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16 September 2014

Dr Richard Chadwick
General Manager, Adjudication
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Dear Dr Chadwick

Medicines Australia: Application for Revocation and Substitution A91436-A91440

As you know, we act for Medicines Australia in respect of its application for authorisation of Edition 18 of the Medicines Australia Code of Conduct (the ***Code***). This letter:

- outlines the results of market research commissioned by Medicines Australia into the attitudes of Australian healthcare professionals to transparency reporting; and
- responds to the ACCC's additional questions of 12 September 2014.

1 Market research on transparency reporting

1.1 Survey methodology and questions

In August 2014 Medicines Australia engaged Cegedim Strategic Data, a market research company specialising in the healthcare sector, to survey healthcare professionals regarding their attitudes to transparency reporting. Provided at **Annexure 1** is document which outlines the key findings of the market research.

Between 17 August and 25 August 2014 Cegedim surveyed 400 healthcare professionals nationally, comprising 200 general practitioners and 200 specialists. Provided at **Annexure 2** is a document containing data on the number of healthcare professionals surveyed, their age, location and their membership of professional bodies.

The healthcare professionals surveyed were asked a number of questions formulated by Medicines Australia in consultation with Cegedim. The questions were based on market research conducted in the UK following the introduction of the European Federation of Pharmaceutical Industries and Associations' (***EFPIA***) activity based transparency reporting regime and modified to reflect Australian conditions.[1] The following questions were asked:

1. Indicate the extent of your agreement to the following statements:

[1] EFPIA: 'Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals' and 'Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations'.

(a) payments from pharmaceutical companies to individually named healthcare professionals should be transparent through public reporting;

(b) disclosure of payments to healthcare professionals should apply to all types of commercial life science organisations (eg medical devices, diagnostics, generic medicines companies, non-prescription medicines companies).

2. How should reports detailing payments to healthcare professionals be made available to the public?
3. Who do you think is most appropriate to host this information?
4. To what extent do you agree that individual healthcare professionals should play a role in verifying the information about them before it is published?
5. Under current privacy legislation you should be asked for consent before information regarding payments from pharmaceutical companies is published about you. How likely are you to give consent?
6. Would your view change if not providing consent meant a pharmaceutical company could no longer provide payments to you?
7. How would you describe your current level of collaboration with pharmaceutical companies (eg have you accepted payments for speaker fees, travel or accommodation costs, consultancy fees, sponsorship to attend educational meetings, registration fees).
8. What impact would the public disclosure of payments have on your collaboration with pharmaceutical companies?

1.2 Survey results: overview

As outlined in Annexure 1, the results of the survey reflect the following attitudes of Australian healthcare professionals to transparency reporting:

- healthcare professionals support transparency surrounding transfers of value from pharmaceutical companies;
- the majority of healthcare professionals consider that transparency reporting should apply to all commercial life science organisations, not only the prescription medicines industry;
- healthcare professionals are split on how details of transfers of value should be made available. Publication of transparency data on a centralised database is slightly preferred and the Australian Health Practitioner Regulation Agency (AHPRA) is considered to be the most appropriate host of the information;
- the majority of healthcare professionals consider that the individual doctor should play a role in verifying information before it is published;
- the majority of healthcare professionals are likely to give consent to publish information about transfers of value made to them (fewer than one in four are unlikely to consent); and
- those healthcare professionals who would refuse to give their consent are unlikely to change their mind even if consent to disclosure was a mandatory requirement in order to obtain a transfer of value from a pharmaceutical company.

We discuss these findings in further detail below.

1.3 Support for transparency and transparency reporting

The results of the survey confirm that Australian healthcare professionals support transparency. The majority of healthcare professionals surveyed agreed with the proposition that payments from pharmaceutical companies to individually named healthcare professionals should be made

transparent through public reporting. Fewer than one in four healthcare professionals disagreed with that proposition.[2]

In relation to whether the healthcare professional surveyed would consent to have information about them published in respect of transfers of value received from pharmaceutical companies:

- the majority of healthcare professionals (approximately 56%) stated that it was likely that they would consent; and
- fewer than one in four healthcare professionals stated that it was unlikely that they would consent.

The results to this survey question are significant as they demonstrate that, already, the majority of healthcare professionals are likely to consent to having their names disclosed under the new transparency regime proposed in Edition 18 of the Code. Medicines Australia expects that once the Code is authorised and is given time to become embedded in the industry, this number will increase exponentially (particularly in respect of respondents who indicated that they were 'neutral' regarding consent) as:

- healthcare professionals become familiar with the new regime;
- Medicines Australia, member companies and healthcare professional bodies undertake further education about the benefits of transparency; and
- once the first set of data is published, the response of stakeholders to the publication are able to be assessed.

As noted in our letter to the ACCC dated 28 August 2014, Medicines Australia considers that seeking consent to disclosure is an important component of the partnership between companies and healthcare professionals in improving transparency. Medicines Australia strongly encourages healthcare professionals to consent to their information being disclosed. The results of this survey suggest that such consent will be forthcoming.

For the minority of healthcare professionals surveyed who indicated that they would be unlikely to consent to publication, most of these healthcare professionals indicated that they would be unlikely to change their view even if not doing so would preclude them from receiving a transfer of value from a pharmaceutical company. Accordingly, if the Code made consent to disclosure mandatory in order to receive a transfer of value:

- these doctors would be unlikely to change their mind and consent to disclosure; and
- as a result, Medicines Australia's member companies would be unable to deal with those healthcare professionals.

Medicines Australia considers that boycotting those healthcare professionals who choose not to consent to disclosure is inappropriate. Medicines Australia's reasons are outlined in our letter of 28 August 2014. In particular, Medicines Australia considers that such a boycott would be contrary to the interests of public health because member companies would be prevented from facilitating medical education for those healthcare professionals, thereby preventing interactions that ultimately improve patient care.

[2] Support for transparency was not limited to the prescription medicines industry, but extended to other commercial life science organisations (such as medical devices companies and generic manufacturers).

1.4 Publication of transparency data – importance of accuracy

In addition to considering the question of consent, the survey also considered publication of the transparency data generally. Over 90% of healthcare professionals agreed that they should play a role in verifying the information to be made available about them, before that information is published.[3]

This figure is not surprising and it reflects the importance of ensuring that any data put into the public domain is accurate. In this regard, Medicines Australia reiterates the difficulties experienced in the United States with the implementation of the Physicians Payments (Sunshine) Act. As noted in our letter of 28 August 2014, and by Dr Cross at the meeting with you on 1 September:

- the transparency reporting associated with the Physician Payments (Sunshine) Act was scheduled for release in September 2014. Healthcare professionals have requested that the reporting be delayed in order to allow more time for doctors to register and review the payment data for 'inaccurate, misleading and false information'. Provided at **Annexure 3** is a copy of a letter from over 100 medical associations and medical specialty societies outlining 'serious concerns' with the implementation of the Act and requesting a delay in publication; and
- the transparency reporting regime has been subject to other set-backs including the removal of access to the payments database (the Open Payments system) for a period in August 2014 following a data integrity issue identified by a physician. Provided at **Annexure 4** is a copy of a press release from the Centres for Medicare and Medicaid Services outlining the investigation undertaken into the data system following a discovery that manufacturers and group purchasing organisations had submitted intermingled and incorrect data for physicians with the same first and last names, information which was then erroneously linked to data in the Open Payments system. The incorrect data would have been made publicly available had the problem not been identified by a physician prior to publication.

The implementation issues experienced in the United States demonstrate the importance of:

- providing healthcare professionals with the ability to review data concerning them before it is published; and
- ensuring that the logistical, legal and technological challenges associated with implementation are addressed effectively before a centralised database is established.

2 Accessible complaints process for non-industry complainants

The ACCC has asked Medicines Australia to provide additional information on the accessibility of the complaints process for members of the public.

As outlined in section 12.2 of Medicines Australia's submission of 2 July 2014 (the ***Submission***), in Edition 18 of the Code Medicines Australia has reviewed its complaints process and made amendments to the Code. These amendments make it easier for non-industry complainants to access the complaints process and are designed to ensure that procedural fairness is afforded to all complainants.[4]

In respect of non-industry complainants, Appendix 1 to Edition 18 of the Code has been amended to make it clear that the Medicines Australia Secretariat will **always** offer the services of an

[3] In Edition 18 of the Code, this verification would occur pursuant to section 41.3.3 under which member companies will provide healthcare professionals for whom they have collected information the opportunity to review and submit corrections to the information.

[4] Further to the ACCC's comments in its Determination in respect of Medicines Australia Code of Conduct Edition 17, 20 December 2012 (***Edition 17 Determination***) at [228].

Independent Facilitator to assist a non-industry complainant to identify relevant sections of the Code. If the offer of an Independent Facilitator is declined, the Secretariat also has the discretion to refer the complaint to the Monitoring Committee (permanent members) and request the Monitoring Committee to advise whether all relevant sections of the Code have been identified in the complaint.[5]

These amendments are designed to reduce the potential burden on non-industry complainants by ensuring that they have access to assistance in formulating their complaints.

These amendments complement the existing steps taken by Medicines Australia to ensure that the complaints process is accessible to non-industry complainants including:

- a prominent link on the Code of Conduct tab on the Medicines Australia website entitled 'How to Make a Complaint';
- detailed Guidelines available on the Medicines Australia website for non-industry complainants (entitled 'Lodging a complaint – Non-industry complainant'); and
- a specific complaint submission form which is two pages long and easy to understand. The form allows a non-industry complainant to request that their identity remain confidential from the subject company.

3 The Monitoring Committee is effective in identifying potential breaches of the Code across a range of activities

The ACCC has asked Medicines Australia to provide additional information regarding the efficacy of the Monitoring Committee in identifying potential breaches of the Code, across a range of activities.

As outlined in section 12 of the Submission, the Code requires the Monitoring Committee to meet certain minimum standards in proactively reviewing member companies' promotional materials and activities.

In Edition 18 of the Code section 31.2 has been amended in respect of the different types of reviews undertaken by the Monitoring Committee. The amendments, which clarify the number of reviews of promotional materials undertaken by the Monitoring Committee within one or more therapeutic classes, demonstrate that the Monitoring Committee continues to undertake a detailed and effective review of the activities of member companies while ensuring that the review is not unduly burdensome.

The Monitoring Committee is effective in identifying breaches of the Code across a range of activities. If, following its review of submitted material, the Monitoring Committee considers that a breach of the Code may have occurred, it will contact the company to request further information and, if necessary, refer the matter to the Code Committee as a complaint: section 35.

This is reflected in the last four Code of Conduct Quarterly Reports (covering the period July 2013 to June 2014) which demonstrate that the Monitoring Committee was responsible for referring to the Code Committee five of the 16 complaints finalised during this period.[6]

[5] The Monitoring Committee will only identify additional sections of the Code if there is an obvious omission by the complainant.

[6] The Code of Conduct Quarterly Reports are available on the Medicines Australia website at: http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/quarterly-reports/

4 Patient Support Programs and Product Familiarisation Programs are effectively regulated

The ACCC has asked for additional information on Patient Support Programs and Product Familiarisation Programs, including whether Medicines Australia has considered the potential for those programs to be viewed as promotional rather than educational.

As part of the Code Review process for Edition 18, Medicines Australia consulted on all sections of the Code, including sections 8 and 17 of the Code which deal with Product Familiarisation Programs and Patient Support Programs respectively.[7] As a result of the Code Review process Medicines Australia made a number of amendments to sections 8 and 17 of the Code, as outlined in section 6.3 and section 9 of the Submission.

The amendments in Edition 18 help to ensure that Patient Support Programs and Product Familiarisation Programs are conducted in a rigorous manner and are appropriately regulated.

With respect to whether those programs could be considered promotional, other sections of the Code are also relevant and ensure that promotion to the general public does not occur. In particular, section 13 of the Code addresses the ways that member companies may interact with patients and reflects the requirements of Commonwealth Therapeutic Goods legislation that any material provided to the general public may not be promotional. Section 13 of the Code has also been amended in Edition 18 to further encourage compliance with existing legislative requirements regarding material that could be considered 'promotional'.

For these reasons, and those outlined in Medicines Australia's letter to the ACCC of 28 August 2014, Medicines Australia considers that these sections of the Code appropriately regulate the provision of such programs and that further amendment to sections 8 and 17 is not currently required.

5 Accessibility of published data

The ACCC has asked Medicines Australia to provide further information on the accessibility of the transparency reports published by Medicines Australia. Medicines Australia currently publishes its reports in PDF format to ensure the integrity and security of the published data. Since November 2012, Medicines Australia has ensured that the published transparency reports are also character readable. The transparency reports that will be published under the new transparency regime proposed in Edition 18 of the Code will also be published in character readable PDF format.

6 Medicines Australia's membership

The ACCC has asked Medicines Australia to provide an estimate of the share of the prescription pharmaceutical industry in Australia which is comprised by Medicines Australia's members.

Medicines Australia's member companies:

- supply approximately 86% of medicines supplied under the PBS (by value); and
- supply approximately 65% of medicines supplied under the PBS (by volume).

These figures do not include the large number of other therapeutic products supplied to Australian patients annually including:

- medical devices (such as prostheses);
- over the counter medicines;

[7] The extensive steps taken by Medicines Australia in undertaking the Code Review process are set out in section 5.3(a) of the Submission.

- complementary medicines; and
- in-vitro diagnostics products.

Yours sincerely

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Medicines Australia

Doctors' attitudes to Transparency of Payments

August 2014

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Strategic Data

Key Findings

Membership

- The large majority of General Practitioners are members of RACGP, a quarter of them are affiliated with AMA. As expected, Specialists tend to have multiple memberships (6 in 10 are a member of RACP).

Attitudes toward public reporting

- More than half of doctors support transparency of payments. Specialists are slightly more inclined to support public reporting.
- The majority of doctors believe disclosure of payments should apply to all types of commercial life science organisations.

Access to reports

- Doctors are split on how details of payments should be made available to the public - between a single, searchable public database and individual reports by pharmaceutical companies hosted on their websites.
- AHPRA is seen as the most appropriate host of payment information (3 in 10 General Practitioners and specialists think so).

Key Findings

Consent

- The majority of doctors agree that individual healthcare professionals should play a role in verifying information about them before it is made available to the public
- Less than 1 in 4 doctors are unlikely to give consent to publish payment information about them.
- Of doctors who would refuse to give consent, the majority are unlikely to change their view even if it meant they may no longer receive payments from pharmaceutical companies.

Level of collaboration

- Specialists and members of RACP are more likely to have a collaboration with pharmaceutical companies.
- For the majority of doctors, public disclosure of payments would have no impact on their level of collaboration with pharmaceutical companies.

Research Objectives & Methodology

This research aimed to help Medicines Australia:

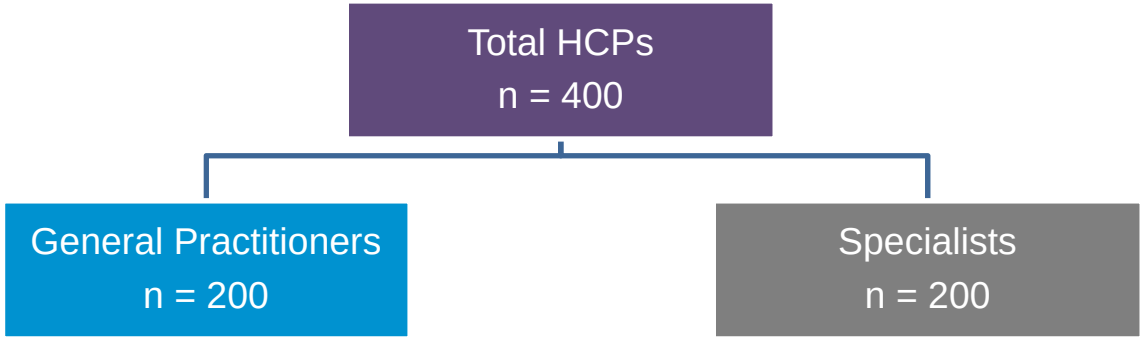
- understand the opinions of healthcare professionals on public reporting of payments they receive from pharmaceutical companies
- determine the impact of public reporting on the healthcare professionals' level of collaboration with pharmaceutical companies
- compare attitudes of General Practitioners vs. Specialists

An online, self-complete survey methodology was used to achieve the research objectives. Fieldwork was conducted on the 17th of August until the 25th of August, 2014. All healthcare professionals were remunerated for their time.

The results were based on a nationally representative sample of 400 healthcare professionals recruited for this research. Statistically significant differences were calculated at 95% confidence level, indicated with ↑ or ↓.

Survey Sample

Healthcare professionals who participated in the survey



Cardiologist	14
Dermatologist	11
Endocrinologist	20
Gastroenterologist	7
Haematologist	4
Neurologist	24
Oncologist	16
Ophthalmologist	19
Psychiatrist	37
Renal physician	17
Rheumatologist	23
Urologist	8

Survey Sample

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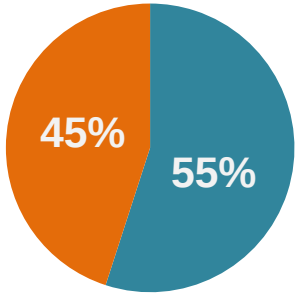
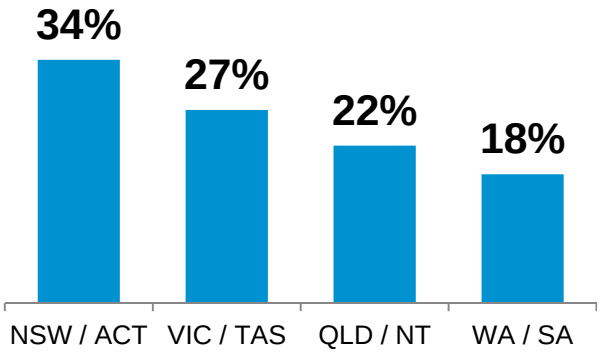
General Practitioners

60% 40%

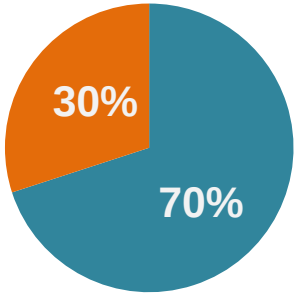


50 yo & below 51 yo & above

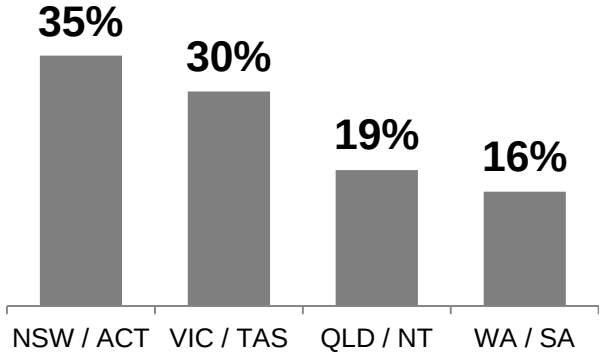


Specialists

71% 29%



50 yo & below 51 yo & above



Gender

Age Group

Practice State

Findings

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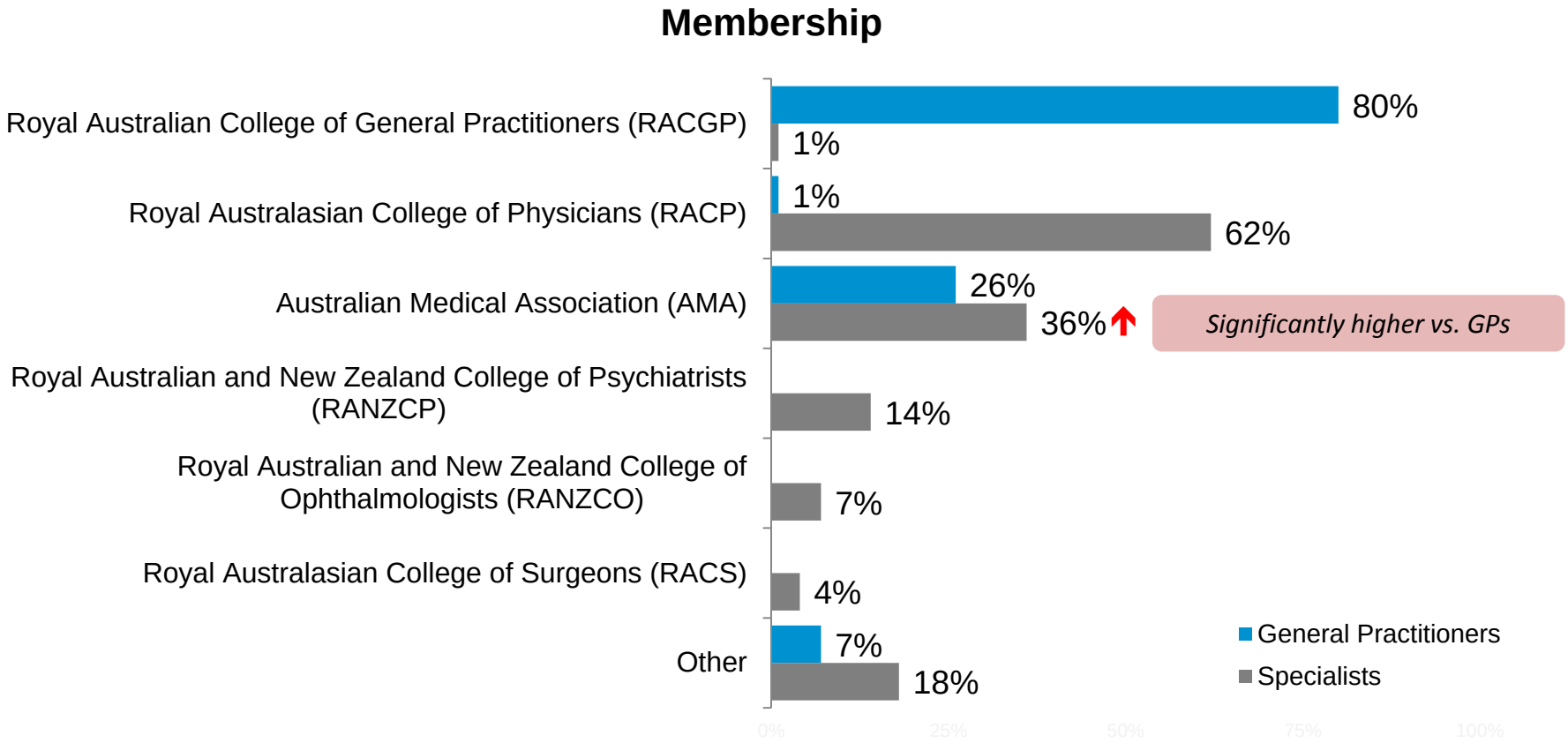
8 in 10 General Practitioners are members of RACGP while 62% of specialists are affiliated with RACP



Specialists are significantly more likely to be members of Australian Medical Association (AMA) and other groups, compared to General Practitioners.

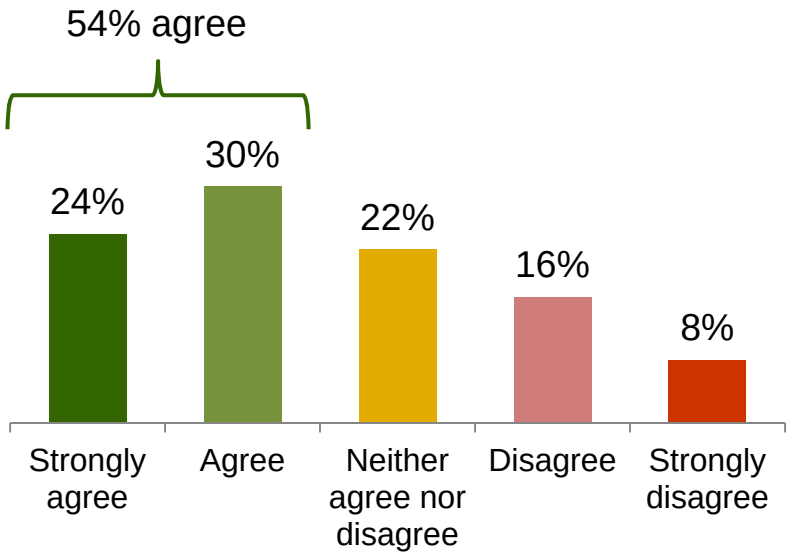
Base: n = 200 General Practitioners, 200 Specialists

Q1: Are you a member of:

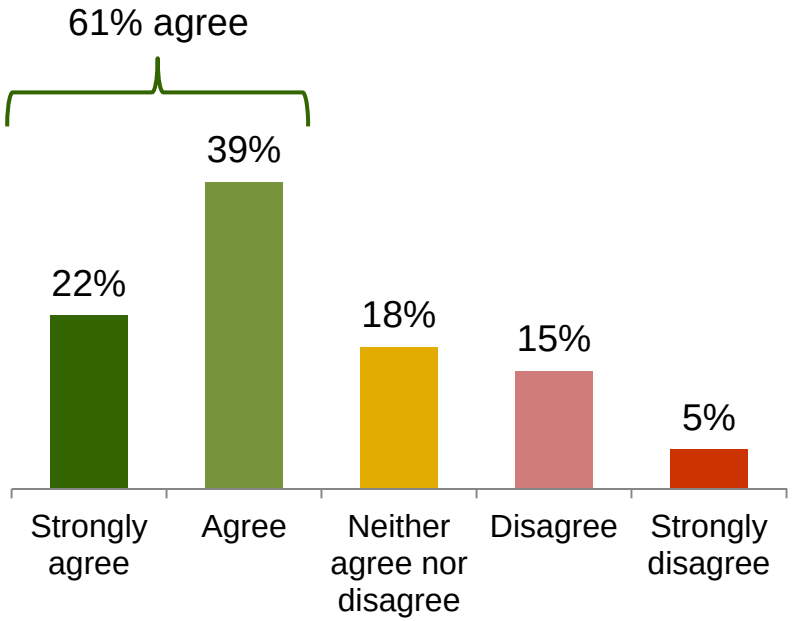
More than half of doctors agree on public reporting of payments, specialists slightly more inclined to think so

“Payments from pharmaceutical companies to individually named health care professionals should be transparent through public reporting”

General Practitioners



Specialists



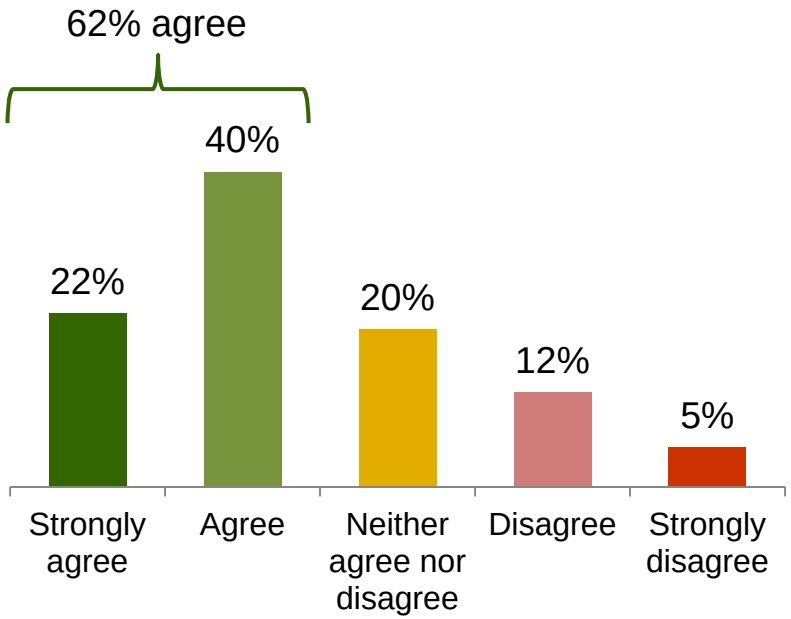
Base: n = 200 General Practitioners, 200 Specialists

Q2a: Please indicate the extent of your agreement to the following statements:

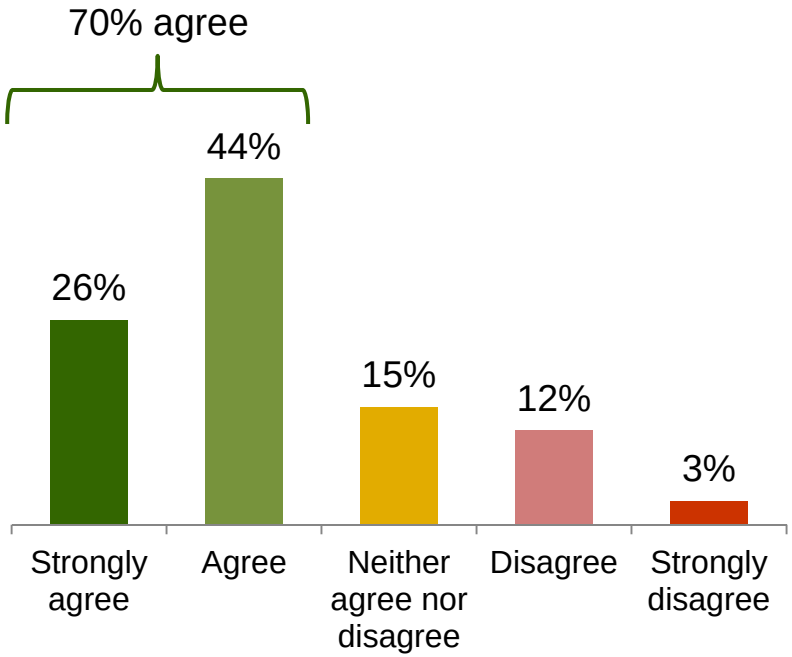
The majority of doctors believe disclosure of payments should apply to all types of commercial life science organisations

"Disclosure of payments to healthcare professionals should apply to all types of commercial life science organisations (e.g. medical devices, diagnostics, generic medicines companies)"

General Practitioners



Specialists



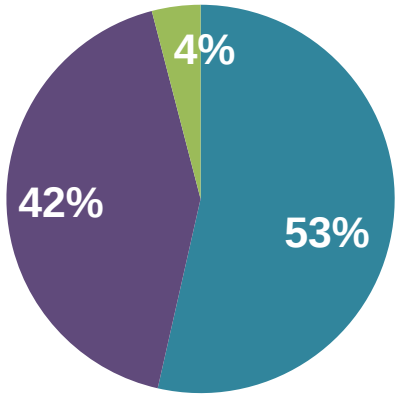
Base: n = 200 General Practitioners, 200 Specialists

Q2b: Please indicate the extent of your agreement to the following statements:

Doctors are split on how details of payments should be made available to the public

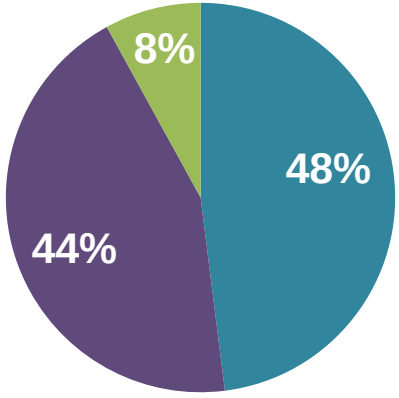
Reports detailing payments to healthcare professionals should be made available to the public via…

General Practitioners



- A single, searchable public database
- Individual reports by pharmaceutical companies hosted on company websites
- Other

Specialists



- A single, searchable public database
- Individual reports by pharmaceutical companies hosted on company websites
- Other

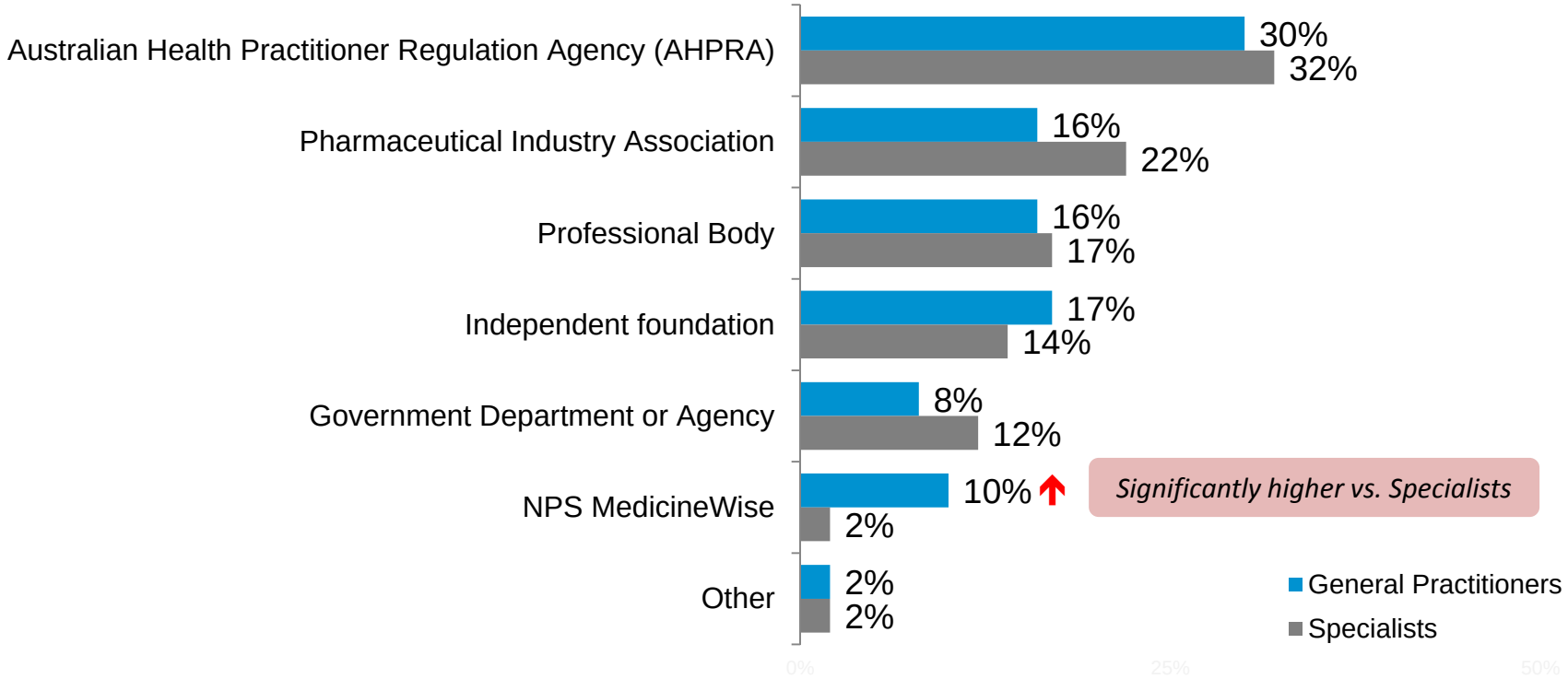
Only a few doctors argue that such reports should not be made available to the public at all (3% of General Practitioners, 2% of Specialists think so).

Base: n = 200 General Practitioners, 200 Specialists

Q3: How should reports detailing payments to healthcare professionals be made available to the public?

AHPRA is seen as the most appropriate host of payment information

Most appropriate host of payment information



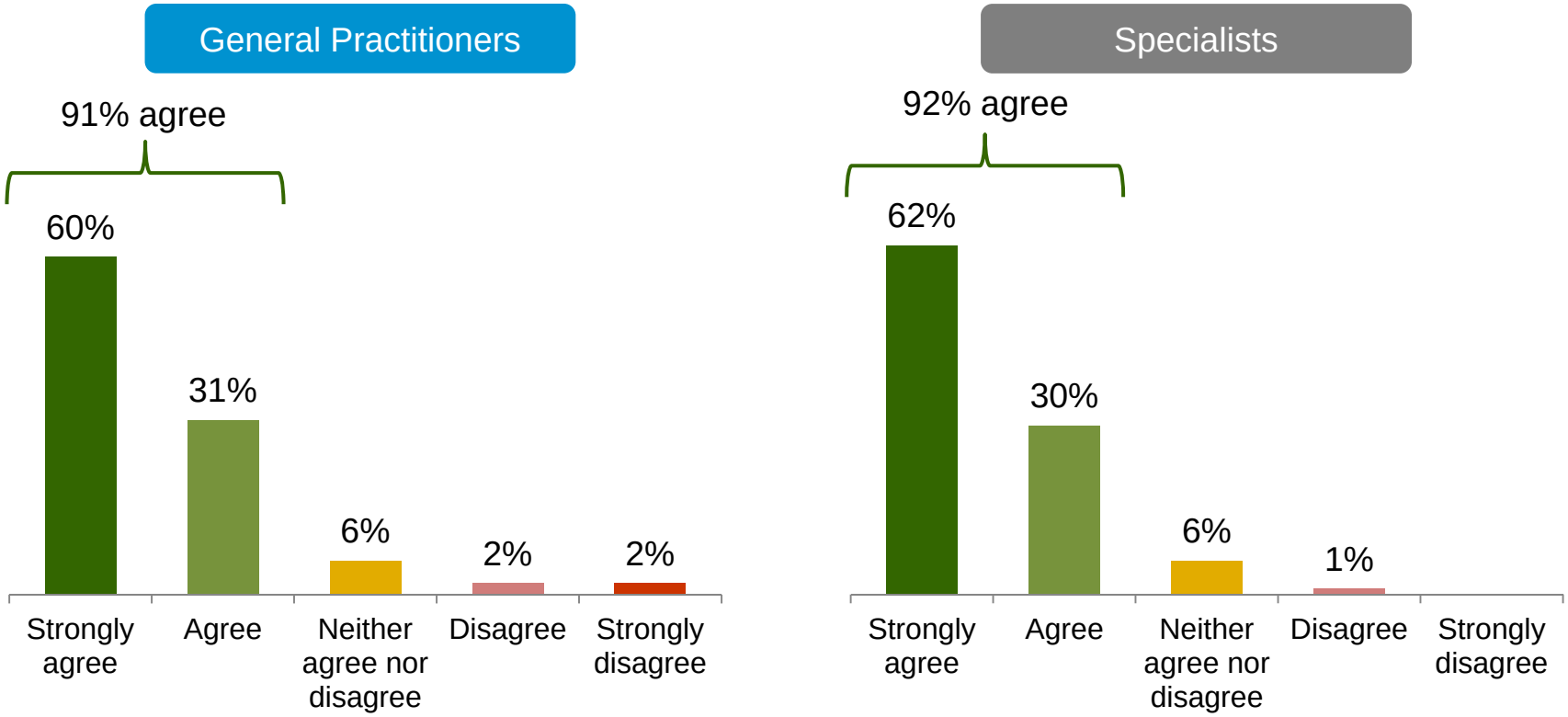
Interestingly, General Practitioners are more likely to consider NPS MedicineWise as the most appropriate host for this type of information (vs. only 2% of specialists).

Base: n = 200 General Practitioners, 200 Specialists

Q4: Who do you think is most appropriate to host this information?

The majority of doctors agree that they should play a role in verifying information about them prior to publication

“Individual healthcare professionals should play a role in verifying the information about them before it is published”



Base: n = 200 General Practitioners, 200 Specialists

Q5: To what extent do you agree that individual healthcare professionals should play a role in verifying the information about them before it is published?

Less than 1 in 4 doctors are unlikely to give consent to publish payment information about them

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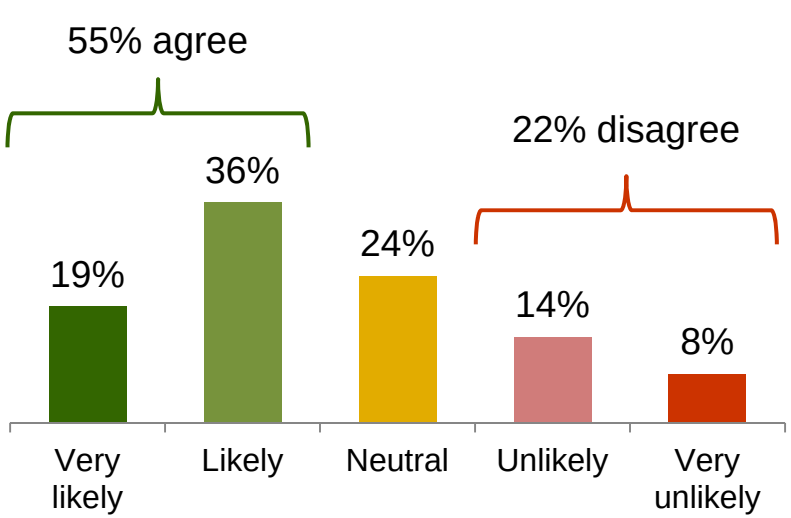
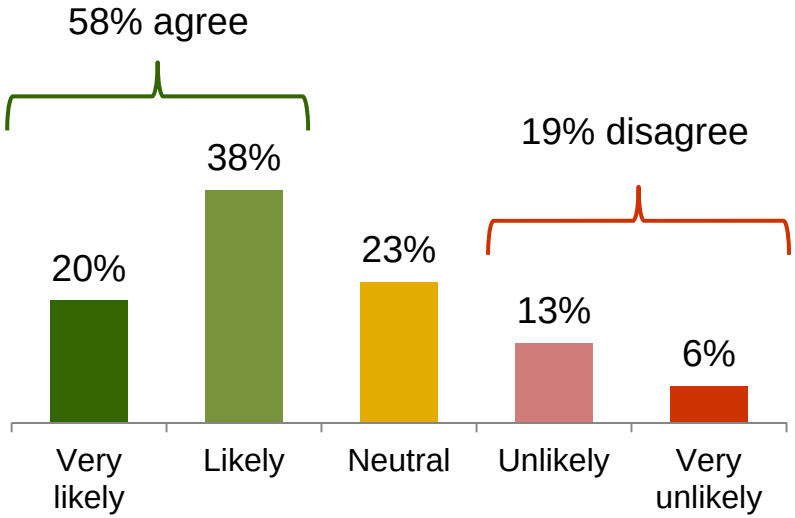
Healthcare professionals to give consent to publish information regarding payments from pharmaceutical companies

General Practitioners



Specialists



Base: n = 200 General Practitioners, 200 Specialists

Q6: Under current privacy legislation you should be asked for consent before information regarding payments from pharmaceutical companies is published about you. How likely are you to give consent?

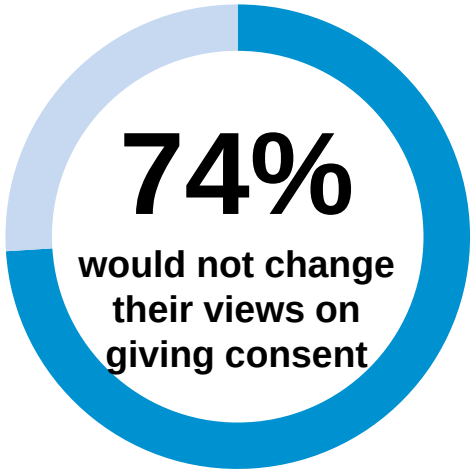
Of doctors who would refuse to give consent, the majority are unlikely to change their view even if it meant that they will not receive payments from pharmaceutical companies

Caution: low sample size

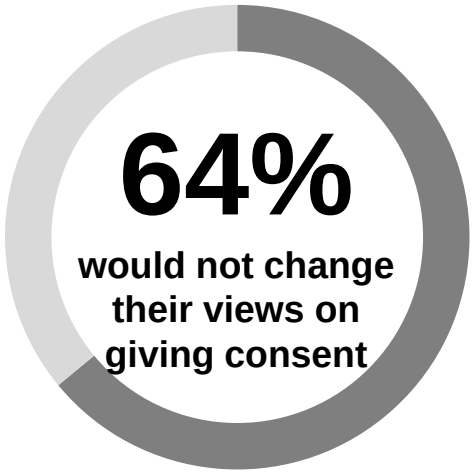
Base: n = 43 General Practitioners, 39 Specialists who are unlikely to give consent

If not providing consent meant a pharmaceutical company could no longer provide payments to healthcare professionals…

General Practitioners



Specialists

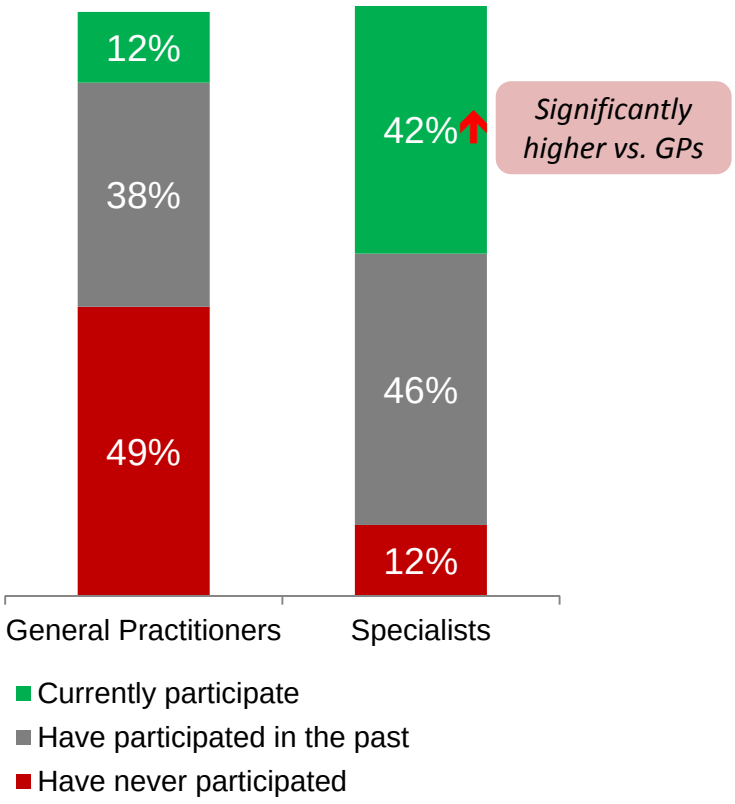


Q7: Would your view change if not providing consent meant a pharmaceutical company could no longer provide payments to you?

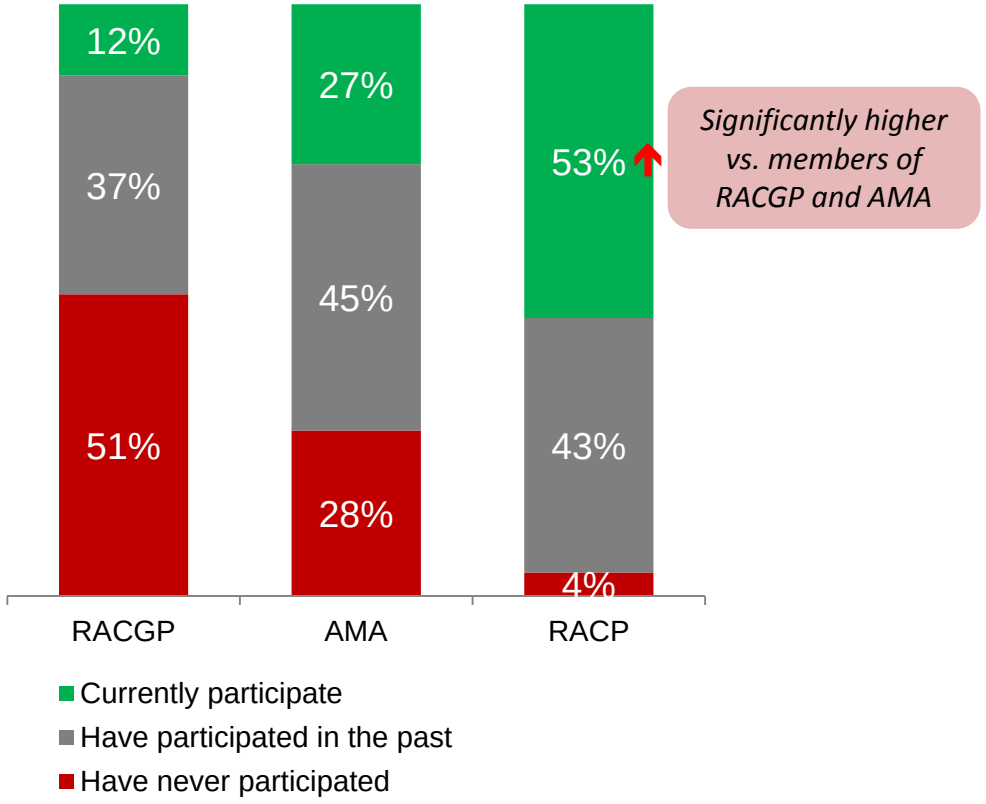
Specialists and members of RACP are more likely to currently collaborate with pharmaceutical companies

Level of collaboration with pharmaceutical companies

Split by HCP type



Split by membership



Base: n = 200 General Practitioners, 200 Specialists

Q8: How would you describe your current level of collaboration with pharmaceutical companies?

For the majority of doctors, public disclosure of payments would have no impact on collaboration. 1 in 5 would be less likely to collaborate

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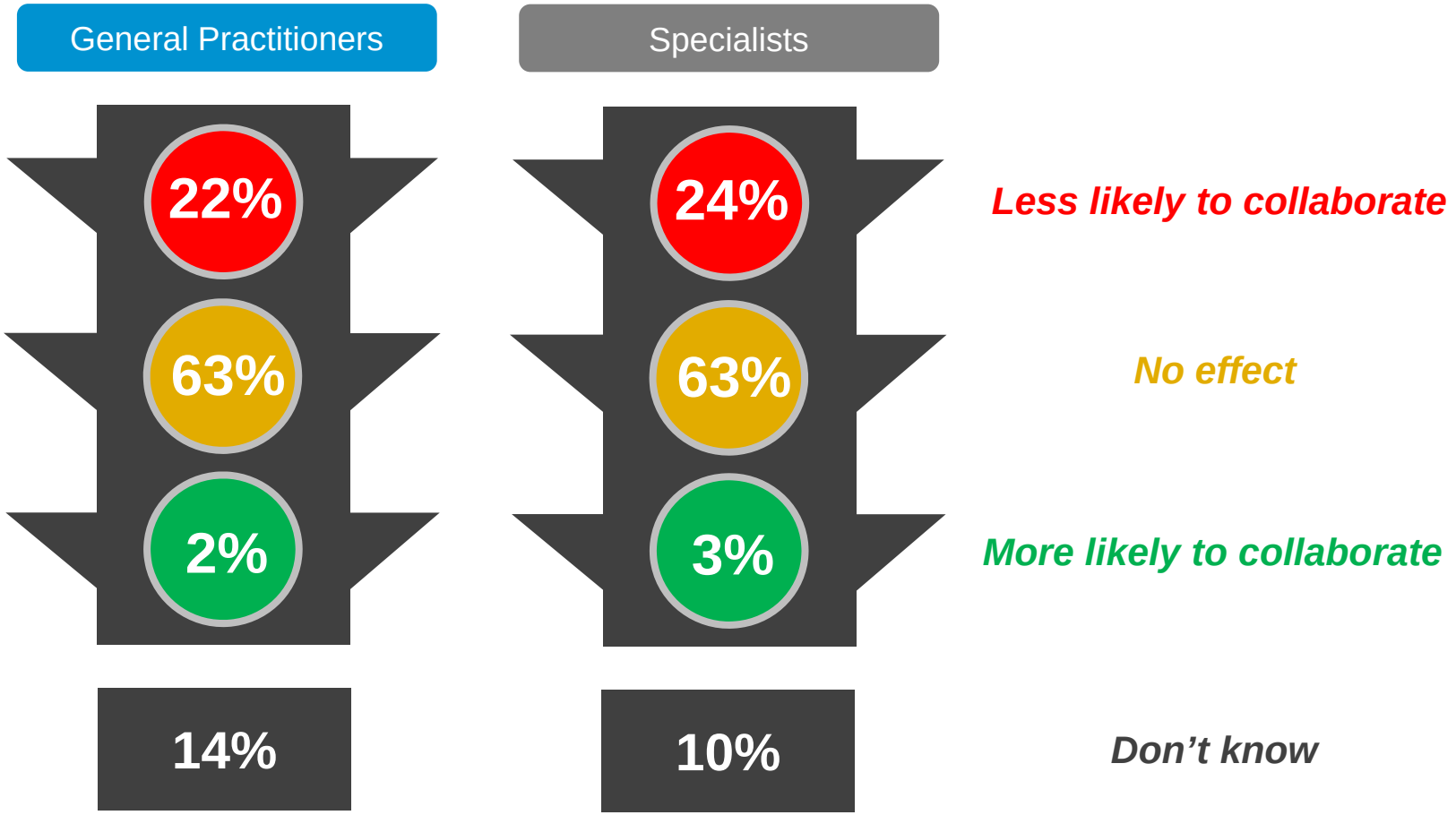
Public disclosure of payments: Impact on level of collaboration



Base: n = 200 General Practitioners, 200 Specialists

Q9: What impact would the public disclosure of payments have on your collaboration with pharmaceutical companies?

Cegedim Group in Australia

cegedim Relationship Management

cegedim Strategic Data

OK	OneKey
MI	Mobile Intelligence
DM	Direct Marketing
PS	Patient Support

PA	Promotion Audit
PD	Prescribing Data
MR	Market Research
KOL	KOL profiling

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Specialty	**Base**	**400**
		100%
	GP	200
		50%
	Specialist	200
		50%
Specialists (n>20)	Endocrinologist	20
		5%
	Neurologist	24
		6%
	Psychiatrist	37
		9%
	Rheumatologist	23
		6%
Membership	Australian Medical Association (AMA)	126
		32%
	Royal Australian College of General Practitioners (RACGP)	162
		40%
	Royal Australasian College of Physicians (RACP)	126
		32%
	Royal Australian and New Zealand College of Psychiatrists (RANZCP)	27
		7%
	Royal Australian and New Zealand College of Ophthalmologists (RANZCO)	14
		4%
	Royal Australasian College of Surgeons (RACS)	9
		2%
	Other	49
		12%
Participation	Currently participate	109
		27%
	Have participated in the past	169
		42%
	Have never participated	122
		30%

Gender	Male	261 *65%*
	Female	139 *35%*
Age	<=50 years old	249 *62%*
	>50 years old	151 *38%*
State	NSW / ACT	137 *34%*
	VIC / TAS	114 *28%*
	QLD / NT	81 *20%*
	WA / SA	68 *17%*

Cell Contents:

- Count
- Column Percentage

August 5, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Tavenner:

The undersigned medical associations and medical specialty societies are writing to register serious concerns with implementation of the Physician Payments Sunshine Act (Sunshine Act) and to request an expanded timeframe to allow recipients to register, review, and dispute their data in the Open Payments System before publication. Our organizations represent physicians who are directly impacted as covered recipients in the Open Payments System or indirectly impacted through their affiliation with teaching hospitals. Many of our organizations supported passage of the Sunshine Act and, fundamentally, we have no issue with efforts to increase transparency in the interactions between physicians and industry. However, we have a number of serious concerns regarding how the Open Payments System has been implemented.

Significant Expansion of Reporting Requirement – Educational Activities

In the proposed Medicare Physician Fee Schedule for 2015, the Centers for Medicare and Medicaid Services (CMS) has proposed revoking the existing Sunshine Act reporting exclusion for continuing medical education (CME) activities, due in large part to requests from other accrediting bodies that they be added to the list of exempt organizations covered by the exclusion. Instead, the proposal would exempt third party transfers to Continuing Education (CE) only where an industry donor is unaware of the recipients/beneficiaries before and after the funds are transferred. Our organizations believe that this raises concerns as industry could learn the identities of speakers/faculty and potentially participants after the funds have been transferred through brochures, programs, and other publications, or through their physician-employees' participation in CE activities (either as speakers/faculty or attendees). Our organizations are concerned that this would have a significant, chilling impact on CE, which runs contrary to the public interest. **We therefore recommend strongly that the CMS slightly modify the proposal to add the language that the exemption applies under section 403.904(i)(1) when an applicable manufacturer provides funding to a CE provider, but does not select or pay the covered recipient speaker/faculty directly, or provide the CE provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CE program. The agency can include the guidance in the regulation or preamble that the foregoing is achieved where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity under section 403.904(i)(1). This accomplishes CMS' goal while eliminating the potential for negatively impacting CE. To allow CE providers time to ensure that their processes comply with the modified exemption, we urge CMS to make this change effective six months after the final rule is issued.**

In addition, when it passed the Sunshine Act Congress outlined 12 specific exclusions from the reporting requirement, including "[e]ducational materials that directly benefit patients or are intended for patient use." In an overbroad interpretation of the statute, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles, and other services used to educate physicians were not covered by this exclusion even though these clearly have a direct benefit to patients and their medical care.

The importance of up-to-date, peer reviewed scientific medical information as the foundation for good medical care is well documented. Independent, peer reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients. The Agency's decision to not cover these materials under the educational materials exclusion is inconsistent with the statutory language on its face, congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge. **Our organizations urge the Agency to reconsider its decision not to cover medical textbooks, journal article supplements, and reprints within the existing statutory exclusion for educational materials that directly benefit patients.**

Physician Registration Impeded by Condensed Timeframe

There are widespread concerns that the implementation of this new system for data collection—without minimally a six month period to upload the data, process registrations, generate aggregated individualized reports, and manage the dispute communications and updates—will not be ready and will likely lead to the release of inaccurate, misleading, and false information. The Agency has not provided effective notification to the vast majority of physicians nor provided a reasonable amount of time for the undersigned organizations to engage and educate physicians on the registration and dispute process. Early in the regulatory process, medicine informed CMS that a minimum of six months would be needed to ensure an adequate amount of time for outreach on registration and the dispute process. As soon as our organizations learned the date that physicians could begin registering for each phase, a concerted communications campaign was launched. The content had to be developed after the abbreviated period for registration began and with limited opportunity to develop materials because of the compressed period for registration and dispute in advance of publication. Thus, we know that it is extremely likely that many physicians impacted by the Sunshine Act reporting are not aware of the registration requirement and based on feedback thus far certainly will not have adequate time to register prior to the deadline for flagging inaccurate data in the public database. Accordingly, **our organizations strongly urge CMS and the Office of Management and Budget (OMB) to postpone for six months, until March 31, 2015, the publication of the information collected in the Open Payments System, to compensate for this year's six months delay in providing the opportunity for physicians to register, contrary to Agency communications throughout 2013 representing that physicians would be permitted to do so beginning January 1.**

Complicated and Incomplete Guidance Exacerbates Condensed Registration Timeframe

Perhaps most troubling, many physicians are expressing frustration at an overly complex registration process which, combined with the condensed timeframe, makes the task of reviewing and disputing reports by August 27 effectively impossible for the Agency's estimated 224,000 covered physician recipients. We have previously stated that CMS' number is likely an extremely low estimate of impacted physicians. CMS has suggested that it will take 30-45 minutes to complete the 5-step process of registering in the Open Payments system. Our own analysis suggests a substantially more complex 11-step registration process, which does not include the pre-registration step of verifying identity in Medicare's Enterprise Identity Management (EIDM) System. Moreover, when the post-registration time it takes to review and dispute data is factored in, there are an additional 5 steps layered on top of the already cumbersome registration process. This process must be streamlined and physicians must be given adequate time to review and dispute their reports. Thus, **we repeat our request that CMS and OMB delay for six months the publication of the information collected in the Open Payments System until March 31, 2015.**

Moreover, our organizations have serious concerns that Agency guidance gives manufacturers the power to unilaterally dismiss disputes that were initiated by physicians or teaching hospitals. These concerns are the result of language that was buried in the supplementary documents of a May 5th Federal Register Notice, stating that manufacturers "after reviewing the disputed information, if they determine that no change is required to the data, may dismiss the dispute or request that physician or teaching hospital who initiated the dispute to withdraw it." The February 2013 Final Rule does not authorize manufacturers or group purchasing organizations (GPOs) to dismiss disputes without both parties agreeing that the dispute is resolved. If no resolution is reached, the manufacturer's or GPO's reported data will be flagged as disputed in the public database until resolution has been reached between the parties. In a June 24th meeting with AMA and specialty society staff, CMS officials stated their intent to issue clarifying guidance that manufacturers and GPOs are not authorized by the agency to unilaterally dismiss disputes. While Agency officials have indicated that they have clarified the guidance to manufacturers, requests from our organizations to see the written changes have gone unanswered. **We request that the Agency provide the clarifying guidance to physicians/teaching hospitals, to manufacturers/GPOs, and to our organizations.**

Sincerely,

American Medical Association
AMDA – The Society for Post-Acute and Long-Term Care Medicine
American Academy of Allergy, Asthma and Immunology
American Academy of Child & Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Disability Evaluating Physicians
American Academy of Emergency Medicine
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association for Geriatric Psychiatry
American Association of Neuromuscular and Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American Clinical Neurophysiology Society
American College of Chest Physicians
American College of Emergency Physicians
American College of Medical Genetics
American College of Occupational and Environmental Medicine
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Phlebology
American College of Radiology
American College of Rheumatology
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Psychiatric Association
American Society for Aesthetic Plastic Surgery
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society for Radiation Oncology
American Society for Reproductive Medicine

American Society for Surgery of the Hand
American Society of Anesthesiologists
American Society of Bariatric Physicians
American Society of Cataract & Refractive Surgery
American Society of Dermatopathology
American Society of Hematology
American Society of Neuroradiology
American Society of Nuclear Cardiology
American Society of Transplant Surgeons
American Thoracic Society
American Urological Association
American Women's Association
American Society of Echocardiography
College of American Pathologists
Digestive Health Physicians Association
Infectious Diseases Society of America
Large Urology Group Practice Association
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Critical Care Medicine
Society of Hospital Medicine
Society of Interventional Radiology
Society of Thoracic Surgeons
The Endocrine Society

Medical Association of the State of Alabama
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association, Inc.
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association

Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wyoming Medical Society

CMS.gov
Centers for Medicare & Medicaid Services

Press release: Open Payments System Reopens, Extends Physician Registration and Review Period

Date	2014-08-15
Title	Open Payments System Reopens, Extends Physician Registration and Review Period
For Immediate Release	Friday, August 15, 2014
Contact	press@cms.hhs.gov

Open Payments System Reopens, Extends Physician Registration and Review Period

CMS announced today that the Open Payments system is once again available for physicians and teaching hospitals to register, review and, as needed, dispute financial payment information received from health care manufacturers. The system was taken offline on August 3 to resolve a technical issue. To account for system down time, CMS is extending the time for physicians and teaching hospitals to review their records to September 8, 2014. The public website will be available on September 30, 2014.

“CMS takes data integrity very seriously and took swift action after a physician reported a problem,” said CMS Deputy Administrator and Director of the Center for Program Integrity Shantanu Agrawal, M.D. “We have identified the root cause of the problem and have instituted a system fix to prevent similar errors. We strongly encourage physicians to review their records before the deadline and before the data are posted publically to identify any discrepancies.”

A full investigation into a physician complaint found that manufacturers and group purchasing organizations (GPOs) submitted intermingled data, such as the wrong state license number or national provider identifier (NPI), for physicians with the same last and first names. This erroneously linked physician data in the Open Payments system.

CMS has implemented system fixes to resolve the issue, and revalidated all data in the system to verify that the physician identifiers used by the applicable manufacturer or GPO are accurate, and that all payment records are attributed to a single physician. Incorrect payment transactions have been removed from the current review and dispute process and this data will not be published.

CMS remains committed to ensuring the data made public from the system is as accurate as possible and extended the time for review and dispute to provide physicians and teaching hospitals with a full 45 days.

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