

# CHILD AND ADOLESCENT PSYCHIATRIST v LUNDBECK

## Promotion of Circadin

A child and adolescent psychiatrist complained about the promotion of Circadin (prolonged release melatonin) by Lundbeck. Circadin was indicated for the short-term treatment of primary insomnia in patients aged 55 or over. It was not recommended for use in children or adolescents below the age of 18 due to insufficient data on safety and efficacy.

The complainant was concerned to find a number of items of stationery advertising Circadin in his clinic. A Lundbeck representative had given them to a paediatrician colleague who had asked for information about Circadin. Although child psychiatrists and paediatricians sometimes prescribed melatonin off licence to children, Circadin was only licensed for the over 55 age group. The complainant's service and all the services in his building worked exclusively with children and so distributing promotional material to a paediatrician seemed to be promoting an unlicensed indication.

The detailed response from Lundbeck is given below.

The Panel noted that the complainant had not seen the Lundbeck representative. The health professional who had seen the representative did not consider that Circadin had been promoted outside the terms of its marketing authorization. The health professional stated that she and other colleagues would not infrequently prescribe melatonin for sleep disorders in children and that she had found the meeting useful as she and her colleagues had learned that the tablet had to be swallowed whole as crushing would affect its efficacy.

The Panel was concerned that the representative had responded to a request from a paediatrician at a children's centre for information about Circadin which was not recommended for use in children due to insufficient data on safety and efficacy. According to the paediatrician the representative had made it clear both before and at the meeting that he could only talk about the licensed use of Circadin and not its use in children. In the Panel's view it would have been more appropriate for the company's medical information department to respond to the paediatrician's request. However there was no complaint about the meeting; the allegation concerned the provision of promotional aids. The Panel was concerned that following a conversation about a product with a health professional who would not be expected to use it within its marketing authorization, the representative had left promotional aids for that product. The Panel considered that the

representative had not maintained a high standard of ethical conduct and a breach of the Code was ruled.

The Panel did not consider that providing promotional aids which consisted solely of the brand name and company name constituted promotion that was inconsistent with the SPC. No breach of the Code was ruled.

The Panel considered that the briefing material supplied by Lundbeck might have benefited from being clearer regarding the licensed indication. A key message appeared to imply that Lundbeck had more choice in the positioning rather than the only positioning being in patients older than 55 years. However, a list of questions which representatives should refer to medical information included 'Is there any evidence for use in children?', 'What if a clinician wants to use Circadin in young age groups?'. Overall the Panel did not consider that the briefing material advocated a course of action that was likely to lead to a breach of the Code. No breach of the Code was ruled.

The Panel noted that promotional material should only be given to those categories of persons whose need for or interest in the particular information could reasonably be assumed. The promotional aids did not contain any information about Circadin other than its brand name and the company name. The Panel did not consider that in these circumstances Lundbeck had breached the Code.

A child and adolescent psychiatrist at a children's centre complained about the promotion of Circadin (prolonged release melatonin) by Lundbeck Ltd.

Circadin was indicated as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients aged 55 or over. It was not recommended for use in children or adolescents below the age of 18 due to insufficient data on safety and efficacy.

## COMPLAINT

The complainant was concerned to find a number of items of stationery advertising Circadin in his clinic. A Lundbeck representative had given them to a paediatrician colleague who had asked for information about Circadin.

Although child psychiatrists and paediatricians sometimes prescribed melatonin off licence to children, Circadin was only licensed for the over 55 age group. The complainant's service and all the

services in his building worked exclusively with children and so distributing promotional material to a paediatrician seemed to be promoting an unlicensed indication.

The complainant was advised by the Authority that this might be a breach of the Code. This case might throw up wider issues if Circadin was being promoted in this way in other child and adolescent/paediatric services.

When writing to Lundbeck, the Authority asked it to respond in relation to Clauses 3.2, 11.1, 15.2 and 15.9 of the Code.

## RESPONSE

Lundbeck confirmed that a specialist paediatrician, at a community area mental health service, specifically requested a meeting with one of its representatives to discuss some of the scientific matters associated with Circadin. The representative did not discuss the use of Circadin in children/adolescents and at all times during the meeting acted within his remit and discussed the product within the terms of the summary of product characteristics (SPC). The representative gave the paediatrician a copy of the Circadin SPC. Lundbeck enclosed written testimony from the paediatrician to confirm this account.

The representative left some post-it notes and pens in response to a specific request from a member of the reception staff. No material containing promotional messages was left at the centre.

The representative in question had passed the ABPI examination.

Lundbeck provided a number of relevant items for sales force training or for use with customers which it submitted clearly stated:

- Circadin was positioned for use within the licensed indication
- Circadin was indicated for use in patients aged 55 years or older
- Circadin was not recommended for use in children and adolescents
- Circadin was not licensed for children or attention deficit hyperactivity disorder (ADHD)
- Questions regarding evidence in children/use in young persons should be referred to the medical information department

Lundbeck stated categorically that it was not its policy to promote Circadin for use in this patient population either through the use of its sales force or any other method.

## PANEL RULING

The Panel noted that the complainant had not seen the Lundbeck representative. The health professional who had seen the representative did

not consider that Circadin had been promoted outside the terms of its marketing authorization. The health professional stated that she and other colleagues would not infrequently prescribe melatonin for sleep disorders in children and that she had found the meeting useful as she and her colleagues had learned that the tablet had to be swallowed whole as crushing would affect its efficacy.

Lundbeck submitted that no material containing promotional messages was left at the centre. The representative had left branded post-it notes which also included the company name and pens which bore the brand name.

The Panel was concerned that the representative had responded to a request from a paediatrician at a children's centre for information about Circadin which was not recommended for use in children due to insufficient data on safety and efficacy. According to the paediatrician the representative had made it clear before and at the meeting that he could only talk about the licensed use of Circadin and not its use in children.

Representatives must always ensure that their conduct complied with the Code regardless of their customers' wishes. In the Panel's view it would have been more appropriate for the company's medical information department to respond to the paediatrician's request rather than a representative. However there was no complaint about the meeting; the allegation concerned the provision of promotional aids. The Panel was concerned that following a conversation about a product with a health professional who would not be expected to use it within its marketing authorization, the representative had left promotional aids for that product. The Panel considered that in providing the promotional aids in these circumstances the representative had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled.

The Panel did not consider that providing promotional aids which consisted solely of the brand name and company name constituted promotion that was inconsistent with the SPC. No breach of Clause 3.2 was ruled.

The Panel considered that the briefing material supplied by Lundbeck might have benefited from being clearer regarding the licensed indication. It might be argued from the key message 'Circadin will be positioned in new patients > 55 years with primary insomnia alongside sleep hygiene' was ambiguous and implied that Lundbeck had more choice in the positioning rather than the only positioning being in patients older than 55 years. However, a list of questions which representatives should refer to medical information included 'Is there any evidence for use in children?', 'What if a clinician wants to use Circadin in young age groups?'. Overall the Panel did not consider that the briefing material advocated a course of action that was likely to lead to a breach of the Code. No

breach of Clause 15.9 was ruled.

The Panel noted that Clause 11.1 required that promotional material should only be given to those categories of persons whose need for or interest in the particular information could reasonably be assumed. The promotional aids did not contain any information about Circadin other

than its brand name and the company name. The Panel did not consider that in these circumstances Lundbeck had breached Clause 11.1 and thus no breach was ruled.

**Complaint received**      **20 November 2009**

**Case completed**        **28 January 2010**

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