CASE AUTH/2914/12/16

HOSPITAL PHARMACIST v PIERRE FABRE

Navelbine bags distributed by representatives

A hospital pharmacist, complained on behalf of a group of pharmacists at a teaching hospital about the distribution of clear plastic bags for Navelbine (vinorelbine) Oral delivered by representatives from Pierre Fabre.

The bags were for pharmacists to give to patients when dispensing Navelbine Oral capsules. The bag was labelled as containing cytotoxic chemotherapy. Advice to keep the medicine in the refrigerator and how to take the capsules was included. The bag could be sealed.

The complainant stated that the bags seemed to be in poor condition. The sealant to close the bags at times did not work, which meant the very bag that was meant to transport the medicine might lead to patients losing their medication on their way home. More concerning was that some of the bags seemed to be dirty. It was reprehensible that Pierre Fabre would put patients at risk by providing such poor-quality material. The complainant queried whether the company had a quality department to check for such defects.

The complainant provided one of the bags after cleaning it and stated that if they had been provided to other hospitals they should be checked immediately.

The detailed response from Pierre Fabre is given below.

The Panel noted that bags which had been stored in a basement for around 3 years were provided to representatives to give to pharmacies. The bags were designed for Navelbine Oral which would be placed in the bag, sealed and given to the patient to take home. The Panel was concerned that the complainant described the bags as in a poor condition with soot and dust on the inside and that the sealant to close the bag at times did not work. The bags supplied to the Panel, one from the complainant and five from the company, did not look dirty but the complainant stated that one he/she sent had been cleaned. The sealants were different in that those supplied by the company had red tape over a flat clear sticky strip and the bag supplied by the complainant had clear tape over a yellow wrinkled sticky strip.

The Panel noted the email correspondence in that the bags had been found in the basement of Pierre Fabre's offices and the managing director instructed them to be distributed to the representatives. The correspondence indicated a difference of opinion in that one person said that the bags could not be used. This was confirmed by the medical director who stated that it would be inappropriate to send out the bags as the company was unaware of how long they had been left in unsuitable storage conditions and patient safety was in question.

The Panel considered that although it had no details on how the bags were stored in the basement, the complainant stated that he/she had received dirty bags with faulty seals. In the Panel's view this did not seem unreasonable given the bags had been in the basement for around 3 years. The email from the medical director referred to the bags having been left in unsuitable storage conditions. Other than a visual inspection by the managing director, it appeared that Pierre Fabre had not checked the quality of the bags before giving them to the representatives to distribute. The Panel considered that Pierre Fabre had not maintained high standards and ruled a breach of the Code.

The Panel was extremely concerned about the company's submission that the managing director having balanced the needs of the business had over-ruled the medical director's advice that the bags should not be distributed citing, *inter alia*, patient safety as a reason. In the Panel's view patient safety was paramount. It was not known how the bags had been stored in the basement nor how many of these had been distributed to the representatives. Similarly there was no information about how many bags had been given out by the representatives. The Panel did not know if every single bag had been visually inspected by the managing director before being given to representatives. The company had not commented specifically on the results of the visual inspection. The Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry and therefore ruled a breach of Clause 2.

The Panel noted Pierre Fabre's submission that it had stopped supplying the bags to the representatives. It did not know whether the representatives had stopped supplying the bags they already had to pharmacies nor how many bags they had already given out. The Panel decided that as there was a potential safety issue with use of the bags it would require Pierre Fabre to suspend use of the bags if Pierre Fabre appealed the Panel's ruling pending the final outcome of the case. This was in accordance with Paragraph 7.1 of the Constitution and Procedure.

A hospital pharmacist, complained on behalf of a group of pharmacists at a teaching hospital about the distribution of bags for Navelbine Oral (vinorelbine) by representatives from Pierre Fabre Limited. Navelbine was available as an infusion and capsules and was indicated for the treatment of certain cancers.

The bags in question were for pharmacists to give to patients when dispensing Navelbine Oral capsules. The bag was clear plastic and was labelled as containing cytotoxic chemotherapy. Advice to keep the medicine in the refrigerator and how to take the capsules was included. The bag could be sealed.

COMPLAINT

The complainant stated that this was a matter of great importance with regard to patient safety.

The complainant stated that the hospital recently received a supply of the patient bags and the chief pharmacist had explained that they should only be used for Navelbine Oral when it was dispensed to patients. The bags, which were made of plastic, seemed to be in poor condition. The sealant to close the bags at times did not work, which meant the very bag that was meant to transport the medicine might lead to patients losing their medication on their way home. More concerning was that some of the bags seemed to be dirty – the complainant used tissue and got dust and soot-like material from the inside of the bags. Given that one of the major side-effects of Navelbine was neutropenia, the complainant found it reprehensible that Pierre Fabre would put patients at risk by providing such poor-quality material. The complainant queried whether the company had a quality department to check for such defects.

The complainant provided one of the bags after cleaning it and stated that if they had been provided to other hospitals they should be checked immediately.

The complainant confirmed that the bags were delivered by the local representative who claimed that they were 'found' by the managing director.

In writing to Pierre Fabre the Authority asked it to bear in mind the requirements of Clauses 2 and 9.1 of the Code.

RESPONSE

Pierre Fabre stated that it had been asked on numerous occasions to supply the Navelbine bags to hospitals. The demand for the bags was fed back to the company by its representatives and by pharmacists to head office. The bags were provided to patients to transport their Navelbine capsules from the dispensing hospital/pharmacy to their home. The bags served as a reminder to patients to keep the Navelbine capsules refrigerated, and provided warnings on what not to do with the medicine. The bags were provided to patients to aid the safe storage and consumption of Navelbine Oral.

The bags in question were originally certified in 2005 and reapproved in 2007. In 2011 the previous product manager decided that the bag was a service item for pharmacists and therefore they were not certified. Pierre Fabre appreciated that this indicated that the Navelbine bags had not been reapproved since 2009 (given the two year approval timeline from 2007). Staff responsible for reviewing or certifying the items were no longer in the employ of Pierre Fabre. To ascertain the approximate age of the bags, the company had a proforma invoice dated 22 April 2013.

Pierre Fabre submitted that the bags were stored in the basement of its offices in Winchester from 2013. During its recent relocation to Reading, the bags in question were discovered and visually inspected by the managing director who did not involve the quality assurance department to check their integrity.

The medical director advised that the bags should not be distributed citing patient safety and Code requirements. However, having balanced the needs of the business, the managing director decided to overrule this advice.

The bags were distributed to the sales team during a meeting, and no briefing document accompanied the bags.

The managing director had ensured that no further Navelbine bags were supplied to Pierre Fabre's sales representatives and stressed that the actions above were of his own volition and were in no way representative of the working processes of Pierre Fabre. [Post submission note: At the completion of this case Pierre Fabre confirmed that its representatives could continue to give out the bags until early January 2017.]

PANEL RULING

The Panel noted that bags which had been stored in a basement for around 3 years were provided to representatives to give to pharmacies. The bags were designed for Navelbine Oral capsules which would be placed in the bag, sealed and given to the patient to take home. The Panel was concerned that the complainant described the bags as in a poor condition with soot and dust on the inside and that the sealant to close the bag at times did not work. The bags supplied to the Panel, one from the complainant and five from the company, did not look dirty but the complainant stated that they had cleaned the one he/she had sent. The sealants were different in that those supplied by the company had red tape over a flat clear sticky strip and the bag supplied by the complainant had clear tape over a yellow wrinkled sticky strip. Neither bag bore an item code linking it to the item codes on the certificates provided. Material accompanying the original certification of the bag referred to Navelbine Oral being supplied in blister packs inside small boxes and the intention was that the boxes would be put in the plastic bag, sealed and given to the patient to take home. The average prescription comprised four small boxes. The bag would keep the boxes together and protect the boxes from any moisture in the patient's refrigerator during storage. The bag included space for a pharmacy label.

The Panel noted the recent email correspondence in that the bags had been found in the basement of Pierre Fabre's offices in Winchester and the managing director instructed them to be distributed to the representatives. The correspondence indicated a difference of opinion in that one person said that the bags could not be used. This was confirmed by the medical director in an email which stated that it would be inappropriate to send out the bags as the company was unaware of how long they had been left in unsuitable storage conditions and patient safety was in question. The medical director also referred to certification and that as the brand and generic names were present prescribing information was required.

The Panel considered that although it had no details on how the bags were stored in the basement,

the complainant stated that he/she had received dirty bags with faulty seals. The Panel noted that extreme dissatisfaction was usually required before an individual was moved to complain. In the Panel's view this did not seem unreasonable given the bags had been in the basement for around 3 years. The email from the medical director referred to the bags having been left in unsuitable storage conditions. Other than a visual inspection by the managing director, it appeared that Pierre Fabre had not checked the quality of the bags before giving them to the representatives to distribute. The Panel considered that Pierre Fabre had not maintained high standards and ruled a breach of Clause 9.1.

The Panel was extremely concerned about the company's submission that the managing director having balanced the needs of the business had over-ruled the medical director's advice that the bags should not be distributed citing, *inter alia*, patient safety as a reason. In the Panel's view patient safety was paramount. It was not known how the bags had been stored in the basement nor how many of these had been distributed to the representatives. Similarly there was no information about how many bags had been given out by the representatives. An email referred to 'numerous pharmacy bags' in the basement, and a subsequent email from the managing director stated 'Please distribute all these to the sales team'. The Panel did not know if every single bag had been visually inspected by the managing director before being given to representatives. The company had not commented specifically on the results of the visual inspection. The Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry and therefore ruled a breach of Clause 2.

The Panel noted Pierre Fabre's submission that it had stopped supplying the bags to the representatives. It did not know whether the representatives had stopped supplying the bags they already had to pharmacies nor how many bags they had already given out. The Panel decided that as there was a potential safety issue with use of the bags it would require Pierre Fabre to suspend use of the bags if Pierre Fabre appealed the Panel's ruling pending the final outcome of the case. This was in accordance with Paragraph 7.1 of the Constitution and Procedure.

The Panel had no information about whether the problems with the bags occurred during storage in the basement, with the representatives or elsewhere. Pierre Fabre had not commented specifically on the faulty sealants. The Panel also noted that the use of the bags was optional. The medicine's packaging would be sufficient. The Panel considered that pharmacists would visually inspect the bags before using them. However the potential safety issue would have been avoided if the decision of Pierre Fabre's medical director had not been overridden by one individual and/or proper quality assurance had been carried out. This was prohibited by the same individual above. The Panel noted its ruling of a breach of Clause 2 which would mean that brief details of the case would be the subject of an advertisement. The Panel decided taking all the circumstances into account not to report Pierre Fabre to the Appeal Board for it to consider in accordance with Paragraph 8.2 of the Constitution and Procedure.

During its consideration of this case, the Panel was concerned about a number of matters. It was disingenuous of the managing director to state that the decision to circulate the bags in no way represented the working practices of Pierre Fabre given he set company standards and the impression given by his decision in this regard. In addition there seemed to be a lack of understanding about the Code: as the bags were to be given to patients they should not include prescribing information but when supplied to pharmacists they were promotional and prescribing information should have been provided. The Panel requested that its concerns be brought to Pierre Fabre's attention.

Complaint received **6 December 2016**

Case completed **31 January 2017**