CASE AUTH/2302/3/10

SENIOR HOSPITAL PHARMACIST v FERRING

Letter about Glypressin

A senior hospital pharmacist alleged that in a letter about Glypressin Solution for Injection (terlipressin acetate) Ferring was scaremongering and misquoting from a safety alert issued by the National Patient Safety Agency (NPSA) to get extra NHS sales.

The letter stated that the new Glypressin Solution had, *inter alia*, the following advantage: 'Ready to use for injection (The National Patient Safety Agency recommends that only licensed ready-to-administer or ready-to-use injectable medicines are supplied)'. The complainant stated that 'only' misrepresented the NPSA which stated it was 'preferable'. The word 'only' was used by the NPSA but that was not how it was meant.

The complainant provided part of the relevant NPSA patient safety alert 'Promoting safer use of injectable medicines'. A section headed 'Implement a "purchasing for safety" policy to promote procurement of injectable medicines with inherent safety features' stated, *inter alia*, 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied'.

The complainant had asked Ferring to confirm where the NPSA 'recommends that only licensed ready-to-administer …'. In response, Ferring medical information had referred the complainant to the statement in the safety alert that 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied. The NPSA suggests that NHS organisations should work with the pharmaceutical industry to identify new products and formulations that could make practice safer.'

The detailed response from Ferring is given below.

The Panel noted that the NPSA in its patient safety alert, 20 (2007), set out six action points to promote safer use of injectable medicines including 'Implement a "purchase for safety" policy to promote procurement of injectable medicines with inherent safety features'. The further information on that action point recommended firstly that policies should advocate the purchase of injectable medicines that included technical information about their preparation and administration and were designed in such a way as to promote safer practice. This was followed by the advice used as a reference for the material at issue that 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied'. The section then referred to the frequent preparation of an unlicensed injectable medicine from a licensed product and that ready-to-use and ready-to-administer products that could not be prepared in the hospital pharmacy department should be sourced from NHS manufacturing units or commercial 'specials' manufacturers. It was essential that the quality of these medicines was assessed and approved before purchase. The NPSA patient safety alert included guidance on risk assessment and action plans as well as protocols and procedures for preparing and administering injectable medicines.

The Panel considered that it was clear from the patient safety alert that the NPSA's preference was that only licensed ready-to-administer or ready-to-use injectables were procured and supplied. However, the NPSA accepted that sometimes unlicensed medicines needed to be used or those from NHS manufacturing units or commercial 'specials' manufacturers.

The Panel considered that the letter at issue was not sufficiently clear regarding the NPSA advice. The claim in full read 'Ready to use for injection (The National Patient Safety Agency recommends that only licensed ready-to-administer or ready-to-use injectable medicines are supplied)'. In the Panel's view there was a difference between a preference and a recommendation. Further the claim at issue had been derived from one sentence in four paragraphs of text which referred to 'purchasing for safety' policies. The context of the NPSA statement had not been fully reflected. The letter was misleading and not capable of substantiation. Breaches of the Code were ruled.

A senior hospital pharmacist complained about a letter (ref GL/317/02/10) which he had received from Ferring Pharmaceuticals Ltd about Glypressin Solution for Injection (terlipressin acetate). The letter was mailed to NHS hospital pharmacists in February 2010 and concerned the award of a national tender in England via the NHS Purchasing and Supply Agency (PASA) for the supply of Glypressin Solution.

COMPLAINT

The complainant alleged that Ferring was scaremongering and misquoting from a safety alert issued by the National Patient Safety Agency (NPSA) to get extra sales at the expense of the NHS.

The letter stated that the new Glypressin Solution had, *inter alia*, the following advantage: 'Ready to use for injection (The National Patient Safety Agency recommends that only licensed ready-to-administer or ready-to-use injectable

medicines are supplied)'.

The complainant stated that the word 'only' misrepresented the NPSA which stated it was 'preferable'. The word 'only' was used by the NPSA but that was not how it was meant.

The complainant provided part of the relevant NPSA patient safety alert 'Promoting safer use of injectable medicines'. A section headed 'Implement a "purchasing for safety" policy to promote procurement of injectable medicines with inherent safety features' stated, *inter alia*, 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied'.

The complainant had asked Ferring to confirm where the NPSA 'recommends that only licensed ready-to-administer …'. In response, Ferring medical information had referred the complainant to page 4, point 4, paragraph 2 which stated:

> 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied. The NPSA suggests that NHS organisations should work with the pharmaceutical industry to identify new products and formulations that could make practice safer.'

When writing to Ferring, the Authority asked it to comment in relation to Clauses 7.2 and 7.4 of the Code.

RESPONSE

Ferring noted that the letter included three bullet points regarding advantages of Glypressin Solution.

The specific bullet point at issue:

> 'Ready to use for injection (The National Patient Safety Agency recommends that only licensed ready-to-administer or ready-to-use injectable medicines are supplied)'

was referenced to the NPSA patient safety alert, 20 'Promoting safer use of injectable medicines' which stated:

> 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied. The NPSA suggests that NHS organisations should work with the pharmaceutical industry to identify new products and formulations that could make practice safer.'

This NPSA patient safety alert aimed to promote safer use of injectable products. In point 4, paragraph 2, the issue of ready-to-administer or ready-to-use injectables was covered. It was clearly stated that it was preferable to use only licensed ready-to-administer or ready-to-use injectables. This appeared to be a clear recommendation to use such formulations in preference to formulations that required reconstitution prior to use. In the glossary on page 10 'Ready-to-use injectable products' were defined as 'These products require no further dilution or reconstitution before transfer to an administration device. For example, a liquid with an ampoule, of the required concentration, that only needs to be drawn up into a syringe'. Glypressin Solution met these criteria of a ready-to-use injectable product.

The background information, page 6 of the NPSA patient safety alert, discussed and put into context the reasoning behind its recommendations. An ethnographic study on the incidence and severity of intravenous medicine errors in 10 wards of a teaching and non-teaching hospital in the UK, over periods of 6 and 10 days respectively, identified 249 errors. 1% of the errors were potentially serious, 29% were potentially moderate errors and 19% were potentially minor errors. Most errors occurred when giving bolus doses or making up medicines that required multiple step preparation.

Tabulated data in the patient safety alert demonstrated that nearly 24% of medication incidents related to incidents with injectable medicines, of which approximately 73% occurred during administration (which might include preparation) and a further 10% during preparation of medicines in all locations/dispensing in a pharmacy.

Ferring concluded that the NPSA patient safety alert clearly recommended ready-to-use injectable products in preference to those requiring reconstitution prior to use. Ferring also believed that the content of the letter accurately represented the spirit of the NPSA patient safety alert and that there was no exaggeration of the NPSA recommendation, either by including the word 'only' or by its interpretation of the NPSA recommendation 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied' as 'The National Patient Safety Agency recommends that only licensed ready-to-administer or ready-to-use injectable medicines are supplied'.

Ferring therefore did not believe that the claim was in breach of Clauses 7.2 or 7.4.

PANEL RULING

The Panel noted that the NPSA in its patient safety alert, 20 (2007), set out six action points for the NHS and independent sector to promote safer use of injectable medicines. The fourth action point was to 'Implement a "purchase for safety" policy to promote procurement of injectable medicines with inherent safety features'. The further information on that action point stated that the NPSA recommended firstly that policies should advocate the purchase of injectable medicines that included technical information about their preparation and administration and were designed in such a way as

to promote safer practice. This was followed by the advice used as a reference for the material at issue that 'It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied'. The section then referred to the frequent preparation of an unlicensed injectable medicine from a licensed product and that ready-to-use and ready-to-administer products that could not be prepared in the hospital pharmacy department should be sourced from NHS manufacturing units or commercial 'specials' manufacturers. It was essential that the quality of these medicines was assessed and approved by appropriate quality assurance pharmacists before being purchased. The NPSA patient safety alert included guidance on risk assessment and action plans as well as protocols and procedures for preparing and administering injectable medicines.

The Panel considered that it was clear from the patient safety alert that the NPSA's preference was that only licensed ready-to-administer or ready-to-use injectables were procured and supplied. However, the NPSA accepted that sometimes unlicensed medicines needed to be used or those from NHS manufacturing units or commercial 'specials' manufacturers.

The Panel considered that the 'Dear Pharmacist' letter at issue was not sufficiently clear regarding the NPSA advice. The claim in full read 'Ready to use for injection (The National Patient Safety Agency recommends that only licensed ready-to-administer or ready-to-use injectable medicines are supplied)'. In the Panel's view there was a difference between a preference and a recommendation. Further the claim at issue had been derived from one sentence in four paragraphs of text which referred to 'purchasing for safety' policies. The context of the NPSA statement had not been fully reflected. The letter was misleading and not capable of substantiation in this regard. The Panel ruled breaches of Clauses 7.2 and 7.4.

Complaint received **9 March 2010**

Case completed **15 April 2010**