Amendments to The Misuse of Drugs Act 1971 affecting Tramadol, Zaleplon, Zopiclone and Lisdexamfetamine

The Misuse of Drugs Act 1971 controls medicines that are ‘dangerous or otherwise harmful’. The drugs subject to the control of this Act are termed Controlled Drugs (CDs). The Misuse of Drugs Regulations 2001 and subsequent amendments set out who is authorised to supply and possess controlled drugs.

On 10 June 2014 amendments to the Misuse of Drugs Act 1971 came into force. These amendments include specification changes for tramadol hydrochloride, zaleplon, zopiclone and lisdexamfetamine. All of these drugs were previously specified as prescription only medicines and are now specified as controlled drugs. The amendments to legislation were recommended to protect the public from the harms associated with misuse of these drugs. In addition the changes bring the specifications of these drugs in line with those of drugs of a similar structure.

Overview and current advice

The Misuse of Drugs Regulations 2001 divides CDs into 5 Schedules, which dictate the degree to which a CD’s use is regulated. Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control. The Schedule in which a CD is placed depends upon its medicinal or therapeutic benefit balanced against its harm when misused. Schedules detail the conditions under which activities such as the import, export, production, supply, possession, prescribing, and record keeping of a drug may be carried out.

The Misuse of Drugs Act 1971 specifies drugs into 3 parts: Part 1 (Class A drugs), Part 2 (Class B drugs) or Part 3 (Class C drugs). The specification of each drug is ‘set with reference to the harm a drug has or is capable of having when misused’ and ‘the type of illegal activity undertaken in regard to that drug’.

These parts establish the maximum penalties which can be imposed in criminal law on persons convicted of any of the offences under the Act.

Tramadol hydrochloride:

- is now controlled as a Class C drug and is exempted from safe custody requirements
• is now listed as a Schedule 3 drug under The Misuse of Drugs Regulations 2001

• is now subject to full prescription writing requirements under regulation 15 when being prescribed in healthcare

Tramadol is a widely prescribed pain killer for people with moderate to severe pain, but in common with other opioid drugs it can be liable to misuse and has adverse effects, particularly in overdose. Tramadol is a prescription-only medicine in the United Kingdom; however evidence demonstrates that there has been an increase in prescribing, harm and misuse.

Zaleplon and zopiclone:

• are now controlled as Class C drugs under the Misuse of Drugs Act 1971

• are now listed under Schedule 4, part 1 of the Misuse of Drugs Regulations 2001

• are now subject to regulations for their possession, supply, manufacture, import and export

Zopiclone, zaleplon and zolpidem are non-benzodiazepine sedative hypnotics (sometimes referred to as Z-drugs). They are indicated for use in the short term management of severe insomnia and through their action on the benzodiazepine receptor induce sleep. The Z-drugs are closely related to the benzodiazepine family of drugs (Class C drugs) and share the same basic mechanism of pharmacological action. The Z-drugs are similar to short acting benzodiazepines in terms of effectiveness, adverse effects, or potential for dependence or abuse and there are no very significant differences.

Zolpidem is already controlled under the Misuse of Drugs Act 1971 as a Class C drug and is listed under Schedule 4 Part 1 of the Misuse of Drugs Regulations 2001. The change in the Act ensures consistency between the three Z-drugs.

Lisdexamfetamine:

• is now controlled as a Class B drug under the Misuse of Drugs Act 1971

• is now listed under Schedule 2 of the Misuse of Drugs Regulations 2001

• is now subject to regulations for its possession, supply, manufacture, import and export

Lisdexamfetamine is an inactive prodrug of dexamfetamine. Administered orally, lisdexamfetamine is rapidly absorbed by the gastrointestinal tract and converted to dexamfetamine which is a stereoisomer of amfetamine.

It is indicated for attention deficit hyperactivity disorder (ADHD) refractory to methylphenidate (under specialist supervision).

Dexamfetamine is already controlled under the Misuse of Drugs Act 1971 as a Class B drug and is listed under Schedule 2 of the Misuse of Drugs Act and Regulations 2001. The change in the Act ensures consistency with dexamfetamine.

References

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