



**Royal
Pharmaceutical
Society**
of Great Britain

Law and Ethics Bulletin

Patients may not legally extemporaneously compound a product that contains a Controlled Drug

The Royal Pharmaceutical Society has recently been made aware of a situation where a pharmacist had provided a patient with the raw ingredients, (one of which was a controlled drug), to produce a medicinal product for his own use. The supply of these items was made against a lawful prescription. The patient had been combining, (compounding), these items to prepare a final extemporaneous medicinal product for self-administration.

Under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001, as amended, only certain persons are lawfully permitted to compound controlled drugs. Pharmacists are listed as persons who may carry out such compounding. The Home Office has confirmed that a patient cannot legally compound and extemporaneously prepare a medicinal product that includes a controlled drug even where the ingredients have been lawfully supplied against a prescription, as to do so would be in breach of the legislation.

Pharmacists who choose to compound a controlled drug must ensure that they act in accordance with the Code of Ethics and Section 4 of the "Professional Standards and Guidance for the Sale and Supply of Medicines" document. They must also ensure that such activities are adequately covered by professional indemnity insurance.

Alternatively, pharmacists may make arrangements for such a product to be lawfully prepared by an appropriately licensed "specials" manufacturer.

Pharmacists must **not** provide patients with controlled drug ingredients for them to mix together to produce a final product.