the columns

correspondence

Monitoring of carbamazepine and valproate prescribing practice

Sir: In their audit-type study of carbamazepine and valproate use, Taylor *et al* (all pharmacists) (*Psychiatric Bulletin*, May 2000, **24**, 174–177) seem to assume 'standards' that are open to question. They take as a starting point that the drug companies' licence represents a gold standard for prescribing practice from which the practitioner deviates at his or her peril. Commenting on the fact that 52% of prescribing of valproate was apparently for indications not listed in the drug's product licence, they issue a sinister warning:

> "Prescribers should be aware of the potential legal consequences of adverse effects resulting from off-licence use."

The difficulty with this is that most controlled trials on psychotropic drugs leading to eventual licences that are carried out by the pharmaceutical companies are on general adult psychiatric populations. One line of explanation for this is that it is easier to gain consent in this population than in others. Whatever the reason, the drug companies' licences often leave glaring gaps in other fields such as child psychiatry and learning disability. Apart from methylphenidate for hyperkinesis and imipramine for enuresis, there are virtually no licences for other drugs in child psychiatry, leaving the practitioner with no choice but to prescribe 'off-licence' in other conditions.

In psychiatry of learning disabilities, service users are rarely able to give accounts of their troubled mental states and full ICD diagnoses are the exceptions rather than the rule. In these circumstances, psychiatrists must make educated guesses as to probable psychopathology if they are to practise ethically. Again, cautious off-licence prescribing in conditions such as aggressive (challenging) behaviour is sometimes mandatory. Carbamazepine and valproate frequently alleviate such behaviour and there may well be a connection between explosive outbursts ('episodic dyscontrol') and epileptic activity.

In January 1997, the British Association of Psychopharmacology convened a 'Round Table' to look at this issue of drug companies' licences. Members included scientists, clinicians, pharmaceutical representatives and pharmacists. It is worth quoting directly from their article, if only to rebut the argument about litigation:

> "There is a great lack of clarity about the meaning of a licence that a company is offered. Many clinicians in the UK and France appear to think that they cannot prescribe off-licence – that it would be almost illegal to do so and that they would be exposing themselves to considerable risks of litigation. In fact, the Medicines Act and the EC Pharmaceutical Directive 89/341/EEC allows doctors to prescribe unlicensed medicines or to use licensed medicines for indications or in doses or by routes of administrations outside the recommendations of the licence as well as to over-ride warnings or precautions given in the licence."

Another assumption the authors make is that there is a consensus that serum carbamazepine and sodium valproate levels should be regularly monitored in the same way as serum lithium. I know of no such consensus and it would seem that most clinicians take blood levels only when there is some suggestion of untoward side-effects. The *British National Formulary* makes no comment on serum carbamazepine levels but is explicit about valproate:

> "Plasma-valproate concentrations are not a useful index of efficacy, therefore routine monitoring is unhelpful." (*British National Formulary*, 1998)

Indeed, I am told that some laboratories will only do valproate levels under special circumstances.

These two objections apart, the study was a salutary reminder that full blood counts and liver function tests are frequently neglected in patients who are on these two anti-epileptic medications in the long term. Also, the point that serum levels, when indicated, need to be taken at trough times (probably 4.00 p.m. before the teatime dose) was well made.

BRITISH ASSOCIATION OF PSYCHOPHARMACOLOGY (1997) BAP Consensus Statement. *Journal of Psychopharmacology*, **11**, 291–294.

BRITISH NATIONAL FORMULARY (1998) *British National Formulary*. September 1998. London: British Medical Association & Royal Pharmaceutical Society of Great Britain.

Padraig Quinn Consultant Psychiatrist, Clevedon and District CLDT, 4 Argyle Road, Clevedon BS21 7BP

Sale of St John's wort

Sir: Maidment's (*Psychiatric Bulletin*, June 2000, **24**, 232–234) review of St John's wort is timely, but fails to mention the problem of its wide availability as a herbal preparation. Randomised trials indicate that it is an effective antidepressant, with a variety of plausible mechanisms for action. Because it is a herbal remedy it is subject to none of the usual regulations applied to drugs. On a recent visit to a well-known high street chemist I found St John's wort on sale with no information about indications, side-effects or interactions, or any of the information which would be expected in a patient information leaflet for prescribed or over the counter medication. This may have serious consequences. First, patients are unaware of the potential interactions (including two recent cases where an interaction with cyclosporin caused rejection of a heart transplant (Ruschitzka *et al*, 2000)). Second, there is no mechanism for reporting serious adverse events. St John's wort is a drug and should be marketed as such. The current situation, where effective herbal remedies are not subject to the usual scrutiny, is an unacceptable double standard.

RUSCHITZKA, F., MEIER, F. J., TURINA, M., *et al* (2000) Acute heart transplant rejection due to Saint John's wort. *Lancet*, **355**, 548–549.

Matthew Hotopf Clinical Senior Lecturer in Psychological Medicine, GKT School of Medicine, Department of Psychological Medicine, 103 Denmark Hill, London SE5 8AZ

https://doi.org/10.1192/pb.24.9.352 Published online by Cambridge University Press