CASE/0727/09/25 *NO BREACH OF THE CODE*

COMPLAINANT v ASTRAZENECA

Alleged facilitation of a switch to Symbicort (budesonide/formoterol)

CASE SUMMARY

This case concerned two materials hosted on AstraZeneca's promotional website which the complainant alleged both promoted and facilitated a switch to Symbicort (budesonide/formoterol) and was a potential risk to patient safety by enabling patients to be switched without clinical review or consideration of inhaler suitability.

The outcome under the 2024 Code was:

No Breach of Clause 23.1	**Requirement that donations and grants 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**
No Breach of Clause 23.2	**Requirement that donations and grants to healthcare organisations, among other requirements, do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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 was received about AstraZeneca UK Limited from an anonymous, non-contactable complainant who described themselves as a member of the public.

COMPLAINT

The complaint wording is reproduced below:

> "I am very concerned that AstraZeneca are both promoting and facilitating a switch via their 'Symbicort Patient Identification Resource' (URL provided), GB-64930. This

website is clearly promotional (it even has prescribing information on the page and the brand name in the name of the resource) and without a doubt provides significant support to doctors or nurses in the identification of patients to encourage and facilitate switching onto Symbicort. It even provides practical support in completing clinical systems (URL provided); GB-52958. From my understanding of the ABPI Code, although a company can promote a switch they CANNOT facilitate one (directly or indirectly), and therefore these resources are blatantly in breach of clause 23. This also provides me significant concern regarding patient safety (in clear breach of clause 2), and whether this resource makes switching so easy that stable patients will end up being switched without clinical review, destabilising them. Or patients ending up on a new inhaler device that they don't know how to use without proper consideration of the most appropriate device they are capable of using, and thereby end up exacerbating. This is particularly worrisome as even mild asthma patients are at risk of exacerbations and death if their asthma is not managed properly."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 23.1, 23.2, 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 10 September 2025 regarding the above, concerning an anonymous complainant who described themselves as a member of the public.

The complainant's allegations can be broken down as follows:

1. AstraZeneca is facilitating a switch via the 'Symbicort Patient Identification Resource' (SPIR).

2. The tool provides significant support to doctors or nurses in identifying these patients and practical support in completing the clinical systems (GB-52958).

3. Provides significant patient safety concern, as this resource makes it so easy to switch patients, patients may be switched to Symbicort without clinical review.

4. Patients will end up on new inhaler that they do not know how to use without proper consideration.

Whilst we welcome scrutiny and the ability to demonstrate the robustness of the compliance steps that sit behind SPIR, we suggest that it may be appropriate for the PMCPA to consider the need to verify the veracity of this complaint from a 'member of the public' based on the detailed information included. In particular, we note that the complainant appears to have either inadvertently or deliberately linked two entirely separate items (i.e the SPIR itself and GB-525958) in order to try to substantiate a complaint.

We will address each of the complainant's allegations according to the relevant clauses of the ABPI Code of Practice (clauses 23.1, 23.2, 5.1 and 2).

Background

The 'Symbicort Patient Identification Resource' (SPIR) is a digital promotional resource, consisting of a list of searches created to assist HCPs in identifying patients who may be eligible for Symbicort, based on its licensed indication per the SmPC. This is similar to other resources that companies produce in order to support identification of patients within the licence for their medicines, and who may benefit from them, subject to appropriate review (e.g. a patient eligibility checklist). The advantage of creating a digital resource to do this, is that the searches have been built and tested separately so they are not reliant on HCPs following detailed guidance.

There are 4 separate patient cohorts included in the search, including:

- Cohort 1: ≥2 SABA monotherapy and no asthma review in last 12 months
- Cohort 2: ≥2 SABA monotherapy
- Cohort 3: ICS + ≥3 SABA
- Cohort 4: ICS/LABA + ≥3 SABA

Cohort 1 and 2 will generate a list of patients potentially suitable for anti-reliever (AIR) therapy, aligned to Symbicort 200/6 license.

Cohort 3 and 4 identify patients inadequately controlled by ICS (+ LABA) and as required SABA, potentially suitable for maintenance therapy, also aligning with the Symbicort license (100/6, 200/6).

Each cohort also includes exclusion criteria, to exclude patients not aligned to the Symbicort license.

All cohorts, therefore, align to the Symbicort license if deemed appropriate by the clinician. It is also relevant to note that the cohorts reflect asthma patients at risk of poor outcomes as defined in current NG245 guidelines (section 1.15 Risk-Stratified care, Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN)). The searches identify patients with uncontrolled asthma and who are at risk of an asthma exacerbation and who may be eligible for Symbicort.

SPIR is hosted on the AstraZeneca owned Symbicort website, found under tab 'Education and Patient Resources' > 'Patient Identification Resource'. Users must verify they are a Healthcare Professional before accessing the website.

[Screenshot provided]

On the SPIR webpage on the Symbicort website, there are two 'register today' buttons, where the HCP can register their interest in the resource. Once an HCP registers interest, AstraZeneca validate that they are the intended user for the resource, i.e. UK based practice with access to EMIS, SystmOne and InPS Vision. The first 'register now' button appears halfway down the webpage and another one towards the bottom of the page. Directly underneath the first 'register today' button, there is a prominent red box with the following information:

'This resource only identifies patients potentially suitable for Symbicort within license. ***It does not replace the need for a clinical assessment of patients identified.*** *Not all patients found in the resource will benefit or be suitable for Symbicort. It is important to note that all decision making and clinical judgement throughout this process remains with the healthcare professional.'*

The above important prominent information is presented on a white background in the red box, ensuring it stands out and is not missed by the HCP. The sentence 'It does not replace the need for a clinical assessment of patients identified' is in bold and underlined to ensure this is explicitly clear.

[Screenshot provided]

We take great care in how this is communicated to ensure the intention of the promotional resource is clear.

There is an instruction guide available for HCPs who have registered interest in the resource, including simple instructions for downloading, importing, running and deleting the searches in their system. This guide can be accessed after they have registered for the resource. Page 2 of this guide repeats the disclaimers noted above in a prominent box (see screenshot below), reminding the HCP of these important points before they use the resource.

[Screenshot provided]

Clause 23

23.1: *Donations and Grants 23.1 Donations and grants are funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited.*

23.2: Donations and grants to healthcare organisations, patient organisations or other organisations are only allowed if they:

- are made for the purpose of supporting healthcare, scientific research or education
- do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines
- do not bear the name of any medicine – although they may bear the name of the company providing them.

Clause 23 *Switch and Therapy Review Programmes* prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another.

<u>AstraZeneca Response to the allegations</u>

1. *AstraZeneca is facilitating a switch via the 'Symbicort Patient Identification Resource' (SPIR).*

We do not agree that SPIR facilitates a switch; it identifies patients that may be eligible for Symbicort within the parameters of its license. It is clear to the HCP both before they register interest for the resource, and afterwards when following the instruction guide, that:

- Not all patients identified through the resource may be suitable for Symbicort
- A clinical assessment is still required before there are any changes to their treatment (at the decision of the HCP).

SPIR is not a service provided by AstraZeneca, it is a promotional resource that HCPs can use, to help identify patients who may be eligible for Symbicort.

As outlined above, once the HCP registers their interest and receives the searches, AstraZeneca provide no further proactive support. There is an email address (owned by the third-party agency) that HCPs may contact for logistics or if they have technical difficulties. There has only been one question received by this email address since SPIR has been available (since mid-2023).

AstraZeneca nor the third-party agency working with AstraZeneca are involved in reviewing patients. HCPs download the resource and conduct the searches themselves, which is the opposite of what happens in a therapy review service as outlined in Clause 23. The HCP has to enter into each patient record after clinical assessment before determining if a patient is eligible for Symbicort.

2. *The tool provides significant support to doctors or nurses in identifying these patients and practical support in completing the clinical systems (GB-52958).*

As detailed above, an instruction guide is available for applicable HCPs that register interest, which includes information about how to download, import and run the searches. There are no other resources available for SPIR. If HCPs are having technical difficulties with the searches, there is an email address contact. Please note this is strictly limited to technical support if any issues arise (reactive only). We have only received one enquiry since SPIR was launched.

‘How to prescribe Symbicort in EMIS and SystmOne’ asset (GB-52958) named by the complainant is hosted on the Symbicort website. It can be found under tab ‘Education and Patient Resources’ > ‘Patient and HCP Resources’. This is a separate webpage to the 'Patient Identification resource’ webpage. The asset is not linked from, nor signposted to, via the ‘Patient Identification resource’ webpage and the HCP would need to search the Symbicort website themselves to find it. On the ‘Patient and HCP Resources’ webpage, there are a number of Symbicort resources, and you have to scroll several times to reach the end of all resources. The asset in question (GB-52958) appears at the very bottom of the webpage, on the last line of available resources. It is not immediately apparent as you click onto the webpage.

[Screenshot provided]

In addition, the briefing document for the dissemination of ‘How to prescribe Symbicort in EMIS and SystmOne’ also does not reference SPIR.

In summary, the two assets are not linked in anyway and appear on separate webpages of the Symbicort website. The ‘How to prescribe Symbicort in EMIS and SystmOne’ asset was created following HCP feedback that there was a lack of available information relating to the prescribing Symbicort in their clinical systems for AIR therapy. This is because the dosing schedule for AIR is not always listed as an option in clinical systems.

Therefore, AstraZeneca rejects the allegation that SPIR provides significant support to doctors or nurses in identifying these patients and practical support in completing the clinical systems (GB-52958).

3. *Provides significant patient safety concern, as this resource makes it so easy to switch patients, patients may be switched to Symbicort without clinical review.*

The 'Patient Identification resource’ webpage and instruction guide makes it abundantly clear that the resource only identifies patients who *may* be eligible for Symbicort, not all patients identified may be suitable for Symbicort, and that a clinical assessment is required before any changes are made to treatment. The cohorts included in the search, as mentioned above, are aligned with the Symbicort license and reflect asthma patients at risk of poor outcomes as defined in NG245 guidelines. We, therefore, do not agree that there has been any potential risk to patient safety, and rather that this resource helps to maintain patient safety. This is because it identifies high risk asthma patients, those who are uncontrolled and at risk of an exacerbation, and who may benefit from treatment with Symbicort license indication if appropriate.

Furthermore, we would like to bring the Panel’s attention to the availability of prescribing information for Symbicort, which is available at the top of each webpage on the Symbicort website, including ‘Patient identification Resource’ page. There is also a separate webpage on the Symbicort website relating to ‘Dosing and Safety’ that the HCP could also navigate to if they wish.

4. *Patients will end up on new inhaler they do not know how to use without proper consideration*

As mentioned above, it is explicitly clear before registering interest in the resource, and after receiving it, that not all patients identified may be suitable for Symbicort and a full clinical assessment is required before any changes are made to patients' treatment. It is a well-known and standard requirement, as flagged to clinicians in publications such as the British National Formulary, that ‘Patients should be instructed carefully on the use of the inhaler device and be able to demonstrate satisfactory technique.’

The Symbicort SmPC also states that:

[Screenshot of SPC patient instructions section]

Based on the above detailed explanation, SPIR does not involve a patient’s medicine being simply changed to another: the HCP has to enter into each patient record after clinical assessment before determining if a patient may be eligible for Symbicort.

This promotional resource tool is not related in any way to the activities outlined in Clause 23 (i.e Donation of services or Therapy review*)* and does not assist a health professional in implementing a switch by means of a third party.

We therefore strongly refute the alleged breaches of clauses 23.1, 23.2, 5.1 and 2 of the ABPI Code of Practice.

It is AstraZeneca's position that:

1. SPIR is a promotional resource that HCPs can utilise if they wish, to identify patients who may be eligible for Symbicort.

2. It is very clear in the materials available before and after downloading SPIR that not all patients identified may be suitable for Symbicort, and a full clinical assessment is still required.

3. Neither AstraZeneca nor the third-party agency working with AstraZeneca are involved in reviewing these patients; there is no assistance provided to HCPs in implementing a switch by a third party.

4. HCPs download the resource and conduct the searches themselves, which is the opposite of what happens in a therapy review service as outlined in Clause 23.

5. Materials for SPIR do not link or signpost to the asset outlining 'How to Prescribe Symbicort in EMIS and SystemOne'. The HCP viewing the website would have to organically navigate to a separate webpage for HCP resources and scroll to the bottom before they can access it.

AstraZeneca is fully committed to the ABPI Code of Practice and takes its responsibilities under the Code very seriously; we strive to maintain high standards at all times."

FURTHER INFORMATION FROM ASTRAZENECA

Following the Panel's request for further information, AstraZeneca provided copies of the briefing documents associated with the assets at issue (*The Symbicort Patient Identification Resource* and *How to Prescribe Symbicort Reliever Therapy (Turbohaler 200/6) EMIS and System One*).

PANEL RULING

This complaint concerned two materials, hosted on AstraZeneca's promotional website, entitled the 'Symbicort Patient Identification Resource' (SPIR) and 'How to prescribe Symbicort in EMIS and SystmOne', which the complainant alleged both promoted and facilitated a switch to AstraZeneca's medicine, Symbicort (budesonide/formoterol fumarate dihydrate). The complainant further alleged a potential risk to patient safety by enabling patients to be switched without clinical review or consideration of inhaler suitability.

The SPIR was hosted on the Symbicort website, under the 'Education and Patient Resources' tab, and was described as a promotional tool designed to support the identification of patients who may be suitable for using Symbicort. The webpage included an overview of the resource, a video explaining its use including a case study, and a 'Register Today' button. A banner stated that the resource was deployed remotely and was available to UK based GP practices,

integrated care boards and primary care networks using EMIS, SystmOne and InPS Vision systems. The banner also stated that the resource 'only identifies patients potentially suitable for Symbicort within licence. It does not replace the need for a clinical assessment of patients identified', that not all patients identified would be suitable for Symbicort, and that 'all decision making and clinical judgement throughout this process remains with the healthcare professional.' Further down, the webpage described the components of the resource, including importable clinical system searches to identify patients who may be suitable for Symbicort, and step-by-step instruction guides, alongside a second 'Register Today' button, frequently asked questions and a registration form. Prescribing information was available via a link at the top of the webpage and the licensed indication for Symbicort appeared at the bottom.

The complainant also referred to a second resource titled 'How to prescribe Symbicort in EMIS and SystmOne', alleging that this provided practical support for implementing the switch alleged for the SPIR. The Panel noted AstraZeneca's submission that the document had been created following feedback that clinical systems lacked information about the dosing schedule for anti-inflammatory reliever (AIR) therapy. The promotional material included system-specific dosage instructions to 'only be used for patients requiring Symbicort 200/6 Turbohaler prescribed as reliever therapy' and included the statement 'this leavepiece is for system directional use only and does not replace the clinical assessment required by a healthcare professional when prescribing Symbicort for a patient'.

The Panel understood the overarching complaint to be that the materials, when taken together, facilitated a switch by identifying patients eligible for Symbicort and providing practical support in prescribing it on the clinical systems. The matter for the Panel to consider was therefore whether the materials went beyond promoting a switch and amounted to the facilitation of a switch service, as prohibited by Clause 23.1.

In considering the matter, the Panel took into account the actions taken by AstraZeneca to make health professionals aware of the SPIR and the process for accessing the resource, including:

- that among other things, the SPIR briefing document (current at the time of complaint) explicitly stated that the AstraZeneca promotional team:
    - could proactively or reactively introduce the availability of the SPIR as a means of identifying patients that may be suitable for Symbicort and not as a risk stratification or case finding tool
    - could not offer any follow up support during the sales call once introduced because they cannot be involved in the provision of services of this nature or in accessing patient data
    - must emphasise the need for the health professional to undertake a full clinical assessment of patients identified by SPIR searches
    - could not provide other assets to support the SPIR or support a practice to download, import or run searches at any time or in any circumstances
    - must direct health professionals to AstraZeneca's third party if they had any queries or difficulties when downloading, importing, running or using the SPIR
- that the SPIR briefing document made no reference to the 'How to prescribe Symbicort in EMIS and SystmOne' material and vice versa
- that AstraZeneca validated health professionals registering their interest to ensure their practice had access to a compatible clinical system before being able to download the SPIR.

The Panel noted the requirements of Clause 23 and its supplementary information, *Switch and Therapy Review Programmes*, which stated that:

> "Clauses 19.1 and 23.1 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a company's medicine was simply changed to another. For example, it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even by means of a third party."

The Panel considered there was a fine line between promoting a switch and providing detailed or operational support such that a switch was facilitated in practice. In this regard, the Panel queried whether patient identification of this nature would ordinarily be undertaken by health professionals as part of routine clinical practice.

However, the Panel acknowledged that switching a patient was a multistage process involving patient identification, clinical review, and implementation of a clinical decision. The Panel noted AstraZeneca's submission that it had no further input into clinical assessment or decision making; the SPIR emphasised that it only identified patients potentially suitable within licence, did not replace the need for a clinical assessment and that all clinical decision making remained the responsibility of the health professional. The briefing documents did not appear to provide any guidance contrary to this.

The Panel further noted AstraZeneca's submission that while the complainant had linked the two materials, these were entirely separate items; the 'How to prescribe Symbicort in EMIS and SystmOne' document was hosted on a separate webpage ('Patient and HCP Resources') and was not linked to, or signposted from, the SPIR webpage or materials. In the Panel's view, taking account of the associated briefing materials, there was no evidence before it to demonstrate that the two assets were used in conjunction or linked.

Taking all the circumstances into account, the Panel determined that the complainant had not established that the use of the materials in question went beyond promoting a switch or that AstraZeneca had facilitated a switch to Symbicort as prohibited by Clause 23.1. The Panel ruled **no breach of Clause 23.1**.

The Panel noted that AstraZeneca had also been asked to respond in relation to Clause 23.2 which set out the requirements for donations and grants including that they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines. The Panel considered the matter in relation to the alleged facilitation of a switch to Symbicort had been covered by its no breach ruling of Clause 23.1 above. In the absence of any additional allegation(s), the Panel ruled **no breach** of **Clause 23.2**.

The Panel then considered the allegation that the materials at issue were a potential risk to patient safety as they made "switching so easy" that patients could be switched without clinical review and prescribed a new inhaler device they did not know how to use.

The Panel noted its determination that the circumstances did not amount to the facilitation of a switch and that the materials clearly stated that they did not replace the need for a clinical

assessment, with treatment decisions remaining the responsibility of the health professional. In the absence of evidence that patients had been switched without appropriate review as alleged, the Panel did not consider that it had been established that AstraZeneca had failed to maintain high standards and **no breach of Clause 5.1** was ruled.

In the light of its rulings above, it followed that the Panel ruled **no breach of Clause 2**.

Complaint received **9 September 2025**

Case completed **5 May 2026**