

PATIENT v GLAXOSMITHKLINE

Alleged out-of-date patient material

An anonymous, non-contactable individual who described him/herself as an asthma patient, complained about a peak flow diary produced by GlaxoSmithKline UK.

The complainant noted the date on the peak flow diary (July 2016) and stated that it would appear that the material had not been certified in the last two years.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's submission that the peak flow diary was originally certified in October 2016 and recertified, with no changes necessary, in October 2018. The material was not out-of-date in this regard as alleged. The Panel ruled no breaches of the Code including Clause 2.

An anonymous, non-contactable individual who described him/herself as an asthma patient, complained about a peak flow diary (ref UK/RESP/0111a/12(2) July 2016) which he/she had been given at his/her named GP surgery. The booklet had been produced by GlaxoSmithKline UK Limited.

COMPLAINT

The complainant noted the date on the peak flow diary (July 2016) and stated that it would appear that the material had not been certified in the last two years. The complainant was surprised that GlaxoSmithKline did not recall out-of-date materials from GPs and alleged breaches of Clauses 2, 9.1 and 14.5 of the Code.

RESPONSE

GlaxoSmithKline explained that the peak flow diary was provided as a patient support item to health professionals to support adult patients monitor their peak flow pressure. The item was originally developed in July 2016 and so carried a date of preparation of July 2016; it was certified for use on 5 October 2016 in accordance with Clause 14.3 of the Code. The item was recertified on 4 October 2018 as required by Clause 14.5 but no changes to the document were required. A copy of the certificate (re-certification) was provided.

GlaxoSmithKline submitted that when materials were re-certified for continued use without any changes, it did not update the materials to amend the date of preparation. To change the date of preparation would require materials to be recalled and re-printed and use significant resources with no associated benefit to patients or health professionals.

GlaxoSmithKline stated that the GP surgery in question ordered sixty peak flow diaries directly from the company website in April 2018. There were no instructions for use of the materials.

GlaxoSmithKline stated that as the material had been re-certified for continued use at an interval of two years, it denied a breach of Clause 14.5. The company also denied breaches of Clause 9.1 for failing to maintain high standards and of Clause 2 for bringing discredit to the industry.

In response to an enquiry about the Asthma UK telephone number on the leaflet, GlaxoSmithKline stated that Asthma UK changed the number in advance of the re-approval date for the peak flow diary. However, there was a voice message referring the caller to the new number. The peak flow diary referred to a current email address.

PANEL RULING

The Panel noted that Clause 14.5 of the 2016 Code stated, *inter alia*, that material which was still in use must be recertified at intervals of no more than two years to ensure that it continued to conform with the relevant regulations related to advertising and the Code.

The Panel noted GlaxoSmithKline's submission that the peak flow diary was originally certified on 5 October 2016 and recertified, with no changes necessary, on 4 October 2018. The material was not out-of-date in this regard as alleged. The Panel ruled no breach of Clause 14.5 of the 2016 Code and consequently no breach of Clauses 9.1 and 2.

Complaint received

20 June 2019

Case completed

6 September 2019