Chief Medical Officer Directorate Pharmacy and Medicines Division



29 June 2020

Medicine Supply Alert Notice

Phenelzine (Nardil) 15mg tablets

Priority: Level 3* Valid until: No confirmed resupply date

Issue

- 1. Phenelzine 15mg tablets (Nardil[®]) have been unavailable since August 2019 and this is now expected to be a long-term supply issue. There is currently no confirmed resupply date.
- Phenelzine is an irreversible monoamine oxidase inhibitor (MAOI) licensed for the treatment of depression clinically characterised as 'atypical', 'non endogenous', 'neurotic' or which has not responded to treatment with other antidepressants.
- 3. It is clinically unsafe to stop or switch this drug abruptly, therefore, any switching or withdrawal will need to be undertaken by a specialist.
- 4. Unlicensed imports of phenelzine 15mg tablets were being used to manage patients and maintain treatment, however, due to global supply issues, these imports have become unreliable.
- 5. Supplies of unlicensed phenelzine 15mg capsule specials have become available.

Advice and Actions

- 6. As supplies of licensed phenelzine 15mg tablets (Nardil[®]) will be unavailable for the foreseeable future, all relevant healthcare professionals in primary, secondary or specialist healthcare services should work to ensure the following actions are undertaken where applicable:
 - no new patients should be initiated on phenelzine;
 - all patients currently prescribed phenelzine should be reviewed by a specialist to determine if this is still the most appropriate treatment and whether gradual withdrawal in order to stop and switch to an alternative agent is a potential management option; and
 - where unlicensed imports of phenelzine 15mg tablets are unavailable, **clinicians should consider prescribing unlicensed specials of phenelzine 15mg capsules**. This will avoid abrupt withdrawal and provide time for a review by a specialist to be scheduled.
- 7. <u>Primary Care</u>: GPs should identify all patients prescribed phenelzine 15mg tablets and:
 - refer these patients for a specialist review regarding their ongoing management; and
 - ensure patients have a sufficient supply until their review to avoid abrupt withdrawal.
- 8. Secondary Care services should:
 - identify all patients under their care (and those referred from primary care) that are currently prescribed phenelzine 15mg tablets and review the ongoing need of this treatment;
 - if it is considered clinically important for a patient to maintain treatment with phenelzine following a review, clinicians should prescribe unlicensed phenelzine 15mg capsules in the absence of unlicensed imports of the tablets; and

- ensure that following a patient's review, ongoing prescribing arrangements between primary and secondary care, determined by the clinical needs of the patient, are agreed.
- 9. GPs and community pharmacists should work together <u>proactively</u> to understand which formulations of phenelzine are available with associated lead times to ensure patients receive their medication in a timely manner. This will avoid abrupt withdrawal and provide time for a review by a specialist to be scheduled.
- 10. Clinicians should explain the situation, actions and agree individual alternative options with patients, their families and carers as appropriate.

Additional Information

Unlicensed Imports

- 11. The following specialist importers may be able to source unlicensed phenelzine 15mg tablets (please note, there may be other companies that can also source supplies):
 - Chemys Limited;
 - Clinigen;
 - Durbin PLC;
 - Rokshaw Pharmaceuticals;
 - UL Global Limited Specials.
- 12. The following companies are able to supply unlicensed phenelzine 15mg <u>capsules</u> specials (please note, there may be other companies that can supply):
 - Ascot Laboratories;
 - Clinigen;
 - Mawdsleys;
 - Rokshaw Pharmaceuticals;
 - Target Healthcare.
- 13. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and/or local governance procedures. Please see the links below for further information.
 - Prescribing unlicensed medicines, General Medical Council (GMC);
 - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA);
 - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society.
- 14. The advice in this circular replaces that given in previous MSANs (2019)4 and (2020)19.

Enquiries

 Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <u>PharmacyTeam@gov.scot</u> (primary care) or <u>NSS.NHSSMedicineShortages@nhs.net</u> (secondary care).