CASE AUTH/3477/2/21

COMPLAINANT v ASTRAZENECA

Promotion of Symbicort Turbohaler

An anonymous, non-contactable complainant who described him/herself as a respiratory nurse, complained about a Symbicort Turbohaler (budesonide/formoterol) package deal offered by AstraZeneca UK Limited and about the company's Turbu+ website. Symbicort was indicated for certain patients with asthma and/or chronic obstructive pulmonary disease (COPD) depending on the formulation.

The complainant alleged that he/she was informed by colleagues that AstraZeneca was offering a deal with Symbicort Turbohaler which also involved supporting patients via a contracted third party healthcare services partner, where a nurse called the patient to talk them through the Turbu+ device. Representatives were also promoting the programme as a deal where there was a requirement to prescribe 15 Symbicort Turbohalers for 1 device which was alleged to be an inducement to prescribe, and the device was only available for selected number of patients. The complainant did not consider that this was a financial deal, rather a set up to get clinicians to prescribe the company's product so the patient would receive a few calls from a nurse.

The complainant also referred to being provided with the Turbu+ website and alleged that the information was aimed at health professional and Turbu+ users, however, prescribing information was missing. The complainant noted that by clicking the AstraZeneca logo in the top left corner of the page, viewers would be directed to AstraZeneca.com which seemed to be a global page without a UK ID. The information on that website was mainly aimed at asthma patients, however, the AstraZeneca representatives were promoting this service for both COPD and asthma patients which the complainant was concerned was misleading the patients and clinicians to increase their prescription numbers.

The detailed response from AstraZeneca is given below.

The Panel noted AstraZeneca's submission that the Symbicort Turbu+ package deal included the 'associated benefits' of the provision of the connected add-on Turbu+ device itself, and an optional nurse resource to register and train those patients whose health professional had offered them the Turbu+ package. The Panel noted AstraZeneca's explanation that the Turbu+ device comprised a connected 'add-on' device,, designed to connect exclusively to a Symbicort Turbohaler inhaler, to help patients optimally manage daily use of the medicine and an associated patient-facing digital bluetooth application to record the patient's medication usage data. The Turbu+ device and app registered actuations of the Turbohaler and could assist patients and their clinicians (remotely) to monitor adherence.

The Panel noted AstraZeneca's submission that the package deal was intended for NHS bodies only and not prescribers; it was not publicised to individual prescribers, practices

or patients and did not offer any direct benefit to a prescriber, pecuniary or otherwise and therefore could not constitute an incentive or inducement to prescribe. The Panel noted AstraZeneca's submission that the package deal was promoted only to senior financial and clinical decision-makers within certain NHS bodies; the identification of GP practices was entirely at the discretion of the registered NHS body. It was the NHS body's responsibility to notify each primary care or secondary care institution of the package deal and to inform AstraZeneca of those that wished to be enrolled. AstraZeneca submitted it had absolutely no influence over which NHS practices (or their prescribers) received access to the package deal.

The Panel noted AstraZeneca's submission that treatment decisions would be made solely by the treating clinician and this programme was not seeking to influence or incentivise the individual prescribing behaviours of any health professional. The Panel further noted that AstraZeneca denied the allegation that the package deal entailed writing 15 additional prescriptions for Symbicort in order to receive one Turbu+ device; the '15:1' ratio was only used to analyse retrospective prescribing data to determine the maximum allocation of Turbu+ devices for any particular NHS body. The data that was used to make that assumption was derived from https://openprescribing.net/, and the process that was followed was clearly explained in detail in the contractual agreement between AstraZeneca and the NHS body. The Panel noted AstraZeneca's explanation that, therefore, it was not possible for that ratio to influence prescribing behaviour. The specimen agreement between AstraZeneca and an NHS body in relation to the package deal stated 'AstraZeneca are offering the package deal whereby for every 15 prescriptions of Symbicort Turbohaler a locality prescribes, 1 Turbo+ device shall be provided'. It did not refer to a maximum allocation or similar.

The Panel noted its comments above and did not consider that the complainant had demonstrated that the package deal was being offered as an inducement to individual health professionals to prescribe and the Panel thus ruled no breach of the Code in that regard.

The Panel noted AstraZeneca's submission that specific representatives were selected and briefed to promote the package deal to senior financial and clinical decision-makers within NHS bodies; other commercial representatives were told about the package deal but were not instructed to take any action. The Panel did not consider that the complainant had made an allegation directly or indirectly about the training or briefing of representatives and thus ruled no breach of the Code.

The Panel noted AstraZeneca's submission that the Turbu+ website was a repository for patient materials, in order to support those who had consented and been enrolled onto the Turbu+ device by their health professionals; AstraZeneca also deemed it appropriate for health professionals to have access to the website, as this was analogous to how print items of patient materials would normally be delivered to health professionals via face-to-face meetings. The Panel noted AstraZeneca's submission that visitors to the website were required, upon the landing page, to make a declaration as to whether they were: health professionals participating in the Turbu+ device programme; patients participating in the Turbu+ device programme or members of the public; the first two options allowed users to view the content within the website, whereas the third option signposted members of the public to the AstraZeneca UK public website.

The Panel noted that it was, of course, acceptable for health professionals to access material designed for patients for whom they had prescribed Symbicort. Package deals were a promotional activity. Although the material in question was ultimately designed for patients for whom the decision to prescribe Symbicort had been made, it was, nonetheless, an integral part of the package deal materials. In the Panel's view, it was arguable that all such package deal materials about the medicine available for health professionals ought to have prescribing information available when viewed by such health professionals. The Panel noted that the website in question stated that it was intended for patients and health professionals participating in the Turbo programme rather than just patients. In such circumstances, the Panel considered that the material ought to have prescribing information available for health professionals, perhaps available by an intervening page after the health professional had clicked the 'I am a health professional' tab. The Panel ruled a breach of the Code.

With regard to directing viewers of the webpage to AstraZeneca.com, which seemed to be a global page without a UK ID, the Panel noted that it was not necessarily unacceptable for a company to link to its company's global corporate website. Further, it was not necessarily a breach of the Code to not include a reference number on the linked website. The Panel did not consider that the complainant had established, on the balance of probabilities, that in linking to the global AstraZeneca.com page without a UK approval number AstraZeneca had failed to maintain high standards and no breach of the Code was ruled.

The Panel noted the complainant's allegation that the information on 'this website', which was considered by the Panel as the UK website, was mainly aimed at asthma patients, however, AstraZeneca representatives were promoting the service for both COPD and asthma patients. The Panel noted AstraZeneca's submission that the materials on the website were suitable for both COPD and for asthma patients as Symbicort Turbohaler was licensed for both and AstraZeneca made the package deal available across both diseases; the main purpose of the patient materials on the Turbu+ website was to outline the device's functionality, which was the same, regardless of whether the patient had asthma or COPD. The Panel further noted AstraZeneca's submission that given that the Turbu+ device was currently predominantly used by asthma patients (96.6% of Turbu+ patients were asthma patients), it was, therefore, reasonable that the user guide might be more directed towards patients with asthma. The Panel did not consider that the complainant had established that the content of the website was such that promoting the service for asthma and COPD was inappropriate as alleged and no breach of the Code was ruled.

The Panel noted its comments and rulings above and did not consider that the complainant had provided evidence to show that the company's activity was misleading patients and clinicians to increase their prescription numbers as alleged and no breach of the Code was ruled.

The Panel noted its ruling above of a breach of the Code with regard to the absence of prescribing information and, noting the requirements for package deals, ruled that AstraZeneca failed to maintain high standards in breach of the Code. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use and no breach was ruled.

An anonymous, non-contactable complainant who described him/herself as a respiratory nurse, complained about a Symbicort Turbohaler (budesonide/formoterol) package deal offered by AstraZeneca UK Limited and about the company's Turbu+ website.

Symbicort was indicated for certain patients with asthma and/or chronic obstructive pulmonary disease (COPD) depending on the formulation.

COMPLAINT

The complainant alleged that he/she was informed by colleagues that AstraZeneca was offering a deal with Symbicort Turbohaler which also involved supporting patients via a contracted third party healthcare services partner, where a nurse called the patient to talk them through the Turbu+ device. The complainant stated that representatives were also promoting the programme as a deal where there was a requirement to prescribe 15 Symbicort Turbohalers for 1 device. The complainant alleged that that was an inducement to prescribe, and the device was only available for selected number of patients. The complainant did not consider that this was a financial deal, rather a set up to get clinicians to prescribe the company's product so the patient would receive a few calls from a third party nurse.

The complainant also referred to being provided with the website www.turbuplus.info.co.uk and alleged that the information was aimed at health professional and Turbu+ users, however, the prescribing information was missing from the website. The complainant noted that by clicking the AstraZeneca logo in the top left corner of the page, viewers would be directed to AstraZeneca.com which seemed to be a global page without a UK ID. The information on that website was mainly aimed at asthma patients, however, the AstraZeneca representatives were promoting this service for both COPD and asthma patients. The complainant was concerned that the company's activity was misleading the patients and clinicians to increase their prescription numbers.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 4.1, 7.2, 9.1, 15.9, 18.1 and 2 of the Code.

RESPONSE

AstraZeneca noted that the complainant had alleged that the Symbicort Turbu+ package deal was an inducement to prescribe because of an alleged requirement to prescribe 15 Symbicort Turbohalers to receive one Turbu+ device. AstraZeneca refuted the allegation for the following reasons:

1 The Symbicort Turbu+ package deal was intended for NHS bodies only (eg CCGs (clinical commissioning groups), PCNs (primary care networks), health boards, or trusts) – it was not intended for prescribers. Moreover, as described below, the package deal did not offer any direct benefit to a prescriber, pecuniary or otherwise – by definition, this could not constitute an incentive or inducement to prescribe.

2 As the package deal was aimed at NHS bodies, AstraZeneca decided to engage senior financial and clinical decision makers within those NHS bodies via a specific group of representatives only – AstraZeneca did not publicise the package deal to individual prescribers, practices or patients.

3 The package deal did not entail writing 15 additional prescriptions for Symbicort in order to receive one Turbu+ device; that allegation was categorically false. A '15:1' ratio was only used to analyse retrospective prescribing data to determine the maximum allocation of Turbu+ devices for any particular NHS body. Therefore, it was not possible, under any circumstances, for that ratio to influence prescribing behaviour.

4 AstraZeneca had no influence over which GP practices were enrolled into the package deal by NHS bodies and so it could not, and did not, direct provision of the offering to any particular practice.

5 AstraZeneca also had no influence over which patients could be issued a Turbu+ device, and so it could not, and did not, direct provision of the offering to any particular patient.

AstraZeneca further explained that the Turbu+ device comprised a connected 'add-on' device, designed to connect exclusively on to a Symbicort Turbohaler inhaler, to help patients optimally manage the use of the medicine on a daily basis (ie the device facilitated improved adherence to daily therapy with an inhaled corticosteroid and a long-acting beta agonist (ICS/LABA)). Turbu+ also included an associated patient-facing digital application, which linked to the device via Bluetooth, to record the patient's medication usage data. The Turbu+ device and app registered actuations of the Turbohaler and could assist patients (via the application) and their clinicians (remotely via the health professional portal) to monitor adherence, which was critical to ensuring that patients remained well-controlled and reduced the risk of severe exacerbations.

The Symbicort Turbu+ package deal had been developed by AstraZeneca in accordance with Clause 18.1 of the Code, which permitted 'the provision of certain associated benefits as part of the purchase price' of a particular medicine. In this instance, the 'associated benefits' of the Turbu+ package deal were:

a) provision of the connected add-on Turbu+ device itself, and
b) an optional nurse resource (via a third party healthcare services partner) to register and train those patients whose health professional had offered them the Turbu+ package.

The package deal (and associated contractual agreements) could only be taken up by NHS bodies (such as CCGs, PCNs, health boards, or trusts), therefore, it was only discussed with senior decision-makers (clinical and financial) within those bodies. Individual prescribers received no personal benefit from the package deal, whether pecuniary or otherwise. Benefit was only received by patients, by virtue of receiving digital or nurse support on how to optimally manage use of their inhaled medicine, with a view to improving symptom control and reducing the risk of exacerbations. By definition therefore, this package deal could not be construed as an incentive or inducement to prescribe in any way.

AstraZeneca submitted that it intentionally selected a specific group of representatives to promote the package deal to senior financial and clinical decision-makers within NHS bodies. The selected representatives received comprehensive training on the conduct, promotion and target audience for the package deal. The group included the regional health manager team, a select number of secondary care account specialists and one regional business manager. Other commercial representatives were told about the package deal but were not instructed to take any action.

AstraZeneca noted that whilst the Code did not preclude engagement on the package deal with a broader group of stakeholders, including prescribers, a business decision had been made to focus engagement solely on senior decision makers within NHS bodies. Furthermore, as an additional precaution, all team members were made aware of the following statement that was present in all relevant briefing materials: 'Any decisions relating to a patient's treatment should be made solely by the treating clinician. Under no circumstances should this programme be introduced in a way to influence or incentivise prescribing behaviours.'

As explicitly stated above, the package deal did not incentivise prescribers to prescribe Symbicort. With regard to the complainant's misunderstanding regarding the alleged requirement to prescribe 15 Symbicort Turbohalers to receive one Turbu+ device, AstraZeneca explained that the maximum allocation of Turbu+ devices for an NHS body was calculated by referencing the number of prescriptions of Symbicort Turbohaler over the previous 12 month period within that region or group of practices. AstraZeneca made an assumption that it would be reasonable to provide a maximum allocation of one Turbu+ device per 15 prior Symbicort prescriptions. The data that was used to make that assumption was derived from https://openprescribing.net/, and the process that was followed was clearly explained in detail in the contractual agreement between AstraZeneca and the NHS body (a copy of the authorisation form was provided). AstraZeneca noted, for the avoidance of any doubt, that the ratio was only used to inform the maximum allocation of Turbu+ devices for particular NHS body.

In summary, AstraZeneca submitted that it was abundantly clear that the complainant had been misinformed regarding the relevance of the 15:1 ratio and how it was applied in the package deal. The ratio was not influenced by, nor could it influence prescribing behaviour, nor which patients were afforded access to Turbu+.

AstraZeneca stated that the identification of GP practices to be included in the package deal was entirely at the discretion of the NHS body that had signed up to it. It was the NHS body's responsibility alone to notify each primary care or secondary care institution of the package deal and to inform AstraZeneca of those that wished to be enrolled.

AstraZeneca acted in an administrative capacity only, facilitating contact between the relevant institution and its third party, when required. Therefore, AstraZeneca had absolutely no influence over which NHS practices (or their prescribers) did or did not receive access to the package deal.

AstraZeneca added that it played no role and exerted no influence over the identification or enrolment of patients onto Turbu+. A patient could be enrolled on to Turbu+ by:

a) the GP practice directly, if that practice had the capability and capacity to register and train patients on the Turbu+ device itself, or
b) the third party, if the GP practice did not have capability/capacity and requested the services of the third party to support registration and training of patients.

In the first scenario, practices would identify, contact, register and train patients in line with their internal processes, which were completely independent of AstraZeneca or its third party. In the second scenario, the third party was invited to sign a master services agreement (MSA) with the practice directly, which would allow it to contact, register and train suitable patients identified by the practice. Consent from patients in order to be contacted by the third party, on behalf of their GP practices, was captured under the MSA, which followed strict protocols (conducted by the

third party). AstraZeneca submitted that it had no influence over patient consent or the process at any point. An example MSA with the third party was provided.

In summary, AstraZeneca submitted that the complainant's allegation that the package deal constituted an inducement to prescribe, was unfounded and false and it denied any breach of Clauses 7.2, 9.1, 15.9, 18.1 and 2.

AstraZeneca noted that the complainant had further raised concerns that the Turbu+ website (ref GB-18532). With regard to the comment that the website required prescribing information, AstraZeneca did not believe that it did; it was neither a requirement, nor standard practice, to place prescribing information on materials that were deliberately intended for patient use. AstraZeneca explained that the Turbu+ website was a repository for patient materials, in order to support those who had consented and been enrolled onto the Turbu+ device by their health professionals. It was also deemed appropriate for health professionals to have access to the website, as this was analogous to how print items of patient materials would normally be delivered to health professionals via face to face meetings in order to discuss with, or to pass on to their patients directly. AstraZeneca noted that patients were signposted to the materials by their health professional only (or delegates with their authority).

When visiting the Turbu+ website, users were required, upon landing, to make a declaration as to whether they were:

a) health professionals participating in the Turbu+ device programme
b) patients participating in the Turbu+ device programme or
c) members of the public.

Choosing either (a) or (b) allowed users to view the content within, whereas option (c) signposted members of the public to the AstraZeneca UK public website (www.astrazeneca.co.uk).

A patient or health professional participating in the Turbu+ device programme had access to two resources, both of which had been certified as standalone items for patient use. The two resources found on the website were:

a) A Turbu+ instruction video (ref GB-16681) which provided the patient with an overview of the functionality of the device and its associated app, and guidance on how to connect the Turbu+ device to the Symbicort Turbohaler.
b) A Turbu+ user guide (ref GB-16682) providing similar content to the video in written form.

The intention of the video and the user guide was to outline the functionality of the add-on Turbu+ device, rather than the use of the Symbicort Turbohaler itself. There was a single mention of Symbicort Turbohaler in the user guide, stating that 'using a Symbicort inhaler bears no obligation to also use the Turbu+ device and programme'. As a result, patient adverse event reporting statements were included in both materials, in line with Clause 26. All materials were written in patient-friendly language and the intended use was clear on each piece.

In summary, AstraZeneca considered that as the patient-facing site focused on the use of an add-on device, prescribing information was not required on the Turbu+ website and therefore it denied any breach of Clauses 4.1, 7.2 or 9.1.

With regard to the complainant's comments about the link to the global AstraZeneca.com page without a UK approval number, AstraZeneca submitted that it was permissible to link to another AstraZeneca website without a UK ID number. The global AstraZeneca website was a public site and, therefore, linking to it did not constitute a breach of the Code. It was not a requirement to restrict links to UK sites only, so long as their content complied with the UK Code. AstraZeneca submitted that again this allegation was misinformed and it refuted any suggestion that Clauses 7.2 or 9.1 had been breached.

AstraZeneca noted the complainant's comments that representatives were promoting the service for COPD and for asthma while the content within the website was mainly aimed at asthma patients. AstraZeneca submitted that the materials on the website were suitable for both COPD and for asthma patients. As Symbicort Turbohaler was licensed for both, AstraZeneca made the package deal available across both diseases so as not to discriminate. The main purpose of the patient materials on the Turbu+ website was to outline the functionality of the Turbu+ device, which was the same, regardless of whether the patient had asthma or COPD. The content of the video was not disease area specific and was suitable for all patients. However, given that the Turbu+ device was currently predominantly used by asthma patients (internal data showed that 96.6% of all patients using the Turbu+ device were asthma patients), it was entirely reasonable that some materials (ie the user guide) might be more directed towards patients with asthma.

AstraZeneca refuted any suggestion that Clauses 7.2 or 9.1 had been breached.

In summary, AstraZeneca submitted that both the Symbicort Turbu+ package deal and the Turbu+ website complied with the spirit and letter of the Code. All activities and materials were accurate, unambiguous and not misleading. Crucially, there was no evidence that any activity or material relating to the package deal or website conferred any benefit to individual prescribers, whether pecuniary or otherwise, and, therefore, the package deal did not, and could not, constitute an incentive or inducement to prescribe.

AstraZeneca strongly refuted any suggestion of breaches of Clauses 4.1, 7.2, 9.1, 15.9, 18.1 or 2 of the Code.

AstraZeneca strongly believed that this complaint had been informed and solicited by a competitor in order to deliberately avoid inter-company dialogue. All of the allegations were false and/or based on misinformation. Whilst the company welcomed the opportunity to defend the activity in question and demonstrate its commitment to compliance with the Code, this response had taken a considerable amount of time to form – AstraZeneca would like to openly express its concern that other companies were using anonymous complaints as a means to divert the attention of its staff from their regular duties by immediately involving the PMCPA, rather than seeking clarification or corrections with AstraZeneca directly. AstraZeneca had seen a considerable reduction in the number of inter-company discussions over recent years, with a dramatic increase in the number of anonymous complaints. AstraZeneca was sensitive to the Panel's challenging position with regard to determining the authenticity of such complaints, but it was eager to work with the Panel to improve the situation, either by investigating options for more thorough screening processes, or by changing the process for inter-company dialogue in order to reduce the differences between it and the relative ease of submitting anonymous complaints.

PANEL RULING

The Panel noted that Clause 18.1 prohibited the provision of, offer or promise of, a gift pecuniary advantage or benefit to health professionals or 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 subject to the provisions of Clauses 18.2 and 18.3. The supplementary information to Clause 18.1 Package Deals states, *inter alia*, that Clause 18.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

The Panel noted AstraZeneca's submission that the Symbicort Turbu+ package deal included the 'associated benefits' of the provision of the connected add-on Turbu+ device itself, and an optional nurse resource (via a third party) to register and train those patients whose health professional had offered them the Turbu+ package. The Panel noted AstraZeneca's explanation that the Turbu+ device comprised a connected 'add-on' device, designed to connect exclusively to a Symbicort Turbohaler inhaler, to help patients optimally manage the use of the medicine on a daily basis. Turbu+ also included an associated patient-facing digital application, which linked to the device via Bluetooth, to record the patient's medication usage data. The Turbu+ device and app registered actuations of the Turbohaler and could assist patients (via the application) and their clinicians (remotely via the health professional portal) to monitor adherence, which was critical to ensuring that patients remained well-controlled and reduced the risk of severe exacerbations.

The Panel noted AstraZeneca's submission that the package deal was intended for NHS bodies only and not prescribers; it was not publicised to individual prescribers, practices or patients and did not offer any direct benefit to a prescriber, pecuniary or otherwise and therefore could not constitute an incentive or inducement to prescribe. The Panel noted AstraZeneca's submission that the package deal was promoted only to senior financial and clinical decision-makers within certain NHS bodies, and that the identification of GP practices to be included in the package deal was entirely at the discretion of the NHS body that had signed up to it. It was the NHS body's responsibility alone to notify each primary care or secondary care institution of the package deal and to inform AstraZeneca of those that wished to be enrolled. AstraZeneca submitted it had absolutely no influence over which NHS practices (or their prescribers) did or did not receive access to the package deal; benefit was only received by patients, by virtue of receiving the device and digital or nurse support on how to optimally manage use of their inhaled medicine, with a view to improving symptom control and reducing the risk of exacerbations.

The Panel noted AstraZeneca's submission that any decisions relating to a patient's treatment would be made solely by the treating clinician and this programme is not seeking to influence or incentivise the individual prescribing behaviours of any health professional. The Panel further noted that AstraZeneca denied the allegation that the package deal entailed writing 15 additional prescriptions for Symbicort in order to receive one Turbu+ device; AstraZeneca submitted that the '15:1' ratio was only used to analyse retrospective prescribing data to determine the maximum allocation of Turbu+ devices for any particular NHS body.

The Panel noted that AstraZeneca made an assumption that it would be reasonable to provide a maximum allocation of one Turbu+ device per 15 prior Symbicort prescriptions; the data that was used to make that assumption was derived from https://openprescribing.net/, and the

process that was followed was clearly explained in detail in the contractual agreement between AstraZeneca and the NHS body. AstraZeneca noted, for the avoidance of any doubt, that the ratio was only used to inform the maximum allocation of Turbu+ devices for a particular NHS body. The Panel noted AstraZeneca's explanation that, therefore, it was not possible, under any circumstances, for that ratio to influence prescribing behaviour. The Panel noted that the specimen agreement between AstraZeneca and an NHS body in relation to the package deal (GB-22920) stated at Schedule 1, Offering of Package Deal that 'AstraZeneca are offering the package deal whereby for every 15 prescriptions of Symbicort Turbohaler a locality prescribes, 1 Turbo+ device shall be provided'. It did not refer to a maximum allocation or similar.

The Panel noted its comments above and did not consider that the complainant had demonstrated that the package deal was being offered as an inducement to individual health professionals to prescribe in breach of Clause 18.1 and the Panel thus ruled no breach of that Clause.

The Panel noted AstraZeneca's submission that specific representatives were selected and briefed to promote the package deal to senior financial and clinical decision-makers within NHS bodies. The group included the regional health manager team, a select number of secondary care account specialists and one regional business manager; other commercial representatives were told about the package deal but were not instructed to take any action. The Panel did not consider that the complainant had made an allegation directly or indirectly about the training or briefing of representatives and thus ruled no breach of Clause 15.9.

The Panel noted AstraZeneca's submission that the Turbu+ website was a repository for patient materials, in order to support those who had consented and been enrolled onto the Turbu+ device by their health professionals; AstraZeneca also deemed it appropriate for health professionals to have access to the website, as this was analogous to how print items of patient materials would normally be delivered to health professionals via face-to-face meetings. The Panel noted AstraZeneca's submission that visitors to the website were required, upon the landing page, to make a declaration as to whether they were: health professionals participating in the Turbu+ device programme; patients participating in the Turbu+ device programme or members of the public; the first two options allowed users to view the content within the website, whereas the third option signposted members of the public to the AstraZeneca UK public website (www.astrazeneca.co.uk).

The Panel noted AstraZeneca's submission that the Turbu+ website contained two certified patient resources: a Turbu+ instruction video (ref GB-16681) which provided the patient with an overview of the functionality of the device and its associated app, and a Turbu+ user guide providing guidance on how to connect the Turbu+ device to the Symbicort (ref GB-16682) providing similar content to the video in written form. The Panel noted AstraZeneca's submission that there was a single mention of Symbicort Turbohaler in the user guide, stating that 'using a Symbicort inhaler bears no obligation to also use the Turbu+ device and programme' and that patient adverse event reporting statements were included in both materials, in line with Clause 26 of the Code. The Panel further noted AstraZeneca's submission that all materials were written in patient-friendly language and the intended use was clear on each piece.

The Panel noted that it was, of course, acceptable for health professionals to access material designed for patients for whom they had prescribed Symbicort. The Panel noted that package deals were a promotional activity. Although the material in question was ultimately designed for

patients for whom the decision to prescribe Symbicort had been made, it was, nonetheless, an integral part of the package deal materials. In the Panel's view, it was arguable that all such package deal materials about the medicine available for health professionals ought to have prescribing information available when viewed by such health professionals. The Panel noted that the website in question stated that it was intended for patients and health professionals participating in the Turbo programme rather than just patients. In such circumstances, the Panel considered that the material ought to have prescribing information available for health professionals perhaps available by an intervening page after the health professional had clicked the 'I am a health professional' tab. The Panel ruled a breach of Clause 4.1 of the Code.

The Panel noted the complainant's statement that by clicking the AstraZeneca logo in the top left corner of the webpage, viewers would be directed to AstraZeneca.com which seemed to be a global page without a UK ID. The Panel noted that it was not necessarily unacceptable for a company to link to its company's global corporate website. Further, it was not necessarily a breach of the Code to not include a reference number on the linked website. Unique reference numbers were, however, referred to in the Guidelines on Company Procedures relating to the Code of Practice at the back of the Code (2019 Code). The Panel did not consider that the complainant had established, on the balance of probabilities, that in linking to the global AstraZeneca.com page without a UK approval number AstraZeneca had failed to maintain high standards and no breach of Clause 9.1 was ruled.

The Panel noted the complainant's allegation that the information on 'this website' was mainly aimed at asthma patients, however, AstraZeneca representatives were promoting the service for both COPD and asthma patients. The Panel considered that the UK, as opposed to the global website, was the subject of this allegation and AstraZeneca had responded accordingly. The Panel made its rulings in that regard. The Panel noted AstraZeneca's submission that the materials on the website were suitable for both COPD and for asthma patients as Symbicort Turbohaler was licensed for both and AstraZeneca made the package deal available across both diseases. The Panel noted AstraZeneca's submission that the main purpose of the patient materials on the Turbu+ website was to outline the functionality of the Turbu+ device, which was the same, regardless of whether the patient had asthma or COPD. The Panel further noted AstraZeneca's submission that the content of the video was not disease area specific and was suitable for all patients; given that the Turbu+ device was currently predominantly used by asthma patients (96.6% of Turbu+ patients were asthma patients). The Panel noted AstraZeneca's submission that it was, therefore, reasonable that the user guide might be more directed towards patients with asthma. The Panel did not consider that the complainant had established that the content of the website was such that promoting the service for asthma and COPD was inappropriate as alleged and contrary to the requirements of Clause 9.1. No breach of Clause 9.1 was ruled.

The Panel noted its comments and rulings above and did not consider that the complainant had provided evidence to show that the company's activity was misleading patients and clinicians to increase their prescription numbers as alleged and no breach of Clause 7.2 was ruled.

The Panel noted its comments and ruling above of a breach of Clause 4.1 and, noting the requirements for package deals, considered that AstraZeneca had in failing to provide prescribing information failed to maintain high standards and a breach of Clause 9.1 was ruled. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use and no breach was ruled.

Complaint received **18 February 2021**

Case completed **21 October 2021**