

## **COMPLAINANT v GSK**

### **Declaration of involvement in an online tool**

#### **CASE SUMMARY**

This case was in relation to an online COPD decision support tool that had been sponsored by GSK. The complainant alleged that there was no declaration of GSK's involvement at the outset of the tool's homepage and that the declaration only appeared at the end of the homepage. The complainant's concerns extended to all materials relating to the tool, including its outputs, and the complainant further alleged that all materials related to or produced by the tool should have been certified.

The outcome under the 2021 Code was:

<b>Breach of Clause 25.3</b>	<b>Failing to ensure sponsorship is clearly acknowledged from the outset.</b>
<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 5.1</b>	<b>Requirement to maintain high standards at all times</b>
<b>No Breach of Clause 8.1</b>	<b>Requirement to certify promotional material</b>
<b>No Breach of Clause 8.3</b>	<b>Requirement to certify non-promotional material</b>
<b>No Breach of Clause 25.3</b>	<b>Requirement that companies must ensure that all sponsorship is clearly acknowledged from the outset</b>

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

#### **FULL CASE REPORT**

A complaint about GSK was received from an anonymous, contactable complainant who later became non-contactable.

#### **COMPLAINT**

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

"The COPD decision tool was sponsored and had been scoped out by GSK. However, all the materials related to the tool and the outputs generated from the tool did not have a declaration from the outset of GSKs sponsorship and involvement. In addition, all the

materials/outputs related/generated by the tool should have been certified as they were HCP and public facing but this was not the case. On the following website about the tool there was no declaration of GSK involvement from the outset but this was only provided at the end of the webpage, [URL provided]. It was concerning that such prominent declarations of GSK involvement were missing from the website but also all the materials (e.g. prompts, alerts, notes) related/produced by to the tool. Prompts, alerts, notes and all aspects of the tool should have been certified. This was paramount to ensure patient safety/full transparency of GSK company involvement. There were breaches of clauses 25.3, 8.3, 5.1 and 2 of the 2021 ABPI Code of practice.”

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 25.3, 8.3, 8.1, 5.1 and 2 of the Code.

## **GSK’S RESPONSE**

The response from GSK is reproduced below:

“The complainant has made a number of allegations regarding the online tool in question and has alleged breaches of Clauses 2, 5.1, 8.3 and 25.3 of the 2021 ABPI Code of Practice. The PMCPA has also asked us to respond to these allegations bearing in mind the requirements of Clause 8.1.

The tool in question is the “COPD Decision Support Tool”, accessible from [URL provided].

The tool was developed by [named organisation] which is a [named university] spin-out company based at the University’s Centre for Medicines Optimisation. [Named organisation] holds the licence rights to the delivery of [named university’s] digital decision support tools and online support tools for healthcare professionals.

Aspects of this tool were sponsored by GSK as set out in a Sponsorship Agreement between GSK and [named organisation], dated 28<sup>th</sup> November 2019, which shall be detailed later in this response.

This tool is intended to assist UK healthcare professionals in the diagnosis and management of chronic obstructive pulmonary disease (COPD) in people aged 16 and older, and this is made clear on the webpage in question. There is no intention or implication that the tool should be used by patients or other members of the public. As detailed below, the Sponsorship Agreement is clear that the tool is not intended to promote GSK products and a signatory checked that the treatment options presented in the tool did not point to any particular medicine.

In short, we deny all breaches of the Code and will detail the reasons below.

### **Relationship with [named university]**

You have asked for full details of GSK’s relationship with [named university]. GSK does not have a direct contractual relationship with [named university] for this project. The contractual relationship is between GSK and [named organisation], a company with offices based at [named university].

[Named university]'s logo appears at the top of the [URL provided] site. The DST website states:

“Developed by [named organisation], Centre for Medicines Optimisation, [department], [named university], [address].”

The Sponsorship Agreement states:

“[Named organisation] is a [named university] spin-out company that holds the exclusive licence rights to the delivery of [named university]'s digital decision support tools and online support tools for healthcare professionals. [Named university], is a body incorporated by Royal Charter, whose administrative offices are at [address].”

The presence of the [named university] logo is therefore due to the relationship that exists between [named organisation] and [named university], where [named organisation] is based.

### **Relationship with [regional pharmacy network]**

The PMCPA has asked for full details of GSK's relationship with [regional pharmacy network]. This organisation's logo appears at the top of the [URL provided] site, alongside the [named university] logo. Further down the page is the statement:

“The [regional pharmacy network] aims to support, encourage and empower clinical pharmacists and pharmacy technicians working in primary care practice in the [region].”

There is no contractual agreement or direct relationship between GSK and [regional pharmacy network] for this project. There is a relationship between [named organisation] and [regional pharmacy network]. Due to the passage of time since the project was conceived and the movement of staff, email communications have not all been preserved, so GSK's primary contact at [named organisation], the Director who signed the Sponsorship Agreement, has re-confirmed in an email to us dated 14<sup>th</sup> May 2024, at 11:37:

“I sit on the [regional pharmacy network] Committee. When appropriate, I work with the [regional pharmacy network] membership to advise on and test primary care applications to help ensure their suitability for HCPs. We also promote the use of certain tools as and when, most usually at [regional pharmacy network] educational workshops which we organise throughout the year.”

It is GSK's understanding that [named organisation] will make healthcare professionals within [regional pharmacy network] aware of applications that it has developed and how to access and use them.

### **How a reader would navigate to or find the DST**

[Named organisation] is an organisation that develops a number of different healthcare tools in partnership with different organisations including pharmaceutical companies. Its main site is located at [URL provided]. [Named organisation] is responsible for publicising its own site to HCPs.

From here, the user can navigate via links and menus on the [named organisation] main site to a page that details the different tools that [named organisation] has developed. Clicking into the COPD DST section brings up a page, that gives a brief description of the DST, including a statement of GSK's involvement and the fact that it is intended for assisting practitioners in the diagnosis and management of COPD. A screenshot of this was taken by GSK on 10<sup>th</sup> May 2024 and sent to [named organisation] in an email as part of GSK's immediate response to the complaint (further details of this email and the responses will be discussed below).

From here the user can click to access the webpage in question.

It is also possible for HCPs to access the webpage in question directly if they know the URL.

### **Sponsorship Agreement and GSK involvement**

Schedule 1 of the Sponsorship Agreement details the project objectives, and Schedule 2 details the financial contribution to be paid by GSK. There were two Computerised Decision Support Tools developed and delivered under the Agreement – a Patient Decision Aid (PDA) for Asthma and the Prescribing Decision Support tool (DST) for COPD. The latter DST for COPD is the subject of this case and will be detailed further below. The PDA for Asthma was separately developed and approved and was hosted on a separate website accessible from the main [named organisation] site, with its own declaration of GSK involvement – this tool was not the subject of the complaint and GSK's sponsorship of its delivery ended on 13<sup>th</sup> July 2023 and so will not be discussed further in this response, however details of the arrangements are available in the Sponsorship Agreement.

The Sponsorship Agreement makes clear that [named organisation] would develop, test and launch the DST as Phase 1 of the project. It states "The Prescribing Decision Support Tool for COPD will provide patient tailored, guidance-based recommendations at the point of care. Each recommendation is generated by the CDST software cross-referencing patient-specific profiles created by the healthcare professional user with multiple treatment algorithms which are developed to reflect clinical guidance." The tool would be an "interactive user experience with dynamic feedback (recommendations, alerts, checks and prompts all consistent with NICE guidance)". It is to be noted that NICE guidance for therapeutic COPD management does not recommend specific medicines, only classes of products.

While the majority of Phase 1 was conducted by [named organisation], there were some activities in which GSK jointly took part with [named organisation]. These were the project kick-off meeting and a project scoping to establish the clinical scope of the tool (ie COPD in patients over 16 years), its functionality and the platform on which the tool would be hosted. During the development of the tool, GSK were also responsible for review and sign-off of the prototype, interface design, amendments and final version in order to ensure the tool was aligned with the requirements of the ABPI Code of Practice. This process would have required some comments to be sent from GSK to [named organisation] following reviews of draft materials, but only for the sole purpose of ensuring compliance with the Code in the final materials. Aside from these aspects, GSK did not

have control or influence on the information, prompts, alerts and notes provided or generated by the tool as this was the responsibility of [named organisation].

The Sponsorship Agreement further details Phase 2 of the project which is for [named organisation] to host the DST on a website from which practitioners can access it. This hosting support was for an initial period of 1 year following completion of Phase 1, with the option to extend the Sponsorship Agreement for further years. In the event, an extension was indeed agreed so that the DST was hosted by [named organisation] with GSK support for a total of 2 years, ending on 13<sup>th</sup> April 2023.

### **Arrangements for disclosing the involvement of GSK**

The PMCPA has asked what the arrangements were for disclosing the involvement of GSK.

Clause 6.1.3 of the Sponsorship Agreement states:

“The Decision Support Tools and all Related Materials produced and distributed or displayed by, or on behalf of the Institution in relation to the Project, shall include the following declaration of sponsorship (or equivalent wording as provided by GSK from time to time) in a sufficiently prominent position to ensure that all users of the Decision Support Tools and all those reading or viewing all materials are aware of GSK’s Sponsorship and the extent of GSK’s involvement in the Project at the outset:

*“The development of this [Decision Support Tool] and its delivery is sponsored by GlaxoSmithKline. GlaxoSmithKline was involved in scoping for the [Decision Support Tool] and has reviewed the [Decision Support Tool] for compliance with the ABPI Code”.*

Clause 9.7 of the Sponsorship Agreement further states:

“In the event that Institution continues to make available the Decision Support Tools to practitioners on expiry or termination of this Agreement and of the Sponsorship Benefits, Institution shall continue to declare GSK’s past sponsorship of the Project in the manner set out in Clause 6.1.3 above, amended as follows:

*“The development of the [Decision Support Tool] was sponsored by GlaxoSmithKline. GlaxoSmithKline no longer sponsors the delivery of the [Decision Support Tool]. GlaxoSmithKline was involved in scoping of the [Decision Support Tool] and has reviewed the [Decision Support Tool] for compliance with the ABPI Code.”*

Clause 9.8 of the Sponsorship Agreement further states:

“[Clause 9.7] will survive the termination of this Agreement for any reason and will continue indefinitely. Termination of this Agreement shall not release either party from any liability or right or action which at the time of termination has already accrued or which may thereafter accrue in respect of any act or omission prior to such termination.”

GSK decided to end its sponsorship of the delivery of the DST on 13<sup>th</sup> April 2023. It was recognised that [named organisation], as owners of the DST may be able to host, update and change the tool after this date without GSK’s knowledge, and it may not be clear to

users that GSK was not involved with such updates. It was therefore felt prudent to ask [named organisation] to add a more detailed transparency statement than required by Clause 9.7 of the Sponsorship Agreement, so that the specific end date of GSK's sponsorship was clarified to users of the DST. On 3<sup>rd</sup> April 2023, an email was sent by GSK's [senior commercial employee] to the Director of [named organisation] who had signed the Sponsorship Agreement. This stated that the declaration wording should be updated to read:

"The development of the Toolkit and its delivery was sponsored by GlaxoSmithKline until 13<sup>th</sup> April 2023. GlaxoSmithKline was involved in scoping for the Toolkit and reviewed the Toolkit for compliance with the ABPI Code."

It was GSK's intention and understanding that the new declaration specifying the end of the sponsorship on 13<sup>th</sup> April 2023 would replace the existing declaration in all places where it was located and that these declarations would be present indefinitely as per Clauses 9.7 and 9.8 of the Sponsorship Agreement.

### **Review for Code compliance during development**

Before moving onto events that have transpired since the end of GSK's sponsorship of the delivery of the DST, it is important to understand the steps taken during development to ensure that materials were compliant with the Code.

[Copy provided] is a chain of emails between GSK's [employee] who was the liaison with [named organisation], and the [senior medical employee] who is a signatory (qualifications: [details provided]). On 11<sup>th</sup> September 2020 at 16:10, the signatory commented on the test site of the webpage in question, stating:

**"I can see the GSK sponsorship declaration is there on the first frame of the page [emphasis added].** The treatment options are based on NICE, and do not point to any particular medicine. Some of the information provided on inhalers is from PCRS [Primary Care Respiratory Society] and is not scientifically incorrect."

This demonstrates that a signatory examined the test site of the webpage and confirmed that the GSK declaration of involvement was present from the outset and also that the DST was non-promotional in nature.

Following some further amendments to clarify the UK licensed indications for classes of products, the output screens which detailed therapeutic recommendations at the class level were reviewed by the signatory who confirmed in an email on 28<sup>th</sup> October 2020 at 17:30 that she was "Happy to proceed". Annotated screenshots of these outputs are attached.

It is important to note at this stage that GSK approval policy goes beyond the requirements of the Code for certain non-promotional materials, and these materials are certified even though only examination is required under the Code. This will be discussed further later in this response when discussing our response to the allegation of breach of Clause 8.3.

Following further development of the hosting platform, another signatory (qualifications: [details provided]) certified the final version on 13<sup>th</sup> April 2021 prior to it being made live on the [URL provided] site. The certificate stating “It is certified that the final electronic version of this non-promotional material has been examined and is believed to be in accordance with the requirements of the relevant regulations relating to advertising and with the GSK UK Code of Practice (incorporating the ABPI Code of Practice the GSK Code of Practice and relevant GSK policies)” is attached. Screenshots from the webpage and a selection of screenshots of the tool taken at the time are attached. This shows that the GSK declaration of involvement was positioned directly underneath the buttons that must be clicked to create or open an existing patient profile and enter the DST tool. This declaration stated:

“The development of the Toolkit and its delivery is sponsored by GlaxoSmithKline. GlaxoSmithKline was involved in scoping for the Toolkit and has reviewed the Toolkit for compliance with the ABPI Code.”

This statement was also present towards the bottom of the page as a reminder for HCPs who were reading the entire page before entering the tool.

The screenshots also show pages of the website which were accessible by clicking the menu buttons underneath the [named university] and [regional pharmacy network] logos – it is to be noted that the user would already have seen the GSK declaration prior to navigating to these other pages and therefore the GSK declaration was not on all subsequent pages. The screenshots also show a selection of static pages from the tool that could be generated by inputting patient characteristics. Due to the dynamic nature of the tool it was not feasible to screenshot every possible selectable combination of options, however output screens recommending different classes of treatment were certified by the second signatory in the final electronic staging site, and had also been previously examined during development by the first signatory in October 2020.

In November 2021, the site was updated. The only material change was to update the MHRA website link for adverse event reporting. The whole site and tool were again certified by the second signatory. The certificate is attached, and the static screenshots of the website taken at the time are attached.

Up until the sponsorship ended, this November 2021 version of the webpage was live. As discussed in the previous section, as the end of the sponsorship approached in April 2023, GSK asked [named organisation] for the declarations of GSK involvement to be updated to accurately reflect the end date of the sponsorship.

### **Complaint investigation and immediate actions**

After learning of this complaint on 9<sup>th</sup> May 2024, GSK’s preliminary investigation confirmed that the statement of GSK involvement was no longer present near the top of the DST site, although it was present further down the page. GSK took swift action to ask [named organisation] to reinstate the declaration in the previously agreed prominent location.

An email was sent on Friday 10<sup>th</sup> May 2024 by GSK’s [senior commercial employee] to the Director of [named organisation] who had signed the Sponsorship Agreement, to request this reinstatement. This email pointed out the location of the previous prominent

declaration from the November 2021 version of the DST site (first screenshot in email) and the blank area in the current live version where the declaration used to be (second screenshot in email). The email also pointed out that the main [named organisation] site still had the older GSK declaration which did not specify the end date of the sponsorship (third screenshot in email).

The Director from [named organisation] replied on Tuesday May 14<sup>th</sup> 2024, at 10:37 to say “Sorry about that. Not entirely sure what happened there but all fixed now.” He also confirmed at 13:28 in the same email chain that he did not know when the declaration had come off from the location near the top of the DST page, but confirmed it had always be present further down the page.

GSK has confirmed that the latest declaration of historical sponsorship is now present at the intended prominent location on the DST site and also on the main [named organisation] site.

GSK exercised due diligence in having specific Clauses in the Sponsorship Agreement that required [named organisation] to maintain the prominent declaration of GSK involvement even after the Agreement ended, and in providing [named organisation] with specific wording to use. As soon as GSK was made aware of the removal of the prominent declaration on the third party site, we took action to ask them to reinstate it under the terms of the Sponsorship Agreement.

### **Clause 25.3 allegation**

The complainant states:

“The COPD decision tool was sponsored and had been scoped out by GSK. However, all the materials related to the tool and the outputs generated from the tool did not have a declaration from the outset of GSKs sponsorship and involvement.”

“On the following website about the tool there was no declaration of GSK involvement from the outset but this was only provided at the end of the webpage, [URL provided].”

“It was concerning that such prominent declarations of GSK involvement were missing from the website but also all the materials (e.g. prompts, alerts, notes) related/produced by to the tool.”

Clause 25.3 of the Code requires that pharmaceutical companies clearly acknowledge all sponsorship **from the outset** [emphasis added]. There is no requirement for sponsorship to be acknowledged at subsequent points in the user’s journey, if the sponsorship has already been clearly acknowledged at the outset. There is no declaration of GSK involvement within the tool itself, as users will have seen the declaration prior to entering the tool. The user of the DST would either go through the main [named organisation] site at [URL provided] before clicking into the DST site at [URL provided] in order to access and use the tool, or they could access the DST site directly if they knew the URL. If users had come via the main [named organisation] site, they would have seen a declaration of GSK involvement before coming to the DST site. Once on the DST site, the declaration of GSK involvement was present prominently in the first frame of the site, as confirmed by a signatory, during the 2-year lifetime of the sponsorship agreement, as well as further down

the webpage. Users of the DST would have been aware of this declaration prior to entering the tool and viewing any information and outputs produced by the tool. This fulfilled the requirements of Clause 25.3 and therefore GSK denies a breach of this Clause.

As explained above, GSK asked [named organisation] to ensure the declaration was updated when the sponsorship ended. The Sponsorship Agreement did require [named organisation] to maintain the declaration so it was apparent from the outset, after the Agreement had ended. At some point after the Agreement ended, the declaration appears to have been inadvertently removed by [named organisation] from near the top of the DST webpage (although it was maintained further down the page), and it has not been possible to determine how or when this happened. While this is indeed regrettable, GSK does not believe this breached Clause 25.3 of the Code as the delivery of the DST was no longer being sponsored by GSK at the point the complaint was made and the tool was owned wholly by [named organisation] at that time. As soon as GSK became aware of this, we asked [named organisation] to reinstate the statement, which they have done promptly, in line with the requirements of the Sponsorship Agreement.

GSK does not believe that there is a requirement under the ABPI Code of Practice for a pharmaceutical company to continue to monitor third party content after a Sponsorship Agreement with the third party has ended, in cases where that content is not owned by the company.

GSK also believes it would be detrimental to the NHS and ultimately to patients if there were a requirement for pharmaceutical companies to stipulate the withdrawal of third party non-promotional sponsored materials that are in use by and beneficial for healthcare professionals in their management of patients, following the end of the sponsored period.

On a practical level, it is not feasible for a pharmaceutical company to constantly monitor a third party website for changes indefinitely, following the end of a contract.

### **Allegations regarding certification (Clauses 8.1 and 8.3)**

The complainant has made allegations about the requirement to certify the DST and related materials as per Clause 8.3 of the Code:

“...all the materials/outputs related/generated by the tool should have been certified as they were HCP and public facing but this was not the case.”

“Prompts, alerts, notes and all aspects of the tool should have been certified.”

You have also asked us to respond with regard to Clause 8.1 of the Code.

It is important to note that contrary to the complainant's allegation, the tool was not public facing. There are clear statements on the [URL provided] site that indicate the tool is for use by healthcare professionals:

“Supporting clinical decision-making & prescribing”

“This decision support tool is designed to assist UK healthcare professionals in the diagnosis and management of chronic obstructive pulmonary disease...”

“The tool is intended to support clinical decision-making and prescribing and not replace the healthcare professional's clinical judgement. The healthcare professional user of the tool should use their own clinical judgement when considering and/or acting upon the prompts, alerts, notes and recommendations arising from using the tool and they are responsible for checking a drug's summary of product characteristics to inform decisions made with individual patients.”

“This tool is only intended for use by qualified healthcare professionals working within the United Kingdom.”

Turning to the issue of certification, it is GSK's position that under the Code the webpage in question and the DST do not require certification.

Clause 8.1 relates to the requirement to certify promotional materials. The DST materials were not promotional materials and therefore Clause 8.1 did not apply in this case.

The Sponsorship Agreement states in Clause 4.7:

“GSK and Institution each confirm that the Sponsorship is not linked in any way to the prescription, supply, administration, recommendation, purchase or sale of any medicine by the Institution, any of its employees or any other participants in or beneficiaries of the Project. GSK is in no way seeking endorsement of its products by Institution, any of its employees or any related party.”

The first signatory who reviewed the test site of the DST stated in an email on 11<sup>th</sup> September 2020 at 16:10:

“The treatment options are based on NICE, and do not point to any particular medicine”.

Screenshots of the tool which do not show any pointing to any particular medicine have also been reviewed by two signatories as described above. One of these signatories certified the final site in April 2021 before it went live for the first time, and again for a minor update in November 2021, and the certificates state these are non-promotional materials.

We consequently deny a breach of Clause 8.1.

Clause 8.3 relates to the requirement to certify certain non-promotional materials. The Code states six categories of non-promotional materials that require certification: educational material for the public or patients; material relating to working with patient organisations; material relating to collaborative working; material and items for patient support; written agreements for donations and grants; and protocols relating to non-interventional studies. The COPD Decision Support Tool did not fall into any of these categories, and therefore the certification requirements of Clause 8.3 did not apply in this case.

Clause 8.3 Supplementary Information states:

“Material issued by companies which is not required to be certified under the Code should be examined by a signatory... to ensure that it does not contravene the Code or the relevant statutory requirements.”

GSK approval policies go beyond the requirements of the Code in this regard and certain non-promotional materials that only require examination under the Code are certified by a signatory. The certificates for such non-promotional materials state: “It is certified that the final electronic version of this non-promotional material has been examined and is believed to be in accordance with the requirements of the relevant regulations relating to advertising and with the GSK UK Code of Practice (incorporating the ABPI Code of Practice the GSK Code of Practice and relevant GSK policies).”

The final electronic versions of the website and tool were certified as non-promotional materials by a signatory. The screenshots of the materials certified are available. The certificates are available.

The materials were certified under GSK policy, however certification was not required under Clause 8.3 of the Code, and we consequently deny a breach of Clause 8.3.

### **Allegations regarding Clauses 5.1 and Clause 2**

Throughout the review process of the DST tool, GSK ensured that its comments to the developer were only made to ensure compliance with the ABPI Code of Practice. This ensured that the declaration of GSK involvement was prominent from the outset to users for full transparency and also ensured that the tool was not promotional as there was no pointing to particular products.

GSK also took steps through the Sponsorship Agreement to ensure that the third party had responsibility to maintain the prominent declaration of GSK’s involvement even after the sponsorship agreement had ended. Although GSK cannot feasibly monitor third party sites for changes indefinitely, we took immediate action as soon as we became aware that the declaration was no longer in a prominent location on the DST site, and we contacted the third party to fix the error which was done promptly. At no point did GSK ask for the declaration to be removed from its prominent location, nor were we aware this had been done until we received the complaint.

The complainant has mentioned patient safety in their complaint however they have not provided any details about why they believe patient safety may have been compromised. Outputs of the DST tool were based on NICE recommendations for classes of products. GSK does not believe that patient safety would be compromised by an HCP using this tool as intended. The tool was clearly not intended to be used by patients.

We consequently believe we have maintained high standards and deny any breach of Clause 5.1. We also do not believe we have acted in any way to bring discredit upon or reduce confidence in the pharmaceutical industry and therefore we deny any breach of Clause 2.

[Information relating to enclosures]

### **Conclusion**

In conclusion, GSK believes it has fulfilled all Code requirements regarding approval of non-promotional materials, and denies breaches of Clauses 8.1 and 8.3.

GSK believes it has ensured its involvement in a sponsored tool for HCPs has been declared from the outset for the entire duration of the sponsorship and denies a breach of Clause 25.3.

Consequently GSK denies breaches of Clauses 5.1 and 2.”

## **PANEL RULING**

This case related to an online COPD decision support tool that had been sponsored by GSK. The complainant alleged that there was no declaration of GSK’s involvement at the outset of the tool’s homepage and that the declaration only appeared at the end of the homepage. The complainant’s concerns extended to all materials relating to the tool, including its outputs, and the complainant further alleged that all materials related to or produced by the tool should have been certified.

GSK submitted the tool was developed by a named organisation that was a spin out company from a UK university and was designed to assist UK healthcare professionals in the diagnosis and management of COPD.

The Panel noted from the sponsorship agreement, dated November 2019, that the named organisation held the exclusive rights to the delivery of the decision support tool and that there were two phases that GSK had sponsored. Phase 1 related to the development, testing and launch of the tool and Phase 2 to its hosting.

In its response, GSK stated while the majority of Phase 1 was conducted by the named organisation, some activities were performed jointly. GSK submitted its involvement in Phase 1 included a kick-off meeting and project scoping to establish the clinical scope of the tool, its functionality and the platform on which it would be hosted. It was also involved in the review and sign off on the final version of the tool to ensure Code compliance. GSK submitted it did not have control or influence on the information, prompts, alerts and notes provided or generated by the tool although the Panel noted from an email that GSK had requested to clarify the licensed indications for certain treatments, including ICS/LABA and LAMA/LABA combinations.

The Panel noted that the sponsorship agreement included an initial one-year hosting period following the tool’s launch date which was made live in April 2021. The agreement was subsequently extended for an additional year, with the sponsorship ending in April 2023.

The Panel noted the sponsorship agreement included an obligation to declare GSK’s sponsorship at the outset of all materials and that the agreement required an amended declaration after the sponsorship period.

The Panel observed from a screenshot provided by GSK that when the sponsorship was live, the original declaration had appeared twice on the homepage: once towards the top of the homepage and another towards the bottom amongst other information about the organisations involved. The wording used during the period of sponsorship stated:

“The development of the Toolkit and its delivery is sponsored by GlaxoSmithKline. GlaxoSmithKline was involved in scoping for the Toolkit and has reviewed the Toolkit for compliance with the ABPI Code”

At the time of the complaint in May 2024, a screenshot provided by the complainant of the tool's homepage showed the declaration at the top of the page had been removed. Only the declaration positioned towards the bottom remained, which had been updated to reflect the end of the sponsorship:

“The development of the Toolkit and its delivery was sponsored by GlaxoSmithKline until 13<sup>th</sup> April 2023. GlaxoSmithKline was involved in scoping for the Toolkit and reviewed the Toolkit for compliance with the ABPI Code.”

GSK submitted it appeared that the declaration had inadvertently been removed after the sponsorship had ended but that it was not possible to determine how or when this had happened. The Panel noted GSK requested the named organisation to reinstate the declaration a day following receipt of the complaint, which was acted upon and confirmed within four days.

The first matter for the Panel to consider was whether the failure to maintain a declaration at the outset on the homepage of the tool, following the expiry of the sponsorship agreement, amounted to a breach of Clause 25.3.

The Panel took into account that the sponsorship agreement included the requirement to disclose GSK's involvement at the outset and that the sponsorship agreement required an amended version upon expiry to remain in the same manner.

The Panel observed an email between GSK and the named organisation, ten days prior to expiry of the agreement, included an action for GSK to “feed back to [named individual at named organisation] on what declaration is needed on the DST [decision support tool] website when the agreement the DST finishes.” The email asked that the current wording be updated once the agreement came to an end. There was no reference to the location or occurrence of the declaration(s).

Clause 25.3 included that companies must ensure that all sponsorship is clearly acknowledged from the outset. The wording of the declaration of sponsorship must be unambiguous and accurately reflect the extent of the company's involvement and influence over the material.

The Panel considered that, in certain circumstances, a declaration of involvement ought to appear on materials after the expiry of a sponsorship agreement and that whether this was so would be decided on a case-by-case basis.

The Panel took into account GSK's involvement as the sole sponsor of the tool and that the declaration appeared at the outset of the homepage during the sponsorship. The declaration at the outset had been removed at a time when the delivery of the tool was no longer sponsored by GSK. The agreement required continued declaration of its involvement after the expiry of the agreement and whilst GSK had requested the declaration be updated prior to the expiry of the sponsorship, the Panel considered it had not ensured this was clearly acknowledged from the outset by taking such steps as to verify that the declaration had been updated. In the Panel's view, that a user could access the tool without scrolling down to the bottom of the page, meant that in the particular circumstances of this case, the failure to include a prominent declaration at

the outset amounted to a failure to ensure the sponsorship was acknowledged in accordance with Clause 25.3. On balance, a **breach of Clause 25.3** was ruled.

The next matter for the Panel to consider was whether a declaration of sponsorship was required on all materials relating to or generated by the tool, including prompts, alerts and outputs, required a declaration of sponsorship. The Panel noted the sponsorship agreement stated:

“the Decision Support Tools and ***all Related Materials produced and distributed or displayed by***, or on behalf of the Institution in relation to the Project, shall include the following declaration of sponsorship (or equivalent wording as provided by GSK from time to time) in a sufficiently prominent position to ensure that all users of the Decision Support Tools and all those reading or viewing ***all materials*** are aware of GSK’s Sponsorship and the extent of GSK’s involvement in the Project at the outset”  
***(emphasis added by the Panel)***

According to GSK, access to the tool required users to either navigate through the named organisation’s website or enter directly via the URL to the decision support tool homepage. GSK submitted that in both cases, a prominent declaration of involvement was present prior to entering the tool during the 2-year sponsorship period. The Panel considered the complainant had not established that users could access the tool or its outputs in any other manner that would bypass these webpages and avoid seeing the declaration.

The Panel noted that the sponsorship agreement referred to “all Related Materials produced and distributed or displayed” in connection with the tool, which could include prompts, alerts and outputs as described by the complainant. However, the Panel considered that the complainant had not established that each individual element generated by the tool required a declaration of involvement. The matter regarding the declaration of involvement at the outset on the homepage, prior to entry into the tool, had already been ruled on above. The Panel therefore ruled **no breach of Clause 25.3** in this regard.

With regard to the allegation regarding certification, GSK submitted that the tool was intended to be used by healthcare professionals to support clinical decision making and was not intended to promote GSK products. Clause 8.1 applied to promotional material and the complainant had not alleged that the tool was promotional nor that it fell under the list of materials requiring certification as specified in Clause 8.3. The Panel therefore considered the complainant had not established that all materials and outputs related to the tool required certification and the Panel therefore ruled **no breach of Clauses 8.1 and 8.3**.

The Panel considered that although it was unfortunate that the declaration did not appear at the outset at the time of the complaint, it appeared to have been inadvertently removed, and GSK took prompt steps to have it reinstated. The Panel took account of its earlier observations that the sponsorship agreement required an ongoing declaration of involvement, and that GSK had requested the wording be amended prior to the end of the sponsorship. The Panel considered that the failure to ensure the updated declaration appeared at the outset was adequately covered by its ruling of a breach of Clause 25.3. Based on the totality of information before it, the Panel did not consider the complainant had established that high standards had not been maintained and ruled **no breach of Clause 5.1**. It followed that the Panel ruled **no breach of Clause 2**.

<b>Complaint received</b>	<b>8 May 2024</b>
<b>Case completed</b>	<b>8 August 2025</b>