

Prif Swyddog Fferyllol
Chief Pharmaceutical Officer



Llywodraeth Cymru
Welsh Government

MEDICINES SHORTAGE ADVISORY GROUP WALES

MEDICINE SHORTAGE

Distribution:	As Annex 1
From:	Andrew Evans, Chief Pharmaceutical Officer
Date:	18 October 2019
Reference:	CPhO/MedsLet/2019/18
Category:	Level 3 - High impact
Title:	Disruption to supply of Detrusitol® and update on Adrenaline auto-injectors and Nardil®
For Action by:	<ul style="list-style-type: none">• All General Practitioners - retain a copy in your 'locum information pack'. Action as below.• Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'. Action as below.• Community Pharmacists - Action as below.• Hospital Chief Pharmacists - Action as below.• Medical Directors of Health Boards - disseminate to relevant clinicians in secondary care setting – Action as below.
Timeframe:	Action within 24 hrs
For Information:	See Annex 1 – Distribution List
Key Recipients:	Chief Executives of Health Boards Nurse Directors Health Boards

Directors of Public Health
Health Board and NHS Trust Chief Pharmacists
Health Board Prescribing Advisers
Chief Executives of NHS Trusts
Director Welsh Medicines Information Centre
NHS Direct Wales

What is this about:

Disruption to supply of Detrusitol XL® 4mg capsules

An update on disruption to supply of Adrenaline auto-injectors (AAI) and Nardil® 15mg tablets

Description of products affected:

- (1) Detrusitol XL® (tolterodine) 4mg capsules
- (2) Adrenaline auto-injectors (Emerade®)
- (3) Nardil® (phenelzine sulfate) 15mg tablets

Detrusitol 4mg XL® (tolterodine)

Due to manufacturing delays, Detrusitol XL® (tolterodine) 4mg capsules will be out of stock until the 6th December 2019.

Action

Tolterodine 4mg prolonged release capsules are available from other manufacturers and clinicians should prescribe generically. The United Kingdom Medicines Information (UKMI) service have advised there is no difference in the bioequivalence of all brands of tolterodine 4mg prolonged release capsules.

Adrenaline auto-injectors (AAI) - Update

A MHRA Class 4 Drug Alert (Ref: CEM/CPhA/2019/23) issued on 3 October 2019 informed of some Emerade auto-injectors failing to activate. The issue makes it particularly important that users carry two adrenaline auto-injectors at all times. Please see the link below for further information:

<https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-emerade-150-300-and-500-microgram-solution-for-injection-in-pre-filled-syringe-mdr-57-08-19>

Recent supply issues affecting some brands of adrenaline auto-injectors have impacted on all manufacturers. There are sufficient supplies of adrenaline auto-injectors overall to meet normal patient demand. However, it may be necessary to switch patients to an alternative brand that they are unfamiliar with. The different brands of adrenaline auto-injector are not used in exactly the same way and therefore specific training and advice is required for each of the devices.

Please follow the links to the relevant training videos below:

EpiPen: <http://www.epipen.co.uk/demonstrationvideo/>

Jext: <https://hcp.jext.co.uk/>

Emerade: <https://www.emerade-bausch.co.uk/patient/how-to-use-emerade>

To ease the supply situation, the MHRA has approved the extension of expiry dates for specific batches of EpiPen® 300 micrograms and Jext® 150 micrograms and 300 micrograms by four months beyond the labelled expiry date.

The company websites list the specific batches that can have their original expiry date extended:

Mylan UK: <http://www.epipen.co.uk/>
ALK-Abello Ltd: <https://jext.co.uk/>

Clinicians should check with patients requesting new EpiPen® 300 micrograms or Jext® 150 micrograms and 300 micrograms to establish if they currently hold one of the batches that can be used beyond the listed expiry. If one of the listed batches is held, further supplies should be delayed until the extended expiry date, counselling the patient on the extended expiry. The **expiry date** means that the adrenaline auto-injector can be used until the **end of the month** listed.

Nardil® (phenelzine sulfate) 15mg tablets –Update

Issue

Further to Medicines Shortage letter CPhO/MedsLet/2019/08 dated 30 July 2019, Kyowa Kirin, the sole supplier of Nardil® (phenelzine sulfate) 15mg tablets in the UK have advised that their resupply date has been delayed until March 2020.

Action

To avoid abrupt withdrawal, clinicians should consider prescribing an unlicensed preparation of phenelzine sulfate 15mg tablets as soon as possible. Clinicians will need to work with local pharmacies to understand the specific unlicensed products that can be sourced and associated lead times.

Unlicensed Preparations

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.

The following specialist importer companies have advised that they can continue to source unlicensed imports from abroad.

Importer
Clinigen
Target
Alium
Mawdsleys
Durbin
WEP Clinical
Waymade

UK Medicine Information previously published information about management options including the need for specialist referral to mental health teams if unlicensed supplies of phenelzine sulfate 15mg tablets are deemed unsuitable:

<https://www.sps.nhs.uk/articles/shortage-of-phenelzine-15mg-tablets-nardil/>

GUIDANCE

When prescribing and dispensing unlicensed preparations, prescribers and pharmacists should always ensure the following:

Use of unlicensed products should be in line with agreed local policies and guidance.

Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and local governance procedures. Please see link to GMC guidance:

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>

Guidance on supplying specials can be found at:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The supply of unlicensed medicinal products specials .pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf)

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf>

QUERIES

For all correspondence please contact:

Medicinesshortages@gov.wales

Please forward to listed recipients.

Yours sincerely



Andrew Evans

Chief Pharmaceutical Officer/Prif Swyddog Fferyllol
Welsh Government/Llywodraeth Cymru

DISTRIBUTION LIST

Send to:

Chief Executives of Health Boards
Medical Directors of Health Boards
Health Board Chief Pharmacists
Hospital Chief Pharmacists
Chief Executives of NHS Trusts
Director of Welsh Medicines Information Centre
NHS Wales Procurement
NHS Direct

NHS Wales Shared Services Partnership to forward to:

General Practitioners
Dispensing General Practitioners
Community Pharmacists
Independent / Private clinics, hospices and hospitals throughout
Wales

Welsh Government:

Chief Medical Officer
Chief Nursing Officer
Director General Health and Social Services Group
Senior Medical Officer, Maternal and Child Health
Healthcare Quality and Patient Safety
Emergency Planning Adviser
HSSG Comms

