

## 1. A Comparison of Publically Available Spontaneous Adverse Drug Reaction Data from National Spontaneous Reporting Schemes

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

**Method:** We reviewed the English sections of websites of those 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 out of spontaneous ADR reports. For example, the Australian Adverse Drug Reaction Bulletin published "Sibutramine - four years experience".<sup>[1]</sup> 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.

**Discussion:** Many regulatory agencies websites make information available in English. A small minority of websites provide aggregated information from spontaneous ADR reports, of whom three agencies allow access to anonymized case reports. There have been changes 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 the freedom of information legislation.<sup>[2]</sup> Provision of data may encourage reporting as it is a form of feedback to reporters and makes reporters aware of the use to which the data is put. It is also useful information for professionals wishing to analyse spontaneous ADR reports. This study was restricted to websites which are available in English and may underestimate the availability of ADR data.

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

### References

1. Australian Adverse Drug Reactions Bulletin. 2006; 25; 3
2. [http://www.cbc.ca/story/canada/national/2005/05/25/adverse-\[ol\]drug05052-5.html](http://www.cbc.ca/story/canada/national/2005/05/25/adverse-[ol]drug05052-5.html)