CASE AUTH/3217/6/19 ***NO BREACH OF THE CODE***

HEALTH PROFESSIONAL v OTSUKA

Jinarc training website

An individual, who described him/herself as a concerned health professional, alleged that the Jinarc (tolvaptan) training website was promotional but did not meet the Code requirements for promotional material. Otsuka Pharmaceuticals (UK) Limited marketed Jinarc which was indicated in certain patients with chronic kidney disease.

The complainant noted that the website provided training on the use of Jinarc for UK health professionals and mentioned the Medicines and Healthcare products Regulatory Agency (MHRA) implying that the MHRA had endorsed the training and supported the promotion of Jinarc. The website contained links to order the medicine. The prescribing information was not accessed via a clear or prominent, direct single link; users were taken to a page where the summary of product characteristics (SPC) must be chosen which did not contain all the requirements of prescribing information such as price.

Otsuka submitted that as part of its marketing authorization, Jinarc had a Risk Management Plan (RMP) as well as Additional Risk Minimisation Measures to ensure that it was used as safely as possible. The additional measures included an educational programme for all health professionals and patient/carers who would be prescribing and/or using the medicine.

The detailed response from Otsuka is given below.

The Panel noted that the supplementary information to the Code stated that RMPs and material approved by the MHRA as part of the company's pharmacovigilance obligations was exempt from the definition of promotion and could be included on a company website without being considered to be promotion of the medicine to which it referred.

The Panel noted that the complaint concerned the alleged link to and content of prescribing information and reference to the MHRA on what the complainant considered was a promotional website. Otsuka stated that the complainant had mistakenly referred to a link to prescribing information which was, in fact, a link to SPCs for Jinarc. The first thing the Panel had to decide was whether the site was promotional, bearing in mind the relevant supplementary information.

It appeared that the first page of the website asked readers to confirm whether they were health professionals: it appeared that clicking 'Yes' took the reader to the training portal. If readers selected 'No' they were taken to a page which stated that the training portal website was for health professionals only and provided links to the otsuka-europe.com/uk website for those who wanted to know more about Otsuka UK or to the Electronic Medicines Compendium for those who wanted to know more about Jinarc. There was a link at the bottom of the page to the Jinarc SPC.

The first page of the training portal read 'The [MHRA] requires Otsuka UK to ensure healthcare professionals who prescribe Jinarc have access to educational materials that provided important information regarding the safe use of the drug and register their details once they had read and understood the educational materials allowing them to become certified prescribers eligible to prescribe Jinarc'. Step 1 appeared to comprise a set of slides which provided safety information on the risks of Jinarc therapy, monitoring requirements, dosing and administration information and details of the mechanism to report adverse events. The Panel did not review these slides in detail. Step 2 required completion of an enrolment form which enabled the health professional to become a certified prescriber. The enrolment form stated that as agreed with the MHRA a register of prescribers who had completed the training on the safety aspects of Jinarc was being maintained to ensure that only those with relevant clinical expertise and a full understanding of the risks of Jinarc therapy could access the medicine. Health professionals certified that they had either reviewed the slides or read the educational guide. The Panel did not review the educational guide but noted that a link to an educational guide appeared beneath the heading 'Additional Resources' to the right of the slide presentation, followed by, *inter alia*, other safety materials, the Jinarc SPC and the Patient Alert Card. The Panel noted that the additional resources included, towards the end of the list, a link to Jinarc prescribing and ordering information and a link to a 'Jinarc request form – to be sent with all Jinarc orders'. The Panel considered that given the risk minimisation requirements it was not unreasonable to provide a copy of the Jinarc request form so that newly registered prescribers or those about to do the training could see the detailed information required. On the information before the Panel there was no ability to order from the link, nor was the request form specifically highlighted in in the list of additional resources.

Noting its comments above the Panel did not consider that the site was promotional as alleged and therefore it did not require prescribing information. No breach of the Code was ruled. The Code prohibited references to, *inter alia*, the MHRA on promotional material and thus given the Panel's comments and ruling above that prohibition did not apply to the material in question. No breach of the Code was ruled.

A contactable individual who described him/herself as a concerned health professional complained about the Jinarc (tolvaptan) training website. Otsuka Pharmaceuticals (UK) Limited marketed Jinarc which was indicated in certain patients with chronic kidney disease.

The complainant provided screenshots of the Welcome page to the training portal.

COMPLAINT

The complainant alleged that the website was promotional but did not meet the requirements for promotional material as set out in the Code.

The complainant noted that the website www.jinarctraining.co.uk/uk/introduction provided training on the use of Jinarc for UK health professionals and mentioned the Medicines and Healthcare products Regulatory Agency (MHRA) implying that the MHRA had endorsed the training and supported the promotion of Jinarc. The website contained links to order the medicine. A link to the prescribing information was not clear or prominent (as users must scroll down to see it) and it was not a direct single link as it took the user to a page where the

summary of product characteristics (SPC) must be chosen, and did not contain all the requirements of prescribing information such as price.

When writing to Otsuka, the Authority asked it to consider the requirements of Clauses 4.1 and 9.5 of the Code.

RESPONSE

Otsuka explained that as part of its marketing authorization, Jinarc had a Risk Management Plan (RMP) as well as Additional Risk Minimisation Measures (ARMMs) to ensure that it was used as safely as possible. The additional measures included an educational programme for all health professionals and patient/carers who would be prescribing and/or using the medicine.

Otsuka submitted that it had worked with the MHRA to create the educational programme (ARMMs) at issue. As agreed with the MHRA, any health professional who wished to prescribe Jinarc must complete the training and register on the Jinarc prescriber database. The MHRA required this database to be maintained to ensure that only health professionals with expertise in managing autosomal dominant polycystic kidney disease (ADPKD) and a full understanding of the risks of Jinarc therapy (including hepatic toxicity and monitoring requirement) could access the medicine.

The website had been created by Otsuka to allow health professionals to complete the educational programme online (ARMMs) and to enrol on the Jinarc prescriber database to be able to prescribe Jinarc. Otsuka noted the details in the supplementary information to Clause 1.2, which stated that risk minimisation materials approved by the MHRA as part of risk management plans were not considered promotional. Given that the website provided obligatory safety training with risk minimisation material for potential prescribers, Otsuka considered that it was non-promotional.

Otsuka explained that those wishing to access the website must confirm that they were health professionals. The homepage then made the purpose of the website very clear in that it was only for UK health professionals that needed to be trained on the educational materials in order to prescribe Jinarc and that the objective of the training was to ensure that Jinarc was used appropriately. For this purpose, the website provided the MHRA-approved ARMMs, a link to the various Jinarc SPCs located on the Electronic Medicines Compendium (eMC), Jinarc ordering information and the enrolment page. Once the training material had been reviewed, the reader was invited to enrol onto the Jinarc prescriber database.

Otsuka noted the complainant's concern that the website was promotional and should therefore meet the Code requirements for promotional materials, in particular, a prominent, single click link to prescribing information. Additionally, the complainant mistakenly referred to a link to prescribing information, which was in fact a link to the various SPCs for Jinarc. Given that the website was non-promotional, none of the requirements for promotional materials would apply, including the provision of a prominent, direct, single click link to the prescribing information. Given the above, Otsuka denied a breach of Clause 4.1.

In relation to references to the MHRA on the website, Otsuka reiterated that the website was not promotional. In that regard, Otsuka considered that as the Code only restricted references to the MHRA in promotional material the requirements of Clause 9.5 did not apply. Otsuka considered it important to refer to the MHRA, as the training programme in question had been

mandated by the Agency and it was important to tell readers that so that they understood the objective of the training materials. Otsuka denied a breach of Clause 9.5.

PANEL RULING

The Panel noted that the supplementary information to Clause 1.2, Risk Minimisation Plans and Material, stated that as part of the marketing authorization process companies could be required to have RMPs and material approved by the MHRA as part of the company's pharmacovigilance obligations. Such approved documentation was exempt from the definition of promotion and could be included on a company website without being considered to be promotion of the medicine to which it referred.

The Panel noted that the complaint concerned the alleged link to and content of prescribing information and reference to the MHRA on what the complainant considered was a promotional website. Otsuka stated that the complainant had mistakenly referred to a link to prescribing information which was, in fact, a link to SPCs for Jinarc. The first thing the Panel had to decide was whether the site was promotional, bearing in mind the relevant supplementary information.

It appeared that the first page of the website asked readers to confirm whether they were health professionals: it appeared that clicking 'Yes' took the reader to the training portal. If readers selected 'No' they were taken to a page which stated that the training portal website was for health professionals only and provided links to the otsuka-europe.com/uk website for those who wanted to know more about Otsuka UK or to the eMC for those who wanted to know more about Jinarc. There was a link at the bottom of the page to the Jinarc SPC.

The first page of the training portal read 'The Medicines and Healthcare Products Regulatory Agency (MHRA) requires Otsuka UK to ensure healthcare professionals who prescribe Jinarc have access to educational materials that provided important information regarding the safe use of the drug and register their details once they had read and understood the educational materials allowing them to become certified prescribers eligible to prescribe Jinarc'. Step 1 comprised training materials which appeared to consist of a set of slides which provided safety information on the risks of Jinarc therapy, monitoring requirements, dosing and administration information and details of the mechanism to report adverse events. The Panel did not review these slides in detail. Step 2 required completion of an enrolment form which enabled the health professional to become a certified prescriber. The enrolment form stated that as agreed with the MHRA a register of prescribers who had completed the training on the safety aspects of Jinarc was being maintained to ensure that only those health professionals with expertise in managing ADPKD and a full understanding of the risks of Jinarc therapy including hepatic toxicity and monitoring requirements could have access to Jinarc. Health professionals certified that they had either reviewed the slides or read the educational guide. The Panel did not review the educational guide but noted that a link to an educational guide appeared beneath the heading 'Additional Resources' to the right of the slide presentation, followed by, *inter alia*, other safety materials, the Jinarc SPC and the Patient Alert Card. The Panel noted that the additional resources included, towards the end of the list, a link to Jinarc prescribing and ordering information and a link from which one could view or download the order form. This form was titled 'Jinarc request form – to be sent with all Jinarc orders'. The Panel considered that given the risk minimisation requirements it was not unreasonable to provide a copy of the Jinarc request form so that newly registered prescribers or those about to do the training could see the detailed information required. On the information before the Panel there was no ability to order

from the link, nor was the request form specifically highlighted in in the list of additional resources.

On completion of the enrolment form it appeared that a pop-up box appeared on the training portal thanking the health professional for their registration.

Noting its comments above the Panel did not consider that the site was promotional as alleged and therefore it did not require prescribing information. No breach of Clause 4.1 was ruled. Clause 9.5 prohibited references to, *inter alia*, the MHRA on promotional material and thus given the Panel's comments and ruling above did not apply to the material in question. No breach of Clause 9.5 was ruled.

Complaint received **19 June 2019**

Case completed **9 January 2020**