



Project Title: Medicines subject to regulatory safety warnings in Australia, Canada the UK and US: a content analysis		Code: SPS16
Host School / Institute: Sydney Pharmacy School/ Charles Perkins Centre		Address: Charles Perkins Centre
Certificates & Clearances required: No		
Primary Supervisor: A/Prof Barbara Mintzes		
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Co-Supervisor/team: Team includes Ms Alice Bhasale, PhD candidate		
Project Type: Data Analysis		
Project Category: Pharmacology; Pharmacy		
Skills / Attributes of a successful student: This study is highly relevant to students with an interest in medicines information services, pharmacy practice, medication safety, regulatory science, and policy-oriented research. The student is expected to develop skills in systematic data extraction and coding, data synthesis into tables and descriptive analysis. Some experience working with Excel is needed.		
Project Keywords: safety advisories; medication safety; medicine use		
<p>Project Description:</p> <p>When a medicine is first approved for marketing, knowledge of rare, serious harmful effects is limited, as generally too few people have been exposed in pre-market trials, often for short time periods, and at-risk populations have been excluded, such as the elderly or people with co-morbidities. Drug regulatory agencies often issue safety advisories for medicines that are already on the market. These advisories inform clinicians and the public about new evidence of harm and provide advice to guide safer medicine use.</p> <p>This summer scholarship project makes use of a database of post-market regulatory safety advisories in Australia, Canada, the United Kingdom (UK) and the United States (US) that our team has developed under an NHMRC-funded research project. (1) The aim of the project is to identify and classify differences in regulatory post-market safety communications between these four countries. The student will carry out additional analysis on the content of these advisories (e.g. types of adverse events described, how is the harm described, advice provided to health professionals and to the public).</p> <p>The student's research is expected to contribute to an article for publication that they would help co-author, as well as the required report and presentation. They will work closely within a team carrying out research on safety advisories, including the primary supervisor and two PhD students.</p> <p>Reference:</p> <ol style="list-style-type: none"> 1. Perry LT, Bhasale A, Fabbri A, Lexchin J, Puil L, Joarder M, Mintzes B. A Comparative Descriptive Analysis of Medicines Safety Advisories released by Australia, Canada, the United States and the United Kingdom. JAMA Intern Med 2019; doi:10.1001/jamainternmed.2019.0294 		