CASE AUTH/1942/1/07

MEMBER OF THE PUBLIC v JANSSEN-CILAG

Disease awareness campaign on schizophrenia.

A member of the public complained about a schizophrenia advertisement placed by Janssen-Cilag in the Big Issue magazine. The advertisement told readers, *inter alia*, that 'Schizophrenia can be very difficult to live with. But the good news is, with modern treatments there's now a real chance of recovery. So it's very important to discuss with your doctor the choices available'.

Janssen-Cilag produced Risperdal (risperidone) and Risperdal Consta (long acting risperidone for intramuscular injection), an atypical antipsychotic.

The complainant alleged that the claim 'the good news is, with modern treatments there's now a real chance of recovery' was misleading and untrue. There was an implied association between visiting the doctor to discuss choices and the modern treatments available from Janssen-Cilag.

The advertisement led to a website (oneinonehundred.co.uk) sponsored by Janssen-Cilag which the complainant alleged promoted a prescription-only medicine as 'long acting injections' was underlined twice, and 'atypical antipsychotics' was underlined three times. This underlining re-reinforced the link between long-lasting injections and atypical antipsychotics. The complainant noted that Risperdal Consta was the only atypical antipsychotic available as a long-acting injection.

The complainant alleged that the statement on the website that atypical antipsychotics were superior to the old-fashioned ones, was not true. Readers were encouraged to 'ask your doctor if any of the newer treatments for schizophrenia would be suitable for you'. No antipsychotics were benign: their adverse effects were more severe than the condition for which they were prescribed. This applied as much to atypical as to the old-fashioned antipsychotics.

The complainant alleged that the claim 'schizophrenia is a disease of the mind', was not proven. The website also stated 'abnormalities in the transfer and processing of information within the brain' were related to schizophrenia; this was not true.

The complainant alleged that the claim that medicines would reduce the risk of further illness was also untrue, since Janssen-Cilag had stated the importance of not stopping the medicine once started on it.

The complainant noted the Brainchip link on the website, a cartoon of a man with a chip in the middle of his brain, was a link to a cartoon serial about schizophrenia. Given the very recent approval of vagus nerve stimulation (VNS) in the US for depression, and the European approval of VNS in epilepsy, depression and bi-polar disorder, this link within the site was deeply sinister; it was an attempt to condition patients with schizophrenia to the possibilities of 'pace-makers for the mind', ie neuroleptics delivered direct to the brain by surgical implant, in the not too distant future.

The Panel noted that the advertisement had been published in the lay press. Schizophrenia was a chronic condition. The Panel considered that some lay people, particularly those who knew very little about schizophrenia, might assume that recovery meant elimination of the illness, particularly as the advertisement referred to a 'real chance' of recovery in the context of 'modern treatments' and described this as 'good news'. The advertisement was misleading in this regard. A breach of the Code was ruled.

The Panel noted that whilst the advertisement referred to modern treatments there was no direct or implied reference to a specific medicine. There were several 'modern' treatment choices. The Panel did not consider that the statement at issue promoted a specific prescription only medicine to the public or would encourage patients to ask their health professional to prescribe a specific prescription only medicine. No breach of the Code was ruled.

The Panel noted that throughout the website certain terms such as 'psychiatrist', 'diagnosis' and 'mental health team' were underlined. These links led to a glossary where an explanation was given. In a section headed 'Newer medications' the phrase 'atypical antipsychotics' was underlined in a sentence which mentioned their mechanism of action and effect on a broader range of symptoms than older medications. The phrase 'long-acting injections' was underlined in the final sentence of the same section which listed the various presentations available. The reference to short-acting injections was not underlined. 'Long-acting injections' was also underlined in the preceding paragraph which dealt with older medications. The Panel noted that Janssen-Cilag's product, Risperdal Consta was the only atypical available as a long-acting injection. Given the format of the site wherein various terms were underlined throughout, the Panel did not consider that the underlining of the phrases at issue was inappropriate. It did not give them undue emphasis such that they either promoted a prescription only medicine to the general public or encouraged members of the public to ask for a specific medicine, as alleged. No breach of the Code was ruled.

The Panel noted that one of the 'Ten Tips to Help you Discuss Treatment with your Doctor' was 'Ask your doctor if any of the newer treatments for schizophrenia would be suitable for you especially if you have had distressing side effects with other

treatments'. The side effect section which appeared earlier in the website explained that the risk of certain side effects associated with newer medicines was much lower but not totally absent. The Panel did not consider the bullet point at issue inferred that atypical antipsychotics were benign and thus superior to older medication as alleged. The website made it clear that side effects were associated with the newer medicines. No breach of the Code was ruled.

The Panel did not consider that the description of schizophrenia as a 'disease of the mind' and references to abnormalities in the transfer and processing of information within the brain were unacceptable as alleged. The section 'Possible causes of Schizophrenia' explained that for the majority of people treatment relied on medicines which modified the effects of the neurotransmitters in the brain. It was also clearly stated that there was no known single cause of schizophrenia. The Panel did not consider that the phrase a 'disease of the mind' was unacceptable as alleged. No breach of the Code was ruled.

The section 'The effect of discontinuing treatment' included the claim 'Antipsychotic drugs reduce the risk of future illness in patients who have recovered from an acute episode'. The claim did not refer to 'further illness' as stated by the complainant. The Panel did not consider that the claim as published on the website was untrue as alleged. The effect of discontinuation of treatment and relapse rates were discussed. It was made clear that even with continued treatment patients might relapse. No breach of the Code was ruled.

The Panel noted that the Brainchip link on the website led to a self-help book for people experiencing psychosis. The booklet was produced with support from Janssen-Cilag. The booklet discussed treatment but did not mention a specific medicine or class of products. The Panel did not consider that it was an attempt to condition schizophrenic patients to the possibility of neuroleptics being delivered straight to the brain by surgical implant as alleged. The computer chip in the cartoon was depicted as a negative aspect of the patient's delusion rather than as part of the solution. No breaches of the Code were ruled.

In considering the campaign as a whole the Panel noted that the material was biased towards atypical antipsychotics ie the newer more modern treatments for schizophrenia. There were however, several atypical agents available. Nonetheless the Panel had some concerns about the bullet point 'Ask your doctor if any of the newer treatments for schizophrenia would be suitable for you especially if you have had distressing side effects with other treatments'. Whilst the atypical antipsychotics might be a rational treatment choice for newly diagnosed patients or those unable to tolerate the older agents, some patients would be satisfactorily controlled on their current treatment such that it would not be prudent to switch them to atypicals and risk a loss of control in the process. The bullet point seemed to open up that possibility to the patient although the final decision would always lie with the prescriber. Although noting its concerns the Panel, however, did not consider that either the advertisement or the website had failed to maintain a high standard; no breaches of the Code were ruled.

A member of the public complained to the Medicines and Healthcare products Regulatory Agency (MHRA) about an advertisement issued by Janssen-Cilag Ltd and sent a copy of her letter to the Authority. The advertisement (RISP/R/06-0108), published in the Christmas 2006 edition of the Big Issue, featured the statement 'Schizophrenia strikes one in one hundred ... and affects many more'. Beneath an image of a painting the advertisement continued '... but the picture's looking brighter. Schizophrenia can be very difficult to live with. But the good news is, with modern treatments there's now a real chance of recovery. So it's very important to discuss with your doctor the choices available'.

Janssen-Cilag produced Risperdal (risperidone) and Risperdal Consta (long acting risperidone for intramuscular injection), an atypical antipsychotic.

COMPLAINT

The complainant alleged that the claim 'the good news is, with modern treatments there's now a real chance of recovery' was misleading. It was simply not true that modern treatments ie atypical antipsychotics such as Risperdal and Risperdal Consta, led to recovery. Readers were exhorted to discuss with their doctor the choices available. There was an implied association between visiting the doctor to discuss choices and the modern treatments available, which would of course be prescribed treatments supplied by Janssen-Cilag.

The advertisement led to a website (oneinonehundred.co.uk) sponsored by Janssen-Cilag which the complainant alleged promoted a prescription-only medicine by underlining 'long acting injections' twice, and 'atypical antipsychotics' three times. Clicking on these underlined words revealed an explanation of the term. No other terms were so underlined. This underlining re-reinforced the link between long-lasting injections and atypical antipsychotics. The complainant noted that Risperdal Consta was the only atypical antipsychotic available as a long-acting injection.

The complainant alleged that other false statements on the website were that atypical antipsychotics were superior to the old-fashioned ones. This was not true. Readers were encouraged to 'ask your doctor if any of the newer treatments for schizophrenia would be suitable for you'. No antipscychotics were benign: their adverse effects were more severe than the condition for which they were prescribed. This applied as much to atypical as to the old-fashioned antipsychotics.

The complainant alleged that the claim 'schizophrenia is a disease of the mind', was not proven. The website also stated 'abnormalities in the transfer and processing of information within the brain' were related to schizophrenia; this was not true.

The complainant alleged that the claim that medicines

would reduce the risk of further illness was a lie, since Janssen-Cilag had also stated the importance of not stopping the medicine once started on it. The effect of rapid withdrawal from antipsychotics was becoming increasingly publicised. It was precisely these effects which were cleverly utilised in the original trials prior to the licensing of risperidone.

The complainant noted that the Brainchip link on website, a cartoon of a man with a chip in the middle of his brain, was a link to a cartoon serial about schizophrenia which could be downloaded. Given the very recent Food and Drug Administration (FDA) approval of vagus nerve stimulation (VNS) for depression, as of July 2005, and the European approval of VNS for use in epilepsy, depression and bi-polar disorder, this link was deeply sinister. This was a blatant attempt to condition patients with schizophrenia to the possibilities of 'pace-makers for the mind', ie neuroleptics delivered direct to the brain by surgical implant in the not too distant future.

When writing to Janssen-Cilag the Authority asked it to respond in relation to Clauses 2, 9.1, 20.1 and 20.2.

RESPONSE

Janssen-Cilag submitted that its 1 in 100 campaign was a public health awareness campaign which was consistent with the provisions of Clause 20.2. The supplementary information to Clause 20.2 stated that 'A company may conduct a disease awareness or public heath campaign provided that that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine'. The wording within the advertisement 'So it's very important to discuss with your doctor the choices available' was consistent with these principles.

Although Janssen-Cilag supported the 1 in 100 campaign it was not developed in isolation. The campaign had received considerable support from numerous patient advocacy groups and was launched at the House of Commons with a keynote address given by an MP and attended by a health minister. In addition, the campaign materials were included as an example of best practice, by the ABPI Informed Patient Initiative Taskforce in the evidence submitted to the Informed Patient Work Stream of the European Union high level Pharmaceutical Forum in May/June 2006.

Janssen-Cilag noted that to date over 20,000 brochures (containing the information on the website) had been distributed; the website itself had received over 13,500 hits since July 2006 (more than 2000 per month) and of 234 feedback cards only 6 had negative comments. This showed how useful users and carers had found the campaign. Janssen-Cilag submitted that based on this type of feedback, as well as input it received during the development of the initiative, it was providing a balanced and factual health awareness campaign for the public.

Janssen-Cilag stated that the initiative was developed in conjunction with both service users and carer groups as well as service providers and various MPs. As such it had incorporated input from diverse and influential groups of people. It aimed to give patients, their families and friends information about schizophrenia and the range of treatments available. Discussion of treatments was not limited to pharmacological interventions, but also discussed psychosocial treatments. With regard to pharmacological interventions, typical and atypical antipsychotics were referred to in a fair and balanced way with advantages and disadvantages for each being clearly stated. The initiative promoted informed choice, and this aspect also featured prominently within the National Institute for Health and Clinical Excellence (NICE) guidance. This was in keeping with its educational objective, and the campaign encouraged patients to discuss the choices available with their doctor. The campaign did not encourage the use of, nor encourage patients to ask their doctor for a specific medicine.

Janssen-Cilag submitted that as well as helping patients to make informed choices (in conjunction with their doctor) the initiative also encouraged patients to discuss treatment options with their care workers and helped to decrease the stigma associated with schizophrenia.

Janssen-Cilag noted that the complainant had alleged that the claim 'the good news is, with modern treatments there's now a real chance of recovery' was misleading and that it was not true that modern treatments ie atypical antipsychotics such as risperidone led to recovery, Janssen-Cilag submitted that within the context of psychiatry, and specifically schizophrenia, recovery did not imply a cure. Schizophrenia was a life-long chronic mental illness, however with the use of modern treatments (the use of the word 'modern' did not exclusively mean atypical antipsychotics, rather current treatment options, pharmacological or otherwise) there might be restoration to a former or better condition. Certainly, various government initiatives regarding schizophrenia were aimed at recovery, with the focus being on recovery of social function for example, as opposed to elimination of the illness altogether. Indeed, the concept of recovery was accepted as being applicable to people with psychosis and was endorsed by the Department of Health (DoH) in a positive way (The Journey to Recovery – the government's vision for mental health care. DoH, November 2001). There were numerous definitions of recovery that did not equate with cure and were focussed for example, on patients returning to work, to independent living or towards having more meaningful relationships (Liberman *et al* 2002).

Three views of recovery from independent sources were:

1 'Recovery can be defined as a personal process of tackling the adverse impacts of experiencing mental health problems, despite their continuing or long-term presence. It involves personal development and change, including acceptance that there are problems to face; a sense of involvement and control over one's life; and the cultivation of hope and using support from others.' (Rethink website)

2 'The vast majority [of patients] have real prospects of recovery - if they were supported by appropriate services, driven by the right values and attitudes.' (DoH. The journey to recovery: the government's vision for mental health care)

3 'The 1 in 100 campaign fits closely to current government policies as reflected in the National Service Framework and NICE guidelines on schizophrenia. Both these sources show that there is now a very strong evidence base that care programmes and new drug therapies can secure recovery for many patients.' (Letter from a Professor at Imperial College London to Janssen-Cilag, January 2007)

Janssen-Cilag submitted therefore that the article was not misleading within the context of schizophrenia and was consistent with the aims and objectives of modern treatment regimens.

Janssen-Cilag noted the complainant's allegation there was an implied association between visiting the doctor to discuss choices and the modern treatments available. Janssen-Cilag submitted that the statement ' … discuss with your doctor the choices available' encouraged patients to go to their doctors and discuss the treatment choices which might include psychosocial as well as pharmacological treatment options. This statement was not inconsistent with the requirements of Clause 20.2 that allowed disease awareness campaigns to be undertaken provided that they encouraged members of the public to seek treatment for their symptoms, but did not promote the use of a specific medicine. Indeed, there was no mention of any medicine anywhere within the advertisement, which encouraged discussion between the patient and their doctor regarding treatment options.

Janssen-Cilag submitted that patient choice featured prominently on the government's agenda for management of mental health issues (National Service Framework for Mental Health: Modern Standards & Service Models. National Health Service / DoH September 1999) and certainly NICE guidance encouraged patient choice and full discussion of the treatment options available. NICE even recommended advanced directives so that the patient's wishes might be taken into account if they were unable to discuss options with their doctor eg because of an acute psychotic episode. Furthermore, Rethink issued a statement in December 2006 in support of patient choice (Pinfold 2006).

Janssen-Cilag submitted that there was no mention of a Janssen-Cilag product (or any other product) within the article and it denied that it had encouraged members of the public to ask their doctor for a specific medicine, or that it had promoted a prescription only medicine to the public.

Janssen-Cilag noted that the complainant had alleged that the website promoted a prescription only medicine underlining certain phrases.

Janssen-Cilag submitted that the website provided fair and balanced information about schizophrenia, its possible causes, symptoms, and both pharmacological and psychosocial treatments. The website stated in a succinct and understandable manner the positive aspects as well as potential side effects of the typical and atypical antipsychotics. All of the above would help the patient to have a more informed discussion with their doctor about the treatment choices available.

Janssen-Cilag explained that in response to a request from carers and users, underlined terms on the website provided links to a glossary where an explanation was given of the word in question. The terms were certainly not all treatment options eg mental health teams was underlined as was the word psychiatrist. To infer that this was a method of linking long-lasting injections and atypical antipsychotics was without grounds in view of the variety of other words also underlined.

Janssen-Cilag noted also that the complainant referred to the fact that Risperdal Consta was the only atypical antipsychotic available as a long-acting injection. Within the context of the broad range of information provided within the web-site there was no undue emphasis upon this particular treatment option. Indeed whether a patient was willing to accept a medicine by injection was part of any discussion about treatment options and acceptability that a doctor would have with their patients. There were also other medicines which could be given by a long-acting injection.

Janssen-Cilag therefore submitted that it had not promoted a prescription only medicine to the general public, and specifically that it had not promoted the use of Risperdal Consta to members of the general public.

Janssen-Cilag rejected the allegation that it had promoted atypical antipsychotics as superior to the old-fashioned ones. Both types of antipsychotics were important treatment options and selection depended on the individual patient and desired therapeutic outcome. Janssen-Cilag presented the potential advantages and disadvantages of each in a considered and balanced way. Other independent bodies such as NICE, however, specifically recommended that an atypical antipsychotic should be considered for a newly diagnosed patient.

Janssen-Cilag agreed with the complainant's view that no antipsychotic was benign. Indeed Janssen-Cilag had noted side effects that might occur with the different classes, but refuted the claim of bias towards atypical antipsychotics.

Janssen-Cilag submitted that the complainant was wrong to conclude that it had encouraged patients to request atypicals from their doctor. Janssen-Cilag had simply advocated patient choice where possible, and it did not comment in this respect on whether antipsychotics were benign or otherwise: indeed it was widely accepted that antipsychotics (whether these be typical or atypical) were associated with significant side effects.

Janssen-Cilag submitted that when referring to newer treatments it had included in this definition psychological therapies including cognitive behavioural therapy. The Layard Report recommended a wider use

of psychosocial treatments in mental health and there was an increasing evidence base for this.

In relation to the statement that schizophrenia was a 'disease of the mind' on the website, Janssen-Cilag submitted that it was widely accepted that schizophrenia was a neuro-developmental disorder of the brain leading to thought disorder. The dopamine hypothesis might account for the development of positive and negative symptoms of schizophrenia, although other hypotheses involving various other neurotransmitters also existed (Carlsson *et al* 1997).

Janssen-Cilag submitted that the statements on the website were therefore not inconsistent with these hypotheses. The word mind was widely accepted as meaning the human consciousness that originated in the brain and was manifested especially in thought, perception, emotion, will, memory and imagination. Many of these functions were affected in patients with schizophrenia and to de-link mind and brain would be incorrect. Importantly, the word mind would be more acceptable to patients and carers than the word brain.

In relation to the allegation that the claim that medicine would reduce the risk of further illness was a lie, Janssen-Cilag submitted that it was widely accepted in mental health that medicines reduced the risk of further illness, provided they were taken regularly. There was published evidence to support this for both typical and atypical antipsychotics, from placebo-controlled studies and discontinuation studies (Schooler 1993, Davis *et al* 1993). NICE considered that pharmacological intervention was important to prevent relapse. Whilst it stated that around 20% of patients might only have one episode, it recommended that, as there was no reliable predictor of prognosis or drug response, pharmacological prevention of relapse should be considered for every patient with schizophrenia. Published evidence established the efficacy of antipsychotics in the prevention of relapse.

Janssen-Cilag submitted in respect of the complainant's comment regarding clever utilisation of data in clinical trials prior to the licensing of risperidone, it observed that the marketing authorization for risperidone was granted following an independent and comprehensive review of the efficacy and safety data submitted to the relevant competent authority.

In relation to the allegations about the link between the Brainchip website link and recent FDA approval for VNS, Janssen-Cilag submitted that the Brainchip link on the website was taken directly from a book called 'The Secret of the Brain Chip' by a psychiatrist which was first published 6 years ago. It included a cartoon of a man with a microchip in the middle of this brain and the purpose was to depict an example of a possible delusion a patient might experience with schizophrenia. This book had been used extensively with many of the early intervention services and young carers, and although its style might not be suitable for all individuals, Janssen-Cilag aimed to provide a wide range of different styles of material to enable patients and health professionals to choose which they might use to obtain further information about schizophrenia. This cartoon had absolutely no association with the recent FDA approval for VNS; Janssen-Cilag was not able to comment further about the complainant's view of this.

In conclusion, Janssen-Cilag refuted any breach of Clauses 20.1 and 20.2; furthermore it also refuted the allegations made by the complainant in respect of the said article and related web-site. With respect to the development of the 1 in 100 campaign and associated materials Janssen-Cilag had undertaken due diligence around the content such that it had maintained high standards and not brought the industry into disrepute. Janssen-Cilag therefore denied a breach of either Clause 9.1 or Clause 2.

Janssen-Cilag submitted that in replying it had considered the views expressed by the complainant very carefully, and without prejudice to the views expressed above, would take these views into consideration in future communications with the general public.

PANEL RULING

The Panel noted that the advertisement had been published in a journal where it would be read by members of the public. Clause 20.1 prohibited the promotion of prescription only medicines to the general public. Clause 20.2 stated, *inter alia*, that information made available to the general public about prescription only medicines must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment. Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel noted that beneath a reproduction of a painting by a patient the advertisement read '… but the picture's looking brighter'. This was followed by less prominent text that read 'Schizophrenia can be very difficult to live with. But the good news is, with modern treatments there's now a real chance of recovery'.

The Panel noted Janssen-Cilag's submission that there were numerous definitions of recovery which did not equate to a cure. These included restoration to a better condition or independent living. The Panel noted the varying definitions but considered that given the intended audience it was important to be extremely clear about what was meant by 'recovery'. Schizophrenia was a chronic condition. The Panel considered that some lay people, particularly those who knew very little about schizophrenia, might assume that recovery meant elimination of the illness, particularly as the advertisement referred to a 'real chance' of recovery in the context of 'modern treatments' and described this as 'good news'. The advertisement was misleading in this regard. A breach of Clause 20.2 of the Code was ruled.

The Panel noted Janssen-Cilag's submission that the statement '… discuss with your doctor the choices available' encouraged patients to go to their doctors and discuss the treatment choices which might include psychosocial as well as pharmacological treatment

options. Whilst the advertisement referred to modern treatments there was no reference direct or implied to a specific medicine. There were several 'modern' treatment choices. The Panel did not consider that the statement at issue promoted a specific prescription only medicine to the public or would encourage patients to ask their health professional to prescribe a specific prescription only medicine. No breach of Clauses 20.1 and 20.2 was ruled.

The Panel noted that throughout the website certain terms were underlined. These links led to a glossary where an explanation was given. Underlined terms included 'psychiatrist', 'diagnosis' and 'mental health team'. In a section headed 'Newer medications' the phrase 'atypical antipsychotics' was underlined in a sentence which mentioned their mechanism of action and effect on a broader range of symptoms than older medications. The phrase 'long-acting injections' was underlined in the final sentence of the same section which listed the various presentations available. The reference to short-acting injections was not underlined. 'Long-acting injections' was also underlined in the preceding paragraph which dealt with older medications. The Panel noted that Janssen-Cilag's product, Risperdal Consta was the only atypical available as a long-acting injection. Given the format of the site wherein various terms were underlined throughout, the Panel did not consider that the underlining of the phrases at issue was inappropriate. It did not give them undue emphasis such that they either promoted a prescription only medicine to the general public or that encouraged members of the public to ask for a specific medicine, as alleged. No breach of Clauses 20.1 and 20.2 was ruled.

The Panel noted that one of the 'Ten Tips to Help you Discuss Treatment with your Doctor' was 'Ask your doctor if any of the newer treatments for schizophrenia would be suitable for you especially if you have had distressing side effects with other treatments'. The side effect section which appeared earlier in the website explained that the risk of certain side effects associated with newer medicines was much lower but not totally absent. The newer treatments were more likely to make people put on weight or have difficulty with sexual arousal. The Panel did not consider the bullet point at issue inferred that atypical antipsychotics were benign and thus superior to older medication as alleged. The website made it clear that side effects were associated with the newer medicines. No breach of Clause 20.2 was ruled.

The Panel did not consider that the description of schizophrenia as a 'disease of the mind' and references to abnormalities in the transfer and processing of information within the brain were unacceptable as alleged. The section 'Possible causes of Schizophrenia' explained that for the majority of people treatment relied on medicines which modified the effects of the neurotransmitters in the brain. It was also clearly stated that there was no known single cause of schizophrenia. The Panel did not consider that the phrase a 'disease of the mind' was unacceptable as alleged. No breach of Clause 20.2 was ruled.

The section 'The effect of discontinuing treatment' included the claim 'Antipsychotic drugs reduce the risk of future illness in patients who have recovered from an acute episode'. The claim did not refer to 'further illness' as stated by the complainant. The Panel did not consider that the claim as published on the website was a blatant lie as alleged. The effect of discontinuation of treatment and relapse rates were discussed. It was made clear that even with continued treatment patients might relapse. No breach of Clause 20.2 was ruled.

The Panel noted that the Brainchip link on the website featured an image of a man's face with a computer chip on his forehead. The link led to a self-help book for people experiencing psychosis, 'The Secret of the Brain Chip', which described a young man's experience of psychosis during which he felt that he was being controlled by a chip implanted in his brain. The booklet was produced with support from Janssen-Cilag. The booklet discussed treatment but did not mention a specific medicine or class of products. The Panel did not consider that it was an attempt to condition schizophrenic patients to the possibility of neuroleptics being delivered straight to the brain by surgical implant as alleged. The computer chip in the cartoon was depicted as a negative aspect of the patient's delusion rather than as part of the solution. No breach of Clauses 20.1 and 20.2 was ruled.

In considering the campaign as a whole the Panel noted that although no statements had been made to encourage a member of the public to ask for a specific prescription only medicine, the material was biased towards atypical antipsychotics ie the newer more modern treatments for schizophrenia. There were however, several atypical agents available. Nonetheless the Panel had some concerns about the bullet point 'Ask your doctor if any of the newer treatments for schizophrenia would be suitable for you especially if you have had distressing side effects with other treatments'. Whilst the atypical antipsychotics might be a rational treatment choice for newly diagnosed patients or those unable to tolerate the older agents, some patients would be satisfactorily controlled on their current treatment such that it would not be prudent to switch them to atypicals and risk a loss of control in the process. The bullet point seemed to open up that possibility to the patient although the final decision would always lie with the prescriber. Although noting its concerns the Panel, however, did not consider that either the advertisement or the website had failed to maintain a high standard; no breach of Clause 9.1 was ruled. Consequently the Panel also ruled no breach of Clause 2.

Complaint received 15 January 2007

Case completed 21 March 2007