CASE/0812/11/25 ***NO BREACH OF THE CODE***

HEALTH PROFESSIONAL v ASTRAZENECA

Allegations about a medication review service

CASE SUMMARY

This case was in relation to a therapy review service organised and funded by AstraZeneca. A health professional alleged that patients in their GP practice with chronic obstructive pulmonary disease (COPD) were switched to a different brand of inhaler without a clear clinical justification. The complainant further alleged that AstraZeneca's involvement in the service was not transparent.

The outcome under the 2024 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement that companies maintain high standards at all times**
No Breach of Clause 5.6	**Requirement to be sufficiently clear as the company's role and involvement**
No Breach of Clause 19.1	**Requirement that no gift, pecuniary advantage or benefit may be supplied, offered or promised to health professionals or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine**
No Breach of Clause 23.1	**Requirement that donations are freely given for the purpose of supporting healthcare with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about AstraZeneca UK Limited was received from a contactable health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "I am a GP partner and research lead at my practice. We were contacted by [third-party service provider]. They offered to perform free of charge COPD medication review for our patients. Several patients were switched to a different brand of inhaler with no clear clinical justification to do so. The only legitimate difference was the manufacturer. I suspect they are receiving commission from AZ for this work and I do not feel they were transparent with this."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 23.1, 19.1, 5.6, 5.1 and 2 of the 2024 Code.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

> "We are writing to you in response to your letter dated 1 December 2025, concerning a complaint from a healthcare professional who described themselves as 'GP Partner and research lead', regarding a medication review service. The complainant's allegations can be broken down as follows:
>
> 1. During a free of charge COPD medication review service provided by [third-party service provider] on behalf of AstraZeneca, several patients were switched to a different brand of inhaler with no clear clinical justification to do so. The only legitimate difference was the manufacturer.
>
> 2. The GP suspects that [third-party service provider] are receiving commission from AZ for this work, which is not transparent.
>
> We will address each of the complainant's allegations according to the following clauses of the ABPI Code of Practice: 23.1, 19.1, 5.6, 5.1 and 2.
>
> A GP contacted [third-party service provider] one day before the PMCPA complaint was submitted with similar allegations.
>
> **<u>Background</u>**
>
> The free of charge COPD medication service referred to by the complainant is not a 'Free of Charge' scheme. This is a patient review service in accordance with Clause 23.1 (details provided below).
>
> The COPD Cardiopulmonary Risk Reduction review service ('the service') is funded by AstraZeneca and delivered by a team of Pharmacists employed by [third-party service

provider]. The contract between AstraZeneca and [third-party service provider] [is provided to the Panel]. The service is provided to primary care healthcare organisations (HCOs) by AstraZeneca as a donated service. The service is designed to support primary care HCOs with clinical capacity to review patients with uncontrolled COPD. These patients undergo a clinical assessment, where their pharmacological and non-pharmacological COPD management is reviewed in line with local and national guidelines.

[Third-party service provider] operates a robust clinical governance framework which ensures that all working practices deliver the highest standards of care and safety and reflect the wider NHS strategy for clinical governance. [Third-party service provider] senior management oversee clinical and information governance adherence, training, policy creation and the design of procedures. The Clinical Director for [third-party service provider] is responsible for ensuring all pharmacists remain abreast of any developments within the therapeutic area.

All [third-party service provider] pharmacists involved in the service:

1. Are registered as pharmacists with the General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland (PSNI)

2. Have completed:
   - Internal training on the COPD Cardiopulmonary Risk Reduction Service Clinical Protocol ('the protocol') overseen by national and regional lead pharmacists (senior clinicians)
   - Annual internal ABPI code compliance training
   - Annual pharmacovigilance training

3. Will have a thorough working knowledge of the relevant guidelines and key principles of COPD management including NICE guidelines, standards, and recommendations relevant to COPD.

4. Will ensure that patient confidentiality is always maintained and are contractually required to comply with relevant data protection legislation in line with the contract with AstraZeneca.

The service is available to all UK based primary care HCOs on a first come, first served basis. Regions across the UK with the highest unmet need (in relation to level of uncontrolled COPD and associated cardiopulmonary risk) are identified by AstraZeneca's Medical Affairs team based on eligibility criteria. During a non-promotional meeting, the service can be introduced in these high-risk areas (by non-promotional field employees, other relevant employees or by [third-party service provider]).

If the HCO decides to register for the service, the following steps are taken:

1. Service Authorisation Form (SAF) is signed by the Lead GP at the HCO. The SAF makes it clear at outset that the service is funded by AstraZeneca. This authorises [third-party service provider], acting on behalf of AstraZeneca, to undertake the service in that HCO. It confirms that the Lead GP has been

provided with information about the service (including what it involves), and that they accept full responsibility for communicating details of the service to all members of the practice who will be involved. AstraZeneca have no further interaction with the site regarding this service; all enquiries and communication are passed over to [third-party service provider].

2. The Lead GP completes the protocol for the service. This is to ensure treatment options considered by [a third-party service provider] pharmacist as part of each patient consultation, are aligned to local formulary and local/national guidelines of the GP's choice. The protocol also makes it clear at outset that the service is funded by AstraZeneca. The protocol is signed by the Lead GP to document approval before it is implemented. [Third-party service provider] pharmacists must work within the confines of the protocol and are directly accountable to the Lead GP. They must be fully trained on this before any patient reviews are conducted.

3. [Third-party service provider] generates a list of patients with COPD who have evidence of symptoms or exacerbations (and therefore high cardiopulmonary risk). This list is shared with the Lead GP for review. Patients approved on the list by the Lead GP are invited in for review with [a third-party service provider] pharmacist.

4. The [third-party service provider] pharmacist conducts the individual patient consultations and makes recommendations regarding their COPD management. This will include both pharmacological and non-pharmacological assessments in line with the protocol. For each patient reviewed, all recommended changes, along with clinical rationale, are documented and discussed with the Lead GP. If the Lead GP agrees with the proposed changes, they are implemented. These expectations are clearly laid out in the protocol as below:

   'Any medicinal recommendations will be made in line with the product's SPC. Where the GP or authorising clinician concurs, they should provide authorisation by signing the individual assessment form. Alternatively, where intervention recommendations are discussed remotely, a collated intervention summary list of all patients discussed detailing the agreed interventions should be emailed to the authorising GP/clinician. The authorising GP/clinician should provide confirmation of authorisation by way of responding to the email. Should the authorising GP/clinician wish for an alternative intervention to be made they should annotate the individual assessment form or authorisation email appropriately.'

   Based on this, [third-party service provider] keeps a record of all approved recommended changes for practices that utilise the service (as approved by the GP on the individual assessment). AstraZeneca do not have sight of these forms due to patient data confidentiality.

It is relevant to note that if the Lead GP isn't available, they may delegate to another GP at the practice to approve the recommended changes to management. As noted above, it is the Lead GP's responsibility to communicate the details of the service to all

members of the practice who are involved. The Lead GP (or delegate GP) at the site has complete oversight and accountability of patients invited for review, and any changes made to their COPD management.

AstraZeneca Response to the allegations

1. *During a free of charge COPD medication review service provided by [third-party service provider] on behalf of AstraZeneca, several patients were switched to a different brand of inhaler with no clear clinical justification to do so. The only legitimate difference was the manufacturer.*

   As mentioned above, a detailed protocol is completed by the Lead GP which specifies which national and local COPD management guideline to follow. The Lead GP also selects which specific medicines should be used in each applicable medicine class. AstraZeneca has no influence over which medicines are selected.

   The [third-party service provider] pharmacist assesses the patient in accordance with the protocol to ensure optimal management of their COPD. After the patient has been clinically assessed by [a third-party service provider] pharmacist, any recommended changes to medicines are discussed and approved by the Lead GP (or delegate GP) before any changes are made. AstraZeneca has no influence over what these recommendations are.

   AstraZeneca's funding of this patient review service is not dependent on the use of AstraZeneca medicines. The medicine selected during an individual patient clinical assessment will always be aligned to the protocol and ultimately the final decision of the Lead GP (or delegate GP). The review service has therefore been carried out in accordance with the requirements of Clauses 19.1 and 23.1

2. *Lack of transparency regarding AstraZeneca's involvement with the clinics*

   It is explicitly clear in the Service Authorisation Form and all materials associated with the review service, including patient letters, that the funding company is AstraZeneca. Therefore, the materials clearly indicate the role of AstraZeneca in line with clause 5.6.

   Although the funding for this service is provided by AstraZeneca as a service to medicine, AstraZeneca has not been involved in the review of patients, nor has it been provided with any patient identifiable information.

We noted above that a GP contacted [third-party service provider] with the same complaint. As part of addressing that complaint, AstraZeneca has confirmed with [third-party service provider] that the complete process, as described above (in line with the protocol and Service Authorisation Form), has been deployed as intended at this practice.

We therefore refute the alleged breach of clauses 23.1, 19.1, 5.6, 5.1 and 2 of the ABPI Code of Practice.

Summary of AstraZeneca's position

It is AstraZeneca's position that:

1. The decision to initiate or change a patient's COPD treatment is documented with associated rationale. The Lead GP chooses which medicines should be used in each applicable medicine class, and which guidelines should be followed, in the protocol based on local practice and formulary. This is not influenced by AstraZeneca in any way.
2. AstraZeneca's involvement is clear in all materials associated with the service, including patient letters, service authorisation form and protocol.

Based on the detailed documentation outlined above and AstraZeneca's clear declaration of involvement in all materials related to the service, we can only assume this complaint has arisen from miscommunication in the practice of the complainant GP.

AstraZeneca is fully committed to the ABPI Code of Practice and takes its responsibilities under the Code very seriously."

PANEL RULING

This complaint was about a chronic obstructive pulmonary disease (COPD) therapy review service funded by AstraZeneca. The complainant, a GP partner, alleged that patients at their practice were switched to a different brand of inhaler following the review, with no clear clinical justification, and that AstraZeneca's involvement in the service was not transparent.

The Panel took note of the fact that the complainant had not provided any documentation as supporting evidence in relation to their allegations. The Panel was not an investigatory body, and it judged complaints on the evidence provided by both parties. The complainant had the burden of proving their complaint on the balance of probabilities.

Therapy review service

AstraZeneca submitted that the 'COPD Cardiopulmonary Risk Reduction review service' was a non-promotional service provided to primary care healthcare organisations by AstraZeneca as a donated service. It was funded by AstraZeneca and delivered by a team of pharmacists employed by a third-party service provider. AstraZeneca submitted that it was a patient review service in accordance with Clause 23.1.

The Panel noted that the requirements relating to switch and therapy review programmes were included in the supplementary information to Clause 23 which stated:

"*Clauses 19.1 and 23.1 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. […]*

A therapeutic review is different to a switch service. A therapeutic review which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. The result of

such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The decision to change or commence treatment must be made for each patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds."

The Panel set out to determine if the activity was a legitimate therapy review service. In its response to this complaint, AstraZeneca provided details of the therapy review service, including a copy of the contract between AstraZeneca and the third party providing the service, a service authorisation form, the service clinical protocol and a letter template to be used to invite patients to a therapy review meeting.

The Panel noted that section one of the clinical protocol included the statement: "*Whilst the service is funded and organised on behalf of AstraZeneca, any change in management of COPD arising from the patient review process remains the choice and sole decision of the authorising GP/clinician. Offering of the service will not be conditional on the past, present or future prescribing or use of any AstraZeneca products or services. The practice remains responsible for the care of their patients and the lead GP retains full control over the entire process.*"

Section two of the clinical protocol included a breakdown of the therapy review process from start to finish, divided into four distinct phases. Each phase included a description of the actions to be performed. The description for the "*Patient Consultation*" phase included the statement: "*The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational clinical grounds*".

Section three of the clinical protocol defined the intervention scope. This included the points to be covered during the face-to-face or remote review with the third-party pharmacist, divided into a review of relevant medical history, an assessment of current COPD management, which included both pharmacological and non-pharmacological management methods, and individual patient recommendations.

The individual patient recommendations available following the therapy review were:

- "*Addition, cessation, or change of current therapy or device licensed for COPD in line with SmPC and practice-agreed management framework*
- *Inhaler technique training on existing or new device*
- *Signposting to training support for inhaler technique (e.g. online video)*
- *Provision of spacer device*
- *Provision of written COPD self-management plan*
- *Provision of other health promotion literature authorised for use within this service*
- *Referral for smoking cessation support*
- *Referral for pulmonary rehabilitation*
- *Referral for relevant specialist care (e.g. COPD, dietitian)*
- *Follow up with practice respiratory team"*

The practice-agreed management framework referenced in the intervention scope was set out in section four of the clinical protocol and defined the interventions available for recommendation during the therapy review. The healthcare organisation was responsible for completing the management framework by providing:

- National/international COPD guideline/report to be referenced when forming non-pharmacological and pharmacological intervention recommendations
- Local COPD management guidelines to be referenced when forming non-pharmacological and pharmacological intervention recommendations
- Local formulary to referenced when forming non-pharmacological and pharmacological intervention recommendations

The practice-agreed management framework also included a list of the medication classes licensed for the treatment of COPD (SABA or SAMA, LABA, LAMA, etc.) and provided space for the healthcare organisation to define up to three medicines for each class which could be recommended as an intervention during the service, as stated within the local or practice-directed formulary.

The requirement that any proposed intervention was authorised by the prescriber was further emphasised in section seven of the clinical protocol, titled "*Conduct of the therapy review"*, which stated that:

- "*Following consultation, proposed management recommendations will be presented to the authorising GP or authorised clinician for each patient*", and
- "*Any medicinal recommendations will be made in line with the product's SPC. Where the GP or authorising clinician concurs, they should provide authorisation by signing the individual assessment form. Alternatively, where intervention recommendations are discussed remotely, a collated intervention summary list of all patients discussed detailing the agreed interventions should be emailed to the authorising GP/clinician. The authorising GP/clinical should provide confirmation of authorisation by way of responding to the email. Should the authorising GP/clinician wish for an alternative intervention to be made they should annotate the individual assessment form or authorisation email appropriately.*"

The Panel noted that, in addition to the clinical protocol, both the service authorisation form and contract between AstraZeneca and the third-party service provider included clear statements that any decision to change or commence treatment must be made by the prescriber and the rational clinical justification must be documented.

The service authorisation form, which the Panel understood was intended to be signed by the Lead GP at the healthcare organisation at the outset of service, stated that by signing the form the signee understands that "*the decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational clinical grounds"*.

The contract between AstraZeneca and the third-party service provider set out the service deliverables. Under the heading "*Approval and implementation",* the contract required that:

> "*The Service Provider pharmacists will explain any proposed changes to the lead GP/respiratory lead and gain authorisation from the GP to implement changes, subject to prior patient approval".*

In the Panel's view, the service documentation provided by AstraZeneca demonstrated that the therapy review contained a range of treatment choices including both medicinal and non-medicinal therapies and, because the medicines available for recommendation were defined by the healthcare organisation, was not limited to AstraZeneca's medicines. The service documentation made it explicitly clear that prior to a patient being switched from one medicine to another, the clinical justification for the proposed switch had to be documented and the switch authorised by the patient's GP or authorised clinician.

The Panel concluded that, on the evidence provided, it appeared that the AstraZeneca-funded activity was not a switch service but a legitimate therapy review and was designed in such a way that it adhered to the requirements of the supplementary information to Clause 23. In the absence of any evidence from the complainant to demonstrate that the service had been conducted contrary to the documents provided by AstraZeneca, the Panel ruled **no breach of Clauses 19.1 and 23.1**.

Transparency of AstraZeneca's involvement

The Panel noted that all the external-facing service documentation provided by AstraZeneca in its response to this complaint (namely the service authorisation form, clinical protocol and patient letter template) included a statement regarding AstraZeneca's involvement in the service.

The service authorisation form, the first service document to be sent to healthcare organisations participating in the service, contained a prominent AstraZeneca logo in the header on all pages alongside the logo of the third-party service provider. The statement, "*The COPD Cardiopulmonary Risk Reduction Service is a non-promotional medical service which is funded by AstraZeneca and delivered by a team of pharmacists employed by [third-party service provider], working on behalf of AstraZeneca*" appeared twice on each page: in a purple banner at the top of the page (beneath the header) and in the footer of the page on a yellow background. The same wording was also included on the first page in the declaration wording to be accepted by the Lead GP in signing the form.

Likewise, the clinical protocol included the AstraZeneca logo at the top of every page. The same declaration statement as on the service authorisation form was included in a coloured footer at the bottom of every page. The declaration statement was also included under the heading in the centre of the cover page, and reference to AstraZeneca's role in the service was also made throughout the introduction section of the document.

The first page of the patient letter template included two short introductory paragraphs outlining the significant health concern of COPD and a statement that having regular COPD reviews can improve quality of life. The third paragraph read:

> "*We would therefore like you to make an appointment so that we can review your COPD symptoms and current COPD management to help reduce your risk of heart and lung events. This review is funded by AstraZeneca.*"

The same declaration statement as was included in both the service authorisation form and the clinical protocol appeared at the end of the patient letter template.

The Panel noted that the service authorisation form and the clinical protocol were intended for the Lead GP at the healthcare organisation. Both documents included a statement that it was the responsibility of the Lead GP to communicate relevant information about the service to appropriate personnel within the practice.

Clause 5.6 required that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company.

In the Panel's view, AstraZeneca's involvement was prominently declared on all the materials relating to the service that had been provided to the Panel.

While AstraZeneca stated that it had received a separate complaint, via the third-party service provider, the Panel made no assumption that the complainant was the same in both cases. The Panel could not, therefore, be certain of what documentation had been provided to the complainant's practice, or any conversation between the practice and the third-party service provider. Noting that the complainant bore the burden of proof, the Panel concluded that there was no evidence that AstraZeneca's involvement in the therapy review service had not been appropriately declared. The Panel ruled **no breach of Clause 5.6**.

Overall

On the basis of its no breach rulings above, the Panel determined that there had not been a failure to maintain high standards and that AstraZeneca's conduct has not brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clauses 5.1 and 2**.

Complaint received **26 November 2025**

Case completed **24 June 2026**