

Self-regulation of pharma industry marketing is unsustainable and failing patients, according to new analysis

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Health care professionals and organizations need to respond more forcefully to unethical marketing from the pharmaceutical industry by



holding offending companies to greater account and by supporting stronger regulation, according to the authors of a new <u>British Medical</u> <u>Journal (BMJ) study</u>.

Research by Dr. Piotr Ozieranski of the University of Bath, and Dr. Shai Mulinari of Lund University in Sweden, suggests that much more could be done to tighten rules about how medicines are marketed by their manufacturers. Such efforts would enhance patient health and safety, ensure value-for-money for the taxpayer, and increase trust in health care systems more broadly, they say.

In most European countries as well as Japan, Canada and Australia, the regulation of marketing practices relies heavily on industry self-regulation in which industry trade groups are trusted to set and police the rules of appropriate industry conduct. Among these, the Code of Practice of the Association of British Pharmaceutical Industry (ABPI) is one of the best-known industry rule books.

The *BMJ* review argues that leaving self-regulation in the industry's hands is not sustainable. The research cites the recent example of the Danish drug company Novo Nordisk, which in March 2023 was suspended from the ABPI for serious breaches of its Code of Practice following a widely publicized scandal involving the unethical marketing of its anti-obesity drug Saxenda.

The <u>complaint that led to its suspension</u> argued that Novo Nordisk had sponsored courses for <u>health professionals</u> on using the company's drug for weight management without making clear the company's involvement. The *BMJ* review highlights how the company "orchestrated a large-scale Saxenda promotional campaign... downplaying [the drug's] side effects."

"Novo Nordisk was suspended from the ABPI for two years and lost



certain membership benefits, including information on and input into industry-wide policy developments and access to working groups and experts' networks. However, the company is still bound by self-regulation and can sell its products in the UK," Dr. Ozieranski from Bath's Centre for the Analysis of Social Policy (CASP) explained.

Novo Nordisk's suspension followed the <u>case of the Japanese company</u> <u>Astellas</u>, suspended from ABPI for one year in 2016. In this case, the company was suspended for, among other things, promoting its prostate cancer drug Xtandi for use in a larger group of patients than had been approved at the time by the drug regulator, which could have seriously endangered patient safety.

Dr. Mulinari from Lund University says, "We have been studying the influence of major drugs companies on health care systems around the world for over a decade. Both cases highlight the pressing need for health care professionals to distance themselves from offending companies and demand much stronger and tougher regulation."

"What both the Novo Nordisk and Astellas cases have in common is the tacit acceptance of a vast majority of health care professionals and organizations exposed to the companies' unethical marketing."

Dr. Ozieranski added, "International research suggests that responses by health care professionals and organizations to industry misbehavior vary. Some have acted proactively, opting to avoid industry funding and sponsorship, while others maintain ties."

"We argue that NHS organizations, universities and medical professionals' organizations need to exercise much greater caution when collaborating with companies; at the very least reviewing and revising ties with companies which have been in breach of the ABPI Code. To enhance trust and transparency, the rationale for actions taken in relation



to offending companies should be available to the public."

"In addition, health care professionals and organizations should harness their economic and professional power to better hold their corporate collaborators accountable for unethical behavior. For example, the Royal Colleges of Physicians and General Practitioners have now ended their partnerships with Novo Nordisk, returning any outstanding grants and pausing any associated projects."

"Such decisive reactions to company misconduct serve as an important precedent in challenging unethical behavior, particularly in a self-regulatory system that rely on appealing to companies' reputations."

The researchers say new training programs need to be developed focusing on health care professionals' ability to recognize and react to questionable marketing. They also call for stronger sector-wide policies on industry collaborations, such as those via NHS England and the Charity Commission.

Dr. Mulinari suggests Sweden might serve as an illustration of the impact of stricter rules on industry. In 2014, Sweden's industry trade group proactively banned drug companies from paying doctors' travel and accommodation and participation at medical conferences—a practice that is still allowed in the UK.

"Replacing self-regulation with a new state-regulatory system is currently difficult to imagine. However, even within the existing system, policymakers could adopt a more probing and punitive strategy to tackling corporate wrongdoing, including investigating whether known misconduct indicates more extensive problems, and extending support for whistleblowing," Dr. Mulinari says.

"We urge health care professionals and those in charge of the NHS,



medical societies, universities and <u>research institutions</u> to help put pressure on policymakers to send a clear message that corporate wrongdoing can no longer be tolerated," he adds.

The researchers hope their analysis will feed into the upcoming UK government consultation into drug company <u>self-regulation</u>, including the transparency of their financial ties with health care professionals and organizations.

More information: Shai Mulinari et al, Unethical pharmaceutical marketing: a common problem requiring collective responsibility, *BMJ* (2023). DOI: 10.1136/bmj-2023-076173

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