Department of Health & Social Care

NHS

Supply Disruption Alert

SDA/2020/011 03 July 2020

This alert was originally issued on 25 June 2020. This version was published on 03 July 2020 and contains updates to the problem/background and Supporting Information sections.

Phenelzine Sulphate 15mg tablets (Nardil®) – Supply Disruption

Schedule 3 (POM)

Material updates are shown in *italics*

Summary

- 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.
- It is clinically unsafe to stop or switch this drug abruptly, therefore, any switching or withdrawal will need to be undertaken by a specialist.
- Unlicensed imports of phenelzine 15mg tablets were being used to manage patients and maintain treatment, however, due to supply issues in other markets globally these imports have become unreliable.
- Supplies of unlicensed phenelzine 15mg capsule specials have become available.

Action

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 specialist mental health services 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 specials of phenelzine 15mg capsules to avoid abrupt withdrawal.

Primary Care:

- GPs should identify all patients prescribed phenelzine 15mg tablets and;
  - refer these patients for a specialist mental health review regarding ongoing management; and
  - ensure they have a sufficient supply until their review, to avoid abrupt withdrawal.

Secondary Care and Community Mental Health services should:

- identify all patients under their care (and those referred from primary care) that are currently prescribed phenelzine 15mg tablets and review 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 phenelzine 15mg capsules in the absence of unlicensed imports of the tablets; and
- ensure that following the patients review, ongoing prescribing arrangements between primary and secondary care, determined by the clinical needs of the patient, are agreed.

Prescribers and pharmacists should work together to understand which formulations of phenelzine are available with associated lead times to ensure patients receive their medication in timely manner.

Deadlines for actions

Actions initiated:	on receipt of this alert
Actions completed:	as soon as possible

Product details

Phenelzine 15mg tablets (Nardil®) (Kyowa Kirin)

Problem / background

Kyowa Kirin are the sole supplier of phenelzine 15mg (Nardil®) tablets in the UK. They have experienced ongoing manufacturing issues since August 2019. The resupply date was initially outlined as October 2019, which was delayed to March 2020. *There is currently no confirmed resupply date.*

Previously, imported supplies of unlicensed phenelzine 15mg tablets were supporting the UK market, however, due to supply issues in other markets globally, these supplies have become limited.

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.

Supporting Information

Unlicensed Imports

- 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
    - *Eaststone Specials Ltd*
    - Rokshaw Pharmaceuticals
    - UL Global Limited
    - *Waymade PLC*

Specials

- The following companies are able to supply unlicensed phenelzine 15mg capsule specials (please note, there may be other companies that can supply):
    - Ascot Laboratories
    - *Aclardian Limited*
    - Clinigen
    - Mawdsleys
    - *Pharma Nord Medical*
    - Rokshaw Pharmaceuticals
    - Target Healthcare

- When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative, prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done by annotating the prescription with the following wording: "**special order**"

- 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)
    - The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
    - Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society

Distribution

Care home staff
General practice
Pharmacy

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All departments
- All staff
- All wards
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists [NEW]
- Community hospitals
- Community nurses
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Mental Health Trusts
- Mental Health Specialists
- Outpatient clinics
- Pharmaceutical advisors
- Pharmacists
- Psychiatrists

NHS England and NHS Improvement Regional Offices

For onward distribution to all relevant staff including:

- Community pharmacists

GP Practices

For onward distribution to all relevant staff including:

- General practitioners
- General practice managers
- General practice nurses

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Enquiries

Send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number **SDA/2020/011 -** Email:supplyresiliencemd@dhsc.gov.uk