CASE AUTH/3105/10/18

PHARMACY TEAM LEADER v ELI LILLY

Compassionate supply of Olumiant

A hospital pharmacist complained that a compassionate supply of Olumiant (baricitinib) by Eli Lilly and Company Limited did not comply with the hospital's governance procedures for the procurement of medicines.

The complainant referred to the compassionate supply of Olumiant 4mg tablets by Lilly, as requested by a named consultant rheumatologist. According to the complainant Lilly discussed the matter with the named consultant; the supply of Olumiant was for a complex patient who had previously been refused commissioning for its use. At no point during the discussions did the Lilly team attempt to confirm if the hospital pharmacy knew about this compassionate request, and therefore Lilly did not adhere to the hospital's strict governance procedures when procuring medicines. Olumiant was restricted to patients upon approval by local commissioning groups for appropriateness and safety and supplied only via hospital pharmacies due to its specialist nature. The patient in question had not completed his/her essential pre-screening checks before Lilly agreed supply without pharmacy input. It was also suggested that the medicine could simply be delivered directly to the patient's local community pharmacy, therefore bypassing the specialist hospital pharmacy team completely. The complainant understood that Lilly had previously made similar supplies direct to community pharmacies in Wales and Scotland after approvals from the respective NHS Boards. This was not undertaken with NHS England in this case. The complainant submitted that this unacceptable practice raised significant safety concerns and undoubtedly put the patient at risk when commencing a specialist medicine without appropriate pharmacy oversight. The complainant stated that he/she had already discussed the issue with a senior manager at Lilly who would raise the issue with his/her team.

The detailed response from Lilly is given below.

The Panel noted that it had with the agreement of Lilly sent Lilly's response to the complainant for his/her comments. The complainant did not respond to the original or follow-up request for comments.

The Panel noted that the complainant provided an extract from the trust's medicines management policy which stated, *inter alia*, that all medicines must be ordered and received via the pharmacy purchasing service. The Panel noted Lilly's submission that it was aware of the hospital's medicine management policy and all aspects of the supply of Olumiant were in line with that policy. The Panel noted that the parties' accounts differed in this regard.

The Panel noted that the request to Lilly for six months supply of Olumiant on a compassionate use basis from a consultant rheumatologist was approved. The Panel noted the consultant rheumatologist's statement that when he/she was informed of the approval by Lilly he/she was told that the medication could be dispensed either from the hospital pharmacy or a local community pharmacy. The Panel queried whether this was in line with the trust's medicines management policy. The Panel noted that the following day the consultant rheumatologist, after discussions with the complainant, informed Lilly that the hospital pharmacy wanted to dispense the supply for governance reasons.

The Panel noted that although it appeared that Lilly had initially approved the consultant's request for the compassionate supply of Olumiant without the hospital pharmacy's involvement, it appeared that discussions between the consultant and the hospital pharmacy took place the following day. The complainant had not established that the supply of Olumiant was not in adherence with the hospital's governance procedures as alleged.

The Panel noted, however, that ultimately the supply of Olumiant in this case had been to the hospital pharmacy following a purchase order raised by it which in the Panel's view meant that the order and supply had occurred with the hospital pharmacy's agreement and in line with the extract of the trust's management policy provided by the complainant. The Panel therefore based on the evidence before it ruled no breach of the Code.

The Panel noted the complainant's further concern that the patient in question had not completed his/her essential pre-screening checks before Lilly agreed supply without pharmacy input. The Panel was unclear which checks the complainant was referring to; no further information was provided by the complainant. The Panel noted that during the conversation in which Lilly informed the consultant rheumatologist that his/her request was approved, the consultant rheumatologist confirmed that the patient was undergoing pre-treatment biologic screenings (as per Olumiant's SPC) which would delay the start of treatment by a week or so. In the Panel's view Lilly was aware that the appropriate screenings were being done and as noted above the pharmacy was involved before Olumiant was supplied by Lilly. Further when Lilly contacted the consultant to state that the hospital pharmacy had taken delivery of the medicine, the consultant rheumatologist stated that he/she was still awaiting the results from pre-treatment biologics screening. In the Panel's view, Lilly was aware that the patient would not receive the medication until the appropriate pre-screening as required by the SPC

had occurred. The Panel did not consider that the complainant had provided evidence to the contrary. The Panel therefore ruled no breaches of the Code including of Clause 2.

A pharmacy team leader complained that a compassionate supply of Olumiant (baricitinib) by Eli Lilly and Company Limited did not comply with the hospital's governance procedures for the procurement of medicines. Olumiant was used in adults with moderate to severe active rheumatoid arthritis.

COMPLAINT

The complainant referred to the compassionate supply of Olumiant 4mg tablets by Lilly, as requested by a local, named consultant rheumatologist. According to the complainant Lilly discussed the matter with the named consultant; the supply of Olumiant was for a complex patient who had previously been refused commissioning for its use. At no point during the discussions, did the Lilly team attempt to confirm if the hospital pharmacy knew about this compassionate request, and therefore Lilly did not adhere to the hospital's strict governance procedures when procuring medicines. Not only was Olumiant a prescription only medicine, it had 'black triangle' status, was high cost and was restricted to patients upon approval by local commissioning groups for appropriateness and safety. It was supplied only via hospital pharmacies due to its specialist nature. The patient in question had not completed his/her essential pre-screening checks before Lilly agreed supply without pharmacy input. It was also suggested that the medicine could simply be delivered directly to the patient's local community pharmacy, therefore bypassing the specialist hospital pharmacy team completely. The complainant understood that Lilly had previously made similar supplies direct to community pharmacies in Wales and Scotland after approvals from the respective NHS Boards. This was not undertaken with NHS England in this case. The complainant submitted that this unacceptable practice raised significant safety concerns and undoubtedly put the patient at risk when commencing a specialist medicine without appropriate pharmacy oversight. The complainant stated that he/she had already discussed the issue with a senior manager at Lilly who would raise the issue with his/her team.

When writing to Lilly, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 15.4 of the Code.

RESPONSE

Lilly submitted that the request for six months' free supply of Olumiant was initiated by the consultant rheumatologist named by the complainant. The consultant had confirmed this in a letter addressed to Lilly. The consultant had also explained the circumstances and the reasons for his/her request along with the relevant timelines. Furthermore, Lilly had conducted its own investigation, details of which are explained below.

Circumstances and key timelines:

30 July 2018 – The local Lilly representative, during his/her call with the consultant rheumatologist, was told by him/her that an individual funding request (IFR) for Olumiant for a patient with long standing rheumatoid arthritis had been rejected by the IFR panel. The consultant's subsequent unsolicited request to Lilly for support in that matter was forwarded by the representative to Lilly's local healthcare development manager (HDM).

16 August – The HDM emailed the consultant to clarify the details of the request.

21 August – The consultant replied and explained the details of the request and asked whether Lilly would be able to provide 6 months' compassionate supply of Olumiant to help inform his/her IFR appeal.

22 August – The HDM forwarded the request to the Lilly pricing reimbursement and access manager.

31 August – The compassionate supply request was approved by Lilly.

10 September – The HDM telephoned the consultant to let him/her know that Lilly had approved the request and that distribution preferences needed to be finalised. The consultant was satisfied with the outcome and told the HDM that the patient was undergoing pre-treatment biologics screening (as per Olumiant's summary of product characteristics (SPC)).

11 September – The consultant contacted the HDM to inform him/her that the hospital pharmacy wanted to dispense the supply for governance reasons. The consultant gave the HDM the complainant's contact details and asked that arrangements were made directly with him/her. The consultant stated that he/she had told the pharmacy that there was no commitment to continue treatment beyond 6 months from Lilly or the trust and that the patient accepted that, pending reapplication to the IFR panel.

12 September – Lilly telephoned the complainant to discuss the free of charge supply of Olumiant. The complainant provided the contact details of the pharmacy supplier and asked Lilly to ask the pharmacy supplier to raise a purchase order.

13 September – Lilly telephoned the pharmacy supplier to inform him/her of the above conversation with the complainant and requested a formal purchase order which was issued.

14 September – Two packs of Olumiant 4mg x 84 tablets were delivered to the hospital pharmacy. The HDM contacted the consultant to inform him/her that the trust had taken the delivery of the supply. The consultant reiterated that he was still awaiting the results from pre-treatment biologics screening.

21 September – The consultant telephoned the HDM to explain that the pharmacy was no longer willing to dispense the compassionate supply of Olumiant despite receiving the delivery and would prefer

to wait for an IFR appeal decision. The consultant reiterated to the pharmacy that neither Lilly, nor the trust, nor the clinical commissioning group (CCG), were under any obligation to provide more than the 6 months supply of Olumiant and that the patient was aware of this situation.

25 September – A Lilly senior medical employee, telephoned the complainant to discuss his/her concerns.

18 October – Lilly received a letter from PMCPA stating that a complaint had been received from the complainant.

In summary Lilly stated that it put patient safety at the heart of all decision making and took compliance very seriously and understood and fully respected the Code. Lilly strove to ensure that all of its activities adhered with the relevant compliance requirements, rules and regulations. As evident from the above, Lilly's response was to an unsolicited request from a consultant rheumatologist. Additionally, as stated by the consultant, the patient was undergoing appropriate pre-treatment biologics screening. Lilly staff were aware of the hospital's medicine management policy and all aspects of this supply were in line with the policy. The approval of supply followed Lilly's local process. The consultant contacted the HDM on 11 September to inform him/her that the hospital pharmacy wanted to dispense the Olumiant supply for governance reasons and provided the complainant's contact details. The consultant further confirmed that he/she had informed the pharmacy that there was no commitment to continue treatment beyond 6 months from Lilly or the trust and that the patient had accepted that, pending reapplication to the IFR panel. On 12 September, Lilly contacted the hospital pharmacy and spoke with the complainant to discuss the consultant's request. Lilly was then given the contact details of the pharmacy supplier by the complainant. On 13 September, a purchase order was issued by the hospital pharmacy (pharmacy purchasing service in line with the hospital's medicines management policy) and sent to Lilly, following which the product supply was dispatched to the hospital pharmacy.

Lilly submitted that it did not, intentionally or unintentionally, try to bypass the specialist hospital pharmacy team at the hospital pharmacy. Lilly contacted the pharmacy to discuss the request and only dispatched the product supply upon receipt of a purchase order from the hospital pharmacy. Since receiving this complaint Lilly had been informed by the consultant that the hospital pharmacy had decided to dispense the supply of Olumiant to the patient in question.

Lilly stated that, in its view, it had acted in the best interest of the patient and the NHS and had strictly adhered to internal procedures and the Code at all times. Lilly denied breaches of Clauses 15.4, 9.1 and 2.

PANEL RULING

The Panel noted that it had with the agreement of Lilly sent Lilly's response to the complainant for his/her comments. The complainant did not respond to the original or follow-up request for comments.

The Panel noted that Clause 15.4 stated, *inter alia*, that the arrangements in force at any particular establishment must be observed.

The Panel noted that the complainant had provided an extract from the trust's medicines management policy which stated, *inter alia*, that all medicines that were supplied for use in the trust must be ordered and received via the pharmacy purchasing service. The Panel noted Lilly's submission that it was aware of the hospital's medicine management policy and all aspects of the supply of Olumiant were in line with that policy. The Panel noted that the parties' accounts differed in this regard. The complainant alleged that the supply of Olumiant by Lilly did not comply with the hospital's governance procedures for the procurement of medicines. According to the complainant Lilly did not attempt to confirm if the hospital pharmacy knew about the request and it was suggested that the medicine could be delivered directly to the patient's local community pharmacy, bypassing the specialist hospital pharmacy team completely.

The introduction to the Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted that the request to Lilly for six months supply of Olumiant on a compassionate use basis from a consultant rheumatologist was approved. The Panel noted the consultant rheumatologist's statement that when he/she was informed of the approval by Lilly he/she was told that the medication could be dispensed either from the hospital pharmacy or a local community pharmacy. The Panel queried whether this was in line with the trust's medicines management policy as noted above. The Panel noted that the following day the consultant rheumatologist, after discussions with the complainant, informed Lilly that the hospital pharmacy wanted to dispense the supply for governance reasons.

The Panel noted Lilly's submission that it contacted the complainant as requested by the consultant rheumatologist to discuss the arrangements. Lilly subsequently contacted the pharmacy supplier, as advised by the complainant, who then raised a purchase order for the supply of Olumiant. The Panel noted Lilly's submission that the pharmacy took delivery of two packs of Olumiant tablets and a week later the consultant rheumatologist contacted Lilly to explain that the pharmacy was no longer willing to dispense the compassionate supply of Olumiant despite receiving the delivery and would prefer to wait for an IFR appeal. The Panel further noted Lilly's submission that the consultant stated that since receiving the complaint the pharmacy had decided to dispense the supplied product to the patient involved.

The Panel noted that although it appeared that Lilly had initially approved the consultant's request for the compassionate supply of Olumiant without the hospital pharmacy's involvement, it appeared that discussions between the consultant and the hospital pharmacy took place the following day. The complainant had not established that the supply of Olumiant was not in adherence with the hospital's governance procedures as alleged.

The Panel noted, however, that ultimately the supply of Olumiant had been to the hospital pharmacy following a purchase order raised by it which in the Panel's view meant that the order and supply had occurred with the hospital pharmacy's agreement and in line with the extract of the trust's management policy provided by the complainant. The Panel therefore based on the evidence before it ruled no breach of Clause 15.4. The Panel ruled, on balance, no breach of Clause 9.1 and subsequently no breach of Clause 2.

The Panel noted the complainant's further concern that the patient in question had not completed his/her essential pre-screening checks before Lilly agreed supply without pharmacy input. The Panel was unclear which checks the complainant was referring to; no further information was provided by the complainant. The Panel noted that during the conversation in which Lilly informed the consultant rheumatologist that his/her request was approved, the consultant rheumatologist confirmed that the patient was undergoing pre-treatment biologic screenings (as per Olumiant's SPC) which would delay the start of treatment by a week or so. In the Panel's view Lilly was aware that the appropriate screenings were being done and as noted above the pharmacy was involved before Olumiant was supplied by Lilly. Further when Lilly contacted the consultant to state that the hospital pharmacy had taken delivery of the medicine, the consultant rheumatologist stated that he/she was still awaiting the results from pre-treatment biologics screening. In the Panel's view, Lilly was aware that the patient would not receive the medication until the appropriate pre-screening as required by the SPC had occurred. The Panel did not consider that the complainant had provided evidence to the contrary. The Panel therefore ruled no breach of Clause 9.1 and consequently no breach of Clause 2.

Complaint received **8 October 2018**

Case completed **25 February 2019**