

# ANONYMOUS v GLAXOSMITHKLINE

## Alleged promotion of a vaccine to the public

An anonymous complainant drew attention to an advertisement for GlaxoSmithKline on the Telegraph Online which appeared on 28 June 2016.

The complainant noted that the advertisement stated something like 'GlaxoSmithKline has been working on the world's first malaria vaccine, which if approved we intend to make available at a reduced cost'. The complainant alleged that this constituted the promotion of an unlicensed medicine direct to patients.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the complainant had been asked for more information including a download of the advertisement on The Telegraph website but had not responded. The Panel noted that GlaxoSmithKline had placed the video on YouTube and its corporate website and noted that it would also be picked up by individuals who searched for certain topics. It was not clear how the complainant had seen the video on the Telegraph Online. GlaxoSmithKline submitted that a targeting algorithm would have placed the material on that webpage if the user had previously searched for relevant items.

The Panel noted that GlaxoSmithKline had been working with partners on a vaccine for malaria for use in children of a specific age in certain areas of Africa. The vaccine had been considered by the European Medicines Agency (EMA) but would not be marketed in the EU. A positive Committee for Medicinal Products for Human Use (CHMP) opinion was adopted in July 2015 for use of the vaccine outside the EU. Further studies were being discussed as well as a pilot implementation programme. The collaboration would help determine in which Sub-Saharan African countries the first marketing authorisations should be submitted. The vaccine was intended to be for malaria and hepatitis B.

The Panel noted GlaxoSmithKline's submission that there was no mention in the video that the vaccine had received a positive approval by the CHMP under Schedule 58. However, screenshots of headlines were included in the video. One from The Daily Telegraph 'GSK Steps closer to making world's first malaria vaccine' and another 'GlaxoSmithKline malaria vaccine trials successful but drug will be not-for-profit'.

In the Panel's view it was relevant that the vaccine was for use in Sub-Saharan Africa in those countries where malaria was highly endemic and that GlaxoSmithKline had no intention at this point of making a licence submission in Europe (including the UK). It also noted the company's submission

that use in the UK was precluded as there would be little, if any, therapeutic need.

The Panel considered that given the content of the video, the nature of the medicine and its potential intended geographical use, the video was a corporate advertisement. It was neither promotion of an unlicensed medicine nor promotion of a prescription only medicine to the public. The Panel thus ruled no breach of the Code in this regard. Further the advertisement would not encourage members of the public to ask their health professional to prescribe the vaccine which was for potential use in Sub-Saharan Africa in those countries where malaria was endemic. The Panel did not consider that GlaxoSmithKline had failed to maintain high standards nor did it consider that the company had brought discredit upon or reduced confidence in the pharmaceutical industry. No breaches of the Code were ruled including Clause 2.

An anonymous complainant drew attention to an advertisement for GlaxoSmithKline on The Telegraph website, the Telegraph Online, which appeared on 28 June 2016.

### COMPLAINT

The complainant noted that the advertisement stated something like 'GlaxoSmithKline has been working on the world's first malaria vaccine, which if approved we intend to make available at a reduced cost'. The complainant alleged that this constituted the promotion of an unlicensed medicine direct to patients.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 3.1, 9.1, 26.1 and 26.2 of the Code.

### RESPONSE

GlaxoSmithKline believed that the complaint might relate to a 30 second video entitled 'How we are tackling malaria on all fronts' which was available on The Telegraph Online on 28 June as it contained similar wording to that referred to by the complainant. The video was hosted on YouTube and also appeared on the GlaxoSmithKline corporate website.

The short transcript which accompanied the video was as follows:

'Malaria kills 1 child every two minutes in Africa. That's why GSK has been working with partners for the past 30 years to develop the world's first malaria vaccine. If approved, we're committed to making it available at a not-for-profit price. We're also joining forces with Comic Relief to help fight malaria in the worst affected countries.'

Because it doesn't matter who solves the problem. Only that someone does.

TITLE: To challenge. To change. GSK Do more, feel better, live longer. Find out more at [gsk.com/change/](http://gsk.com/change/).

GlaxoSmithKline explained that the video was part of a campaign run by the corporate and government affairs, global brand team in GSK House, which was specifically designed to enhance the corporate image and reputation of the company with the 'informed' public (defined as 25 years or older, with at least a first degree, connected on social media, with interests such as current affairs, healthcare, charitable giving, science education and innovation). The need for such a campaign was based on the results of a market research initiative, conducted in 2014 and again in 2016 which sought to determine how the UK public perceived GlaxoSmithKline as a company amongst its industry peers and how its image and reputation could be further enhanced. One of the key findings of this research was that the company should be more transparent in its research activities as well as with the various stakeholders with whom it engaged.

The malaria video formed part of the campaign to highlight the role played by GlaxoSmithKline as a global healthcare company in a specific therapeutic area ie malaria which still placed a significant global healthcare burden in Sub-Saharan Africa. The film highlighted the commitment and longevity of research that GlaxoSmithKline had been engaged in over the last 30 years, as well as its collaboration with Comic Relief, which were aimed at implementing a variety of other initiatives related to the prevention and spread of malaria in these regions. The 30 second film was developed in collaboration with Comic Relief, which supplied the image of a named celebrity and approved its use. In addition, Comic Relief acknowledged GlaxoSmithKline as an international partner on its website and gave some information as how together, the two organisations planned to fight malaria in Africa. Comic Relief was not involved with the vaccine itself, the research which had been undertaken, nor the distribution of the vaccine when it eventually became available for use in Sub-Saharan Africa.

The video started with the World Health Organisation (WHO) facts about the number of childhood deaths in Africa directly attributable to malaria. Two sentences then referred to the GlaxoSmithKline vaccine 'That's why GSK has been working with partners for the past 30 years to develop the world's first malaria vaccine. If approved, we're committed to making it available at a not-for-profit price'. Finally, the partnership with Comic Relief was mentioned. The video showed African children and African health professionals and the opening footage referred to Africa, so it was quite clear that all these initiatives were and would take place in Africa.

GlaxoSmithKline explained that the film was targeted at the informed public (defined above) or someone who had specifically Googled topics like malaria etc. If someone had searched for an item on

Google, eg shoes, Google retained the information and used cookies to serve him/her relevant and similar advertisements as it knew he/she had had an intention to purchase or view shoes. So the malaria film might have appeared on the complainant's screen as part of a targeting algorithm, which had identified him/her as someone who was interested in that sort of topic. There was no editorial control with this sort of advertisement placement by the media owner, so the film was not amended or changed by The Telegraph Online – it was solely bought advertising space. These advertisements were frequency capped to ensure a user would not see a specific advertisement more than was reasonable, subject to individual privacy settings and the tracking ability of the software serving the advertising.

GlaxoSmithKline submitted that the malaria vaccine featured in the video was Mosquirix (*Plasmodium falciparum* and hepatitis B vaccine) although it was not referred to as such in the video. The vaccine was intended for use in areas where malaria was regularly found, for the active immunisation of children aged 6 weeks to 17 months against malaria caused by the *Plasmodium falciparum* parasite, and against hepatitis B.

The vaccine was submitted to the European Medicines Agency (EMA) under a regulatory procedure (Article 58) that allowed the EMA to assess the quality, safety and efficacy of a medicine or vaccine and its benefit-risk balance, although it would not be marketed in the EU. This meant that the EMA could help facilitate access to new medicines for people living outside the EU.

As in all Article 58 procedures, the Committee for Medicinal Products for Human Use (CHMP) worked closely with other experts, including those from the WHO and regulatory authorities from the relevant countries. In its assessment, the CHMP applied the same rigorous standards as for medicines to be marketed within the EU. On 24 July 2015 the CHMP adopted a positive scientific opinion for Mosquirix for use outside the EU. From this press release it was clear that this vaccine would not be made available for use in Europe (including the UK).

GlaxoSmithKline stated that it was now working with the WHO with respect to what further clinical trials might be required to evaluate the vaccine in phase 4 studies, and a pilot implementation program as recommended by WHO's advisory bodies (Strategic Advisory Group of Experts on Immunisation and the Malaria Policy Advisory Committee). This collaboration would help to determine how best to implement a global vaccination policy for malaria and in which Sub-Saharan African countries the first marketing authorisations should be submitted. The malaria vaccine was currently a 'pipeline product' for GlaxoSmithKline as no submissions for marketing authorisation had yet been made.

The fact that marketing authorisations for the vaccine, which was intended for use in very young children aged 6 weeks to 17 months, would only be submitted in countries where malaria was highly endemic precluded its use in the UK, for which there would be

very little, if any, therapeutic need. Thus any mention of the vaccine to the UK public did not constitute promotion prior to the grant of a market authorisation as the vaccine would never be made available to UK patients. As Clause 3.1 stated that 'A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply', GlaxoSmithKline denied a breach of Clause 3.1.

GlaxoSmithKline submitted that the video could not therefore be considered as being 'promotional' to patients within the UK as Clause 1.2 of the Code stated that 'The term 'promotion' is defined as any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines'. As stated above, the vaccine currently was not licensed anywhere in the world, and there was no intention at this point for a licence submission to be made in Europe (including the UK) as was shown by GlaxoSmithKline choosing the Article 58 Procedure in the European Regulatory Process. GlaxoSmithKline therefore denied any breach of Clause 26.1 which stated that 'Prescription only medicines must not be advertised to the public'.

The 30 second video only included a two sentence reference to the malaria vaccine as follows:

'That's why GSK have been working with partners for the past 30 years to develop the world's first malaria vaccine. If approved, we're committed to making available at a not-for-profit price.'

GlaxoSmithKline believed that information about the vaccine was presented in a fair and balanced way. The above statement simply reflected the longevity of this research and then placed a caveat with 'If approved' therefore signifying that the benefit:risk profile had yet to be determined by a national regulatory authority. Indeed, there was no mention in the video that the malaria vaccine had received a positive approval by the CHMP under Schedule 58 in July 2015. In not mentioning this, nor making any claims regarding the efficacy of the vaccine *per se*, GlaxoSmithKline did not consider that it had raised any unfounded hopes about the success that it might have in preventing malaria in very small children. There was also no references to the safety of the vaccine. Clause 26.2 stated 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 be misleading with respect to the safety of the product'. GlaxoSmithKline therefore denied any breach of Clause 26.2.

In view of the above, GlaxoSmithKline submitted that it had not breached the Code and thus was not in breach of Clauses 9.1 or 2.

## PANEL RULING

The Panel noted that the complainant had been asked for more information including a download of the advertisement on The Telegraph website

but had not responded. The Panel noted that GlaxoSmithKline had placed the video on YouTube and its corporate website and noted that it would also be picked up by individuals who searched for certain topics. The complainant had seen the video on the Telegraph Online. GlaxoSmithKline submitted that a targeting algorithm would have placed the material on that webpage if the user had previously searched for relevant items. It was not clear how the complainant had come to see the advertisement.

The Panel noted that GlaxoSmithKline had been working with partners on a vaccine for malaria for use in children of a specific age in certain areas of Africa. The vaccine had been considered by the EMA but would not be marketed in the EU. A positive CHMP opinion was adopted in July 2015 for use of the vaccine outside the EU. Further studies were being discussed as well as a pilot implementation programme. The collaboration would help determine in which Sub-Saharan African countries the first marketing authorisations should be submitted. The vaccine was intended to be for malaria and hepatitis B.

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In the Panel's view it was relevant that the vaccine was for use in Sub-Saharan Africa in those countries where malaria was highly endemic and that GlaxoSmithKline had no intention at this point of making a licence submission in Europe (including the UK). It also noted the company's submission that use in the UK was precluded as there would be little, if any, therapeutic need.

The Panel noted the efficacy results of the data gathered so far which were described as 'modest protection' and 'limited' in the CHMP press release. It also noted the importance of continuing to use the established protective measures eg insecticide-treated bed nets. The WHO question and answer document included similar comments.

The Panel noted that the purpose of the advertisement was to increase awareness of GlaxoSmithKline as a global healthcare company and to be more transparent about its research activities and collaborations. The Panel noted that the vaccine was an interesting development and it was understandable that GlaxoSmithKline wanted to promote its role in the progress to date.

The Panel considered that given the content of the video, the nature of the medicine and its potential intended geographical use, the video was a corporate advertisement. It was neither promotion of an unlicensed medicine nor promotion of a prescription only medicine to the public. The Panel thus ruled no breach of Clauses 3.1 and 26.1. Further the advertisement would not encourage members

of the public to ask their health professional to prescribe the vaccine which was for potential use in Sub-Saharan Africa in those countries where malaria was endemic. No breach of Clause 26.2 was ruled. Given its rulings the Panel did not consider that GlaxoSmithKline had failed to maintain high standards nor did it consider that the company had

brought discredit upon or reduced confidence in the pharmaceutical industry and no breaches of Clauses 9.1 and 2 were ruled.

**Complaint received**      **28 June 2016**

**Case completed**      **22 August 2016**

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