

# PCT PRESCRIBING SUPPORT PHARMACIST v ASTELLAS

## Qutenza journal insert

A prescribing support pharmacist at a primary care trust (PCT) complained about a loose insert for Qutenza (capsaicin patch) issued by Astellas which was placed in Guidelines in Practice, November 2011.

The advertisement was headed 'Consensus statement on the use of Qutenza ... in peripheral neuropathic pain'. Beneath the heading 'Recommendations of the Consensus Panel' was a diagram headed 'Qutenza may be considered for the treatment of peripheral neuropathic pain at any stage in the algorithm alone or in combination with other therapies'. There then followed an algorithm including first, second and third line treatments for neuropathic pain (excluding diabetic patients). To the right of the algorithm was an indication that Qutenza could be considered at any point in this algorithm (ie first, second or third line). Beneath the algorithm was the statement 'A suggested Drug Treatment Algorithm adapted from NICE [National Institute for Health and Clinical Excellence] Guidelines. Please refer to full NICE Guidelines for further details'.

Whilst the advertisement stated in tiny print that the meeting and resulting consensus statement document were entirely funded and organised by Astellas, the complainant strongly objected to the use of a NICE guidance treatment algorithm for pain, with Qutenza, (never assessed by NICE) sitting within its guidance. A tag at the bottom stated 'A suggested Drug Treatment Algorithm adapted from NICE Guidelines'.

The complainant alleged that this was misleading, particularly as the style and presentation mimicked NICE guidelines. The complainant suggested that if NICE was to assess Qutenza it would almost certainly not be positioned as shown in the advertisement as potentially a first line treatment.

The detailed response from Astellas is given below.

The Panel noted that the prominent title of the advertisement was 'Consensus statement on the use of QUTENZA (capsaicin 8% w/w) in peripheral neuropathic pain'. The fact that the consensus statement resulted from a meeting of eight health professionals that was organised and entirely funded by Astellas was not clear at the outset. A statement explaining the position appeared as paragraph four of the document, approximately half way down the first page in a small font size. The Panel considered that the initial impression created by the title was that the 'consensus' was reached by an independent authority, rather than an Astellas advisory board. The Panel considered that the title was misleading in this regard and ruled a breach of the Code.

The Panel examined the algorithm for the treatment of peripheral neuropathic pain which depicted first, second and third line therapy for neuropathic pain (excluding diabetic patients). To the right of the algorithm a diagram indicated that Qutenza could be considered at any point (ie first, second or third line). Beneath the algorithm and the Qutenza diagram was the statement 'A suggested Drug Treatment Algorithm adapted from NICE Guidelines. Please refer to full NICE Guidelines for further detail'.

The Panel considered that the advertisement was not sufficiently clear that the medicine had not been reviewed by NICE. Some readers would indeed gain the misleading impression that Qutenza had been reviewed by NICE. This was compounded by the content and layout of the page which implied that there was detail about Qutenza in the full NICE Guidelines and by the fact that the algorithm was presented in a similar, albeit simplified, flowchart to that used in the NICE clinical guideline. The Panel considered the advertisement was misleading about the status of Qutenza in relation to NICE and the content of the NICE guideline as alleged. A breach of the Code was ruled.

A prescribing support pharmacist, at a primary care trust (PCT), complained about a loose insert (ref QUT11153UK) for Qutenza (capsaicin patch) issued by Astellas Pharma Ltd which was placed in Guidelines in Practice, November 2011. An electronic version was also available to subscribers of Guidelines in Practice.

The advertisement was headed 'Consensus statement on the use of Qutenza ... in peripheral neuropathic pain'. Beneath the heading 'Recommendations of the Consensus Panel' was a diagram headed 'Qutenza may be considered for the treatment of peripheral neuropathic pain at any stage in the algorithm alone or in combination with other therapies'. There then followed an algorithm including first line, second line and third line treatments for neuropathic pain (excluding diabetic patients). To the right of the algorithm was an indication that Qutenza could be considered at any point in this algorithm (ie first, second or third line). Beneath the algorithm was the statement 'A suggested Drug Treatment Algorithm adapted from NICE [National Institute for Health and Clinical Excellence] Guidelines. Please refer to full NICE Guidelines for further details'.

## COMPLAINT

The complainant noted that although the advertisement stated in tiny print that the meeting and resulting consensus statement document were entirely funded and organised by Astellas Pharma

Ltd, she strongly objected to the use of a NICE guidance drug treatment algorithm for pain, with Qutenza, (never assessed by NICE) sitting within its guidance. A tag at the bottom stated 'A suggested Drug Treatment Algorithm adapted from NICE Guidelines'.

The complainant alleged that this was misleading, particularly as the style and presentation mimicked NICE guidelines. The complainant also suggested that if NICE did assess Qutenza it would almost certainly not be positioned as shown in the advertisement as potentially a first line treatment.

The complainant queried whether Astellas had the right (under copyright) to publish this altered version.

When writing to Astellas, the Authority asked it to consider Clause 7.2 of the Code.

## RESPONSE

Astellas stated that the Qutenza consensus advisory board was implemented in order to provide guidance, based on expert opinion, on the use of Qutenza in a real-life clinical context in the UK. The advertisement at issue was an outcome of this meeting.

The item was clearly presented as promotional material; it contained prescribing information, the Astellas company logo, text stated that 'Both the meeting and resulting consensus statement were entirely funded and organised by Astellas Pharma Ltd', a heading declared that the insert was a 'Promotional Article' and it was in a significantly different style to the Guidelines in Practice publication.

The NICE guidance 'The pharmacological management of neuropathic pain in adults in non-specialist settings' was the only UK specific guidance available for the treatment of neuropathic pain and as such provided the logical basis for discussion as to where Qutenza would fit into a treatment algorithm for peripheral neuropathic pain.

The diagram of the treatment algorithm proposed by the advisory board was labelled with the text 'A suggested Drug Treatment Algorithm adapted from NICE Guidelines'. This wording informed the reader that this was a proposed, original care pathway based on the NICE guideline but with no suggestion that Qutenza had been assessed by NICE which, as the complainant rightly stated, it had not. The reader was also referred to the original guideline. Additionally, the diagram itself was within the section of the statement titled 'Recommendations of the Consensus Panel' and as such was defined as an outcome of the advisory board meeting rather than a reproduction of an existing guideline.

Astellas submitted that although the presentation of this algorithm as a flow chart was similar to the NICE guideline, the content had been substantially altered and the associated text as described above clearly

indicated that this was not a reproduction of the guideline itself.

As there was no claim that Qutenza had been assessed by NICE, there was no agreement in place between Astellas and NICE regarding this material.

In summary, Astellas considered that the clear declaration of Astellas' involvement in producing this piece, the stated promotional nature of the piece and the clear explanation of the origins of the consensus advisory board members meant that it had been completely transparent and had not attempted to suggest that NICE had reviewed Qutenza. Astellas therefore did not consider that this piece breached Clause 7.2 as alleged.

## PANEL RULING

The Panel noted that at the top right hand corner of the first page of the document was the statement 'Promotional Article'. In addition, the document included prescribing information on the reverse, the Qutenza logo appeared clearly on the bottom right hand corner of the first page and the Astellas company logo appeared opposite this. The Panel considered that it was clear that this was a promotional piece placed by the company.

The Panel noted that the prominent title of the advertisement was 'Consensus statement on the use of QUTENZA (capsaicin 8% w/w) in peripheral neuropathic pain'. The fact that the consensus statement resulted from a meeting of eight health professionals that was organised and entirely funded by Astellas was not clear at the outset. A statement 'Both the meeting and resulting consensus statement document were entirely funded and organised by Astellas ...' only appeared as paragraph four of the document, approximately half way down the first page in a small font size. The Panel considered that the initial impression created by the title was that the 'consensus' was reached by an independent authority, rather than an Astellas advisory board. The Panel considered that the title was misleading in this regard and ruled a breach of Clause 7.2.

The Panel examined the algorithm for the treatment of peripheral neuropathic pain which depicted first, second and third line therapy for neuropathic pain (excluding diabetic patients). First and second line treatments were either amitriptyline or pregabalin or a combination of the two. Third line treatments were 'refer and consider Tramadol or Lidocaine 5% plaster'. To the right of the algorithm a diagram indicated that Qutenza could be considered at any point in the algorithm (ie first, second or third line). Beneath the algorithm and the Qutenza diagram was the statement 'A suggested Drug Treatment Algorithm adapted from NICE Guidelines. Please refer to full NICE Guidelines for further detail'.

The Panel considered that the advertisement was not sufficiently clear that the medicine had not been reviewed by NICE. Some readers would indeed gain the misleading impression that Qutenza had been

reviewed by NICE. This was compounded by the content and layout of the page which implied that there was detail about Qutenza in the full NICE Guidelines and by the fact that the algorithm was presented in a similar, albeit simplified, flowchart to that used in the NICE clinical guideline. The Panel considered the advertisement was misleading about the status of Qutenza in relation to NICE and the

content of the NICE guideline as alleged. A breach of Clause 7.2 was ruled.

<b>Complaint received</b>	<b>13 September 2011</b>
<b>Case completed</b>	<b>27 January 2012</b>

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