



A comparison of publicly available spontaneous adverse drug reaction data from national spontaneous reporting schemes

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Introduction

We wished to see what data on spontaneous adverse drug reactions (ADR) were available on the websites of regulatory bodies.

Methods

We reviewed the English sections of websites of regulatory bodies who are members of the WHO international drug monitoring programme. Where the site was available in English, assessment was made in the English section of the site. Only information that was readily available for download on the website was assessed.

Results

A total of 55 websites were reviewed, of which 41 (75%) had some or all information available in English. Of these, 15 provided a drug safety bulletin that contained some information on drug safety issues arising from spontaneous ADR reports. For example, the Australian Adverse Drug Reaction bulletin published "*Sibutramine - four years experience*".

Four sites gave direct access to aggregated information from spontaneous ADR reports of specific reactions to specific drugs, although the format and presentation of data differed. Of these sites, three also provided direct access to individual anonymized case reports of suspected ADRs.

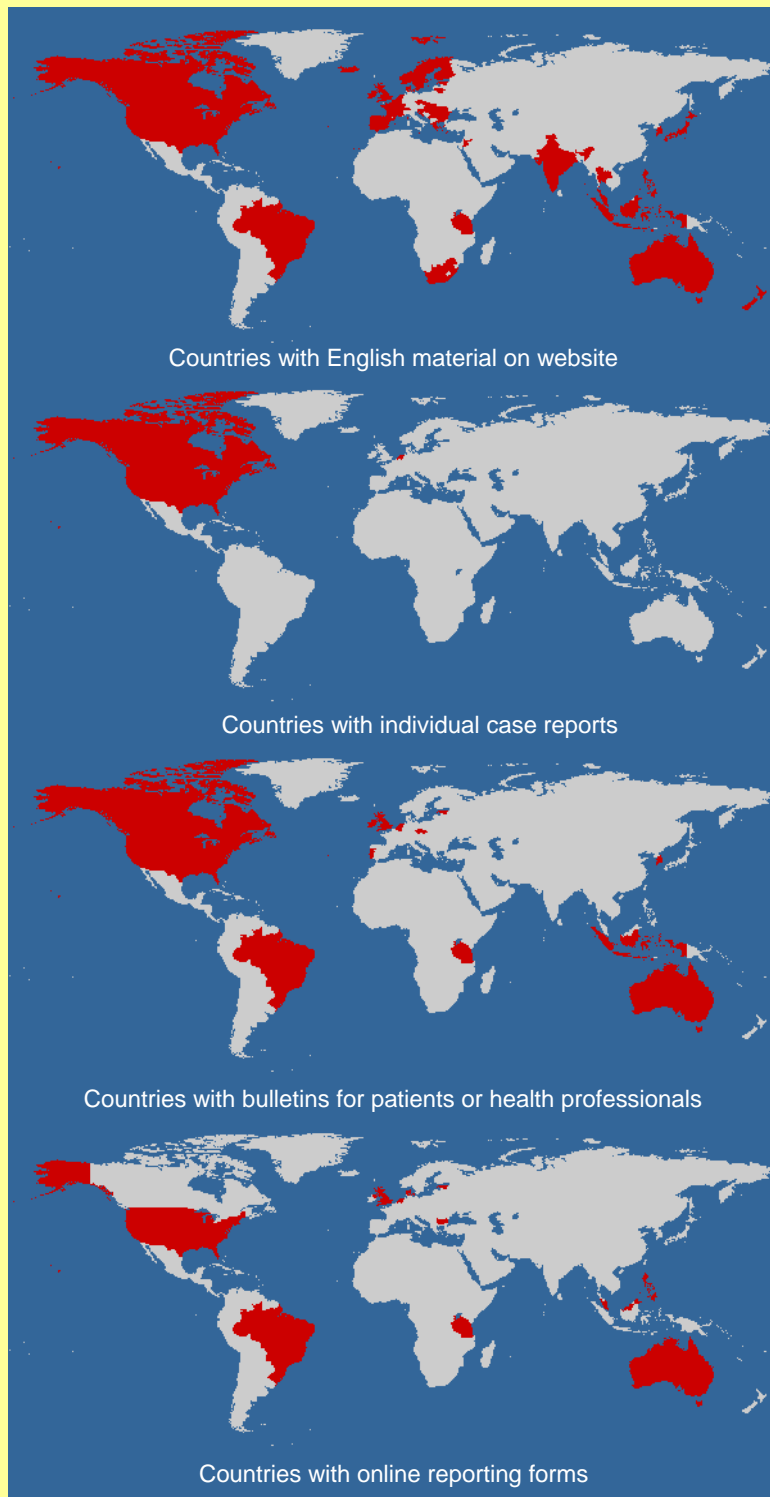
Twelve websites provided an online form for ADR reporting, with a further eleven supplying a printable version.

Discussion

Many regulatory agencies' websites make information available in English. Only a small minority of websites provide aggregated information from spontaneous ADR reports. As well as providing useful information for professionals wishing to analyse spontaneous ADR reports, such open provision of data may encourage further ADR reporting by reinforcing the benefits of the data to the public and healthcare professionals.

There have been changes in access policies of regulators in recent years because of legislation. For example, the Canadian database has been made available online after the Canadian Broadcasting Corporation challenged its non-availability under freedom of information legislation. The United Kingdom's Medicine and Healthcare products Regulatory Agency (MHRA) has also opened up access to aggregated data online, following an independent review of the Yellow Card scheme. More detailed data, such as anonymized case reports, requires specific requests under the Freedom of Information Act 2000. The MHRA will not release information for reactions with five or fewer cases due to confidentiality concerns.

Three agencies allow access to anonymized case reports, in different formats. Both the Canadian and Netherlands case reports are easy to access, in comparison with the FDA's data which are provided in large flat file databases which require expertise to interrogate. While the higher level of detail provided by the FDA's reports may allow causality assessments to be made, there is a debate about the balance between simplicity and utility of these differing formats. It is arguable that international standards, or best practice guidelines, for the presentation of spontaneous reporting data online may improve both the availability of, and usefulness of, data to healthcare professionals.



Limitations

Our strategy of only assessing information supplied in English, may have discounted information made available to a nation's indigenous healthcare professionals.

Conclusions

Countries vary widely in the amount of information on adverse drug reactions they make publicly available. Regulatory bodies should be encouraged to provide as much information as possible within legal constraints.