

SENIOR COMMUNITY MENTAL HEALTH NURSE/ MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY v JANSSEN-CILAG

Promotion of Risperdal and Risperdal Consta

A senior community mental health nurse complained to the Medicines and Healthcare products Regulatory Agency (MHRA) about a three page mailing for Risperdal (risperidone) sent by Janssen-Cilag. The front cover of the mailing showed a bedroom and two clothed, silhouetted figures: a woman standing in the doorway and man sitting on the bed. Across the top of the front cover a brief profile of the woman read 'Convinced she's a siren, Tricia lures total strangers back from the park and from taxi queues for unprotected sex. To date she's had two terminations and one divorce'. In the middle of the front cover was the caption 'Mania wrecks lives'.

The MHRA considered that whilst the content of the mailing might not be in good taste, its particulars were not in breach of the Advertising Regulations. With the complainant's agreement, the matter was accordingly referred to the Authority for consideration in relation to the Code.

The complainant stated that the mailing had been received by all sixteen members of his multi-disciplinary team. They found the front cover to be extremely stigmatising; not one of them had ever encountered a case as outlined in the mailing.

All received the mailing despite having never provided names/addresses to the company voluntarily. It appeared that in 2005 a Janssen-Cilag representative had asked a secretary for all the names of the team members and this material was then put on a database. The complainant queried if this was ethical.

The team had also been subjected to very heavy marketing of the injectable form of Risperdal (Risperdal Consta) throughout the autumn of 2005 when virtually on a weekly basis a representative would visit and distribute large amounts of office material ie diaries, wrist pads and paper shredders.

The Panel noted that as an example of how mania wrecked lives, the mailing had profiled a fictional patient who exhibited inappropriate sexual behaviour. Janssen-Cilag submitted that such characteristics of mania were commonly encountered in clinical practice. This appeared to be at odds with the complainant's experience. Hirschfeld *et al*, however, showed that increased sexual interest or sexual activity was not uncommon in patients suffering from mania. The Panel thus did not consider that the mailing failed to recognise the special nature of medicines or the professional standing of the audience. The issue highlighted was relevant to the disease area. The mailing had caused some concern to the complainant but the Panel did not consider that it was likely to offend the majority of those who would see it. No breach of the Code was ruled.

With regard to the frequency of visits by sales representatives, the Panel noted that there were two sales forces promoting Risperdal; the schizophrenia team and the bipolar/mania team. The complainant's mental health unit had sixteen health professionals and was the base for a large

number of others. There thus appeared to be multiple representatives calling on multiple health professionals. The sales team for Risperdal Consta had held 28 meetings in the unit in the first five months of the year which included nine with nurses. Six meetings were held, including four with nurses, by members of the bipolar/mania sales team. According to Janssen-Cilag's records the complainant had not met any Janssen-Cilag representatives. From the material supplied by Janssen-Cilag it appeared that the Code had been followed. Thus the Panel ruled no breach of the Code.

With regard to the distribution of the mailing the Panel noted that Janssen-Cilag used mailing lists compiled by a third party. This was quite usual in the industry. The Panel considered that the mailing had been sent to people whose need for, or interest in, it could reasonably be assumed. Thus no breach of the Code was ruled.

A senior community mental health nurse complained to the Medicines and Healthcare products Regulatory Agency (MHRA) about a three page mailing (ref 06799b) for Risperdal (risperidone) received from Janssen-Cilag Ltd. The front cover of the mailing showed a bedroom and two clothed, silhouetted figures: a woman standing in the doorway and man sitting on the bed. Across the top of the front cover a brief profile of the woman read 'Convinced she's a siren, Tricia lures total strangers back from the park and from taxi queues for unprotected sex. To date she's had two terminations and one divorce'. In the middle of the front cover was the caption 'Mania wrecks lives'.

The MHRA considered that whilst the content of the mailing might not be in good taste, its particulars were not in breach of the Advertising Regulations. With the complainant's agreement, the matter was accordingly referred to the Authority for consideration in relation to the Code and, in particular, the requirements of Clause 9 relating to suitability and taste.

COMPLAINT

The complainant stated that the mailing had been received by all the members of his multi-disciplinary team. They found the front cover to be extremely stigmatising of the diagnosed mental illness the product was aimed at. They also considered that the mailing had picked a very rare complication of mania and presented it in a way as to suggest an actual case history. Within the team of sixteen mental health professionals, each with between 6 to 25 years'

experience in psychiatric settings, not one had ever encountered a case as outlined in the mailing.

All received the mailing despite having never provided names/addresses to the company voluntarily. It appeared that in 2005 a Janssen-Cilag representative has asked a secretary for all the names of the team members and this material was then put on a database. The complainant queried if this was ethical particularly given the disturbing nature of the mailing.

The team had also been subjected to very heavy marketing of the injectable form of Risperdal (Risperdal Consta) throughout the autumn of 2005 when virtually on a weekly basis a representative would visit and distribute large amounts of office material ie diaries, wrist pads, paper shredders; some offices now resembled a Janssen-Cilag stock depot.

When writing to Janssen-Cilag the Authority asked it to respond in relation to Clauses 9.2, 12.1 and 15.4 of the Code.

RESPONSE

Janssen-Cilag noted that the mailing, which described the benefits of Risperdal in the treatment of mania, was mailed to mental health nurses earlier this year. The imagery and text had been used across various media for two and a half years and had been well received by many health professionals. An analysis of the Hospital Readership Survey 2005/2006 revealed that a 99.99% coverage of senior grade psychiatrists had been achieved during the previous two years, allowing them several opportunities to view this material. This was the first complaint about this material.

Tricia, the fictional character depicted on the front cover, was based on a real patient described to Janssen-Cilag by a community psychiatric nurse, although the details had been changed to ensure patient confidentiality. Janssen-Cilag submitted that the scenario described was a fair and accurate representation of some of the characteristics experienced by patients with mania. Tricia represented a patient who was sexually disinhibited, who was behaving recklessly and was consequently vulnerable and at risk of further harm. Such characteristics of mania were well documented throughout the literature and featured prominently in two of the most widely used sets of diagnostic criteria for psychiatric illness, the International Classification of Disease (ICD 10, World Health Organization) and the Diagnostic and Statistical Manual of Mental Disorder (DSM IV, American Psychiatric Association).

According to the ICD 10, patients in the hypomanic phase of the illness might exhibit a persistent mild elevation of mood, increased energy and activity, and usually marked feeling of well-being, and both physical and mental efficiency. Increased sociability, talkativeness, over-familiarity, increased sexual energy, and a decreased need for sleep were often present but not to the extent that they led to severe disruption of work or resulted in social rejection (ICD 10 Ch 5 F30.0).

Furthermore, in full-blown mania, mood was elevated out of keeping with the patient's circumstances and

might vary from carefree joviality to almost uncontrollable excitement. Elation was accompanied by increased energy, resulting in overactivity, pressure of speech, and a decreased need for sleep. Attention could not be sustained and there was often marked distractibility. Self-esteem was often inflated with grandiose ideas and overconfidence. Loss of normal social inhibitions might result in behaviour that was reckless, foolhardy, or inappropriate to the circumstances, and out of character (ICD 10 Ch 5 F30.1).

The DSM IV offered a similar classification of disease, although it was more often used in the US. It identified criteria that needed to be fulfilled for a manic episode. During the period of mood disturbance, three (or more) of the following symptoms had persisted (four if the mood was only irritable) and had been present to a significant degree: inflated self-esteem or grandiosity; decreased need for sleep; more talkative than usual or pressure to keep talking; flight of ideas or subjective experience that thoughts were racing; distractibility; increase in goal-directed activity (either socially, at work or school, or sexually) or psychomotor agitation; excessive involvement in pleasurable activities that had a high potential for painful consequences eg engaging in unrestrained buying sprees, sexual indiscretions, or foolish business investments.

The mood disturbance was sufficiently severe to cause marked impairment in occupational functioning or in usual social activities or relationships with others, or to necessitate hospitalisation to prevent harm to self or others, or there were psychotic features.

In a questionnaire-based study which examined the perceptions and impact of bipolar disorder, the majority of respondents experienced excessive irritability or aggressive behaviour, reckless behaviour, erratic eating, or increased sexual interest or sexual activity (Hirschfeld *et al* 2003). Furthermore during the time that the illness was untreated or improperly treated, the most frequently experienced psychosocial problems were relationship problems (80%), including interpersonal conflicts with family and friends (68%) and marital difficulties (49%). Some of these features were reflected by the mailing.

A study of sexual and reproductive behaviours among people with mental illness found that women with mental illness had more lifetime sexual partners than women in the comparative group representative of the US population matched for age and race. The authors concluded that this finding might reflect the chaotic pattern of sexual relationships and the high rate of non-consensual sex that had been observed among women with mental illness (Dickerson *et al* 2004).

Janssen-Cilag submitted that the evidence cited above supported the fact that the characteristics of mania represented in the mailing were commonly encountered in clinical practice and demonstrated the vulnerability of such patients. It was thus entirely appropriate to highlight these issues to health professionals in marketing materials. On the contrary, rather than stigmatizing patients with mania, the mailing drew much needed attention to the sexual

and relationship problems they sometimes had. Janssen-Cilag did not suggest that this issue affected all patients with mania.

With reference to Clause 9.2 of the Code, Janssen-Cilag was aware of the special nature of medicines, and recognised the professional standing of the target audience for its marketing materials. It did not consider that this mailing undermined or contravened Clause 9.2.

With reference to Clause 12.1, Janssen-Cilag knew that promotional material should only be distributed to those persons whose need for, or interest in, the particular information could be reasonably assumed. The mailing was created for, and distributed to, mental health nurses as they were fundamentally involved in the management of patients with mania. Therefore Janssen-Cilag did not consider that the distribution of the mailing undermined or contravened Clause 12.1.

With regard to the concern about the use of address details on a mailing list, Janssen-Cilag noted that like many other pharmaceutical companies it relied on an agency to supply accurate details about health professionals for its promotional mailings. If someone wanted to be removed from the company's mailing list there were processes in place to allow them to do that.

In response to the complainant's concern regarding the volume of promotional activity seen at his unit by Janssen-Cilag representatives promoting Risperdal Consta, it was of course company policy to ensure strict adherence to the Code. For this reason representatives did not see any health professional more than three times per year on average except in the following circumstances (Clause 15.4 of the Code): attendance at group meetings, including audio-visual presentations and the like; a visit which was requested by a doctor or other prescriber or a call which was made in order to respond to a specific enquiry; a visit to follow up a report of an adverse reaction.

In a unit of sixteen health professionals such as the one in which the complainant worked, this could reasonably be expected to amount to approximately one visit from a representative per week to see different individuals. Records for the first five months of 2006 of one-to-one meetings between health professionals and Janssen-Cilag staff at the unit in question revealed that 28 such meetings were held, including nine with nurses, with members of the Risperdal Consta team (schizophrenia). Six such meetings were also held, including four with nurses, with members of the bipolar/mania team. The unit in question was a large one and was the base for a large number of mental health professionals, far in excess of sixteen. Records revealed the complainant had not had a one-to-one meeting with anyone from Janssen-Cilag in either 2005 or 2006 and therefore had not been inconvenienced directly by legitimate promotional activity. Other health professionals in the unit were happy to see representatives from Janssen-Cilag.

Therefore Janssen-Cilag did not consider that the behaviour of its representatives, or the frequency with

which they had visited health professionals at the complainant's unit, undermined or contravened Clause 15.4.

Janssen-Cilag trusted that its response demonstrated that the mailing, rather than being misleading and stigmatizing was a fair representation of one aspect of a patient with bipolar mania, exhibiting some of the important and not uncommon characteristics and vulnerabilities that this patient group might display. Furthermore it considered that the material was relevant and appropriate for the intended audience of health professionals. Janssen-Cilag believed that it had demonstrated that the quantity and frequency of the promotional activity undertaken by its representatives was appropriate and thus it refuted the alleged breaches of the Code.

PANEL RULING

The Panel noted that as an example of how mania wrecked lives, the mailing had profiled a fictional patient who exhibited inappropriate sexual behaviour. Janssen-Cilag submitted that such characteristics of mania were commonly encountered in clinical practice. This appeared to be at odds with the complainant's experience. Data supplied by Janssen-Cilag (Hirschfeld *et al*), however, showed that increased sexual interest or sexual activity was not uncommon in patients suffering from mania. The Panel thus did not consider that the mailing failed to recognise the special nature of medicines or the professional standing of the audience. The issue highlighted was relevant to the disease area. The mailing had caused some concern to the complainant but the Panel did not consider that it was likely to offend the majority of those who would see it. No breach of Clause 9.2 of the Code was ruled.

With regard to the frequency of visits by sales representatives, the Panel noted that there were two sales forces promoting Risperdal; the schizophrenia team and the bipolar/mania team. The complainant's mental health unit had sixteen health professionals and was the base for a large number of others. There thus appeared to be multiple representatives calling on multiple health professionals. The sales team for Risperdal Consta had held 28 meetings in the unit in the first five months of the year which included nine with nurses. Six meetings were held, including four with nurses, by members of the bipolar/mania sales team. According to Janssen-Cilag's records the complainant had not met any Janssen-Cilag representatives.

The limits in the Code referred to frequency of calls by a representative to a doctor or other prescriber. The wishes of individuals on whom representatives wished to call and the arrangements in force at any particular establishment must be observed. The supplementary information to Clause 15.4 of the Code stated that the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. From the material supplied by Janssen-Cilag it appeared that the supplementary information to the Code had been followed. Thus the Panel ruled no breach of Clause 15.4.

With regard to the distribution of the mailing the Panel noted that Janssen-Cilag used mailing lists compiled by a third party. This was quite usual in the industry. Janssen-Cilag had not commented on the point raised by the complainant regarding a representative asking a secretary for names of team members. Individuals could ask for their names to be removed from lists (Clause 12.3 of the Code). The

Panel considered that the mailing had been sent to people whose need for, or interest in, it could reasonably be assumed. Thus no breach of Clause 12.1 of the Code was ruled.

Complaint received **2 June 2006**

Case completed **7 August 2006**
