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ORIGINAL RESEARCH ARTICLE

Sustained Decline of Direct General Practitioner Reporting of Adverse Drug Reactions in Australia and Paucity in Details of Australian Reports in Safety Advisories

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Abstract

Introduction There have been substantial changes in the nature of reporting pathways and review of suspected adverse drug reactions (ADRs) in Australia since the establishment of the now defunct Advisory Committee on Safety of Medicines early in 2010.

Objectives The aim of this study was to (1) examine the reporting in Australia of suspected ADRs from various sources, including general practitioners (GPs), since 1990; (2) compare the reporting of Australian GPs with that in two other countries (New Zealand and the United Kingdom [UK]) with comparable safety monitoring programmes for the period 2007–2019; and (3) explore the extent to which Australian reporting of suspected adverse reactions has motivated communication to healthcare professionals in the period 1995–2019.

Methods Annual reporting of sources of ADRs in Australia were obtained from Government reports, the Australian Statistics in Medicines and Therapeutic Goods Administration (TGA) websites. Details of the annual reporting by GPs in the UK were obtained from published sources and have been provided on request by the Medicines and Healthcare products Regulatory Agency. Details of the annual reporting by GPs in New Zealand were provided on request from the Centre for Adverse Reaction Monitoring. All issues of the Australian Adverse Drug Reactions Bulletin were accessed from the National Library of Australia, and issues of the Medicines Safety Update from February 1995 to December 2019 were accessed online from the TGA website. Each issue was searched to identify and score safety advisories.

Results From 1990 to 2002 in Australia, overall reporting gradually increased, and the three major groups of reporters (GPs, hospitals and sponsors) each contributed about 30%. The relative contributions to reporting changed in the period 2002 to 2009. There was then a steep fall in reporting from GPs and the start of a very marked increase in reporting from product sponsors. GP reporting in Australia was lower than the two other comparable countries (New Zealand and the UK), and continues to fall, while in the UK at least, GP reporting is rising. The analysis of safety advisories shows a relatively stable Australian content from 1995 to 2008, followed by a sharp decline, so that by 2019 and 2020 there was barely any Australian reporting-driven content. In 1995 and 1996, Australian reports of suspected adverse reactions were the sole apparent reason for the publication of safety advisories. From 1997 to about 2008, Australian reports of suspected adverse reactions were the major reason for publication, but after this time, Australian reports became less important. During this later period, the apparent motive for publication of the safety advisory shifted to being based primarily on a publication in the medical literature, or publicity, but was sometimes based on an overseas regulator's advice or action, or action by a product sponsor.

Conclusion It is our contention that the decline in GP reporting in Australia and the current paucity in details of Australian reports in safety advisories are closely linked.

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Key Points

There has been a steady decline in reporting of adverse drug reactions from general practitioners (GPs) in Australia since the early 2000s.

GP reporting in Australia was lower than the two other comparable countries.

Australian content of safety advisories has sharply declined.

1 Introduction

There have been substantial changes in the nature of reporting pathways and review of suspected adverse drug reactions (ADRs) in Australia since the establishment of the now defunct Advisory Committee on Safety of Medicines early in 2010. Major recommendations about ADR reporting were made in the Report of the Review of Medicines and Medical Devices Regulation, March 2015.

This study examined the reporting in Australia of suspected ADRs from various sources, including general practitioners (GPs), since 1990. The degree of reporting directly to the national medicine safety monitoring authority ('direct' reporting) by Australian GPs for the period 2007 to 2019 is compared with that in two other countries with comparable safety monitoring programmes and who were also foundation members of the WHO Programme on International Drug Monitoring (PIDM; i.e. New Zealand and the United Kingdom [UK]). The extent to which Australian reporting of suspected adverse reactions has motivated communication to healthcare professionals in the period 1995–2019 is also explored.

2 Methods

2.1 Reporting of Adverse Drug Reactions (ADRs) in Australia

Annual reporting of sources of ADRs for 1990–1993 were included in an Australian Government annual report [1]. Annual reporting for 1994–1997 was estimated from the graph of reports to the Australian Adverse Reactions Advisory Council (ADRAC) 1990–1998 in Australian Statistics on Medicines 1998, published by the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Scheme [2]. Actual annual reporting numbers were published in Australian Statistics on Medicines from 1998 to 2015. Although there were some changes in the categories used, it was possible to determine annual reporting by GPs, sponsors, hospitals and others [2]. This information was also published on the Therapeutic Goods Administration (TGA) website from 2013 to 2017 [3].

As a result of the report of the Review of Medicines and Medical Devices Regulation in March 2015, the TGA introduced a new Adverse Event Management Section in June 2018, and from that date reporting has been in different categories of reporters, which are not consistent with the previous categories. In the half-yearly performance snapshots for 2018–2020, GPs and specialists have been pooled as 'medical practitioners' [4]. In the annual performance statistics reports for 2019 and 2020, medical practitioner contributions have been pooled into 'reports by health professionals' [5]. Furthermore, from 2018, the TGA has no longer included reporting from 'hospitals (including hospital pharmacists)' in its published statistics. On request, the TGA has provided medical practitioner reporting details for 2018 to June 2020 that are now in three categories—GPs, medical practitioner (specialist) and medical practitioner (other).

The TGA has advised that the GP classification is used for community medical practitioners (where this is identified) and medical practitioner (other) may be used for any medical practitioner who is neither a GP nor a specialist.

2.2 Details of General Practitioner (GP) Reporting in New Zealand and the United Kingdom (UK)

The practice of medicine in the UK, New Zealand and Australia has many common characteristics. Details of the annual reporting by GPs in the UK for the period 2008–2012 have been published [6]. The number in 2013 has been estimated from Fig. 1 in a published report [7]. Details of the annual reporting for 2014–2019 inclusive have been provided on request by the Medicines and Healthcare products Regulatory Agency (MHRA), UK. Details of the annual reporting by GPs in New Zealand involving medicines for the period 2006–2019 have been included in information provided on request by the Centre for Adverse Reaction Monitoring (CARM), New Zealand.

In New Zealand and the UK, reports of reactions to vaccines are counted separately from medicines for each group of reporters. Uncommonly, when a report implicates both a medicine and a vaccine, it will be counted in both categories. In Australia, separate counts of medicine and vaccine implicating reports have not been published for each group of reporters. Reporting of reactions to vaccines has been dominated by state and territory health authorities, giving some assurance that high proportions of reports from other subgroups, including GPs, relate to medicines, but not excluding some inflation by vaccine reports of the numbers of GP and other subgroup medicine reports.

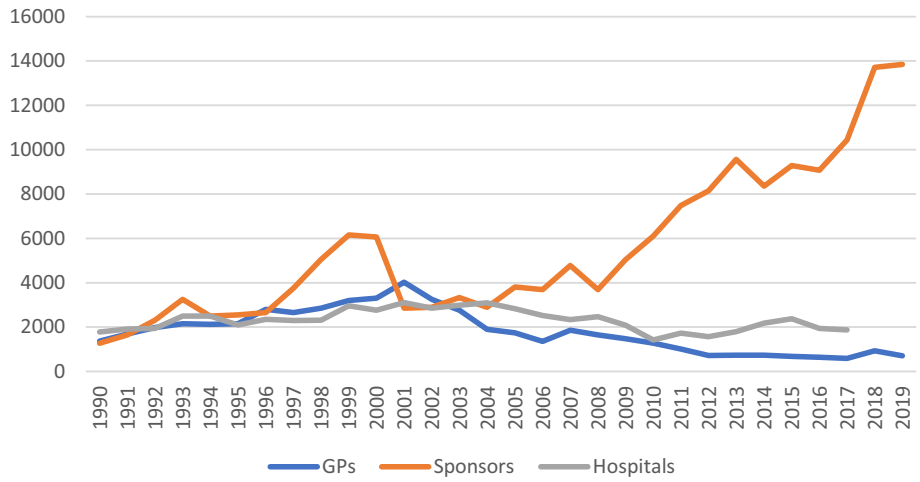

Fig. 1 Number of reports of adverse drug reactions to the TGA from GPs, sponsors and hospitals. *GPs* general practitioners, *TGA* Therapeutic Goods Administration

2.3 Comparison of Spontaneous ADR Reporting by GPs in Three Countries

The annual numbers of reports from GPs in Australia, New Zealand and the UK in the period 2008–2019 have been taken from the information described above. An exploratory comparison of reporting in the three countries in the years 2007–2019 has been undertaken. The numerator for each year is the number of GP reports identified as above, and the denominator is that year's mid-year population statistic [8–10].

There are some data to indicate that the fall in GP reporting in New Zealand after 2011 is being substantially compensated by an increase in reporting by nurses, as with GPs, based in primary care practices (Dr Michael Tatley, Director, New Zealand Pharmacovigilance Centre, personal communication). Such a phenomenon has not occurred in Australia.

2.4 Identification of Changes in Sources of Triggers for Publication of Items in the Australian Adverse Drug Reactions Bulletin and the Medicines Safety Update

2.4.1 General Procedure

All issues of the Australian Adverse Drug Reactions Bulletin were accessed from the National Library of Australia, and issues of the Medicines Safety Update (MSU) from February 1995 to December 2019 ($n = 124$) were accessed online from the TGA website [11, 12]. Each issue was searched to identify and score safety advisories. Each author undertook independent screening, and any differences were resolved by discussion and consensus. An expansion of the definition of a safety advisory used by Perry and co-workers, i.e. "notifications to prescribers and/or the public about a potential or confirmed safety risk that was inherent to a medicine and not due to manufacturing problems or improper use" was used, and was expanded to include non-prescription medicines as described in our previous publication [13, 14]. All items meeting the definition were reviewed using two methods.

2.4.2 Identification of Safety Advisories Based on Australian Reports

In this method, each reviewed item was scored using a simple points system. Items where publication was judged to be based largely or totally on information in Australian reports of suspected ADRs were scored 2 points; items with a different primary reason for publication (e.g., information from a pharmaceutical company or a regulatory agency outside Australia) but including mention of Australian reporting were scored 1 point; items without mention of Australian reporting were scored 0 points. Points were summed for the items in an issue (e.g., an issue with four items all based on Australian reporting was scored $4 \times 2 = 8$ points). Issue points were then summed to give an annual score. Over the years 1995–2009, the mean number of issues per year of the Bulletin was 4.93 (range 4–6); from 2010 to 2018, the mean number of MSU issues per year was 5.56 (range 4–6). In 2019, issues were no longer published and each item was published separately. No attempt to adjust the score for issues per year has been made.

2.4.3 Identification of the Apparent Reasons for the Publication of Safety Advisories

In this method, each reviewed item was also examined for the most likely reason for publication of the item. Seven categories were used (Table 1) and the number of safety advisories in each category were identified and summed on an annual basis.

Table 1 Apparent reasons for publication of an article in the Australian Adverse Drug Reactions Bulletin or Medicines Safety Update

Designation	Apparent reason
A	Based primarily on Australian reports
B	Based primarily on a publication or publicity
C	Update to a previous Bulletin or Update item with no new Australian report information
D	Other safety advisories comprised of clinical safety advice following consideration by the TGA or one of its advisory committees, or alerting to a product information amendment for safety reasons not apparently triggered by the sponsor
E	Based primarily on an overseas regulatory agency's advice (Safety Advisory) or regulatory action (including requiring change to product information)
F	Based on action by a product sponsor (not including reporting as in [A] above)
G	Based on a report from a coroner

TGA Therapeutic Goods Administration

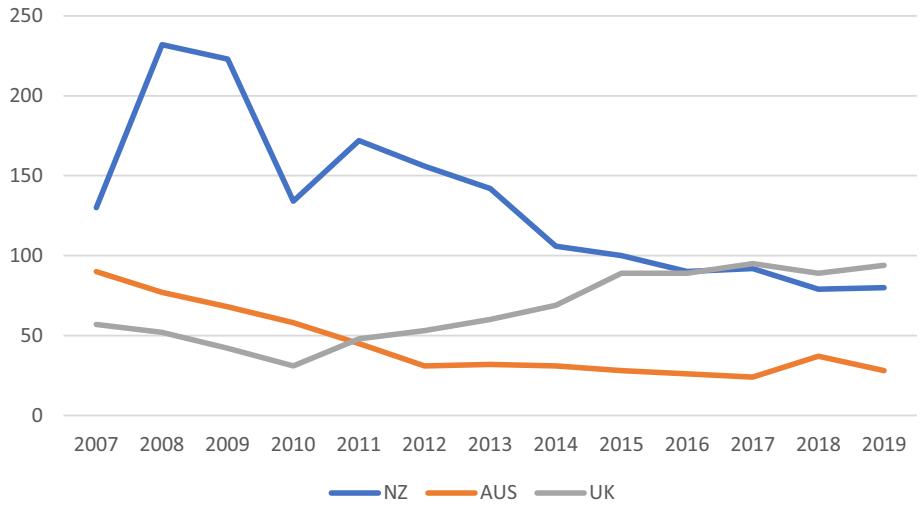

Fig. 2 Reports from GPs per million inhabitants from New Zealand, Australia and the UK. *GPs* general practitioners

3 Results

3.1 Reporting in Australia of Suspected ADRs from Three Sources

The results from 1990 to 2019 are shown in Fig. 1 (see the Electronic Supplementary Tables). From 1990 to 2002, overall reporting gradually increased, with the three major groups of reporters (GPs, hospitals and sponsors) each contributing about 30%. The relative contributions to reporting changed during the period 2002–2009. There was then a steep fall in reporting from GPs and the start of a very marked increase in reporting from product sponsors. At the same time, reporting from hospitals started to fall in a somewhat erratic fashion.

3.2 GP Reporting in Australia, New Zealand and the UK

The results from 2007 to 2019 are shown in Fig. 2 (see the electronic supplementary tables). Figure 2 shows GP reporting per million inhabitants, and also shows that GP reporting in Australia was lower than the two other comparable countries, and continued to fall, while in the UK at least, GP reporting was on the rise. The analysis was sufficiently sensitive such that Fig. 2 shows a drop in UK reporting in 2018 followed by a rise in 2019, presumably in response to publicity [15].

3.3 Safety Advisories Based on Australian Reports

The results from 1995 to 2020 are shown in Fig. 3 (see the electronic supplementary tables). Figure 3 shows the scores accumulated each year on the basis of Australian reporting (see the Methods section), and shows relatively stable Australian content from 1995 to 2008 followed by a sharp decline, so that by 2019 and 2020, there was barely any Australian reporting-driven content.

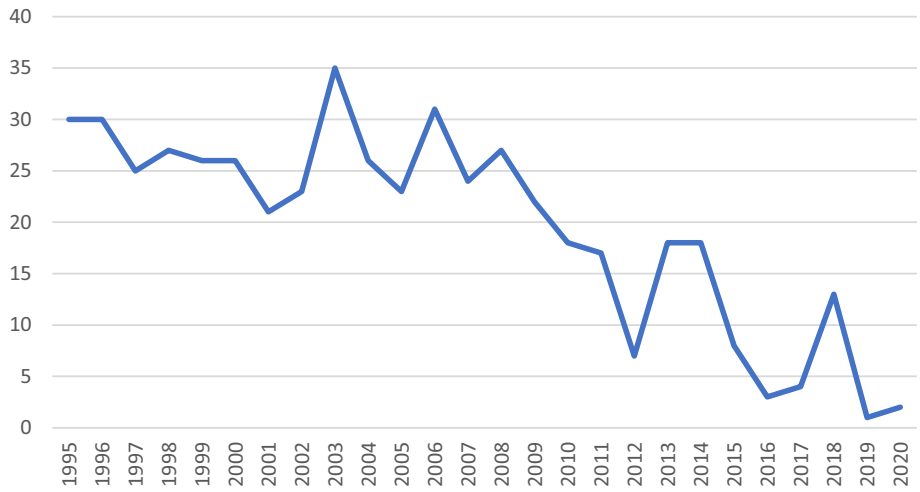

Fig. 3 Annual score of Australian content of safety advisories

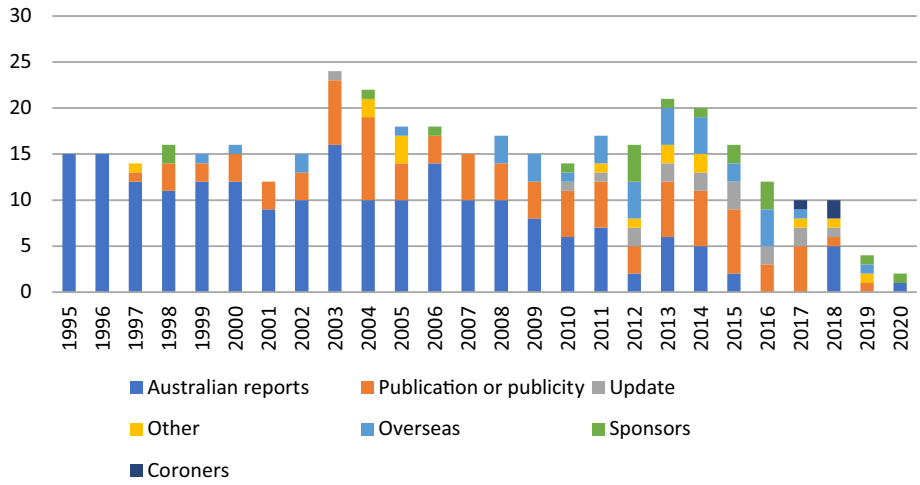

Fig. 4 Annual distribution of the apparent reason for publication of safety advisories

3.4 Apparent Reasons for the Publication of Safety Advisories

The results from 1995 to 2020 are shown in Fig. 4 (see the electronic supplementary tables). The detailed legend for this figure is provided in Table 1. Figure 4 shows that in 1995 and 1996, Australian reports of suspected adverse reactions were the sole apparent reason for the publication of safety advisories. From 1997 to approximately 2008, Australian reports regarding suspected adverse reactions were the major reason for publication, but after this time, Australian reports became less important. During this later period, the apparent motive for publication of the safety advisory shifted to being based primarily on a publication in the medical literature, or publicity, but was sometimes based on an overseas regulator's advice or action, or action by a product sponsor.

4 Discussion

In our previous publication, we demonstrated that the number of safety advisories published by the TGA in the Australian Adverse Drug Reactions Bulletin initially and then in the MSU had decreased alarmingly in recent years [13]. In this publication we demonstrate two other concerning trends. First, the number of reports of suspected ADRs submitted by GPs has dramatically and almost continually declined since about the year 2008. Second, the apparent motivation for the publication of safety advisories has changed.

Although reports to the TGA of ADRs have increased over the years, the number of reports from GPs has decreased dramatically. There has been an obvious shift in Australia's pharmacovigilance from dependence on GP and medical specialist reports to receipt of much greater numbers of pharmaceutical company (sponsor) reports that lack quality and yield little in terms of safety messages. Apart from the obvious increase in sponsor reports, we examined

other sources that may have increased, however none were found. Reports from consumers have been low and relatively steady throughout this time, generally in the range of 3–4%. There was a small increase in consumer reporting in 2016 and 2017 (5.6%), but by 2015, the fall in GP reporting was such that it was at the same level of consumer reporting (both 4%). There may have been some transfer from GPs to consumers in the period 2016–2018 but it would have been small, and by 2019, the level of reporting for both groups was again about the same, at a little over 3%.

The comparison with the two other healthcare systems that are similar to Australia, i.e. New Zealand and the UK, further highlights the significance of this problem. In our experience, direct reports from medical practitioners have a very high value because direct contact from the TGA seeking additional clinical information about serious or previously unsuspected adverse reactions is most readily achieved. In addition, as Roughead and Lexchin noted, "it is health professionals, in consultation with patients, who must identify adverse drug events in practice" [16]. The low level of reporting by GPs (4% of the total in 2016) in Australia was highlighted by Li and colleagues [17], who noted that as consumers are more likely to report ADRs to their doctors or pharmacists rather than to the pharmaceutical industry, healthcare professionals also play a significant role in ensuring a robust pharmacovigilance system [17]. Martin and Lucas, similarly noting very low reporting from medical practitioners, only some of whom were GPs, observed that health professionals used to receive printed copies of the MSU publication and the 'blue card' reporting form [18]; the blue card is now only available on the TGA website. In their view, if these hard copies, which are no longer printed, were visual cues for prescribers, perhaps raising expectations and awareness that adverse events are common and should be reported, their absence may have led to less reporting. Furthermore, the MSU is now only published as relevant topics arise rather than in a bi-monthly scheduled publication, as was previously the case, thereby reducing the profile of reporting [18].

It is important to note a further recent change in the TGA policy with the MSU. From April 2022, a monthly version of the MSU 'Product Information Safety Updates' has been published setting out changes to approved Australian product information that was negotiated and agreed, often after some delay, with product sponsors. The July issue listed changes to 38 product information safety updates. In the period from April to 6 August 2022, one single-topic MSU has been published [12]. The extent to which MSUs with a shorter latency than product information safety updates, highlighting single emerging safety issues as soon as relevant topics arise, will be published is unclear.

The Australian Government's Independent Review of Medicines and Medical Devices Regulation, having noted the high regard in which Australian pharmacovigilance was held internationally, observed that, "Currently, the vast majority of adverse event reports are made by sponsors, with only a small proportion being made by health professionals such as doctors and pharmacists" [19]. The Panel further noted that, "It is clear that there could be greater scope for adverse event reporting by health professionals and consumers" [19].

The review's Expert Panel based its comments on a plot of the origin of adverse event reports received by the TGA (2007–2013), reproduced as Fig. 13 in its report. The Expert Panel had not noted that, for example, annual reporting by GPs had already fallen from more than 4000 in 2002 to 1866 in 2007, suggesting that the Expert Panel was not adequately appraised of the extent of the already substantial decline in reporting by healthcare professionals [19].

The Expert Panel made five recommendations for the development of a more comprehensive postmarket monitoring scheme for medicines and medical devices (Recommendation 27); two are especially relevant to reporting by GPs and other medical practitioners. From May 2018, the TGA has implemented the Black Triangle Scheme in response to the recommendation for implementation of a scheme to alert practitioners and consumers that a drug is newly registered and to encourage reporting of any adverse events. It is possible that the scheme has increased reporting to sponsors by medical practitioners but to date there has not been an obvious boost in direct reporting. Similarly, there has yet to be any clear impact on GP reporting of the recommended provision of electronic reporting of adverse events.

Direct reports represent an action arising from a patient–health professional interchange, whereas reports from companies are a second-hand report of such an interchange where detail will inevitably be lost. Follow-up is also straightforward with a report from a health professional, whereas follow-up from a company report is convoluted. Internationally, sponsor reports have been found to be seriously deficient. A study of reports submitted by 25 manufacturers submitting 5000 or more reports to the US FDA in 2014 found that completeness of all variables ranged from 24.4% complete to 67% complete. Patient death cases had the lowest completeness scores—only 28.6% included all four variables (age, sex, a partial or complete event date, and at least one medical term that described a medical condition) [20].

In Australia, the TGA undertakes a Pharmacovigilance Inspection Program, which commenced in September 2017. The program's report for the year ending 31 December 2020 relates to six routine (not 'for-cause') inspections. Deficiency in the management of ADRs was observed in every inspection and included two critical deficiencies and 27 major deficiencies. The report observed that deficiencies in this area have a potential impact on individual case safety

report (ICSR) reporting to the TGA, and, furthermore, company signal detection activities or analysis of safety information. Deficiency in reporting serious ADRs was observed in four of six inspections conducted during the reporting period and included four major deficiencies [21].

As noted above, safety advisories such as those occasionally published in the MSU can convey clinically important safety messages based on reports of ADRs to Australian prescribing doctors and other health professionals [18]. It is anticipated that this would be particularly important when the safety advisory is based on an analysis of Australian reports. In a pilot study on the reasons for reporting adverse reactions, which was conducted in 12 countries contributing to the WHO Collaborating Centre for International Drug Monitoring (including Australia), it was found that reporting was stimulated by a positive relationship between the National Centre and the reporter, or at least the perception by the reporter of a positive relationship [22]. Reporting was inhibited or actively prevented by, among other things, lack of feedback or encouragement. Importantly, lack of evidence that any positive national use was made of ADR reports was a considerable disincentive to some [22].

The decline in Australian content in safety advisories, from its peak in 2004 to a very low level in 2019 and 2020, is quite clear, as shown in Fig. 3. It is compelling how closely this fall relates to the decline in reporting by GPs, as illustrated in Fig. 1. The nature of the decline in Australian content is further illustrated in Fig. 4. The total reliance on Australian reporting to stimulate safety advisories as observed in 1995 and 1996 was gradually replaced, first by publications or other forms of publicity, then by an overseas regulatory agency's advice or regulatory action, as well as being based on action by a product sponsor, in addition to smaller contributions from other sources of information, as described in Table 1.

5 Conclusion

It is our contention that the decline in GP reporting in Australia and the current paucity of details regarding Australian reports in safety advisories are closely linked.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40264-023-01321-4.

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Declarations

Funding No funding was used in the preparation of the paper.

Conflicts of Interest As an employee of the Department of Health from 1986 to 2007, Ian Boyd had responsibility for the content and publication of Australian Adverse Drug Reactions Bulletins. As an employee of the Department of Health from 1979 to 1989 and from 1994 to 2005, John McEwen had involvement in the preparation and publication of Australian Adverse Drug Reactions Bulletins.

Ethics Approval Not applicable.

Consent to Participate Not applicable.

Consent for Publication Not applicable.

Availability of Data and Materials All data generated or analysed during this study are included in this published article and its supplementary information.

Code Availability Not applicable.

Author Contributions Both authors contributed equally to this study, and both authors read and approved the final version.

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