# Pharmaceutical industry self-regulation of off-label drug promotion in the UK

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The UK's self-regulatory approach to preventing pharmaceutical companies from promoting off-label use of their drugs detects mainly high-visibility promotional activity such as print advertising, according to a document analysis of off-label promotion rulings published this week in *PLOS Medicine* by Shai Mulinari and colleagues at Lund University, Sweden, and King's College London, UK. The study indicates that the UK self-regulatory approach is less capable of uncovering complex marketing campaigns than the government-led approach in the US.

In the US, the Food and Drug Administration (FDA) regulates and prosecutes off-label promotion, but legal actions against companies can also be brought by federal and state prosecutors, often following whistleblower (company insider) complaints facilitated by the False Claims Act. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) has delegated this responsibility to a self-regulatory body set up by the pharmaceutical industry—the Prescription Medicines Code of Practice Authority (PMCPA). In this review of 74 off-label promotion rulings made by the PMCPA between 2003 and 2012, Mulinari and colleagues compare off-label promotion cases from the UK with whistleblower-initiated cases from the US.

They find that while several US whistleblower-initiated cases alleged multifaceted and covert marketing campaigns, UK rulings described a more restricted range of promotional activities and typically referred to a single advertisement. The UK rulings cited efforts to expand drug use to unapproved indications (50%), diseases (39%) and dosing strategies (38%); competing companies lodged the majority (57%) of complaints whereas prescribers (the prime target of off-label promotion) lodged only 22% of the complaints. Almost half of the 43 violating companies were found to have promoted products off-label more than once in the UK, and about one-fourth were ruled in breach three or more times.

The study describes PMCPA rulings and whistleblower-initiated US cases, and therefore provides an incomplete view of off-label marketing in the UK and US. However, the results suggest that the UK's self-regulatory mechanism for detecting, deterring, and sanctioning off-label promotion may be inadequate. The authors state, "UK authorities should consider introducing increased incentives and protections for whistleblowers combined with US-style governmental investigations and meaningful sanctions. UK prescribers should be attentive to, and increasingly report, off-label promotion."

**More information:** Vilhelmsson A, Davis C, Mulinari S (2016) Pharmaceutical Industry Off-label Promotion and Self-regulation: A Document Analysis of Off-label Promotion Rulings by the United Kingdom Prescription Medicines Code of Practice Authority 2003-2012. *PLoS Med* 13(1): e1001945. DOI: 10.1371/journal.pmed.1001945

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