

THE SCOTTISH OFFICE

NHS MEL(1996)9

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Addresses

COMMON SERVICES AGENCY

13 FER 1996

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General Manager, Health Education Board for Scotland

Chief Executives **NHS Trusts**

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Dear Colleague

DRUGS (AMENDMENT) (NO MISUSE OF **REGULATIONS 1995 (SI 1995 No 3244)**

SUMMARY

- This letter draws attention to the effect of the Misuse of Drugs (Amendment) (No 2) Regulations 1995 which make changes to the regime of control which is applicable to the drug temazepam.
- The above named Regulations came into force on 2. 15 January 1996. They have the effect of transferring temazepam from Schedule 4 to Schedule 3 of the Misuse of Drugs Regulations 1985, making possession of the drug without authority an offence, and imposing a requirement for import and export licences. Transitional provision has been made so that the safe custody provision of the Misuse of Drugs (Safe Custody) Regulations 1973 will not apply to temazepam until 18 April 1996.

ACTION

Health Boards and where appropriate NHS Trusts are asked to bring the Memorandum to this letter as quickly as possible to the attention of all NHS prescribers, chemist contractors, proprietors of nursing homes including homes for the mentally ill/mentally handicapped which are registered with them. Bulk supplies of the Memorandum are being sent under separate cover for this purpose.

Yours sincerely

A ROBSON

Director of Primary Care

General Medical Practitioners
Hospital Doctors
Chemist Contractors and Hospital Pharmacists
All Dentists in the Community, General and Hospital Dental Services

MISUSE OF DRUGS (AMENDMENT) (NO 2) REGULATIONS 1995 (SI 1995 No 3244)

- 1. This memorandum advises doctors, chemist contractors and dentists of the effect of the Misuse of Drugs (Amendment) (No 2) Regulations 1995 which make changes to the regime of control which is applicable to the drug temazepam
- 2. The above named Regulations have the effect of transferring temazepam from Schedule 4 to Schedule 3 of the Misuse of Drugs Regulations 1985 making possession of the drug without authority an offence and imposing a requirement for import and export licences. They came into force on 15 January 1996. Transitional provision has been made so that the safe custody provision of the Misuse of Drugs (Safe Custody) Regulations 1973 will not apply to temazepam until 18 April 1996 please see paragraphs 10 and 11 below.

Production, Supply and Possession

- 3. The amending Regulations transfer temazepam from Schedule 4 of the Misuse of Drugs Regulations 1985 (SI 1985 No 2066), as amended, to **Schedule 3**, but exempt it from the requirements of Regulation 15 (form of prescriptions) please see paragraphs 7 and 8 below.
- 4. Temazepam is currently exempted when in the form of a medicinal product from the prohibition on possession. As a Schedule 3 drug, the exemption will no longer apply and any person wishing to possess temazepam will have to come within those categories of person authorised in the Regulations or be issued with an appropriate Home Office authority (under Regulation 10).
- 5. Persons already authorised by the Regulations or by a written Home Office authority to produce, supply or possess Schedule 3 drugs will automatically be so authorised in respect of temazepam. In the case of persons not already authorised by the Regulations to possess, supply or produce Schedule 3 drugs, an appropriate written authority will be required.

6. As a Schedule 3 drug, the requirements of Regulation 14 (documentation); Regulation 16 (supply on prescription); Regulation 18 (marking of containers); and Regulation 24 (preservation of records) will apply to temazepam. Regulations 22 and 23 (keeping and preservation of records); Regulation 25 (furnishing of information); and Regulation 26 (destruction - which only affect producers, practitioners and pharmacists who produce Schedule 3 drugs and holders of written authorities to supply) which apply to Schedule 3 and 4 drugs will continue to apply to temazepam.

Regulation 15 (Form of Prescriptions)

- 7. The Misuse of Drugs (Amendment) (No 2) Regulations 1995 exempt temazepam and preparations containing the drug from all the requirements of Regulation 15 (form of prescriptions) of the Misuse of Drugs Regulations 1985, as amended. It follows that temazepam is exempt from requirement of Regulation 15(1)(b) which provides that prescriptions containing a controlled drug should be written by the person issuing it in his own handwriting.
- 8. Unlike phenobarbitone, phenobarbitone sodium and preparations containing either of these substances, which are exempted <u>only</u> from the handwriting requirements of Regulation 15(1)(b), temazepam is exempt from <u>all</u> the controlled drug prescription requirements of Regulation 15.

Importation/Exportation

9. As a Schedule 3 drug, licences will be required for imports and exports of temazepam.

Safe Custody Requirements

- 10. The provisions of the Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798), as amended, will also apply to temazepam as from 18 April 1996. Those regulations require chemist contractors, dispensing doctors, nursing homes, residential or other establishments under the Social Work (Scotland) Act 1968, mental nursing homes and private hospitals to keep Schedule 2 and 3 controlled drugs (other than those specifically exempted) in a locked safe, cabinet, or room with specified characteristics. Manufacturers and wholesalers are also required to keep these drugs in safe custody.
- 11. A period until 18 April 1996 has been allowed to give those affected time to make changes to enable them to comply with the new requirements.
- 12. Further information and advice on the legal changes described in this letter can be obtained from Miss J S Mitchell of the Home Office Drugs Branch, Telephone 0171-273-3474 or from the regional office of the Drugs Branch Inspectorate whose address and telephone number is given overleaf:-

Home Office Drugs Branch Inspectorate Northern Regional Office 10th Floor Dudley House 133 Albion Street LEEDS LS2 8PN Tel: 0113-2429941

Scottish Office Department of Health St Andrew's House Edinburgh & February 1996