

Transparency Reporting
A Quick Guide

THE PURPOSE OF THIS QUICK GUIDE

The purpose of this Quick Guide is to provide a snapshot of 'how to' meet transparency reporting requirements. It is designed for Medicines Australia member companies who commit to reporting transparently as part of their compliance with the Medicines Australia Code of Conduct. However, it also applies to any other non-member innovative pharmaceutical company that chooses to report transparently as an optional approach to demonstrate high ethical standards. Medicines Australia welcomes all companies to report transparently.



"Companies are committed to transparency in their interactions with healthcare professionals and other stakeholders, to maintain trust and confidence in the industry."

- OVERARCHING PRINCIPLE 2, CODE OF CONDUCT

Medicines Australia recognises that reporting transparently is a public benefit, and this is articulated in the Medicines Australia Code of Conduct at Part E, Section 14. Further information on those reporting mechanisms:

https://www.medicinesaustralia.com.au/code/transparency-reporting/

The Three Reporting Arms

Medicines Australia has three separate reporting mechanisms to report payments and other activities:



<u>Payments and Transfers of Value made to healthcare professionals:</u> information about healthcare professionals who receive payments or educational support through airfares, accommodation or registration fees.



<u>Third Party Meeting Sponsorship and grants and donations to healthcare</u> <u>organisations:</u> supporting independently organised educational activities that support the enhancement of medical knowledge and the quality use of medicines and grants and donations made to healthcare organisations to support QUM programs, medical research or education and training



<u>Patient Organisation Support</u>: financial and in-kind relationships with health consumer organisations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Reporting Timeframes

Each of the three reporting mechanisms has its own timeframe, as identified in the Code (Section 14.4) and <u>on this webpage</u>. Where a due date falls on a holiday or weekend, the nearest business day will apply. The below timetable provides a more detailed version:

Report Type	Report Format	Report Timeframe	Due	Submit to	Published
HCP Payments / Transfers of Value	CSV or XLS	1 Jan – 30 June	31 Oct	Disclosure Australia	10 Nov
Accompanying HCP/ToV verification form	PDF, XLS or email		7 Nov	Medicines Australia	N/A
Third Party Meeting Sponsorships & Grants and Donations	CSV or XLS	1 Jan – 30 June	31 Oct	Medicines Australia	10 Dec
Accompanying Third Party/G&D verification form	PDF, XLS or email		7 Nov		N/A
Patient Organisation Support	CSV or XLS	1 Jan – 31 Dec	30 Apr	Medicines Australia	30 June
Patient Organisation verification form	PDF, XLS or email		7 May		N/A
HCP Payments / Transfers of Value	CSV or XLS	1 July – 31 Dec	30 Apr	Disclosure Australia	10 May
Accompanying HCP/ToV verification form	PDF, XLS or email		7 May	Medicines Australia	N/A
Third Party Meeting Sponsorships & Grants and Donations	CSV or XLS	1 July – 31 Dec	30 Apr	Medicines Australia	10 June
Accompanying Third Party/G&D verification form	PDF, XLS or email		7 May		N/A

Medicines Australia provides Excel spreadsheet templates for companies to use in their reporting. There are three templates, corresponding to each of the report categories available on our <u>Code Resource Toolkit here.</u>



Tips consistent for all reporting practice

Don't Duplicate

Wherever reporting is published on the Medicines Australia website or the Disclosure Australia website, it is not mandatory for member companies to duplicate that information on their own corporate websites. The most important principle is that member companies meet their transparency requirements and ensure their relevant reporting is easily accessible by external stakeholders.

Companies which rely on the reports being published on the Medicines Australia website or the Disclosure Australia website should still ensure their corporate websites clearly articulate their approaches to transparency reporting and make available the various links to where any such reporting can be viewed.

Verify your report

For each reporting round, member companies are required to submit to Medicines Australia a verification that the information provided is truthful and complete. Medicines Australia will accept this verification via a variety of formats. Verification forms are due seven calendar days following submission of each required report.

A word template is provided in our <u>Code</u> <u>Resource Toolkit here</u> as well as a separate sheet in the excel spreadsheet template. Alternatively, an email from the Managing Director or equivalent, will also be accepted. Electronic and digital signatures are accepted.

"Being transparent about payments and other activities means that everyone can easily understand the nature and extent of programs we support, including programs which might lead to the next discovery of a new and innovative medicine, vaccine or treatments" - ELIZABETH DE SOMER, CEO, MEDICINES AUSTRALIA

What does the Code say?

Section 14.1: It is reasonable for healthcare professionals to be fairly compensated for legitimate expertise and services provided to the industry, and that such compensation be publicly disclosed by the pharmaceutical industry

Section 14.2: It is reasonable for the pharmaceutical industry to financially support the education of healthcare professionals through sponsorship of meetings and symposia organised by third parties, and that such support is publicly disclosed. It is also reasonable for the industry to provide a grant or donation to a healthcare organisation in accordance with Section 5.2.

Section 14.3: It is reasonable for Companies to provide financial support and/or significant direct or indirect non-financial support to organisations that work to benefit Australian patients, and it is appropriate for these activities to be reported.



Payments and Transfers of Value to Healthcare Professionals Reports

Work that needs to be done well before reporting due-dates:

- Companies must provide healthcare professionals with a period of at least six weeks to review, verify or correct collected information about payments and transfers of value relating to them.
- Companies must not make a transfer of value unless they have taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.
- There are two rounds of reporting annually January to June and July to December.

The Code Resource Toolkit hosts example statements which companies can use in relation to engaging healthcare professionals and their duty to collect and report on any such engagements, both pre and post-engagement. These differ from the reporting templates – see <u>the Code Resource Toolkit here</u> (Collection Statement for use in HCP engagements (Example)).

Payments and Transfers of Value to Healthcare Professionals are often abbreviated to "ToV to HCPs."

- Disclosure Australia is the central reporting system, from which a search engine is available through <u>disclosureaustralia.com.au</u>.
- Reports are to be emailed to Disclosure Australia via <u>reporting@disclosureaustralia.com.au</u> on the due dates provided in the reporting timeframes table.
- On receipt of your report, the provided data will be loaded into Disclosure Australia. During this process data is validated to ensure all fields have appropriate values. If there are any anomalies in the data, such as non-numerical figures or empty fields, the data requires correction and resubmission. Validated data does not mean the accuracy of the data has been verified by Medicines Australia; this is the responsibility of the member company.
- In either case, your submitted report will be acknowledged and you will receive confirmation when the data is validated and ready for publishing,
- A summary table of aggregated information about your report is not required.
- By COB on the publication date, the data is published to Disclosure Australia, searchable by the public.

<u>Pre-publication update:</u> Medicines Australia delivers a pre-publication data summary for members. This is an opportunity to provide members with an overview of the aggregated data, and trends ahead of publication. This will be advertised through the Medicines Australia member portal. Please see Section 14.1 in the Code of Conduct Edition 20 for more detail about reporting of transfers of values to healthcare professionals.



DID YOU

Third Party Educational Meeting Sponsorship and Grants and Donations to Healthcare Organisation Reports

It is reasonable for the pharmaceutical industry to financially support the education of healthcare professionals through sponsorship of meetings and symposia organised by third parties, and that such support is publicly disclosed. Section 4 of the Code of Conduct details the types of third-party educational events that need to be reported.

It is also reasonable for the pharmaceutical industry to provide grants or donations to healthcare organisations to implement QUM programs, provide education and training or conduct medical research as described in Section 5.2 of the Code.

Under Code Edition 20, grants and donations to healthcare organisations will be reported in the same report as third-party educational meeting sponsorships.

There are two rounds of reporting annually.

- Third party meeting sponsorships and grants and donations are not included in the central reporting system. Instead, they are published on the <u>Medicines Australia</u> <u>website here</u>.
- Medicines Australia provides an Excel template for reporting which is located on our <u>Code Resource Toolkit here (Sponsorship of Third Party Meetings and Symposia and grants and donations to healthcare organisations (Template))</u>, with the three additional 'number only' columns used for Medicines Australia auditing purposes.
- Reports are to be emailed to <u>codehelpdesk@medicinesaustralia.com.au</u> on the due dates provided.
- On receipt of your report, Medicines Australia will check the data for numerical consistency. Validated data does not mean that Medicines Australia has verified the accuracy of the data; this is the responsibility of the company.
- Your submitted report will be acknowledged, and you will receive confirmation that the data is validated, or that you need to fix discrepancies.
- We will request a PDF document (with the three additional columns deleted) once we have checked the Excel version.
- The final PDF reports are then published on the Medicines Australia website <u>here</u> on the publication date.

Please see Section 14.2 in the Code of Conduct for more detail about reporting of thirdparty sponsorships and grants and donations.



Patient Organisation Support Reports

It is reasonable for companies to provide financial support and/or significant direct or indirect non-financial support to patient organisations that work to benefit Australian patients, and it is appropriate for these activities to be reported.

There is one annual report covering January to December each year.

- Patient organisation support reports are not presented in the central reporting system. Instead, they are published on the <u>Medicines Australia website here</u>.
- Note that the Excel template provided in the <u>Code Resource Toolkit</u> includes some examples to guide members in what is applicable for this report, and what is not.
- Reports are to be emailed to <u>codehelpdesk@medicinesaustralia.com.au</u> on the due date provided.
- On receipt of your report, Medicines Australia will check the data for numerical consistency. Validated data does not mean that Medicines Australia has verified the accuracy of the data; this is the responsibility of the company.
- Your submitted report will be acknowledged and you will receive confirmation that the data is validated, or that you need to fix discrepancies.
- We will request your PDF document (with the one additional column deleted) once we have checked the Excel version.
- The final PDF reports are then published on the Medicines Australia website <u>here</u> on the publication date.

Please see Section 14.3 in the Code of Conduct for more detail about reporting of support for patient organisations.

