SHPA response to TGA targeted consultation on Maintaining and improving transparency of medicine adverse event information – April 2022

1. Do you support the TGA maintaining transparency of the adverse events we receive?

Yes. Maintaining the transparency of adverse events is key in providing clinicians and consumer with choice and informed decisions around treatments.

2. Is there a need for the TGA to continue publishing Australian adverse event information in the DAEN-medicines?

Yes. It provides an Australian context to post-marketing event reports and allows clinicians to consider which medicines could have contributed to possible adverse events. The removal of this valuable resource potentially has negative implications on early recognition of emerging adverse events and ultimately on timely patient care. Whilst adverse event notification and reporting is often duplicated at state-wide levels or local hospital network levels, which sit alongside notifications to the TGA, maintaining reporting channels to the Australian regulator is of utmost importance, and SHPA recommends more work can be done by all stakeholders to harmonise adverse event reporting to minimise administrative inefficiencies in the next iteration from 1 October 2022.

3. Do you support the TGA initially remaking the Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012 without any change, noting that further changes are being explored and we will consult publicly on any proposed changes to the amount of information displayed in the DAEN-medicines?

Yes, provided there is no change to its open access for consumers, health professionals and the medicines industry.

4. Why do you support or not support the proposed approach? Include any other related comments.

Hospital pharmacists utilise the Database of Adverse Event Notifications (DAEN)-medicines resource when receiving queries from medical, nursing and pharmacy colleagues posed regarding 'unknown' or very rare adverse events to examine any post-marketing data reported to the TGA that is relevant to their queries.

Whilst hospital pharmacists do utilise worldwide resources such as WHO Vigiaccess, if the DAEN-medicines access ceased, it would not give clinicians access to adverse events occurring in an Australian context. Hospital pharmacists are often asked by clinicians if a particular Adverse Drug Reaction (ADR) has already been reported in Australia and they will check DAEN-medicines for this purpose. If there are reports, it may give more weight to the ADR occurring in their individual patient. If not, it can also encourage users to report their ADR.

Despite TGA expressing that there were increased number of ADR reports in 2021, ADR reporting overall is significantly decreasing[1] [2], therefore continuing the DAEN-medicines database and encouraging the reporting of ADRs is vital.

5. Do you have any comment about the proposal to display additional case data associated with existing approved medicines in the DAEN-medicines (serious/not serious classification and categories, management of event and reporter type)?

The Society of Hospital Pharmacists of Australia
PO Box 1774 Collingwood Victoria 3066 Australia
(03) 9486 0177 | shpa.org.au | shpa@shpa.org.au | ABN: 54 004 553 806

Displaying a ‘seriousness’ classification would assist users to understand the search results and could be used to ascertain the risks of continued treatment for clinicians and consumer alike. Given that the current DAEN only lists the adverse event of death, including information on the management of the event such as hospitalisation or GP referral, would also give understanding to the seriousness of the adverse event and aid decision making.

Hospital pharmacists, who are responsible for medicines governance in hospitals and undertake leadership roles in medicines safety and quality use of medicines, are already very familiar with Incident Severity Ratings (ISR) systems when assessing adverse events. Such systems would be broadly applicable and relevant to enhancing the information and detail of adverse events in DAEN-medicines.

6. Do you have any comment about the proposal to display adverse event data associated with medicines prescribed through the SAS and AP schemes and clinical trials?

Given that TGA already receives reports of adverse effects relating clinical trials medicines and unapproved medicines accessed through SAS and AP schemes, including them in the database would unify ADR reporting in one place. The siloed nature of ADR reporting in Australia may be a barrier in not only the access to, but also the reporting of this information.

7. Do you have any comment about the continued protection of individuals’ privacy as a result of the TGA’s proposals to release additional data?

Privacy of the reporter must be maintained to encourage further reporting. Categories such as healthcare professional, consumer or pharmaceutical company would suffice. However, on request, further information regarding a case should be provided to healthcare professionals to assist in ascertaining if a medicine is likely to be a causative agent, while maintaining the consumers privacy.

8. Is there any other medicine adverse event data that you believe would be beneficial to display publicly in the DAEN-medicines? If so, why?

The current DAEN does not include the total number of patients who are taking the medicine, or how long they’ve taken it for, therefore data cannot be used to attribute causality. It does help determine if such rare adverse events have possibly occurred previously and are ‘more’ or ‘less’ likely to be attributed to a particular medicine.

SHPA understands it was previously possible to request a more detailed ADR report (Type 16) from the TGA, which would give clinically significant information on onset of reaction, other medicines and doses used and any treatment given, as well as a Type 19 ADR report which listed drugs reported to cause a specific reaction. This information allowed the possibility of assessing likely causality for single and clusters of similar cases, sometimes before similar case reports are published. This can assist with timely remedial actions when a similar unusual case arises locally. SHPA understands this information is no longer accessible and would be of benefit in any further changes to the DAEN-medicines. The Australian Adverse Drug Reactions (ADRAC) bulletins were also of use to hospital pharmacists to highlight emerging ADRs and pharmacovigilance trends for clinicians to be aware of, which are no longer published.

Accessing further details regarding cases has also been a barrier as this information cannot be released freely when contacting the TGA, unless you are the original reporter. This limits clinical usefulness of the data if clinicians are unable to correlate the consumers timeline with a particular ADR. Data sharing and transparency regarding adverse event notification should be a two-way process between health professionals and the regulator to enhance its relevance and usefulness.

SHPA recommends that the database also be configured so that it can be searched which medicines have been reported to cause a particular ADR i.e., not just the ADRs attributed to a particular medication. This option is available in the Food and Drug Administration Adverse Event Reporting System (FAERS).

References

[1]NPS MedicineWise. (2021). Reporting adverse drug events to the Therapeutic Goods Administration. Available at: https://www.nps.org.au/australian-prescriber/articles/reporting-adverse-drug-events-to-the-therapeutic-goods-administration

[2] Medicines and Healthcare products Regulatory Agency. (2019). Yellow Card: please help to reverse the decline in reporting of suspected adverse drug reactions. Available at: https://www.gov.uk/drug-safety-update/yellow-card-please-help-to-reverse-the-decline-in-reporting-of-suspected-adverse-drug-reactions