JOHNSON & JOHNSON WOUND MANAGEMENT v BAXTER HEALTHCARE

Promotion of Tisseel Fibrin Sealant Kit

Johnson & Johnson Wound Management complained that Baxter had promoted Tisseel Fibrin Sealant Kit in a large number of hospital departments, including burns and plastic surgery as a haemostat and sealant. As there had previously been some confusion about the licensed indication for Tisseel (Case AUTH/1751/8/05), Johnson & Johnson wrote to the Medicines and Healthcare products Regulatory Agency (MHRA) asking it to clarify the meaning of the sentence 'Tisseel is intended to complement good surgical technique in achieving haemostasis, or obtaining a watertight seal of the dura mater' and to comment as to whether Tisseel was authorised for use outside the areas of cardiovascular surgery and neurosurgery.

The MHRA had replied that the haemostasis could only reflect the benefit in relation to neurosurgery. It could not be used to promote the product for a general haemostasis indication. The presence of the comma should not be used as justification.

Johnson & Johnson therefore considered that Baxter's promotional activities in respect of Tisseel were in breach of the Code as described in Case AUTH/1751/8/05. As well as promoting Tisseel in neurosurgery and cardiovascular surgery (for which it was licensed), Baxter also promoted it for use in burns and plastic surgery. As the MHRA had ruled that Tisseel had in fact a narrow indication, Johnson & Johnson alleged that Baxter's promotional activities breached the Code.

The Panel noted its ruling in Case AUTH/1751/8/05 that, according to Section 4.1 of its SPC dated January 2005, the therapeutic indications were that Tisseel was intended, *inter alia*, to 'complement good surgical technique in achieving haemostasis, or obtaining a watertight seal of the dura mater'. The Panel considered that the punctuation was such that this could be interpreted in one of two ways; either Tisseel was indicated for haemostasis generally, or it was only so indicated in relation to obtaining a watertight seal of the dura mater. The following paragraph of the SPC gave details about the use of Tisseel in cardiopulmonary surgery and as an adjunct to dura sealing. The Panel noted the submissions of the parties.

The Panel noted the advice from the MHRA that the haemostasis could only reflect the benefit in relation to neurosurgery. However there had been no change to the SPC since the previous case. The Panel noted that the product was alleged to be promoted in hospital departments other than neurosurgery and cardiovascular surgery.

The promotional material provided by Baxter Healthcare discussed the use of Tisseel. The Panel did not consider that the material provided, nor the promotion in hospital departments other than neurosurgery and cardiovascular surgery, was inconsistent with the SPC as alleged. No breach of the Code was ruled.

Johnson & Johnson Wound Management complained about the promotion of Tisseel Fibrin Sealant Kit by Baxter Healthcare Ltd.

COMPLAINT

Johnson & Johnson stated that Tisseel was promoted in a large number of hospital departments, including burns and plastic surgery as a haemostat and sealant, Clause 3.2 of the Code stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics. As there had previously been some confusion about the licensed indication for Tisseel (Case AUTH/1751/8/05), Johnson & Johnson wrote to the Medicines and Healthcare products Regulatory Agency (MHRA) asking for clarification of the sentence, 'Tisseel is intended to complement good surgical technique in achieving haemostasis, or obtaining a watertight seal of the dura mater.' and to comment on its use outside the areas of cardiovascular surgery and neurosurgery.

The MHRA replied that the haemostasis could only reflect the benefit in relation to neurosurgery. It could not be used to promote the product for a general haemostasis indication. The presence of the comma should not be used as justification.

Johnson & Johnson therefore considered that Baxter's current promotion of Tisseel was in breach of the Code as described in Case AUTH/1751/8/05. As well as promoting Tisseel in neurosurgery and cardiovascular surgery (for which it was licensed), Baxter had promoted it for use in burns and plastics surgery.

As the MHRA had ruled that Tisseel had in fact a narrow indication, Johnson & Johnson alleged that Baxter's current promotional activities breached the Code.

RESPONSE

Baxter Healthcare stated that it did not understand why the MHRA would, if it had passed guidance on Baxter Healthcare's licence to a competitor company, not share their response openly with Baxter. The summary of product characteristics (SPC) for a medicine was the agreed text between the marketing authorization holder and the MHRA, so it seemed strange that the MHRA did not raise any concerns directly with Baxter Healthcare.

Johnson & Johnson correctly quoted the current licensed indication but claimed that Baxter Healthcare was in breach of Clause 3.2 of the Code. Baxter Healthcare would refute this and believed firmly its promotion of Tisseel in the situations described were appropriate and in accordance with the marketing authorization.

Baxter Healthcare acknowledged that when Tisseel was originally licensed in the UK the indication was

limited to haemastasis in cardio-pulmonary bypass surgery only and its promotional material reflected this limitation. In December 2003 the Tisseel indication was broadened following a thorough review by the CSM. This resulted in the addition of the first sentence of the current licence;

'Tisseel is intended to complement good surgical technique in achieving haemostasis, or obtaining a watertight seal of the dura mater.'

and also the specific neurosurgical indication;

'Tisseel kit is used as an adjunct to dural sealing when control of cerebrospinal fluid leakage by conventional neurosurgical techniques including sutures and patches is considered insufficient or impractical.'

Baxter Healthcare acknowledged that Johnson & Johnson had asked it in writing, for evidence of the MHRA's intention as to the interpretation of the Tisseel approved indication. The wording of the current Tisseel SPC reflected the approved indications by the MHRA.

Baxter Healthcare could only assume that the apparent reply from the MHRA, might be a section of a more full email response. The response suggested that Baxter Healthcare had seen the addition of the neurosurgical indication, alone, as justification for a general haemostasis indication. This was not the case. When the variation was approved in 2003 the wording of the indication changed significantly following the full review by the committee on safety of medicines, as outlined previously.

Baxter Healthcare therefore refuted Johnson & Johnson's conclusion, that 'the MHRA have ruled that Tisseel in fact has a narrow indication', since it did not consider that the quoted section of the email from the MHRA reflected the official view of the MHRA.

It was most unfortunate that Johnson & Johnson seemed determined to pursue this issue rather than accepting that it and Baxter Healthcare worked alongside one another in what had been credible and appropriate marketing activities. Baxter Healthcare hoped that the Authority felt the previous guidance provided by it was not impacted by this and equally that Baxter Healthcare's explanations were satisfactory.

PANEL RULING

The Panel noted its ruling in the previous case, Case AUTH/1751/8/05, that according to Section 4.1 of its SPC dated January 2005 the therapeutic indications were that Tisseel was intended, *inter alia*, to 'complement good surgical technique in achieving haemostasis, or obtaining a watertight seal of the dura mater'. The Panel considered that the punctuation was such that this could be interpreted in one of two ways; either Tisseel was indicated for haemostasis generally, or it was only so indicated in relation to obtaining a watertight seal of the dura mater. The following paragraph of the SPC gave details about the use of Tisseel in cardiopulmonary surgery and as an adjunct to dura sealing. The Panel noted the submissions of the parties.

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The promotional material provided by Baxter Healthcare discussed the use of Tisseel. The Panel did not consider that the material provided, nor the promotion in hospital departments other than neurosurgery and cardiovascular surgery, was inconsistent with the SPC as alleged. No breach of Clause 3.2 was ruled.

Complaint received **8 May 2006**

Case completed **19 July 2006**