title page**

4 **2 Eroded transparency around Pharma payments to the healthcare sector in Australia: Observational**
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6 **3 database study**
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12 **5 Lisa Parker, Postdoctoral Research Fellow¹ lisa.parker@sydney.edu.au**

13
14
15 **6 Emily A Karanges, Postdoctoral Research Fellow¹ emily.karanges@sydney.edu.au**

16
17
18 **7 Lisa Bero, Professor¹ lisa.bero@sydney.edu.au**

19
20 **8**
21
22 **9 ¹Charles Perkins Centre, School of Pharmacy, Faculty of Medicine and Health, The University of**
23
24 **10 Sydney**
25
26

27 **11**

28
29
30 **12 Corresponding author:**

31
32 **13 Lisa Parker**

33
34 **14 D17, The Hub, 6th floor, Charles Perkins Centre, The University of Sydney, NSW, 2006, Australia.**

35
36 **15 Phone: +61 2 86276422 lisa.parker@sydney.edu.au**

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2
3 18 **Abstract**
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5 19 Objectives: To describe and quantify disclosed payments from the pharmaceutical industry to the
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7 20 healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system
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9 21 of transparency.
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12 22 Design: Observational database study
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15 23 Setting: Australia
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18 24 Participants: Publically available reports submitted by members of Australian pharmaceutical
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20 25 industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines
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22 26 Association (Oct 2011 to April 2017).
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25 27 Exposure: Changes to transparency reporting requirements with the updates of pharmaceutical
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27 28 industry Codes of Conduct in 2015.
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30 29 Main outcome measures: Elements of healthcare sector spending that members of industry
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32 30 organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly
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34 31 average, pre and post October 2015).
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37 32 Results: New transparency requirements from 2015 require disclosure of identification of recipients of
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39 33 Medicines Australia member funding, including individual medical professionals. Reporting of many
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41 34 hospitality and event costs has declined, with an overall 34.1% decrease in reported industry spending
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43 35 amongst Medicines Australia members, from \$AUS 89,658,566 to \$AUS 59,052,551.
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46 36 Conclusions: This study shows the limitations of a self-regulatory system around industry disclosure
47
48 37 of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory
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50 38 long-lasting public transparency.
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41 **Strengths and Limitations of this Study**

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

54

55 **Introduction**

56 Financial relationships between healthcare professionals and the pharmaceutical industry influence
57 healthcare.¹ Exposure of health professionals to the pharmaceutical industry is widespread² but the
58 financial details and extent of these relationships may be unclear. The United States and some
59 European countries have legislated mandatory reporting of payments from pharmaceutical and
60 medical device manufacturers to healthcare professionals³ and Ontario, Canada has recently
61 introduced similar legislation.⁴ Other jurisdictions rely on self-regulation governed by industry
62 associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).⁵
63 Australia has previously been at the forefront of transparency reporting.⁶ For example, the prominent
64 trade association Medicines Australia (MA) introduced a self-regulatory transparency program over a
65 decade ago, when its 2007 Code of Conduct required member companies to publically report their
66 spending on educational events for health professionals.⁷ Importantly, this included spending for
67 “educational” events and spending on health professionals from many disciplines including nurses,
68 pharmacists, physiotherapists and dieticians, as well as medical practitioners. The Generic and
69 Biosimilar Medicines Association (GBMA), formerly the Generic Medicines Industry Association,
70 introduced a similar requirement for its members in 2010, although this became non-compulsory in
71 2013.⁸ GBMA also requested that members report “non-price benefits” to pharmacists, including, for
72 example, provision of training, pharmacy aids, merchandising, software and vouchers.

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

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3 82 were criticised at the time.¹¹ The objective of this paper is to describe changes in the types of spending
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5 83 disclosed and cumulative amount of spending following the 2015 changes in industry-regulated
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7 84 reporting requirements. In this paper we highlight exactly what information has been lost from the
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9 85 public record in Australia, and report on the impact of these changes.

10 11 86 **Methods**

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14 87 We conducted an observational study of publically available reports submitted by members of
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16 88 Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and
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18 89 Biosimilar Medicines Association (Oct 2011 to April 2017).

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21 90 Details on current and previous Medicines Australia and GBMA reporting requirements are available
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23 91 through their respective websites: <https://medicinesaustralia.com.au/> and <https://www.gbma.com.au/>.

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25 92 We used the relevant Codes and/or related documents associated with the current⁹ and previous¹²
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27 93 Medicines Australia Codes of Conduct, and the current¹⁰ and previous¹³ GBMA Codes of Practice to
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29 94 identify changes to transparency information required from organisation members.

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31 95 **Data sources and analysis.** Transparency reports on Medicines Australia and GMBA member
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33 96 company spending are available through the respective industry body websites as separate reports
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35 97 (usually PDF files) for each company, reporting period, and report category. Our research group has
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37 98 previously downloaded and compiled Medicines Australia reports on educational events for
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39 99 healthcare professionals (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically
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41 100 accessible) and payments to individual healthcare professionals (May 2016 to Apr 2017), converting
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43 101 them into databases for research purposes and public use.^{5,6} These data are publically available for
44
45 102 download: <https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB> and [https://research-](https://research-data.sydney.edu.au/index.php/s/OMmrflPyiQrf53a)
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47 103 [data.sydney.edu.au/index.php/s/OMmrflPyiQrf53a](https://research-data.sydney.edu.au/index.php/s/OMmrflPyiQrf53a) respectively. The current project extends on this
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49 104 work by updating these pre-existing databases and compiling additional databases from more recent
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51 105 reports downloaded from Medicines Australia and GMBA. In total, this project employed 895
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53 106 Medicines Australia reports (Oct 2011 - Apr 2017) collated into six distinct databases (see Table 1)
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55 107 detailing Medicines Australia member payments related to: (1) Educational Events for Healthcare
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3 108 Professionals (Oct 2011 – Sep 2015); (2) Healthcare Professional Consultants (Jan 2013 – Sep 2015);
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5 109 (3) Advisory Board Meetings (Jan 2013 – Sep 2015); (4) Health Consumer Organisations (Jan 2013 –
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7 110 Dec 2016); (5) Third Party Educational Events (Oct 2015 - Apr 2017); (6) Individual Healthcare
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9 111 Professionals (Oct 2015 - Apr 2017). We also generated two databases (see Table 2) from the 64
10
11 112 available GBMA reports (Oct 2011 – Jun 2015) detailing GBMA member payments related to: (1)
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13 113 Educational Events for Healthcare Professionals (Oct 2011 – Jun 2015); and (2) Non-Price Benefits to
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15 114 Pharmacists (Oct 2011 – Jun 2015).

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17 115 We identified 39 Medicines Australia members filing transparency reports in the year preceding the
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19 116 changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year
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21 117 (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most
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23 118 recent period for which reports were requested by their industry body (i.e. ending June 2015),
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25 119 compared to none in the following year, and since.

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28 120 Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each
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30 121 category as a monthly average over the given reported period. Change in total expenditure from
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32 122 Medicines Australia and GBMA member companies over time was used to assess the impact of
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34 123 changes in reporting requirements in October 2015 and July 2015 respectively.

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37 124 ***Patient or public involvement.*** No patients or members of the public were involved in this study.

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40 125 ***Ethical approval.*** None required.

41 42 126 **Results**

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45 127 The changes to self-regulatory codes regarding transparency reporting in 2015 have resulted in
46
47 128 increased transparency on specific items but a decrease in transparency regarding other items (Table
48
49 129 1). Specifically, there has been enhanced transparency around individual health care provider
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51 130 recipients of Medicines Australia member funding such that it is now possible to identify payments
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53 131 received by named healthcare professionals. However, the changes in 2015 resulted in reduced
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55 132 transparency around Medicines Australia member spending on running costs, including food and

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3 133 beverages, for industry-run events and meetings; and hospitality to sponsored professionals attending
4 134 events and meetings (See Table 1). In addition, there has been a complete loss of transparency around
5 135 GBMA member spending on education and other forms of promotion within the healthcare sector
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8 136 (Table 2).

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10
11 137 Figure 1 shows that the 2015 changes to the Medicines Australia and GBMA Codes were associated
12 138 with a large overall reduction in reported spending. In the year preceding the regulatory changes,
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14 139 industry payments disclosed by Medicines Australia members totalled \$AUS 89,658,566 (Oct 2014 –
15
16 140 Sep 2015). The corresponding figure in the following year was \$AUS 59,052,551, a drop of 34.1%.

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20 141 An additional \$AUS 2,580,402 (88.3% non-price benefits to pharmacists) in payments were disclosed
21 142 by GMBA members in the year preceding regulatory change (Jul 2014 – Jun 2015), with \$AUS 0
22 143 payments reported after this, a drop of 100%.

23 144 **Discussion**

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27 145 Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient
28 146 identities but an overall reduction in transparency around industry funding in the healthcare sector.
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30 147 Dropping the requirements for transparency around items such as expenditure on food and beverages
31 148 means that over a third of industry spending on healthcare professionals is now hidden.

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33
34 149 This erosion of transparency has taken place in a time of increasing societal interest in disclosure.
35 150 The public have an expectation that all transfers of value between the pharmaceutical industry and
36 151 healthcare sector will be available for scrutiny in order to assess and judge the appropriateness of such
37 152 interactions. Transparency is unlikely to be a complete solution to concerns about commercial sway
38 153 within the healthcare sector.¹⁴ There are many other important elements involved in managing this
39 154 issue, including, for example, stamping out clinical trials that seek to familiarise prescribers with new
40 155 medications rather than add to scientific knowledge (so-called “seeding trials”), banning honorary
41 156 authorships for healthcare professionals, and stopping the release of free drug samples into clinic
42 157 rooms.¹⁵ However transparency is a necessary first step towards assessing and analysing the level of

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3 158 industry influence, and may act as a deterrent to individual professionals engaging inappropriately
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5 159 with industry.
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8 160 Self-regulated transparency programs may avoid the usual checks and balances of a more formal
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10 161 regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical
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12 162 industry to make changes associated with significant reductions in disclosed spending. Self-regulated
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14 163 transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It
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16 164 also fails to regulate companies that are not members of the relevant industry body. We advocate for
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18 165 legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise
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20 166 loss of transparency data in ways such as we report on here. In this particular case, we recommend
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22 167 that the Australian Government introduce transparency legislation. We advocate for new legislation
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24 168 that maintains the current Medicines Australia transparency focus around spending on healthcare
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26 169 professionals and health consumer groups, and extends this requirement to include all companies in
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28 170 the pharmaceutical and medical device sector including GBMA members and companies with no
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30 171 affiliation to trade organisations. We also recommend that legislation should reinstate previously
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32 172 compulsory reporting of food, beverages and venue costs at company-run educational events and
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34 173 advisory board meetings; and food and beverages provided to individual healthcare professionals.
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36 174 Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015
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38 175 and post-2015 periods may be an under-estimate. There may be some companies that are not
39
40 176 members of Medicines Australia or GBMA and hence do not disclose their spending. In addition,
41
42 177 compliance with the GBMA Code was not compulsory for GBMA members from 2013,¹⁶ so the true
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44 178 pre-2015 spending figure is likely to have been higher than our calculated figure. There may be
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46 179 inaccuracies in the spending disclosed by the companies in the original reports: we could not verify
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48 180 the accuracy and completeness of the data, but many companies do provide independent audits of
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50 181 their reports. The reduction in Medicines Australia member companies submitting reports, from 39 in
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52 182 the year prior to the change in reporting requirements to 34 after the change, contributed to the
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54 183 reduction in the cumulative disclosed sum, although was unlikely to have had a big impact. Together,
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56 184 these five companies only disclosed a total of \$4,199,674 between October 2014 and September 2015,
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3 185 which was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot
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5 186 prove a causal relationship between changing industry Codes and cumulative disclosed spending. We
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7 187 think it likely that current spending remains similar to 2015 levels, and that the apparent reduction in
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9 188 cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative
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11 189 spending may have truly decreased, or that spending patterns may have coincidentally (or even
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13 190 deliberately) altered at the same time that the new Code came in, perhaps reflecting different ways of
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15 191 industry promotional spend in the healthcare sector that were not captured by the previous or current
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17 192 transparency program.

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19 193 Once a leader in transparency, Australia is now falling behind other countries. This study provides a
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21 194 clear example of the limitations of a self-regulatory system, which can be quietly changed in such a
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23 195 way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend
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25 196 that countries insist on legislation rather than self-regulation to promote long-lasting public
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27 197 transparency around industry spending.

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29
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31
32 199 database of disclosed payments from publically accessible industry documents.

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34
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36
37 201 or not-for-profit sectors.

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39
40 202 **Competing interests:** The authors have no completing interests.

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42 203 **Contributors:** All authors conceived of the study. LP wrote the first and subsequent drafts. EAK
43
44 204 extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB
45
46 205 participated in creating the original database and critically revised the manuscript. All authors
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48 206 reviewed and approved the final manuscript.

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51 207 **Patient and public involvement:** Not required.

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54 208 **Ethics approval:** Not required.

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3 209 **Data sharing statement:** Limited data from this study are publically available. Data on
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5 210 Pharmaceutical Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are
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7 211 available at: <https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB>. The
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9 212 Pharmaceutical Industry Payments to Healthcare Professionals (May 2016 to Apr 2017) database is
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11 213 available at: <https://research-data.sydney.edu.au/index.php/s/0MmrflPyiOrf53a>. Neither of these
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13 214 available databases currently include all Educational Events Reports or Individual Payments Reports
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15 215 included in this manuscript.
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216 **Figure Legends and Tables**217 **Table 1. Characteristics of reports from Medicines Australia members. Shading indicates major**218 **differences in data capture in current/ongoing versus discontinued reports.**

	<i>DISCONTINUED REPORTS</i>			<i>ONGOING REPORTS</i>		
	<i>Educational Event Reports</i>	<i>HCP Consultants Reports</i>	<i>Advisory Board Meeting Reports</i>	<i>Health Consumer Organisation Support Reports</i>	<i>Third Party Educational Events Reports</i>	<i>Healthcare Professionals Report</i>
DESCRIPTION	<i>Payments related to educational events for HCPs that are held or sponsored by the company</i>	<i>Payments to HCPs for consultancy services/advice</i>	<i>Payments to HCPs contracted to provide advice to the company as part of an advisory board</i>	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	<i>Oct 2011 – Sep 2015[#]</i>	<i>Jan 2013 – Sep 2015</i>	<i>Jan 2013 – Sep 2015</i>	Jan 2013 –	Oct 2015 –	Oct 2015 –
PAYMENTS REPORTED						
<i>Educational events for HCPs held by the company</i>						
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	✓		Payments no longer captured
Event running costs	✓		Payments no longer captured
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	Enhanced transparency from January 2013		✓		
Other support (e.g. publications)	Enhanced transparency from January 2013		✓		
REPORT FORMAT					
Itemised (per event/individual)	✓		✓	✓	✓
Aggregated (no. per period)		✓	✓		§
Disclosure of recipient required	Enhanced transparency from October 2015		✓ (Organisation)	✓ (Third Party)	✓ (Individual HCP) [§]
219	HCP: Healthcare professional				
220	[#] Reports go back to 2007, but they are not available prior to Oct 2011				

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3 221 [†]Excludes ground transfers, taxis, parking.
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5 222 [‡] Reporting is not required if food and beverages are the company's only contribution to the event.
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7 223 [§] Prior to the introduction of mandatory reporting of payments to HCPs on 1 October 2016, disclosure of a
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9 224 HCP's identifying information was contingent on the consent of the HCP. All payments received by non-
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11 225 consenting HCPs were reported in aggregated format.
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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			
<i>Educational events for HCPs held by the company</i>			
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)	✓		
<i>Non-Price Benefits to Pharmacists</i>			
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			

228 ¹ Reports limited to prescribing HCPs and pharmacists

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3 230 **Figure 1. Cumulative monthly expenditure disclosed in transparency reports from Medicines**

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5 231 **Australia and GBMA members***

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7 232 Legend: *arrow indicates date of change to Medicines Australia reporting requirements

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10 233 NB: The health consumer organisation reports are submitted per calendar year, and therefore only

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12 234 extend to Dec 2016 rather than to April 2017. This doesn't impact the calculations in the text, but for

13
14 235 the purpose of this graph, we have extrapolated the monthly average from Jan-Dec 2016

15
16 236 (\$674,491.91) to cover the missing data Jan-April 2017.

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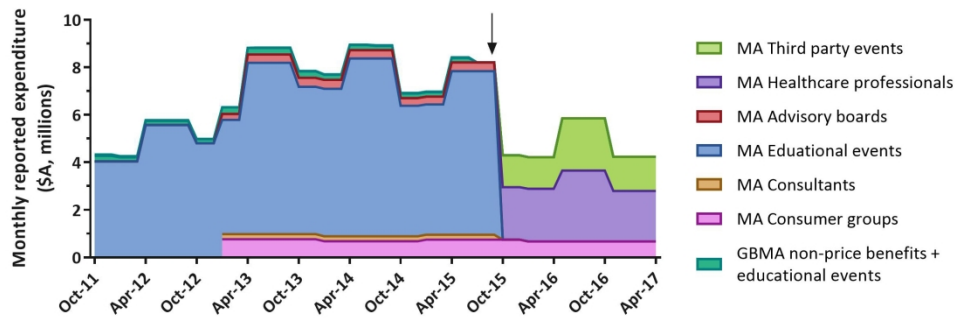


Figure 1. Cumulative monthly expenditure disclosed in transparency reports from Medicines Australia and GBMA members*

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.

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.

BMJ Open

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

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Keywords:	pharmaceutical industry, transparency, industry relationships

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3 **1 Title page**
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6 **2 Changes in the type and amount of spending disclosed by Australian pharmaceutical companies: an**
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8 **3 observational study**
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10
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12
13 5 Lisa Parker, Postdoctoral Research Fellow¹ lisa.parker@sydney.edu.au
14

15
16 6 Emily A Karanges, Postdoctoral Research Fellow¹ emily.karanges@sydney.edu.au
17

18
19 7 Lisa Bero, Professor¹ lisa.bero@sydney.edu.au
20

21
22 8
23
24 9 ¹Charles Perkins Centre, School of Pharmacy, Faculty of Medicine and Health, The University of Sydney
25

26
27 10
28
29
30 **11 Corresponding author:**
31

32
33 12 Lisa Parker
34

35 13 D17, The Hub, 6th floor, Charles Perkins Centre, The University of Sydney, NSW, 2006, Australia.
36

37 14 Phone: +61 2 86276422 lisa.parker@sydney.edu.au
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3 **16 Abstract**

4
5 **17 Objectives:** To describe and quantify disclosed payments from the pharmaceutical industry to the
6
7 **18 healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system of**
8
9 **19 transparency.**

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12 **20 Design:** Observational database study

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15 **21 Setting:** Australia

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18 **22 Participants:** Publically available reports submitted by members of Australian pharmaceutical industry
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20 **23 trade organisations, Medicines Australia and the Generic and Biosimilar Medicines Association (Oct**
21
22 **24 2011 to Oct 2017).**

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25 **25 Exposure:** Changes to transparency reporting requirements with the updates of pharmaceutical industry
26
27 **26 Codes of Conduct in 2015.**

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30 **27 Main outcome measures:** Elements of healthcare sector spending that members of industry organisations
31
32 **28 are required to publically disclose. Cumulative amount of disclosed spending (monthly average) in the**
33
34 **29 year prior to and following the revision.**

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37 **30 Results:** There was a 34.1% reduction in disclosed spending from Medicines Australia member
38
39 **31 companies in the year after the 2015 changes to the Code of Conduct were introduced (\$AUS 89,658,566**
40
41 **32 in the preceding year, Oct 2014 to Sep 2015; \$AUS 59,052,551 in the following year). The new Code**
42
43 **33 allowed for reduced reporting of spending on food and beverages at events and for sponsored healthcare**
44
45 **34 professionals. However, there was enhanced transparency around identification of individual health**
46
47 **35 professionals receiving payments. GBMA member reporting totalled \$AUS 2,580,402 in the year prior to**
48
49 **36 the revision, then ceased.**

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3 37 Conclusions: This study shows the limitations of a self-regulatory system around industry disclosure of
4
5 38 spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory long-
6
7 39 lasting public transparency.
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13 41 **Article Summary**

15 42 **Strengths and Limitations of this Study**

- 18 43 • We compiled and analysed over 900 transparency reports on pharmaceutical industry payments to
19
20 44 the Australian healthcare sector, including payments to medical practitioners and other healthcare
21
22 45 professionals, third parties such as medical organisations and hospitals, and health consumer
23
24 46 groups.
- 26 47 • We identified key changes in the industry's self-regulatory codes regarding transparency
27
28 48 reporting and examined changes in disclosed spending occurring concurrently with these
29
30 49 changes; our analysis could not determine causality.
- 33 50 • We relied on information provided by pharmaceutical companies in their transparency reports and
34
35 51 did not verify the accuracy or completeness of the data.
- 37 52 • Only member companies of Australia's pharmaceutical industry trade organisations are required
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39 53 to submit transparency reports, therefore our data do not reflect total spending and changes in
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41 54 membership status may affect disclosed payments.
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56 Introduction

57 Financial relationships between healthcare professionals and the pharmaceutical industry influence
58 healthcare.^{1 2} Exposure of healthcare professionals to the pharmaceutical industry is widespread³ but the
59 financial details and extent of these relationships may be unclear. The United States and some European
60 countries have legislated mandatory reporting of payments from pharmaceutical and medical device
61 manufacturers to healthcare professionals⁴ and Ontario, Canada has recently introduced similar
62 legislation.⁵ Other jurisdictions rely on self-regulation governed by industry associations such as the
63 European Federation of Pharmaceutical Industry Associations (EFPIA).⁶
64 Australia has previously been at the forefront of transparency reporting.⁷ For example, the pharmaceutical
65 industry trade association Medicines Australia introduced a self-regulatory transparency program over a
66 decade ago, when its 2007 Code of Conduct required member companies to publically report their
67 spending on educational events for healthcare professionals.⁸ Importantly, this included spending for
68 “educational” events attended by healthcare professionals from many disciplines including nurses,
69 pharmacists, physiotherapists and dieticians, as well as medical practitioners. The Generic and Biosimilar
70 Medicines Association (GBMA), formerly the Generic Medicines Industry Association, introduced a
71 similar requirement for its members in 2010, although this became non-compulsory in 2013.⁹ GBMA also
72 requested that members report “non-price benefits” to pharmacists, including, for example, provision of
73 training, pharmacy aids, merchandising, software and vouchers.
74 In 2015, after pressure from the Australian Competition and Consumer Commission, Medicines Australia
75 amended its Code to require public reporting of the amounts paid to individual healthcare professionals.
76 At the same time, however, the requirements to report on spending for educational events were watered
77 down.¹⁰ The GBMA followed suit, noting that ‘Medicines Australia has removed this requirement [for
78 educational event reporting] of its members’, and citing the ‘significant compliance burden placed on
79 members’ and the ‘consistently demonstrated ... appropriate conduct over the past five years’ as further
80 reasons to remove these reports on spending.^{11p6} Unlike Medicines Australia, the GBMA did not

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3 81 introduce any requirements to report spending to individual healthcare professionals, educational events
4
5 82 run by third parties, or consumer groups. These transparency losses were criticised at the time.¹² The
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7 83 objective of this paper is to describe changes in the types of spending disclosed and cumulative amount of
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9 84 spending following the 2015 changes in industry-regulated reporting requirements. We highlight exactly
10
11 85 what information has been lost and gained from the public record in Australia, and report on the financial
12
13 86 changes.

16 87 **Methods**

18
19 88 We conducted an observational study of publically available reports submitted by members of Australian
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21 89 pharmaceutical industry trade organisations, Medicines Australia and the Generic and Biosimilar
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23 90 Medicines Association (Oct 2011 to Oct 2017).

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26 91 Details on current and previous Medicines Australia and GBMA reporting requirements are available
27
28 92 through their respective websites: <https://medicinesaustralia.com.au/> and <https://www.gbma.com.au/>. We
29
30 93 used the relevant Codes and/or related documents associated with the current¹⁰ and previous¹³ Medicines
31
32 94 Australia Codes of Conduct, and the current¹¹ and previous¹⁴ GBMA Codes of Practice to identify
33
34 95 changes to transparency information required from organisation members.

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37 96 **Data sources and analysis.** Transparency reports on Medicines Australia and GMBA member company
38
39 97 spending are available through the respective industry body websites as separate reports (usually PDF
40
41 98 files) for each company, reporting period, and report category. Our research group has previously
42
43 99 downloaded and compiled Medicines Australia reports on educational events for healthcare professionals
44
45 100 (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically accessible) and payments to
46
47 101 individual healthcare professionals (May 2016 to Apr 2017), converting them into databases for research
48
49 102 purposes and public use.^{6,7} These data are publically available for download: <https://research->
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51 103 [data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB](https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB) and <https://research->
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53 104 [data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a](https://research-data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a) respectively. The current project extends on this work
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105 by updating these pre-existing databases and compiling additional databases from more recent reports
 106 downloaded from Medicines Australia and GMBA. In total, this project employed 905 Medicines
 107 Australia reports (Oct 2011 - Dec 2017) collated into six distinct databases according to the report
 108 categories defined by Medicines Australia. Specifically, these databases contain reports on payments
 109 related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Sept 2015); (2) Healthcare
 110 Professional Consultants (Jan 2013 - Sep 2015); (3) Advisory Board Participation (Jan 2013 - Sep 2015);
 111 (4) Health Consumer Organisation Support (Jan 2013- Dec 2017); (5) Third Party Meeting Sponsorship
 112 (Oct 2015 – Oct 2017); (6) Payments to Healthcare Professionals (Oct 2015 – Oct 2017). We generated
 113 two databases from the 64 available GBMA reports detailing GBMA member payments related to: (1)
 114 Educational Events (for healthcare professionals) ; and (2) Non-Price Benefits to Pharmacists. See Table
 115 1 for a description of each category and Figure 1 for a timeline of available reports. Further information
 116 about each report category is provided in Supplementary Files 1 and 2.

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

Report category	Dates reported	Description	Payments reported
<i>MEDICINES AUSTRALIA REPORTS</i>			
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)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	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)
18	GBMA REPORTS			
19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40	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)
41 42 43 44 45 46	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

119 ^aData presented from Oct 2011

120

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

123 Figure 1 footnotes:

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

129
130 We identified 39 Medicines Australia members filing transparency reports in the year preceding the
131 changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year
132 (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most recent
133 period for which reports were requested by their industry body (i.e. ending June 2015), compared to none
134 in the following year, and since.

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

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

140 ***Ethical approval.*** None required.

141 Results

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

149 **Table 2. Types of payments publically reported by Medicines Australia members before and after**
 150 **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)	✓	✓

151 HCP: Healthcare professional

152 ^aCaptured in the HCP Consultants Reports (pre-2015) and HCP Reports (post-2015)

153 ^bCaptured in the Educational Events and Advisory Board Reports (pre-2015) and HCP Reports (post-2015)

154 ^cCaptured in the Educational Events Reports (pre-2015), and Third Party and HCP Reports (post-2015)

155 ^dCaptured in the Health Consumer Organisation Reports (pre- and post-2015)

156 [#]Airfares only

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

158

159 **Table 3. Summary of gains and loss in current Medicines Australia and GBMA reports compared**
 160 **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)

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

161

162 In the year preceding the 2015 changes to the Medicines Australia code, industry payments disclosed by

163 Medicines Australia members totalled \$AUS 89,658,566 (Oct 2014 to Sep 2015) across four reporting

164 categories. Reported payments included \$74,264,438 (82.8%) on Educational Events run by the company

165 or third party, \$8,743,250 (9.8%) on Health Consumer Organisation Support, \$4,158,819 (4.6%) on costs

166 associated with Advisory Board Participation, and \$2,492,059 (2.8%) on Healthcare Professional

167 Consultants.

168 In the year following the 2015 change, reported payments from Medicines Australia members totalled

169 \$59,205,301 (Oct 2015 to Sep 2016), an overall reduction of 34.1%. Payments reported in the new

170 categories, Healthcare Professional Reports and Third Party Educational Events, totalled \$30,380,145 and

171 \$20,364,929 respectively. There was little change in the total reported expenditure on Health Consumer

172 Organisation Support (\$8,461,228), which was the only reporting category to remain unchanged in the

173 revised code (See Figure 2). Excluding payments associated with this category, there was a 37.3%

174 reduction in disclosed Medicines Australia payments. As shown in Table 2 the reduction in disclosed

175 payments coincides with loss of information about spending on: running costs for industry-run events and

176 meetings (including food and beverages); hospitality to sponsored healthcare professionals attending

177 events and meetings.

1
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3 **178 Figure 2. Cumulative monthly expenditure disclosed in transparency reports from Medicines**
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5 **179 Australia and GBMA members***
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8 180 Legend: *arrow indicates date of change to Medicines Australia reporting requirements
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11 181 In the year preceding the 2015 changes to the GBMA code, industry payments disclosed by GBMA
12
13 182 members totalled \$AUS 2,580,402 (Jul 2014 – Jun 2015). 88.3% of these reported payments were for
14
15 183 Non-Price Benefits to Pharmacists and the remainder were for Educational Events. After July 2015,
16
17 184 \$AUS 0 payments have been reported by GBMA members, a drop of 100%.
18
19

20 **185 Discussion**
21

22
23 186 Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient
24
25 187 identities but an overall reduction in transparency around industry funding in the healthcare sector.
26
27 188 Dropping the requirements for transparency around items such as expenditure on food and beverages
28
29 189 means that over a third of previously reported industry spending on healthcare professionals is now
30
31 190 hidden. In addition, the new Code failed to include other disclosures about industry interactions with
32
33 191 health professionals that countries such as the UK and USA have introduced, such as pharmaceutical
34
35 192 company spending on free drug samples and funding for research.⁶ The changes have also added an extra
36
37 193 layer of complexity to what is already difficult-to-understand data on disclosed payments. This
38
39 194 complexity hinders transparency.
40
41
42

43 195 This erosion of transparency has taken place in a time of increasing societal interest in disclosure.
44

45 196 Transparency around pharmaceutical industry spending in the healthcare sector is important for several
46
47 197 reasons. First, the public have a legitimate expectation that all transfers of value between the
48
49 198 pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and judge
50
51 199 the appropriateness of such interactions. Second, transparency may assist those reading or receiving the
52
53 200 disclosure to judge the risk of bias in those making the disclosure. For example, disclosures of competing
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55 201 interests by research authors makes academic readers more critical of an article.¹⁵ Receiving conflicts of
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3 202 interest information may, however, have limited impact on the audience. Individuals disclosing conflicts
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5 203 of interest are more likely to exaggerate their claims,¹⁶ and even critical readers tend not to sufficiently
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7 204 discount the credibility of biased information sources,¹⁷ Third, transparency requirements may change
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9 205 behaviour of those making the disclosure. In situations where disclosures are required or expected,
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11 206 individuals may avoid accepting the conflicts of interest in order to avoid making the declaration ¹⁸ and
12
13 207 the same may apply to corporations. For example, if industry is required to declare costs associated with
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15 208 food and beverage provision at third party events such as medical grand rounds and journal clubs, they
16
17 209 may be less likely to provide this kind of sponsorship. While doctors may be disappointed at the
18
19 210 reduction in ‘free’ lunches, this change would reduce industry influence on healthcare, because receipt of
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21 211 industry-sponsored meals, even low-cost meals, influences doctors to prescribe more of the brand-name
22
23 212 drug being promoted at the time.¹

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27 213 The erosion of organisational transparency that we document in the paper is particularly significant.
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29 214 Although disclosure is a burden for the pharmaceutical industry, organisational transparency has the
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31 215 advantage of not relying on disclosures from individual healthcare professionals. These disclosures are
32
33 216 potentially counterproductive since patients may feel extra pressure to follow the advice of those who
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35 217 declare conflicts of interests, in order to avoid implying distrust of their practitioner.^{16 19} Dropping
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37 218 organisational disclosure of food and beverage spending also seems to send the wrong message to
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39 219 potential recipients, i.e. that this transfer of value is not significant enough to warrant reporting. As a
40
41 220 result, doctors may be more likely to participate in industry-sponsored lunches,

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44
45 221 Transparency is unlikely to be a complete solution to concerns about commercial influence within the
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47 222 healthcare sector.²⁰ There are many other important elements involved in managing this issue, including,
48
49 223 for example, the prohibition of: clinical trials that seek to familiarise prescribers with new medications
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51 224 rather than add to scientific knowledge (so-called “seeding trials”), honorary authorships for healthcare
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53 225 professionals, and the release of free drug samples into clinic rooms.²¹ However transparency is a

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

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

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

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3 251 Australia member companies submitting reports, from 39 in the year prior to the change in reporting
4
5 252 requirements to 34 after the change, contributed to the reduction in the cumulative disclosed sum,
6
7 253 although was unlikely to have had a big impact. Together, these five companies only disclosed a total of
8
9 254 \$4,199,674 between October 2014 and September 2015, which was 4.68% of the total disclosure by all
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11 255 companies over this period. Finally, our results cannot prove a causal relationship between changing
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13 256 industry Codes and cumulative disclosed spending. We think it likely that current spending remains
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15 257 similar to 2015 levels, and that the apparent reduction in cumulative spending is due to changed reporting
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17 258 patterns. It is possible, however, that cumulative spending may have truly decreased, or that spending
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19 259 patterns may have coincidentally (or even deliberately) altered at the same time that the new Code came in,
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21 260 perhaps reflecting different ways of industry promotional spend in the healthcare sector that were not
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23 261 captured by the previous or current transparency program. Finally, as mentioned above, the program of
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25 262 required reporting is complex, and changes are difficult to follow. There may be some elements that we
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27 263 have misinterpreted.

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31 264 Once a leader in transparency, Australia is now falling behind other countries. This study provides a clear
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33 265 example of the limitations of a self-regulatory system, which can be quietly changed in such a way as to
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35 266 reduce overall public reporting of industry funding in the healthcare sector. We recommend that
36
37 267 countries insist on legislation rather than self-regulation to promote long-lasting public transparency
38
39 268 around industry spending.

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47
48 271 of disclosed payments from publically accessible industry documents.

49
50
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52
53 273 not-for-profit sectors

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56 274 **Competing interests:** The authors have no completing interests.

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3 275 **Contributors:** All authors conceived of the study. LP wrote the first and subsequent drafts. EAK
4
5 276 extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB
6
7 277 participated in creating the original database and critically revised the manuscript. All authors reviewed
8
9 278 and approved the final manuscript.

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12 279 **Patient and public involvement:** Not required.

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15 280 **Ethics approval:** Not required.

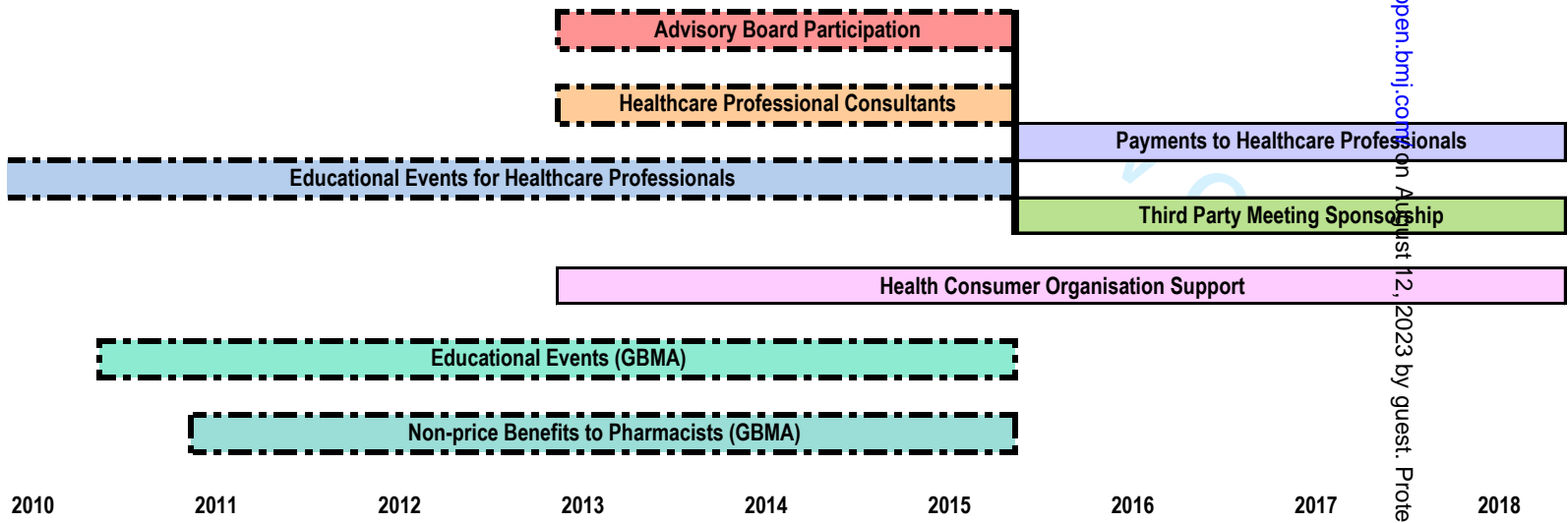
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18 281 **Data sharing statement:** Limited data from this study are publically available. Data on Pharmaceutical
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20 282 Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are available at:
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22 283 <https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB>. The Pharmaceutical Industry
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24 284 Payments to Healthcare Professionals (May 2016 to Apr 2017) database is available at: [https://research-](https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a)
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26 285 [data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a](https://research-data.sydney.edu.au/index.php/s/0MmrflPyiQrf53a). Neither of these available databases currently include
27
28 286 all Educational Events Reports or Individual Payments Reports included in this manuscript.

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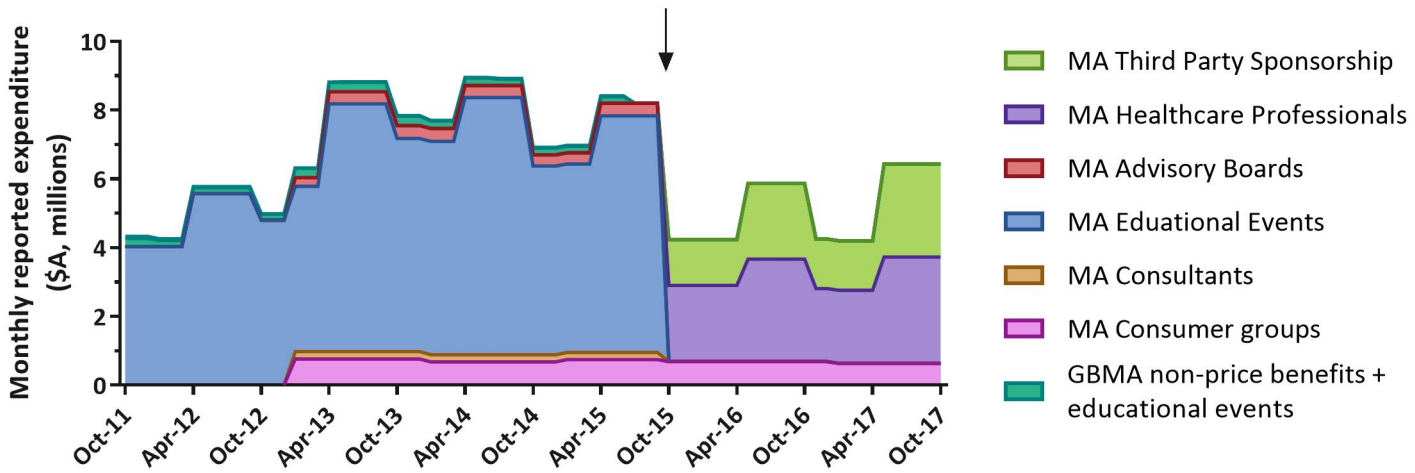
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Supplementary File 1. Characteristics of reports from Medicines Australia members. Shading indicates major differences in data capture in current/ongoing versus discontinued reports.

	<i>DISCONTINUED REPORTS</i>			<i>ONGOING REPORTS</i>		
	<i>Educational Events for Healthcare Professionals</i>	<i>Healthcare Professional Consultants</i>	<i>Advisory Board Participation</i>	<i>Health Consumer Organisation Support</i>	<i>Third Party Meeting Sponsorship</i>	<i>Payments to Healthcare Professionals</i>
DESCRIPTION	<i>Payments related to educational events for HCPs that are held or sponsored by the company</i>	<i>Payments to HCPs for consultancy services/advice</i>	<i>Payments to HCPs contracted to provide advice to the company as part of an advisory board</i>	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	<i>Oct 2011 – Sep 2015[#]</i>	<i>Jan 2013 – Sep 2015</i>	<i>Jan 2013 – Sep 2015</i>	Jan 2013 –	Oct 2015 –	Oct 2015 –
PAYMENTS REPORTED						
<i>Educational events for HCPs held by the company</i>						
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	✓					

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5 beverages at event

6
7 Event running
8 costs (e.g. venue ✓
9 hire, event
10 organiser)

11
12 ***Internal company meetings and consulting***

13
14 Fees to individual
15 HCPs for
16 consulting or ✓
17 other services ✓
18 (e.g.
19 speaking/chairing)

20
21 Hospitality
22 (accommodation,
23 travel) associated ✓
24 with HCP services ✓⁺

25
26
27 Hospitality (food/beverages)
28 associated with ✓
29 HCP services
30
31 Payments no longer captured

32 ***Advisory boards***

33
34 Fees to advisory ✓
35 board members ✓

36
37 Hospitality (accommodation,
38 travel) for board ✓
39 members ✓⁺

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42 Hospitality (food/
43 beverages) for ✓
44 board members
45
46 Payments no longer captured

47 Food and ✓
48 beverages at ✓
49 meeting

50
51 Event running ✓
52 costs

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54 ***Third party (independent) meetings***

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56 Food and ✓
57 beverages at ✓[‡]

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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	Enhanced transparency from January 2013		✓	
Other support (e.g. publications)	Enhanced transparency from January 2013		✓	
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

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5 [†]Excludes ground transfers, taxis, parking.

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

7
8 [§] Prior to the introduction of mandatory reporting of payments to HCPs on 1 October 2016, disclosure of a
9
10 HCP's identifying information was contingent on the consent of the HCP. All payments received by non-
11
12 consenting HCPs were reported in aggregated format.
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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			
<i>Educational events for HCPs held by the company</i>			
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)	✓		
<i>Non-Price Benefits to Pharmacists</i>			
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			

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

¹ Reports limited to prescribing HCPs and pharmacists

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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.

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024928.R2
Article Type:	Research
Date Submitted by the Author:	21-Nov-2018
Complete List of Authors:	Parker, Lisa; The University of Sydney, Charles Perkins Centre, School of Pharmacy, Faculty of Medicine and Health Karanges, Emily; The University of Sydney, Charles Perkins Centre, School of Pharmacy, Faculty of Medicine and Health Bero, Lisa; University of Sydney, Charles Perkins Centre, School of Pharmacy, Faculty of Medicine and Health
Primary Subject Heading:	Health policy
Secondary Subject Heading:	Ethics
Keywords:	pharmaceutical industry, transparency, industry relationships

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Manuscripts

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3 **1 Title page**
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6 **2 Changes in the type and amount of spending disclosed by Australian pharmaceutical**
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8 **3 companies: an observational study**
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13 5 Lisa Parker, Postdoctoral Research Fellow¹ lisa.parker@sydney.edu.au
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16 6 Emily A Karanges, Postdoctoral Research Fellow¹ emily.karanges@sydney.edu.au
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19 7 Lisa Bero, Professor¹ lisa.bero@sydney.edu.au
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24 9 ¹The University of Sydney Charles Perkins Centre, Faculty of Medicine and Health, School of
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26 Pharmacy
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32 **12 Corresponding author:**
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34
35 13 Lisa Parker
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37 14 D17, The Hub, 6th floor, Charles Perkins Centre, The University of Sydney, NSW, 2006, Australia.
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39 15 Phone: +61 2 86276422 lisa.parker@sydney.edu.au
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3 **17 Abstract**

4
5 **18 Objectives:** To describe and quantify disclosed payments from the pharmaceutical industry to the
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7 **19 healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system**
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9 **20 of transparency.**

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12 **21 Design:** Observational database study

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15 **22 Setting:** Australia

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18 **23 Participants:** Publically available reports submitted by members of Australian pharmaceutical
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20 **24 industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines**
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22 **25 Association (Oct 2011 to Oct 2017).**

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24
25 **26 Exposure:** Changes to transparency reporting requirements with the updates of pharmaceutical
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27 **27 industry Codes of Conduct in 2015.**

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30 **28 Main outcome measures:** Elements of healthcare sector spending that members of industry
31
32 **29 organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly**
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34 **30 average) in the year prior to and following the revision.**

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36
37 **31 Results:** There was a 34.1% reduction in disclosed spending from Medicines Australia member
38
39 **32 companies in the year after the 2015 changes to the Code of Conduct were introduced (\$AUS**
40
41 **33 89,658,566 in the preceding year, Oct 2014 to Sep 2015; \$AUS 59,052,551 in the following year).**

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43
44 **34 The new Code allowed for reduced reporting of spending on food and beverages at events and for**
45
46 **35 sponsored healthcare professionals. However, there was enhanced transparency around identification**
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48 **36 of individual health professionals receiving payments. GBMA member reporting totalled \$AUS**
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50 **37 2,580,402 in the year prior to the revision, then ceased.**

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53 **38 Conclusions:** This study shows the limitations of a self-regulatory system around industry disclosure
54
55 **39 of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory**
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57 **40 long-lasting public transparency.**

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3 42 **Article Summary**

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5 43 **Strengths and Limitations of this Study**

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8 44 • We compiled and analysed over 900 transparency reports on pharmaceutical industry
9
10 45 payments to the Australian healthcare sector, including payments to medical practitioners and
11
12 46 other healthcare professionals, third parties such as medical organisations and hospitals, and
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14 47 health consumer groups.
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16 48 • We identified key changes in the industry's self-regulatory codes regarding transparency
17
18 49 reporting and examined changes in disclosed spending occurring concurrently with these
19
20 50 changes; our analysis could not determine causality.
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23 51 • We relied on information provided by pharmaceutical companies in their transparency reports
24
25 52 and did not verify the accuracy or completeness of the data.
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27 53 • Only member companies of Australia's pharmaceutical industry trade organisations are
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29 54 required to submit transparency reports, therefore our data do not reflect total spending and
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31 55 changes in membership status may affect disclosed payments.
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57 **Introduction**

58 Financial relationships between healthcare professionals and the pharmaceutical industry influence
59 healthcare.^{1 2} Exposure of healthcare professionals to the pharmaceutical industry is widespread³ but
60 the financial details and extent of these relationships may be unclear. The United States and some
61 European countries have legislated mandatory reporting of payments from pharmaceutical and
62 medical device manufacturers to healthcare professionals⁴ and Ontario, Canada has recently
63 introduced similar legislation.⁵ Other jurisdictions rely on self-regulation governed by industry
64 associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).⁶
65 Australia has previously been at the forefront of transparency reporting.⁷ For example, the
66 pharmaceutical industry trade association Medicines Australia introduced a self-regulatory
67 transparency program over a decade ago, when its 2007 Code of Conduct required member companies
68 to publically report their spending on educational events for healthcare professionals.⁸ Importantly,
69 this included spending for “educational” events attended by healthcare professionals from many
70 disciplines including nurses, pharmacists, physiotherapists and dieticians, as well as medical
71 practitioners. The Generic and Biosimilar Medicines Association (GBMA), formerly the Generic
72 Medicines Industry Association, introduced a similar requirement for its members in 2010, although
73 this became non-compulsory in 2013.⁹ GBMA also requested that members report “non-price
74 benefits” to pharmacists, including, for example, provision of training, pharmacy aids, merchandising,
75 software and vouchers.

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

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3 84 healthcare professionals, educational events run by third parties, or consumer groups. These
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5 85 transparency losses were criticised at the time.¹² The objective of this paper is to describe changes in
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7 86 the types of spending disclosed and cumulative amount of spending following the 2015 changes in
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9 87 industry-regulated reporting requirements. We highlight exactly what information has been lost and
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11 88 gained from the public record in Australia, and report on the financial changes.
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14 89 **Methods**

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17 90 We conducted an observational study of publically available reports submitted by members of
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19 91 Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and
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21 92 Biosimilar Medicines Association (Oct 2011 to Oct 2017).
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24 93 Details on current and previous Medicines Australia and GBMA reporting requirements are available
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26 94 through their respective websites: <https://medicinesaustralia.com.au/> and <https://www.gbma.com.au/>.
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28 95 We used the relevant Codes and/or related documents associated with the current¹⁰ and previous¹³
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30 96 Medicines Australia Codes of Conduct, and the current¹¹ and previous¹⁴ GBMA Codes of Practice to
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32 97 identify changes to transparency information required from organisation members.
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36 98 **Data sources and analysis.** Transparency reports on Medicines Australia and GBMA member
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38 99 company spending are available through the respective industry body websites as separate reports
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40 100 (usually PDF files) for each company, reporting period, and report category. Our research group has
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42 101 previously downloaded and compiled Medicines Australia reports on Educational Events for
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44 102 Healthcare Professionals (Oct 2011 to Sep 2015; reports prior to Oct 2011 are no longer publically
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46 103 accessible), and Payments to Healthcare Professionals (May 2016 to Apr 2017), converting them into
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48 104 databases for research purposes and public use.^{6,7} These data are publically available for download:
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50 105 <https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB> and <https://research->
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52 106 [data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a](https://research-data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a) respectively. The current project extends on this
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54 107 work by updating these pre-existing databases and compiling additional databases from more recent
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56 108 reports downloaded from Medicines Australia and GBMA. In total, this project employed 905
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58 109 Medicines Australia reports (Oct 2011 - Dec 2017) collated into six distinct databases according to the
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3 110 report categories defined by Medicines Australia. Specifically, these databases contain reports on
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5 111 payments related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Sept 2015); (2)
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7 112 Healthcare Professional Consultants (Jan 2013 - Sep 2015); (3) Advisory Board Participation (Jan
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9 113 2013 - Sep 2015); (4) Health Consumer Organisation Support (Jan 2013- Dec 2017); (5) Third Party
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11 114 Meeting Sponsorship (Oct 2015 – Oct 2017); (6) Payments to Healthcare Professionals (Oct 2015 –
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13 115 Oct 2017). We generated two databases from the 64 available GBMA reports detailing GBMA
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15 116 member payments related to: (1) Educational Events (for healthcare professionals) ; and (2) Non-Price
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17 117 Benefits to Pharmacists. See Table 1 for a description of each category and Figure 1 for a timeline of
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19 118 available reports. Further information about each report category is provided in Supplementary Files
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21
22 119 1 and 2.

25 120 **Table 1 – Description of required reporting categories from Medicines Australia and GBMA**
26 121 **members**

Report category	Dates reported	Description	Payments reported
<i>MEDICINES AUSTRALIA REPORTS</i>			
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

^aData presented from Oct 2011

^bAirfares only; excludes ground transfers, taxis, parking.

^cReporting is not required if food and beverages are the company’s only contribution to the event.

^dPrior to 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.

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

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3 133 • The Payments to Healthcare Professionals category is a partial merger (with some exclusions) of three former categories:
4 134 Healthcare Professional Consultants; Advisory Board Participation; Educational Events
5 135 • The Third Party Educational Events category is a subset of the former Educational Events category

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9 137 We identified 39 Medicines Australia members filing transparency reports in the year preceding the
10 138 changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year
11 139 (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most
12 140 recent period for which reports were requested by their industry body (i.e. ending June 2015),
13 141 compared to none in the following year, and since.

14 142 Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each
15 143 category as a monthly average over the given reporting period. Change in total expenditure from
16 144 Medicines Australia and GBMA member companies over time was used to assess the impact of
17 145 changes in reporting requirements in October 2015 and July 2015 respectively.

18 146 ***Patient or public involvement.*** No patients or members of the public were involved in this study.

19 147 ***Ethical approval.*** None required.

20 148 **Results**

21 149 The 2015 changes to the Medicines Australia code resulted in merging and crossover of pre-existing
22 150 reporting categories, as well as inclusion of some new elements and discontinuation of others. For
23 151 example, information formerly captured in the Educational Events Database is now reported in the
24 152 Third Party and Healthcare Professional databases. The main required reporting elements in the old
25 153 and new Medicines Australia Codes of Conduct are listed in Table 2 with further details in
26 154 Supplementary Files 1 and 2. The transparency gains and losses from Medicines Australia and GBMA
27 155 members are summarised in Table 3.

28 156 **Table 2. Types of payments publically reported by Medicines Australia members before and**
29 157 **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)	✓	✓

158 HCP: Healthcare professional

159 ^aCaptured in the HCP Consultants Reports (pre-2015) and HCP Reports (post-2015)

160 ^bCaptured in the Educational Events and Advisory Board Reports (pre-2015) and HCP Reports (post-2015)

161 ^cCaptured in the Educational Events Reports (pre-2015), and Third Party and HCP Reports (post-2015)

162 ^dCaptured in the Health Consumer Organisation Reports (pre- and post-2015)

163 ^eAirfares only

164 ^fReporting is not required if food and beverages are the company's only contribution to the event.

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166 **Table 3. Summary of gains and loss in current Medicines Australia and GBMA reports**
 167 **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:- <ul style="list-style-type: none"> - Food and beverages and small travel costs (taxi, 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

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169 In the year preceding the 2015 changes to the Medicines Australia code, industry payments disclosed
170 by Medicines Australia members totalled \$AUS 89,658,566 (Oct 2014 to Sep 2015) across four
171 reporting categories. Reported payments included \$74,264,438 (82.8%) on Educational Events run by
172 the company or third party, \$8,743,250 (9.8%) on Health Consumer Organisation Support, \$4,158,819
173 (4.6%) on costs associated with Advisory Board Participation, and \$2,492,059 (2.8%) on Healthcare
174 Professional Consultants.

175 In the year following the 2015 change, reported payments from Medicines Australia members totalled
176 \$59,205,301 (Oct 2015 to Sep 2016), an overall reduction of 34.1%. Payments reported in the new
177 categories, Healthcare Professional Reports and Third Party Educational Events, totalled \$30,380,145
178 and \$20,364,929 respectively. There was little change in the total reported expenditure on Health
179 Consumer Organisation Support (\$8,461,228), which was the only reporting category to remain
180 unchanged in the revised code (See Figure 2). Excluding payments associated with this category,
181 there was a 37.3% reduction in disclosed Medicines Australia payments. As shown in Table 2 the
182 reduction in disclosed payments coincides with loss of information about spending on: running costs
183 for industry-run events and meetings (including food and beverages); hospitality to sponsored
184 healthcare professionals attending events and meetings.

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

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

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

192 **Discussion**

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3 193 Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient
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5 194 identities but an overall reduction in transparency around industry funding in the healthcare sector.
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7 195 Dropping the requirements for transparency around items such as expenditure on food and beverages
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9 196 means that over a third of previously reported industry spending on healthcare professionals is now
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11 197 hidden. In addition, the new Code failed to include other disclosures about industry interactions with
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13 198 health professionals that countries such as the UK and USA have introduced, such as pharmaceutical
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15 199 company spending on free drug samples and funding for research.⁶ The changes have also added an
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17 200 extra layer of complexity to what is already difficult-to-understand data on disclosed payments. This
18
19 201 complexity hinders transparency.

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23 202 This erosion of transparency has taken place in a time of increasing societal interest in disclosure.
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25 203 Transparency around pharmaceutical industry spending in the healthcare sector is important for
26
27 204 several reasons. First, the public have a legitimate expectation that all transfers of value between the
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29 205 pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and
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31 206 judge the appropriateness of such interactions. Second, transparency may assist those reading or
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33 207 receiving the disclosure to judge the risk of bias in those making the disclosure. For example,
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35 208 disclosures of competing interests by research authors makes academic readers more critical of an
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37 209 article.¹⁵ However, authors who disclose conflicts of interest are more likely to exaggerate their
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39 210 claims,¹⁶ and even critical readers tend not to sufficiently discount the credibility of biased
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41 211 information sources, so the audience may still take home a biased message.¹⁷
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45 212 Third, transparency requirements may change behaviour of those making the disclosure. In situations
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47 213 where disclosures are required or expected, individuals may avoid accepting payments in order to
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49 214 avoid making the declaration¹⁸ and the same may apply to corporations. For example, if industry is
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51 215 required to declare costs associated with food and beverage provision at third party events such as
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53 216 medical grand rounds and journal clubs, they may be less likely to provide this kind of sponsorship.
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55 217 While healthcare professionals may be disappointed at the reduction in 'free' lunches, this change
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57 218 would reduce industry influence on healthcare, because receipt of industry-sponsored meals, even
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59 219 low-cost meals, increases prescribing of the brand-name drug being promoted at the time.¹

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3 220 The erosion of organisational transparency that we document in the paper is particularly significant.
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5 221 Although disclosure is a burden for the pharmaceutical industry, organisational transparency has the
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7 222 advantage of not relying on disclosures from individual healthcare professionals. These disclosures
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9 223 are potentially counterproductive since patients may feel extra pressure to follow the advice of those
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11 224 who declare conflicts of interests, in order to avoid implying distrust of their practitioner.^{16 19}
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13 225 Dropping organisational disclosure of food and beverage spending also seems to send the wrong
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15 226 message to potential recipients, i.e. that this transfer of value is not significant enough to warrant
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17 227 reporting. As a result, healthcare professionals may be more likely to participate in industry-
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19 228 sponsored lunches,
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23 229 Transparency is unlikely to be a complete solution to concerns about commercial influence within the
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25 230 healthcare sector.²⁰ There are many other important elements involved in managing this issue,
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27 231 including, for example, the prohibition of: clinical trials that seek to familiarise prescribers with new
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29 232 medications rather than add to scientific knowledge (so-called “seeding trials”), honorary authorships
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31 233 for healthcare professionals, and the release of free drug samples into clinic rooms.²¹ However
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33 234 transparency is a necessary first step towards assessing and analysing the level of industry influence,
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35 235 and may act as a deterrent to inappropriate interactions between individual professionals and industry.
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38 236 Self-regulated transparency programs may avoid the usual checks and balances of a more formal
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40 237 regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical
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42 238 industry to make changes associated with significant reductions in disclosed spending. Self-regulated
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44 239 transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It
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46 240 also fails to regulate companies that are not members of the relevant industry body. We advocate for
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48 241 legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise
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50 242 loss of transparency data in ways such as we report on here. In this particular case, we recommend
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52 243 that the Australian Government introduce transparency legislation. We recommend new legislation
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54 244 that maintains the current Medicines Australia transparency focus around spending on healthcare
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56 245 professionals and health consumer groups, and extends this requirement to include all companies in
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58 246 the pharmaceutical and medical device sector including GBMA members and companies with no
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3 247 affiliation to trade organisations. We propose mandatory disclosure on spending on drug samples and
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5 248 research. We also recommend that legislation should reinstate previously compulsory reporting of
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7 249 aggregated food, beverages and venue costs at company-run educational events and advisory board
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9 250 meetings; and food and beverages provided to healthcare professionals where costs per head are over
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11 251 a minimum amount as required by the US legislation.
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14 252 Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015
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16 253 and post-2015 periods may be an under-estimate. There are companies that are not members of
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18 254 Medicines Australia or GBMA and hence do not disclose their spending. In addition, compliance
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20 255 with the GBMA Code was not compulsory for GBMA members from 2013,²² so the true pre-2015
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22 256 spending figure is likely to have been higher than our calculated figure. There may be inaccuracies in
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24 257 the spending disclosed by the companies in the original reports: we could not verify the accuracy and
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26 258 completeness of the data, but many companies do provide independent audits of their reports. The
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28 259 reduction in Medicines Australia member companies submitting reports, from 39 in the year prior to
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30 260 the change in reporting requirements to 34 after the change, contributed to the reduction in the
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32 261 cumulative disclosed sum, although was unlikely to have had a big impact. Together, these five
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34 262 companies only disclosed a total of \$4,199,674 between October 2014 and September 2015, which
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36 263 was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot prove a
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38 264 causal relationship between changing industry Codes and cumulative disclosed spending. We think it
39
40 265 likely that current spending remains similar to 2015 levels, and that the apparent reduction in
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42 266 cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative
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44 267 spending may have truly decreased as a result of the changes in reporting and/or other requirements
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46 268 introduced in the new Code (e.g. introduction of a \$120 limit per head on meals for healthcare
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48 269 professionals), or that reductions in spending may reflect a move toward alternative methods of
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50 270 promotion to healthcare professionals not captured by the previous or current transparency program.
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52 271 Finally, as mentioned above, the program of required reporting is complex, and changes are difficult
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54 272 to follow. There may be some elements that we have misinterpreted.
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3 273 Once a leader in transparency, Australia is now falling behind other countries. This study provides a
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5 274 clear example of the limitations of a self-regulatory system, which can be quietly changed in such a
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7 275 way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend
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9 276 that countries insist on legislation rather than self-regulation to promote long-lasting public
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11 277 transparency around industry spending.
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16
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18
19 280 database of disclosed payments from publically accessible industry documents.
20

21
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23
24 282 or not-for-profit sectors
25

26
27 283 **Competing interests:** The authors have no completing interests.
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29
30 284 **Contributors:** All authors conceived of the study. LP wrote the first and subsequent drafts. EAK
31
32 285 extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB
33
34 286 participated in creating the original database and critically revised the manuscript. All authors
35
36 287 reviewed and approved the final manuscript.
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39 288 **Patient and public involvement:** Not required.
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42 289 **Ethics approval:** Not required.
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44
45 290 **Data sharing statement:** Limited data from this study are publically available. Data on
46
47 291 Pharmaceutical Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are
48
49 292 available at: <https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB>. The
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51 293 Pharmaceutical Industry Payments to Healthcare Professionals (May 2016 to Apr 2017) database is
52
53 294 available at: <https://research-data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a>. Neither of these
54
55 295 available databases currently include all Educational Events for Healthcare Professionals Reports or
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57 296 Payments to Healthcare Professional Reports included in this manuscript. The complete Health
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297 Consumer Organisation database (Jan 2013 to Dec 2016) is available at:
298 <https://researchdata.andis.org.au/pharmaceutical-industry-funding-december-2016/1330638>.

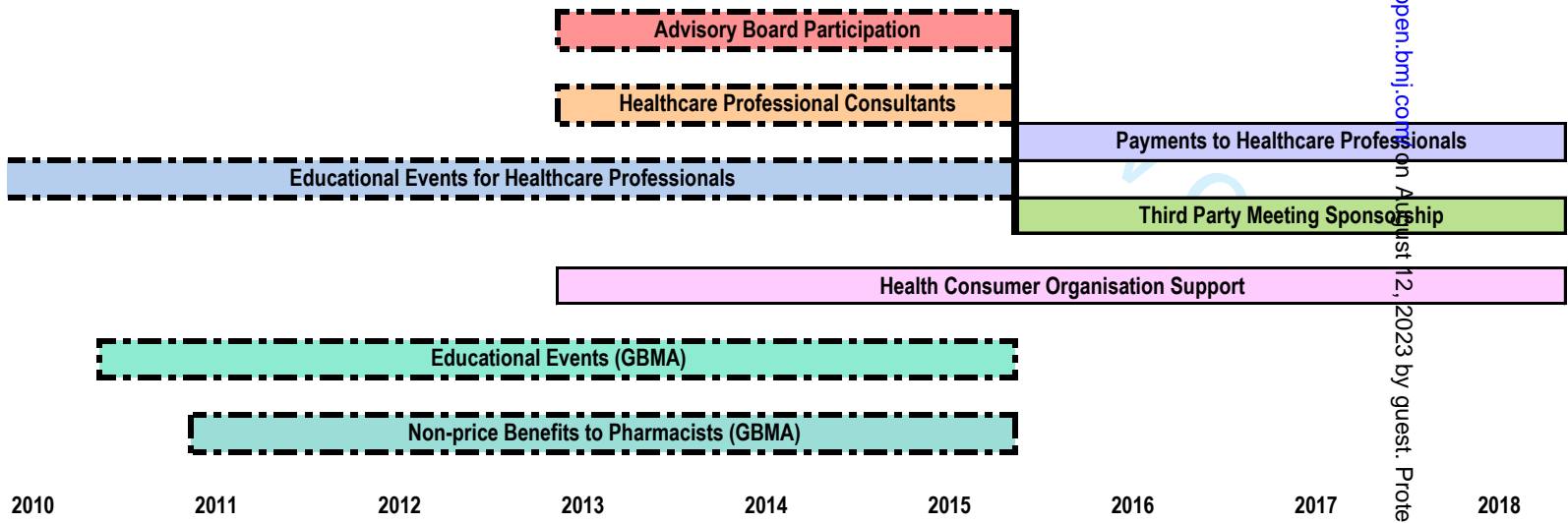
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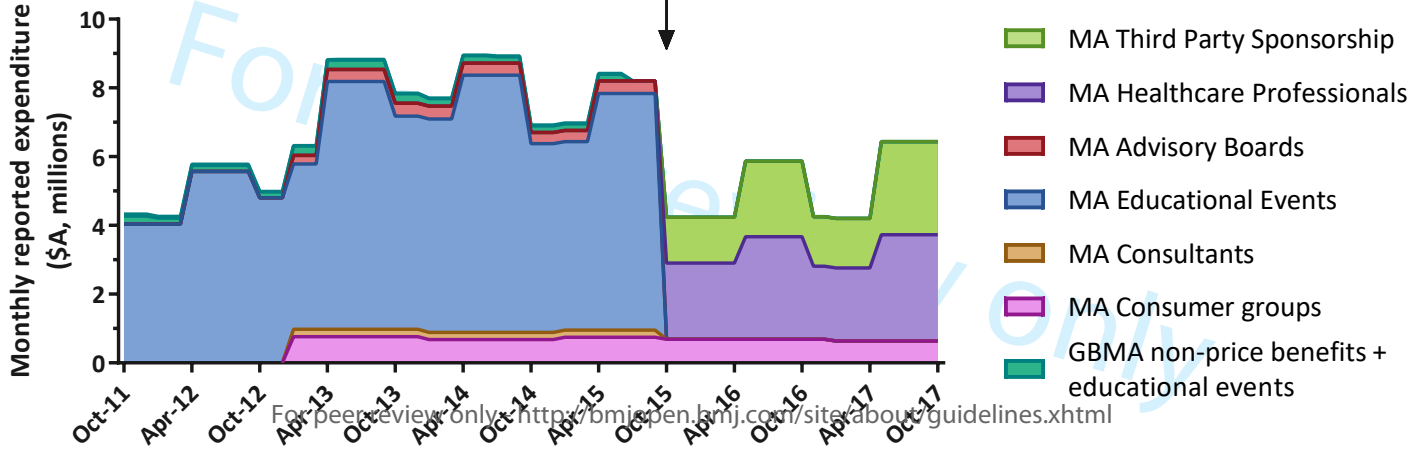


Figure Legends and Tables

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

	<i>DISCONTINUED REPORTS</i>			ONGOING REPORTS		
	<i>Educational Event Reports</i>	<i>HCP Consultants Reports</i>	<i>Advisory Board Meeting Reports</i>	Health Consumer Organisation Support Reports	Third Party Educational Events Reports	Healthcare Professionals Report
DESCRIPTION	<i>Payments related to educational events for HCPs that are held or sponsored by the company</i>	<i>Payments to HCPs for consultancy services/advice</i>	<i>Payments to HCPs contracted to provide advice to the company as part of an advisory board</i>	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	<i>Oct 2011 – Sep 2015[#]</i>	<i>Jan 2013 – Sep 2015</i>	<i>Jan 2013 – Sep 2015</i>	Jan 2013 –	Oct 2015 –	Oct 2015 –
PAYMENTS REPORTED						
<i>Educational events for HCPs held by the company</i>						
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	✓	Payments no longer captured
Event running costs	✓	Payments no longer captured

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)

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			
<i>Educational events for HCPs held by the company</i>			
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)	✓		
<i>Non-Price Benefits to Pharmacists</i>			
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

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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			
<i>Educational events for HCPs held by the company</i>			
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)	✓		
<i>Non-Price Benefits to Pharmacists</i>			
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			

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

¹ Reports limited to prescribing HCPs and pharmacists

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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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6 **2 Changes in the type and amount of spending disclosed by Australian pharmaceutical**
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8 **3 companies: an observational study**
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13 5 Lisa Parker, Postdoctoral Research Fellow¹ lisa.parker@sydney.edu.au
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16 6 Emily A Karanges, Postdoctoral Research Fellow¹ emily.karanges@sydney.edu.au
17

18
19 7 Lisa Bero, Professor¹ lisa.bero@sydney.edu.au
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23
24 9 ¹The University of Sydney Charles Perkins Centre, Faculty of Medicine and Health, School of
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26 10 Pharmacy
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31
32 **12 Corresponding author:**
33

34
35 13 Lisa Parker
36

37 14 D17, The Hub, 6th floor, Charles Perkins Centre, The University of Sydney, NSW, 2006, Australia.
38

39 15 Phone: +61 2 86276422 lisa.parker@sydney.edu.au
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3 **17 Abstract**

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5 **18 Objectives:** To describe and quantify disclosed payments from the pharmaceutical industry to the
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7 **19 healthcare sector, and to examine the impact of the 2015 changes to Australia's self-regulated system**
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9 **20 of transparency.**

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12 **21 Design:** Observational database study

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15 **22 Setting:** Australia

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18 **23 Participants:** Publically available reports submitted by members of Australian pharmaceutical
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20 **24 industry trade organisations, Medicines Australia and the Generic and Biosimilar Medicines**
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22 **25 Association (Oct 2011 to Oct 2017).**

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25 **26 Exposure:** Changes to transparency reporting requirements with the updates of pharmaceutical
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27 **27 industry Codes of Conduct in 2015.**

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30 **28 Main outcome measures:** Elements of healthcare sector spending that members of industry
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32 **29 organisations are required to publically disclose. Cumulative amount of disclosed spending (monthly**
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34 **30 average) in the year prior to and following the revision.**

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37 **31 Results:** There was a 34.1% reduction in disclosed spending from Medicines Australia member
38
39 **32 companies in the year after the 2015 changes to the Code of Conduct were introduced (\$AUS**
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41 **33 89,658,566 in the preceding year, Oct 2014 to Sep 2015; \$AUS 59,052,551 in the following year).**

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44 **34 The new Code allowed for reduced reporting of spending on food and beverages at events and for**
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46 **35 sponsored healthcare professionals. However, there was enhanced transparency around identification**
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48 **36 of individual health professionals receiving payments. GBMA member reporting totalled \$AUS**
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50 **37 2,580,402 in the year prior to the revision, then ceased.**

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53 **38 Conclusions:** This study shows the limitations of a self-regulatory system around industry disclosure
54
55 **39 of spending. We advocate for robust regulatory systems, such as legislation, to promote mandatory**
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57 **40 long-lasting public transparency.**

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3 42 **Article Summary**
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5 43 **Strengths and Limitations of this Study**
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- 8 44 • We compiled and analysed over 900 transparency reports on pharmaceutical industry
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10 45 payments to the Australian healthcare sector, including payments to medical practitioners and
11
12 46 other healthcare professionals, third parties such as medical organisations and hospitals, and
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14 47 health consumer groups.
15
16 48 • We identified key changes in the industry's self-regulatory codes regarding transparency
17
18 49 reporting and examined changes in disclosed spending occurring concurrently with these
19
20 50 changes; our analysis could not determine causality.
21
22
23 51 • We relied on information provided by pharmaceutical companies in their transparency reports
24
25 52 and did not verify the accuracy or completeness of the data.
26
27 53 • Only member companies of Australia's pharmaceutical industry trade organisations are
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29 54 required to submit transparency reports, therefore our data do not reflect total spending and
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31 55 changes in membership status may affect disclosed payments.
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57 **Introduction**

58 Financial relationships between healthcare professionals and the pharmaceutical industry influence
59 healthcare.^{1 2} Exposure of healthcare professionals to the pharmaceutical industry is widespread³ but
60 the financial details and extent of these relationships may be unclear. The United States and some
61 European countries have legislated mandatory reporting of payments from pharmaceutical and
62 medical device manufacturers to healthcare professionals⁴ and Ontario, Canada has recently
63 introduced similar legislation.⁵ Other jurisdictions rely on self-regulation governed by industry
64 associations such as the European Federation of Pharmaceutical Industry Associations (EFPIA).⁶
65 Australia has previously been at the forefront of transparency reporting.⁷ For example, the
66 pharmaceutical industry trade association Medicines Australia introduced a self-regulatory
67 transparency program over a decade ago, when its 2007 Code of Conduct required member companies
68 to publically report their spending on educational events for healthcare professionals.⁸ Importantly,
69 this included spending for “educational” events attended by healthcare professionals from many
70 disciplines including nurses, pharmacists, physiotherapists and dieticians, as well as medical
71 practitioners. The Generic and Biosimilar Medicines Association (GBMA), formerly the Generic
72 Medicines Industry Association, introduced a similar requirement for its members in 2010, although
73 this became non-compulsory in 2013.⁹ GBMA also requested that members report “non-price
74 benefits” to pharmacists, including, for example, provision of training, pharmacy aids, merchandising,
75 software and vouchers.

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

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3 84 healthcare professionals, educational events run by third parties, or consumer groups. These
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5 85 transparency losses were criticised at the time.¹² The objective of this paper is to describe changes in
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7 86 the types of spending disclosed and cumulative amount of spending following the 2015 changes in
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9 87 industry-regulated reporting requirements. We highlight exactly what information has been lost and
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11 88 gained from the public record in Australia, and report on the financial changes.
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14 89 **Methods**

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17 90 We conducted an observational study of publically available reports submitted by members of
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19 91 Australian pharmaceutical industry trade organisations, Medicines Australia and the Generic and
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21 92 Biosimilar Medicines Association (Oct 2011 to Oct 2017).
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24 93 Details on current and previous Medicines Australia and GBMA reporting requirements are available
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26 94 through their respective websites: <https://medicinesaustralia.com.au/> and <https://www.gbma.com.au/>.
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28 95 We used the relevant Codes and/or related documents associated with the current¹⁰ and previous¹³
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30 96 Medicines Australia Codes of Conduct, and the current¹¹ and previous¹⁴ GBMA Codes of Practice to
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32 97 identify changes to transparency information required from organisation members.
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36 98 **Data sources and analysis.** Transparency reports on Medicines Australia and GBMA member
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38 99 company spending are available through the respective industry body websites as separate reports
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40 100 (usually PDF files) for each company, reporting period, and report category. Our research group has
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42 101 previously downloaded and compiled Medicines Australia reports on ~~educational~~ Educational events
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44 102 Events for ~~healthcare~~ Healthcare professionals ~~Professionals~~ (Oct 2011 to Sep 2015; reports prior to
45
46 103 Oct 2011 are no longer publically accessible), and ~~payments~~ Payments to ~~individual healthcare~~
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48 104 Healthcare professionals ~~Professionals~~ (May 2016 to Apr 2017), converting them into databases for
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50 105 research purposes and public use.^{6 7} These data are publically available for download: [https://research-](https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB)
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52 106 [data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB](https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB) and [https://research-](https://research-data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a)
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54 107 [data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a](https://research-data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a) respectively. The current project extends on this
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56 108 work by updating these pre-existing databases and compiling additional databases from more recent
57
58 109 reports downloaded from Medicines Australia and GBMA. In total, this project employed 905
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3 110 Medicines Australia reports (Oct 2011 - Dec 2017) collated into six distinct databases according to the
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5 111 report categories defined by Medicines Australia. Specifically, these databases contain reports on
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7 112 payments related to: (1) Educational Events for Healthcare Professionals (Oct 2011 – Sept 2015); (2)
8
9 113 Healthcare Professional Consultants (Jan 2013 - Sep 2015); (3) Advisory Board Participation (Jan
10
11 114 2013 - Sep 2015); (4) Health Consumer Organisation Support (Jan 2013- Dec 2017); (5) Third Party
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13 115 Meeting Sponsorship (Oct 2015 – Oct 2017); (6) Payments to Healthcare Professionals (Oct 2015 –
14
15 116 Oct 2017). We generated two databases from the 64 available GBMA reports detailing GBMA
16
17 117 member payments related to: (1) Educational Events (for healthcare professionals) ; and (2) Non-Price
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19 118 Benefits to Pharmacists. See Table 1 for a description of each category and Figure 1 for a timeline of
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21 119 available reports. Further information about each report category is provided in Supplementary Files
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23 120 1 and 2.

27 121 **Table 1 – Description of required reporting categories from Medicines Australia and GBMA**
28 122 **members**

Report category	Dates reported	Description	Payments reported
<i>MEDICINES AUSTRALIA REPORTS</i>			
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 <u>Event running costs (e.g. venue hire, food and beverages)^c</u>

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Payments to Healthcare Professionals	Oct 2015- ongoing	Payments to individual, <u>identified</u> 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 <u>individual</u> HCPs to cover costs of attendance at events (registration, travel, accommodation)
18	GBMA REPORTS			
19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40	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 <u>individual</u> HCPs for services at events (e.g. speaking, chairing) Sponsorship to <u>individual</u> 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)
41 42 43 44 45 46 47	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

123 ^aData presented from Oct 2011

124 ^bAirfares only; excludes ground transfers, taxis, parking.

125 ^cReporting is not required if food and beverages are the company's only contribution to the event.

126 ^dPrior to 1 October 2016, disclosure of a HCP's identifying information was contingent on the consent of the HCP. All payments received by
127 non-consenting HCPs were reported in aggregated format.

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3 **129 Figure 1. Timeline of required reporting by Medicines Australia and GBMA members**
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5 **130 according to industry defined categories (see Table 1 for further information)**
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8 131 Figure 1 footnotes:

- 9
10 132 • Dates are approximate only
11 133 • Educational Events disclosures started July 2007
12 134 • The Payments to Healthcare Professionals category is a partial merger (with some exclusions) of three former categories:
13 135 Healthcare Professional Consultants; Advisory Board Participation; Educational Events
14 136 • The Third Party Educational Events category is a subset of the former Educational Events category

15 137

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18 138 We identified 39 Medicines Australia members filing transparency reports in the year preceding the
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20 139 changes to their reporting requirements (Oct 2014 to Sept 2015), compared to 34 in the following year
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22 140 (Oct 2015 to Sep 2016). There were five GBMA members filing transparency reports in the most
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24 141 recent period for which reports were requested by their industry body (i.e. ending June 2015),
25
26 142 compared to none in the following year, and since.

27
28
29 143 Due to the aggregate nature of many reports, we calculated the cumulative expenditure in each
30
31 144 category as a monthly average over the given reporting period. Change in total expenditure from
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33 145 Medicines Australia and GBMA member companies over time was used to assess the impact of
34
35 146 changes in reporting requirements in October 2015 and July 2015 respectively.

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37
38 147 ***Patient or public involvement.*** No patients or members of the public were involved in this study.

39
40
41 148 ***Ethical approval.*** None required.

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44 149 **Results**

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47 150 The 2015 changes to the Medicines Australia code resulted in merging and crossover of pre-existing
48
49 151 reporting categories, as well as inclusion of some new elements and discontinuation of others. For
50
51 152 example, information formerly captured in the Educational Events Database is now reported in the
52
53 153 Third Party and Healthcare Professional databases. The main required reporting elements in the old
54
55 154 and new Medicines Australia Codes of Conduct are listed in Table 2 with further details in
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57 155 Supplementary Files 1 and 2. The transparency gains and losses from Medicines Australia and GBMA
58
59 156 members are summarised in Table 3.

157 **Table 2. Types of payments publically reported by Medicines Australia members before and**
 158 **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)	✓	✓

159 HCP: Healthcare professional

160 ^aCaptured in the HCP Consultants Reports (pre-2015) and HCP Reports (post-2015)

161 ^bCaptured in the Educational Events and Advisory Board Reports (pre-2015) and HCP Reports (post-2015)

162 ^cCaptured in the Educational Events Reports (pre-2015), and Third Party and HCP Reports (post-2015)

163 ^dCaptured in the Health Consumer Organisation Reports (pre- and post-2015)

164 ^eAirfares only

165 ^fReporting is not required if food and beverages are the company's only contribution to the event.

166

167 **Table 3. Summary of gains and loss in current Medicines Australia and GBMA reports**
 168 **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:- <ul style="list-style-type: none"> - Food and beverages and small travel costs (taxi, 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
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170 In the year preceding the 2015 changes to the Medicines Australia code, industry payments disclosed
 171 by Medicines Australia members totalled \$AUS 89,658,566 (Oct 2014 to Sep 2015) across four
 172 reporting categories. Reported payments included \$74,264,438 (82.8%) on Educational Events run by
 173 the company or third party, \$8,743,250 (9.8%) on Health Consumer Organisation Support, \$4,158,819
 174 (4.6%) on costs associated with Advisory Board Participation, and \$2,492,059 (2.8%) on Healthcare
 175 Professional Consultants.

176 In the year following the 2015 change, reported payments from Medicines Australia members totalled
 177 \$59,205,301 (Oct 2015 to Sep 2016), an overall reduction of 34.1%. Payments reported in the new
 178 categories, Healthcare Professional Reports and Third Party Educational Events, totalled \$30,380,145
 179 and \$20,364,929 respectively. There was little change in the total reported expenditure on Health
 180 Consumer Organisation Support (\$8,461,228), which was the only reporting category to remain
 181 unchanged in the revised code (See Figure 2). Excluding payments associated with this category,
 182 there was a 37.3% reduction in disclosed Medicines Australia payments. As shown in Table 2 the
 183 reduction in disclosed payments coincides with loss of information about spending on: running costs
 184 for industry-run events and meetings (including food and beverages); hospitality to sponsored
 185 healthcare professionals attending events and meetings.

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

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

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

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3 191 Non-Price Benefits to Pharmacists and the remainder were for Educational Events. After July 2015,
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5 192 \$AUS 0 payments have been reported by GBMA members, a drop of 100%.

8 193 **Discussion**

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11 194 Recent changes to Australian self-regulatory codes have delivered gains in disclosure of recipient
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13 195 identities but an overall reduction in transparency around industry funding in the healthcare sector.
14
15 196 Dropping the requirements for transparency around items such as expenditure on food and beverages
16
17 197 means that over a third of previously reported industry spending on healthcare professionals is now
18
19 198 hidden. In addition, the new Code failed to include other disclosures about industry interactions with
20
21 199 health professionals that countries such as the UK and USA have introduced, such as pharmaceutical
22
23 200 company spending on free drug samples and funding for research.⁶ The changes have also added an
24
25 201 extra layer of complexity to what is already difficult-to-understand data on disclosed payments. This
26
27 202 complexity hinders transparency.

30
31 203 This erosion of transparency has taken place in a time of increasing societal interest in disclosure.

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33 204 Transparency around pharmaceutical industry spending in the healthcare sector is important for
34
35 205 several reasons. First, the public have a legitimate expectation that all transfers of value between the
36
37 206 pharmaceutical industry and healthcare sector will be available for scrutiny in order to assess and
38
39 207 judge the appropriateness of such interactions. Second, transparency may assist those reading or
40
41 208 receiving the disclosure to judge the risk of bias in those making the disclosure. For example,
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43 209 disclosures of competing interests by research authors makes academic readers more critical of an
44
45 210 article.¹⁵ ~~Receiving conflicts of interest information may, however, have limited impact on the~~
46
47 211 ~~audience.~~ However, authors who disclose ~~individuals disclosing~~ conflicts of interest are more likely to
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49 212 exaggerate their claims,¹⁶ and even critical readers tend not to sufficiently discount the credibility of
50
51 213 biased information sources, so the audience may still take home a biased message.¹⁷

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55 214 Third, transparency requirements may change behaviour of those making the disclosure. In situations
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57 215 where disclosures are required or expected, individuals may avoid accepting ~~the conflicts of~~
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59 216 ~~interest payments~~ in order to avoid making the declaration¹⁸ and the same may apply to corporations.

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3 217 For example, if industry is required to declare costs associated with food and beverage provision at
4
5 218 third party events such as medical grand rounds and journal clubs, they may be less likely to provide
6
7 219 this kind of sponsorship. While ~~doctors~~ healthcare professionals may be disappointed at the reduction
8
9 220 in ‘free’ lunches, this change would reduce industry influence on healthcare, because receipt of
10
11 221 industry-sponsored meals, even low-cost meals, ~~influences~~ increases ~~doctors to prescribe~~
12
13 222 ~~more~~ prescribing of the brand-name drug being promoted at the time.¹
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16
17 223 The erosion of organisational transparency that we document in the paper is particularly significant.
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19 224 Although disclosure is a burden for the pharmaceutical industry, organisational transparency has the
20
21 225 advantage of not relying on disclosures from individual healthcare professionals. These disclosures
22
23 226 are potentially counterproductive since patients may feel extra pressure to follow the advice of those
24
25 227 who declare conflicts of interests, in order to avoid implying distrust of their practitioner.^{16 19}
26

27 228 Dropping organisational disclosure of food and beverage spending also seems to send the wrong
28
29 229 message to potential recipients, i.e. that this transfer of value is not significant enough to warrant
30
31 230 reporting. As a result, ~~doctors~~ healthcare professionals may be more likely to participate in industry-
32
33 231 sponsored lunches,
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35
36 232 Transparency is unlikely to be a complete solution to concerns about commercial influence within the
37
38 233 healthcare sector.²⁰ There are many other important elements involved in managing this issue,
39
40 234 including, for example, the prohibition of: clinical trials that seek to familiarise prescribers with new
41
42 235 medications rather than add to scientific knowledge (so-called “seeding trials”), honorary authorships
43
44 236 for healthcare professionals, and the release of free drug samples into clinic rooms.²¹ However
45
46 237 transparency is a necessary first step towards assessing and analysing the level of industry influence,
47
48 238 and may act as a deterrent to inappropriate interactions between individual professionals and industry.
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52 239 Self-regulated transparency programs may avoid the usual checks and balances of a more formal
53
54 240 regulatory system, and in the case described here, self-regulation has allowed the pharmaceutical
55
56 241 industry to make changes associated with significant reductions in disclosed spending. Self-regulated
57
58 242 transparency enables voluntary reporting, as in the early stages of the Medicines Australia program. It
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3 243 also fails to regulate companies that are not members of the relevant industry body. We advocate for
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5 244 legal mandating of comprehensive transparency about industry sponsorship in an effort to minimise
6
7 245 loss of transparency data in ways such as we report on here. In this particular case, we recommend
8
9 246 that the Australian Government introduce transparency legislation. We recommend new legislation
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11 247 that maintains the current Medicines Australia transparency focus around spending on healthcare
12
13 248 professionals and health consumer groups, and extends this requirement to include all companies in
14
15 249 the pharmaceutical and medical device sector including GBMA members and companies with no
16
17 250 affiliation to trade organisations. We propose mandatory disclosure on spending on drug samples and
18
19 251 research. We also recommend that legislation should reinstate previously compulsory reporting of
20
21 252 aggregated food, beverages and venue costs at company-run educational events and advisory board
22
23 253 meetings; and food and beverages provided to ~~individual~~ healthcare professionals where costs per
24
25 254 head are over a minimum amount as required by the US legislation.

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29 255 Limitations: The calculated amount of industry spending in the healthcare sector for both the pre-2015
30
31 256 and post-2015 periods may be an under-estimate. There are companies that are not members of
32
33 257 Medicines Australia or GBMA and hence do not disclose their spending. In addition, compliance
34
35 258 with the GBMA Code was not compulsory for GBMA members from 2013,²² so the true pre-2015
36
37 259 spending figure is likely to have been higher than our calculated figure. There may be inaccuracies in
38
39 260 the spending disclosed by the companies in the original reports: we could not verify the accuracy and
40
41 261 completeness of the data, but many companies do provide independent audits of their reports. The
42
43 262 reduction in Medicines Australia member companies submitting reports, from 39 in the year prior to
44
45 263 the change in reporting requirements to 34 after the change, contributed to the reduction in the
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47 264 cumulative disclosed sum, although was unlikely to have had a big impact. Together, these five
48
49 265 companies only disclosed a total of \$4,199,674 between October 2014 and September 2015, which
50
51 266 was 4.68% of the total disclosure by all companies over this period. Finally, our results cannot prove a
52
53 267 causal relationship between changing industry Codes and cumulative disclosed spending. We think it
54
55 268 likely that current spending remains similar to 2015 levels, and that the apparent reduction in
56
57 269 cumulative spending is due to changed reporting patterns. It is possible, however, that cumulative
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3 270 spending may have truly decreased as a result of the changes in reporting and/or other requirements
4
5 271 introduced in the new Code (e.g. introduction of a \$120 limit per head on meals for healthcare
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7 272 professionals), or that reductions in spending may reflect a move toward alternative methods of
8
9 273 promotion to healthcare professionals not captured, ~~or that spending patterns may have coincidentally~~
10
11 274 ~~(or even deliberately) altered at the same time that the new Code came in, perhaps reflecting different~~
12
13 275 ~~ways of industry promotional spend in the healthcare sector that were not captured~~ by the previous or
14
15
16 276 current transparency program. Finally, as mentioned above, the program of required reporting is
17
18 277 complex, and changes are difficult to follow. There may be some elements that we have
19
20 278 misinterpreted.

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23 279 Once a leader in transparency, Australia is now falling behind other countries. This study provides a
24
25 280 clear example of the limitations of a self-regulatory system, which can be quietly changed in such a
26
27 281 way as to reduce overall public reporting of industry funding in the healthcare sector. We recommend
28
29 282 that countries insist on legislation rather than self-regulation to promote long-lasting public
30
31 283 transparency around industry spending.

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36
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38
39 286 database of disclosed payments from publically accessible industry documents.

40
41
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43
44 288 or not-for-profit sectors

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46
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49
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51
52 291 extracted and analysed the data, prepared the tables, and critically revised the manuscript. LB
53
54 292 participated in creating the original database and critically revised the manuscript. All authors
55
56 293 reviewed and approved the final manuscript.

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59 294 **Patient and public involvement:** Not required.
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3 295 **Ethics approval:** Not required.
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6 296 **Data sharing statement:** Limited data from this study are publically available. Data on
7
8 297 Pharmaceutical Industry-funded Events for Australian Health Professionals (Oct 2011-Sept 2015) are
9
10 298 available at: <https://research-data.sydney.edu.au/index.php/s/npni79P4NhVQ0XB>. The
11
12 299 Pharmaceutical Industry Payments to Healthcare Professionals (May 2016 to Apr 2017) database is
13
14 300 available at: <https://research-data.sydney.edu.au/index.php/s/0MmrfIPyiQrf53a>. Neither of these
15
16 301 available databases currently include all Educational Events [for Healthcare Professionals](#) Reports or
17
18 302 [Individual Payments to Healthcare Professional Payments](#) Reports included in this manuscript. [The](#)
19
20 303 [complete Health Consumer Organisation database \(Jan 2013 to Dec 2016\)](#) is available at:
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22 304 <https://researchdata.andis.org.au/pharmaceutical-industry-funding-december-2016/1330638>.
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