



Drug Driving (Specified Limits) (Scotland), Regulations, October 2019

New legislation has been introduced into Scotland regarding drug driving limits and new road side tests which is similar to legislation introduced in England and Wales four years ago (DTC supplement 146, March 2015) and can be summarised as follows:

Zero tolerance drugs include: cocaine, delta-9-tetrahydrocannabinol (THC, psychoactive component of cannabis), ketamine, lysergic acid diethylamide

(LSD), methylamphetamine, heroin and methylenedioxymethamphetamine (MDMA).

Medicines with a higher threshold which are generally above the normal therapeutic range include: benzodiazepines, methadone, morphine and amphetamine.

Information on whether any particular medicine is affected by the new

legislation can be found in the Summary of Product Characteristics for that medicine.

Drivers have a duty not to drive if a medicine has affected their ability to drive and this new legislation does not alter the existing impairment offence.

Advice for healthcare professionals can be found [here](#).

Adrenaline auto-injectors: recent action taken to support safety and class 2 recall of Emerade®

The MHRA has issued a class 2 medicines recall for all strengths of Emerade® due to an error in one component of the auto-injector which can cause some devices to fail to activate as intended. This is an update to a previously issued class 4 medicines defect information for all strengths of Emerade®. Emerade® stock held by patients is not being recalled; however patients and caregivers in possession of Emerade® pens need to be informed of safety information about the risk of failure to activate. The MHRA has provided [additional information](#) for patients and carers who have Emerade® pens (see pages 4 and 5). Healthcare professionals are urged to share this

information with all patients and carers who have been prescribed an Emerade® pen. A link to information on the MHRA website on the [class 2 medicines recall for Emerade®](#) has been added to the [Emerade® entry in the TAF](#).

A link to October's Drug Safety Update – [Adrenaline auto-injectors: recent action taken to support safety](#) which includes information relating to all adrenaline auto-injectors, including extended use beyond labelled expiry dates for EpiPen® and Jext, has been added to Emerade®, EpiPen® and Jext® entries in TAF (section [03.04.04 Anaphylaxis](#)).

Formulary Applications

There is an ongoing test of change with the formulary application form. The current version may receive further updates. Those wishing to submit a formulary application should always access a new form via the [formulary \(TAF\) homepage](#) by clicking on the 'Formulary Application' link and then the same link again on the next page to ensure the current version of the form is completed.

Montelukast (Singulair): reminder of the risk of neuropsychiatric reactions

[September's Drug Safety Update](#) reminds healthcare professionals that neuropsychiatric reactions (e.g. sleep disturbance, behaviour and mood changes) may occur with montelukast treatment and that montelukast should be reviewed if patient experiences any of these side effects. Patients and caregivers should be advised to read carefully the list of neuropsychiatric reactions in the patient information leaflet and seek medical advice immediately should they occur.

For full information on any of the drugs listed below use the link to the Scottish Medicines Consortium (SMC) website below to search by generic, brand or SMC no.

See NHS Tayside 'Local Decisions on SMC Advice' database (link below) for full details on Board decisions - these are currently listed alphabetically by page.

SMC Advice

Published September 2019

dacomitinib 15mg, 30mg and 45mg film-coated tablets (Vizimpro®) SMC2184
dapagliflozin 5mg film coated tablets (Forxiga®) SMC2185
dolutegravir 50mg / lamivudine 300mg film-coated tablets (Dovato®) SMC2205
inotersen 284mg solution for injection in pre-filled syringe (Tegsedi®) SMC2188
ospemifene 60mg film-coated tablets (Senshio®) SMC 2170
pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC2187
tildrakizumab 100mg solution for injection in pre-filled syringe (Ilumetri®) SMC2167
tisagenlecleucel 1.2 x 10 ⁶ to 6 x 10 ⁸ cells dispersion for infusion (Kymriah®) SMC2200
SMC 'Not recommended' medicines - September 2019
eribulin 0.44mg/mL solution for injection (Halaven®) SMC2231
melatonin 1mg and 5mg prolonged-release tablets (Slenyto®) SMC2168
osimertinib 40mg and 80mg film-coated tablet (Tagrisso®) SMC2171

Published October 2019

triptorelin sustained-release 3mg powder for suspension for injection (Decapeptyl SR®) SMC2186
risankizumab 75mg solution for injection in pre-filled syringe (Skyrizi®) SMC2196
axicabtagene ciloleucel 0.4 – 2 x 10 ⁸ cells dispersion for infusion dispersion for infusion (Yescarta®) SMC2189
pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC2207
SMC 'Not recommended' medicines - October 2019
pertuzumab 420mg concentrate solution for infusion (Perjeta®) SMC 2197
enzalutamide 40mg soft capsules (Xtandi®) SMC2195
eculizumab 300mg concentrate for solution for infusion (Soliris®) SMC2236
glibenclamide 0.6mg/mL, 6mg/ml oral suspension (Amlidia®) SMC2237

Medicines within the Tayside Area Formulary are intended to guide choice on a rational selection of medicines for **adults** which have been included on the basis of clinical efficacy, safety, patient acceptability and cost-effectiveness.

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Area Drug and Therapeutics Committee. Please direct any queries to:

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New & Updated Formulary Links

[HRT Quick Reference Guide - 29 November 2019](#)

[NHS Tayside Antifungal Prescribing Guidance in Respiratory Patients](#)

[NHS Tayside Chronic Non Neuropathic Pain prescribing algorithm](#)

[NHS Tayside Chronic Neuropathic Pain prescribing algorithm](#)

[Ophthalmology Infection Guidance](#)

Other Formulary Updates

- Perindopril now non-formulary – it should be continued in existing patients where appropriate; patients stabilised on treatment with perindopril should not be switched to an alternative formulary ACE inhibitor unless clinically necessary.
- Evolocumab (Repatha® SureClick® ▼) and alirocumab (Praluent® ▼) indications updated to be in line with SMC advice and updated local prescribing guidance: [PCSK9 inhibitors - Consultant Only Initiation \(CV Risk Clinic\) Prescribing Flowchart](#).
- Theophylline – Nuelin SA® and Slo-Phyllin® (all strengths) discontinued; these formulations removed and note added.
- Aciclovir eye ointment – now discontinued and note added to refer to [new Ophthalmology infection guidance](#) for advice.
- Raloxifene – changed from Green to Amber traffic light following review; indication remains the same: as a treatment option for the prevention of vertebral fractures in postmenopausal women when other treatments are contraindicated or unsuitable.
- Dronedarone - link to eMC for manufacturer's [Prescriber Guide](#) added

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [Policy on Prescribing of Non-Formulary Medicines](#)

Links to Additional Information

Monthly Drug Safety Updates:

www.gov.uk/government/publications/drug-safety-update-monthly-newsletter

For full details of medicines and forthcoming SMC Advice see **SMC Website:**

www.scottishmedicines.org.uk

For a Summary of a Product's Characteristics (SPCs) see **Electronic Medicines Compendium Website:**

<http://www.medicines.org.uk/emc/>

For full details on NHS Board decisions see **Tayside Area Formulary - Local Decisions on SMC Advice database:**

<http://www.nhstaysideadtc.scot.nhs.uk/approved/formular/NewMedsHomepage.htm>

Local implementation of SMC recommendations is taken forward by the Tayside Prescribing Support Unit (PSU). This bulletin is based on evidence available to the Tayside Prescribing Support Unit at time of publication and is covered by the [NHS Tayside Privacy and Accessibility Statements](#).