CASE AUTH/3037/4/18

HEALTH PROFESSIONAL v SHIELD

Promotion of Feraccru and unlicensed medicines to the public

An anonymous complainant who described themselves as a 'concerned UK health professional' complained about information on Shield Therapeutics' website. The information in question related to Feraccru (ferric maltol), which was used to treat iron deficiency, and three pipeline products, PT20, PT30 and PT40.

The complainant noted that Shield's website had no separate areas for different groups of people such as prescribers and the public.

Under the heading 'lead products' there was a section for Feraccru and the three pipeline product candidates. The information on Feraccru was clearly promotional, yet the page in question had not been screened from the public and it had no link to prescribing information for health professionals. The complainant stated that the information about the pipeline products promoted them to the public and additionally promoted such medicines before they had been reviewed by the regulatory authorities. In light of the above, the complainant queried whether the material has been adequately reviewed by Shield before it made it available on the Internet.

The detailed response from Shield is given below.

The Panel noted that the website had not been certified and therefore ruled a breach of the Code.

The page for Feraccru positioned Feraccru favourably compared to other iron therapies. The site could be accessed by the public and was promotional, therefore the Panel ruled a breach of the Code.

The failure to include the Feraccru prescribing information or a clear, prominent statement as to where it could be found was ruled in breach of the Code.

The Panel noted that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The Panel noted its comments and rulings above. The website contained promotional material which was not directed towards health professionals and other relevant decision makers as set out in the relevant supplementary information and a breach was ruled.

The Panel ruled a further breach as Shield had failed to maintain high standards. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

The Panel noted its comments above and Shield's submission that although the website was intended to be non-promotional it had become promotional. The Panel noted that the pipeline product candidate pages gave more than a brief summation of the pipeline. The section on PT20 described PT20 as novel and a more efficient phosphate binder compared to iron oxide, that it had generally good tolerability across the dose range and its absorption of phosphate in dialysis-dependent CKD patients was favourably compared with the limitations of current therapies including in relation to GI side effects and significant toxicity. The Panel considered that the section on PT20 was promotional.

The Panel noted Shield's submission that PT20 was a phosphate binder that had completed a Phase II clinical study. It was not licensed and therefore, *de facto*, could not be a prescription only medicine. The Code prohibited the promotion of prescription only medicines to the public. The Panel noted that the product was not currently classified as a prescription only medicine. On this narrow technical point, the Panel ruled no breach of the Code.

The Panel considered that the section on PT20, PT30 and PT40 was promotional and would generate interest in and elicit questions about unlicensed medicines. The Panel noted Shield's submission that both PT30 and PT40 were in early clinical development. The Panel ruled that the website promoted unlicensed medicines in breach of the Code.

The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorization as an example of an activity that was likely to be in breach of that Clause. The Panel considered that Shield had thus brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled.

An anonymous complainant who described themselves as a 'concerned UK health professional' complained about information on the website for Shield Therapeutics (www.shieldtherapeutics.com). The information in question related to Feraccru (ferric maltol), which was used to treat iron deficiency, and three pipeline products, PT20, PT30 and PT40.

COMPLAINT

The complainant noted that Shield's website was for a company registered in the UK with two UK offices and apparently no offices in other Anglophone countries. The website had no separate areas for different groups of people such as prescribers and the public.

Under the heading 'lead products' there was a section for Feraccru and pipeline product candidates namely PT20, PT30 and PT40. The information on Feraccru was clearly promotional, yet the page in question had not been screened from the public and it had no link to prescribing information for health professionals.

The information on each of PT20, PT30 and PT40 contained details that appeared to promote the benefits of the products – eg that the product had been designed to be hypoallergenic, potentially overcoming one of the most significant drawbacks of current intravenous iron therapies. The complainant stated that as above, this information promoted the products to the public and additionally promoted such medicines before they had been sufficiently reviewed by the regulatory authorities.

In light of the above, the complainant queried whether the material has been adequately reviewed by Shield before it made it available on the Internet.

When writing to Shield, the Authority asked it to consider the requirements of Clauses 2, 3.1, 4.1, 4.6, 9.1, 14.3, 26.1 and 28.1.

RESPONSE

Shield submitted that the website at issue was intended for investors and members of the public. As such, it was non-promotional with factual and balanced information only in compliance with Clause 26 and it did not require certification under Clause 14, although company procedures required that all such materials were reviewed by the senior leadership team before being posted on the site. As the website was non-promotional, it did not require separate pages for health professionals and patients nor links to the prescribing information as defined in Clauses 4.1 and 4.6, however it clearly provided links to the European Public Assessment Report (EPAR), the summary of product characteristics (SPC) and the patient information leaflet (PIL).

Shield stated that when notified of the complaint, it reviewed the specific pages relating to Feraccru and the pipeline product candidates (PT20, PT30 and PT40) that were live on the website on the date of the complaint.

With regard to the pipeline products, Shire explained that PT20 was a phosphate binder that had completed a Phase II clinical study. It was not licensed and therefore, *de facto*, could not be a prescription only medicine. The paragraph discussed the chemical properties of PT20, the outcome of the Phase II study in general terms and the goal for further development. It made no specific promotional claim, nor did it encourage members of the public to ask their health professionals to prescribe a specific prescription only medicine. Therefore, it did not breach Clauses 26.1, 26.2 or 3.1.

The short paragraph for PT30 and PT40 covered the development goals for the products and discussed some of the challenges of current medicines. Both PT30 and PT40 were in early clinical development. The statements were not promotional and therefore did not breach Clauses 26.1, 26.3 or 3.1. Shield submitted that as these areas were not promotional, Clause 14.3 did not apply and given there were no breaches of Clauses 26.1, 26.2, 3.1 or 14.3, there could be no breach of Clause 2.

Shield submitted that as the website at issue was intended to be non-promotional, it had developed a separate promotional site for Feraccru (www.feraccru.com); this site provided greater information and was appropriately separated into areas for health professionals and those designed for the public. The company was therefore shocked and deeply concerned that the website at issue contained what could be considered promotional claims for Feraccru. Investigation revealed that a contractor had changed the website without following company procedures and had added information to the corporate site. These changes were not seen by the senior team and would not have been sanctioned had they been reviewed. In view of the changes made, it was clear that the site became promotional and so additional requirements of the Code applied. As a promotional site, it followed that there were breaches of Clauses 28.1, 26.1, and 14.3. In view of this, the company accepted that there might be a perception that Shield has failed to maintain high standards in breach of Clause 9.1. Although there were clear links to the Feraccru EPAR, SPC and PIL on the site, these did not carry all the information required in the prescribing information under Clause 4, and as such, there were also breaches of Clauses 4.1 and 4.6.

In view of the findings Shield ensured that the corporate website was amended immediately and stated that the contractor no longer worked at the company. Policies had also been enhanced so

that all content of the corporate site must be certified in the same manner as the promotional site to avoid issues in future.

While Shield was extremely disappointed that this error had occurred, it was confident that it had identified and addressed the cause and strengthened its processes to avoid it happening in the future. Given the availability of the EPAR, SPC and PIL on the site, patient safety was not compromised and the company considered that this was a genuine error that did not merit particular censure as indicated by a breach of Clause 2.

PANEL RULING

The Panel disagreed with Sheild's submission that the website at issue was intended for investors and members of the public and as such, it was non-promotional and did not require certification under Clause 14. Clause 14.3 required that educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines must be certified in advance in a manner similar to that provided for by Clause 14.1. The Panel noted that the website had not been certified and therefore ruled a breach of Clause 14.3.

The Panel noted Shield's submission that a contractor had changed the website at issue without following company procedures and had added information to the corporate site which meant that the site became promotional and so additional requirements of the Code applied. The relevant page for Feraccru compared its tolerability, patient outcomes and compliance with salt-based oral iron therapies. It also compared Feraccru to iv iron therapies and stated that iv iron therapies quickly increased iron stores via direct administration of very large doses of iron, causing an increase in Hb levels that was physiologically controlled and occurred over a period of weeks, as was the case with Feraccru. It stated that IV iron therapies, however, were invasive, costly, inconvenient and complex to administer, and also came with potentially life-threatening, spontaneous hypersensitivity reactions. It was clearly promotional and positioned Feraccru favourably compared to other iron therapies. The site could be accessed by the public and was promotional, therefore the Panel ruled a breach of Clause 26.1.

The Panel noted that the website did not include the Feraccru prescribing information or a clear, prominent statement as to where it could be found and breaches of Clauses 4.1 and 4.6 were ruled.

The Panel noted that the supplementary information to Clause 28.1 stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The Panel noted its comments and rulings above. The website contained promotional material which was not directed towards health professionals and other relevant decision makers as set out in the relevant supplementary information to Clause 28.1 and a breach of Clause 28.1 was ruled.

The Panel considered that Shield had failed to maintain high standards and a breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

The Panel noted its comments above and Shield's submission that although the website was intended to be non-promotional it had become promotional. The Panel noted that the pipeline product candidate pages gave more than a brief summation of the pipeline. The section on PT20 described PT20 as novel and a more efficient phosphate binder compared to iron oxide, that it had

generally good tolerability across the dose range and its absorption of phosphate in dialysis-dependent CKD patients was favourably compared with the limitations of current therapies including in relation to GI side effects and significant toxicity. The Panel considered that the section on PT20 was promotional.

The Panel noted Shield's submission that PT20 was a phosphate binder that had completed a Phase II clinical study. It was not licensed and therefore, *de facto*, could not be a prescription only medicine. Clause 26.1 prohibited the promotion of prescription only medicines to the public. The Panel noted that the product was not currently classified as a prescription only medicine. On this narrow technical point, the Panel ruled no breach of Clause 26.1 of the Code.

The Panel noted that Clause 3.1 which required that a medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply. The Panel noted that Shield considered the site to be promotional. PT30 was described as a novel IV iron formulation that was designed to be hypoallergenic, potentially overcoming one of the most significant drawbacks of current IV iron therapies. It stated that PT40 was designed to be the first generic version of IV iron sucrose, which would significantly lower the cost of IV iron sucrose. The Panel considered that the section on PT20, PT30 and PT40 was promotional and would generate interest in and elicit questions about unlicensed medicines. The Panel noted Shield's submission that both PT30 and PT40 were in early clinical development. The Panel considered that the website at issue promoted unlicensed medicines and a breach of Clause 3.1 was ruled.

The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorization as an example of an activity that was likely to be in breach of that Clause. The Panel considered that Shield had thus brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled.

Complaint received **26 April 2018**

Case completed **24 August 2018**