CASE AUTH/3899/5/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Allegations about classification of, and certification of materials associated with, a Joint Working Project

CASE SUMMARY

This case concerned a therapy review service which, allegedly, had been misclassified as a joint working project on the basis that not all parties' contributions would be significant. The complainant also alleged that software, educational materials for patients, and consultation summaries associated with the therapy review service had not been certified.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 8.3 (x11)	**Requirement to certify non-promotional material**
No Breach of Clause 20.4	**Requirement for joint working projects to be carried out in a manner compatible with the requirements of Clause 20 and other relevant requirements of the Code**

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 GlaxoSmithKline UK Limited was received from an anonymous, contactable complainant who described themselves as a health professional. The complainant subsequently became non-contactable.

COMPLAINT

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

> "A therapy review service which was classified as a donation under the ABPI code had been misclassified as a joint working project. The joint working project was a COPD [Chronic Obstructive Pulmonary Disease] legacy project across -[named locality] involving GSK and the NHS. A copy of the executive summary is: [URL provided] A joint working project required sig[n]ificant contribution from all parties. Within this project, GSK had simply utilised a 3rd party (named) to conduct COPD reviews in a

therapy review fashion. Therefore, it was difficult to understand how a sig[n]ificant contribution would be made by GSK and the practices when [named third party] would complete the sig[n]ificant majority of patient identification, all patient reviews, recommendations and provide mentorship at times to individuals in a given practice. The practice would need to authorise such recommendations made by [named third party] reviews but that was a very small contribution vs the majority of work [named third party] would be conducting. [Named third party] conducted therapy review services for pharmaceutical companies and this was project was no different considering it entailed the same features as a therapy review service, so the classification should have been as a donation as opposed to joint working. Furthermore, there was reference to provision of independent guided consultation software within the executive summary but this was [named third party] software used during reviews. All parts of the software should have been certified by GSK as educational material could be obtained from the software to provide to patients whilst action plans and printed consultation summaries could also be given. Therefore, all of the software (algorithm driven) and all materials provided from the software should have been certified separately. Any software updates that could have occu[r]red during the project should also have been certified. This had not happened. The relevant clauses which were not adhered to are 20.4, 8.3, 5.1 and 2. Request PMCPA to keep complaint anonymous."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 20.4, 8.3, 5.1 and 2 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

"Thank you for your letter dated 10th May 2024 where you informed us of concerns a healthcare professional has over the classification of a Joint Working project. GlaxoSmithKline UK Limited (GSK) is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations.

Joint Working project details

The PMCPA has asked for details about the Joint Working project.

GSK has worked with [named third party] to assist GP practices to provide therapy reviews for patients with Chronic Obstructive Pulmonary Disease (COPD) in line with Code requirements. [Named third party] is an independent service provider which supplies specialist nurses to conduct therapy reviews [URL provided]. [Named third party] has provided this service under the overarching banner ' [Named] **E**ducation **G**uided Consultation **A**ssessment of **C**OPD patients – **Y**our solution' (LEGACY).

These therapy reviews have taken place in a number of locations under distinct Code frameworks, depending on the specific timing and circumstances:
Medical and Educational Goods and Services (MEGS) under Clause 19 of the 2019 ABPI Code (herein referred to as the 'Code';
Donations under Clause 23 of the 2021 Code;
Joint Working under Clause 20 of the 2021 Code.

The project at issue is the 'COPD LEGACY Project Across [named locality]'. This service was delivered by [named third party] on behalf of GSK as part of a Joint Working arrangement between GSK and [named locality] Integrated Care Board (ICB).

The Project Initiation Document (PID) [copy provided] of the Joint Working project details the relevant background history. The certificate for the PID is attached [copy provided]. In summary, prior to the Joint Working project in [named locality] ICB, a COPD therapy review service took place in what was then called [named locality] CCG between December 2020 and December 2021, under the MEGS classification. This was funded by GSK and carried out by [named third party] and took place in 26 GP practices. The CCG and GP practices did not make a significant contribution to the service and therefore these would not have been suitable to conduct as Joint Working. Following the conclusion of the MEGS therapy reviews, the newly formed ICB requested additional support for COPD therapy reviews at GP practices that had not received the MEGS service. It was agreed in discussions that the ICB and GP practices would make significant contributions in terms of resources for these additional therapy reviews, which led to the setting up of this Joint Working arrangement. The Joint Working arrangement additionally allowed for a more bespoke service catering for the specific local needs of the ICB. As well as following recognised guidelines for the management of COPD, the Joint Working service was tailored to align with and support the local the local Pulmonary Rehabilitation Strategy for the benefit of patients and the local 'Green Agenda', as detailed in the PID [copy provided]. The older MEGS service did not cater specifically for those local needs as MEGS were provided by GSK without significant contributions from the NHS so there was no significant NHS input into the local service design and delivery.

The Joint Working project benefited COPD patients by ensuring they received therapy reviews aligned to recognised national and local guidelines for their chronic condition, that the GP practices had been unable to provide themselves due to a lack of resources and an appointment backlog following the COVID-19 pandemic. There was a significant contribution from all parties due to the pooling of resources, skills and experience, and outcomes were measured as detailed further below. This fulfilled the requirements of Clause 20.4 of the Code.

The Joint Working arrangement between GSK and [named locality] ICB ran from June 2023 until the end of November 2023 and all patient reviews conducted by [named third party] as part of the arrangement took place during that time.

Instructions provided to [named third party] to conduct therapy reviews

The PMCPA has asked for all relevant instructions, briefings and training provided to [named third party] to conduct the patient reviews.

GSK certified all instructions, briefings and training materials associated with the GSK-supported Joint Working COPD therapy reviews, which included materials for the overarching arrangements applicable across all Joint Working projects and also the specific [named locality] project.

Please find the following relevant documents and certificates as Enclosures [copies provided]:

Nurse Briefing Document and certificate.
Nurse Training Deck and certificate.
Spirometry Training Deck and certificate.
LEGACY Documentation Suite which includes the Practice Treatment Protocol and certificate.
Protocol Addendum for [named locality] ICB and certificate.

Joint Working compliance with the Code

The PMCPA has asked how GSK satisfied itself that the Joint Working project and its ongoing implementation complied with the Code.

GSK has robust procedures in place to review, approve and monitor Joint Working projects to ensure they comply with the Code. The process is defined in the Collaborative Working SOP [copy provided].

In summary, proposed Joint Working projects are first scoped in discussion with the proposed external partner and a Checklist is completed which guides the decision about whether the project is suitable as a Collaborative Working or Joint Working project. GSK's Checklist is based upon the one publicly available in the ABPI Joint Working Toolkit. The completed Checklist for the [named locality] Joint Working project is attached [copy provided]. This shows that no 'red' or 'amber' flags were raised that may have indicated the project was unsuitable as a Joint Working project.

In the next stage, the proposed project was discussed at GSK's Internal Review Committee (IRC), which takes place at the Non-Promotional Governance Board (NPGB). This consists of senior representatives from Medical, Legal, Compliance, and Commercial. As GSK were concurrently discussing a number of proposed Joint Working COPD therapy review projects with [named third party] in different areas of the country, a programme level approval was granted by NPGB, as per the Collaborative Working SOP, which enabled development of overarching agreements and documentation with [named third party] which would apply as a framework across all Joint Working COPD therapy review projects that were later developed. There would of course be differences between them as, by their nature, these are bespoke.

The next stage was development of the PID and the Joint Working Agreement (JWA) with each specific NHS organisation who would be a Joint Working partner, in this case [named locality] ICB. Under GSK's process, the PID is appended to and forms part of the JWA. The Collaborative Working SOP [copy provided] defines the details that must be included in the JWA, aligned with the requirements of the Supplementary Information of Clause 20 of the Code. The development of the PID and the Joint Working Agreement is an iterative process until all parties are satisfied with the details.

The project was then discussed again at the NPGB and the equivalent IRC in [named locality] ICB to gain internal approvals to proceed at each partner organisation.

Following this process, the PID was certified by a medical signatory and then appended to the JWA which was itself then signed by authorised representatives from GSK and [named locality] ICB.

The [named locality] PID (and certificate [copies provided] are attached, as is the JWA [copy provided].

During the project regular fortnightly meetings were held between members of the Joint Working Project Group which included staff from GSK, [named locality] ICB, and [named third party]. The membership of the group is detailed [in] the PID and the details for monitoring progress against the objectives and milestones and escalating any Code compliance issues.

Measuring outcomes of the project

The PMCPA has asked how GSK measured outcomes and whether the Joint Working Project was successful.

GSK did not have any access to patient data during this project. [Named third party] tracked a number of parameters including those defined in the PID. Progress reports were discussed at the fortnightly project meetings.

At the conclusion of the Joint Working project at the end of November 2023, [named third party] sent GSK a report detailing the measured outcomes [copy provided]. Please note the job code and date of preparation on this Enclosure relate to the unpopulated template document which [named third party] uses to report outcomes of LEGACY Joint Working projects to GSK, not to the approval of this specific report. The specific [named locality] outcomes sent to us by [named third party] are an internal document and have not been approved for external use. GSK is in the process of preparing a Summary of Outcomes in consultation with [named locality] ICB which we shall publish in due course.

In summary, the outcomes show that 1,098 COPD patients were reviewed across 24 GP practices. Of these, 39.2% received at least one non-pharmacological intervention only, 4.7% received at least one pharmacological intervention only, and 41% received at least one pharmacological and at least one non-pharmacological intervention. 522 patients were referred to the local pulmonary rehabilitation service as a non-pharmacological intervention – one of the aims of the Joint Working project specifically implemented by [named locality] ICB, as defined in the PID, was to increase referrals to this service. Further analysis and discussion with [named locality] ICB is needed to decide whether the aims of the Joint Working project were met.

Significant contributions from all parties

The complainant has made allegations regarding the contributions of the parties to the Joint Working arrangement. The complainant states:
'A joint working project required significant contribution from all parties. Within this project, GSK had simply utilised a 3rd party [named] to conduct COPD reviews in a therapy review fashion. Therefore, it was difficult to understand how a significant contribution would be made by GSK and the practices when [named third party] would

complete the significant majority of patient identification, all patient reviews, recommendations and provide mentorship at times to individuals in a given practice. The practice would need to authorise such recommendations made by [named third party] reviews but that was a very small contribution vs the majority of work [named third party] would be conducting.'

The Code states that 'Collaborative working, including its implementation, must have and be able to demonstrate the pooling of skills, experience and/or resources from all of the parties involved for the joint development and implementation of patient and/or healthcare centred projects. There must be a shared commitment to successful delivery from all parties, and each party must make a significant contribution.'

The complainant has cited the Executive Summary of the Joint Working project [copy provided] in their complaint. The certificate is attached. This document which is available on the GSK UK public site clearly states that there will be **'the pooling of skills, experience and resources from both parties'**. The Executive Summary shows the contributions:

'GSK will fund [named third party] to conduct patient reviews, provide access to independent guided consultation software, and carry out audits, in up to 50 practices at an approximate cost of £5,271 per practice, to a total of approximately £263,560. In addition, GSK will contribute a total of approximately £15,200 in indirect costs such as colleagues' time across the project. GSK will not have any influence over treatment decisions.

'The NHS will contribute up to approximately 4,950 hours of resource across primary care colleagues' time and ICB project management time at an approximate indirect cost of £6,341 per practice in up to 50 practices, to a total of approximately £317,055. The NHS contribution to the project does not include any transfer of money, it is based on the approximate costs of resource allocation.'

For ease of reference and comparison, it is GSK practice to convert hours of staff time into a monetary value, which is the basis of the indirect costs cited in the Executive Summary. The calculations are broken down further in the PID [copy provided]. This details specific hourly rates for different roles within the NHS organisations and the expected number of hours each role will contribute at the ICB level and the GP practice level for conducting different activities. The expected number of hours of GSK staff time are also detailed. It is clear from the Executive Summary [copy provided] cited by the complainant and the PID [copy provided] that there was a significant expected contribution from both GSK and [named locality] ICB to the Joint Working project.

As discussed above, the outcomes show that patients were reviewed at 24 practices so the expected total figures can be scaled down accordingly. While the totals can be approximately halved, it is clear that there was still a significant contribution from GSK in terms of direct and indirect costs, and from the ICB and GP practices as indirect costs.

The complainant has provided no evidence for their allegation that GSK and the practices did not make a significant contribution to the project. GSK denies any breach of Clause 20.4 as alleged by the complainant in this regard.

Classification as Joint Working

The complainant made a number of allegations regarding the classification of the Joint Working project:

'A therapy review service which was classified as a donation under the ABPI code had been misclassified as a joint working project.'

'[Named third party] conducted therapy review services for pharmaceutical companies and this was project was no different considering it entailed the same features as a therapy review service, so the classification should have been as a donation as opposed to joint working.'

It appears that the complainant may be under the assumption that therapy review services can only be provided as Donations under the Code. This is incorrect. The supplementary information to Clause 20 of the 2021 Code states that 'If the Collaborative Working involves services, then the supplementary information to Clause 23 Donations and Grants should be considered'. The supplementary information to Clause 23 discusses the provision of therapy review programmes. It is clear therefore that services involving therapy review can be classified under Joint Working, provided the criteria for Joint Working are met. This is supported by the case report to Case AUTH/3193/4/19 (Anonymous v Novartis) where 'The Panel noted that the therapy review service was part of the joint working project'.

While GSK is not privy to details of therapy reviews that [named third party] may have conducted for other pharmaceutical companies, as discussed above, GSK did fund [named third party] to carry out COPD therapy reviews as Donations under Clause 23 of the 2021 Code, and as MEGS under Clause 19 of the 2019 Code, in a number of locations. These were projects where the NHS organisations did not make a significant contribution to the service and therefore these would not be have been suitable to conduct as Joint Working. The large bulk of the work for these Donations and MEGS therapy reviews was conducted by [named third party] with funding from GSK. The arrangements for the provision of therapy review services as Donations or MEGS was distinct to the arrangements for Joint Working projects. GSK maintains a clear separation between therapy reviews provided as Donations or, historically, MEGS, and those provided as part of Joint Working. Briefing documents and training for the [named third party] nurses conducting the therapy reviews, as well as any project documentation seen by NHS staff or patients were different depending on whether the therapy review was provided as a MEGS, Donation, or Joint Working.

As discussed above, a COPD therapy review service under the MEGS classification took place in [named locality] CCG between December 2020 and December 2021. Following this, the new ICB requested additional support for COPD therapy reviews with bespoke local arrangements to align with the ICB's Pulmonary Rehabilitation Strategy and 'Green Agenda'. This would involve significant contributions of resource,

skills and experience from the ICB and local GP practices, as well as from GSK. Therefore, a Joint Working project was set up.

GSK is confident that this Joint Working project meets all the criteria for Joint Working as defined in Clause 20 of the Code:

'Collaborative working, including its implementation must have and be able to demonstrate the pooling of skills, experience and/or resources from all of the parties involved for the joint development and implementation of patient and/or healthcare centred projects. There must be a shared commitment to successful delivery from all parties, and each party must make a significant contribution.'

'Joint working between one or more pharmaceutical companies and the NHS and others which is patient centred and always benefits patients is an acceptable form of collaborative working'

'…for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment for successful delivery. Each party must make a significant contribution and the outcomes must be measured. Treatments, when mentioned, must be in line with nationally accepted clinical guidance where such exists.'

The PID for the Joint Working project [copy provided] clearly show that the service design is for the primary benefit of patients, with significant contributions from all parties, following nationally accepted clinical guidance and with measured outcomes. The Checklist [copy provided] also confirms that the criteria for classification as Joint Working were met.

GSK refutes the complainant's allegation that the therapy review services provided under Donations were 'no different' from the services provided under Joint Working. There are clear differences in the levels of resource contribution provided by the NHS, and a clear rationale for why this project was classified as a Joint Working project. GSK denies a breach of Clause 20.4 in this regard.

Independent guided consultation software

The complainant states:
'There was reference to provision of independent guided consultation software within the executive summary but this was [named third party] software used during reviews. All parts of the software should have been certified by GSK as educational material could be obtained from the software to provide to patients whilst action plans and printed consultation summaries could also be given. Therefore, all of the software (algorithm driven) and all materials provided from the software should have been certified separately. Any software updates that could have occurred during the project should also have been certified. This had not happened.'

The software that the complainant refers to is [named software]. The PID [copy provided] states that part of GSK's input into the project will be [named third party] support which itself partly consists of a license for the GP practice to use [named

software], which each GP practice can optionally select to receive. The GP practice can select this [in] the LEGACY Documentation Suite [copy provided] when they sign the Practice Treatment Protocol.

While [named third party] does provide GP practices with a license to access [named software], this is not [named third party] software, as alleged by the complainant. The [named] software was developed independently by [named software provider] which is a separate company to [named third party]. The Nurse Training Deck [copy provided] which was put together by [named third party] states:

'[Named] software was developed independently by three respiratory physicians with many years of clinical experience in COPD management as well as other respiratory conditions.'

'[Named software developer] has developed three products, the COPD Guided Consultation, Asthma Guided Consultation and SleepHealth Guided Consultation which are all unique, evidence-based software applications hosted within the NHS HSCN Server [url provided]**.'**

The [named] COPD Guided Consultation software was independent of GSK and already existed and was in use by the NHS prior to the Joint Working project. The software and its algorithms were not in GSK's control, and GSK staff did not have direct access to the software as this required an NHS computer and a user license. It was not possible for GSK to make any changes to the independent software. Nevertheless, as GSK were funding access to the software, we decided, out of an abundance of caution, to carry out non-promotional certification of static screenshots of the software that were provided to us by [named third party]. Furthermore as part of the approval process, the medical signatory reviewed a remote demonstration of the live software over a video call (led by an [named third party] and NHS respiratory consultant physician) to ensure that the software did not contravene the Code. This demonstration involved the consultant entering dummy patient data into the software so that the medical signatory could assess the functionality of the software, as well as checking that the live software aligned with the screenshots provided to GSK.

The screenshots provided by [named third party] are attached and the certificate [copies provided]. GSK denies any breach of Clauses 8.3 or 20.4 as alleged in this regard.

The complainant has mentioned that 'action plans and printed consultation summaries could also be given' to patients. We believe this refers to the Consultation Report which can be generated as an integral functionality of the [named] software and summarises the consultation, which can then be used by the GP in their clinical records or sent to the patient. As integral parts of the software functionality which were created by the [software provider], and which existed prior to the Joint Working project, the format of the Consultation Reports were not within GSK's control. Nevertheless, as mentioned above, screenshots of the software provided to us by [named third party] were indeed certified as non-promotional by a medical signatory under GSK's approval processes. The screenshot of a Consultation Report with dummy patient data is found [in] [copy provided]. The live functionality for generating the Consultation Report with dummy data was reviewed by the medical signatory during the remote demonstration

mentioned above. GSK denies any breach of Clauses 8.3 or 20.4 as alleged in this regard.

The complainant states that 'educational material could be obtained from the software to provide to patients'. From the [named software] interface, it was possible for the HCP user to access and download non-promotional educational leaflets intended to be given to patients who had been seen in the therapy reviews. While [named software] could provide access to these leaflets, they were not an integral part of the software. The leaflets were within the control of GSK and [named third party] to develop as part of the Joint Working arrangement, and therefore fell under the certification requirements of the Code. Each GP practice could optionally select up to eight leaflets when they signed the Practice Treatment Protocol (LEGACY Documentation Suite, [copy provided]) which could be made accessible via [named software] and could be given to COPD patients if appropriate, depending on the outcome of the therapy review.

The eight materials intended for patients are listed below:
Wishes about future care and certificate [copies provided].
Relaxation and certificate [copies provided].
What is COPD? and certificate [copies provided].
Useful contact details and appointments and certificate [copies provided].
Why exercise? and certificate [copies provided].
Breathing control and certificate [copies provided].
Coping strategies and certificate [copies provided].
COPD self-management plan and warning signs and certificate [copies provided].

All of the leaflets above were certified as non-promotional items by a medical signatory. GSK denies any breaches of Clauses 8.3 or 20.4 in this regard.

The complainant states that 'any software updates that **could have occurred** [emphasis added] during the project should also have been certified', however GSK is not aware that any such software updates took place while the Joint Working project was ongoing and the complainant has not provided any evidence that the software was updated. Had GSK been aware of any updates we would have asked for new screenshots for certification and a further remote demonstration of the software to ensure that any changes did not contravene the Code. GSK denies breaches of Clauses 8.3 and 20.4 in this regard.

Clauses 5.1 and 2

As GSK deny any breaches of Clauses 8.3 and 20.4, as alleged, and as GSK have robust procedures in place for the implementation of Joint Working projects, we also deny that we have failed to maintain high standards or that we have brought discredit or reduced confidence in the pharmaceutical industry. We consequently deny breaches of Clause 5.1 and Clause 2.

Qualifications of signatories

The qualifications of the signatories who certified materials in this project are found in [document provided].

Conclusion

In conclusion, GSK denies all allegations made by the complainant including breaches of Clauses 8.3, 20.4, 5.1 and 2."

PANEL RULING

The complaint concerned two matters: an allegation that a therapy review service, which was classified as a donation under the Code, had been misclassified as a joint working project; and an allegation that all parts of the [named third party] software used during the therapy reviews, and materials provided from the software, should have been certified by GSK. The complaint further alleged that any software updates that could have occurred during the project should have been certified.

Classification of the service

The Panel noted that the complainant's allegation appeared to be based on their view that it was difficult to understand how a significant contribution would be made by GSK and the practices when [named third party] would complete a significant amount of the work. The complainant stated that the project had the features of a therapy review service.

GSK submitted that the therapy reviews had taken place in a number of locations under distinct Code frameworks, depending on the specific timing and circumstances and referred to the 2019 and 2021 Codes. The Panel noted that the complaint included a link to an executive summary headed 'GlaxoSmithKline (UK Ltd) and NHS [named locality] ICB [Integrated Care Board] Executive Summary, COPD legacy project across [named locality]' which covered the project from May to December 2023; the Panel considered that the 2021 Code therefore applied to the project at issue.

The Panel noted that according to the Project Initiation Document titled 'COPD Legacy Project across [named locality]', the ICB requested additional support to help to close the ongoing gap in the remaining 79 practices that didn't receive support through a previous Legacy COPD MEGS service and agreed that project working via Joint Working, with the pooling of NHS and GSK resources would be the most effective way to continue to support the locality.

According to the Executive Summary the project aims included: validating the COPD disease register in participating practices; delivering reviews for certain patients in line with COPD management and prescribing guidelines; supporting local Green Agenda objectives in the 'Chronic Obstructive Pulmonary Disease (COPD) Inhaler Types and Devices Aug 22' guideline; supporting [named locality's] 5 year pulmonary rehabilitation strategy; and aligning to the 'Triple Aim' set out by government Health and Care Bill. The Executive summary set out the intended benefits to patients, the NHS and GSK.

The Panel noted the requirements for joint working and collaborative working were set out in Clause 20. Clause 20.1 described joint working as a limited form of collaborative working as set out in Clause 20.4. The latter stated that joint working, which was patient centred and always benefitted patients, was an acceptable form of collaborative working providing it was

carried out in a manner compatible with Clause 20 and other relevant requirements of the Code. The Supplementary Information to Clause 20.4 reproduced the Department of Health's definition of joint working between the NHS and the pharmaceutical industry, as situations where for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment for successful delivery. Each party must make a significant contribution, and the outcomes must be measured. The pooling of skills, experience and/or resources for collaborative working was a requirement of Clause 20.2.

The Panel noted the provision of donations, referred to by the complainant, was covered by Clause 23 which described donations and grants as, among other things, benefits in kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return. The supplementary information referred to therapy review services.

Therapy review services varied and in the Panel's view, depending on the arrangements, a therapy review service could be a donation, collaborative working or joint working. The Panel did not agree with the complainant's implication that if the arrangements had features of a therapy review it had to be provided as a donation. Other than referring to the parties' respective contributions to the project the complainant had not identified those features which in their view meant that the project should be classified as a donation.

The Panel noted that the complainant's concerns were limited to whether GSK and the NHS had made a bona fide contribution to the project. In the Panel's view the complainant appeared to have misunderstood the role of [named third party], it was not a third party to the agreement but was providing services funded by GSK as set out in the joint working materials.

The Panel noted that the Section 10 of the Joint Working Agreement, 'Contribution and Finances', stated that 'The Parties will contribute the resources of a financial and/or non-financial nature to the Project as described in the PID [Project Initiation Document].' The Panel noted the Executive Summary set out the parties' respective contributions to the joint working project, which, although set out slightly differently, were consistent with those outlined in the Project Initiation Document. GSK would fund [named third party] to conduct patient reviews, provide access to independent guided consultation software, and carry out audits, in up to 50 practices at an approximate cost of £5,271 per practice, to a total of approximately £263,560. In addition, GSK would contribute a total of approximately £15,200 in indirect costs such as colleagues' time across the project. GSK would not have any influence over treatment decisions. The NHS would contribute up to approximately 4,950 hours of resource across primary care colleagues' time and ICB project management time at an approximate indirect cost of £6,341 per practice in up to 50 practices, to a total of approximately £317,055. The NHS contribution to the project did not include any transfer of money, it was based on the approximate costs of resource allocation.

In the Panel's view given that [named third party] was funded by GSK and therefore part of that company's contribution to the project, both the NHS and GSK had pooled resources and each party appeared to have made a significant contribution. The complaint was limited to whether each party had made a significant contribution and on this basis the Panel considered that the project had not been misclassified as a joint working arrangement as

alleged. The Panel therefore ruled **no breach of Clause 20.4** which required joint working to be carried out in a manner compatible with Clause 20.

Certification

In relation to the allegation that all parts of the [named third party] software used during the therapy reviews and materials provided from the software should have been certified by GSK, the Panel noted that, funded by GSK, [named third party] provided GP practices with a license to access independently developed software known as [named software], This was not software owned or developed by [named third party] as implied by the complainant.

The Panel noted that the software and its algorithms were not in GSK's control, and GSK staff did not have direct access to the software as this required an NHS computer and a user license. It was not possible for GSK to make any changes to the independent software.

The Panel queried whether the complainant's reference to 'all parts of the software' was an accurate reflection of a company's responsibilities under the Code in relation to certification and third party material provided as part of a joint working project. The company had to ensure that the material seen and used by the health professional and any educational material for patients was Code compliant which was narrower than the term 'software'.

Clause 8.3 required material relating to collaborative working as described in Clause 20 and its supplementary information to be certified. Clause 20.3 required material relating to collaborative working to be certified. Joint working was a subset of collaborative working.

The Panel noted that the software provider had developed three guided consultation products, one of which was the COPD guided consultation utilised in this case. GSK had carried out non-promotional certification of static screenshots of the software that were provided to it by [named third party] and in addition a signatory had reviewed a remote demonstration of the live software over a video call to ensure that the software did not contravene the Code. This demonstration involved entering dummy patient data into the software so that the medical signatory could assess the functionality of the software, as well as checking that the live software aligned with the screenshots previously provided to GSK.

Noting GSK's submission and supporting evidence the Panel considered that the software which comprised the COPD guided consultation had been certified as required by the Code and ruled **no breach of Clause 8.3.**

In relation to materials provided from the software and the allegation that educational material could be obtained from the software to provide to patients whilst action plans and printed consultation summaries could also be given, GSK submitted that from the software provider's interface, a health professional user could access and download up to eight non-promotional educational leaflets intended to be given to patients who had been seen in the therapy reviews. The leaflets were within the control of GSK and [named third party] to develop and GSK accepted that these fell under the certification requirements of the Code. GSK provided copies of the certificates for each leaflet which showed they had been certified as non-promotional items by a medical signatory. **No breach of Clause 8.3** was ruled accordingly in relation to each leaflet.

In relation to the Consultation Summaries that GSK stated could be generated as an integral functionality of the software and provided to the patient or retained by the health professional, GSK had certified a screenshot of a Consultation Report with dummy patient data and live functionality for generating the Consultation Report with dummy data was reviewed by the medical signatory. The Panel considered that a template for the consultation report had been certified and **ruled no breach of Clause 8.3** accordingly.

In relation to the allegation that any software updates that could have occurred during the project should have been certified the Panel was concerned that this appeared to be speculative, the complainant was unclear whether such updates had occurred, and the Panel therefore queried whether there was a valid complaint on this point.

The Panel bore in mind GSK's submission that it was not aware that any such software updates took place while the Joint Working project was ongoing, and the complainant had not provided any evidence that the software was updated; had GSK been aware of any updates it would have asked for new screenshots for certification and a further remote demonstration of the software to ensure that any changes did not contravene the Code.

Bearing in mind its comments above the Panel did not consider that it had a valid complaint on this point and therefore **ruled no breach of Clause 8.3**.

Clauses 5.1 and 2

Bearing in mind the allegations and rulings of no breach above the Panel considered that the complainant had not established that GSK had failed to maintain high standards and **ruled no breach of Clause 5.1 and consequently no breach of Clause 2.**

Complaint received **9 May 2024**

Case completed **12 June 2025**