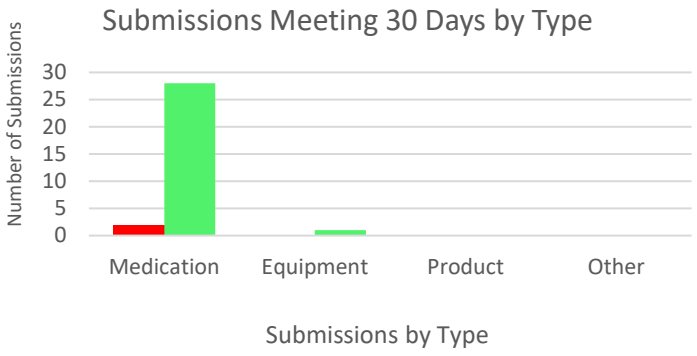
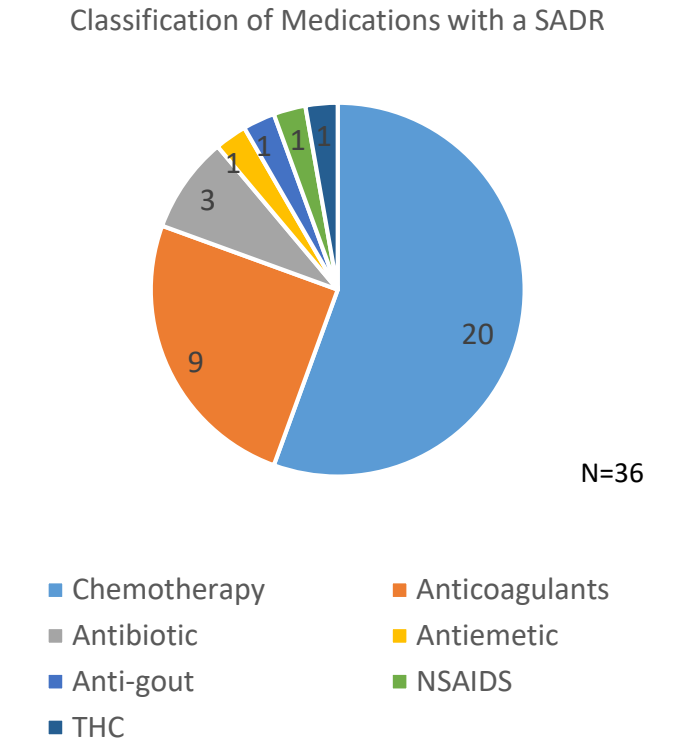
Annual Analysis 2022/23
Mandatory Reporting to Health Canada
Serious Adverse Drug Reaction (SADR)/ Medical Device Incident (MDI)





Summary

Thirty-one (31) reports were received for the fiscal year (April 1, 2022 – March 31, 2023). Of the 31 reports (30) were classified as SADRs and (1) MDI.

The following table to the left is a breakdown of submissions per category including the (30) day mandatory timeline from date of first documentation of event to date of submission to Health Canada. Of all the submissions, we are meeting the mandatory reporting requirements in a timely manner at 93%. The percentage of on-time submission ↑ from last year which = 81%.

The highest number of reports received are from the regional centers (30) with (1) under the category "Other" from a program/service voluntarily submission.

A monthly report of regional submissions for mandatory reporting of SADR and MDI are posted on the Health Care Provider Site. Click HERE to view all previous reports.

Trends and Themes

There was a significant ↑ in reporting of 31 reports compared to the previous fiscal year of 16. The COVID-19 pandemic had impacted reporting due to high volumes in workload, limited human resources etc.. Now that we are in a COVID recovery phase, reporting has doubled.

An analysis of the 30 SADR reports received included a total of 36 medications. Some reports had multiple medications contributing to a SADR. The medications are listed according to drug classification and frequency of submissions.

SADR medications by drug classification & frequency of submissions:

1) Chemotherapy agents = 20 (55%)
2) Anticoagulants/Antiplatelet/Thrombolytic = 9 (25%)
3) Anitbiotic = 3 (8 %)
4) Antiemetic = 1 (3%)
5) Anti-gout agent= 1 (3%)
6) NSAIDS (nonsteroidal anti-inflammatory drug) = 1 (3%)
7) THC=1 (3%)

The most common theme of harm was hypersensitive reactions to chemotherapy i.e.) flushing, itchy rash, back pain, chest tightness, and shortness of breath. All symptoms presented within ~10 minutes of the infusion and required further actions i.e.) stopping of the infusion, administration of IV antihistamines/corticosteroids and restarting the infusion at a lower rate. There were 7 patients with GI Bleeds, 3 patients with severe diarrhea (one + for C.difficile) and 2 deaths.

MDI:

1) Equipment (ceiling lift used with an incompatible sling resulting in a fall with minor harm)

The MDI event resulted in action being taken i.e.) Family purchasing a compatible sling

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