PMAC Working Group on Voluntary Adverse Effects Reporting

Presentation to the

Pest Management Advisory Council

8 November 2005

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Terms of Reference

Creation: agreed at the June 2003 PMAC meeting;

Purpose: to develop advice on the establishment of a voluntary pesticide adverse effects reporting system;

Mandate: to provide advice to PMAC on the voluntary reporting of adverse effects through the establishment of strong linkages between the PMRA, the medical community including public health organizations and poison control centres;

Membership: Membership consists of interested members of PMAC or their alternate and one designate from the PMRA.

Background

Members:

- Dr. Benoit Bailey, Canadian Pediatric Society
- Kathleen Cooper, Canadian Environmental Law Association
- Derek Daws, B.C. Drug and Poison Information Centre
- Todd Denofreo, CropLife
- Dr. Eric Young, B.C. Deputy Provincial Health Officer
- Jean-Pierre Lachaîne, PMRA (Chair)

Meetings:

- 13 July, 2004 (1 hour teleconference)
- 3 November, 2004 (all day, face to face)
- 4 February, 2005 (1 hour teleconference)
- 7 June, 2005 (1/2 day, face to face)
- 7 November, 2005 (1/2 day, face to face)

Purpose of meetings:

- to develop recommendations on the scope of voluntary AERP

Who Will Report?

The public;

Health professionals and physicians;

Public health & environmental associations/organizations:

- Association of Poison Control Centres;
- Canadian Public Health Association (including local public health units which could receive AERs);
- Occupational Health and Safety Organizations;
- Canadian Centre for Occupational Health and Safety;
- Workman's Compensation Programs;
- NGOs;
- Canadian Child Care Federation;
- Provincial governments for water residues and food residues;
- Others, especially related to animal health & environment.

Organisations may report AEs they receive to the PMRA or inform people on how to report directly to the PMRA or to the registrants.

What to Report?

Members recommend:

- developing voluntary reporting forms based on the mandatory forms, by reducing data items and making them simple to use and more suitable for the public;
- reducing voluntary forms to only what is necessary to evaluate causality;
- to identify duplication, asking on the form if the AE has already been reported to the manufacturer;
- asking if the label directions were followed. If negative, ask why: was it because the label was not clear, not readable, etc.?

How to Report?

To reduce data entry, the WG feels that electronic reporting should be strongly encouraged (and promoted) by providing e-forms on the web which allow direct entry in database fields;

Using the PMRA call-line would be the second preferred option – the PMRA call-line staff will fill in the forms on-line;

As e-forms are not accessible to all public, other means such as fax and mail should be accepted but could cause time delays and incomplete data collection;

To avoid incomplete data, the PMRA should acknowledge receipt of the report and inform the reporter that insufficient data was provided and include a copy of the reporting forms to fill in.

When to Report?

Encourage people to report AEs as soon it happens (instead of “as soon as possible”) and explain that the sooner it is reported, the sooner the AE will be disclosed and evaluated.

Receiving Reports

The WG feels that the PMRA should acknowledge reports – failing to do so will result in a lot of questions from reporters through calls or e-mails;

If necessary, the PMRA could request more information on the AE and send reporting forms to fill in;

Questions: In the case of serious AEs being reported, should registrants be contacted before publication on register, to allow them to investigate? Check with drugs to see what they are doing.

Evaluation of Reports

The members recommend that voluntary reports be evaluated the same way as mandatory reports;

In order to aggregate voluntary and mandatory AE data, we must make sure that similar data fields are collected, therefore, the forms must be similar.

Disclosure of Reports

The WG recommends that the process for posting voluntary AERs would be the same as the mandatory process, i.e. posting all AERs as soon as possible, then posting conclusions when available;

Flag voluntary and mandatory reports;

Question: Should registrants be allowed to provide additional information or respond to a voluntary report?

Privacy Issues

Members recommend to extend the PIA for mandatory AER to cover the voluntary program;

It should be made known to health professionals, physicians or public health associations/organizations who receive AE information, that avoiding collecting PI on data subjects means that they do not have to obtain consent from them.

Resources

The members discussed the possibility of cost recovery:

It was felt that cost recovery would not be feasible as most of the information will be on the Registry and ATI could be used if more information is required;

It was also thought to be a deterrent for NGOs as they often do not have the money.

Communications/Promotion

Members recommend:

- creating a voluntary AER page on PMRA's website and establishing hyperlinks with all partners;
- publishing a pamphlet that contains:
  - PMRA website address and 1-800 #, not mailing address;
  - a screen shot of the forms;
  - the statement 'or report to registrant who must report to us;
  - instructions on how to access AERs on web site;
  - a list of key information that will be required, e.g. product name, symptoms, etc.
- pamphlets and other promotion material (e.g. magnets, etc.) should be placed:
  - where domestic and commercial products are sold;
  - in public health units and community centres.

Alternatives

The two following alternatives were examined:

- Use data collected by other organisations?

  Members feel that the PMRA should look into accessing data from poison control centres. They strongly recommend that PCCs should have a central database similar to the US. Re-instigating Prod-Tox should be promoted in Health Canada for funding.

- Contracting out?

  Members feel that it would be difficult to contract out evaluation of the AERs, since the PMRA will use extensive in-house information when evaluating the reports which is not available to others. The expertise may also be difficult to find.

Implementation

Members recommend that the voluntary AER program should be implemented as soon as possible.

What is the advice of Council on the proposed Voluntary Adverse Effects Reporting System and the work of the WG?