Chief Medical Officer Directorate Pharmacy and Medicines Division

Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

Medicine/Drug in short supply: Nardil (phenelzine sulfate) 15mg tablets (MAOI)

Priority: Level 2 Valid until: March 2020

Issue

1. This Medicine Supply Alert Notice provides information regarding the current supply issues for Nardil (Phenelzine sulfate) 15mg tablets (MAOI). Nardil (Phenelzine sulfate) 15mg tablets (MAOI) is out of stock until March 2020.

Details

2. There is a short-term supply issue affecting Nardil (Phenelzine sulfate) 15mg tablets (MAOI) manufactured by Kyowa Kim, the sole UK supplier of Nardil (Phenelzine sulfate) 15mg tablets (MAOI) in the UK. This is caused by manufacturing delays.

3. New supplies of Nardil (Phenelzine sulfate) 15mg tablets (MAOI) are expected by March 2020. Currently, new supplies are expected by March 2020.

Advice

4. Specialist importer companies have advised they can continue to source unlicensed imports from abroad. Clinigen, Target, Alium, Mawdsleys, Durbin, WEP Clinical and Waymade can import unlicensed phenelzine tablets.

5. Please see guidance which UK Medicines Information previously published about management options including the need for specialist referral to mental health teams if unlicensed supplies of phenelzine sulfate 15mg tablets are deemed unsuitable: <u>https://www.sps.nhs.uk/articles/shortage-of-phenelzine-15mg-tablets-nardil/</u>



11 October 2019

Addressees:

<u>For action</u> Community Pharmacy Scotland Medicines Shortage Response Group (Scotland) Scottish Prescribing Advisor Network

General Enquiries to:

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www.gov.scot

6. For patients who do not have sufficient supplies of Nardil (phenelzine sulfate) 15mg to last until March 2020, clinicians should consider prescribing an unlicensed preparation of phenelzine sulfate 15mg tablets as soon as possible in order to avoid abrupt withdrawal. Clinicians will need to work with local pharmacies to understand more about the specific unlicensed products that can be sourced and associated lead times.

7. Unlicensed imports can be obtained through normal wholesaler routes. However, if pharmacies are unable to obtain supplies they are advised to contact specialist importer companies directly.

8. Clinicians should refer to the UKMI memo for advice on alternatives management options.

Actions

9. Healthcare professionals are asked to note the content and actions outlined in this circular and Annex and circulate as appropriate.

Yours sincerely,

Lose Marie Para

Rose Marie Parr Chief Pharmaceutical Officer/ Deputy Director Pharmacy & Medicines Division

Medicines Shortages Response Group (Scotland) priority definitions

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration (up to one month) where immediately available measures are expected to be sufficient and there is minimal additional management requirement.	 Business as usual. Response likely to involve using the same medicine. Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where <u>alternatives in</u> <u>the same therapeutic class are</u> <u>available but which may require</u> <u>some management</u> such as switching to those alternatives, which may include unlicensed medicines. Level two shortages also include level one shortages that continue for more than a month.	 Business as usual. Response not likely to require a change in the class of medicine. Alternative strength/formulation available but clinical advice is required to help manage the switch. Alternative medicine in the same therapeutic class. Unlicensed alternatives may be available.
Level three (high impact)	Supply problems where there are <u>limited or no alternatives in the same</u> <u>therapeutic class and which require</u> <u>significant management</u> , potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> such as anaphylaxis or involving <u>patient</u> <u>groups considered as vulnerable</u> , such as neonates, pediatrics or people with learning disabilities.	 Serious shortage situation. Response likely to require a change in the therapeutic class of medicine. Alternative therapeutic class of medicine available. The use of a 'serious shortage protocol'. Additional clinical advice. Exceptional MHRA regulatory measures. Issuing a Medicine Supply Alert Notice (MSAN) to the NHS via the MSAN system.
Level four (critical impact)	Supply problems where there is <u>no</u> <u>viable therapeutic alternative</u> and were responses may also require support from the wider NHS and outside the health system and / or which trigger the use of national resilience structures.	 Very serious shortage situation. Wider burden on NHS and public sector. Non-medicine support provided to patients. National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required.