[1] The BMJ

[2] Department of Sociology, Lund University, Sweden

[3] University of Bath, Bath, UK

hboytchev@bmj.com

Cite this as: *BMJ* 2024;384:q365
http://dx.doi.org/10.1136/bmj.q365

BMJ INVESTIGATION

Delays in dealing with complaints against drug companies are growing, *BMJ* finds

A major backlog has developed in handling complaints over UK drug companies' marketing practices. Hristio Boytchev, Shai Mulinari, and Piotr Ozieranski report

Hristio Boytchev, [1] Shai Mulinari, [2] Piotr Ozieranski[3]

Processing times for complaints against drug companies suspected of having breached the industry's code of practice governing the promotion of pharmaceuticals have more than tripled in nearly two decades, an investigation by *The BMJ* has found. Delays mean that any problematic practices highlighted in complaints can continue for an average of eight months—and in many cases for more than a year.

To tackle the backlog, the Association of the British Pharmaceutical Industry (ABPI) has now raised the fees charged to companies in relation to these complaints by more than 40%.

Complaints against ABPI members and non-members that have ratified the ABPI's code of practice are dealt with by the arm's length body the Prescription Medicines Code of Practice Authority (PMCPA). In the most severe cases the ABPI can suspend members. For example, the Danish drug giant Novo Nordisk is currently suspended from the ABPI until 2025 for sponsoring weight loss programmes that promoted its products.

Commenting on the delays, Susan Bewley, former chair of the charity HealthSense-UK, said, "Matters have gone adrift over the past two decades if it now takes over three times as long to process complaints. It's a privilege for an industrial sector to have 'light touch' self-regulation and … mark their own homework."

The BMJ's analysis of PMCPA data shows that the average processing time of a complaint more than tripled between 2004 and 2021, sending the time for an average complaint to be resolved from less than three months (11.8 weeks) to more than 8.5 months (38.4 weeks).

For cases that were subject to appeal, the duration more than doubled from under five months (20.4 weeks) to 10 months (43.3 weeks) in the same period. Numerous complaints have taken more than a year to resolve.

In January the ABPI increased the "administrative charges" to those companies found to be in breach of its code of practice from £3500 to £5000. Drug companies that make unsuccessful complaints about other companies' practices face the same fee. The ABPI has also increased the annual levy charged to its member companies.

In correspondence seen by *The BMJ*, an ABPI executive, writing in December 2023, said that the hike in the charges would "partly" help the PMCPA reduce long processing times. "The uplift in PMCPA income will help support the PMCPA to reach its target of considering 90% of cases within 90 days of receipt by the end of 2024," the letter said.

"No one wants cases left unresolved, least of all those companies referred to the regulator," Amit Aggarwal, executive director of medical affairs at the ABPI, told *The BMJ*. "This is why the ABPI board fully supports giving the PMCPA the resources they need to address any backlog."

"In recent years, there has been an increase in both the number and complexity of complaints, which has unfortunately caused some cases to take longer to resolve than we want," said Alex Fell, director of the PMCPA. "Addressing this is our highest priority," he added. The issues raised in the complaints were often highly complex, and many recent complaints included multiple allegations, he said. Fell invited *The BMJ*'s readers to engage with an ongoing public consultation on proposed changes to the ABPI code and constitution.[1]

Does the self-regulation system work?

Critics have questioned whether the PMCPA's remit is adequate to meet the current scale of challenges posed by unethical pharmaceutical marketing.

Since 2019 the PMCPA has adjudicated against Novo Nordisk several times for undue marketing of its weight loss drug Saxenda (liraglutide). These have not served as a deterrent, as Novo Nordisk went on to engage in serious breaches in 2021 and 2022, when it covertly orchestrated a Saxenda marketing campaign that included free training to pharmacists and funding to aid in the prescribing of the drug.[2-4]

The PMCPA needed more than a year to resolve the complaints. It characterised the company's effort as an inducement to "prescribe, supply, administer and/or recommend" the drug. The ruling resulted in Novo Nordisk's two year suspension from the ABPI. After the suspension the Royal College of General Practitioners and the Royal College of Physicians stopped collaborating with the company.

Novo Nordisk takes "any breach of the ABPI Code extremely seriously," a company spokesperson told *The BMJ*. "Since the suspension, we have continued to strengthen our compliance framework to ensure

that we are meeting the standards required by the code, and our progress is being monitored through PMCPA audits."

Even with the relatively harsh outcome of the Novo Nordisk case, Margaret McCartney, honorary senior lecturer at the University of St Andrews' School of Medicine, questioned whether the sanctions delivered under the current system improve compliance. The charges are "nothing to massive companies," and reputational damage hasn't, for example, prevented the NHS's decision to allow Novo Nordisk to fund obesity clinics, she said.[5]

Reliance on complaints

The PMCPA relies on complaints and not on proactive monitoring. Complaints can be made by anyone. In 2004 most of the complaints were made by drug companies and healthcare professionals, while in 2021 most were anonymous.

Alan Black, a retired drug industry senior doctor, said he has extensive experience with filing and defending complaints and has noticed a deterioration in processing times. He has shared his concerns with the ABPI, the PMCPA, and the Medicines and Healthcare Products Regulatory Agency (MHRA).

The MHRA has statutory responsibility to oversee the self-regulation system of the ABPI and the PMCPA and should provide "a means of enforcement should self-regulation fail," according to its "blue guide" on the advertising and promotion of medicines in the UK.[6] Yet the correspondence between Black and the MHRA reviewed by *The BMJ* shows that the MHRA has no expectations concerning the duration of the PMCPA's handling of complaints.

"It is not possible for MHRA to state a reasonable average timeframe for handling of a complaint, since individual complaints will be investigated on their own merits," a letter from an MHRA official said. In an answer to a freedom of information request, the MHRA said that it had no set of criteria under which it would consider self-regulation to have failed, as "such instances are determined on a case-by-case basis."

"The MHRA is firmly committed to supporting the role and importance of the PMCPA in upholding the highest standards in self-regulation of the pharmaceutical industry," an MHRA spokesperson told *The BMJ*. "If self-regulation fails, the MHRA will act to ensure a company is fully compliant with UK medicines law to ensure that safety is not compromised," they added, without specifying how the agency would determine this to be the case.

But Black added, "Processing times have been clearly deteriorating for the best part of a decade, yet neither the MHRA nor the ABPI appears to have been sufficiently concerned to do anything about it. The current time to deal with any complaint now appears to be over a year, a delay which risks seriously undermining public confidence in the independence and utility of the entire self-regulatory system."

Data analysis for this article was conducted by authors SM and PO.

This news story has been funded by the BMJ Investigations Unit. For details see bmj.com/investigations

1 Prescription Medicines Code of Practice Authority. Consultation on proposed changes to 2021 code. https://www.pmcpa.org.uk/the-code/consultation-on-proposed-changes-to-2021-code

2 Prescription Medicines Code of Practice Authority. AUTH/3525/6/21—Complainant *v* Novo Nordisk: Concerns about sponsored courses offered on LinkedIn. https://www.pmcpa.org.uk/cases/completed-cases/auth3525621-complainant-v-novo-nordisk

3 Prescription Medicines Code of Practice Authority. AUTH/3711/11/22—Complainant *v* Novo Nordisk: Allegations about training for weight management services. 2022. https://www.pmcpa.org.uk/cases/completed-cases/auth37111122-complainant-v-novo-nordisk

4 Mulinari S, Ozieranski P. Unethical pharmaceutical marketing: a common problem requiring collective responsibility. *BMJ* 2023;382:e076173. doi: 10.1136/bmj-2023-076173 pmid: 37726130

5 Das S, Ungoed-Thomas J. Revealed: maker of Wegovy "skinny jab" is funding NHS weight-loss services. *Guardian*. Apr 2023. https://www.theguardian.com/business/2023/apr/02/revealed-maker-of-wegovy-skinny-jab-is-funding-nhs-weight-loss-services

6 Medicines and Healthcare Products Regulatory Agency. The blue guide: advertising and promotion of medicines in the UK (third edition). Nov 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956846/BG_2020_Brexit_Final_version.pdf