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| Improving access to medicine adverse event data – sponsor survey |
| Medicines Adverse Event Data Exchange (MAEDX) |
| Version 1.0, January 2022 |

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All submissions received will be placed on the TGA’s Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked “IN CONFIDENCE”. Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA’s Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

## Overview

The Therapeutic Goods Administration (TGA) monitors the safety of medicines (including vaccines) by collecting and assessing reports of adverse events and taking regulatory action to improve medicine safety. The sponsors of medicines in Australia also have pharmacovigilance responsibilities, including the need to collect and assess adverse event reports and inform the TGA where any significant safety issues have been identified for their products.

The Medicines Adverse Event Data Exchange project seeks to improve the management of medicines safety signals by:

* improving how we share medicine adverse event data held in TGA systems with sponsors, jurisdictions and the public; and
* making it easier for health professionals to report adverse events to the TGA.

This survey is specifically seeking feedback on improving access to adverse event data for **medicine sponsor organisations** to assist with their pharmacovigilance obligations.

### Sponsor access to medicine adverse event data

Medicine sponsors need access to product related adverse event data to fulfill their pharmacovigilance responsibilities. There is currently no ability for sponsors to automatically view or export de-identified adverse event data held in TGA systems. Instead, sponsors seek to access relevant data by manually searching the public Database of Adverse Event Notifications (DAEN) - Medicines and through email requests to the TGA. Both of these methods are inefficient for sponsors and the TGA, resulting in delays in access to important safety information.

We propose to implement functionality that allows sponsors to view and export relevant de-identified medicine adverse event data from TGA systems using their existing sponsor authentication processes. To develop this functionality, we are seeking feedback on:

* What medicine adverse event data do sponsors wish to view and/or extract from TGA’s Adverse Events Management System (AEMS).
* The preferred format(s) for the extracted data to support its upload into sponsor pharmacovigilance systems.
* Sponsors’ ability to transition to use the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ([ICH) Enterprise to Business (E2B) R3 standard](https://ich.org/page/e2br3-individual-case-safety-report-icsr-specification-and-related-files) for submitting and receiving adverse event reports via the secure Electronic Data Interchange (EDI) service.

## We want your feedback

We invite you to provide your feedback by completing our online survey.

[Start the survey](https://consultations.tga.gov.au/tga/sponsor-access-tga-medicine-adverse-event-data)

All survey responses will be published on the TGA Consultation Hub, unless requested to be kept confidential.

Please contact us at [medsafetyprojects@health.gov.au](mailto:medsafetyprojects@health.gov.au) if you have any issues with completing this survey.

## Access to tailored adverse event data

The Adverse Events Management System (AEMS) is the TGA database that contains details of all medicine Individual Safety Case Reports (ICSRs) that have been submitted to the TGA.

The data model in AEMS is based on the [E2B(R3) Data Elements and Message Specification](http://www.ich.org/products/electronic-standards.html), with additional fields (also known as ‘attributes’) included within AEMS for TGA regulatory purposes.  Although, there are hundreds of data attributes that can be captured for an ICSR, typically many of these fields will not contain data or may contain data that is not relevant to sponsor pharmacovigilance needs.

The most populated data fields within AEMS are those related to the minimum data concepts for a valid ICSR. This includes:

* the medicine that is suspected to have caused the event (most commonly identified by its active ingredient/s or trade name or occasionally the intended use)
* the reaction reported (coded using MedDRA terminology)
* the case narrative
* report date
* patient characteristics (age, sex)
* sender information (e.g. sender type, location details)

On request from sponsors, the TGA currently manually releases in pdf format the following AEMS data relevant to the sponsor’s products (trade name and active ingredient):

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| Type of information | Data |
| Case details | Report Date, Modified on, Causality, Serious ICSR |
| Patient details | Sex, Age, State |
| Sender details | Type |
| Reporter details | Qualification |
| Case narrative | Free text narrative from reporter |
| Reactions | Preferred term, Onset date, End date, Management of event, Outcome |
| Drug information | Drug name, Dosage, Route of administration, Treatment details, Indication, Action taken |

The TGA proposes to provide sponsors streamlined access to relevant AEMS data to support their pharmacovigilance responsibilities, while continuing to protect information that may identify the individual patient or reporter. Your feedback to the questions below will help to inform how to best tailor what de-identified AEMS data sponsor organisations would like to view or extract.

### Questions

1. What medicine adverse event data does your organisation currently request from the TGA and other sources (e.g. through the public DAEN-Medicines search, through direct requests to the TGA/overseas medicine regulators or through the World Health Organization’s Vigibase)?
2. Where adverse event data is requested, what purpose is that data used for (e.g. imported into company pharmacovigilance systems, used to supplement reporting to international regulators/pharmacovigilance networks, used to inform internal safety monitoring, other)?
3. Does your organisation currently submit ICSRs to TGA through the EDI Gateway? Yes/No

If no, are there any barriers to your organisation submitting ICSRs through the EDI Gateway?

1. Would you use the proposed functionality to view tailored AEMS data? Yes/No.

If yes what data attributes would you wish to have displayed?

1. For which products would you like to use this functionality i.e. data related to your ARTG entries only vs a broader subset (e.g. all medicines with the same active ingredient as your products)?

If other, please specify

1. Would you want to extract relevant ICSRs directly into your pharmacovigilance system? Yes/No

If yes what data fields would you wish to extract?

1. For which products would you want to extract ICSRs directly into your pharmacovigilance system i.e. data related to your ARTG entries only vs a broader subset (e.g. all medicines with the same active ingredient as your products)?

If other, please specify

1. What is your preferred file format for extracting AEMS data (e.g. flat .csv file or E2B R3 ICSR message)?

If other, please specify

1. Would you want to receive ICSRs directly via your EDI Gateway in the E2B R3? Yes/No

Why/why not?

1. User profiles: Should agents have the same user profile access to tailored data as sponsors? Yes/No

Why/why not?

1. Do you wish to access historical AEMS data (i.e. ICSRs older than 6 months)? Yes/ No

If yes, what extent of historical data would you wish to access e.g. previous 6 months, 1 year, 2 years, up to 2018 (limit of AEMS mapped data) or other? If other, please specify.

1. Are there other ways that you would also like access to AEMS data to assist with meeting your pharmacovigilance responsibilities?

## Voluntary transition to E2B(R3) for submitting case reports

Many sponsors currently submit ICSRs to the TGA via the EDI Gateway using the ICH E2B(R2) standard.

The ICH E2B(R3) standard for transmitting ICSRs allows sponsors to submit more granular data compared to ICH(R2) including providing attachments. Comparable overseas regulators, such as the US Food and Drug Administration (US FDA), European Medicines Agency (EMA), and Japan's Ministry of Health, Labour and Welfare (MHLW) have all moved to adopt E2B(R3) as their standard submission format.

Although the TGA’s AEMS data model is based on the R3 standard and the R3 standard is used for uploading ICSRs to the World Health Organization, only an E2B(R2) input channel for sponsors, has been implemented to date. The TGA proposes to create the ability for sponsors to opt-in and gradually transition to use the updated E2B(R3) standard for submitting ICSRs.

### **Questions**

1. Do you currently submit ICSRs to overseas regulators using the ICH E2B(R3) standard? Yes/No
2. Do you support the TGA creating a voluntary input channel using the ICH E2B(R3) standard for submitting ICSRs via the EDI Gateway? Yes/No

Why/why not?

1. What timeframes would your organisation need to transition to submitting ICSRs using the updated ICH E2B(R3) standard via the EDI Gateway e.g. 6 months-1 year, 1-2 years, 3-4 years, other?

If other, please specify.

1. What structured medicine terminology set/s do you currently use for coding product information in your internal system e.g. bespoke, extended EudraVigilance medicinal product dictionary (XEVMPD), WHO drug dictionary, etc?

If other, please provide further details.

1. What structured medicine terminology set/s can you use for coding product information in ICSRs submitted in the E2B R3 format e.g. bespoke, extended EudraVigilance medicinal product dictionary (XEVMPD), WHO drug dictionary, ISO IDMP standards?

If other, please provide further details.

## Respondent details

Name

Email address

Name of organisation

Type of organisation (Sponsor, Agent, Manufacturer, Other). If other, please specify.

Would you like to be contacted about the outcomes of this survey? Yes/No

Would you like to be involved in user acceptance testing of the proposed IT changes? Yes/No

### Privacy information

All responses will be published on the TGA website, unless specifically requested to be kept confidential. How much of your feedback would you like us to publish?

* Publish everything I have submitted, including the name of my organisation but **excluding** my contact details.
* Publish everything I have submitted, **excluding** the name of my organisation and my contact details.
* Publish everything I have submitted, **excluding** my answers to the following questions.
* Do not publish any of my feedback.

The TGA collects your personal information in this survey to:

* contact you if we need to clarify issues raised in your feedback or to check whether you are happy for the information that you provided to be made publicly available.
* help provide context about your feedback (e.g. to determine whether you are a consumer or a director of a company or representing an interest group).
* seek your feedback about how the survey was run.

Please do not include personal information about other people in your feedback. Personal information here means information or an opinion about another person whose identity can be easily guessed based on the information provided.

Version history

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| Version | Description of change | Author | Effective date |
| V1.0 | Original publication | TSIS/Pharmacovigilance Branch | January 2022 |

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| Reference/Publication # D21-3359282 |