THIS CASE SHOULD NOT BE RELIED UPON AS A VALID PRECEDENT.

THE RULING OF A BREACH OF CLAUSE 26.1 IN CASE/0568/04/25 TAKES PRECEDENCE OVER, AND IN EFFECT SUPERSEDES, THE RULING OF NO BREACH OF CLAUSE 26.1 IN CASE/0269/08/24 FOR THE REASONS SET OUT IN CASE/0874/02/26 AND CASE/0568/04/25.

ALL THREE CASES ARE INTERRELATED AND SHOULD BE READ TOGETHER, ALONGSIDE THE PMCPA'S Q&A (What is meant by "approved by the health ministers" in Clause 26.1?), WHICH CLARIFIES THAT IT IS THE MHRA THAT PROVIDES SUCH APPROVAL.

CASE/0269/08/24 ***NO BREACH OF THE CODE****

COMPLAINANT v GSK

Alleged promotion to the public

CASE SUMMARY

This case was in relation to a GSK video about an NHS shingles vaccination programme. The video was shown as an advertisement on several TV channels of a mainstream broadcaster and provided information, such as the eligibility criteria, for the shingles vaccination programme. The complainant alleged that this advertisement constituted advertising of a prescription only medicine to the public.

GSK appealed three of the Panel's rulings.

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 [Panel's breach ruling overturned at appeal]	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1(x2)	**Requirement that information/ claims/ comparisons must not be misleading**
No Breach of Clause 26.1 [Panel's breach ruling overturned at appeal]	**Requirement to not advertise prescription only medicines to the public**
No Breach of Clause 26.2 [Panel's breach ruling overturned at appeal]	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to**

	ask their health professional to prescribe a specific prescription only medicine

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

COMPLAINT

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

> "GSK advert for shingles vaccine that is being shown on prime time mainstream TV channels (e.g. sky sports on Tues 13 August). I don't understand why this isn't classed as promotion to the public, as the vaccine is a prescription product. Although code clause 26.1 states 'this prohibition does not apply to vaccination campaigns carried out by companies and approved by the health ministers' the code also states 'statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine'. This advert overtly and obviously refers to 'GSK's shingle vaccine' (this wording is written on the screen text) that you should ask your GP for, rather than explaining the disease or raising awareness of the benefits of vaccination that you would expect from a vaccine awareness campaign. The advert also doesn't seem to say that other shingles vaccines may be available (at least not that I could see clearly). I believe this advert is misleading in that it massively promotes a specific company's product whilst providing little evidence to support the risk/benefit of the vaccine. Are we to allow vaccine companies to develop vaccines for any minor illnesses and make huge profits from them by encouraging the public to ask their doctor for them?!"

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 26.1, 26.2, 6.1, 5.1 and 2 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

> "Thank you for your letter dated 14th August 2024, notifying GSK of a complaint from a non-contactable member of the public/media regarding a television clip which appeared on Sky Sports TV on Tues 13 August, (the 'Video'). When responding, you have asked that GSK consider the requirements of Clauses 26.1, 26.2, 6.1, 5.1, and 2 of the 2021 Code.
>
> GSK takes its obligations under the ABPI Code of Practice extremely seriously and is committed to following both the letter and spirit of the Code. While we are disappointed to see this complaint raised, GSK is confident that its activities are fully compliant with the Code and strongly refutes breaches of Clauses 26.1, 26.2, 6.1, 5.1, and 2.

The crux of the complaint is the allegation that the Video, '*overtly and obviously refers to "GSK's shingle [sic] vaccine" (this wording is written on the screen text).'* However, there is no mention of 'GSK's shingle [sic] vaccine,' anywhere in the Video - not the on-screen text (as alleged), the voiceover, or the imagery. Moreover, this factual inaccuracy appears to be the basis of all the allegations – with the complainant consequently alleging the Video constitutes *'promotion to the public, as the vaccine is a prescription product' (Clause 26.1); that it is 'misleading in that it massively promotes a specific companies [sic] product whilst providing little evidence to support the risk/benefit of the vaccine' (Clause 6.1);* and encourages members of the public to ask for GSK's shingles vaccine *with allegations such as, 'GSK's shingle [sic] vaccine...that you should ask your GP for' and 'Are we to allow vaccine companies to develop vaccines for any minor illnesses and make huge profits by encouraging the public to ask their doctor for them' (Clause 26.2).* This fundamentally incorrect statement is the critical foundation of all allegations and, given the complainant has not provided any other arguments or evidence in support of their case, GSK believes the case to be without merit and therefore respectfully requests that it is not progressed to the Code of Practice Panel.

The Video

The Video was developed for a member of the public audience. It provides factual, balanced, and non-promotional information about the UK NHS Shingles National Immunisation Programme (the 'Programme') and its eligibility criteria, which were significantly expanded in September 2023. This development represented the most significant and substantial change to the Programme eligibility criteria since its introduction a decade earlier.

Consequently, many more individuals became eligible for the Programme. A significant knowledge gap amongst eligible members of the public regarding the new criteria for this important public health initiative also resulted, with a clear need for appropriate information to address this. The expanded Programme criteria are relatively complex – for example, individuals in the severely immunosuppressed cohort are not necessarily the same adults who are eligible for the more widely known NHS influenza and/or COVID programmes, and there is also potential for confusion around the 65-year-old cohort – which further underlined the need for clear and consistent messaging.

GSK worked with the UK Health Security Agency (UKHSA) [the governmental body responsible for the design, planning, communication (to the public and healthcare professionals) and implementation of the Programme] and NHS England (which is responsible for the Programme commissioning and delivery) from the outset of the implementation of the expanded Programme, to determine the public need for information about the Programme and to agree and align on the overarching messaging and imagery being used by GSK.

The Video is 30 seconds in duration and focusses entirely on the Programme; it is not disease awareness. It shows age appropriate and ethnically diverse adults, who are representative of the Programme eligibility cohorts, engaged in everyday activities such as gardening, baking, an evening out and going to watch a football game. The imagery is accompanied by a voiceover and on-screen text which provides information about the Programme eligibility criteria. GSK's role in the Video is made clear from the outset

and the prominent statement, *'Developed and funded by GSK,'* appears in the top right-hand corner of the Video throughout. The voiceover and on-screen text (the "Transcript") are provided below:

Video voiceover:

Are you ready to step up against shingles?
The free NHS shingles vaccination is available all year round.
If you're 50 or over, with a severely weakened immune system, or aged 70-79, you're eligible now.
If you turn 65 on or after 1st of September last year, you can get yours from your birthday.
If you're eligible, your GP surgery should send you an invitation, but if you're worried you've missed yours, get in touch with them today.
Step up against shingles.

Video on-screen text:

Developed and funded by GSK.
50 or over with a severely weakened immune response.
If you get any side effects, report them to your nurse or doctor.
Or aged 70-79 you're eligible now.
If you get any side effects, report them to your nurse or doctor.
Turning 65 on or after 1st of September 2023.
If you get any side effects, report them to your nurse or doctor.
Step up against shingles. Visit GSK's [named website]

As evidenced by the on-screen text and the voiceover, the Video does not refer to specific prescription only medicines (which includes vaccines), either directly or indirectly; nor are there any promotional claims about prescription only medicines, or the Programme itself. Although the Video does not advertise prescription only medicines to the public, GSK nevertheless worked with both the UK Health Security Agency (UKHSA), and NHS England, from the inception stage to agree the messaging and imagery being used to raise awareness of the Programme and the Video was shared with them in advance of it being shown on TV.

GSK also undertook other measures to ensure that the Video was fully compliant with the ABPI Code of Practice, GSK standard operating procedures/internal processes and UK regulations and requirements. Careful channel and programme selection was utilised to ensure the Video was targeted to those audiences for whom it was most likely to be relevant. Audiences in age ranges most aligned to the Programme eligibility cohorts were targeted via the selection of the '55-64' and '65+' age ranges from the available TV audience categories (i.e. 16-24, 25-34, 35-44, 45-54, 55-64 and 65+ years of age).

We understand the Video was seen by the complainant on Sky Sports on 13th August. GSK can confirm that the Video appeared once on Sky Sports on that date, airing on

the Sky Sports Cricket Channel at 19:59. This was the only time the Video appeared on Sky Sports that day, and it appeared on two other occasions on Sky Sports News channel later that month. The Video was aired by several broadcasters and on a variety of channels, appearing contemporaneously with programmes aligned with the target audience for the Video. The broadcast schedule for the 'Sky-named channels' for August 2024 is provided, which includes the Sky Sports channel where the Video was seen by the complainant. The schedule provides the details of exactly when (including the date, time, and programme) the Video was aired on these specific channels. Responding to the point raised in your letter regarding the provision of instructions/briefings to the broadcasters and/or media buyers, GSK can confirm that the media buyers/agency were briefed in-line with the above objectives regarding audience targeting. GSK also reviewed the schedule in advance of the Video being broadcast and had the opportunity to make changes where required. The Video was also approved by [named compliance body for TV commercials], a non-governmental organisation which reviews advertisements for television to ensure compliance with the UK Code of Broadcast Advertising (the BCAP), which sets out standards to help ensure that broadcast content is not misleading, harmful, or offensive.

In addition, in accordance with ABPI Code and GSK standard operating procedures, the Video was certified (as non-promotional information for the public) by a UK qualified physician and registered ABPI Signatory. GSK also has a specific governance framework for such materials, which involves several stringent processes (including review by the Non-Promotional Governance Board which consists of senior stakeholders from medical, legal and compliance), all of which have been followed.

The [named] website

At the end of the Video, the [named] website (the 'Website') address is provided although a direct link is not included. The Website provides high quality, non-promotional information about the Programme for the public, including details about the eligibility cohorts (in multiple languages to facilitate accessibility for those individuals who do not speak English), an interactive shingles vaccination eligibility checker tool, frequently asked questions about the Programme and detailed information about which patient groups are likely to be considered as having severely weakened immune system. Background information about shingles, including its causes, risk factors, symptoms, and complications, is provided to set the Programme in context and help members of the public to understand the associated disease risk. In common with the Video, there are no mentions of *'GSK's shingle [sic] vaccine,'* or any specific prescription only medicines, including vaccines, anywhere on the Website.

The Shingles National Immunisation Programme

The aim of the Programme is to reduce the incidence and severity of shingles disease and subsequent post-herpetic neuralgia (PHN). Following recommendations by the Joint Committee on Vaccination and Immunisation (JCVI), the Programme was first introduced into the routine schedule in September 2013, for adults aged 70 years, with a phased catch-up for 71–79-year-olds.

The JCVI is an independent Departmental Expert Committee and a statutory body. It is the role of the JCVI to make recommendations to the UK Government relating to new

or updated national immunisation programmes. JCVI recommendations are based on careful appraisal and evaluation of evidence, including public health need, burden of disease, scientific and clinical data, and the impact and cost effectiveness of immunisation strategies. Once a recommendation has been made by the JCVI, it is the duty of the UK Government to implement the recommendation.

The UK Health Security Agency (UKHSA) is an executive agency of the Department of Health and Social Care. It hosts the secretariat for JCVI and provides clinical and public health expertise and evidence to support JCVI recommendations. It is also the government agency charged with the design, planning, and implementation of the Programme, including the procurement of a central supply of vaccines via a tender process. Following further JCVI recommendations in 2019, relating to patient unmet need and public health benefit, and subsequent approval by the Government, the Programme was expanded in September 2023, to include immunocompetent adults turning 65 years from 1st September 2023 and severely immunocompromised individuals aged 50 years and older.

Unlike other adult National Immunisation Programmes (NIPs) which the public would be familiar with, such as the NHS influenza and COVID vaccinations which are seasonal, the NHS shingles vaccination is available all year round. This is an important distinction. Consequently, individuals can be invited for the shingles vaccination as they become eligible, for example, when individuals turn 65 or 70 years old, rather than having to wait until a specific time of the year. This also affords GP surgeries flexibility to phase the shingles vaccination throughout the year, which may enable more effective management of the resources required to deliver the adult NHS vaccination schedule. The invitation process for the shingles vaccination also differs from some of the other adult NIPs. For example, those eligible for the NHS influenza vaccination can choose to proactively book to receive their vaccination at a participating pharmacy or to take up the invitation from their GP surgery when it arrives. In contrast, those individuals eligible for the NHS shingles vaccination should receive their invitation from their GP surgery when they become eligible.

GSK strongly disagrees that shingles and its complications are ‘minor illnesses’ as the complainant implies with the question, *‘Are we to allow vaccine companies to develop vaccines for any minor illnesses and make huge profits from them by encouraging the public to ask their doctor for them?!’* Shingles and its complications are serious conditions, which occur with high incidence in the cohorts eligible for the Programme. Data from GP-based studies performed prior to the introduction of the Shingles National Immunisation Programme showed that, in immunocompetent adults aged ≥70 years alone, there were over 50,000 cases of shingles every year in England and Wales (van Hoek et al, 2009). Whilst the severity of shingles can vary, older people and those who are immunocompromised are more likely to experience severe forms of the disease, secondary complications, hospitalisations, and fatalities.

PHN, a type of neuropathic pain, is the most common complication of shingles. It is defined as pain that lasts at least 90 days after the shingles rash has healed and reflects peripheral nerve damage. Whilst many patients with PHN make a full recovery within a year, occasionally symptoms last for several years or may be permanent. Both the acute pain of shingles and the longer-term pain associated with PHN have a substantial adverse impact on quality of life. Other complications of shingles include:

secondary skin infections; herpes zoster ophthalmicus (which can result in a variety of ocular complications including keratitis, uveitis and visual loss); Ramsay Hunt syndrome (which is associated with facial paralysis, vertigo, tinnitus and hearing loss); radiculopathy; skin scarring and pigmentation; stroke and myocardial infarction; and more rarely, disseminated disease which can lead to conditions such as encephalitis, pneumonia or hepatitis. These are not trivial conditions.

Clauses 26.1 and 26.2

In our response, you have asked us to consider Clauses 26.1 and 26.2.

Clause 26.1 requires that, '*Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by health ministers*.'

The crux of all the complainant's allegations is the incorrect allegation that the Video, *'overtly and obviously refers to 'GSK's shingles [sic] vaccine' (this wording is written on the screen text) that you should ask your GP for, rather than explaining the disease or raising awareness of the benefits of vaccination that you would expect from a vaccine awareness campaign.'* However, there is no mention of *'GSK's shingles [sic] vaccine,'* anywhere in the Video - not the on-screen text (as alleged), the voiceover, or the imagery. In fact, there are no (direct or indirect) mentions of any prescription only medicines (including vaccines) in the Video whatsoever.

The Video is not disease awareness; it provides non-promotional information about an important UK Government initiative to members of the public, for whom it is likely to be relevant. Whilst the Video does not advertise prescription only medicines to the public, GSK can confirm that it worked with both the UK Health Security Agency (UKHSA) and NHS England to determine the public need for information about the Programme and to agree and align on the messaging and imagery used by GSK.

The Video specifically highlights the Programme's year-round nature, which differs from other NHS adult vaccination programmes which the public might be more familiar with, such as the NHS influenza and COVID vaccinations. This was deemed to be an important Programme message by GSK, UKHSA and NHS England. The Video also provides details of the Programme eligibility criteria; together with information on the action individuals should take if they are eligible for the NHS shingles vaccination or if they experience side effects. The Video closes with the statement, '*Step up against shingles. Visit GSK's [named website].'* There is no direct link to the website. However, the address is provided so that viewers can access more information about the Programme and its eligibility criteria.

'The free NHS shingles vaccination is available all year round,' is the only reference to shingles vaccination anywhere in the Video. This terminology was specifically selected as a more user-friendly reference to 'the NHS Shingles National Immunisation Programme,' as it is wording which is more likely to be readily understood by the intended audience within the context of a 30 second Video. 'Vaccination,' is defined by the Centre for Disease Control and Prevention as, 'T*he act of introducing a vaccine into the body to produce protection from a specific disease,'* and by the Cambridge Dictionary as, *'The process or act of giving someone a vaccine...'*. GSK is confident

that the use of this wording, alongside information on the eligibility criteria, does not constitute direct or indirect promotion of a prescription only medicine to the public.

Clause 26.2 stipulates that, '*Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment* (or prevention) *or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their HCP to prescribe a specific prescription only medicine.'*

The complainant alleges the Video encourages members of the public to ask for GSK's shingles vaccine with allegations that it '*overtly and obviously refers to "GSK's shingle vaccine" (this wording is written on the screen text) that you should ask your GP for,' and 'Are we to allow vaccine companies to develop vaccines for any minor illnesses and make huge profits from them by encouraging the public to ask their doctor for them?!'*

As clarified previously, there is no mention of *'GSK's shingles [sic] vaccine...that you should ask your GP for,'* anywhere in the Video - not in the on-screen text (as alleged), in the voiceover, nor in the imagery. In fact, there are no direct or indirect mentions of any prescription only medicines (including vaccines) in the Video whatsoever.

The Video is entirely focussed on the Programme. It clearly and unambiguously clarifies the cohorts eligible for NHS shingles vaccination and the voiceover is reinforced with on-screen text. The actors that appear in the Video are age appropriate, ethnically diverse and representative of individuals who could fall within the different eligibility cohorts. The Video voiceover and on-screen messaging are factual and presented in a balanced, non-sensational way. There are no product efficacy or safety claims, nor are there any claims about the efficacy of the Programme - indeed the complainant correctly states that the Video does not raise '*awareness of the benefits of vaccination.'* A general reference to the reporting of side effects within the context of the Programme is included for 20 of the total 30 second Video duration. Eligible members of the public are also informed their GP surgery should reach out to them with an invitation for the NHS shingles vaccination - contact with their GP surgery is only proposed if eligible individuals think they have missed their invitation.

The Video does not raise unfounded hopes of successful treatment, or prevention, nor does it mislead with regard to the safety of any prescription only medicine or encourage members of the public to ask their healthcare professional to prescribe a specific prescription only vaccine.

Clause 26.1 and 26.2 - summary:

The Video is non-promotional and entirely focussed on the UK Government Programme. Whilst it does not advertise prescription only medicines to the public, GSK nevertheless worked with both NHS England and the UK Health Security Agency (UKHSA) to determine the need for such information by the public and agree and align on GSK messaging and imagery. NHS England is responsible for the commissioning and delivery of the Programme and UKHSA is the government agency charged with

the design, planning, communication (to the public and healthcare professionals) and implementation of the Programme.

The Video does not make any claims about prescription only medicines (or the Programme itself), raise unfounded hopes of successful treatment (or prevention), or mislead about safety of a product (or the Programme itself). Furthermore, it does not contain any statements made for the purposes of encouraging members of the public to ask their healthcare professional to prescribe a specific medicine. The statements in the Video are made with the purpose of informing eligible members of the public about an important public health initiative which is available on the NHS to individuals in specific risk cohorts. The Programme criteria are clearly and unambiguously stated in the Video. The Video also provides clarity on the invitation process, informing eligible individuals they should receive an invitation from their GP surgery, which differs from other adult vaccination programmes which the audience may be more familiar with – for example, for the NHS influenza vaccination, eligible individuals can either proactively book to receive their vaccination at a participating Pharmacy or wait until they receive their invitation from their GP surgery.

Given the totality of factual, balanced information focused on educating the public on the Programme and it's eligibility criteria, and the absence of any direct or indirect mentions of prescription only medicines or claims, GSK is confident that the Video does not constitute promotion of a prescription only medicine to the public, nor does it encourage members of the public to ask their healthcare professional to prescribe a specific prescription only medicine, as alleged. GSK strongly refutes breaches of Clauses 26.1 and 26.2.

It is noteworthy that all allegations appear to be based on the incorrect assertion that the Video refers to, *'GSK's shingle [sic] vaccine...that you should ask your GP for,'* on the on-screen text, which it does not; and the complainant has not provided any other arguments or evidence in support of the allegations of breaches of Clauses 26.1 or 26.2.

Clause 6.1

GSK have been asked to consider Clause 6.1 in its response, presumably because the complainant alleges the Video, *'is misleading in that it massively promotes a specific companies [sic] product whilst providing little evidence to support the risk/benefit of the vaccine,'* an allegation which has also been addressed in our response to Clauses 26.1 and 26.2.

Clause 6.1 requires that, '*Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration, or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.'*

The Video does not contain any mention of specific prescription only medicines, neither are there any product claims or comparisons. The Video content provides accurate, fair, balanced, unambiguous, up-to-date information about the Programme and its

recently expanded eligibility criteria. The information provided does not mislead either directly or indirectly and is sufficiently complete to enable the viewer to understand whether they are likely to be eligible for the Programme.

GSK is confident that the Video is fully compliant with the requirements of Clause 6.1. Moreover, GSK notes that the complainant has provided no evidence in support of the allegation that the Video is *'misleading.'*

Clauses 5.1 and 2

The Video provides high quality, non-promotional, educational information to the public about an important Government public health initiative. This is not unacceptable under the Code provided certain conditions are met, and GSK is confident that the Video is fully compliant with these requirements as detailed above.

The Video was certified by a UK qualified physician and registered ABPI Signatory, in accordance with the ABPI Code and GSK standard operating procedures. GSK also has a specific governance framework for such materials, which involves several stringent processes, all of which were followed. Furthermore, GSK worked with both the UK Health Security Agency (UKHSA) and NHS England, to agree and align on the overarching messaging and imagery used to raise awareness of the Programme and its updated eligibility criteria. The Video was also approved by [named compliance body for TV commercials] prior to being aired.

GSK is confident that all requirements of the Code have been met (as outlined above) and that high standards have been maintained and thus refutes a breach of Clause 5.1. Accordingly, GSK also refutes a breach of Clause 2.

Conclusion

In summary, GSK is confident that the Video is fully compliant with the requirements of the Code, as detailed above, and strongly refutes breaches of Clauses 26.1, 26.2, 6.1, 5.1 and 2."

FURTHER INFORMATION REQUESTED BY THE PANEL

The Panel raised two questions with GSK and asked for additional information:

1. "Please confirm if GSK's shingles vaccine was the only one on the market at the time of the video advert. If it was not, please provide the names of the alternative vaccines, including whether they were available on the NHS.

2. Your response refers to GSK working with the UKHSA [the UK Health Security Agency] and sharing a copy of the video with them in advance. However, it is not clear to the Panel if you are seeking to rely on the exemption to Clause 26.1 ("*This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers*")? Do you have any documentation demonstrating approval for this campaign by health ministers? If so, please provide a copy of it."

FURTHER INFORMATION PROVIDED BY GSK

GSK's response to Question 1:

> "The NHS Shingles National Immunisation Programme (the 'Programme') was first introduced into the routine schedule in September 2013, for adults aged 70 years, with a phased catch-up for 71–79-year-olds. Prior to September 2023, [named alternative] vaccine was used routinely in the Programme, with GSK's Shingrix vaccine available for immunosuppressed individuals aged 70 to 79 years who were contraindicated to receive [named alternative vaccine] from September 2021.
>
> In September 2023, the Programme was expanded to include immunocompetent adults turning 65 years from 1st September 2023, and severely immunocompromised individuals aged 50 years and older, in addition to those aged 70-79 years. At that time, Shingrix replaced [named alternative vaccine] in the Programme. However, [named alternative vaccine] continued to be offered to adults aged 70 to 79 years who were eligible for the programme prior to September 2023, until supplies of the vaccine were depleted. Whilst GSK is not aware of exactly when stocks of [named alternative vaccine] were depleted, it is expected to have occurred at some point in 2024."

GSK's response to Question 2:

> "There are no mentions of specific prescription only medicines, including vaccines, anywhere in the TV video (or the Website). However, GSK recognises the potential complexities of implementing the requirements of the Code when undertaking Programme awareness activities when only one product is available and therefore also sought "health minister" approval to conduct its Programme awareness activities from the UK Health Security Agency (UKHSA). GSK therefore sought to rely on the exemption to Clause 26.1 at the point in time at which there became only one vaccine available.
>
> The UKHSA is an executive agency of the Department of Health and Social Care. It was established by the Secretary of State for Health and Social Care as the UK's "permanent standing capacity to prepare for, prevent and respond to infectious diseases and other threats to health. In performing its role, UKHSA fulfils the Secretary of State for health and social care's statutory duty to protect the nation's health and address inequalities."
>
> Regarding vaccination specifically, UKHSA hosts the secretariat for Joint Committee on Vaccination and Immunisation (JCVI) and provides clinical and public health expertise and evidence to support JCVI recommendations. It is also the government organisation accountable and responsible for the design, planning, and implementation of the Programme, including the procurement of a central supply of vaccines via a tender process.
>
> GSK noted with interest an update to the online Q&A section of Clause 26.1 in June 2025, which provided information regarding what "approved by health ministers" means in practice, clarifying that it, "refers to approval being required by the Medicines and Healthcare products Regulatory Agency (MHRA)." However, GSK would respectfully suggest that UKHSA is the appropriate government body for approval of vaccination

campaigns referred to within the context of “vaccination and other campaigns,” in Clause 26.1.

In support of this position, GSK would refer to the social media adverts for the ‘Get Winter Strong’ vaccination campaign for COVID and flu, which also serve to demonstrate the key role that UKHSA has in NHS vaccination campaigns; with the NHS responsible for Programme commissioning and delivery.

In summary, GSK has consulted with both UKHSA and NHS England (NHSE) since March 2023, to determine the public need for information about the Programme and to agree and align on imaging and messaging used in GSK Programme awareness activities. GSK can confirm that the TV video in this case were developed in consultation with, and with approval from, the UKHSA and NHSE, who also reviewed a version of both before they were aired on television.

We have prepared a table which shows the meetings which have taken place between GSK, UKHSA and NHSE to discuss GSK’s Programme awareness activities, which details the meeting frequency and the role of those who attended from UKHSA and NHSE.

PANEL RULING

This complaint was in relation to a GSK video about an NHS shingles vaccination programme. The video was shown as an advertisement on several Sky TV channels between 12-25 August 2024 (“the advert”).

GSK provided the Panel with a copy of the 30 second advert. The Panel accepted that the voiceover, and the words that appeared in large white font in the middle of the screen, were those as described by GSK in its response above.

The Panel interpreted the complainant’s allegations as being that the advert breached the following clauses of the Code for these reasons:

1. Clause 26.1 – promoting a prescription only medicine to the public,
2. Clause 26.2 – referring to 'GSK's shingle vaccine' and encouraging the viewer to ask their GP for it,
3. Clause 6.1 – no reference to other vaccines being available, and
4. Clause 6.1 – misleading by promoting a vaccine without providing evidence of the risk/benefit.

GSK’s response to these allegations was in summary that:

1. This was a factual, balanced, and non-promotional advert for a vaccination programme that was part of a UK government initiative.
2. The advert was not a disease awareness campaign.
3. The advert did not mention ‘GSK’s shingles vaccine’ nor any *specific* prescription only medicine.
4. The advert was educational and did not make any claims or comparisons.
5. It had consulted with UKHSA and NHS England about the advert.

The Panel considered each of the complainant's four allegations.

Clause 26.1 – promoting a prescription only medicine to the public

The Panel accepted GSK's submission that this was not a disease awareness campaign. The advert focused on eligibility criteria for a specific vaccination campaign. It did not include any information about shingles that went beyond vaccination.

The Panel then considered whether the advert amounted to promotion to the public of GSK's shingles vaccine.

Clause 26.1 stated:

> "*Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.*"

The Panel's overall impression of the advert was that it was encouraging members of the public in certain age groups to get vaccinated against shingles. The opening shots were of people walking, with close-ups of their shoes. The later images showed those people looking content and determined. For example, by standing with their arms folded or with hands on hips. The voiceover encouraged individuals within certain age groups, who had not already received an invitation for a vaccination, to contact their GP. The concluding wording on the screen and accompanying voiceover was "Step up against shingles". In the Panel's view this was clearly promoting the concept of people within certain age ranges getting an NHS shingles vaccine.

GSK submitted that, at the time the complainant viewed the advert (13 August 2024), the GSK Shingrix vaccine was the only one available for use in this vaccination programme. Shingrix replaced another company's vaccine in the Programme in September 2023. The Panel noted GSK's submission that there may have been some leftover vaccine produced by another company, the stocks of which would have been depleted "*at some point in 2024*". The Panel concluded that predominantly, and most likely exclusively, there was only one vaccine being used in this programme in August 2024, which was the one that was approved - Shingrix. It therefore followed that an advert promoting an NHS vaccination campaign at that time, when there was only one vaccine available within that programme, could be considered as promotional of that vaccine. The Panel also bore in mind that material could be promotional for a specific medicine even if that medicine was not named in the material.

However, the second sentence of Clause 26.1 does contain an exception, which is that the prohibition on advertising a prescription only medicine to the public does not apply to vaccination campaigns approved by heath ministers.

In its further information, GSK referred to meetings that it had had with UKHSA (an Executive Agency of the Department of Health and Social Care), which GSK submitted is, in legal terms, the same entity as health ministers. In June 2025, the PMCPA published a Q&A that stated:

> "'*…approved by the health ministers' in Clause 26.1, in practice, refers to approval being required by the Medicines and Healthcare products Regulatory Agency (MHRA).*"

The Panel acknowledged that this Q&A post-dated both the vaccination campaign in question and the complaint. However, the Panel considered that it nevertheless reflected the long-standing interpretation of this clause. The Panel noted that, in its original response to this complainant, and in its response to the request for further information on this specific point, GSK had not provided a document/correspondence to evidence that this campaign was approved by health ministers. GSK submitted that the advert in this case was developed in consultation with, and with approval from, the UKHSA and NHSE, who also reviewed a version before it was aired on television. GSK did provide a list of dates on which it submitted that it had met with UKHSA and NHSE about the vaccination campaign. However, by only seeing a list of meeting dates, and without knowing what was discussed at those meetings, or having any information about the role of the MHRA, the Panel was not satisfied that approval had actually been given in accordance with Clause 26.1. If there was a documented approval, the Panel considered it likely that GSK would have provided it in its response. On the balance of probabilities, and based on the evidence before it, the Panel considered that there likely was no such approval document.

The Panel concluded that because:

(a) the advert was not a disease awareness campaign (as acknowledged by GSK),
(b) the advert was promotional of an NHS vaccine campaign in which GSK had the only approved vaccine for NHS use, and
(c) GSK had not provided evidence of approval by health ministers,

the advert amounted to advertising a prescription only medicine to the public and was a **breach of Clause 26.1**.

Clause 26.2 – referring to 'GSK's shingle vaccine' and encouraging the viewer to ask their GP for it

The Panel interpreted part of the complaint to be referring to the final sentence of Clause 26.2, which stated:

> "*Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine*."

The Panel accepted GSK's submission that the complainant was incorrect in their allegation that the advert referred "*overtly*" to "*GSK's shingle vaccine*", and that this wording was written on the screen text.

However, the Panel took account of the following aspects of the advert, some of which related to the visuals; some of which were part of the accompanying voiceover:

1. The concluding frame of the advert showed smiling sports fans, over which was the following text in large white font: "*Step up against shingles. Visit GSK's [named website]*" (Panel's emphasis). Given the website is referred to as being "*GSK's*", the Panel considered that a viewer would reasonably assume that the website would give more information about GSK's vaccine.

2. Part of the voiceover included the statement: "*The free NHS shingles vaccination is available all year round*." The Panel considered the availability and lack of any cost

would likely contribute to the overall encouragement for people to request the vaccine.

3. The voiceover also stated: "*If you're eligible, your GP surgery should send you an invitation, but if you're worried you've missed yours, get in touch with them today*." The Panel considered that this amounted to an encouragement to anyone who had not received a letter from their GP about this vaccine to promptly contact their GP for it.

In general, the Panel did not think that members of the public would be likely to ask for a specific brand of vaccine. However, given that there was only one vaccine available for shingles at the relevant time (GSK's Shingrix vaccine) within the NHS programme, and given the Panel's finding that the advert promoted GSK's vaccine to the general public, the Panel considered that the combined effect of the aspects of the advert listed above, in the context of a vaccination campaign, would be that members of the public were being encouraged to ask their health professional to prescribe a specific prescription only medicine.

The Panel therefore ruled a **breach of Clause 26.2**.

Clause 6.1 – no reference to other vaccines being available

It follows from its rulings above and the Panel's conclusion that predominantly, and most likely exclusively, there was only one vaccine being used in this programme in August 2024, which was the one that was approved (Shingrix), that it would not have been appropriate, or indeed possible, for GSK's advert to refer to other vaccines being available. The Panel therefore ruled **no breach of Clause 6.1**.

Clause 6.1 – misleading by promoting a vaccine without providing evidence of the risk/benefit

In relation to this allegation that the advert ought to have evidenced the risks and benefits of the vaccine, the Panel took account of the following:

1. Although the thrust of the advert was to "*step up against shingles*", it did not make any claims or comparisons and nor did it refer to any risks or benefits.

2. The statement "*If you get any side effects, report them to your nurse or doctor.*" does appear in, what the Panel considered to be, a reasonable size of font across the bottom of the advert for 20 of the 30 seconds. Whilst, as set out above, the Panel did not consider the advert to be a vaccination program directed at the public and approved by the health ministers, GSK asserted otherwise. The relevant supplementary information required such campaigns for the public to include a general reference to the reporting of side effects.

3. The majority of the 30 second video is devoted to explaining eligibility to receive the NHS vaccine and encouraging eligible members of the public to participate in the program. It did not discuss clinical matters in relation to GSK's vaccine. In the Panel's view, it would be inappropriate to include detail about risks and benefits of a specific medicine in that context.

4. The complainant had not established any specific risk, the omission of which they considered to be misleading in this type of advert.

For all of these reasons, and that a prescription only medicine ought not to be promoted to the public, the Panel concluded that the advert's absence of information in relation to the risks and benefits, did not make it misleading. The Panel therefore ruled **no breach of Clause 6.1**.

Clause 5.1 – failure to maintain high standards

Although not raised by the complainant in express terms, the case preparation manager had asked GSK to consider the requirements of Clause 5.1 and Clause 2 in relation to this complaint. The Panel therefore considered GSK's conduct that led to the breaches of Clauses 26.1 and 26.2 above.

The essence of GSK's defence to the Clause 26.1 allegation was that it had met to discuss the advert with UKHSA (who it considers to be the relevant Executive Agency for approval of such campaigns), along with NHSE, and it therefore followed that there had been health minister approval for the purposes of Clause 26.1. However, the Panel was not satisfied that GSK had received approval given the absence of any clear evidence to demonstrate it, and the Panel was concerned that GSK sought to rely on such approval in the absence of such evidence.

Approval from health ministers is an express exemption from companies being in breach of Clause 26.1. The Panel also bore in mind the requirements in the MHRA's 'Blue Guide' which, in relation to advertising to the public, states that "*advertisements for a licensed vaccine product that have been approved by Health Ministers as part of a Government controlled vaccination campaign are exempt from this prohibition*" (emphasis added by the Panel to demonstrate the additional requirements of the Blue Guide).

In relation to Clause 26.2, the Panel considered that an advert that was clearly promotional of a shingles vaccine (at a time when GSK's Shingrix was the only vaccine that was approved for use on the NHS), was not an appropriate approach for GSK to have taken. If this had been a disease awareness campaign in relation to shingles, which referred to the vaccine among other options and treatments etc., the Panel considered that it might have been possible for GSK to create a disease awareness campaign that was Code compliant.

The Panel also took account of the fact that this advert was widely disseminated on several Sky TV channels for a two-week period and therefore material that promoted a prescription only medicine to the public would have likely reached a wide audience.

Given the above, and GSK's overall approach to the advert which had led to the breaches of Clauses 26.1 and 26.2, the Panel considered that GSK had failed to maintain high standards in this case. The Panel ruled a **breach of 5.1**.

Clause 2 – bringing discredit upon, or reducing confidence in, the pharmaceutical industry

The Panel considered a Clause 2 ruling to be a sign of particular censure and reserved for such use. The Panel noted that the examples of activity likely to be in breach of Clause 2, listed in the supplementary information to that clause, did not apply to the activity in this case. The Panel's view was that the breach rulings above were sufficient in relation to this complaint and the threshold for a Clause 2 ruling had not been met in the circumstances of this case.

The Panel ruled **no breach of Clause 2**.

APPEAL BY GSK

GSK's written basis for appealing is reproduced below with some typographical errors corrected:

> "The complaint pertains to a TV Video (the 'Video') which was seen by the non-contactable, anonymous complainant in August 2024 on a Sky TV channel. The Video raises awareness of the Government recommended - and UKHSA implemented - NHS Shingles National Immunisation Programme (the 'Programme').
>
> GSK acknowledges and welcomes the Panel's rulings of no breach of Clauses 6.1 and 2 of the 2021 ABPI Code of Practice ('the Code'); but disagrees with rulings of a breach of Clause 26.1, 26.2 and 5.1.
>
> GSK is committed to adhering to both the letter and spirit of the Code and all other relevant UK rules and regulations. The Video was part of a campaign to support and raise awareness of the Programme with eligible members of the public. GSK firmly believed it satisfied the requirements for the 'approved by health ministers' exemption for vaccination campaigns referred to in Clause 26.1. As such, GSK refutes a breach of Clause 26.1 and, by extension, Clause 26.2. Furthermore, GSK acted diligently and in good faith at all times and remains confident that high standards have been maintained in compliance with Clause 5.1.
>
> GSK is therefore appealing the Panel rulings of a breach of Clause 26.1, 26.2 and 5.1; and the rationale for the appeal is outlined below:
>
> **The Video does not include the wording 'GSK's shingle [sic] vaccine,' as alleged**
> The complainant alleges that, 'this advert overtly and obviously refers to "GSK's shingle [sic] vaccine" (this wording is written on the screen text) that you should ask your GP for….' However, this is allegation is completely inaccurate. 'GSK's shingle [sic] vaccine' is not stated anywhere in the 30 second Video – it does not appear as text on screen or in the voiceover. Whilst the Panel acknowledges, the 'complainant was incorrect in their allegation that the advert referred "overtly" to "GSK's shingle [sic] vaccine,"['] this was only referenced in relation to its ruling on Clause 26.
>
> However, GSK firmly asserts that this inaccuracy is a fundamental part of all the complainant's allegations. The complainant believed that the Video explicitly mentioned 'GSK's shingle [sic] vaccine' and the complaint was made on this basis. As the complainant is anonymous and non-contactable, it is not possible to determine to what extent this misunderstanding influenced their complaint, or whether the complaint would have otherwise been made. GSK strongly believes this misunderstanding is at the root of, and inextricably linked to, all allegations. As such, it undermines the arguments made by the complainant, who has the burden of proving their complaint and GSK does not believe they have done this.
>
> **The Video promotes the Programme and its eligibility criteria, not a specific vaccine product**
> The Video does not contain any specific mentions of GSK's shingles vaccine, Shingrix, nor does it contain any other particulars which might advertise this specific vaccine

product to the public. The only reference to shingles vaccination is in relation to the Programme, which would not in itself advertise a specific vaccine to the public. Government approved vaccination programmes vary widely in terms of the number vaccine products offered and, in the absence of actively seeking out such information, the public would be unlikely to be aware how many vaccine products are available for each programme. GSK maintains the Video does not contain information which advertises a specific vaccine product, Shingrix, to the public.

'Approved by health ministers' in practice (exemption to Clause 26.1)
Nevertheless, recognising the potential complexities of implementing the requirements of Clauses 26.1 and 26.2 when pharmaceutical companies support a government approved vaccination programme which offer one vaccine product, GSK also sought to fulfil the requirements of the exemption to Clause 26.1 for its Programme awareness campaign (which included the Video).

Neither Clause 26.1, nor its supplementary information, provides any information regarding which organisation (or organisations) would, in practice, provide the defacto health minister approval required to fulfil this exemption. Similarly, there is no information on the approval process or any required documentation.

In the absence of any available information to the contrary, and for the reasons outlined in its correspondence to the PMCPA, GSK firmly believed UKHSA (an Executive Agency of the Department of Health and Social Care) was the appropriate party to provide the approval by health ministers for the 'vaccination' campaigns referred to in the exemption to Clause 26.1. GSK provided the PMCPA with examples of social media posts for a winter vaccination awareness programme campaign, with clear demonstration these are led by UKHSA and NHSE, further underlining the role of UKHSA in vaccination campaigns.

Evidence of approval by 'health ministers' (exemption to Clause 26.1)
Following a request for information in relation to the exemption to Clause 26.1, GSK provided the PMCPA with a document outlining the dates of regular meetings GSK had with UKHSA and NHSE to discuss GSK's Programme awareness activities. These tripartite meetings commenced in April 2023, well before GSK launched any Programme awareness materials, including the Video. Meeting minutes were created by GSK and shared with attendees.

GSK also made the PMCPA aware of the existence of the minutes for these tripartite meetings advising that, should these be required by the PMCPA, GSK would need to consult with UKHSA and NHSE stakeholders before providing them. However, the minutes were not requested by the PMCPA. Nevertheless, the Panel concluded that, 'without knowing what was discussed at those meetings, or having any information about the role of the MHRA, the Panel was not satisfied that approval had actually been given in accordance with Clause 26.1.'

Relevant extracts from the meeting minutes – with unrelated topics and personal identifiers removed – are therefore provided. This is a confidential document and therefore should not appear in any case reports. These extracts provide evidence that GSK worked collaboratively, and met frequently with, UKHSA and NHSE stakeholders, to discuss and align on the Programme awareness campaign. The Video was aligned with

UKHSA/NHSE, and the final iteration shared with both parties in advance of it being aired on TV. In the absence of any publicly available information to the contrary, GSK firmly believed that this way of working with UKHSA would be sufficient to satisfy the requirements for the exemption to Clause 26.1.

Publication of PMCPA Q&A guidance in June 2025

Almost a year after the PMCPA received the complaint about the Video - and whilst a ruling was awaited - the PMCPA published a Q&A on its website to address the question, 'what is meant by "approved by the health ministers" in Clause 26.1?' It clarified that, '… "approved by the health ministers" in Clause 26.1, in practice, refers to approval being required by the Medicines and Healthcare products Regulatory Agency (MHRA).'

Although the Panel acknowledged that the Q&A post-dated the Video it 'considered that it nevertheless reflected the longstanding interpretation of this clause,' presumably referring to an industry-wide, established understanding that the MHRA is the defacto delegate for the approval of 'vaccination and other campaigns' referred to in the exemption to Clause 26.1. However, GSK, respectfully, disagrees. Prior to the publication of this information, GSK is not aware of any relevant PMCPA case rulings or case precedence regarding vaccination campaigns approved by health ministers, or of any other information source which documents this as the accepted standard. Neither is there any information on the approval process itself, or any documentation which might be required to fulfil the requirements of the exemption to Clause 26.1. The members of the UK medical team directly working on the campaign have extensive experience as ABPI Code signatories, and over 25 years combined experience working on vaccines specifically, across several pharmaceutical companies. As the government agency charged with the design, planning, communication (to the public and healthcare professionals) and implementation of UK vaccination programmes, UKHSA is considered the relevant stakeholder for vaccination campaigns and – in the absence of any information to the contrary - was also considered the defacto health minister for the purposes of the exemption to Clause 26.1.

Correspondence with the MHRA

In light of the new information from the PMCPA, GSK duly contacted the MHRA to obtain clarification regarding the process for health minister approval of vaccination programme awareness campaigns carried out by companies. In their correspondence:

- The MHRA directed GSK to Section 5.2 of the Blue Guide, titled 'Medicines suitable for advertising to the public,' which states that, 'advertisements for a licensed vaccine product that have been approved by Health Ministers as part of a Government controlled vaccination campaign are exempt from this [advertising of a prescription only medicine to the public] prohibition.'
- The MHRA advised that the above **'exception is not Industry-led,'** and that, 'a pharmaceutical company's role and liaison in supporting a national immunisation campaign **should be discussed with the health bodies overseeing the programme'** [emphasis added]. GSK is confident that this is exactly the **way of working GSK has had with the UKHSA (the organisation responsible for the Programme)**.
- The MHRA further clarified that it does not interact directly with pharmaceutical companies regarding the approval of such campaigns; rather that, 'the relevant bodies are likely to contact the MHRA to ask for assistance in this regard.' This would appear to imply that the responsibility does not lie with the company. However, the entire process remains unclear for vaccination campaigns.

Maintaining high standards (Clause 5.1)

In addition to seeking 'health minister' approval as outlined above, the Video included the statement, 'If you get any side effects, report them to your nurse or doctor,' in compliance with the supplementary information to Clause 26.1 which requires that such campaigns contain a 'general reference to the reporting of side effects.' In their ruling, the Panel acknowledges this wording appears in 'a reasonable size of font across the bottom of the advert for 20 of the 30 seconds.' The Video was certified by a UK qualified physician and registered ABPI Signatory, in accordance with the ABPI Code. The Video was also approved by [named compliance body for TV commercials], a non-governmental organisation which reviews adverts for television to ensure compliance with the UK Code of Broadcast Advertising (the BCAP), which sets out standards to help ensure that broadcast content is not misleading, harmful of offensive.

In summary,

- Clause 26.1 lacks any information regarding which organisation (or organisations) would provide the defacto approval to satisfy the 'approved by the health ministers' exemption to Clause 26.1. In addition, at the time the complaint was received, there was no other information, guidance or case precedence specifying the MHRA as the sole authority for health minister approval.
- The PMCPA's Q&A was published nearly a year after the complaint was received and should not be retroactively applied.
- GSK believes that regulatory expectations, particularly requirements which would appear to be unequivocal, must be clearly communicated to Industry in advance to ensure fairness and facilitate compliance with the Code and other applicable laws and regulations.
- GSK strongly asserts that it acted in-line with the available information regarding the 'health minister' approval exemption to Clause 26.1. GSK believed that UKHSA, given its direct role in the communication and implementation of the Programme, was an appropriate organisation, both from a practical and legal perspective, to engage with to fulfil the requirements of Clause 26.1 for its Programme awareness campaign.
- GSK worked collaboratively with UKHSA and NHSE, regularly and consistently engaging with them regarding its campaign and acting on feedback. In doing so, GSK believes it had satisfied the requirements for the exemption to Clause 26.1.
- Accordingly, GSK refutes a breach of Clause 26.1 and by extension Clause 26.2.
- Although the PMCPA's publication of the Q&A post-dated the complaint by almost a year, GSK contacted the MHRA to seek clarity on the process that companies should follow on becoming aware of it. However, despite these efforts, the process remains unclear.
- GSK acted diligently and in good faith at all times and remains confident that high standards have been maintained. GSK therefore refutes a breach of Clause 5.1."

APPEAL BOARD RULING

The focus of this appeal was whether GSK's shingles vaccination campaign fell within the exemption to Clause 26.1 of the Code that the prohibition on advertising prescription only medicines to the public did not apply to "*vaccination and other campaigns carried out by companies and approved by the health ministers*".

At the appeal hearing, GSK's representatives did not dispute that such approval by the health ministers was required for its shingles vaccination campaign. GSK's position was that they effectively had that approval, via another government agency.

The Appeal Board observed that the Panel had based its ruling on the insufficient evidence from GSK to demonstrate that approval had been given by *any* government body. All GSK had provided to the Panel was a list of dates on which it had met with NHS England and the UKHSA. The substance of those meetings had not been provided.

Before its appeal, GSK provided meeting minutes showing that GSK's shingles vaccine campaign had been discussed in great detail with NHS England and UKHSA, and that the content of the campaign had, in GSK's opinion, been implicitly approved. The Appeal Board accepted GSK's evidence at the Appeal Board meeting that these minutes had been shared with the UKHSA who had not raised any objections to the content of the minutes. Following questioning, GSK representatives told the Appeal Board that the exemption in Clause 26.1 and the requirement for approval from "health ministers" was explicitly discussed with the UKHSA. The Appeal Board accepted that the company's intent when interacting with NHS England and UKHSA was to satisfy the exemption in Clause 26.1.

The Appeal Board acknowledged that companies would be likely to engage with multiple government bodies in relation to vaccination campaign material. The Appeal Board took into consideration that at the time of the activity in question, which pre-dated the published PMCPA guidance, there was insufficient clarity about the route for companies to take in obtaining approval by "health ministers" for the purposes of the Clause 26.1 exemption.

It was not for the Appeal Board to determine which government body could approve vaccination campaigns. In the circumstances of this case, the Appeal Board concluded that it would not be appropriate to find GSK in breach of Clause 26.1 because it had sought, and believed in good faith that the collaboration and agreed meeting minutes amounted to, approval for the vaccination campaign from government via the UKHSA, and the UKHSA had not told GSK that it needed approval from MHRA, from any other government body or from the health ministers directly in order to meet the exemption. The Appeal Board therefore ruled **no breach of Clause 26.1**. The appeal on this point was successful.

It followed that it would also not be appropriate to find GSK in breach of Clauses 5.1 and 26.2 given the Appeal Board's conclusion that there was no breach of Clause 26.1. The Appeal Board therefore ruled **no breaches of Clause 26.2 and 5.1**. The appeal on this point was successful.

The Appeal Board requested that the PMCPA work with the MHRA to further clarify the process for companies seeking the exemption referred to in Clause 26.1.

[SEE THE HEADER AT THE START OF THIS CASE REPORT IN RELATION TO THE APPEAL BOARD'S FURTHER CONSIDERATION OF THIS MATTER]

Complaint received **14 August 2024**

Case completed **12 November 2025**