ANONYMOUS GENERAL PRACTITIONER v PROFILE PHARMA

Promotion of Promixin

An anonymous general practitioner queried whether Profile's provision of I-neb nebulisers with Promixin (colistimethate sodium) was an inducement to prescribe. The nebuliser was operated by a disc which was provided in boxes of Promixin vials. The complainant noted that Promixin was much more expensive than comparable presentations of colistimethate sodium and asked if this was the way in which Profile was able to offer nebulisers on free loan.

The complainant further alleged that claims made by Profile representatives ie that 1MIU of Promixin via the I-neb was as effective as 2 MIU of colistimethate sodium via other nebulisers, could not be proven.

The Panel noted that built into the price of each 30 vial pack of Promixin was an element for the provision of the I-neb system and the continued supply of associated disposables. The Panel considered that the I-neb was not on long-term loan; it was supplied as part of a package deal with the purchase of Promixin. Package deals, whereby the purchaser of a particular medicine received other associated benefits, such as apparatus for administration, were permissible under the Code provided that the transaction as a whole was fair and reasonable and the associated benefits were relevant to the medicine involved. The Panel considered that the package deal offered with Promixin was not unreasonable. No breach of the Code was ruled.

The Panel noted the allegation that claims made by representatives about the lung deposition of Promixin could not be proven ie that 1 MIU of Promixin via the I-neb was as effective as 2 MIU colistimethate sodium via other nebulisers. The product support pack explained that the I-neb had a very low residual volume (0.1ml) which allowed for smaller volumes of medicine to be place in the medication chamber. Profile produced data to show the 1 MIU/1ml delivered by the I-neb would achieve a lung dose similar to that achieved by 2 MIU/4ml delivered by a conventional nebuliser. Given that the complainant was anonymous, the Panel had no way of knowing exactly what representatives had said, nor was it possible to ask the complainant to comment on the company's response prior to a ruling being made. Profile submitted that it did not promote to GPs. The Panel considered that on the material before it there was no evidence that representatives had made misleading claims. No breach of the Code was ruled.

An anonymous complainant, writing as 'an overspent and annoyed GP', complained about the promotion of Promixin (colistimethate sodium) by Profile Pharma Ltd. Promixin was powder to be reconstituted and used as a nebuliser solution in the treatment of lung infections in patients with cystic fibrosis.

COMPLAINT

The complainant was concerned that Profile's I-neb nebuliser was offered to cystic fibrosis patients on a 'free loan' basis. The device only operated when a disc containing a microchip was inserted. The disc was supplied in a box of Promixin vials. Patients were told that the only way to get a disc was to get a repeat prescription for Promixin. Did this imply that no other colistimethate sodium vial could be used with the device? If so, was this not an inducement to prescribe? The complainant provided an article from the Pharmaceutical Services Negotiating Committee (PSNC) website which commented on the use of Promixin.

The complainant noted that there were significant budgetary implications for both primary and secondary care when prescribing Promixin: Promixin 1 MIU vial cost £4.60 vs colistimethate sodium 1 MIU which cost £1.68. Was this huge differential in price the way in which Profile was able to offer nebulisers on free loan?

The complainant alleged that claims made by Profile representatives about the lung deposition of Promixin could not be proven, ie that 1 MIU of Promixin via the I-neb was as effective as 2 MIU of colistimethate sodium via other nebulisers.

When writing to Profile, the Authority asked it to respond in relation to Clauses 7.2, 7.3, 15.2 and 18.1 of the Code.

RESPONSE

Profile explained that I-neb was supplied by Respironics UK and offered on a long-term loan basis to patients; not as a 'free loan' as stated by the complainant. It was acknowledged that the higher cost for the medicine paid for the long-term loan of the nebuliser.

Promixin could be used with any conventional nebuliser suitable for delivery of antibiotic solutions but boxes of 30 Promixin vials included a disc which enabled the product to be used with an I-neb device.

The I-neb device could be used with other products intended for nebulisation by means of a disc which was supplied with the nebuliser. If patients/health workers did not wish to use the long-term loan option, but still wanted to obtain an I-neb they could purchase one and appropriate discs would be supplied.

The article referred to by the complainant was factually incorrect and Profile thanked the complainant for bringing it to its attention. The Promixin summary of product characteristics (SPC) clearly stated that 'Promixin may be reconstituted with Water for Injections (WFI) to produce a hypotonic solution or a 50:50 mixture of WFI and 0.9% saline to produce an isotonic solution. When reconstituted, Promixin may be used with any conventional nebuliser suitable for delivery of antibiotic solutions'.

Profile noted that the complaint had been received from a GP. Profile did not promote to GPs.

The need to use 1 MIU in an I-neb to obtain an equivalent dose to 2 MIU delivered through a conventional nebuliser was related to the concentration of the solutions placed in the nebulisers, and not related to lung deposition. This point had previously been covered in correspondence with the Medicines and Healthcare products Regulatory Agency (MHRA) which agreed with Profile's stance on the issue.

Promixin was supplied as a sterile dry powder for nebulisation. It could be administered via conventional nebulisers or via the I-neb nebuliser system. Promixin was prescribed and supplied separately to the nebuliser system and this was in common with other pharmaceutical products intended for nebulisation. As there was a wide variation between the different types of nebuliser available, Promixin might need to be reconstituted to different volumes dependent upon the manufacturers' instructions for the specific nebuliser being used.

Profile explained that the delivery of drugs from nebulisers was highly variable due to the large variation in nebuliser technology and the variable efficiency of nebulisers. The I-neb system, utilising adaptive aerosol delivery (AAD) technology was developed to address this problem. Conventional air-stream nebulisers required a minimum volume in the nebulisation chamber to operate and so a fill volume would be recommended by the manufacturer of the nebuliser and part of this would be nebulised until the residual volume was left in the chamber. Conventional nebulisers generated an aerosol continuously even while the patient was exhaling so a lot of aerosolised medicine was wasted to the atmosphere. The I-neb was designed to deliver medicine during inhalation only, reducing the amount of medicine wasted to the atmosphere. Hence a significantly lower fill volume was required in order to achieve a lung dose equivalent to that of a conventional nebuliser. The residual volume of the I-neb was low and such efficiencies made it possible to use smaller fill volumes of a higher concentration to deliver approximately the same amount to the lungs. Such efficiencies also resulted in rapid dose delivery with associated improvement in compliance. Based on these data the I-neb delivered an approximately equivalent dose to a conventional nebuliser but required only half the amount of dose due to reduced wastage and higher concentration.

Profile conceded that Promixin was more expensive than other brands of colistimethate sodium. This was to allow for the long-term loan of the I-neb system and the continued supply of the associated disposable items. Due to the efficiency of the I-neb, the cost of the 1 MIU and 2 MIU Promixin doses were the same when using this nebuliser. The product monograph openly discussed the differences in cost.

PANEL RULING

The Panel noted from the Promixin SPC that the product was supplied in packs of 30 vials each of which contained a disc to enable use with the I-neb system. Built into the price of each 30 vial pack (£138) was an element for the provision of the I-neb system and the continued supply of the associated disposable items. The Panel considered that the I-neb was not on long-term loan; it was supplied as part of a package deal with the purchase of Promixin. The supplementary information to Clause 18.1 stated that Clause 18.1 did not prevent the offer of package deals whereby the purchaser of a particular medicine received with it other associated benefits, such as apparatus for administration, provided that the transaction as a whole was fair and reasonable and the associated benefits were relevant to the medicine involved. In the Panel's view the provision of an I-neb was clearly relevant to the use of Promixin. The section on 'Costs' in the product monograph clearly stated that the cost of Promixin included the provision of the I-neb system.

The Panel noted that Promixin could be used with other nebulisers – although as the cost of the product included provision of the I-neb system to use another delivery device would seem illogical. Alternatively the I-neb system could be bought as a separate item and used to nebulise products other than Promixin. The Panel noted that the article from the PSNC website had wrongly stated that Promixin could only be used with a Prodose nebuliser.

The Panel considered that the package deal offered with Promixin was not unreasonable. No breach of Clause 18.1 of the Code was ruled.

The Panel noted that the complainant had alleged that claims made by representatives about the lung deposition of Promixin could not be proven ie that 1 MIU of Promixin via the I-neb was as effective as 2 MIU colistimethate sodium via other nebulisers. The product support pack contained a sheet which explained the I-neb system. It was stated that the I-neb had a very low residual volume (0.1ml) which allowed for smaller volumes of medicine to be placed in the medication chamber. The fill volume was only 1ml. This enabled less medicine to be used to deliver the same dose to patients. Profile produced data to show that 1 MIU/1ml delivered by the I-neb would achieve a lung dose similar to that achieved by 2 MIU/4ml delivered by a conventional nebuliser. Given that the complainant was anonymous, the Panel had no way of knowing exactly what representatives had said, nor was it possible to ask the complainant to comment on the company's response prior to a ruling being made. Profile submitted that it did not promote to GPs. The Panel considered that on the material before it there was no evidence that representatives had made misleading claims. No breach of Clauses 7.2, 7.3 and 15.2 of the Code was ruled.

Complaint received **3 July 2006**

Case completed **8 August 2006**