

An analysis of off-licence prescribing in psychiatric medicine

By *Petrina Douglas-Hall, BPharm, MRPharmS, Andrew Fuller, BPharm, MRPharmS, and Stuart Gill-Banham, BSc, MRPharmS*

AIM • To assess the incidence of off-licence prescribing.

DESIGN • A cross sectional survey of psychiatric prescription cards. Information relating to medicines prescribed, dosage and indication was collected.

SUBJECTS AND SETTING • Psychiatric wards in 14 trusts in the south-east of England.

RESULTS • A total of 1,387 prescription items were reviewed in the study, with 103 (7.5%), of these being for either unlicensed indications or at doses which

exceeded the maximum stated by the product licence. The most frequent unlicensed indications were olanzapine prescribed for a psychotic illness other than schizophrenia, and sodium valproate prescribed for an affective disorder.

CONCLUSIONS • The prevalence of off-licence prescribing was comparable to that found by a recent retrospective study. Although off-licence prescribing is a necessary part of clinical practice, the implications appear to be poorly appreciated by most practitioners and attention needs to be given to appropriate documentation.

Many psychiatrists see the use of drugs for indications outside those specified in their product licence, or at doses which exceed the maximum recommended, as a necessary part of clinical practice. A recent study found that 65 per cent of psychiatrists admitted to prescribing off-licence in the preceding month.¹ This practice, which has been described as a necessary part of the art of medicine,² has implications for practice, particularly regarding legal accountability and consent to treatment.

Medicines for human use must receive a product licence if they are to be promoted and be available for prescription within the United Kingdom. However, legislation does allow a prescriber to use medicines in ways outside the recommendations of this product licence on his or her own personal responsibility.³

Previous studies have looked at unlicensed (off-licence) prescribing in different medical specialties. In some instances, insufficient evidence to support a licence application necessitates off-licence use (eg, use of some medicines in children).⁴ Other studies highlight evidence-based but off-licence use of medicines. Taylor *et al* reported that up to 52 per cent of sodium valproate usage in psychiatry was apparently for unlicensed indications.⁵

The aim of this study was to assess the scale of off-licence prescribing across a large number of hospital settings. The implications for future prescribing practice were also considered.

METHOD

Members of the South East Psychiatric Pharmacy Network were invited to participate in this study of prescriptions on acute adult psychiatric wards. Using a standard data collection form the following information was gathered on all medicines pre-

scribed, including regular and *prn* prescriptions: daily dose; indication; whether dose exceeded the maximum recommended in the British National Formulary; whether the pharmacist collecting data thought the indication was outside the product licence; if either the dose exceeded the maximum recommended or the indication was outside the product licence and whether this fact was acknowledged in the patient's medical notes. In addition, the diagnosis or current best working diagnosis was recorded for each patient. Forms were returned to the authors who double-checked the indications with product licences, using the BNF or Association of the British Pharmaceutical Industry Datasheet Compendium as references.

RESULTS

Prescriptions from 266 patients, in 14 trusts, were analysed. A total of 1,387 items had been prescribed; 764 were regular and 623 were on a *prn* basis. Of these, 103 (7.5 per cent) were outside the terms of the product licence, 75 per cent of these were for indications not covered by the licence and 25 per cent were doses which exceeded the maximum permitted. Eighty-one patients (30 per cent) were prescribed at least one medicine off-licence and most of these, 90 per cent, were for an unlicensed indication.

Of the 76 prescriptions for an unlicensed indication, 30 (40 per cent) were pre-

scriptions for an atypical antipsychotic prescribed for a psychotic illness other than schizophrenia. Sixteen (20 per cent) were for an anticonvulsant, principally sodium valproate, prescribed for an affective disorder (Table 1).

Of the 26 prescriptions that exceeded the maximum licensed dose, 10 were prescriptions for zopiclone at a dose greater than 7.5mg/day. In only three cases were antipsychotics prescribed at greater than the maximum licensed dose, and in all three cases these were prescriptions for olanzapine greater than 20mg/day.

Of the 103 prescriptions that fell outside the terms of the product licence, an acknowledgement of this was recorded in the patient's medical notes in only 10 cases.

DISCUSSION

This study supports the retrospective, postal questionnaire study by Lowe-Ponsford and Baldwin,¹ which found that 65 per cent of psychiatrists had prescribed at least one drug off-licence in the preceding month. It should be remembered that this study focused on acute adult wards so the number of off-licence prescriptions would undoubtedly have been higher if wards for children and the elderly had been included.

The use of atypical antipsychotics for a psychotic illness other than schizophrenia, along with sodium valproate being used to treat an affective disorder, were the most common unlicensed indications found. It may be argued that in most clinical situations these prescriptions would have been justified given the evidence which exists supporting the use of sodium valproate in mania and the more favourable side effect profile of olanzapine and other atypical antipsychotics. Despite being necessary and of obvious benefit to patients' off-licence prescribing has both legal and political implications.

Ms Douglas-Hall is a pharmacist at HM Prison Service, the Home Office, Mr Fuller is principal pharmacist clinical services, South West London and St Georges Mental Health NHS Trust and Mr Gill-Banham is a clinical pharmacist at Oxleas NHS Trust. Correspondence to Mr Gill-Banham, Pharmacy Department, Oxleas NHS Trust, Pinewood House, Pinewood Place, Dartford DA2 7WG

TABLE 1: SUMMARY OF UNLICENCED INDICATIONS ACCORDING TO DRUG CLASS

Drug	Number of times prescribed	Number of times prescribed off-licence	Examples of unlicensed indication
<i>Antipsychotics</i>			
Olanzapine	35	18	Psychotic depression (6) Mania (3) Schizoaffective disorder (3) Psychosis, other (6)
Amisulpiride	15	7	Schizoaffective disorder (4) Mania (1) Psychosis, other (2)
Droperidol	99	4	Psychosis (3) Insomnia (1)
Quetiapine	9	4	Mania (2) Psychotic depression (2)
Sulpiride	9	4	Psychotic depression (2) Anxiety (1) Psychosis, other (1)
Thioridazine	40	2	Insomnia (2)
Clozapine	2	1	Mania
Flupenthixol	27	1	Aggressive behaviour
Zuclopenthixol	26	1	Aggressive behaviour
<i>Antidepressants</i>			
Citalopram	6	1	Anxiety/OCD
Imipramine	2	1	Nocturnal enuresis in an adult
Reboxetine	2	1	Anxiety
<i>Anticonvulsants</i>			
Sodium valproate	12	11	Mood stabiliser (10) Schizoaffective disorder (1)
Carbamazepine	19	5	Challenging behaviour (2) Depression (2) Aggression (1)
Lamotrigine	2	2	Mood stabiliser (2)
<i>Anxiolytics</i>			
Oxazepam	2	2	Insomnia (2)
Clonazepam	1	1	Psychosis
Lorazepam	95	1	Elated mood
Diazepam	44	1	Disturbed behaviour
<i>Others</i>			
Propranolol	3	3	Movement disorder (2) Agitation (1)
Promethazine	2	2	Psychosis (1) Aggression (1)
Gamolenic acid	1	1	"General well being"
Hyoscine	1	1	Hypersalivation
Tetrabenazine	1	1	Drug induced movement disorder

Anecdotal evidence exists within the south-east area of England that health care commissioners will attempt to limit the use of expensive drugs by stipulating that they are only prescribed for their licensed indications. This practice is of questionable value since our study shows atypical antipsychotics to be widely prescribed for indications outside their product licence.

It is also questionable how sensible this policy may be from a legal point of view. If a prescriber failed to prescribe a particular medicine purely on the grounds that it was for an unlicensed indication, despite reasonable evidence indicating efficacy and safety, then that individual could still be sued for malpractice.⁶

Despite this, fear of litigation was cited by some respondents in Lowe-Ponsford and Baldwin's study as a reason for not prescribing drugs off-licence. In an attempt to limit the consequences of any legal actions they proposed a procedure for prescribing medication off-licence. Exactly how many prescribers would follow such a rigorous procedure is open to debate. In our study only 10 per cent of off-licence prescriptions

were supported by the simple procedure of fully documenting such use in the medical notes. This highlights either a lack of concern for off-licence prescribing or a lack of awareness of when a medicine is being used off-licence. In either case better documentation should be recommended as a standard course of action.

In all probability failure to record off-licence prescribing in the patient's medical notes results from a poor awareness of when an indication is off-licence. During analysis of data from the study, it became apparent to the authors that there was confusion among the pharmacists who collected the data as to the full extent of specific product licences. Particular areas causing confusion were the varying licences of atypical antipsychotics and selective serotonin reuptake inhibitors. Greater familiarity with licensed indications on both the pharmacist's and the doctor's part is needed. However, legalistic observations should not dissuade clinicians from prescribing the most suitable medicine for a given clinical situation, even if that means prescribing off-licence.

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