

ORPHAN EUROPE v SPECIAL PRODUCTS and CHEMICAL DEVELOPMENTS

Promotion of unlicensed medicines

Orphan Europe complained about the promotion of N-carbamyl-L-glutamic acid powder and anhydrous betaine powder by Special Products and Chemical Developments. Neither product was licensed anywhere in Europe

Orphan Europe stated that in November 2007 both websites, www.specialproducts.biz and www.chemicaldevelopments.com, provided the same and similar information on the products which the site stated, to any visitor to the site, were available to 'buy'. Both websites provided printed materials and the website data sheets for each product, with sections headed 'Therapeutic Indications', listed the medical conditions and patients for which these products were indicated for use. Further information regarding dosages, adverse events, etc was also provided.

As of 19 March 2008, the information was still freely available on the Chemical Developments' website, despite Special Products' letter of 7 January 2008 stating that 'this site has been temporarily removed since December 2007 while we make the appropriate changes'. On the Special Products' website, information regarding N-carbamyl-L-glutamic acid powder appeared to have been removed. However, full prescribing information, advice, indications etc, was still available with regard to anhydrous betaine powder.

Despite inter-company correspondence both Special Products and Chemical Developments continued to proactively make such information openly available. Furthermore, the bold highlighted strapline on Special Products' homepage proclaimed: "'Specials' are unlicensed medicinal products prescribed by doctors when a licensed product for a particular illness does not exist'. Licensed products did exist in the same presentation for the same indications, Carbaglu and Cystadane, for which Orphan Europe SARL was the marketing authorization holder, and which both benefited from special orphan drug status in the EU. The Special Products website was thus misleading to the detriment of Orphan Europe's licensed portfolio.

In Case AUTH/2108/3/08 the Panel noted the submission that Chemical Developments was a chemicals only supplier. The Code applied to the activities of pharmaceutical companies and so the question arose as to whether Chemical Developments could be considered to be a pharmaceutical company subject to the Code.

The Panel noted that the pages of the Chemical

Developments' website provided were headed with the picture of, *inter alia*, someone who appeared to be a doctor in that he had a stethoscope around his neck. Text in the heading read 'Our products can be used as Active Pharmaceutical Ingredients (API) to manufacture pharmaceuticals'. It thus appeared that the company did not view its products as pharmaceuticals in their own right. The product description, however, referred to the medical use of the compounds. The Panel considered that the boundary between a chemical supplier and a pharmaceutical company had become blurred. On balance the Panel decided that given the depiction of a health professional and inclusion of medical information for each product, Chemical Developments, via its website, was acting as a pharmaceutical company and was thus subject to the Code.

The website provided information about N-carbamyl-L-glutamic acid and betaine including indications. The Panel considered that the material provided by the complainant dated 19 March 2008 amounted to promotion of medicines which were not the subject of marketing authorizations and ruled a breach of the Code.

The Panel noted the alleged breach of the prohibition in the Code on the use of abbreviated advertisements on the Internet. The advertisements at issue did not include prescribing information. This would not be possible in any event as the products did not have marketing authorizations and thus no summaries of product characteristics (SPCs) upon which to base the prescribing information. In the circumstances the Panel considered the matter was covered by its ruling above.

In Case AUTH/2109/3/08, the Panel noted that on its website, Special Products described itself as a wholesale pharmaceutical company; it had a wholesale dealer's licence issued by the MHRA. The company worked to convert 'specials' into licensed products. Inasmuch as the company was thus working towards selling medicines with marketing authorizations, the Panel considered that Special Products was a pharmaceutical company subject to the Code.

The Panel noted the company's comments in relation to the MHRA guidance about promoting specials. It did not accept Special Products' submissions that the use of a password before being able to access product information meant that Special Products was responding to requests.

The Panel was concerned that the full prescribing information, advice, indications etc was still available for anhydrous betaine powder. Further the statement that specials were unlicensed medicines prescribed when a licensed product did not exist confused matters given there was a licensed product, that of the complainant. The Panel considered that the material in effect promoted a product that did not have a marketing authorization. A breach of the Code was ruled.

The Panel noted the alleged breach of the prohibition in the Code of the use of abbreviated advertisements on the Internet. The advertisements at issue did not include prescribing information. This would not be possible in any event as anhydrous betaine powder did not have a marketing authorization and thus no SPC upon which to base the prescribing information. In the circumstances the Panel considered the matter was covered by its ruling of a breach above.

Orphan Europe complained about the Internet promotion of unlicensed medicines by Special Products Limited and Chemical Developments Ltd. Orphan Europe stated that inter-company correspondence had failed to resolve the issues.

COMPLAINT

Orphan Europe stated that in November both websites, www.specialproducts.biz and www.chemicaldevelopments.com, provided the same and similar information on N-carbamyl-L-glutamic acid powder and anhydrous betaine powder which the site stated, to any visitor to the site, were available to 'buy'. Neither was licensed anywhere in Europe. Breaches of Clauses 3 and 5.2 of the Code were alleged.

In both websites, the printed materials and the website data sheets for each product were provided, each with a section headed 'Therapeutic Indications', under which Special Products and Chemical Developments listed the medical conditions and patients for which these products were indicated for use in treatment. Further information regarding dosages, adverse events, etc was also provided.

As of 19 March 2008, all such information referred to above with regard to each of these products was still freely available on the Chemical Developments' website, despite Special Products' letter of 7 January 2008 stating that 'this site has been temporarily removed since December 2007 while we make the appropriate changes'.

On the Special Products' website, information regarding N-carbamyl-L-glutamic acid powder appeared to have been removed. However, full prescribing information, advice, indications etc, was still available with regard to anhydrous betaine powder, by simply clicking a button that indicated that you desired this information.

Despite inter-company correspondence both Special

Products and Chemical Developments were evidently continuing to proactively make such information openly available.

Furthermore, the bold highlighted strapline on Special Products homepage proclaimed: "'Specials" are unlicensed medicinal products prescribed by doctors when a licensed product for a particular illness does not exist'.

With regard to N-carbamyl-L-glutamic acid powder and anhydrous betaine powder being openly promoted by Special Products and Chemical Developments, licensed products did in fact exist in the same presentation for the same indications, namely Carbaglu and Cystadane respectively, for which Orphan Europe SARL held the marketing authorizations; both benefited from a special orphan drug status in the EU.

Therefore, Orphan Europe alleged that the current website of Special Products was misleading to the detriment of its licensed portfolio, and that the continued actions of both Special Products and Chemical Developments represented the advertising and promotion of unlicensed medicines.

RESPONSE

Special Products stated that it would keep Chemical Developments separate from Special Products as it was a chemicals only supplier rather than a specials manufacturer.

Case AUTH/2108/3/08 Chemical Developments Ltd

When Orphan Europe originally complained, Special Products instructed the Malaysian Internet service provider hosting its site to remove it from the web while Special Products corrected the issues that caused the problem – this it did and notified Special Products: 'ChemicalDevelopments.com website was disabled on Thu, Dec 13, 2007 at 11:32PM'.

Special Products tested the website uniform resource locator (URL) and found that it came back with a message: 'This website is temporarily closed for maintenance' and was therefore inaccessible via the www.chemicaldevelopments.com URL to potential viewers.

Unfortunately, and unbeknown to Special Products, the online store could still be accessed through searches on the Internet for a specific product listed in this store if, like Orphan Europe, one knew where to find it. The website was not freely available as alleged. This loophole was closed as soon as Special Products was notified of this complaint and on testing again on 9 April the URL example sent by Orphan Europe could not be accessed. Special Products would review the whole Chemical Developments site to ensure that when it did go online again, it made no medical claims.

Special Products apologised for this oversight.

Case AUTH/2109/3/08 Special Products Ltd

Special Products specialized in the manufacture of 'specials' in accordance with the exemption contained within the Medicines for Human Use (Marketing Authorisation) Regulations 1994.

Guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) on the manufacture and supply of specials stated that 'A specials manufacturer, importer or wholesaler may advertise the service he provides but in particular, "specials" must not be advertised. He may, however, respond to requests for information on specific products'.

Special Products submitted that it adhered to this guidance.

As stated previously, the Special Products website www.specialproducts.biz described the services provided by the company. In order to request information about specific products, a user must be a health professional and register with the website. Only following vetting by Special Products to gain a user name and password could a user access product information. Requests for information on products required a double opt-in approach so that any medical information had to be requested, in compliance with MHRA guidance.

PANEL RULING

Case AUTH/2108/3/08 Chemical Developments Ltd

The Panel noted Special Products' submission that Chemical Developments was a chemicals only supplier. The Code applied to the activities of pharmaceutical companies and so the question arose as to whether Chemical Developments could be considered to be a pharmaceutical company subject to the Code.

The Panel noted that the pages of the Chemical Developments' website provided were headed with the picture of, *inter alia*, someone who appeared to be a doctor in that he had a stethoscope around his neck. Text in the heading read 'Our products can be used as Active Pharmaceutical Ingredients (API) to manufacture pharmaceuticals'. It thus appeared that the company did not view its products as pharmaceuticals in their own right. The product description, however, referred to the medical use of the compounds. The Panel considered that the boundary between a chemical supplier and a pharmaceutical company had become blurred. On balance the Panel decided that given the depiction of a health professional and inclusion of medical information for each product, Chemical Developments, via its website, was acting as a pharmaceutical company and was thus subject to the Code.

The Panel noted that the website provided information about two products, N-carbamyl-L-

glutamic acid and betaine. Indications were included. The Panel considered that the material provided by the complainant dated 19 March 2008 amounted to promotion of the medicines which were not the subject of marketing authorizations. Thus the Panel ruled a breach of Clause 3.1.

The Panel noted the alleged breach of Clause 5.2 which, *inter alia*, prohibited the use of abbreviated advertisements on the Internet. The advertisements at issue did not include prescribing information. This would not be possible in any event as the products did not have marketing authorizations and thus no summaries of product characteristics (SPCs) upon which to base the prescribing information. In the circumstances the Panel considered the matter was covered by its ruling of a breach of Clause 3.1.

Case AUTH/2109/3/08 Special Products Ltd

The Panel noted that on its website, Special Products Limited described itself as a wholesale pharmaceutical company; it had a wholesale dealer's licence issued by the MHRA. The company worked to convert 'specials' into licensed products. Inasmuch as the company was thus working towards selling medicines with marketing authorizations, the Panel considered that Special Products was a pharmaceutical company subject to the Code.

The Panel noted the company's comments in relation to the MHRA guidance about promoting specials. It did not accept Special Products' submissions that the use of a password before being able to access product information meant that Special Products was responding to requests.

The complainant stated that this website was similar to that of Chemical Developments.

The Panel was concerned that the full prescribing information, advice, indications etc was still available for anhydrous betaine powder. Further the statement that specials were unlicensed medicines prescribed when a licensed product did not exist confused matters given there was a licensed product, that of the complainant. The Panel considered that the material in effect promoted a product that did not have a marketing authorization. A breach of Clause 3.1 was ruled.

The Panel noted the alleged breach of Clause 5.2 which, *inter alia*, prohibited the use of abbreviated advertisements on the Internet. The advertisements at issue did not include prescribing information. This would not be possible in any event as anhydrous betaine powder did not have a marketing authorization and thus no SPCs upon which to base the prescribing information. In the circumstances the Panel considered the matter was covered by its ruling of a breach of Clause 3.1.

Complaint received 25 March 2008

Cases completed 5 June 2008