CASE AUTH/3480/3/21

COMPLAINANT v GLAXOSMITHKLINE

Alleged breach of undertaking

A complainant who described him/herself as a concerned healthcare professional complained about an alleged breach of undertaking by GlaxoSmithKline UK.

The complainant referred to a LinkedIn post which outlined a background review of historic cases with GlaxoSmithKline repeatedly breaching the same clause but the separate cases not being linked. The complainant referred to the rulings of breaches of the Code in Case AUTH/2787/8/15, Case AUTH/3148/1/19, Case AUTH/3328/4/20 and Case AUTH/3341/5/20, and alleged that GlaxoSmithKline had therefore recurrently breached several clauses on several similar materials which was in breach of undertaking.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's submission that, given no new evidence had been put forward by the complainant and the circumstances since the latest cases in the previous year had not changed, GlaxoSmithKline believed there was no new case for the Panel to consider. The Panel noted that the present complaint concerned an alleged breach of undertaking which had not been the subject of adjudication in, and was therefore not closely similar to, any of the previous cases cited by the complainant; the discretion referred to in Paragraph 5.2 of the Constitution and Procedure was not applicable.

The complainant referred to a LinkedIn post by a third party in which the author had commented on four historic GlaxoSmithKline cases, Cases AUTH/2787/8/15, AUTH/3148/1/19, AUTH/3328/4/20 and AUTH/3341/5/20. The complainant stated that GlaxoSmithKline had recurrently breached several clauses on several similar materials and alleged a breach of the Code.

The Panel reviewed carefully the timing and details of each case including GlaxoSmithKline's submission about its remedial actions beyond immediate removal of all affected materials to ensure all possible steps were taken to avoid similar breaches of the Code occurring in the future.

The Panel noted that it was the responsibility of the complainant to state his/her case clearly. The Panel considered, on balance, that the complainant was concerned that the undertaking given in Case AUTH/2787/8/15 was breached by the subsequent cases and made its ruling on this basis.

The Panel noted that the complainant cited the rulings of a breach of one clause in all four cases and alleged a breach of undertaking in that regard. The Panel noted that it was for the complainant to establish their case on the balance of probabilities. That a similar clause had been ruled in breach of the Code across the cited cases did not

necessarily mean that such cases were automatically in breach of an undertaking. Whether a case was in breach of an undertaking depended on a consideration of all the circumstances and each case should be looked at on its individual merits. The nature of the materials/activities in question and the steps taken to avoid similar breaches in the future would be relevant. It was not possible to determine whether there was a breach of undertaking merely based on breaches of the same clause.

The Panel considered that Case AUTH/3148/1/19 was not closely similar to Case AUTH/2787/8/15 such that it was not in breach of the undertaking given in that case. In particular, the Panel noted the role of a third party in Case AUTH/3148/1/19. It followed that no breach of the Code was ruled, in relation to the alleged breach of undertaking.

The Panel considered that there were similarities between Cases AUTH/3328/4/20 and AUTH/3341/5/20 and the first case, Case AUTH/2787/8/15. In the latter case (Case AUTH/2787/8/15), the breach arose as a result of an unexpected difference in the legibility of the generic name between a staging site and the live site. In the subsequent cases, the breach arose as a result of a failure to check, in accordance with the company's standard operating procedure (SOP), the HTML format on the staging site in addition to the final form PDF format. The Panel noted the passage of time between the cases but considered that compliance with the undertaking given in Case AUTH/2787/8/15 would reasonably include checking relevant formats of digital material to ensure legibility of the non-proprietary name. The Panel considered, given that the signatory failed to undertake such checks, GlaxoSmithKline was in breach of the undertaking given in Case AUTH/2787/8/15. The Panel noted that the material at issue in the voluntary admission in Case AUTH/3341/5/20 was identified by GlaxoSmithKline as part of the company's investigation of Case AUTH/3328/4/20 to identify closely similar material to withdraw. The Panel therefore considered that a separate ruling of a breach of undertaking for each case was not warranted. A breach of the Code was ruled accordingly.

The Panel considered that an undertaking was an important document and by failing to comply with it, GlaxoSmithKline had failed to maintain high standards; a breach of the Code was ruled. The Panel noted that the supplementary information to Clause 2 included inadequate action leading to a breach of undertaking as an example of an activity likely to be in breach of Clause 2. The Panel noted the broad steps taken by GlaxoSmithKline to comply with the undertaking given in Case AUTH/2787/8/15 and to ensure that all possible steps were taken to avoid a similar breach in the future. Those actions included putting in place new processes to ensure enhanced quality control checks, review of content on different browsers and devices; the Panel considered that these appeared to be proportionate. It appeared that, had the policy implemented had been followed by the signatory, it would, on the balance of probabilities, have prevented the breach of Clause 4.3. The Panel considered that its concerns in relation to the breach of undertaking were, in the particular circumstances of this case, adequately dealt with by its breach of the Code above. On balance, the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and no breach was ruled.

A complainant who described him/herself as a concerned healthcare professional complained about an alleged breach of undertaking by GlaxoSmithKline UK Limited.

COMPLAINT

The complainant stated that he/she had read a very interesting post by a named individual on LinkedIn which outlined a background review of historic cases with GlaxoSmithKline repeatedly making the same breach but the separate cases not being linked.

The complainant referred to the text of the LinkedIn post:

> 'In 2015 GSK breached the Code (case 2787) because their non-proprietary name in a digital banner ad was illegible. GSK denied a breach of Clause 2 and the (PMCPA) Panel agreed.
>
> In 2019 it happened again (case 3148) and the PMCPA did not even rule a breach of Clause 9.1, despite this being a basic and easy-to-comply-with requirement.
>
> In 2021 it happened two more times; case 3328 - no Clause 2 was raised by the PMCPA despite the final signatory's failing to follow company approval procedures and case 3341 (again, the PMCPA did not ask GSK to consider the requirements of Clause 2).
>
> Clause 2 is alleged by the PMCPA when there are 'cumulative breaches of a similar and serious nature...' but, in most of these instances, GSK were not even asked by the PMCPA to consider a Clause 2... WHY? Clearly processes have not improved, and GSK have not learnt from past (easy-to-correct) mistakes - is this not the point of self-regulation???.'

The complainant stated that in the first case (Case AUTH/2787/8/15) GlaxoSmithKline voluntarily admitted breaches of Clauses 4.1, 4.3, 9.1, 14.1 and 28.1 of the Code. The complainant also referred to Case AUTH/3148/1/19, which again was in breach of Clause 4.3, Case AUTH/3328/4/20, which again was in breach of Clauses 4.3 and 9.1 and Case AUTH/3341/5/20, which again breached Clauses [4.9] and 9.1.

The complainant stated that GlaxoSmithKline had therefore recurrently breached several clauses on several similar materials. This was therefore in breach of Clause 29 – breach of undertaking.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 29 of the Code.

RESPONSE

GlaxoSmithKline noted that the complainant was alleging a breach of undertaking made in respect of four past Panel decisions:

a) Case AUTH/2787/8/15: Online advertisements for Incruse and Relvar ('Incruse + Relvar Voluntary Admission')
b) Case AUTH/3148/1/19: Online promotion of Seretide ('Seretide Complaint')
c) Case AUTH/3328/4/20: Illegibility of the non-proprietary name ('Avamys Complaint')
d) Case AUTH/3341/5/20: Illegibility of the non-proprietary name ('Avamys Voluntary Admission' and together with the Avamys Complaint, the 'Avamys Cases').

GlaxoSmithKline reassured the Panel that it took its obligations under the Code extremely seriously and was somewhat perturbed at the nature of this complaint which appeared to be directed towards the PMCPA and GlaxoSmithKline.

GlaxoSmithKline noted the unusual nature of the complaint in that it appeared to have been made following publication of an opinion on LinkedIn by a self-described 'Healthcare compliance and medical approval expert'. The LinkedIn post briefly described four cases concerning GlaxoSmithKline relating to banner advertising dating between 2015 and 2021 and expressed surprise that the Panel did not rule a breach of Clause 9.1 in Case AUTH/3148/1/19 and was very concerned that Clause 2 was not raised by the Authority for consideration in the two subsequent cases given apparent 'cumulative breaches of a similar and serious nature'. It would appear that the original LinkedIn post was intended as a rebuke against the Panel as much as GlaxoSmithKline and used these examples to question whether self-regulation was working.

In contrast, GlaxoSmithKline believed these cases confirmed that self-regulation was working; two of the cases were voluntary admissions, illustrating that the company was abiding by the self-regulatory principle of proactively bringing matters to the attention of the Authority on discovering materials that appeared to be non-compliant.

GlaxoSmithKline also believed that the PMCPA was correct in its decisions as to which clauses should be considered in these cases given the nature of the complaints in these cases. Simply noting that a clause had been breached more than once by a company ignored the necessity to review complaints and reports on a case-by-case basis, in detail and with specific circumstances needing to be taken into consideration. The application of the Code and continued success of self-regulation over the last sixty years was a result of careful evaluation of arguments and evidence by the PMPCA and could not be distilled in to a 'code by numbers' checklist as implied by the author of the LinkedIn post. GlaxoSmithKline believed the decisions made by the PMCPA in these cases were correct and did not reflect that self-regulation was not working, or that any breach of undertaking had occurred.

GlaxoSmithKline noted that despite the allegation of a breach of undertaking, the Authority had not taken up this complaint in the name of the Director which was the usual course of action as the Authority was responsible for ensuring compliance with undertakings.

GlaxoSmithKline also noted that the PMCPA Constitution and Procedure, Paragraph 5.2 stated: 'If a complaint concerns a matter closely similar to one which had been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint'. This wording suggested that matters that had been subject to a previous adjudication should otherwise not be reconsidered. GlaxoSmithKline presumed this was to avoid unnecessary duplicative work by the Panel and companies involved in investigating breaches that had already been thoroughly investigated and ruled upon.

As further set out below, GlaxoSmithKline asserted that neither the complaint nor the LinkedIn article mentioned any new evidence that might suggest that GlaxoSmithKline had breached specific undertakings. Rather, the complainant had drawn the unfounded conclusion that GlaxoSmithKline necessarily breached its previous undertakings on the basis that it had had four findings of a breach in relation to 'several clauses on several similar materials'. This

allegation did not reflect the detailed consideration required when reviewing case reports. Cases were considered on their own merits, and simply because GlaxoSmithKline was found in breach of Clause 4.3 in each of the four cases over a period of five years did not automatically mean there had been a breach of undertaking and it was for the complainant to prove their case on the balance of probabilities. In this case, the complainant had provided no evidence that any of the findings after the initial case were due to a breach of undertaking.

GlaxoSmithKline stated that the four cases did not show that GlaxoSmithKline had recurrently breached 'several' clauses as stated by the complainant; the only clause that was found in breach in all Cases was 4.3 (legibility of generic name), and 9.1 was in breach in three of them. Only one of the cases (the original voluntary admission) was found in breach of any other clauses.

Although they were all electronic advertisements, the materials themselves were not 'similar' as asserted by the complainant. They were for three different indications and four different brands with entirely different messaging and visuals.

A breach of undertaking was a serious matter, and GlaxoSmithKline assured the Authority that, in each of the cases, it had taken all possible steps to avoid similar breaches in the future. GlaxoSmithKline provided a summary table below.

Given no new evidence had been put forward by the complainant and the circumstances since the latest cases last year had not changed, GlaxoSmithKline believed there was no new case for the Panel to consider. GlaxoSmithKline, however, acknowledged it was at the discretion of the Director to consider whether to allow such a case to proceed in line with the Code's Constitution and Procedure. GlaxoSmithKline stated, notwithstanding its position in this regard, it had thoroughly investigated the allegations made and set out its response below.

Clause 29 – Alleged breach of undertaking

a) Incruse+Relvar Voluntary Admission (Case AUTH/2787/8/15)

GlaxoSmithKline explained that the original Case (AUTH/2787/8/15) was a voluntary admission by GlaxoSmithKline relating to an advertisement for two products for Chronic Obstructive Pulmonary Disease (COPD), Relvar and Incruse, where the generic names were noticed to be blurry in an electronic advertisement on the live site. As was usual practice across the industry, the material had been certified on a staging site. During certification on the staging site, the generic names were not blurry. This difference in the live site legibility versus that certified on the staging site was unexpected and led to an internal investigation across all electronic advertisements for these products, which uncovered a lack of prescribing information for one product mentioned in the advertisement, and release prior to certification for two other advertisements. This led GlaxoSmithKline to institute comprehensive remedial action (copy of table provided) and submission of the voluntary admission.

GlaxoSmithKline stated that it was not aware of any other breaches made in relation to these or related materials, and the complainant had not provided any evidence to the contrary. GlaxoSmithKline therefore asserted that it had fully complied with its undertakings to remove all materials found in breach and took all necessary action to ensure those errors were not repeated as set out and confirmed above.

b) Seretide Complaint (Case AUTH/3148/1/19)

Four years later, a complaint came in relating to a product in a different therapy area, asthma, (Case AUTH/3148/1/19). The dynamic digital banner advertisement at issue was made up of four rotating frames which appeared in sequential order. All obligatory elements were present and correct, with the generic name at first mention of the brand name as required by the Code. This was on the first frame of the advertisement and was found not in breach by the Panel. During investigation of the complaint, GlaxoSmithKline discovered that a static, one frame advertisement had been issued by the agency without the knowledge of GlaxoSmithKline. The agency had taken the second frame from the four-frame advertisement and supplied it for use with devices that did not support flash or moving images. In this stand-alone second frame the non-proprietary name was not immediately adjacent to the first appearance of the brand name and its appearance as part of the brand logo was not readily readable. The Panel therefore ruled a breach of Clause 4.3. In these unusual circumstances, where GlaxoSmithKline had clearly been let down by the agency, the Panel did not consider that the circumstances were such that GlaxoSmithKline had failed to maintain high standards and thus ruled no breach of Clause 9.1 of the Code.

Despite being a second finding of breach of Clause 4.3, GlaxoSmithKline disputed that this resulted from a breach of the undertaking made in the previous case. A breach of Clause 29 compliance with undertakings was generally reserved for cases where a breach of a similar nature was made with respect to the same product or activity. These two cases concerned materials in respect of different products (Incruse + Relvar vs Seretide) used in the treatment of two different therapy areas (COPD vs asthma) and published 4 years apart by different teams and as part of completely different promotional campaigns.

Importantly, the nature and root cause of the breach was different to that of the 2015 ruling and did not arise from a failure by GlaxoSmithKline to take appropriate corrective action to avoid a similar breach of the Code (GlaxoSmithKline provided a table).

GlaxoSmithKline stated that it was not aware of any similar breaches made in relation to these or related materials, and the complainant had not provided any evidence to the contrary. GlaxoSmithKline therefore asserted that it had fully complied with its undertakings to remove all materials found in breach and taken all necessary action to prevent a similar breach of the Code as set out and confirmed above.

c) The Avamys Cases (Cases AUTH/3328/4/20 and AUTH/3341/5/20)

The following year, there was a complaint that an advertisement in another therapy area (allergic rhinitis) for a product (Avamys) had a generic name that was not easily readable. The advertisement was found in breach of Clauses 4.3 and 9.1. In this case the signatory had certified the final form PDF but had not reviewed the HTML form of the advertisement on a staging site as required by GlaxoSmithKline procedures. This had meant they did not realise the generic name was blurry as the final form PDF certified in the job bag had been easily legible. On receiving the complaint, an internal review of all associated electronic advertisements revealed two others for the same medicine reviewed by the same signatory also had legibility issues and these formed the voluntary admission that was the fourth case in this complaint, Case AUTH/3341/5/20. GlaxoSmithKline was found in breach of Clause 4.3 of the Code in both these cases. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was also ruled as acknowledged by GlaxoSmithKline.

GlaxoSmithKline confirmed that it fully complied with its undertakings to remove all non-compliant materials and took all necessary action to prevent a similar breach of the Code (copy of table provided). GlaxoSmithKline stated that the complainant had not provided any evidence to suggest GlaxoSmithKline had breached its undertakings made with respect to these two cases.

While GlaxoSmithKline acknowledged high standards had not been maintained, GlaxoSmithKline asserted this did not result from a breach of undertakings made following the Incruse+Relvar Case and/or Seretide Case. As set out above, a breach of Clause 29 compliance with undertakings was generally reserved for cases where the same or similar breach was made in the respect of the same or similar materials. These latest cases concerned materials in respect of a different product (Avamys) used in the treatment of a different therapy area (allergic rhinitis) produced by a different team (and in fact a global team as opposed to local UK pharma teams as in the previous cases) and as part of completely different promotional campaigns.

GlaxoSmithKline submitted that the following three tables set out remedial actions beyond immediate removal of all affected materials to ensure all possible steps were taken to avoid similar breaches of the Code occurring in the future in line with the undertakings and assurances given in each case.

Table 1

Case AUTH/2787/8/15 (Relvar/Incruse VA)	
a)	statement to the organisation on 13 August 2015 to highlight the need to maintain the highest of standards and comply fully with both the GlaxoSmithKline internal governance framework and the Code.
b)	A review (completed 21 August 2015) of current digital advertising materials across all therapy teams.
c)	A further independent audit was carried out by an external agency following the findings, terminated in January 2016.
d)	Two senior managers presented on the case to the UK respiratory team at a meeting on 26 August 2015.
e)	A further briefing on the case together with updates to ongoing CAPA (corrective actions, preventative actions) related to digital advertising were rolled out to individual therapy brand teams within the respiratory therapeutic area.
f)	When the case was concluded with the PMCPA, it was further presented in detail at an internal GlaxoSmithKline Code Forum meeting (in October 2015).
g)	A detailed re-training was provided by a third party agency out on the requirements of the Code in November 2015 across all the in house therapy teams.
h)	A comprehensive review of the interfaces between GlaxoSmithKline and its various digital agencies was also conducted in 2015.
i)	Further, GlaxoSmithKline worked with the agency involved to put in place new processes to ensure enhanced quality control checks, review of content on

	different browsers and devices and reiterated the importance of publishing only certified material.
j)	GlaxoSmithKline also confirmed that the non-compliant advertisements were taken down immediately on finding of the breach before an investigation and subsequent voluntary admission was made.

Table 2

Case AUTH/3148/1/19 (Seretide Complaint)	
a)	GlaxoSmithKline held discussions with the agency on the deviation and they subsequently changed their processes such that all 'back-up' images were left blank, unless an approved static banner was provided. The agency ceased use of the uncertified static image on 17 January 2019 in line with its undertaking.
b)	Learnings from the ruling were shared with all marketing teams at a GlaxoSmithKline Code and Government Forum on 13 May 2019.
c)	Internal guidance documents (slide decks and checklists) on Banner advertisements were updated to include a requirement for a static, back-up image for banner advertisements as well as further clarification about the final form of banner advertisements and the need to check legibility in an image file.
d)	A communication was circulated to all relevant teams including the GlaxoSmithKline UK Pharma digital marketing team to highlight the update in guidance documents.

Table 3

Cases AUTH/3328/4/20 and AUTH/3341/5/20 (Avamys cases)	
a)	Suspending the approval of promotional items by the team of individuals who were involved in the approval of these items pending assessment of their understanding of GlaxoSmithKline processes and knowledge of Code requirements.
b)	A review of all banner advertisements relating to Avamys. This found the same legibility issue in two other advertisements and formed the Avamys Voluntary Admission.
c)	Retraining of all item owners and signatories involved on GlaxoSmithKline guidance and processes relating to digital content (in April and May 2020).
d)	ABPI Code signatory reassessment for relevant medical team on 20 May 2020.
e)	A comprehensive and company-wide external Copy Approval Audit was carried out in March 2020.
f)	Training with the agency involved for banners development and technical considerations on 14-15 May 2020.
g)	Sharing of learnings from the case at GlaxoSmithKline's regular UK Code Forum for UK pharma commercial and medical teams on 11 August 2020 for training

	purposes.
h)	Further front end monitoring process of the team involved in the breach in April-October 2020.

Following each case, GlaxoSmithKline made an undertaking that it had removed all items found in breach from circulation. GlaxoSmithKline re-confirmed that such items were discontinued and no subsequent evidence had been provided to suggest otherwise.

While GlaxoSmithKline sincerely regretted the finding of breaches in relation to its online promotional materials, each of these occurrences arose from a different root cause. In each case, GlaxoSmithKline took comprehensive action to investigate complaints, quickly and entirely withdraw all material found in breach and related material and ensured that relevant information about the matter was communicated internally to appropriate members of staff, in line with paragraph 3 of the Code guidelines on company procedures relating to the Code. The complainant had not put forward any evidence to suggest otherwise.

GlaxoSmithKline further noted that two of the cases mentioned in the complaint concerned voluntary admissions made by GlaxoSmithKline as a result of internal investigations and action taken to ensure compliance with the Code and successful self-regulation. In particular, the Avamys Voluntary Admission was initiated as a result of corrective and preventative action taken by GlaxoSmithKline to comply with its undertakings made with respect to the first Avamys Case. GlaxoSmithKline asserted it should not be penalised for making voluntary admissions and taking appropriate corrective action in relation to breaches found as a result of internal investigations.

It was never possible to guarantee a similar breach would not occur in the future, but GlaxoSmithKline took its undertakings extremely seriously and had outlined all the remedial actions that had been put in place which addressed all possible steps in order to ensure a similar breach of the Code did not happen again. Therefore, it demonstrated the commitment to self-regulation. GlaxoSmithKline also contend that whilst the cases mentioned in the complaint all involved a breach of Clause 4.3 of the Code, the nature and root cause of the first three breaches were different and did not arise from a failure by GlaxoSmithKline to take appropriate corrective action.

GlaxoSmithKline therefore denied any breach of Clause 29.

Clause 2 – Discredit to, and Reduction of Confidence in, the Industry

The Panel had asked GlaxoSmithKline to consider Clause 2 of the Code with respect to the complaint. GlaxoSmithKline noted that a Clause 2 finding was reserved for such circumstances that warranted particular censure such as (1) where patient and/or public health might be prejudiced or there was risk of inducement or pre-authorisation promotion, (2) where there was found to be inadequate action leading to a breach of undertaking or (2) where there was found to be cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

The LinkedIn article mentioned in the complaint questioned why the Panel did not ask GlaxoSmithKline to consider a Clause 2 breach as part of its response to complaints made in the Seretide and Avamys cases in particular as the author considered these to amount to

cumulative breaches of a similar and serious nature. Although all breaches were regrettable, the breaches in these cases were not so serious as to warrant a Clause 2 ruling and neither were they over a short period of time or in the same therapeutic area. Two of the cases were voluntary admissions, with one of them arising during the investigation of the third case. The repeated breach was the fact that the generic name was blurry when associated with the first mention of the brand name. The generic names appeared elsewhere in each of the advertisements apart from Incruse/Relvar, and the products were well known to their target audience. This did not prejudice patient safety, was not misleading, did not promote to the public or prior to licence and as such it was right that the Authority determined that Clause 2 did not need to be considered in the three cases where the only complaint was the generic name being blurry. The determination of which clauses were required to be considered by the respondent when the complainant was not a pharmaceutical company had to reflect the content of the complaint. It was not the role of the case preparation manager or the Panel to determine the concerns of the complainant over and above what they alleged in their complaint. In the two cases that were not voluntary admissions, the complaints were solely that the generic name was not easily readable and the Panel asked GlaxoSmithKline to consider Clauses 4.3 and 9.1 in its responses. This seemed a proportionate request based on the complaints. GlaxoSmithKline stated that it did not want an overburdensome self-regulatory system that required extra clauses be considered beyond those that the complaint would appear to warrant.

The self-regulatory system allowed for an appeal by either party if they believed the Panel had ruled incorrectly. None of the rulings went through to appeal on the grounds that Clause 2 had not been considered or that there had been a breach of undertaking.

As such, GlaxoSmithKline refuted the allegation of a breach of Clause 2.

Clause 9.1 – Maintenance of high standards

The complainant had not put forward any new evidence to suggest that GlaxoSmithKline did not, in the past and did not currently, maintain high standards with respect to ensuring compliance with the Code of its digital advertising materials. As set out above, GlaxoSmithKline asserted it had not breached any undertakings made with respect to the previous cases, had not brought the industry in to disrepute or reduced confidence in the industry and had maintained high standards to ensure all possible action was taken to implement these undertakings. As such, GlaxoSmithKline denied any further breach of Clause 9.1.

GlaxoSmithKline had taken this complaint seriously and thoroughly investigated all action taken at the time of each previous case to confirm that all undertakings were indeed complied with. medical and commercial teams involved at the time had confirmed that all corrective action communicated to the Panel as part of its response to previous decisions was taken. The complainant had not provided evidence of any specific breach in this regard.

PANEL RULING

The Panel noted that, as acknowledged by GlaxoSmithKline, as the complaint concerned an alleged breach of undertaking, this complaint would normally proceed in the name of the Director in addition to that of the complainant as the Authority is responsible for the enforcement of undertakings. The Panel noted that this was in accordance with advice previously given by the Code of Practice Appeal Board. The Panel noted that the case had, nonetheless, proceeded in accordance with the Constitution and Procedure.

The Panel noted that the complaint raised matters in relation to both GlaxoSmithKline and the PMCPA. In relation to those matters that pertained to the PMCPA, the Panel noted that those comments would be seen by the Code of Practice Appeal Board when it reviewed the report on the case prior to its publication. The Panel noted that all of the cited cases were either voluntary admissions or from non-pharmaceutical company complainants; in each case, the clauses cited by the case preparation manager were solely based on the subject matter of the original admission/complaint which would be the subject of adjudication rather than points subsequently raised in the company's responses.

The Panel noted GlaxoSmithKline's submission that, given no new evidence had been put forward by the complainant and the circumstances since the latest cases in the previous year had not changed, GlaxoSmithKline believed there was no new case for the Panel to consider. In this regard, the Panel noted that Paragraph 5.2 of the Constitution and Procedure related, *inter alia*, to the Director exercising discretion in relation to certain complaints which concerned matters which were closely similar to one which had been the subject of a previous adjudication and stated that they may be allowed to proceed at the discretion of the Director if new evidence was adduced or a change in circumstances raised doubts as to whether the same decision would be made in respect of the current complaint. The Panel noted that the present complaint concerned an alleged breach of undertaking which had not been the subject of adjudication in, and was therefore not closely similar to, any of the previous cases cited by the complainant. In the view of the Panel, the discretion referred to in Paragraph 5.2 of the Constitution and Procedure was not applicable.

The complainant referred to a LinkedIn post by a third party in which the author had commented on four historic GlaxoSmithKline cases, Cases AUTH/2787/8/15, AUTH/3148/1/19, AUTH/3328/4/20 and AUTH/3341/5/20. The Panel noted that the complainant had apparently cited a breach of Clause 4.9 rather than Clause 4.3 in error in relation to Case AUTH/3341/5/20. The complainant stated that GlaxoSmithKline had recurrently breached several clauses on several similar materials and alleged a breach of Clause 29.

The Panel noted that in Case AUTH/2787/8/15, a voluntary admission, the non-proprietary names for Relvar and Incruse were not readily readable on the online advertisements at issue and GlaxoSmithKline acknowledged breaches of Clause 4.3. The Panel noted that the material had been certified on a staging site where the generic names did not appear to be blurry. The difference between the live site legibility versus that certified on the staging site was unexpected. A number of other clauses were raised, and ruled upon, including a breach of Clause 9.1. The Panel noted GlaxoSmithKline's submission about its remedial actions beyond immediate removal of all affected materials to ensure all possible steps were taken to avoid similar breaches of the Code occurring in the future in line with the undertaking and assurance given in that case on 30 September 2015. These actions included a review (completed 21 August 2015) of current digital advertising materials across all therapy teams and work with an agency to put in place new processes to ensure enhanced quality control checks, review of content on different browsers and devices.

The Panel noted that four years later, in Case AUTH/3148/1/19, it was alleged that the ingredients for Seretide could not be seen in an online four frame advertisement for Seretide Evohaler (fluticasone/salmeterol). The Panel noted that in that case, a third-party agency, unbeknown to GlaxoSmithKline, had arranged for frame two of the four frame advertisement to be the static 'back up' frame that would be shown if there were problems with digital material when viewed on certain browsers. The Panel considered that the 'back up' frame was, in effect,

a separate advertisement for some viewers. The Panel noted that frame one of the four frame advertisement included the non-proprietary name immediately adjacent to the first appearance of the brand name and this was legible and ruled no breach of Clause 4.3 of the 2016 Code. In relation to the advertisement which consisted solely of frame two, the Panel noted that the non-proprietary name was given but it was not immediately adjacent to the first appearance of the brand name and its appearance as part of the brand logo was not readily readable, the Panel therefore ruled a breach of Clause 4.3 of the 2016 Code. The Panel did not consider that the circumstances were such that GlaxoSmithKline had failed to maintain high standards and thus ruled no breach of Clause 9.1 of the 2016 Code. The Panel noted the remedial actions beyond immediate removal of all affected materials to ensure all possible steps were taken to avoid similar breaches of the Code occurring in the future in line with the undertaking and assurance given by GlaxoSmithKline on 17 May 2019.

The Panel noted GlaxoSmithKline's submission, in relation to Case AUTH/3148/1/19, that the nature and root cause of the breach in that case was different to that of the 2015 ruling (Case AUTH/2787/8/15) and did not arise from a failure by GlaxoSmithKline to take appropriate corrective action to avoid a similar breach of the Code.

The Panel noted that in Case AUTH/3328/4/20, which was received in 2020, an online advertisement for Avamys in allergic rhinitis had a generic name that was not easily readable. In that case, the signatory had certified the final form PDF but had not reviewed the HTML form of the advertisement on a staging site as required by GlaxoSmithKline procedures and so did not realise the generic name was blurry as the final form PDF certified in the job bag had been legible. On receipt of the complaint, an internal review by GlaxoSmithKline of all associated electronic advertisements revealed two others for the same medicine reviewed by the same signatory also had legibility issues and these formed the voluntary admission that was the fourth case cited in this complaint, Case AUTH/3341/5/20. In each cited case, GlaxoSmithKline was found in breach of Clause 4.3 of the Code and in both cases, the Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled as acknowledged by GlaxoSmithKline.

The Panel noted that it was the responsibility of the complainant to state his/her case clearly. The Panel considered, on balance, that the complainant was concerned that the undertaking given in Case AUTH/2787/8/15 was breached by the subsequent cases and made its ruling on this basis.

The Panel noted that the complainant cited the rulings of a breach of Clause 4.3 in all four cases and alleged a breach of undertaking in that regard. The Panel noted that it was for the complainant to establish their case on the balance of probabilities. That a similar clause had been ruled in breach of the Code across the cited cases did not necessarily mean that such cases were automatically in breach of an undertaking. Whether a case was in breach of an undertaking depended on a consideration of all the circumstances and each case should be looked at on its individual merits. The nature of the materials/activities in question and the steps taken to avoid similar breaches in the future would be relevant. It was not possible to determine whether there was a breach of undertaking merely based on breaches of the same clause. In that regard, the Panel noted GlaxoSmithKline's submission that although it was found in breach of Clause 4.3 in each of the four cases over a period of five years, it did not automatically mean there had been a breach of undertaking.

The Panel noted the details set out in the Code of Practice Panel's rulings for each of the cases and GlaxoSmithKline's comments set out above. The Panel considered that Case AUTH/3148/1/19 was not closely similar to Case AUTH/2787/8/15 such that it was not in breach of the undertaking given in that case. In particular, the Panel noted the role of the third party in Case AUTH/3148/1/19. It followed that no breach of Clause 29 was ruled.

The Panel considered that there were similarities between Cases AUTH/3328/4/20 and AUTH/3341/5/20 and the first case, Case AUTH/2787/8/15. In the latter case (Case AUTH/2787/8/15), the breach arose as a result of an unexpected difference in the legibility of the generic name between a staging site and the live site. In the subsequent cases, the breach arose as a result of a failure to check, in accordance with the company's SOP, the HTML format on the staging site in addition to the final form PDF format. The Panel noted the passage of time between the cases but considered that compliance with the undertaking given in Case AUTH/2787/8/15 would reasonably include checking relevant formats of digital material to ensure legibility of the non-proprietary name. The Panel considered, given that the signatory failed to undertake such checks, GlaxoSmithKline was in breach of the undertaking given in Case AUTH/2787/8/15. The Panel noted that the material at issue in the voluntary admission in Case AUTH/3341/5/20 was identified by GlaxoSmithKline as part of the company's investigation of Case AUTH/3328/4/20 to identify closely similar material to withdraw. The Panel therefore considered that a separate ruling of a breach of Clause 29 for each case was not warranted. A breach of Clause 29 was ruled accordingly.

The Panel considered that an undertaking was an important document and by failing to comply with it, GlaxoSmithKline had failed to maintain high standards; a breach of Clause 9.1 was ruled. The Panel noted that the supplementary information to Clause 2 included inadequate action leading to a breach of undertaking as an example of an activity likely to be in breach of Clause 2. The Panel noted the broad steps taken by GlaxoSmithKline to comply with the undertaking given in Case AUTH/2787/8/15 and to ensure that all possible steps were taken to avoid a similar breach in the future. Those actions included putting in place new processes to ensure enhanced quality control checks, review of content on different browsers and devices; the Panel considered that these appeared to be proportionate. It appeared that, had the policy implemented had been followed by the signatory, it would, on the balance of probabilities, have prevented the breach of Clause 4.3. The Panel considered that its concerns in relation to the breach of undertaking were, in the particular circumstances of this case, adequately dealt with by the breach of Clause 9.1 above. On balance, the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and no breach was ruled.

Complaint received **1 March 2021**

Case completed **4 November 2021**