CASE AUTH/3108/10/18

COMPLAINANT v MITSUBISHI TANABE PHARMA EUROPE

Promotion to the public

A complainant who described him/herself as a concerned UK health professional complained about four pharmaceutical companies' websites including that of Mitsubishi Tanabe Pharma Europe who market Exembol (argatroban – used for anticoagulation in certain adult patients) and Tanatril (imidapril – indicated for the treatment of essential hypertension in adults) in the UK.

The complainant noted that Mitsubishi Tanabe Pharma Europe was based in London. The complainant drew parallels with another company's website which he/she had complained promoted to the general public because there was information including the generic name, the brand name and the indication. The complainant stated that Mitsubishi Tanabe Pharma Europe's website similarly had no separate area for patients and merely stated that certain pages were for patients and that the product pages were similarly promoting to the general public, particularly if one selected the 'read more' button.

The detailed response from Mitsubishi Tanabe Pharma Europe is given below.

The Panel noted Mitsubishi Tanabe Pharma Europe's submission that its website was intended to provide corporate information in relation to the company and its products at a European level; and that the webpages in question were not promotional and provided accurate, factual information for health professionals and the public in relation to Exembol and Tanatril.

The Panel noted the webpage in question contained statements related to argatroban (non-proprietary name for Exembol) and Tanatril.

In relation to argatroban, the webpage stated:

> **'Developed in Japan, argatroban was the first licensed synthetic direct thrombin inhibitor. Approved in twelve European countries, argatroban is marketed for anticoagulation in adult patients with Heparin-Induced Thrombocytopenia Type II (HIT Type II) who require parenteral antithrombotic therapy. Argatroban is given as a continuous intravenous infusion.'**

The same page had the following statement in relation to Tanatril:

> **'Tanatril is used to treat high blood pressure (hypertension). Tanatril is one of a group of medicines called ACE (angiotensin-converting enzyme) inhibitors. Tanatril is available in 5mg, 10mg and 20mg tablet formulation.'**

The Panel noted that there was a 'read more' button within the highlighted text box for each product and to the right of the page an adverse event reporting statement. At the bottom of each webpage within the products section, in small font, was the statement 'Please note: certain pages are intended for healthcare professionals only'. The Panel noted that the 'certain pages' were not identified and thus in the Panel's view the intended audience for each page was unclear. The section did not clearly separate pages aimed at health professionals from those containing information for the public. The Panel also noted Mitsubishi Tanabe's submission that the webpages were non-promotional and there was accordingly no requirement to restrict access.

The Panel noted that if the 'read more' button was selected for argatroban, the user was taken to a page which repeated the argatroban statement above and further stated: 'You can find specific information on our products in individual countries by choosing the relevant country from the menu below'. The four brand names for argatroban were listed with links to the relevant country/ countries for each. If the user selected the UK link for Exembol, a pop-up box appeared stating that the following pages were intended for viewing by UK health professionals only. If the user selected 'continue' the user was taken to a page that contained: links to the Exembol summary of product characteristics and patient information leaflet; contact details for Mitsubishi Tanabe Pharma Europe; an adverse event reporting statement; and a link to an Exembol website. If the user had selected 'cancel' in response to the pop-up box, he/she would stay on the current page.

The Panel further noted that when the user selected the Tanatril 'read more' button from the main product webpage, he/she would be taken to a page titled 'How to order Tanatril' which gave information regarding ordering the product from a named wholesaler, including the wholesaler's contact details and the PIP codes for each tablet strength. The same page featured: links to the Tanatril summary of product characteristics and patient information leaflet; Mitsubishi Tanabe Pharma Europe's contact details; and an adverse event reporting statement. The bottom of the page stated: 'Please note: certain pages are intended for healthcare professionals only'. The Panel noted its comments on this statement above. The content of this page was such that it appeared to be aimed at health professionals.

The Panel queried whether the products homepage and the pages linked via the read more buttons could be considered reference information as set out in the supplementary information of the Code given the lack of information provided for members of the public. There appeared to be nowhere for members of the public to go to access further information on argatroban; the SPC and PIL could only be accessed after the reader confirmed that he/she was a health professional. The page for Tanatril, which included the SPC and PIL, related to how to order the product and appeared therefore to be aimed at health professionals.

The Panel considered that the statement '… argatroban was the first licensed synthetic direct thrombin inhibitor. Approved in twelve European countries …' which appeared, *inter alia*, on the main product webpage constituted a product claim. The Panel noted that whilst the homepage of the products section in question did not include the brand name for argatroban it did include its non-proprietary name and indication. If a member of the public clicked on the read more button for argatroban they were provided with the brand name of the product in individual countries including Exembol in the UK. The initial webpage also included the brand name and indication for Tanatril.

The Panel also noted that members of the public looking for information on one particular medicine would automatically be faced with the non-proprietary or brand name and indication of Mitsubishi Tanabe Pharma Europe's other medicine.

Noting its comments above the Panel considered that the webpage advertised prescription only medicines to the public and a breach of the Code was ruled.

The Panel noted its comments and ruling above. In the Panel's view, the webpage at issue promoted prescription only medicines and therefore access should have been restricted to health professionals and other relevant decision makers because information had not been provided for the public as required by the relevant supplementary information. The Panel noted that access to the webpage had not been so restricted and therefore a breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that Mitsubishi Tanabe Pharma Europe had failed to maintain high standards and a breach of the Code was ruled.

The Panel did not consider that the circumstances in this particular case warranted a ruling of a breach of Clause 2 and no breach was ruled accordingly.

A complainant who described him/herself as a concerned UK health professional complained about four pharmaceutical companies' websites including that of Mitsubishi Tanabe Pharma Europe who market Exembol (argatroban – used for anticoagulation in certain adult patients) and Tanatril (imidapril – indicated for the treatment of essential hypertension in adults) in the UK.

COMPLAINT

The complainant noted that Mitsubishi Tanabe Pharma Europe was based in London. The complainant drew parallels with another company's website which he/she had complained promoted to the general public because there was information including the generic name, the brand name and the indication. The complainant stated that Mitsubishi Tanabe Pharma Europe's website http://www.mt-pharma-eu.com/products/ similarly had no separate area for patients and merely stated that certain pages were for patients and that the product pages were similarly promoting to the general public, particularly if one selected the 'read more' button.

When writing to Mitsubishi Tanabe Pharma Europe, the Authority asked it to consider the requirements of Clauses 26.1, 28.1, 9.1 and 2 of the Code.

RESPONSE

Mitsubishi Tanabe Pharma Europe stated that it was surprised and disappointed that such a complaint had been made; the company was committed to maintaining high standards in relation to all communications concerning its medicinal products and in complying with the Code in all relevant activities.

Mitsubishi Tanabe Pharma Europe stated that it sponsored the website which was intended to provide corporate information in relation to the company and its products at European level.

The European 'Products' webpage referred to two medicinal products: argatroban (marketed as Exembol in the UK) and Tanatril. Both products were the subject of UK marketing authorisations granted to Mitsubishi Tanabe Pharma Europe by the Medicines and Healthcare products Regulatory Agency (MHRA), as well as authorisations granted nationally in other EU Member States by other national competent authorities.

In relation to argatroban, the webpage stated:

> 'Developed in Japan, argatroban was the first licensed synthetic direct thrombin inhibitor. Approved in twelve European countries, argatroban is marketed for anticoagulation in adult patients with Heparin-Induced Thrombocytopenia Type II (HIT Type II) who require parenteral antithrombotic therapy. Argatroban is given as a continuous intravenous infusion.'

A 'Read More' button linked to a further webpage specifically dedicated to argatroban which stated:

> 'Test Developed in Japan, argatroban was the first licensed synthetic direct thrombin inhibitor. Approved in twelve European countries, argatroban is marketed for anticoagulation in adult patients with Heparin-Induced Thrombocytopenia Type II (HIT Type II) who require parenteral antithrombotic therapy. Argatroban is given as a continuous intravenous infusion.'

The user was informed that if he/she clicked on one of the EU countries listed he/she would find information on the products applicable to that country. If the UK symbol was selected, the user was asked to confirm that he/she was a UK health professional, following which he/she was directed to a webpage entitled 'Exembol® (UK)'. Exembol was the brand name for argatroban in the UK; different brand names were used in other Member States, which was why the initial European Products webpage referred to the product by its international non-propriety name. The Exembol (UK) webpage provided links to both the UK summary of product characteristics (SPC) and the UK patient information leaflet (PIL) for Exembol, advising the user that they would be directed away from the Mitsubishi Tanabe Pharma Europe webpage if they chose to proceed. If the user clicked 'Continue', they were directed to the electronic Medicines Compendium (eMC) website, where the UK SPC and UK PIL for Exembol could be accessed.

Mitsubishi Tanabe Pharma Europe submitted that the statements made on the above webpages in relation to argatroban were factually correct and the complainant did not suggest otherwise.

In relation to Tanatril, the European Products webpage stated:

> 'Tanatril is used to treat high blood pressure (hypertension). Tanatril is one of a group of medicines called ACE (angiotensin-converting enzyme) inhibitors. Tanatril is available in 5mg, 10mg and 20mg tablet formulation.'

A 'Read More' button linked to a further webpage specifically dedicated to the product which provided details on how to order Tanatril which gave information regarding ordering the product from a named wholesaler, including the wholesaler's contact details and the PIP codes for each tablet strength. It stated that if you have any queries, please contact the wholesaler support team on the telephone number or email address provided.

It also provided the wholesaler's telephone number to call to set up a new account.

The webpage then provided links to the Tanatril UK SPC and PIL. When these links were clicked, the user was notified that they would be directed away from the Mitsubishi Tanabe Pharma Europe website if they chose to proceed. If the user clicked 'Continue', he/she was directed to the eMC website where the Tanatril UK SPC and PIL could be accessed.

Mitsubishi Tanabe Pharma Europe submitted that the statements made on the above webpages in relation to Tanatril were factually correct and the complainant did not suggest otherwise.

Mitsubishi Tanabe Pharma Europe noted Clause 26.1 and the relevant supplementary information.

Mitsubishi Tanabe Pharma Europe submitted that in relation to Clause 26, the PMCPA's 'Guidance about Digital Communications' stated:

> 'Whilst promotion is prohibited, factual and balanced information about prescription only medicines can be made available to the public either directly or indirectly. However, statements must not be made for the purpose of encouraging members of the public to ask a health professional to prescribe a specific prescription only medicine.'

The company submitted that Section 2(iv), Annex B of the 'EFPIA [European Federation of Pharmaceutical Industries and Associations] HCP [health professional] Code' and Section 7.5 of the MHRA's Blue Guide were also relevant.

Mitsubishi Tanabe Pharma Europe stated that Clause 26.1 prohibited advertising directed towards members of the public and that the complainant asserted that the European products webpage was promotional on the basis that it used both generic and brand names for medicinal products and identified the indications for use.

Mitsubishi Tanabe Pharma Europe submitted that it disagreed with the criticisms made by the complainant. The corporate webpages in question were not promotional. They provided accurate, factual information for health professionals and the general public in relation to Exembol and Tanatril consistent with the PMCPA guidance on digital communications and the EFPIA Code. The webpages included links to the approved UK SPC and PIL as required under the EFPIA Code.

Mitsubishi Tanabe Pharma Europe submitted that the use of both generic names was not promotional. The use of brand names was promotional only if such use was excessive. The European products webpage and subsequent pages used the brand name Exembol only once on two webpages and the brand name Tanatril seven times on two webpages. This did not involve excessive use of the brand for either product. A factual statement about the authorised indications for use was informative rather than promotional. The provision of such information reflected PMCPA guidance, the EFPIA Code and MHRA's advice that 'other non-promotional reference information about the product that fairly reflected the current body of evidence about the product and its benefit risk profile' was permitted. Furthermore, any prohibition of neutral, factual information stating the approved indication for use, would be inconsistent with the fact that companies are encouraged to include copies of or links to UK SPCs and PILs on websites aimed at members of the public. The European product webpage linked to a webpage containing instructions on how to order Tanatril directed towards health professionals and administrative staff. While the complainant did not criticise the provision of ordering information, this page was not in any event promotional and advised users 'Please note: certain pages are intended for healthcare professionals only'. None of the identified pages made product claims comparable to those which were the subject of criticism in Case AUTH/2436/9/11 and Case AUTH/3037/4/18 and none were made for the purpose of encouraging members of the public to ask a health professional to prescribe Exembol, Tanatril or any other specific prescription only medicine.

Mitsubishi Tanabe Pharma Europe noted the requirements of Clause 28.1 and the relevant supplementary information.

The company also referred to Section 2(iii) of Annex B to the EFPIA HCP Code and Section 6.3 of the MHRA's Blue Guide.

Mitsubishi Tanabe Pharma Europe submitted that Clause 28.1 was directed towards promotional material that may be accessed by members of the public. For the reasons set out in response to Clause 26.1, the information contained on the identified webpages were not promotional and Clause 28.1 was not therefore applicable. However, for completeness, Mitsubishi Tanabe Pharma Europe submitted that it identified on the website those pages which were intended for health professionals. As described above, the European 'Products' webpage listed both argatroban and Tanatril and stated beneath the brief factual information in relation to those products, 'Please note: certain pages are intended for healthcare professionals only.'

Argatroban

The 'Read More' button relevant to argatroban directed users to a webpage where users could select the correct jurisdiction in order to 'find specific information on [Mitsubishi Tanabe Pharma Europe] products'. Beneath this selection frame was a statement which read 'Please note, certain pages are intended for healthcare professionals only'. If a user clicked on the UK webpage, a pop-up appeared which stated:

> 'The following pages are intended for viewing by healthcare professionals residing in the UK only. By clicking "Continue" below you confirm that you are a resident of the UK and that you agree to the terms & conditions of use associated with this website. If you are not a resident of the UK or you do not agree to the terms & conditions of use associated with this website you should click "Cancel" now to return to the previous page. The full terms & conditions associated with this website can be accessed at "Terms of Use".'

If the user confirmed that they were a health professional, they were directed to a webpage entitled 'Exembol® (UK)'. At the bottom of this webpage, there was a message which stated 'Please note: certain pages are intended for healthcare professionals only'. If the user clicked on the links to these documents, they were directed to the eMC website, with the requisite notice that they would be directed away from Mitsubishi Tanabe Pharma Europe's webpage.

An alternative route to access the Exembol webpage was to open the main Mitsubishi Tanabe Pharma Europe webpage and then click 'Site Map', which opens a webpage that listed the company's product webpages. If the user clicked on 'Exembol® (UK)' a pop-up appeared which again stated:

> 'The following pages are intended for viewing by healthcare professionals residing in the UK only. By clicking "Continue" below you confirm that you are a resident of the UK and that you agree to the terms & conditions of use associated with this website. If you are not a resident of the UK or you do not agree to the terms & conditions of use associated with this website you should click "Cancel" now to return to the previous page. The full terms & conditions associated with this website can be accessed at "Terms of Use".'

Tanatril

If the user clicked on the 'Read More' button relevant to Tanatril, the user was directed to the Tanatril webpage which repeated the previous statement, 'Please note: certain pages are intended for healthcare professionals only'. As well as providing information about how to order Tanatril, links were provided to the SPC and PIL for this product and these linked to the relevant page of the eMC which when clicked notified users that if they chose to proceed they would be directed away from Mitsubishi Tanabe Pharma Europe's webpages.

An alternative route to access the Tanatril webpage was to open the main Mitsubishi Tanabe Pharma Europe webpage and then click 'Site Map', which opened a webpage that listed the company's product webpages. If the user clicked on 'Tanatril' he/she was directed to the Tanatril webpage described above, which repeated the statement, 'Please note: certain pages are intended for healthcare professionals only'.

In summary, Mitsubishi Tanabe Pharma Europe stated that none of the webpages identified by the complainant were promotional and there was accordingly no objection, for the purposes of Clause 28.1, to the included material being accessed by members of the public as well as health professionals. Nevertheless, Mitsubishi Tanabe Pharma Europe provided information on the cited webpages which advised users that certain material (eg the ordering information for Tanatril) was not directed towards members of the public. For completeness, while in circumstances where the content of the webpages was not promotional, there was no requirement formally to restrict access to any of the identified pages to health professionals, the review of the website carried out for the purposes of this response, had shown that the approach followed was not fully consistent throughout. Mitsubishi Tanabe Pharma Europe therefore proposed to streamline the content of the website so that the messages were provided in a similar form throughout which would, it believed, improve the clarity of the messages.

Mitsubishi Tanabe Pharma Europe submitted that Clause 9.1 required member companies to maintain high standards at all times; it did not believe that any of the information contained in the cited webpages was of a promotional nature or that there was any inappropriate lack of delineation between pages intended for the general public and those intended for health professionals. It did not therefore believe there was any failure by Mitsubishi Tanabe Pharma Europe to meet high standards. Furthermore, the

website was managed by Mitsubishi Tanabe Pharma Europe's corporate function with cross-functional input. The website was last updated in June 2018 to reflect required changes related to disclosure and was recertified. This was in keeping with its Standard Operating Procedure on Managing & Maintaining Company Corporate Website, which required that the content of the website was maintained as current and relevant as it provided information about Mitsubishi Tanabe Pharma Europe and its products on the internet. Staff from all relevant functions were routinely trained on these SOPs using an electronic training system. The SOPs were in line with the company policies and regularly updated and reviewed on the electronic training system to ensure that the latest requirements were fulfilled. The Standard Operating Procedure on Managing & Maintaining Company Corporate Website was last updated on 26 April 2017. Mitsubishi Tanabe Pharma Europe submitted that any allegation that it had not maintained high standards was unfounded; there had been no breach of the relevant provisions of the Code, comprehensive SOPs were in place, and these SOPs were regularly updated and monitored in order to ensure that Mitsubishi Tanabe Pharma Europe did not fall below standard required by the applicable legislation and the Code.

Mitsubishi Tanabe Pharma Europe submitted that Clause 2 stated: 'Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry' and the supplementary information provided in relation to this Clause stated: 'A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances. Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that falls short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time'.

Mitsubishi Tanabe Pharma Europe stated that it had not breached any part of the Code and as such there was no basis for finding of breach of Clause 2. In particular, the identified webpages on the website were non-promotional and there was no inappropriate access by members of the public. The examples provided in the supplementary information to Clause 2 did not relate in any way to issues raised in the case and the website could not be considered to have brought discredit upon, or reduced the confidence in, the industry.

Overall conclusion

Mitsubishi Tanabe Pharma Europe stated it did not believe the criticisms raised by the complainant had merit.

The webpages identified in the complaint did not include any promotional information. The use of brand names in relation to the two listed products was limited and the remaining information was accurate and factual. None of the information was provided for the purpose of encouraging members of the public to ask a health professional to prescribe a specific prescription only medicine. While the content of the webpages was non-promotional and there was accordingly no requirement to restrict access by members of the public, Mitsubishi Tanabe Pharma Europe nevertheless advised users where certain pages were intended for health professionals. Mitsubishi Tanabe Pharma Europe therefore respectfully suggested that there was no credible basis for findings of breach of Clauses 26.1 and 28.1 in this case.

Mitsubishi Tanabe Pharma Europe had robust SOPs in place for Managing & Maintaining Company Corporate Website and Preparation, Review and Approval of Promotional Materials respectively, which staff were expected to follow and upon which they were trained. In circumstances where there was no evidence of any breach of Clauses 26.1 or 28.1, Mitsubishi Tanabe Pharma Europe believed there could be no basis for a finding that it had failed to maintain high standards contrary to Clause 9 or had, in any way, brought discredit upon the pharmaceutical industry contrary to Clause 2.

As a result of this review, Mitsubishi Tanabe Pharma Europe had identified that, in some discrete areas, its webpages adopted different approaches to the provision of information and to meeting Code requirements. Whilst this situation did not constitute a breach of the Code, it proposed to update the website in order to implement a single approach throughout.

Following a request for further information from the Panel, Mitsubishi Tanabe Pharma Europe provided a certificate in relation to updates to the product pages in question, dated July 2016.

PANEL RULING

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public.

The Panel noted Mitsubishi Tanabe Pharma Europe's submission that its website was intended to provide corporate information in relation to the company and its products at a European level; and that the webpages in question were not promotional and provided accurate, factual information for health professionals and the public in relation to Exembol and Tanatril.

The Panel disagreed with Mitsubishi Tanabe Pharma Europe's submission that the use of generic names was not promotional and the use of brand names was promotional only if such use was excessive. The Panel noted that it was an accepted principle under the Code that a product could be promoted without its name ever being mentioned.

The Panel noted Mitsubishi Tanabe Pharma Europe's submission that a factual statement about the

authorised indications for use was informative rather than promotional and that the provision of such information reflected PMCPA guidance, the EFPIA Code and MHRA's advice that 'other non-promotional reference information about the product that fairly reflects the current body of evidence about the product and its benefit risk profile' was permitted. The Panel noted that its role was to consider the matter in relation to the Code.

The Panel noted that Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public but such information must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted that the supplementary information to Clause 26.2 set out the detailed requirements for reference information which was intended to provide a comprehensive library resource for members of the public giving information relating to prescription only medicines which had marketing authorizations. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

The Panel noted the webpage in question contained statements related to argatroban (non-proprietary name for Exembol) and Tanatril.

In relation to argatroban, the webpage stated:

> 'Developed in Japan, argatroban was the first licensed synthetic direct thrombin inhibitor. Approved in twelve European countries, argatroban is marketed for anticoagulation in adult patients with Heparin-Induced Thrombocytopenia Type II (HIT Type II) who require parenteral antithrombotic therapy. Argatroban is given as a continuous intravenous infusion.'

The same page had the following statement in relation to Tanatril:

> 'Tanatril is used to treat high blood pressure (hypertension). Tanatril is one of a group of medicines called ACE (angiotensin-converting enzyme) inhibitors. Tanatril is available in 5mg, 10mg and 20mg tablet formulation.'

The Panel noted that there was a 'read more' button within the highlighted text box for each product and to the right of the page an adverse event reporting statement. At the bottom of each webpage within the products section, in small font, was the statement 'Please note: certain pages are intended for healthcare professionals only'. The Panel noted that the 'certain pages' were not identified and thus in the Panel's view the intended audience for each page was unclear. The section did not clearly separate pages aimed at health professionals from those containing information for the public. The Panel also noted Mitsubishi Tanabe's submission that the webpages were non-promotional and there was accordingly no requirement to restrict access.

The Panel noted that if the 'read more' button was selected for argatroban, the user was taken to a page which repeated the argatroban statement above and further stated: 'You can find specific information on our products in individual countries by choosing the relevant country from the menu below'. The four brand names for argatroban were listed with links to the relevant country/countries for each. If the user selected the UK link for Exembol, a pop-up box appeared stating that the following pages were intended for viewing by UK health professionals only. If the user selected 'continue' the user was taken to a page that contained: links to the Exembol summary of product characteristics and patient information leaflet; contact details for Mitsubishi Tanabe Pharma Europe; an adverse event reporting statement; and a link to an Exembol website. If the user had selected 'cancel' in response to the pop-up box, he/she would stay on the current page.

The Panel further noted that when the user selected the Tanatril 'read more' button from the main product webpage, he/she would be taken to a page titled 'How to order Tanatril' which gave information regarding ordering the product from a named wholesaler, including the wholesaler's contact details and the PIP codes for each tablet strength. The same page featured: links to the Tanatril summary of product characteristics and patient information leaflet; Mitsubishi Tanabe Pharma Europe's contact details; and an adverse event reporting statement. The bottom of the page stated: 'Please note: certain pages are intended for healthcare professionals only'. The Panel noted its comments on this statement above. The content of this page was such that it appeared to be aimed at health professionals.

The Panel queried whether the products homepage and the pages linked via the read more buttons could be considered reference information as set out in the supplementary information to Clause 26.2 given the lack of information provided for members of the public. There appeared to be nowhere for members of the public to go to access further information on argatroban; the SPC and PIL could only be accessed after the reader confirmed that he/she was a health professional. The page for Tanatril, which included the SPC and PIL, related to how to order the product and appeared therefore to be aimed at health professionals.

The Panel considered that the statement '… argatroban was the first licensed synthetic direct thrombin inhibitor. Approved in twelve European countries …' which appeared, *inter alia*, on the main product webpage constituted a product claim. The Panel noted that whilst the homepage of the products section in question did not include the brand name for argatroban it did include its non-proprietary name and indication. If a member of the public clicked on the read more button for argatroban they were provided with the brand name of the product in individual countries including Exembol in the UK. The initial webpage also included the brand name and indication for Tanatril.

The Panel also noted that members of the public looking for information on one particular

medicine would automatically be faced with the non-proprietary or brand name and indication of Mitsubishi Tanabe Pharma Europe's other medicine.

Noting its comments above the Panel considered that the webpage advertised prescription only medicines to the public and a breach of Clause 26.1 was ruled.

The Panel noted that Clause 28.1 required that promotional material about prescription only medicines directed to a UK audience which was provided on the internet must comply with all relevant requirements of the Code. The supplementary information 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 ruling above. In the Panel's view the webpage at issue promoted prescription only medicines and therefore access should have been restricted to health professionals and other relevant decision makers because information had not been provided for the public as required by the relevant supplementary information. The Panel noted that access to the webpage had not been so restricted and therefore a breach of Clause 28.1 was ruled.

The Panel noted its comments and rulings above and considered that Mitsubishi Tanabe Pharma Europe had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The Panel did not consider that the circumstances in this particular case warranted a ruling of a breach of Clause 2 and no breach was ruled accordingly.

Complaint received **29 October 2018**

Case completed **20 February 2019**