



### Special points of interest for Primary Care

- Yellow card reporting
- Rivaroxaban - Update

#### SMC advice:

- Bortezomib (Velcade®)
- Fentanyl citrate (Breakyl®)
- Golimumab (Simponi®)
- Saxagliptin plus metformin (Komboglyze®)
- Tocilizumab (RoActemra®)
- Trastuzumab (Herceptin®)
- Mannitol (Bronchitol®)

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## Yellow Card Reporting - Scotland

### Yellow Card Reporting for NHS Tayside - April 2012 to March 2013

There has been a steady rate of decline in the reporting trend for Scotland from 2008 onwards. This requires reversal to ensure safety signals with medicines are not missed due to a lack of reports via the Yellow Card Scheme.

#### Summary for NHS Tayside

- The Yellow Card reporting rate for suspected adverse drug reactions from NHS Tayside increased slightly in 2012/13 (59 reports) as compared to 2011/12 (56 reports). However a decreasing trend is evident overall since 2008.
- Reporting rate per 100,000 population was marginally lower (15) than the Scottish average reporting rate per 100,000 population (16)
- Reports for serious suspected reactions were slightly lower (53%) than the Scottish average (56%) – 31 reports
- Reports for Black Triangle medicines were lower (29%) than the Scottish average (37%) - 17 reports
- Reports relating to paediatric patients were lower (10%) than the Scottish average (12%) - 6 reports
- There was one herbal report, for bladderwrack, which was serious

#### Key Messages:

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

- all suspected serious reactions for all medicines
- 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](mailto:Tay-UHB.medinfo@nhs.net)) can be reported directly to the MHRA from their in-house database.

[Yellow Card Centre \(YCC\) Scotland](#) has co-produced with NHS Education Scotland six e-learning modules on adverse drug reactions. These modules will be freely available via the [NES website](#) from March 2014.



## Drug Safety Updates

Please follow link - [Volume 7, Issue 6, January 2014](#)  
[Volume 7, Issue 7, February 2014](#)



# Prescribing Changes

## Rivaroxaban - DVTs & PTEs - NHS Tayside - Update

Rivaroxaban has now been approved locally for use in patients who inject recreational drugs in the treatment of DVTs & PTEs. [NHS Tayside PTE protocol](#) and [Ninewells DVT protocol](#) have been updated accordingly.

Local DVT protocols for PRI and Angus are in the process of being updated.

Rivaroxaban is first line treatment for all DVTs & PTEs in NHS Tayside (unless contra-indicated\*).

Warfarin remains 1st line for [thromboprophylaxis in AF patients](#).

\*Contraindications to rivaroxaban for the treatment of DVT or PTE:

- Patients who require anticoagulation for longer than 12months
- Patients with eGFR<30mls/min
- Patients with active cancer or who are having chemotherapy
- Pregnant patients
- Patients with hepatic disease associated with coagulopathy
- Patients on interacting drugs, such as azole-antimycotics, rifampicin, NNRTIs or protease inhibitors. See [BNF](#) or individual SPCs for further information.

### Rivaroxaban - lifestyle & bleeding advice

Remember:

- Rivaroxaban must be taken with food & around the same time each day
- All patients on 15mg & 20mg doses **must be given an alert card** and advised to carry it with them at all times.
- Patients should be counselled on bleeding risks and potential drug interactions

Patient brochures\*\* for AF, DVT and PTE, available from the manufacturer, contain lifestyle advice and FAQs, and should be given out with all new rivaroxaban prescriptions. These brochures contain an alert card.

The prescriber guide brochure\*\* contains useful information on doses, missed doses, conversion from other anticoagulants, peri-operative use and management of bleeding complications.

\*\*Brochures can be found on the [Xarelto® Bayer website](#), but will also be available on relevant wards and pharmacy departments.

Medicine	Indication	Local recommendation category	Comments and useful links
Bortezomib 3.5mg powder for solution for injection (Velcade®) (927/13) – Full submission	In combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.  <b>SMC restriction:</b> use as triple therapy in combination with dexamethasone and thalidomide.	<b>Hospital Only</b>  <b>Haematology / Oncology</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Fentanyl citrate (Breakyl®) 200mcg, 400mcg and 800mcg buccal film (947/13) – Non-submission	Treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Golimumab (Simponi®) 50 mg and 100mg solution for injection (946/13) – Non-submission	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Saxagliptin plus metformin, 2.5mg / 850mg and 2.5mg / 1000mg film-coated tablets (Komboglyze®) (929/13) – Abbreviated submission	In combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus when the maximally tolerated dose of both metformin and the sulphonylurea does not provide adequate glycaemic control.	<b>Formulary</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Saxagliptin is the 1st choice gliptin in Tayside</i>
Tocilizumab, 20mg/mL concentrate for infusion (RoActemra®) (930/13) – Abbreviated submission	In combination with methotrexate for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with methotrexate. Tocilizumab can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate.	<b>Hospital Only</b>  <b>Paediatric Rheumatology Clinic</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Trastuzumab, 600mg/5mL solution for injection (Herceptin®) (928/13) – Full submission	Treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (full details of licensed indication presented later in advice document).  <b>SMC restriction:</b> Subcutaneous trastuzumab injection is accepted for use in line with previous SMC advice for intravenous trastuzumab (this excludes its use in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab).	<b>Hospital Only</b>  <b>Haematology / Oncology</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>

'Local processes exist to allow consideration of prescribing outwith SMC advice or outwith NHS Tayside formulary. Details 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
Mannitol 40mg inhalation powder hard capsule (Bronchitol®) (837/13) - Resubmission	Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care.  <b>SMC restriction:</b> As an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining lung function and in whom other osmotic agents are considered unsuitable.	Non-formulary - Alternatives preferred.	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Dornase alfa - may be prescribed via a <a href="#">Shared Care Agreement</a></i>

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## Tayside Area Formulary (TAF) Updates - Jan/Feb 2014

TAF Section	Drug(s)/topic	Changes
<a href="#">Specialist formulary lists and formulary development</a>	<a href="#">Cardiology</a>	Formulations of medicines in list added for clarification. Esmolol, labetalol and metoprolol injections added to specialist list and formulary section 2.4 as Hospital Only. Hydralazine tablets, methyldopa tablets, moxonidine tablets, and valsartan capsules or tablets added to specialist list and formulary section 2.5 (GPs may prescribe under specialist direction). Several protocol links updated.
	<a href="#">Renal</a>	Tinzaparin added to specialist formulary list and formulary section 2.8 as Hospital Only for anticoagulation during haemodialysis.
	<a href="#">Rheumatology</a>	<a href="#">Abatacept protocol</a> and links to <a href="#">Shared Care Agreement – Biologic Therapies for Rheumatic Disease</a> added to specialist formulary list (NHS Tayside Staffnet intranet links only).
<a href="#">6.1</a>	Gliptins (Dipeptidylpeptidase-4 inhibitors)	Saxagliptin plus metformin, 2.5mg / 850mg and 2.5mg / 1000mg film-coated tablets (Komboglyze®) - updated indication as per SMC advice (page 3 of this bulletin) (triple combination therapy with a sulphonylurea).

**SMC Briefing Note:**  
[Click here](#) for January 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.

Please direct any queries to either:

Karen Harkness  
Principal Pharmacist - Clinical Effectiveness  
email: [kharkness@nhs.net](mailto:kharkness@nhs.net)

or

Claire James  
Senior Pharmacist - Clinical Effectiveness  
email: [clairejames@nhs.net](mailto:clairejames@nhs.net)

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