MEDIA/DIRECTOR v BAUSCH & LOMB

Promotion of Emerade

A letter published in The Pharmaceutical Journal entitled 'Superior Shelf-Life of Emerade (adrenaline)' July 2017 was critical of claims made by Bausch & Lomb UK.

In accordance with Paragraph 6.2 of the Constitution and Procedure the matter was taken up as a complaint under the Code. The author of the letter was contacted and was willing to be treated as the complainant.

In the letter at issue, the complainant stated that he/she went into anaphylactic shock after being stung by a wasp and his/her general practitioner suggested that he/she carry an adrenaline auto-injector pen. Emerade was chosen because in addition to having a higher and more realistic dose (500mcg) it had a 30 month shelf-life compared with only 18 months for EpiPen. However, the best the local pharmacist could supply was an Emerade pen with a 13-month shelf-life.

The complainant explained that he/she had exchanged emails with Bausch & Lomb and alleged that '…they just make a big song and dance about how superior in terms of shelf-life [there] product is over Epipen'. The complainant considered that it was nothing more than noise and expected an ethical company to do better.

In response to a request for any additional information from the case preparation manager the complainant provided a time-line of the circumstances which led to the publication of his/her letter in the Pharmaceutical Journal. This included his/her correspondence with Bausch & Lomb (12 January 2017) to ask how to obtain Emerade with a full 30 months shelf-life. As no progress was made the complainant decided to resolve the situation publicly and wrote to the Editor of the Pharmaceutical Journal on 31 January 2017. The letter was published in July 2017.

The complainant stated that whilst writing to the Authority in late August 2017 he/she did a search to look at Bausch & Lomb's claims again because he/she had thrown away the original documentation where 30 months' shelf-life was claimed. To the complainant's surprise the search produced a document headed 'Patient information: Important information for patients using Emerade solution for injection in prefilled pen notification'. A copy was provided and was dated 20 January 2017.

The document stated that the claimed shelf-life of Emerade was to be reduced from 30 months to 18 months from February 2017. The complainant was surprised and equally puzzled how this statement tied up with the note at the end of his/her letter in the Pharmaceutical Journal where the Editor stated 'Bausch & Lomb declined to comment on the allegations made in this letter'. The complainant stated that it sounded like the right hand of Bausch & Lomb did not actually know what the left hand was doing or had done 6 months previously.

The complainant stated that since Bausch & Lomb had changed its shelf-life claims to something more realistic there was little point in pursuing his/her complaint further. The complainant stated that what was clearly wrong had been put right or at least the complainant hoped so because he/she didn't know whether the pharmacist would now be able to get hold of a product with a shelf-life of even 18 months. 13 months was the best he/she could manage last time. It was also unclear to the complainant how patients are or were supposed to know that things had changed. Nobody from Bausch & Lomb contacted the complainant not even when he/she complained publicly. The complainant stated that whilst it was still slightly messy, he/she didn't think there was enough justification for continuing to make a complaint and hoped that the Authority agreed that the obvious and sensible thing to do now was nothing.

The case preparation manager noted Paragraph 15.1 of the Constitution and Procedure that a complainant can withdraw the complaint up until the time that the response is received from the company. As Bausch & Lomb's response had already been received the matter could not be withdrawn.

The detailed response from Bausch was given below.

The Panel noted that the complainant's letter in the Pharmaceutical Journal criticised claims made by Bausch & Lomb about the 30 month shelf-life of Emerade.

No specific materials were identified and the Panel noted the complainant's submission that he/she had thrown away the original documentation where 30 months' shelf-life was claimed. The Panel was unsure what material the complainant had received or which materials had been seen by the complainant's GP or pharmacist.

The Panel noted Bausch & Lomb's submission that prior to 18 January 2017, Emerade had a 30 month shelf-life at the point of manufacture and it used the same wording consistently across its promotional materials, ie 30 months shelf-life at time of manufacture and it did not promote to the public. Bausch & Lomb provided a leavepiece which claimed that with a shelf-life at production of 30 months, Emerade had a 12 month longer shelf-life at production than Jext (18 months) and Epipen (18 months). The leavepiece was certified on 6 January 2016.

The Panel further noted Bausch & Lomb's submission that on 18 January 2017 a variation was approved to amend Emerade's shelf-life to 18 months from date of manufacture and all materials were amended to reflect this. A promotional item provided by Bausch & Lomb with June 2017 as the date of preparation did not include any claims regarding shelf-life. The Panel also noted Bausch & Lomb's submission that the variation to the marketing authorisation on this point was as a consequence of stability testing and was not related to supply to the market as inferred by the complainant.

The Panel noted Bausch & Lomb's submission that the shelf-life was assigned at the point of manufacture. Following product manufacture, there were further processes that needed to be completed prior to Emerade reaching the UK market. The Panel noted Bausch & Lomb's submission that this delay also applied to products with an 18 month shelf-life from manufacture.

The Panel accepted that the complainant was frustrated by his inability to obtain the product with a longer shelf-life as evidenced by the published letter. The Panel, however, did not consider that the complainant had shown, on the balance of probabilities, that claims and information regarding the shelf-life at production provided by Bausch & Lomb was not factual nor presented in a balanced way and was not capable of substantiation. The Panel ruled no breach of the Code.

A letter published in The Pharmaceutical Journal entitled 'Superior Shelf-Life of Emerade' July 2017 was critical of claims made by Bausch & Lomb UK Ltd about Emerade (adrenaline).

In accordance with Paragraph 6.2 of the Constitution and Procedure the matter was taken up as a complaint under the Code. The author of the letter, was contacted and was willing to be treated as the complainant.

COMPLAINT

In the letter at issue, the complainant stated that he/she went into anaphylactic shock after being stung by a wasp last summer. Upon recovering his/her general practitioner suggested that he/she carry an adrenaline auto-injector pen and together they chose Emerade. Emerade was chosen over EpiPen because in addition to having a higher and more realistic dose (500mcg) it had a 30 month shelf-life compared with only 18 months for EpiPen. However, the best the local pharmacist could supply was an Emerade pen with a 13-month shelf-life and the pharmacist was unable to obtain one with a longer shelf-life.

The complainant explained that he/she had exchanged emails with Bausch & Lomb and alleged that '…they just make a big song and dance about how superior in terms of shelf-life [their] product is over Epipen'. The complainant considered that it was nothing more than noise and expected an ethical company to do better.

In a subsequent letter to the Authority the complainant explained that in practical terms his/her inability to get hold of the product with the claimed shelf-life meant that he/she now had the trouble of getting a repeat prescription almost 18 months before needed and more importantly that the NHS would have to fork out another £50 or so prematurely.

In response to a request for any additional information from the case preparation manager to support his/her case, the complainant provided a time-line of the circumstances which led to the publication of his/her letter in the Pharmaceutical Journal. In early August the complainant was stung by a wasp and had a severe anaphylactic reaction. His/her general practitioner prescribed Emerade 500mcg. This preparation was chosen rather than EpiPen because the dose was in line with the BNF recommendations, and the makers, Bausch& Lomb, claimed it had a shelf-life of 30 months.

The complainant stated that his/her pharmacist dispensed the product on 4 August 2016 with an expiry date of 19 September 2017; a remaining shelf-life of 13 months and not the 30 months as claimed by Bausch & Lomb. The complainant complained to the pharmacist who agreed to try to find a replacement product which fitted the claims. The complainant kept the originally dispensed product in case he/she was stung again. Over the next few months the pharmacist tried on several occasions to find a replacement and failed.

By January 2017 the complainant was exasperated by the situation and wrote to Bausch & Lomb (12 January 2017) to ask how to obtain Emerade with a full 30 months shelf-life. The complainant provided his/her correspondence with Bausch & Lomb and noted that no progress was made and so he/she decided that a more productive way to resolve the situation would be to ask some questions publicly and where better than the Pharmaceutical Journal.

The complainant's records showed that he/she wrote to the Editor on 31 January 2017 but the letter was not actually published until months later in July 2017.

The complainant stated that whilst writing to the Authority in late August 2017 he/she did a google search to look at Bausch & Lomb's claims again because he/she had thrown away the original documentation where 30 months' shelf-life was claimed. To the complainant's surprise the search produced a document dated 30 January 2017 headed 'Patient information: Important information for patients using Emerade solution for injection in prefilled pen notification'. A copy was provided and was dated 20 January 2017.

The document stated that the claimed shelf-life of Emerade was to be reduced from 30 months to 18 months from February 2017. The complainant was surprised and equally puzzled how this statement tied up with the note at the end of his/her letter in the Pharmaceutical Journal where the Editor stated 'Bausch & Lomb declined to comment on the allegations made in this letter'. The complainant

stated that it sounded like the right hand of Bausch & Lomb did not actually know what the left hand was doing or had done 6 months previously.

The complainant stated that since Bausch & Lomb had changed its shelf-life claims to something more realistic there was little point in pursuing his/her complaint further. The complainant stated that what was clearly wrong had been put right or at least the complainant hoped so because he/she didn't know whether the pharmacist would now be able to get hold of a product with a shelf-life of even 18 months. 13 months was the best he/she could manage last time. It was also unclear to the complainant how patients are or were supposed to know that things had changed. Nobody from Bausch & Lomb contacted the complainant not even when he/she complained publicly. The complainant stated that whilst it was still slightly messy, he/she didn't think there was enough justification for continuing to make a complaint and hoped that the Authority agreed that the obvious and sensible thing to do now was nothing.

The case preparation manager noted Paragraph 15.1 of the Constitution and Procedure that a complainant can withdraw the complaint up until the time that the response is received from the company. As Bausch & Lomb's response had already been received the matter could not be withdrawn.

In writing to Bausch and Lomb attention was drawn to the requirements of Clauses 7.2 and 7.4.

RESPONSE

Bausch & Lomb stated that as members of the ABPI it took compliance with the Code seriously. Bausch & Lomb submitted that in relation to the complaint, the marketing authorisation holder (MAH) had not breached Clauses 7.2 and 7.4 for the following reasons:

- The clock on expiry started once the chemical compound was manufactured. Subsequently further in-process checks and qualified person (QP) release would need to be performed hence no stock could be made available to the market at 30 months. This was a process, in alignment with all other AAIs and pharmaceutical manufacturers. The marketing authorisation holder could also confirm that it had not received any other complaints of shorter shelf-life following the launch of Emerade.

- The same wording about Emerade's 30 month shelf life was used, consistently ie 30 months at time of manufacture.

- As with all products, the marketing authorisation holder had no control of the supply chain once it left the warehouse.

- The marketing authorisation holder communicated that prior to 18 January 2017 it had a 30 month shelf-life at the point of manufacture for Emerade. Subsequently, the marketing authorisation holder's promotional materials were reviewed as part of a previous complaint, Case AUTH/2796/9/15. The PMCPA ruled no breach of Clauses 7.2 and 7.4.

- On 18 January 2017 a variation was approved to amend Emerade shelf-life to 18 months from date of manufacture and all materials were amended accordingly to reflect this.

- Bausch & Lomb further submitted that it did not promote directly to patients.

Bausch & Lomb concluded that for the reasons above it disagreed that there had been a breach of Clauses 7.2 and 7.4 in this instance.

In response to a request for further information from the case preparation manager, Bausch & Lomb stated that the new summary of product characteristics (SPC) was developed for the application of the variation on 21 September 2016 but was not used until the approval of that variation on 18 January 2017. The old SPC was the one used prior to the final approval.

Bausch & Lomb stated that it had no further comment as it had already stated its position that the 30 month shelf-life was from the date of manufacture and it had no direct control over the supply chain. This was a similar situation with all auto injector manufacturers. The current shelf-life stated was 18 months from manufacture.

In response to the complainant's follow-up letter relating to his/her concerns regarding the claims made prior to the change in shelf-life from 30 months to 18 months, Bausch & Lomb submitted that its material was accurate regarding shelf-life and was consistent with the SPC. Bausch & Lomb submitted that the marketing authorisation holder assigned the 30 months shelf-life at the point of manufacture. Following finished product manufacture, there were further processes that needed to be completed prior to Emerade reaching the UK market.

Bausch & Lomb submitted that it continued to work extensively with its wholesalers to move stock around its depots to keep it as fresh as possible but this could not be achieved at pharmacy level, as the marketing authorisation holder had no control over these consignments.

Bausch & Lomb noted that in September 2016, the marketing authorisation holder submitted a variation on the shelf-life to reduce it to 18 months. This was not related to supply to the market as the complainant inferred but as a consequence of stability testing. Bausch & Lomb submitted that as per regulations it was unable to discuss any proposed changes to an SPC or product variation until full approval to do so and could not misrepresent the current status in its promotional materials. Therefore, the best it could do was advise the complainant that there was stock in the market with a shelf-life of 24 months which the company was aware of as it was his/her question. Bausch & Lomb submitted that arguably some more dialogue could have explained in greater detail the production and release process but the complainant became persistent in his/her request for a pen with a 30 months shelf-life ignoring any explanation the

company was trying to provide. Bausch & Lomb noted that as stated in the complainant's letter, there was a more important reason for the choice of the physician to recommend Emerade as an adult male over 60kgs according to the BNF required a 500mcg dose which could only be found in Bausch & Lomb's range.

Bausch & Lomb submitted that issues with supply chain affected all pharmaceutical products in that manner as a wholesaler would sell stock into the market at up to 6 months as per the Healthcare Distributors Association gold standards of distribution. However, this was not such an issue with a monthly course of treatment perhaps as it was with a product that most likely would not be used in its shelf-life. As to the complainant's request as to where he/she could obtain a product with an 18 months shelf-life, it was an impossible request as per the previous explanation as there was the same 2 to 3 month requirement to complete manufacture prior to release to market. This was consistent with regulations on stating shelf-life in the product dossier and SPC.

PANEL RULING

The Panel noted that the complainant wrote a letter to the Editor of the Pharmaceutical Journal on 31 January 2017 criticising claims made by Bausch & Lomb about the 30 month shelf-life of Emerade. The letter was not published until July 2017.

No specific materials were identified. The Panel noted the complainant's submission that he/she had thrown away the original documentation where 30 months' shelf-life was claimed. The Panel was unsure what material the complainant had received. It appeared that the complainant was a doctor but the Panel was unsure if he/she was a medical doctor that might have received materials directed at health professionals or materials directed to patients who had been prescribed Emerade. The complainant stated that such claims were taken into account when his/her GP decided to prescribe Emerade, rather than EpiPen. It was not known which materials had been seen by the complainant's GP or, indeed, his/her pharmacist.

The Panel noted Bausch & Lomb's submission that prior to 18 January 2017, Emerade had a 30 month shelf-life at the point of manufacture and it used the same wording consistently across its promotional materials, ie 30 months shelf-life at time of manufacture and it did not promote to the public. The Panel noted Bausch & Lomb's submission about Case AUTH/2796/9/15. Bausch & Lomb provided a leavepiece (ref EME-UK-601-002DA) which included a section comparing the shelf-life of Emerade versus Jext and Epipen. The leavepiece claimed that with a shelf-life at production of 30 months, Emerade had a 12 month longer shelf-life at production than Jext (18 months) and Epipen (18 months). The leavepiece was certified on 6 January 2016.

The Panel further noted Bausch & Lomb's submission that on 18 January 2017 a variation was approved to amend Emerade's shelf-life to 18 months from date of manufacture and all materials were amended to reflect this. A promotional item provided by Bausch & Lomb (ref EME-UK-1706-004DA) with June 2017 as the date of preparation did not include any claims regarding shelf-life. The Panel also noted Bausch & Lomb's submission that the variation to the marketing authorisation on this point was as a consequence of stability testing and not related to supply to the market as inferred by the complainant.

The Panel noted Bausch & Lomb's submission that the marketing authorisation holder assigned the shelf-life at the point of manufacture. Following product manufacture, there were further processes that needed to be completed prior to Emerade reaching the UK market. The Panel noted Bausch & Lomb's submission that this delay also applied to products with an 18 month shelf-life from manufacture.

The Panel accepted that the complainant was frustrated by his inability to obtain the product with a longer shelf-life as evidenced by the published letter. The Panel, however, did not consider that the complainant had shown, on the balance of probabilities, that claims and information regarding the shelf-life at production provided by Bausch & Lomb was not factual nor presented in a balanced way and was not capable of substantiation. The Panel ruled no breach of Clauses 7.2 and 7.4.

During its consideration of this case, the Panel noted Bausch & Lomb's submission that whilst the marketing authorisation holder submitted a variation on the shelf-life to reduce it to 18 months in September 2016, the company was unable to discuss any proposed changes to an SPC or product variation until full approval had been granted (which was on 18 January 2017) and could not misrepresent the current status in its promotional materials as per regulations. The Panel considered that, as acknowledged by Bausch & Lomb, it could have explained in greater detail the production and release process to the complainant. The Panel also queried why Bausch & Lomb had not written back to the complainant once approval was granted or when the document headed 'Patient information: Important information for patients using Emerade solution for injection in prefilled pen notification' and dated 20 January 2017 was published considering the complainant had first written to Bausch & Lomb on 12 January 2017. The Panel also queried whether it was appropriate to include claims about a 30 month shelf-life in materials when the company was aware of stability issues before the variation was granted. The Panel had no information about the stability issues. This was not the subject of complaint and the company had not been asked to respond to this point. The Panel asked that Bausch & Lomb be advised of its views in this regard.

Complaint received **8 August 2017**

Case completed **14 December 2017**