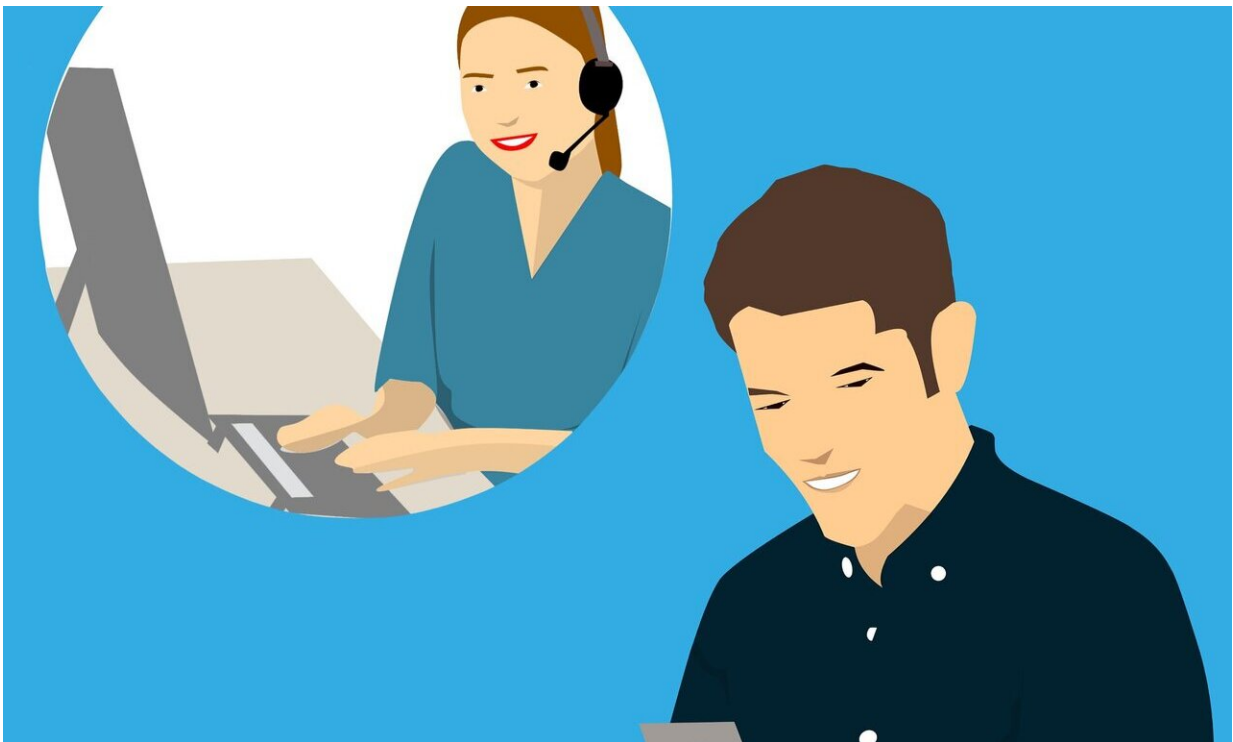


# Huge delays in dealing with complaints against UK drug companies revealed

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Credit: Pixabay/CC0 Public Domain

Processing times for complaints against drug companies suspected of having breached their industry code of practice have more than tripled in a nearly two-decade period, an investigation by *The BMJ* has found.

Data analysis by Shai Mulinari at Lund University and Piotr Ozieranski

at the University of Bath show that the average processing [time](#) of a complaint more than tripled between 2004-2021, from less than three months to more than 8.5 months. Numerous [complaints](#) have taken more than a year to resolve.

The industry's trade body, the Association of the British Pharmaceutical Industry (ABPI), has now raised fees related to these complaints by more than 40% in order to tackle the backlog.

Complaints against ABPI members and non-members that have ratified the ABPI code of practice are dealt with by the arms-length body, The Prescription Medicines Code of Practice Authority (PMCPA), the authors explain. For example, Novo Nordisk, the Danish drug giant, is currently suspended from the ABPI until 2025 for sponsoring weight loss programs that promoted its products.

Commenting on the delays, Susan Bewley, former chair of 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."

In correspondence seen by *The BMJ*, an ABPI executive said the hike in the charges would 'partly' support the PMCPA to reduce long processing times.

"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.

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. This did not serve as a deterrent, as Novo Nordisk went on to engage in serious breaches in 2021 and 2022.

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."

But Margaret McCartney, honorary senior lecturer at University of St Andrews, 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 NHS's decision to allow Novo Nordisk to fund obesity clinics, she said.

Alan Black, a retired pharmaceutical industry senior doctor, said he has noticed a deterioration in processing times. He shared his concerns with the ABPI, the PMCPA, and the Medicines and Healthcare Products Regulatory Agency (MHRA), which has a statutory responsibility to oversee the self-regulation system.

Yet the correspondence between Black and the MHRA reviewed by *The BMJ* shows that the MHRA has no expectations for the duration of handling of complaints by PMCPA. "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," an MHRA press officer told *The BMJ*, without specifying how the agency would determine this to be the case.

"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," said Black. "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," he added.

**More information:** Shai Mulinari et al, Huge delays in dealing with complaints against UK drug companies revealed, *The BMJ* (2024). [DOI: 10.1136/bmj.q365](#)

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