

**Table 5: Examples of problems in postmarketing surveillance of drugs**

Problem	Examples
Failure to perform required postmarketing studies	Among drugs approved in 2008, only a minority of required postmarketing studies had been completed within approximately 5 years, and only 9% of the required studies had been submitted to the FDA. <sup>37</sup>
	Only 15.2% of studies required by the FDA between 2007 and 2011 were started by 2011; none had yet been fully fulfilled. <sup>38</sup>
	Ten drugs approved in Canada under its "Notice of Compliance with conditions" pathway have remained on the market for more than 6 years without the completion of required postmarketing studies; of these, 6 have been on the market for more than 10 years (Joel Lexchin, unpublished data).
Post-approval safety problems	Cox-II inhibitors had serious safety issues that both the industry and the FDA delayed addressing. <sup>39</sup>