# GENERAL PRACTITIONER v OTSUKA

## Jinarc patient materials

**A general practitioner alleged that Jinarc (tolvaptan) patient support materials, issued by Otsuka, portrayed the medicine as a treatment for autosomal dominant polycystic kidney disease (ADPKD) which constituted advertising to the public and ran the risk of raising patients' hopes and expectations. Jinarc was indicated to slow the progression of cyst development and renal insufficiency of ADPKD in adults with chronic kidney disease (CKD) stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.**

**The detailed response from Otsuka is given below.**

**The Panel noted the complainant had not provided any materials or explained why, in his/her view, the patient literature described Jinarc as a treatment for ADPKD, advertised it to the public or risked raising patients' hopes and expectations. The complainant had not responded to a request for more information. The patient materials provided by Otsuka were a patient alert card, a patient/carer brochure, a user guide for a patient support line and a PDF and link to a disease awareness website for the public and health professionals. The Panel noted Otsuka's submission that the alert card and brochure were part of the risk management plan materials as agreed with the regulatory authorities and would be given by a health professional to patients prescribed Jinarc.**

**In the Panel's view the complaint included an allegation that the materials in question stated or implied that ADPKD could be cured. The patient alert card was clearly labelled as such and contained brief safety advice and referred in particular to adverse effects on the liver and to the severe dehydration that could occur with Jinarc. The brochure was entitled 'Jinarc (tolvaptan) Patient/carer education brochure'. The section which outlined the purpose of the brochure made the intended audience clear: 'for people with [ADPKD] who are being treated with Jinarc'. The brochure explained what Jinarc was, what it was used for etc and in answer to the question 'What is Jinarc' it was stated, *inter alia*, that Jinarc 'can slow down the growth of kidney cysts'. It was not stated or implied that Jinarc would stop the cysts from growing or otherwise cure the condition. The user guide was headed 'Otsuka Patient Support Service'; it was stated that the information therein was to help patients or their family members understand the service they would receive, how the service operated and how Otsuka would work with the hospital to help the patient. The open access disease awareness website had sections clearly marked for either health professionals or patients. According to the home page of the patient section, the website offered information, advice and support for ADPKD patients and their families or friends. One web page clearly stated 'There is no cure for ADPKD, but support from my family and doctor makes life a lot easier'. In a section of the website about managing chronic conditions it was stated that there was currently no cure for ADPKD. The patient section of the website did not refer to Jinarc.**

**The Panel noted that the patient alert card and brochure were part of the product's risk management plan and provided to patients prescribed Jinarc by health professionals. The Panel considered that these items were factual and discussed the product in a non-promotional context. The Panel noted its comments on the user guide and patient section of the disease awareness website above. The Panel did not consider that any of the patient materials promoted Jinarc to the public as alleged. No breach of the Code was ruled. The Panel could find no evidence that Otsuka had described Jinarc as a cure for ADPKD or implied that it was such. In that regard the Panel did not consider that the material raised unfounded hopes of successful treatment as alleged. No breach of the Code was ruled.**

**The Panel noted its rulings above and considered that Otsuka had not failed to maintain high standards and thus ruled no breaches of the Code including Clause 2.**

A general practitioner, complained about Jinarc (tolvaptan) patient support materials issued by Otsuka Pharmaceuticals (UK) Ltd. Jinarc was indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.

**COMPLAINT**

The complainant alleged that Jinarc was being portrayed as a treatment for ADPKD in patient literature which constituted advertising to the public and ran the risk of raising patients' hopes and expectations.

The case preparation manager asked the complainant to provide more information about the materials in question but did not receive a response.

When writing to Otsuka, the Authority asked it to consider the requirements of Clauses 2, 9.1, 26.1 and 26.2 of the 2016 Code.

**RESPONSE**

Otsuka noted that the complainant had not referred to any specific materials or activities and therefore it was unable to properly assess the merits of the complaint or respond meaningfully. Otsuka reserved full comment until such time as further information was provided by the complainant as requested by the Authority.

Otsuka stated that an enquiry into its activities relating to Jinarc did not reveal any activities or materials that could be considered in breach of Clauses 26.1, 26.2, 9.1, 2 or any other clause.

In response to a request for further information from the case preparation manager, Otsuka provided copies of its patient materials relating to Jinarc as follows:

- patient alert card (ref OPUK/0315/JIN/1091d) and patient brochure (ref OPUK/0315/JIN/1091c) distributed by health professionals to Jinarc patients as part of the risk management plan materials agreed with the regulatory authorities

- user guide for a patient support line (ref OPUK/0116/JIN/1032) distributed by health professionals to Jinarc patients to provide an overview of the patient support line provided by a third party on behalf of Otsuka

- disease awareness website (ref OPUK/0115/GEN/1010) developed for health professionals and the public. A link to the website and pdf of the content of the public area were provided.

**PANEL RULING**

The Panel noted that Clause 26.1 prohibited the advertising of prescription only medicines to the public. Clause 26.2 permitted information to be supplied directly or indirectly to the public but such information had to be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or mislead with respect to the safety of the product and statements must not be made for the purpose of encouraging members of the public to ask their doctor to prescribe a specific prescription only medicine. The Panel noted that companies could provide health professionals with material concerning a medicine with a view to its provision to patients to whom the medicine had already been prescribed as long as such material was factual and non-promotional and clearly stated the intended audience.

The Panel noted that a complainant had the burden of proving their complaint on the balance of probabilities; all complaints were judged on the evidence provided by the parties. The complainant in this case had not provided any materials or explained why, in his/her view, the Jinarc patient literature described the medicine as a treatment for ADPKD, advertised it to the public or risked raising patients' hopes and expectations. The complainant had not responded to the case preparation manager's request for more information. The patient materials provided by Otsuka were a patient alert card, a patient/carer brochure, a user guide for a patient support line and a PDF and link to a disease awareness website for the public and health professionals. The Panel noted Otsuka's submission that the alert card and brochure were part of the risk management plan materials agreed with the regulatory authorities and would be given by a health professional to patients prescribed Jinarc.

In the Panel's view the complaint included an allegation that the materials in question stated or implied that ADPKD could be cured.

The patient alert card was clearly labelled as such and contained brief safety advice and referred in particular to adverse effects on the liver and to the severe dehydration that could occur with Jinarc. The brochure was entitled 'Jinarc (tolvaptan) Patient/carer education brochure'. The section which outlined the purpose of the brochure made the intended audience clear: 'for people with [ADPKD] who are being treated with Jinarc'. The brochure explained what Jinarc was, what it was used for and how it should be used; it provided safety information and set out potential side-effects and what to do if they occurred. In answer to the question 'What is Jinarc' it was stated, *inter alia*, that Jinarc 'can slow down the growth of kidney cysts'. It was not stated or implied that Jinarc would stop the cysts from growing or otherwise cure the condition. The user guide was headed 'Otsuka Patient Support Service'; it was stated that the information therein was to help patients or their family members understand the service they would receive, how the service operated and how Otsuka would work with the hospital to help the patient. The website was an open access disease awareness resource with sections clearly marked for either health professionals or patients. According to the home page of the patient section, the website offered information, advice and support for ADPKD patients and their families or friends. There were sections entitled 'About ADPKD', 'ADPKD and you' and 'Managing ADPKD'. One web page clearly stated 'There is no cure for ADPKD, but support from my family and doctor makes life a lot easier'. In a section of the website about managing chronic conditions it was stated that there was currently no cure for ADPKD and that treatment focussed on managing symptoms and maintaining a healthy lifestyle. The patient section of the website did not refer to Jinarc.

The Panel noted that the patient alert card and brochure were part of the product's risk management plan and provided to patients prescribed Jinarc by health professionals. The Panel considered that these items were factual and discussed the product in a non-promotional context. The Panel noted its comments on the user guide and patient section of the disease awareness website above. The Panel did not consider that any of the patient materials promoted Jinarc to the public as alleged. No breach of Clause 26.1 was ruled. The Panel could find no evidence that Otsuka had described Jinarc as a cure for ADPKD or implied that it was such. In that regard the Panel did not consider that the material before it raised unfounded hopes of successful treatment as alleged. No breach of Clause 26.2 was ruled.

The Panel noted its rulings above and considered that Otsuka had not failed to maintain high standards and thus ruled no breach of Clause 9.1 and consequently ruled no breach of Clause 2.

**Complaint received** **3 February 2016**

**Case completed** **23 March 2016**