



### Special points of interest for Primary Care

- NHS Tayside Yellow Card Report
- BNF - electronic access
- Medicines Compliance Aids
- Respiratory Update

### SMC advice - November:

- Aflibercept (Eylea<sup>®</sup>)
- Brinzolamide, brimonidine (Simbrinza<sup>®</sup>)
- Daclatasvir (Daklinza<sup>®</sup>)
- Denosumab (Prolia<sup>®</sup>)
- Everolimus (Afinitor<sup>®</sup>)
- Ipilimumab (Yervoy<sup>®</sup>)
- Mifepristone, misoprostol (Medabon<sup>®</sup>)
- Pertuzumab (Perjeta<sup>®</sup>)
- Saxagliptin (Onglyza<sup>®</sup>)
- Telavancin hydrochloride (Vibativ<sup>®</sup>)
- Voriconazole (Vfend<sup>®</sup>)

### Inside this issue :

Guidelines & Protocols	1
Drug Safety Updates	1
Drug Safety	2
Information Technology	2
Prescribing changes	2-3
SMC Advice published in November 2014	4
Updates from previous SMC Advice	5
TAF Updates	5-6
SMC Briefing Note	6
Forthcoming SMC Advice	6

## Guidelines and Protocols

### Lidocaine medicated plaster

The local treatment protocol for lidocaine 5% medicated plaster (Versatis<sup>®</sup>) in neuropathic pain [off-label] (licensed for postherpetic neuralgia) has been updated.

General practitioners who are referring a patient to the NHS Tayside Pain Clinic can now initiate lidocaine 5% medicated plaster for neuropathic pain [off-label] in patients who are intolerant of first and second-line treatment options (involving amitriptyline, gabapentin and pregabalin), or where these therapies have been ineffective or are contra-indicated, as a 2 week trial and then for continuation of therapy.

Lidocaine 5% medicated plaster may also be considered for an area of localised neuropathic

pain and/or where systemic therapy is undesirable in the elderly or frail patient [off-label].

The Pain Clinic will review the lidocaine plaster at the patient's next clinic appointment to assess continued efficacy. The outcome of this review will be communicated to the patient's GP.

Consideration should be given to a treatment free period of 1 week after 6 months of continuous use to assess continued efficacy and need.

[CLICK HERE](#) for the updated protocol (Staffnet intranet link).

### Fosfomycin - resistant UTI

Multi drug resistant urinary tract infections are an increasing issue. These include ESBL (extended spectrum beta lactamase) producing Enterobacteriaceae such as *E. coli*. Oral treatment options for these infections which can be given in primary care can be extremely limited.

Although some of these isolates may be sensitive to pivmecillinam or nitrofurantoin, on some occasions oral fosfomycin may be the only available option. Oral fosfomycin is unlicensed in the UK but may be obtained by community pharmacists from several 'Specials' suppliers.

Guidance for primary care prescribers on the use and prescribing of oral fosfomycin is available [here](#). The formulary traffic light status has been updated from a red to amber. [CLICK HERE](#) for formulary section 05.01.13 Urinary-tract infections.

### Antipsychotics in dementia

Tayside guidance on the use of antipsychotics in older people with dementia (after excluding delirium) has been finalised and added into the Tayside Area Formulary within sections 04.02.01 and 04.11.

This guidance has been developed with input from Old Age Psychiatry and Medicine for the Elderly and has been reviewed by the Medicines Advisory Group.

Oral haloperidol is now the preferred choice for Stress and Distress (Behavioural and psychological symptoms of dementia (BPSD))

in Alzheimer's disease [off-label]. Oral risperidone [off-label] and oral quetiapine [off-label] are alternative options, with quetiapine preferred for this indication in Dementia with Lewy Bodies [off-label].

[CLICK HERE](#) to see the guidance for further information (Staffnet intranet link).



## Drug Safety Updates

Please follow link - [Volume 8, Issue 5, December 2014](#)





## Drug Safety

### NHS Tayside Yellow Card Report - 2013 / 14

NHS Tayside is to be commended on a significant increase in the Yellow Card reporting rate for suspected adverse drug reactions (ADRs) from 2013/14 (102 reports) as compared to 2012/13 (59 reports). While this increase is encouraging, continued efforts of healthcare professionals and patients are required to ensure safety signals with medicines are not missed as a result of lack of reports via the Yellow Card Scheme. [CLICK HERE](#) for the Yellow Card Scotland annual report.

All healthcare professions are requested to report via the Yellow Card Scheme <https://yellowcard.mhra.gov.uk/>

- all suspected **serious** reactions for all medicines (including prescription only, over the counter and herbal preparations)
- **any** suspected reactions for medicines under intensive monitoring i.e. Black triangle medicines.
- any adverse event reported to Medicines Information (MI), Pharmacy, Ninewells Hospital (email: Tay-UHB.medinfo@nhs.net) can be reported directly to the MHRA from their in-house database with no further documentation required.

See [DTC supplement 140 - July / August 2014](#) for information on launch of e-learning modules on ADRs. They are accessible via the Tayside Area Formulary, NHS Education for Scotland (NES) website or via LearnPro on staffnet under CPD option.

A future version of VISION GP software will include yellow card functionality. Opportunities exist to establish yellow card reporting as part of the General Practice annual appraisal process.



## Information Technology

BNF

### Electronic Access - British National Formulary

It is no longer possible to access the BNF content through [bnf.org](http://bnf.org). To access the BNF go to [www.medicinescomplete.com](http://www.medicinescomplete.com). From NHS computers you should automatically be signed in to the BNF. If accessing outwith the NHS click on 'Sign in with a different account' (bottom left hand side), then click 'Sign in via OpenAthens' (bottom left hand side). Enter your Athens username & password to proceed. If you do not have an Athens account any NHS employee can register via [The Knowledge Network](#). Click the login tab at top right hand side (The Knowledge Network) which will direct you to register.

**NB. If accessing the BNF from individual drug entries in the [Tayside Area Formulary](#) you will not need to enter your Athens username & password unless you are using a non NHS computer.**

### UKMi Medicines Compliance Aid Database

The UK Medicines Information Pharmacist network (UKMi) have launched a database that provides information on the majority of licensed solid dose forms of medicines and their suitability for inclusion in medicines compliance aids (MCAs). It is aimed at health care professionals, mainly pharmacists and pharmacy technicians working in hospital & primary care. It is accessible without a password from [www.ukmi.nhs.uk](http://www.ukmi.nhs.uk). Click on MCA stability database and click on 'Notes read confirmation box' at the bottom to proceed to the database.



## Prescribing Changes

### Prescribing in renal impairment

Local specialists have agreed in line with advice in the BNF, calculation of creatinine clearance (CrCl) using the Cockcroft and Gault formula (CG) is not required for every patient where drug dosage adjustments may be required in renal impairment. Locally renal function is reported on the basis of estimated glomerular filtration rate (eGFR) normalised to a body surface area of 1.73m<sup>2</sup> and derived from the Modification of Diet in Renal Disease (MDRD) formula. In practice, for most drugs and for most patients (over 18 years) of average build and height, eGFR (MDRD 'formula') can be used to determine dosage adjustments in place of creatinine clearance. However for potentially toxic drugs with a small safety margin and for patients at extremes of weight, advice on [prescribing in renal impairment](#) within the BNF should be followed. (Continued on next page)



## Prescribing in renal impairment continued

Within local prescribing guidance that refers to 'creatinine clearance', this is intended to be based upon either method (eGFR or calculated CrCl using the CG formula) depending what is most appropriate for the individual patient as per [BNF Principles of dose adjustment in renal impairment](#).

Local guidance on Thromboprophylaxis for patients with non-valvular atrial fibrillation (AF) uses eGFR as the measure of renal function, as do several other local guidelines, as this is the measure of renal function most commonly used in practice throughout Tayside for most patients (over 18 years) of average build and height.

Prescribers are reminded that many contra-indications / cautions to warfarin therapy also apply to novel oral anticoagulants such as rivaroxaban e.g. high bleeding risks (including risks of gastro-intestinal bleeding), severe renal impairment\*, coagulation disorders, and consideration of risks and benefits of treatment in frail older patients.

\*Tayside cut off for rivaroxaban: eGFR<30mL/min

## COPD formulary guidance

[COPD \(chronic obstructive pulmonary disease\) guidelines](#) within the Tayside Area Formulary have been updated to reflect some changes to links, to update the table on inhaled treatment according to step, and to update information on formulary choices of ICS (inhaled corticosteroid)/LABA (long-acting beta-2 agonist) inhalers.

SAMA (short-acting antimuscarinic antagonist) (e.g. ipratropium bromide) has been removed from the table on inhaled treatment according to step as it is not a formulary first choice option in maintenance therapy.

## Respiratory Update

### **Advance supply of medication**

The use of medicines supplied in advance e.g. prednisolone and/or antibiotics for exacerbation of COPD (chronic obstructive pulmonary disease) to appropriate patients can be effective in reducing severity of exacerbations and potentially hospital admissions.

The Respiratory MCN (Managed Clinical Network) advises that these medicines are not available to patients on repeat prescription and that patients contact their GP practice to notify them when they have started these to:

- Confirm response to medication
- Request further course for future use

### **Patient counselling/information to patients on inhalers**

Due to the increasing choice of inhaler devices in varying colours, the Respiratory MCN are advising that the terms "reliever inhaler" and "preventer inhaler" are used instead of "blue inhaler" and "brown inhaler" respectively. The terms "reliever" and "preventer" should be used when discussing inhaled medicines with patients and it is good practice for these terms to be added to the directions on inhaler prescriptions.

### **Fluticasone/vilanterol inhalation powder (Relvar® ▼ Ellipta®)**

Further to information provided in [DTC supplement No 136 - March/April 2014](#) on safety concerns with Relvar® ▼ Ellipta®, the manufacturer is changing the colour of the inhaler mouthpiece cover and packaging from pale blue to yellow. The manufacturer is distributing information on this change to retail pharmacies and dispensing surgeries. Information is also available on the manufacturer's website - [click here](#).



Medicine	Indication	Local recommendation category	Comments and useful links
Aflibercept, 40mg/mL solution for injection (Eylea®) (1003/14) - Full submission	For adults for the treatment of visual impairment due to diabetic macular oedema (DMO). <b>SMC restriction:</b> treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.	<b>Formulary</b> 2nd line choice for DMO in patients unresponsive to ranibizumab treatment <b>Hospital Only</b> Ophthalmology Specialist List Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops, suspension (Simbrinza®) (991/14) - Abbreviated submission	Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	<b>Formulary</b> - 2nd line choice (GPs may prescribe under direction of Ophthalmology) Ophthalmology Specialist List	<a href="#">SMC advice</a> <a href="#">SPC link</a> <b>Contraindicated in eGFR &lt; 30mL/min</b>
Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®) (1002/14) - Full submission	In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults. <b>SMC restriction:</b> use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis.	<b>Formulary</b> <b>Hospital Only - Hepatitis Team</b> Gastroenterology Specialist List	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Denosumab (Prolia®) 60 mg solution for injection in a pre-filled syringe (1013/14) - Non-submission	Osteoporosis in men at increased risk of fractures.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) (595/10) - Resubmission	The treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF) -targeted therapy.	<b>Non-formulary</b> - absence of clinician demand	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) (997/14) - Full submission	Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use).	<b>HOSPITAL ONLY</b> Oncology Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Mifepristone 200mg tablet and misoprostol 0.2mg vaginal tablets combipack (Medabon®) (913/13) - Abbreviated submission	For medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea.	<b>Formulary</b> <b>Hospital Only</b> Obstetrics & Gynaecology Specialist List	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) (897/13) - Resubmission	For use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Saxagliptin, 2.5mg and 5mg, film-coated tablets (Onglyza®) (772/12) - Full submission	In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	<b>Non-formulary</b> - absence of clinician demand	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Telavancin hydrochloride (Vibativ®) 250 mg and 750 mg powder for concentrate for solution for infusion (1015/14) - Non-submission	Treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant <i>Staphylococcus aureus</i> (MRSA).	<b>Not recommended</b>	<a href="#">SMC advice</a>
Voriconazole (Vfend®) 50 mg and 200 mg film-coated tablets / 200 mg powder for solution for infusion / 200 mg powder and solvent for solution for infusion / 40 mg/mL powder for oral suspension (1014/14) - Non-submission	Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients.	<b>Not recommended</b>	<a href="#">SMC advice</a>

'Local processes exist to allow are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#)'



## Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®) (909/13) - Full submission	Treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed.	<b>Formulary</b> (GP under direction of Mental Health Specialist)  Mental Health Specialist List (2nd line)	<a href="#">SMC advice</a> <a href="#">SPC link</a> <a href="#">Adult ADHD Shared care agreement</a>



## Tayside Area Formulary (TAF) Updates - Nov/Dec 2014

TAF Section	Drug(s)/topic	Changes
<a href="#">Chapter 3: Respiratory System</a>	COPD (Chronic Obstructive Pulmonary Disease)	COPD formulary guidelines updated. <a href="#">Click here</a> for updated guidance. See page 3 for further information.
<a href="#">04.02.01</a>	Antipsychotic Drugs	Links added to <a href="#">Tayside guidance - Antipsychotics in older people with dementia (after excluding delirium)</a> (Staffnet intranet link). Haloperidol now listed as first choice for stress and distress (behavioural and psychological symptoms of dementia (BPSD)) in Alzheimer's disease [off-label] (licensed for agitation and restlessness in the elderly). Risperidone listed for this indication [off-label] as an alternative to haloperidol (risperidone licensed for persistent aggression in Alzheimer's dementia (up to 6 weeks)). See also page 1 for further information.
<a href="#">04.04</a>	CNS stimulants and other drugs used for attention deficit hyperactivity disorder (ADHD)	Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®) added to formulary and <a href="#">Mental Health Specialist formulary list</a> for treatment of ADHD in adults (GP under the direction of Mental Health Specialist) as per SMC advice (see Updates from previous SMC advice above). Link added to <a href="#">Adult ADHD Shared Care Agreement</a> (Staffnet intranet link).
<a href="#">04.07.03</a>	Lidocaine plaster	Link added to updated <a href="#">local treatment protocol</a> from lidocaine plaster formulary entry and on <a href="#">Chronic Pain Specialist Formulary List</a> . See page 1 for further information.
<a href="#">04.11</a>	Drugs for dementia	Link added to <a href="#">Tayside guidance - Antipsychotics in older people with dementia (after excluding delirium)</a> (Staffnet intranet link). Link to Tayside guidance - Antipsychotics in older people with dementia (after excluding delirium) (Staffnet intranet link) also added to quetiapine entry on the <a href="#">Dementia specialist formulary list</a> .
<a href="#">05.01.13</a>	Urinary-tract infections	Oral fosfomycin [unlicensed] now Amber traffic light (GPs may prescribe on ID or microbiology advice; or if <b>proven</b> sensitivities) for multi drug resistant urinary tract infections (including ESBL (extended spectrum beta lactamase) producing Enterobacteriaceae such as <i>E. coli</i> . See page 1 for further information.
<a href="#">05.03.03.02</a>	Chronic hepatitis C	Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®) added to formulary and <a href="#">Gastroenterology specialist formulary list</a> as Hospital Only - Hepatitis Team. See SMC advice on page 4.
<a href="#">07.01.02</a>	Mifepristone and misoprostol	Mifepristone 200mg tablet and misoprostol 0.2mg vaginal tablets combipack (Medabon®) added to formulary and <a href="#">Obstetrics &amp; Gynaecology specialist formulary list</a> as Hospital Only. See SMC advice on page 4.

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TAF Section	Drug(s)/topic	Changes
<a href="#">11.06</a>	Carbonic anhydrase inhibitors	Brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops, suspension (Simbrinza®) added to formulary and <a href="#">Ophthalmology specialist formulary list</a> (GPs may prescribe under direction of Ophthalmology) as a second line treatment option where both brinzolamide and brimonidine are appropriate to decrease elevated intraocular pressure (IOP) in adults with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. See SMC advice on page 4.
<a href="#">11.08.02</a>	Subfoveal choroidal neovascularisation	Aflibercept, 40mg/mL solution for injection (Eylea®) added to formulary and <a href="#">Ophthalmology specialist formulary list</a> (Hospital Only) as 2nd line treatment for treatment of visual impairment due to diabetic macular oedema (DMO). See SMC advice on page 4.
<a href="#">15.01.07</a>	Naloxone	Prescribing status of naloxone hydrochloride injection changed to Green traffic light for use in the community e.g. by GPs.
<a href="#">Wound Management Formulary</a>	Section 14: Specialist dressings	Format update and addition of Specialist dressings for Burns added.
<a href="#">Chapter 20: Continence products</a>		New Chapter added with links to <a href="#">Continence Product Order form</a> and <a href="#">Form for the prescription of non-formulary continence products</a> .



## SMC Briefing Note:

[Click here](#) for November Briefing Note

## Forthcoming SMC Advice

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Drug and Therapeutics Committee.

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