

**COMPLAINANT v GLAXOSMITHKLINE**

**Alleged promotion of Shingrix on a TV advertisement and disease awareness website**

**CASE SUMMARY**

This case was in relation to a TV advert from GlaxoSmithKline broadcast on television on 7 January 2023. The advertisement included the URL of the GlaxoSmithKline disease awareness website for shingles.

The Panel ruled no breach of the following Clauses of the 2021 Code, noting the balance of the webpage and content of the advert:

<b>No Breach of Clause 5.1</b>	<b>Requirement to maintain high standards at all times</b>
<b>No Breach of Clause 26.1</b>	<b>Requirement not to advertise prescription only medicines to the public</b>
<b>No Breach of Clause 26.2</b>	<b>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</b>

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

**FULL CASE REPORT**

A complainant who described themselves as a UK physician complained about a TV advertisement from GlaxoSmithKline on Sky TV on Saturday 7 January 2023. Whilst they noted the advertisement aimed to educate the public about shingles, their concern was that this was indirectly promoting GlaxoSmithKline's shingles vaccine Shingrix which received marketing authorisation in 2018. The complainant noted that Merck Sharp & Dohme also had a vaccine for shingles which was licenced in 2006 called Zostavax.

**COMPLAINT**

The complainant stated that given the timing/placement of the advertisement which seemed to have been approved by GlaxoSmithKline in 2021, which was broadly aligned with the timing of receiving its marketing authorisation, they were surprised this was allowed and how it could not be seen as disguised promotion to the public. It only took a click or two on Google to know that GlaxoSmithKline had a recently approved vaccine, despite Zostavax being available from 2006.

The complainant stated given Merck Sharp & Dohme's vaccine was approved in 2006, the only reason for GlaxoSmithKline to do this campaign, was for the public to ask their GP about Shingrix, especially as there had been 13 years between approval of both medicines. This campaign was indirectly pointing to Shingrix, otherwise what was the point in doing this campaign?

The complainant further stated that in the spirit of fairness, a doctor would be able to offer both vaccines to a patient. However, the complainant noted the NHS website stated 'Most people will have the Zostavax vaccine. The Shingrix vaccine is recommended if Zostavax is not suitable for you, for example if you have a condition that affects your immune system'. This further compounded the problem as if patients had failed on Zostavax, the only vaccine they could get was Shingrix. The complainant stated whilst disease campaigns were acceptable if more than one treatment existed, in this case, there was only one treatment available if a patient had failed on Zostavax.

This was totally unacceptable in the complainant's view and needed to be investigated as GlaxoSmithKline had promoted to the public indirectly and not maintained high standards as expected from a pharmaceutical company.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 26.1, 26.2 and 5.1 of the Code.

## **RESPONSE**

GlaxoSmithKline stated that it took its obligations under the Code extremely seriously and was committed to following both the letter and spirit of the Code. While GlaxoSmithKline were disappointed to see this complaint raised, GlaxoSmithKline was confident that its activities were fully compliant with the Code and GlaxoSmithKline strongly refuted breaches of Clauses 26.1, 26.2 and 5.1.

### **Disease awareness campaign**

GlaxoSmithKline stated that it began its disease awareness campaign to educate the public and increase awareness of shingles in September 2021. The video as described by the complainant (the video), formed part of the campaign. It was a 30 second video providing general information on shingles that was shown on specified television channels including Sky TV, where it was seen by the complainant. The video comprised imagery showing older adults (some with the shingles rash), on-screen text and a voiceover. The on-screen text and voiceover transcript were provided below:

#### **Video on-screen text**

Developed and paid for by GSK  
90% of adults in the UK carry the virus that causes shingles.  
Shingles risk increases with age.  
Other risk factors include having a weakened immune system.  
According to people who experienced shingles. Symptoms may vary and not everyone will experience these symptoms.  
Ask your healthcare professional about shingles.  
[disease awareness website for shingles]

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## **Video voiceover**

90% of adults in the UK have had chickenpox which is caused by the varicella zoster virus. Afterwards, the virus remains dormant in your body. There is a 1 in 4 lifetime risk of the virus reactivating and causing shingles and the risk increases with age. Patients describe shingles as a tingling, burning, stabbing, or itching feeling, usually accompanied by a painful rash on one side of the body. Shingles and its complications may impact your quality of life. Ask your pharmacist, nurse or doctor about shingles and visit our site to learn more.

## **Background**

GlaxoSmithKline stated that two shingles vaccines were licensed and available in the UK: Zostavax (Merck Sharp & Dohme) and Shingrix (GlaxoSmithKline). GlaxoSmithKline held the marketing authorisation for Shingrix (adjuvanted recombinant herpes zoster vaccine) which was indicated for the prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN) in adults 50 years of age or older; and adults 18 years of age or older at increased risk of HZ. It must be used in accordance with official recommendations.

Shingrix was licensed for use in the UK via the centralised European authorisation route in 2018.

The UK Shingles National Immunisation Programme (NIP) was available for adults aged 70–79 years of age. Unless contraindicated, the use of Zostavax was recommended; Shingrix might be used in adults for whom Zostavax was contraindicated.

## **Clauses 26.1 and 26.2**

The case preparation manager had asked GlaxoSmithKline to consider Clauses 26.1 and 26.2.

Clause 26.1 stated that prescription only medicines must not be advertised to the public. Clause 26.2 stated that information about prescription only medicines which was 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 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 health professional to prescribe a specific prescription only medicine.

The Supplementary Information (SI) to Clause 26.2 addresses Disease Awareness Campaigns (DACs) and cautions regarding likely the implications of using brand or non-proprietary names and/or restricting the range of treatments described in the campaign. It also drew attention to the MHRA Blue Guide DAC Guideline (the 'Guideline'), which recognised that DACs 'can provide a valuable source of information to the public on diseases and conditions, aid recognition of symptoms and highlight appropriate sources of advice'. The Guideline clarified that the 'primary purpose of a DAC must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management' and reiterated that DACs 'should not promote the use of a specific medicine'. It further highlighted that 'the emphasis of the material should be on the condition and its recognition rather than treatment options'.

In common with the MHRA and the ABPI, GlaxoSmithKline recognised the importance of providing high quality educational information to the public about health and disease. The MHRA Guideline and the Code allowed for the provision of DACs by pharmaceutical companies, subject to certain requirements and GlaxoSmithKline was confident that the video was fully compliant with both the MHRA Guideline and the Code:

#### *Video*

GlaxoSmithKline submitted that the video provided the public with non-promotional, up-to-date, factual, balanced, substantiable information about shingles (specifically, signs and symptoms, cause and risk factors) and finished by highlighting appropriate sources of further information, such as the GlaxoSmithKline disease awareness website for shingles website or their healthcare professional. The video did not constitute promotion of any medicine or vaccine. GlaxoSmithKline had taken particular care to avoid drawing attention to any medicinal or vaccine product. The video did not refer to Shingrix, nor did it reference, directly or indirectly, any medicinal or vaccine product and did not encourage members of the public to request a specific medicine or vaccine from their HCP. GlaxoSmithKline noted from the letter of complaint that after watching the video, the complainant then chose to perform a Google search in order to identify that GlaxoSmithKline held a market authorisation for a vaccine in this therapy area.

#### *Disease awareness website*

GlaxoSmithKline stated that at the end of the video, the address of the GlaxoSmithKline disease awareness website (the 'website') was provided and listeners were encouraged to visit the website or speak to their healthcare professional to learn more. The website provided high quality, non-promotional information about shingles for the public. It was a comprehensive information source which included facts about the disease, including its cause, signs and symptoms, risk factors, complications, treatment and prevention. The information about treatment and prevention constituted only one component of the overall disease information available on the website and appeared within the context of the wider disease area. Of note, this information appeared after information about the cause, signs and symptoms and complications of shingles had been provided. The text from the website was provided below:

#### CAN SHINGLES BE TREATED OR PREVENTED?

##### Treatment/Management:

If you think you may have shingles, please speak with your healthcare professional as soon as possible. They may prescribe appropriate medicines to help reduce the severity and duration of your symptoms.

##### Prevention:

Shingles can be prevented through vaccination. Speak with your pharmacist, nurse or doctor to discuss prevention options. There is a national immunisation programme for shingles available for people aged 70–79.

GlaxoSmithKline submitted that to substantiate information provided on the website references had been included; however, to prevent any link to specific medicines or vaccines, there were no links to any third-party websites. Whilst the terms 'medicines' and 'vaccination' were mentioned generally on the website, no specific vaccine or medicine was directly or indirectly referenced. 'Medicines' referred to a number of different medicine types including, but not limited to, pain medications and antivirals. The website encouraged the public to speak to their

healthcare professional as soon as possible, but it did not provide any details on the types of medicine which could be used by their healthcare professional as the appropriate treatment (if any) for a patient was for the healthcare professional to decide in consultation with the patient. 'Vaccination' is used within the context of the UK Health Minister-approved shingles National Immunisation Programme for people aged 70–79. As previously highlighted, there were two shingles vaccines available via the NIP and very clear guidance existed for healthcare professionals regarding which vaccine should be used; Shingrix was only available for those adults in whom Zostavax was contraindicated.

In summary, the video contained factual, balanced, non-promotional information about shingles for the public. It raised awareness of the cause, signs and symptoms and risk factors for the disease and encouraged the public to learn more about the condition by visiting GlaxoSmithKline's disease awareness website or asking their healthcare professional. There were no references to specific medicines or vaccines; nor was there any information on treatment or prevention. The website address was provided at the end of the video although there was no direct link to it. Whilst the website was not specifically highlighted by the complainant, for completeness and transparency, it had also been addressed in this letter. The website did contain information about treatment and prevention, but this was provided within context of the wider shingles disease area and there were no references to specific medicines or vaccines.

Given the totality of factual, balanced information focused on educating the public on shingles, and the absence of any names of specific medicines or vaccines, GlaxoSmithKline was satisfied that neither the video (nor the associated website) constituted promotion of a prescription only medicine to the public, nor would they encourage members of the public to ask their healthcare professional to prescribe a specific prescription only medicine. GlaxoSmithKline was confident that the requirements of Clauses 26.1 and 26.2 had been met.

### **Clause 5.1**

Clause 5.1 required companies to maintain high standards at all times, GlaxoSmithKline took the requirements of this Clause very seriously.

GlaxoSmithKline stated that the Code and MHRA Blue Guide allowed for the provision of proactive, non-promotional, disease information to the public, providing certain conditions were met, and GlaxoSmithKline was confident that the video (and the associated website) were fully compliant with these requirements as detailed above.

Educational material for the public issued by companies which related to diseases required certification and the video was certified by a UK registered signatory for GlaxoSmithKline, in accordance with the Code and GlaxoSmithKline standard operating procedures. Furthermore, GlaxoSmithKline had a specific governance framework for the development of disease awareness campaigns, which involved several stringent processes, all of which had been followed. Consequently, GlaxoSmithKline was confident that high standards had been maintained and refuted a breach of Clause 5.1.

### **Conclusion**

To conclude, GlaxoSmithKline was confident that the video was fully compliant, complied with the requirements for disease awareness as stated within the MHRA Blue Guide DAC Guidelines and the Code. GlaxoSmithKline strongly refuted breaches of Clauses 26.1, 26.2 and 5.1.

## PANEL RULING

The Panel noted the TV advertisement at issue was a 30 second video on shingles that was shown on specified television channels including Sky TV, where it was seen by the complainant. The video comprised imagery showing older adults (some with the shingles rash) and included the following on-screen text along with GlaxoSmithKline disclaimers:

'90% of adults in the UK carry the virus that causes shingles. Shingles risk increases with age. Other risk factors include having a weakened immune system. According to people who experienced shingles. Symptoms may vary and not everyone will experience these symptoms. Ask your healthcare professional about shingles.  
The URL to GlaxoSmithKline's disease awareness website for shingles .

The accompanying voiceover stated:

'90% of adults in the UK have had chickenpox which is caused by the varicella zoster virus. Afterwards, the virus remains dormant in your body. There is a 1 in 4 lifetime risk of the virus reactivating and causing shingles and the risk increases with age. Patients describe shingles as a tingling, burning, stabbing, or itching feeling, usually accompanied by a painful rash on one side of the body. Shingles and its complications may impact your quality of life. Ask your pharmacist, nurse or doctor about shingles and visit our site to learn more'.

The Panel noted the website referred to in the video was intended for members of the public and started with the prominent heading '1 in 4 people will get shingles in their lifetime. Don't let shingles affect life's plans.' This was followed by in smaller font 'you may have heard how serious the pain of shingles can be. Learn more about the signs, symptoms, complications, treatment, and prevention options.' The website went on to provide disease information about shingles, including causes and symptoms, along with information on people at risk, complications of shingles and treatment/prevention.

The section for treatment stated 'if you think you may have shingles, please speak with your healthcare professional as soon as possible. They may prescribe appropriate medicines to help reduce the severity and duration of your symptoms'. Notably, the prevention section stated 'Shingles can be prevented through vaccination. Speak with your pharmacist, nurse or doctor to discuss prevention options. There is a national immunisation programme for shingles available for people aged 70–79'.

The Panel noted GlaxoSmithKline's submission that to prevent any link to specific medicines or vaccines, there were no links to any third-party websites from the disease awareness website and that no specific vaccine or medicine were directly or indirectly referenced on the website.

Clause 26.1 prohibited promotion of prescription only medicines to the public. The supplementary information to Clause 26.2, information to the public, stated 'Any information so provided must observe the principles set out in this clause; that is, it should be factual, balanced and must not encourage members of the public to ask their doctors or other prescribers to

prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 26.1'. In relation to disease awareness campaigns, Clause 26.2 supplementary information stated that a company could conduct a disease awareness campaign provided that the purpose was to encourage the public to seek treatment for symptoms while in no way promoting the use of a specific medicine; particular care must be taken where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question.

In the Panel's view, the website provided a balanced overview of shingles, with similar emphasis placed on each section such as the disease nature, complications and treatment/prevention. Whilst the Panel considered that there was particular mention of vaccination as a preventative option, whereas only 'appropriate medicines' were mentioned within the treatment section, the Panel nonetheless did not consider that sole reference to vaccinations meant that a specific prescription only medicine had been promoted; at the time of the advertisement in question and receipt of the complaint, GlaxoSmithKline's shingles vaccination, Shingrix, was not the only company to have a shingles vaccination. In this regard, the Panel noted there was another shingles vaccine that had been available, Merck Sharp & Dohme's Zostavax.

The Panel noted Section 4.1, therapeutic indications, of the Shingrix SPC stated it was indicated for prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older; adults 18 years of age or older at increased risk of HZ. **The use of Shingrix should be in accordance with official recommendations'** (emphasis added by the Panel).

In this regard, the Panel noted at the time of the complaint, the complainant and GlaxoSmithKline submitted that the Shingrix vaccine was available to those for whom Zostavax was not suitable; the UK Shingles National Immunisation Programme was available for adults aged 70-79 years of age according to GlaxoSmithKline. The Panel, noting its comments above regarding the balance of the webpage, considered that the complainant had not established that the video advertisement nor webpage promoted Shingrix to the public as alleged and therefore **no breach of Clause 26.1** was ruled. In the Panel's view, the video and website material might have led to a member of the public to ask about preventing or treating shingles, which included but was not limited to GlaxoSmithKline's medicine. The Panel ruled **no breach of Clause 26.2**.

The Panel noted its rulings of no breach of Clauses 26.1 and 26.2 above and ruled **no breach of Clause 5.1** accordingly.

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**Complaint received**      **10 January 2023**

**Case completed**         **15 November 2023**