CASE AUTH/2499/4/12

PHARMACIST ADVISER v SANOFI

Mozobil email

A pharmacist adviser for a specialised commissioning group complained about an email sent by a haematology sales representative from Sanofi to a hospital clinician in relation to the local funding arrangements for Genzyme's medicine Mozobil (plerixafor). Mozobil was indicated to enhance the mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in certain patients with lymphoma and multiple myeloma. Genzyme was a Sanofi company.

The email advised the clinician to submit an individual funding request (IFR) for Mozobil to the primary care trust (PCT) and 'they will approve it'. Furthermore, the representative suggested that this should be the approach 'at the minute' until 'the [specialised commissioning group] give clarity' about the source of funding. The complainant stated that the email was inappropriate, unhelpful and inaccurate.

The detailed response from Sanofi is given below.

The Panel noted the complainant's submission that a communication from his commissioner colleague had highlighted the regional policy agreed with local commissioners and described the differences in funding sources due to existing contractual arrangements. The Panel further noted Sanofi's submission that there was evidence that the clarity around contractual arrangements referred to by the complainant did not exist.

Sanofi provided a number of emails between the representative and clinicians all of which appeared to be about whether regional funding for Mozobil had been agreed.

The Panel considered that the emails received by the representative in response to her enquiries indicated that whilst there was some confusion about funding it was possible for clinicians to apply to the relevant PCT for funding for Mozobil.

The Panel considered that, contrary to the complainant's assertion, it was not necessarily inappropriate for the representative to discuss funding issues with health professionals so long as such discussions complied with the Code. However, the Panel was concerned that the representative had stated in the email at issue that the PCT 'will approve' the IFR. This was a broad claim and inappropriate as alleged. The email responses submitted by Sanofi from clinicians based in the area indicated that there was no certainty as to whether an IFR would be successful. The representative's email was therefore misleading in that regard and a breach was ruled. It was not the representative's role to reassure health professionals that every request would be funded, nor could the representative be certain that every request would be funded. The Panel considered that the representative had not maintained a high standard of ethical conduct and a breach of the Code was ruled.

A pharmacist adviser for a specialised commissioning group, complained about the conduct of a haematology sales representative from Sanofi. The matter involved funding arrangements for Genzyme's medicine Mozobil (plerixafor). Mozobil was indicated to enhance the mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in certain patients with lymphoma and multiple myeloma.

COMPLAINT

The complainant provided a copy of an email sent by the representative and alleged that the representative's intervention in local discussions about funding arrangements for Mozobil was inappropriate. The complainant was concerned that correspondence which he had been copied into, sent by the representative to a member of staff at a hospital trust, gave incorrect advice and highlighted ignorance of local NHS contracting arrangements.

Following a number of emails to the commissioning group of which the complainant was a member, from clinicians about the funding of Mozobil in one part of the region, one of the complainant's colleagues emailed relevant stakeholders in November 2011 to clarify current contractual arrangements for stem cell transplant services and, in particular, the funding of Mozobil. This highlighted the regional commissioning policy for the medicine agreed with local commissioners in July 2011 and described the differences in funding sources due to existing contractual arrangements. Having a commissioning policy agreed aimed to avoid clinicians making individual funding requests (IFRs) to patients' primary care trusts (PCTs). Yet, in March 2012, the representative advised one clinician by email to submit an IFR to the PCT and 'they will approve it'. Furthermore, the representative suggested that this should be the approach 'at the minute' until 'the [specialised commissioning group] give clarity' about the source of funding.

The complainant stated that this intervention was unhelpful and inaccurate. Rather than contribute to the ignorance in this situation, the representative should have realised the limitation of her knowledge and referred the clinician to a more appropriate NHS contact.

Genzyme was a Sanofi company. When writing to Sanofi, the Authority asked it to respond in relation to Clauses 7.2 and 15.2 of the Code.

RESPONSE

Sanofi explained that a general policy for the use of Mozobil across the strategic health authority in question was established in July 2011 by the relevant specialist commissioning group (a copy of the document was provided). Sanofi submitted that this document did not make the financial arrangements for Mozobil clear and so there had been continued confusion about the provision of Mozobil in the local hospitals trust for patients undergoing bone marrow transplant.

Sanofi submitted that there was evidence that the clarity around contractual arrangements mentioned by the complainant did not exist. Clinicians based at the region had stated that this confusion had prevented timely treatment of a patient group who would benefit from Mozobil.

Genzyme, and more recently Sanofi, had tried to engage with the regional cancer network to clarify the situation and develop a solution to an obvious blockage which prevented clinicians accessing Mozobil for their patients.

Sanofi submitted that the representative in question sent the emails in good faith; they reflected her understanding of the funding position.

Sanofi denied any breach of Clauses 7.2 or 15.2.

PANEL RULING

The Panel noted that according to the complainant an email had been sent in November 2011 by his commissioner colleague to relevant stakeholders to clarify contractual arrangements for stem cell transplant services and in particular the funding of Mozobil. The complainant had stated that the communication highlighted the regional commissioning policy for the medicine agreed with local commissioners in July and described the differences in funding sources due to existing contractual arrangements. This email was not provided. The Panel further noted Sanofi's submission that there was evidence that the clarity around contractual arrangements referred to by the complainant did not exist.

The Panel noted that the specialist commissioning group policy document referred to and submitted by Sanofi was effective from 22 July 2011. However the recommended implementation date was noted on the document as 'TBC'. The section entitled 'Financial Implications (PCTs)' stated:

> 'Estimated cost per patient is £10-£20,000 depending on duration of treatment.
> The financial implications are likely to be different dependent upon the provider. Currently there are significant differences in the prices that commissioners pay for bone marrow transplants (BMTs) to different providers. A sub-group of the BMT expert panel is working to determine actual costs. Plerixafor has been introduced during 2010/11 and providers have maintained that it is not included in the locally agreed tariff for the service. Consequently some providers have made IFR requests which have been funded by PCTs.'

The evidence to support Sanofi's submission about the lack of clarity around contractual arrangements included an extract from the minutes of the regional cancer network pharmacists group which referred to three issues with plerixafor. It did not mention what the problems were other than patients were being denied medicines. An email from the cancer network pharmacist to the oncology commissioning representative at Sanofi in March 2012 was also provided. This stated:

> 'What is clear is that commissioners in [the strategic health authority] commission it, our commissioners say that they already pay [the trust] for it, and [the trust] dispute this. In addition it appears that Trusts outside of [the local trust] who are asked to administer it should not go to their PCTs with IFRs or policy requests for funding (as its commissioned) and should instead ask [the trust] to either provide the vials or the money to procure the drug. [The trust] dispute this. This means we are gong round in circles that only the [specialist commissioning group] can stop'

Sanofi also provided a number of emails between the representative in question and clinicians based in the region. All the emails appeared to be in relation to the whether regional funding of Mozobil had been agreed. The representative's emails were sent in October/November 2011. Two responses received by the representative in October 2011 stated, *et al*:

> 'In theory we can apply by IFR, no patient to test on yet.'

And:

> 'The funding is still very up in the air, I did try to clarify, but was told that I had to speak to local managers, but they say to speak to commissioners?! So still not clear.
>
> Certainly we can apply via IFR, but unclear if our local managers will allow treatment at risk.'

A further email, received in November in response to the representative in question stating that she understood that the PCTs in the region had been informed that Mozobil funding was available for patients, read, *et al*:

> 'Sadly this is not the case for the region, though is the case for some parts of the region. There is still significant issue over funding for [the region]. It is still under discussion.'

The Panel noted that the email provided by the complainant stated, *et al*:

> 'At the minute you can submit an IFR for Mozobil to [PCT] or whichever PCT for your patient and they will approve it, until the [specialist commissioning group] give clarity on which pot of money it will be funded from.'

The Panel considered that the emails received by the representative in response to her enquiries in October and November 2011 indicated that whilst there was some confusion about funding it was possible for clinicians to apply to the relevant PCT for funding for Mozobil.

The Panel considered that, contrary to the complainant's assertion, it was not necessarily inappropriate for the representative to discuss funding issues with health professionals so long as such discussions complied with the Code. However, the Panel was concerned that in relation to the email in question the representative stated that the PCT 'will approve' the IFR. The Panel considered that this was a broad claim and inappropriate as alleged. The email responses submitted by Sanofi from clinicians based in the region indicated that there was no certainty as to whether an IFR would be successful. The representative's email was therefore misleading in that regard and a breach of Clause 7.2 was ruled. It was not the representative's role to reassure health professionals that every request would be funded, nor could she be certain that every request would be funded. The Panel considered that the representative had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled.

Complaint received **18 April 2012**

Case completed **22 June 2012**