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Unethical pharmaceutical marketing: a common problem requiring collective responsibility

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Shai Mulinari and **Piotr Ozieranski** argue healthcare professionals and organisations should respond more forcefully to unethical marketing and support stronger regulatory action

Key messages

- Neither existing self-regulation nor regulation by government has effectively tackled unethical pharmaceutical marketing
- The healthcare sector must assume a bigger role in responding to industry misconduct by re-evaluating, suspending, or terminating collaborations with unethical companies
- This requires strengthening professional education and organisational guidelines
- Stringent professional responses could build a critical mass for developing a more probing and punitive regulatory approach to corporate wrongdoing

The marketing practices used by pharmaceutical companies have been a longstanding concern,[1,2] with controversial techniques including the use of medical opinion leaders and third parties such as patient advocacy groups. In many jurisdictions, including Europe,[3] Japan,[4] Canada,[5] and Australia,[6] marketing by pharmaceutical companies is largely regulated by the industry itself, based on codes of practice drawn up by national industry trade groups. The UK has one of the most advanced and extensively studied self-regulatory systems in Europe[7,8,9,10] and globally (**box 1**).[3,4]

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Box 1

UK's pharmaceutical industry self-regulation

Oversight of prescription drug marketing in the UK is delegated by the medicines and medical device regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), to the industry trade group, the Association of the British Pharmaceutical Industry (ABPI), and its self-regulatory body, the Prescription Medicines Code of Practice Authority (PMCPA).[7] The PMCPA's jurisdiction is accepted by virtually all drug companies operating in the UK, including about 70 ABPI members and over 60 non-members that follow the ABPI code voluntarily.[11]

PMCPA sanctions

Companies found to be in breach of the ABPI code are required to pay "administrative charges" to contribute to the costs of processing complaints.[11] These charges, which are explicitly defined as not being fines, are typically £3500 but increase to £12 000 if an appeal against a ruling is unsuccessful.

In cases of more serious wrongdoing, the PMCPA can publicly reprimand a company or require it to issue a corrective statement. For both sanctions the company pays the cost of advertising these in medical (*The BMJ*), pharmaceutical (*Pharmaceutical Journal*), and nursing (*Nursing Standard*) publications.

The PMCPA can also request compulsory audit of a company, which costs £15 000 to £20 000 depending on complexity. In the most severe instances, the PMCPA can report a company to the ABPI board, which may consider suspension or expulsion of the company from membership. For companies that are not members, the ABPI can inform the MHRA that the company is no longer participating in self-regulation, meaning the MHRA is responsible for investigating any complaints.

What ABPI suspension means

A suspended company is still bound by self-regulation and can market and sell its products but temporarily loses membership benefits.[12] These include:

- Access to information on, and input into, industry-wide policy developments and cross industry initiatives
- Access to education and networking events, including meeting politicians, advisers, stakeholders, and patient organisations from across the UK
- Access to working groups and expert networks to keep up with developments, including senior level forums

However, self-regulation often falls short of ensuring appropriate corporate conduct. This is shown by the recent two year suspension of Novo Nordisk from the Association of the British Pharmaceutical Industry (ABPI)[13]—the harshest penalty ever levied by the ABPI—— following a widely publicised scandal around marketing of the anti-obesity drug liraglutide (Saxenda).[14] Novo Nordisk was found to have orchestrated a "large-scale Saxenda promotional campaign which [it] knowingly paid for and which was disguised." This included "heavily biased"

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training of healthcare professionals that downplayed the drug's side effects, potentially endangering patient safety.[13]

Healthcare professionals and organisations, including the NHS, professional bodies, and research institutions, now need to strengthen their responses to unethical marketing and hold offending companies accountable for unethical behaviour. Such actions can also build support for regulatory strategies and reforms tackling marketing that violates industry codes and other regulatory requirements.

Regulatory failures

The gradual expansion of self-regulation globally over the preceding decades has led policy makers and drug regulatory bodies to delegate responsibilities for defining, monitoring, and enforcing standards of conduct to industry itself.[7] Proponents of this approach argue that self-regulation improves corporate behaviour through education and persuasion,[3] and by appealing to the ethical and social values of a company and its managers.[15] Others, however, highlight insufficiently comprehensive standards,[5,9] coupled with divergent interpretations by companies[16] and weak enforcement.[17,18]

In the UK, the frequency of code breaches ruled by the Prescription Medicines Code of Practice Authority (PMCPA), the ABPI's self-regulatory body is a growing concern.[7] Between 2004 and 2020, 1057 cases were ruled in breach of the ABPI code according to PMCPA annual reports,[11] averaging more than one breach a week. Of these, the PMCPA considered 208 (nearly 20%) particularly concerning, with 55 such cases reported in 2019 and 2020 alone. These "particularly concerning" breaches of the ABPI code may involve marketing practices posing health risks, violating key terms of a medicine's marketing authorisation, or undermining self-regulation itself, including misleading the PMCPA or disregarding its rulings.[7] The reported breaches represent the minimum extent of unethical marketing behaviour, chiefly because the PMCPA relies on well informed insiders, competitors, and healthcare professionals and organisations to formulate a complaint.[8]

When responding to the code breaches, the PMCPA's main sanction is naming and shaming offending companies (**box 1**). This includes publishing case reports on its website and brief summaries of particularly concerning cases in professional publications.[7] In the most severe instances, the ABPI board can suspended company membership after additional investigation. In the past 20 years, the ABPI has suspended MSD and Abbott (now AbbVie) in 2006,[19,20] Roche in 2008,[21] Astellas in 2016,[12] and, most recently, Novo Nordisk in 2023.[13]

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Importantly, failures to deter corporate misconduct are not limited to self-regulation. Concerns regarding unethical pharmaceutical marketing also extend to government-led regulatory systems, such as in the US.[22,23,24] The US approach might be more effective at identifying and punishing misconduct than self-regulation, but has not eliminated the problem.[8,9] For instance, between 2003 and 2016, 22 out of 26 of the largest drug companies faced substantial financial penalties from US federal and state governments amounting to $33bn (£26bn; €30bn) for involvement in illegal activities, including kickbacks and bribes, engaging in misleading or deceptive marketing practices, and off-label marketing.[24]

Problematic corporate marketing

The ongoing difficulties in regulating drug marketing across jurisdictions can be attributed to several factors, such as lax regulatory oversight and insufficient sanctions.[5,9,16,17,18] However, the cases of Astellas and Novo Nordisk, the two most recent companies suspended from the ABPI, serve as a stark reminder of the underlying issue: that corporations prioritise commercial goals above compliance responsibilities and ethical standards.[13,25]

In June 2016, the Japanese company Astellas was suspended from the ABPI for one year because of how it promoted its prostate cancer drug enzalutamide (Xtandi).[12] The PMCPA investigations found that Astellas had convened spurious advisory board meetings with hundreds of participants to promote the drug off-label and evaluate the likely success of promotional claims; and that senior Astellas managers had repeatedly and deliberately lied to the PMCPA to cover up these facts.[9,12]

The PMCPA reprimand noted that the totality of the evidence considered revealed "multiple organisational and cultural failings"[25] and characterised a corporate culture where "business concerns prevailed over compliance concerns,"[25] while the ABPI accused company senior staff of "deception on a grand scale which was appalling and shocking" during the investigations.[25]

As with Astellas, the PMCPA investigation into Novo Nordisk's marketing of Saxenda revealed serious institutional failings, including a "wide-ranging lack of understanding of the requirements of the [ABPI] code and an obfuscation of responsibilities."[13] Similarly, the ABPI expressed concerns "about the company's compliance culture, Novo Nordisk's internal governance systems and processes, and a perceived naivety and lack of accountability from Novo Nordisk."[13] During the investigation, Novo Nordisk claimed that its actions were neither unusual nor inappropriate, calling the complaint "grossly defamatory against it and actionable" as it "included a totally unfounded allegation that Novo Nordisk had bribed health

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professionals."[13] However, the PMCPA ruled that the "heavily biased" healthcare worker training and the funding of a patient group direction to prescribe Saxenda for attendees who wished to offer Saxenda as part of their weight management service were an inducement to supply and recommend Saxenda, a decision which Novo Nordisk accepted.[14]

Acquiescence of healthcare professionals and organisations

The Astellas and Novo Nordisk cases not only highlight how self-regulation failed to ensure corporate compliance and ethical marketing behaviour but also point to the professionals and professional organisations that seem to tolerate it.

Worryingly, most health professionals participating in or targeted by the two companies' unethical marketing either seemed unaware that it was unethical or recognised it but did not report it. For example, thousands accepted free, biased training from Novo Nordisk, and at least 599 healthcare professionals accepted funding that was effectively an inducement to recommend and use Saxenda.[13] Yet, apparently no one complained to the authorities. Similarly, Astellas promoted off-label prescribing to hundreds of professionals and used them to evaluate the likely success of promotional claims, yet only one person complained.[9]

Strengthening professional and organisational responses

International research suggests that responses by healthcare professionals and organisations to industry misbehaviour vary. Some have opted to avoid industry funding and sponsored education altogether[30,31]; many others, however, maintain extensive industry ties.[4,29] Those that have kept ties with pharmaceutical companies need to exercise caution in such collaborations given their societal and moral responsibility not to be complicit in or accept unethical marketing that can undermine patient care.[32,33] At the very least, collaborations with companies committing severe breaches of the ABPI code, indicated by advertisements in the professional press, should be revisited and reviewed as a matter of course to assess risks that they may pose to professional integrity and organisational missions. The rationale for any actions taken, including continued collaboration, should be publicly available to ensure accountability.

Healthcare professionals and organisations should also harness their economic and professional power as well as public trust to hold their collaborators accountable for unethical behaviour. The few examples, such as the two royal colleges taking a stance, may be a drop in the ocean, but they set important precedents that can pave the way for challenging unethical companies, particularly in self-regulatory systems. PMCPA says that "publicity is the main

sanction when breaches of the Code are ruled."[11]However, for publicity to translate into the reputational damage that companies would be concerned about[15,34,35] it needs to be amplified and acted on by others.

Consequently, if the ABPI identifies corporate practices as problematic enough to warrant a suspension, we suggest that all collaborations with that company should be suspended or terminated. In practice, this would mean refusing donations, grants, sponsorships, consultancies, and "collaborative working"[36] projects, which are central for companies' marketing of new products.[4] These measures should be upheld at least until the company has taken auditable and convincing remedial actions and been readmitted to the ABPI. Overall, our proposal reflects the principle of proportionality,[37] where the severity of the response is matched to the seriousness of the problem.

To deliver consistent responses across the health system, training programmes need to be developed to improve healthcare professionals' capacity to recognise and react to dubious marketing.[33,38] Separately, sector-wide policies on industry collaborations, such as the NHS England guidance on managing conflicts of interest[39] or the Charity Commission guidelines that apply to many professional organisations,[40] should incorporate instructions on appraising, suspending, and terminating partnerships with drug companies and other corporate donors.

Catalyst for change

Yet it would be unrealistic to rely solely on professional standards and organisational policies to tackle unethical marketing within the pharmaceutical sector, considering its highly financialised nature driven by the imperative of maximising shareholder value.[41] Nevertheless, the experience that health professionals and organisations gain from engaging with this issue can also lead to better regulation. Crucially, sustained collective response can reshape the debate on measures—taken by industry and others—used to target unethical marketing. In Sweden, which has a self-regulatory system similar to the UK's,[7] the industry trade group banned sponsorship of healthcare professionals' conferences, following longstanding public and professional criticism.[42,43]

In the UK, too, ample opportunity exists to bolster self-regulation. For example, the ABPI could follow the Swedish example by banning industry sponsorship of people attending conferences. Investigations into company misconduct also need to be more transparent if healthcare professionals and organisations are to review their corporate partnerships. Therefore, the audits the PMCPA demands of companies facing severe charges should be publicly

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available, even if this entails disclosing "sensitive" company data.[9] Additionally, companies publicly reprimanded by the PMCPA should inform their collaborators about the offences and any remedial action taken.

Replacing self-regulation with a state regulatory system is currently difficult to imagine politically and practically in the UK, as self-regulation has wide support among professional bodies, regulators, and industry. Nevertheless, the government should adopt a more probing and punitive strategy to tackling corporate wrongdoing, which goes beyond self-regulation.[44] One key example would be the MHRA adopting a "risk based" approach to investigate whether known instances of severe misconduct, such as the Astellas and Novo Nordisk cases, indicate more extensive misconduct by the breaching company.[9] To effectively uncover misconduct, the government should also extend legal support for whistleblowing. This would provide better insight into complex marketing practices, which may be difficult for outsiders to detect and understand.[12,23]

For cases that raise serious concern, the MHRA should also consistently implement enforcement actions—including, where necessary, prosecution—in addition to ABPI suspension, since suspension alone is unlikely to sufficiently deter companies from unethical marketing.[45] This approach would be in line with the MHRA's current remit, which "reserves [it] the right to take action if serious public health concerns are raised or if self regulation fails."[46] The infrequent use of such actions to date represents a missed opportunity to send a message that corporate wrongdoing will not be tolerated.

Contributors and sources: SM and PO have researched pharmaceutical industry marketing, transparency and self-regulation in the UK and other countries for many years. SM is the guarantor of the article.

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