

Number 11

Prescription of Unlicensed Psychiatric Medicines

Although most prescribed medicines are licensed, some are not, and some (known as “off label”) are used for unlicensed purposes - such as the prescription of adult psychiatric medicine for children.

What is the legal position regarding the use of unlicensed drugs (or, the use of drugs for the purposes for which they are not strictly licensed)?

Under the Medicines Act 1968, doctors are permitted in specific circumstances to use or advise the use of licensed medicines for indications or in doses or by routes outside the recommendation of the licence. Section 9 Medicines Act will usually exempt doctors using a drug outside its licensed indication as will Section 10 exempt pharmacists under similar such circumstances. However, this does not mean that there is no possibility of a legal claim.

In the event of an accident occurring as a result of a particular medicine, an individual might be entitled to compensation either against the healthcare provider in negligence or possibly against the producer of the medicine if it can be shown that the medicine was defective.

If an individual suffers injury as a result of the use of a licensed medicine within the constraints set out in the product licence, liability for injury is only likely to fall on the manufacturer. Obviously, if the constraints of the product licence are not observed or the clinical circumstances are inappropriate, then liability could also fall on the prescriber.

If injury occurs as a result of using a product off label i.e outside its licence and not because of any defect in that product, then there can be no liability under the relevant consumer protection legislation and the only possible liability will be that which might fall on the clinician for prescribing it.

The use of a psychiatric drug licensed for adults but not for children raises specific issues of consent when prescribed for children. Undertaking testing on children raises difficult ethical and consent issues and most psychiatric drugs are therefore not licensed for children. This does not mean necessarily that a drug is unsafe for children, simply that the drug company makes no assertion about that use.

It is well known that a parent can give consent to treatment for any child up to the age of 18. In addition, if the child is Gillick competent or over 16, the child too has the power to give consent. If either the parent or the child in these circumstances give valid consent to treatment, they will have agreed to the treatment and the risks involved. Valid consent will need to be properly informed consent and therefore the parent will have to have been warned of the risks involved. The risks which must be notified are those that any reasonable practitioner would refer to. The fact that the drug is unlicensed for a particular use is one which should be raised. As a matter of good practice, in such circumstances:-

- (a) the drug should only be prescribed by a consultant;
- (b) the consultant should record in writing that in his judgment the particular drug will benefit the patient, setting out details of the drug including its form and strength, route of administration, duration of therapy and any side effects, risks, etc anticipated and explained.

MENTAL HEALTH LAW

RadcliffesLeBrasseur
5 Great College Street
Westminster
London SW1P 3SJ

Tel +44 (0)20 7222 7040
Fax +44 (0)20 7222 6208
LDE 113

6-7 Park Place
Leeds LS1 2RU

Tel +44 (0)113 234 1220
Fax +44 (0)113 234 1573
DX 14086 Leeds Park Square

25 Park Place
Cardiff CF10 3BA

Tel +44 (0)29 2034 3035
Fax +44 (0)29 2034 3045
DX 33063 Cardiff 1

info@rlb-law.com
www.rlb-law.com

This will not, however, provide total absolution from all liability for the doctor. The doctor will retain responsibility for the prescription and will owe a duty of care to the patient in that respect. Therefore, if the doctor prescribes medication for a child who comes to harm as a result, he could be responsible for that harm but only if it could be said that valid consent was not obtained and/or that he was negligent in prescribing in these circumstances. That is, it will have to be shown that the prescription was such that would not be supported as being reasonable clinical practice by a responsible body of medical opinion. The establishment of guidelines or protocols for the use of drugs is one way of demonstrating what is perceived to be reasonable clinical practice.

The use of protocols/guidelines is obviously increasing and can be of great assistance in both establishing what is to be seen as acceptable practice and in improving clinical practice.

A protocol can, however, be a double-edged sword. Although useful guidance for clinicians as an approach to take to a particular matter, if a protocol is adopted and not adhered to, this may be grounds for suggesting that the care given to the patient was not of an appropriate standard. This is particularly so as protocols are often referred to as reflecting the views of a substantial body of medical opinion and may therefore be used as a measure of allegations of negligence. It is, therefore, essential that any guidelines do indeed reflect good clinical practice which is widely supportable.

RadcliffesLeBrasseur

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For more information on Mental Health Law contact Andrew Parsons at RadcliffesLeBrasseur on 020 7227 7282, or email: andrew.parsons@radleb.com.

Out of office advice available 24hrs on 07802 506 306.

Readers are advised to take specific advice before acting in reliance on the matters set out in this briefing.