An overview of spontaneous reporting of adverse drug reactions (ARDs) in Zimbabwe

The deaths of over 100 people in 1937 in the USA from the ingestion of antifreeze used as a solvent for sulfanilamide and the foetal malformations of thalidomide in Europe in the 1960s resulted in the development of drug regulatory agencies as we know them today.[1] These authorities licence medicines for the market using the criteria of safety, efficacy and quality. However, clinical trials are inefficient at determining safety since they involve relatively few, selected patients in controlled prescribing environments.

It is necessary to monitor marketed medicines for safety under normal prescribing. This is post marketing surveillance or pharmacovigilance. Various systems are available ranging from compulsory reporting of adverse drug reactions (ADRs) through intensive hospital monitoring to spontaneous voluntary reporting.[2] The latter is more common since it is inexpensive and easy to implement whilst being useful in identifying uncommon ADRs. This letter provides an overview of the voluntary reporting scheme in Zimbabwe and the reports received up to the end of 1998.

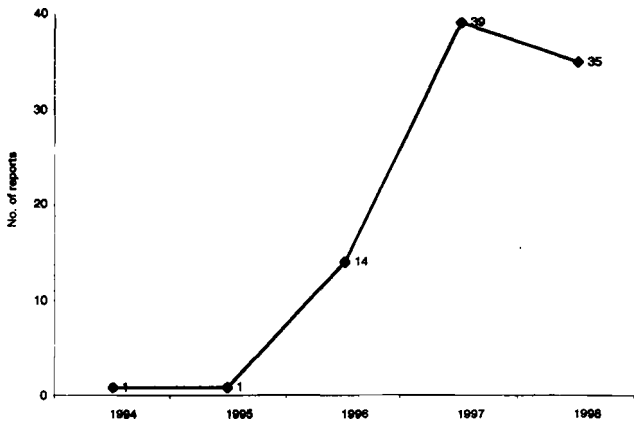
Reporting ADRs in Zimbabwe.

Prior to 1994, reports of ADRs were collected *ad hoc* by the Medicines Control Authority of Zimbabwe (MCAZ; then the Drugs Control Council of Zimbabwe) and the Drug and Toxicology Information Service, University of Zimbabwe. In 1994 this was formalised with doctors, nurses and pharmacists encouraged to report any suspected adverse drug reaction to any medicine (Table 1) to the MCAZ with report forms incorporated into EDLIZ.[3] The MCAZ collaborates with the World Health Organisation (WHO) drug safety monitoring centre in Uppsala, Sweden. The Uppsala centre receives reports from around the world and enters them into a "super-database". This information is used for signal generation - identifying warning signs of a drug safety problem. ADR reporting in Zimbabwe has been slow, but has improved following increased awareness, research [4] and educational interventions (Figure I). The reports are assessed for causality according to WHO criteria before being forwarded to Uppsala.

Table I: Types of ADRs to be reported to the Medicines Control Authority of Zimbabwe.

- All suspected reactions to any prescription or over the counter (OTC) medicine.
- All reactions to vaccines.
- All suspected reactions to traditional or herbal remedies.
- Cases of suspected therapeutic failure.

Figure I: Total number of ADR reports received by the MCAZ since 1994.



Summary of Reports.

A total of 95 reports have been received (five pre-1994). Of these, 67.0% have involved female patients and the majority (86.3%) have involved adults, with 62.1% of patients taking more than one drug. Nine (9.5%) reports involved drugs registered in the three years prior to the report date ("new" drugs). Doctors (50.0%) and pharmacists (40.0%) have submitted most of the reports with the remainder from nurses and pharmacy technicians. In 1997 and 1998, two thirds of reports originated from Harare.

Whilst there are insufficient reports in the MCAZ database for signal generation, drugs with more than three reports submitted include: co-trimoxazole (six reports; five involving skin reactions), isoniazid (six; five skin reactions), and pefloxacin (four; two tendonopathy). The numbers are not meaningful at this stage, but this allows one to see how the process of signal generation proceeds, taking into account the market life of the drug, recent promotions or public interest and the like.

Conclusion.

Reporting of ADRs in Zimbabwe is still in its infancy. There is a need to encourage health practitioners to report as part of their clinical duties and to examine other means of increasing reporting as well as raising general awareness of the aims of pharmacovigilance.

References

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